EURO HEALTH GROUP

Mid-Term Evaluation of Gavi's 2021-2025 Strategy

Final report
Volume II (Annexes)

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List of Abbreviations and Acronyms

CCEOP	Cold Chain Equipment Optimization Platform
CDS	COVID-19 Vaccine Delivery Support
CET	Central Evaluation Team
COVAX	COVID-19 Vaccines Global Access
CPMPM	Country programme monitoring and performance management framework
CRT	Current reality tree
CSCE	Civil Society and Community Engagement
CSO	Civil society organisation
CTC	Controlled temperature chain
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
FCAS	Fragile and conflict affected states
FFA	Force field analysis
FGHI	Future of Global Health Initiatives
FPP	Full portfolio planning
GNI	Gross national income
HI	High impact (countries)
HLQ	High level evaluation question
HLRP	High Level Review Panel
HPV	Human papillomavirus vaccination
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
LMC	Leadership, management and coordination
LMIC	Low- and middle-income country
M&R&S	Maintain, restore, and strengthen (Gavi COVID-19 initiative)
MCV	Measles-containing vaccine

MFF	MICs Financing Facility
MI	Mission indicator
MIC	Middle-income country
MTE	Mid-term evaluation of Gavi's 2021 – 2025 Strategy
MTR	Mid-term review
NRA	National regulatory authorities
PCA	Performance capacity assessment
PCV	Pneumococcal conjugate vaccine
PEF	Partners' engagement framework
PHC	Primary health care
PPC	Programme and Policy Committee
R&P	Respond and Protect (Gavi COVID-19 initiative)
RfP	Request for proposal
RI	Routine immunisation
SCM	Senior country manager
SFA	Strategic Focus Area
SG	Strategic goal
SI	Strategy indicator
SII	Strategy implementation indicator
TCA	Targeted country assistance
ToC	Theory of change
VCF	Vaccine catalytic funding
VfM	Value for money
VIPS	Vaccine Innovation Prioritisation Strategy
VIS	Vaccine investment strategy
WUENIC	WHO and UNICEF estimates of national immunisation coverage
YF	Yellow fever
ZD	Zero Dose

Annex 1: Request for proposal (ToR) as received from Gavi

2.1 Background

Gavi Mission
To save children's lives and protect people's health by increasing access to immunisation in poor countries.
Gavi, the Vaccine Alliance is a public-private partnership that helps vaccinate half the world's children against some of the world's deadliest diseases. The Vaccine Alliance brings together developing country and donor governments, the World Health Organization, UNICEF, the World Bank, the vaccine industry, technical agencies, civil society, the Bill & Melinda Gates Foundation and other private sector partners. Since its inception in 2000, Gavi has helped immunise a whole generation – over 888 million children – and prevented more than 15 million deaths, helping to halve child mortality in 73 developing countries. Gavi also plays a key role in improving global health security by supporting health systems as well as funding global stockpiles for Ebola, cholera, meningitis and yellow fever vaccines. After two decades of progress, Gavi is now focused on protecting the next generation and reaching the unvaccinated children still being left behind, employing innovative finance and the latest technology – from drones to biometrics – to save millions more lives, prevent outbreaks before they can spread and help countries on the road to self-sufficiency. Learn more at www.gavi.org.

The Gavi 2021-2025 Strategy
Gavi's new five-year strategy (2021-25) – focuses on 'leaving no one behind with immunisation' and pursuing an ambitious equity agenda, which prioritizes zero-dose (ZD) children and missed communities. The Strategy is aligned with the Immunisation Agenda 2030 of the World Health Organisation, which sets out the ambitious target of reducing the number of ZD children worldwide by 25% by 2025 and by 50% by 2030. It builds on the Alliance's achievements under Gavi 4.0 (2016–2020) against its coverage & equity targets and prioritises solutions to address the key challenges highlighted.

The strategy is intended to contribute across the following four strategic goals:

- Strategy Goal 1: Introduce and Scale Up Vaccines
- Strategy Goal 2: Strengthen Health Systems to increase Equity in Immunisation
- Strategy Goal 3: Improve Sustainability of Immunisation Programmes
- Strategy Goal 4: Ensure Healthy Markets for Vaccines and Related Products

And incorporates several key shifts in Gavi's strategy to deliver on its mission, including:

- A core focus on reaching "zero-dose" children and missed communities, with equity as the organising principle
- More differentiated, tailored and targeted approaches for Gavi-eligible countries
- An increased focus on programmatic sustainability
- Providing limited and catalytic support for select former and never Gavi-eligible countries

Operationalisation of the strategy and recalibration of programmatic priorities made in response to COVID-19
Operationalisation of the strategy commenced following the June 2019 Board decision endorsing the Strategy. This operationalisation phase initially focused on reviewing and transforming Gavi's policies, strategic approaches, processes, and tools to align with the revised strategic focus and

included a structured process with six main workstreams (Dec. 2019 Board _ Section C: Operationalisation of Gavi 5.0).

However, in response to the COVID-19 pandemic, Gavi recalibrated its strategic priorities as summarised in the Dec. 2020 Board paper Strategy, Programmes and Partnerships: Progress, Risks and Challenges. While acknowledging that leaving no one behind with immunisation and Gavi's strategic goals and objectives for the next strategic period were more relevant than ever, the Alliance adopted the following recalibrated priorities for the 2021-2025 strategic period:

- Maintaining, restoring, and strengthening routine immunisation, including preventing backsliding and catching up on missed children who missed their timely vaccinations because of disrupted services,
- Reaching zero-dose children and missed communities to advance Gavi's ambitious equity agenda, rendered even more urgent by COVID-19 which has thrust millions more into deep poverty, exacerbating inequities and gender disparities,
- Supporting delivery of COVID-19 vaccines to priority populations, and
- Safeguarding domestic financing for immunisation in a fiscally constrained environment.

Given limited country and Alliance partner capacity, Gavi paced new vaccine introductions, deferred the introduction of new vaccines approved through the Vaccine Investment Strategy (VIS) in 2018 ('VIS vaccines'), as well as rephasing the approach for engagement with middle-income countries (MICs). Fig. 1 below shows how these recalibrated priorities map against the original strategic goals and objectives captured in the Gavi 5.0 strategy framework "one-pager". Note that the new priority to support delivery of COVID-19 vaccines to priority populations falls outside the scope of the mid-term evaluation and will be evaluated separately (see scope section below). The Board reconfirmed the recalibrated priorities in December 2021.

Fig. 1: Gavi 5.0 Recalibrated Priorities by Strategic Goal

5.0 Strategic Goals (original)	5.0 Recalibrated Priorities		
	New Priority	Unchanged Priority	Rephased (further details on how rephasing for each is explained is here pg. 10 and 11)
SG 1: Introduce and scale-up vaccines	Supporting delivery of COVID-19 vaccines to priority populations	SG1a: Vaccine prioritisation SG1c: Outbreak response	SG1b: Introduce & scale up coverage of new vaccines (new vaccine introductions paced and VIS vaccines deferred)
SG 2: Strengthen Health Systems to Increase Equity in Immunisation	Maintaining and restoring routine immunisation to prevent backsliding and catch-up missed children (in light of COVID-19)	SG2a: Reaching under-immunised and zero-dose children (incl. SG2b, SG2c)	
SG 3: Improve Sustainability of		SG3a: Strengthen commitment	SG3c: Engage self-financing countries (MICs)

Immunisation Programmes		SG3b: Promote domestic public resources for immunisation	
SG 4: Ensure Healthy Markets for Vaccines and Related Products		SG4: Ensure healthy markets for vaccines and related products	

Implementation of Gavi 5.0 Strategy as of June 2022

2021 was the first year of the new strategic period and focused on establishing strategic and operational alignment towards achieving Gavi 5.0 goals. This was achieved, for example, through the development of new guidelines and application materials to help strengthen country programming, the realignment of existing funding streams, and the creation of a new dedicated funding stream (pg. 9&10) targeting zero-dose children and missed communities (the Equity Accelerator Fund (EAF)). Following the Secretariat organisational review, 2021 also saw the introduction of a differentiated approach to managing Gavi's country portfolio, tailoring support based on new country segmentation (pg. 10) (e.g., high impact, fragile and conflict, core).

In 2022, as the Alliance enters the second year of Gavi 5.0, focus is shifting to 'executing for impact' against the backdrop of continued COVID-19 related disruptions. The pandemic has placed a strain on immunisation programmes, contributing to an estimated 3.1 million increase[1] in the number of zero-dose children across Gavi-57 eligible countries in 2020. Routine immunisation has been impacted as countries have ramped up COVID-19 vaccinations, particularly in the second half of 2021. Equity gaps are widening, reversing the pre-pandemic hard won gains. While 2021 was devoted to supporting countries in preventing backsliding and laying the foundations for Gavi 5.0 and the zero-dose agenda, in 2022 the focus is shifting to in-country programming to both sustain coverage and stretch to reach zero-dose children.

Several critical countries such as India and Pakistan are going through their Full Portfolio Planning (FPP)[2] process to access Gavi funding, putting unprecedented efforts on identifying zero-dose children and missed communities and developing targeted strategies to reach them. In addition, up to 40 countries are expected to apply for EAF support to help reach zero-dose children. A portion of the EAF support has also been dedicated to new multi-country partnerships know as Zero-Dose Immunization Programme (ZIP). Two consortia of humanitarian partners have been selected to implement new approaches to reach zero-dose children and missed communities in fragile, conflict and cross-border settings in 11 countries. In 2022, increased engagement with local partners and Civil Society Organisations (CSOs) is also a priority to ensure context appropriate partnerships are in place to better address equity challenges. Opportunities to leverage synergies between COVID-19 vaccination and routine immunisation strengthening are also ongoing in several countries, bringing together these two critical priorities.

Gavi 5.1

The COVID-19 pandemic has dramatically transformed the global health and immunisation landscape. While the work on scaling up COVID-19 vaccines in countries is far from over and there are still uncertainties in the trajectory of the pandemic, Gavi now needs to start exploring how its

[1] https://www.gavi.org/our-alliance/strategy/phase-5-2021-2025/equity-goal/zero-dose-children-missed-communities

[2] FPP process helps countries to map out the portfolio of support needed to achieve their ambitions. It integrates all types of Gavi support to best achieve national immunisation goals. Countries are expected to prepare periodically (approximately every 3-5 years) an integrated request for support comprising all support provided by Gavi, including Health System Strengthening (HSS), the Cold Chain Equipment Optimization Platform (CCEOP) targeted country assistance (TCA) provided through the partners' engagement framework (PEF), existing vaccine support, and newly planned introductions and campaigns.

role in COVID-19 vaccination is to evolve from 2023 onwards and how COVID-19 vaccination and COVID-19 learnings will come together with Gavi's core 5.0 strategy and operating model. This shift is being referred to as Gavi 5.1, reflecting the natural evolution of Gavi 5.0 – keeping zero dose children and equity at its core – while encompassing the integration of the impact of the pandemic, COVAX and its learnings. Specifically, there are four key areas that will be explored, with the aim of bringing Gavi 5.1 to the Board in December 2022 for approval:

- Implications of the pandemic (including COVID-19 vaccination, learnings and the impact on RI) on Gavi's strategic priorities.
- Defining Gavi's role in COVID-19 vaccination going forward, including the design of a COVID-19 vaccine programme and how future support would align with core Gavi programmes.
- Evolution of Gavi's role in pandemic preparedness and response, noting that our work on systems strengthening is already at the heart of PPR; as well as furthering Gavi's engagement in regional manufacturing in Africa
- The need to continue shaping the organisation to deliver on this recalibrated and expanded mission, as well as optimising business operations and processes and the partner engagement model.

Gavi 5.0 Theory of Change

An overarching Gavi 5.0 Theory of Change (TOC) was developed in 2019[3] which showed how the operationalisation of the Strategy is assumed to deliver against the Strategic Goals. This key tool is used to guide measurement, programmatic activities, and Alliance-wide understanding of Gavi's key levers are the domains in which the Alliance can influence shifts and outcomes across the program cycle. These levers are operationalized through two key intervention areas at country level. Health System and Immunization Strengthening (HSIS) grants and vaccine supply investments which are, in turn, supported by program support (including technical assistance), as well as through advocacy, coordination, and accountability. The levers and intervention areas are the key link between the Alliance and country-level outcomes. The causal pathways are articulated through the inputs, outputs/intermediate outcomes, and outcomes columns.

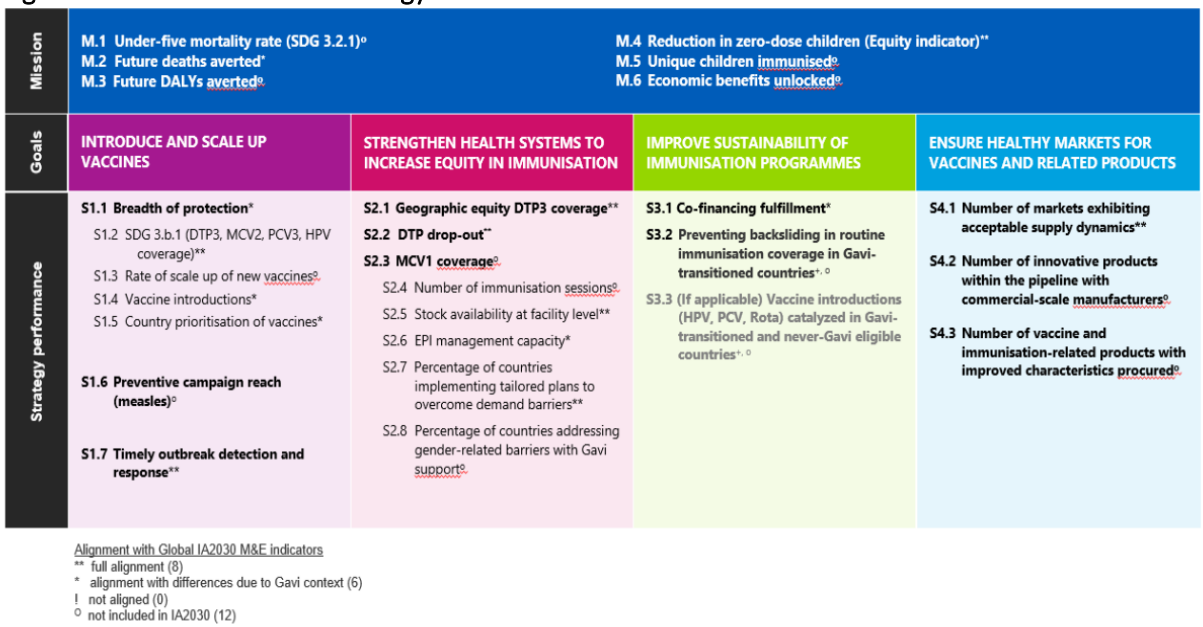
Strategy Performance Monitoring

To help the Gavi Alliance Board assess the extent to which the 2021-2025 strategy is on track, Gavi 5.0 mission and strategy performance indicators (Fig. 2)4 have been developed to measure progress towards the goals and objectives as described in the Gavi 5.0 strategy framework "one-pager". They focus on key portfolio-level impacts, outcomes, or outputs, with shared Alliance accountability. Mission indicators measure progress on the overarching goals of the 5.0 strategy, demonstrate Gavi's global impact and enable advocacy. Some are part of commitments in the Gavi 2021-2025 Investment Opportunity.

[3] 5.0 Theory of Change does not reflect the recalibrated priorities and updates to the TOC are currently underway as part of the broader integration work (Gavi 5.1)

[4] Revisions to targets are discussed below but not indicators.

Fig. 2: Gavi 5.0 Mission and Strategy Performance Indicator Dashboard



The Board approved the final baselines/targets for these indicators in December 2021. Similar to the principle used for selecting indicators, target development has been linked to operational considerations to ensure targets are ambitious but connected to the activities Gavi anticipates supporting during the strategy period.

The COVID-19 pandemic introduced considerable uncertainty for target setting for the period 2021-2025, both in terms of establishing a baseline and establishing targets for 2025. Conventionally, 2020 would be the baseline year for the 2021-2025 strategy period. However, there is considerable uncertainty around the reported immunisation coverage figures for 2020 and it is assumed that the WUENIC estimates of immunisation coverage for 2020 will continue to be revised over the next few years as additional survey data becomes available. Given this, 2019 is the baseline for Gavi 5.0 strategy targets, as it provides a more stable reference point for tracking progress to 2025 as compared to using 2020. A similar approach has been implemented in the development of the IA2030 M&E framework.

Given the strong recovery in routine immunisation coverage seen in the second half of 2020, Gavi's approach to target setting for coverage indicators assumed that this recovery would be maintained, and that 2021 coverage levels would be similar to 2019 levels, and then increase from 2022 onwards. The vision of success can therefore be partitioned into recovery to 2019 levels in 2021, followed by four years to make progress against 2025 targets over the 2019 baseline.

Based on monthly administrative data reported by countries as of June 2022, it appears that the disruption to routine immunisation may be more prolonged than originally anticipated, and therefore some of the Alliance's targets for Gavi 5.0 may be at risk. The impact of the pandemic and COVID-19 vaccination will become clearer following the release of WUENIC coverage data in July 2022.

The COVID-19 pandemic has meant a further challenge with using results from the monitoring approach if looking to assess the success of operationalising Gavi 5.0. Based on previous experience, results from the initial countries that operationalise the programmatic priorities under Gavi 5.0 will mainly appear in coverage and other higher-level results reported in 2024 onwards.

2.2 Objectives and scope of this evaluation

The purpose of the mid-term evaluation (MTE) is mainly to inform the development of Gavi 6.0 (2026 – 2030), as well as support course-correction in the 2021-2025 strategy, through the timely delivery of evidence-based findings, conclusions, lessons learned and recommendations. The MTE's purpose is primarily to support learning rather than meeting accountability needs. The primary audiences for the evaluation are the Gavi Board, Gavi Secretariat, Alliance partners and countries.

The evaluation will therefore focus on meeting the following three key objectives:

1. Evaluating the status of implementation of Gavi's fifth strategy by end 2023 and identifying the drivers and barriers that explain that status
2. Assessing the extent to which implementation of the strategy on its current trajectory will plausibly result in achievement of the prioritised strategic goals and objectives and identify areas for course correction
3. Generate a series of findings, conclusions, lessons learned and recommendations that can inform development of Gavi 6.0 (2026 – 2030).

These objectives will mainly be met through delivery of two products:

- By September 2023, an interim product drawing together and synthesising evidence available on the status of implementation of Gavi's current strategy and setting out preliminary findings, conclusions and strategic lessons learnt on whether it is plausible that implementation of the strategy on its current trajectory will deliver against its strategic goals and objectives. This interim product is intended to inform contextual analysis and initial Board/Secretariat discussions on development of Gavi 6.0.
- By December 2023, delivery of a draft synthesis report of evidence against the specific MTE questions, conclusions, lessons learned and recommendations to inform the 2024 Board Retreat on Gavi 6.0, the Board decision in June 2024 and subsequent planning for its operationalisation from mid-2024 by the Secretariat.

Supporting timely access to and delivery of COVID-19 vaccines – will be outside the scope of the MTE. Performance of the COVAX Facility and COVAX Advanced Market Commitment (AMC) are managed separately from the main body of Gavi's work, not covered within the Gavi 5.0 Strategic Framework and are subject to a separate evaluation. The impact of the COVID-19 pandemic and the COVAX Facility will only be considered as major explanatory factors that explain performance in areas that are within the scope of the MTE.

Mid-term Evaluation questions:

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

    a. To what extent do Gavi's strategy performance indicators show recovery to 2019 baseline levels in 2021?
    b. To what extent do Gavi's performance indicators meet the strategy targets at mid-term?
    c. What factors explain the results against the targets in the Gavi results framework? Where have the successes been? What have been the major barriers and what barriers to further success are important to address?
    d. To what extent did Gavi effectively and efficiently implement approaches to safeguard routine immunization programs and support recovery in countries from COVID-19 disruption? Were these flexible enough to allow rapidly adapting programmatic,

administrative, or financial processes to be implemented in a timely fashion? Which approaches were most/least effective and efficient?

e. To what extent have Gavi's recalibrated priorities in response to COVID-19 affected the timeliness of expected delivery against the strategic goals and influenced rebound from the effects of COVID-19 on RI programmes?
f. What have country level stakeholders' experiences been of the implementation of the differentiated, tailored, and targeted support for countries under the current strategy? Have there been major barriers to this approach being implemented as intended and has Gavi anticipated those barriers and moved to effectively address them?
g. 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?
h. 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?
i. What progress has been made against strategy goal (SG) 4 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?

2. To what extent will implementation of Gavi's 2021-2025 strategy on its current trajectory plausibly result in achievement of the prioritized Strategic Goals and objectives? Which areas are important for course correction?
    a. Has operationalization of the recalibrated priorities positioned the Gavi Alliance for success by 2025?
    b. To what extent is there evidence that countries have adjusted their immunisation programming intentions related to Strategic Goals 1, 2 and 3?
    c. To what extent have the implementation mechanisms[5] to operationalise Gavi's 2021-2025 strategy supported/influenced countries to adjust their immunisation programming intentions related to Strategic Goals 1, 2 and 3?
    d. What has been the contribution to SG4 in relation to the following key Market Shaping Strategy 5.0 pillars?
        i. Healthy Demand
        ii. Partnership Optimization
        iii. Regulatory Environment
        iv. Future Supplier Base
    e. Is SG4 as originally articulated still relevant in a post-COVID context?
    f. To what extent do the implementation mechanisms to operationalise Gavi's 2021-2025 strategy align with how Gavi will contribute to all its strategic goals as identified in the TOC?
    g. Was the TOC undermined during the initial phase of the COVID-19 pandemic or by another significant contextual shift? Is the TOC and assumptions underpinning the TOC still relevant as countries build back from the pandemic?

3. What are the major findings, conclusions, lessons learned and recommendations that can inform development of Gavi 6.0 (2026 – 2030)?
    a. To what extent are Gavi's strategic goals, policies and programs aligned with, supportive of and contribute to the relevant Sustainable Development Goals (SDGs) and IA2030?

[5] Evaluation of the Operationalisation of Gavi's Strategy through Gavi's Policies, Programmatic Guidance and Use of Funding Levers

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

It is expected that the contracted evaluation supplier will refine and propose additional evaluation questions as part of their inception report, with justification.

Methodology

Bidders are expected to propose the overall evaluation design and methods that they would use, but to the extent possible the mid-term evaluation should draw on and synthesise evidence from sources such as but not limited to: (i) other Gavi (or Alliance partner) evaluations currently on-going or being commissioned; (ii) Gavi's broader learning system; (iii) results and evidence reported to the Gavi Board. The intent is that the MTE will fill gaps in evidence to answer the Eqs where this is not already available from other evaluations/evidence sources.

The proposal should therefore set out how the design and methods will deliver a rigorous and transparent approach to synthesis of existing data in answering the evaluation questions and the proposed approach to identifying key data gaps and filling them. The design should respond to the evaluation questions while remaining cognisant of the fact that the significant empirical country-level results of Gavi 5.0 will probably only start emerging from 2024.

In development of their proposed design and methods, bidders should be aware of the following:

i. Gavi's Evaluation Policy and hence the evaluation quality and ethical standards that will be applied can be found here.
ii. Gavi's policies and levers under the current strategy continue to undergo change and simplification. A detailed briefing of status will be provided at the start of the inception phase for the MTE.
iii. Indicators and targets in Gavi's results framework for 5.0 can be found here (Summary of approved and proposed baselines/targets for Gavi 5.0 indicators). Results are reported annually in the August, drawing on WUENIC data for consideration in the September Gavi Board meeting (found here). It is anticipated that the impact of Covid-19 on regular immunisation activities may require revision of the targets set.
iv. This is the latest version of the Gavi 2021-2025 strategy Theory of Change. Clear articulation of how the changes under operationalisation of Gavi 5.0, as discussed above, and the link to the impact pathways in the TOC has not been carried out. Some teams within Gavi have developed TOCs specific to their programmatic areas and related to operationalisation of aspects of Gavi 5.0. Where relevant, these will be provided to winning evaluation supplier. As such, where required, further elaboration of the Gavi 5.0 TOC will need to be done by the independent evaluation supplier during the inception phase.
v. Other Gavi evaluations that are expected to be sources of evidence by evaluation sub-question are set out in the Table below.

EQ	Relevant evaluation	Other Gavi evaluation
	1. What is the status of implementation of Gavi's fifth strategy by end 2023? What are the drivers and barriers that explain that status?	
1.a	To what extent do Gavi's strategy performance indicators show recovery to 2019 baseline levels	Evaluation of Gavi's Initial Response to COVID-19

EQ	Relevant evaluation	Other Gavi evaluation
	in 2021?	
1.c	What factors explain the results against the targets in the Gavi results framework. Where have the successes been, what have been the major barriers and what barriers to further success are important to address?	Evaluation of the Operationalisation of Gavi's Strategy through Gavi's Policies, Programmatic Guidance and Use of Funding Levers
		Evaluation of Gavi's Initial Response to COVID-19
		Evaluation of Gavi's contribution to reaching zero dose children and missed communities
		COVAX Facility and COVAX Advance Market Commitment Evaluability, Evaluation Design and Baseline Study
1.d	To what extent did Gavi effectively and efficiently implement approaches to safeguard routine immunization programs and support recovery in countries from COVID-19 disruption? Were these flexible enough to allow rapidly adapting programmatic, administrative, or financial processes to be implemented in a timely fashion? Which approaches were most/least effective and efficient?	Evaluation of Gavi's Initial Response to COVID-19
1.e	To what extent have Gavi's recalibrated priorities in response to COVID-19 affected the timeliness of expected delivery against the strategic goals and influenced rebound from the effects of COVID-19 on RI programmes?	Evaluation of Gavi's Initial Response to COVID-19
		COVAX Facility and COVAX Advance Market Commitment Evaluability, Evaluation Design and Baseline Study
		Evaluation of the Operationalisation of Gavi's Strategy through Gavi's Policies, Programmatic Guidance and Use of Funding Levers
1.f	What have country level stakeholders' experiences been of the implementation of the differentiated, tailored, and targeted support for countries under the current strategy? Have there been major barriers to this approach being implemented as intended and has Gavi anticipated those barriers and moved to effectively address them?	Evaluation of the Operationalisation of Gavi's Strategy through Gavi's Policies, Programmatic Guidance and Use of Funding Levers
		Evaluation of Gavi's contribution to reaching zero dose children and missed communities
1.g	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?	Evaluation of the Operationalisation of Gavi's Strategy through Gavi's Policies, Programmatic Guidance and Use of Funding Levers
		Evaluation of Gavi's contribution to reaching zero dose children and missed communities
		Evaluation of Gavi's Initial Response to COVID-19
1.h	To what extent have the implementation of Gavi's levers and mechanisms for operationalising 5.0 led to intended and unintended consequences at global or country level?	Evaluation of the Operationalisation of Gavi's Strategy through Gavi's Policies, Programmatic Guidance and Use of Funding Levers
		Evaluation of Gavi's Initial Response to COVID-19
		Evaluation of Gavi's contribution to reaching zero dose children and missed communities
	2. To what extent will implementation of Gavi's 2021-2025 strategy on its current trajectory plausibly result in achievement of the prioritized Strategic Goals and objectives? Which areas are important for course correction?	
2.a	Has operationalization of the recalibrated priorities positioned the Gavi Alliance for success by 2025?	Evaluation of the Operationalisation of Gavi's Strategy through Gavi's Policies, Programmatic Guidance and Use of Funding Levers

EQ	Relevant evaluation	Other Gavi evaluation
		Evaluation of Gavi's Initial Response to COVID-19
		Evaluation of Gavi's contribution to reaching zero dose children and missed communities
2.b	To what extent is there evidence that countries have adjusted their immunisation programming intentions related to Strategic Goals 1, 2 and 3?	Evaluation of Gavi's contribution to reaching zero dose children and missed communities
2.c	To what extent have the implementation mechanisms to operationalise Gavi's 2021-2025 strategy supported/influenced countries to adjust their immunisation programming intentions related to Strategic Goals 1, 2 and 3?	Evaluation of the Operationalisation of Gavi's Strategy through Gavi's Policies, Programmatic Guidance and Use of Funding Levers
		Evaluation of Gavi's contribution to reaching zero dose children and missed communities
2.f	To what extent do the implementation mechanisms to operationalise Gavi's 2021-2025 strategy align with how Gavi will contribute to all its strategic goals as identified in the TOC?	Evaluation of the Operationalisation of Gavi's Strategy through Gavi's Policies, Programmatic Guidance and Use of Funding Levers
		Evaluation of Gavi's contribution to reaching zero dose children and missed communities
2.g	Was the TOC undermined during the initial phase of the COVID-19 pandemic or by another significant contextual shift? Is the TOC and assumptions underpinning the TOC still relevant as countries build back from the pandemic?	Evaluation of the Operationalisation of Gavi's Strategy through Gavi's Policies, Programmatic Guidance and Use of Funding Levers
		Evaluation of Gavi's contribution to reaching zero dose children and missed communities

iv. Delivery dates for key products under other Gavi evaluations are summarised in the table below:

Evaluation	**Dates**
Evaluation of Gavi's Initial Response to COVID-19	Completed November 2022
Evaluation of the Operationalisation of Gavi's Strategy through Gavi's Policies, Programmatic Guidance and Use of Funding Levers	Inception phase starts September 2022 Completed July 2023
Evaluation of Gavi's contribution to reaching zero dose children and missed communities	Inception phase starts Sept 2022 Series of initial findings will be available between February and September 2023. Evidence of results at country level won't be available for this deliverable.
COVAX Facility and COVAX Advance Market Commitment Evaluability, Evaluation Design and Baseline Study (Annex 21)	Complete March 2023

iv. As part of the inception phase, EVLU will support the evaluation supplier to identify key evaluations delivered by other Alliance partners.

v. Key areas in which evidence gaps are clear and need to be included in the MTE include: (i) results of the maintaining, restoring, and strengthening immunisation responses to COVID-19 from 2nd quarter 2022 onwards to cover the period not included in the evaluation of Gavi's initial response to COVID-19; and (ii) the Secretariat's support to mitigating problems in raw material supply chains and manufacturer prioritisation decisions during the COVID emergency (Strategic Goal 4). Work proposed to fill these two gaps should be reflected in bidders' technical and financial proposals. Identifying other evidence gaps is a major focus of the inception phase. Technical proposals should indicate how bidders would approach identifying such gaps during the inception phase and developing technical and financial proposals. Which gaps would be filled, and agreement of additional budget would be agreed as part of agreement of the inception report.

Evaluation management

Gavi's Evaluation Policy and hence the evaluation quality and ethical standards that will be applied can be found here.

i. Evaluation Advisory Committee (EAC)
   a. The Gavi Evaluation Advisory Committee (EAC) is established to support the Board in fulfilling its oversight responsibilities in respect to the management of Gavi's evaluation activities. The Terms of Reference for the EAC are available here.
   b. As part of its important role in safeguarding evaluation independence and providing quality assurance, the EAC will assign focal points (FPs) with direct oversight on the evaluation process. Engagement with the EAC FPs is outlined in the table below on deliverables.

ii. Centralised Evaluation Team (CET)
   b. The CET is responsible for implementation of centralised evaluations including commissioning and managing independent centralised evaluations including ensuring the utility, quality and timely delivery of evaluation reports and disseminating the findings.
   c. The Evaluation Manager manages the ongoing contact with the evaluators including sharing relevant documents, facilitating contacts within the Gavi Secretariat and Gavi governance structures, ensuring engagement with primary users, ensuring the Communication and Learning Plan is regularly revisited with evaluators and updated if needed, bi-weekly calls with the evaluators and where relevant, support the Evaluator to organise relevant workshops with key stakeholders.
   d. The CET will facilitate early and continued engagement through the inception and implementation phases across evaluations and between the evaluators (i.e. facilitate collaboration between the evaluators for the MTE and other evaluators undertaking ongoing evaluations commissioned by CET).

1.2 Deliverables and key dates

Key Milestones and Deliverables	Due Date	Engagement and review approach
Bi-weekly update calls with the evaluation manager (including meeting minutes)	Throughout the evaluation	
Milestone 1: Inception phase	**Due Date**	**Engagement & Review Approach**
In-person kick-off meeting		
Deliverable 1: Draft inception phase report including approach and methods, interview guides, a communication and learning plan for the evaluation, and a draft Theory of Change	04-Nov-22	To be reviewed by the Secretariat, and QA by EAC FPs
Deliverable 2: EAC and Gavi Secretariat engagement (with slide deck presentation)	w/c 14-Nov-22 (TBC)	EAC FPs, Secretariat
Deliverable 3: Final inception phase report with an Executive Summary (format TBC) as well as finalized evaluation theory of change (word document)	28-Nov-22	To be reviewed by the Secretariat, EAC FPs
Milestone 2: Interim Phase	**Due Date**	**Engagement & Review Approach**
Deliverable 1: Progress update report including preliminary findings (relevant Annexes)	24-Feb-23	To be reviewed by the Secretariat, EAC FPs
Deliverable 2: EAC and Gavi Secretariat engagement (with slide deck presentation).	w/c 06-Mar-23(TBC)	To be presented to EAC FPs, Secretariat
Deliverable 3: Engagement at the Evaluation Advisory Committee (EAC) (with slide deck presentation).	Late March / early April	

Deliverable 4: Draft Interim Report 1	14-Apr-23	To be reviewed by MEL
Deliverable 5: Revised Interim Report 1	12-May-23	To be reviewed by the Secretariat, and EAC FPs
Deliverable 6: EAC and Gavi Secretariat engagement (with slide deck presentation).	w/c 22-May-23 (TBC)	To be presented to EAC FPs, Secretariat
Deliverable 7: Updated Interim report	04-Aug-23	To be reviewed by Secretariat, EAC FPs and key stakeholders
Deliverable 8: PowerPoint slide deck summarising the updated interim report, including draft recommendations	11-Aug-23	Pre-read for stakeholder meeting
Deliverable 9: Facilitate key stakeholder meetings	w/c 21-Aug-23 (TBC)	
Deliverable 10: Final interim report	01-Sep-23	Assessed by the EAC and reviewed by Secretariat
Milestones 3: Final Synthesis Report	**Due Date**	**Engagement & Review Approach**
Deliverable 1: Draft Synthesis Report	**17-Nov-23**	**To be reviewed by MEL**
Deliverable 2: Revised Draft Synthesis Report	04-Dec-23	To be reviewed by the Secretariat, and EAC FPs
Deliverable 3: EAC and Gavi Secretariat engagement (with slide deck presentation).	w/c 18-Dec-23 (TBC)	To be presented to EAC FPs, Secretariat
Deliverable 4: Updated synthesis report	08-Jan-24	To be reviewed by Secretariat, EAC FPs and key stakeholders
Deliverable 5: PowerPoint slide deck summarising the updated synthesis report, including draft recommendations	12-Jan-24	Pre-read for stakeholder meetings
Deliverable 6: Facilitate key stakeholder meetings	w/c 22-Jan 2024	
Deliverable 7: Draft final synthesis report	09-Feb-24	To be quality-assessed by the EAC and reviewed by the Secretariat
Deliverable 8: Final Synthesis report and slide deck summarizing the Final Report	01-Mar-24	Assessed by the EAC and reviewed by Secretariat
Milestone 4: Finalisation phase	**Due Date**	**Engagement & Review Approach**
Draft Policy Brief summarising the main findings, lessons learnt and final recommendations	16-Feb-24	To be reviewed by MEL
Final Policy Brief summarising the main findings, lessons learnt and final recommendations	08-Mar-24	
Dissemination meeting (Presentations of Final Report at Gavi Secretariat to key audiences)	By end Mar-2024	

2.4 Duration of the Work

The scope of work is expected to be finalised over the period from October 2022 to Mid-2024.

2.5 Location of the Work

The scope of work shall be performed at the Bidder's registered office, at Gavi offices or such other location as may be agreed to by Gavi and the successful applicant.

2.6 Work Context

The tasks shall be performed for The Evaluation and Learning Unit under the supervision of and in collaboration with relevant internal and external stakeholders.

Annex 2: Gavi 5.0 Theory of Change

We have elaborated the original Gavi 5.0 ToC (see Figure 1) in collaboration with Gavi and the strategy operationalisation evaluation and ZD evaluation teams' evaluations. By their nature, the strategy operationalisation evaluation had a strong focus on the left-hand side of the ToC 5.0 pathway, and the ZD evaluation focuses on pathways towards SG2 ("The Equity Goal"), while the MTE has a much broader focus across all Goals and from the left to the right side of the ToC. To avoid duplication, we have worked with Gavi and the other evaluation teams to agree where to focus our respective efforts, with each evaluation team focusing on elaborating the most relevant area of the ToC. For example, the strategy operationalisation evaluation team identified assumptions in the causal pathways between the 5.0 ToC inputs/ levers and intervention levers, as well as between the specific funding levers (HSIS, TCA etc.) and the interventions they support (see Figure 2); while the ZD evaluation has identified assumptions in the pathways towards SG2 (see Figure 3).

Based on review of documentation to date, including assumptions identified in the other evaluations, available 5.1 documentation and ToCs developed for various components of 5.0, such as ZD, market shaping, FCAS, community and private sector engagement etc. – we have developed an elaborated 5.0 ToC diagram (Figure 4) and mapped out underlying assumptions across the ToC from inputs/ levers to intervention areas, outputs and outcomes (Table 1). As noted in our inception report, we are aware that work on a 5.1 ToC is ongoing, which may still require adjustments to our ToC.

The following additions to the 5.0 ToC diagram (in red) were made at least partly on review of available 5.1 documentation:

Interventions:

- SG1: Support improved outbreak and pandemic response and connection back to RI.
    - This is an explicit addition based on the integration of pandemic response under 5.1, but also aligns with the December 2020 recalibrated priorities, which included "Supporting timely access to COVID-19 vaccines", and other recalibrations which also related to the COVID-19 pandemic. As the MTE includes reviewing activities conducted under the M&R&S framework, which was initially a response to COVID-19, including this in the elaborated 5.0 MTE ToC is appropriate.

Outputs/Intermediate outcomes:

- SG1: Global stockpiles for outbreak and pandemic-prone diseases efficiently and equitably deployed.
    - As above, the addition of pandemic-prone diseases is relevant given the work conducted in the context of COVID-19 to date, as well as planned work under 5.1. The addition of "and equitably" is not related to 5.1, but is from the general focus on equity under SG2.

Outcomes:

- SG2: Increased demand for quality and resilient RI services for ZD children, under-immunised & their communities.
    - The addition of resilience reflects explicit increased emphasis under 5.1, but we see that under 5.0, resilience was still reflected in work planned (and already underway) in the FCAS context etc. Therefore, we see this as a relevant addition to the 5.0 ToC to capture Gavi work to date during the 5.0 strategy period and work planned.
- SG4: Improved health of markets with diversified supply for vaccines and related products.
    - The addition of diversified supply also reflects explicit increased emphasis under 5.1, but from review of Market-Shaping related nested 5.0 ToCs that have been developed, we see this as a relevant addition to the 5.0 ToC to capture Gavi work to date during the 5.0 strategy period and work planned.

As already outlined, other additions are based on review of wider 5.0 documentation.

We are using the ToC, including these assumptions, to evaluate the extent that design and implementation of the strategy have progressed as intended. In our final analysis using this elaborated ToC, the degree to which individual pathways, including assumptions, appear to have held, will be red-amber-green rated to indicate whether the pathway/assumption entirely/mostly held (green); partially held (amber) or failed to hold (red). A preliminary version of this analysis is provided in Figure 4.

Figure 1: Original Gavi 5.0 theory of change

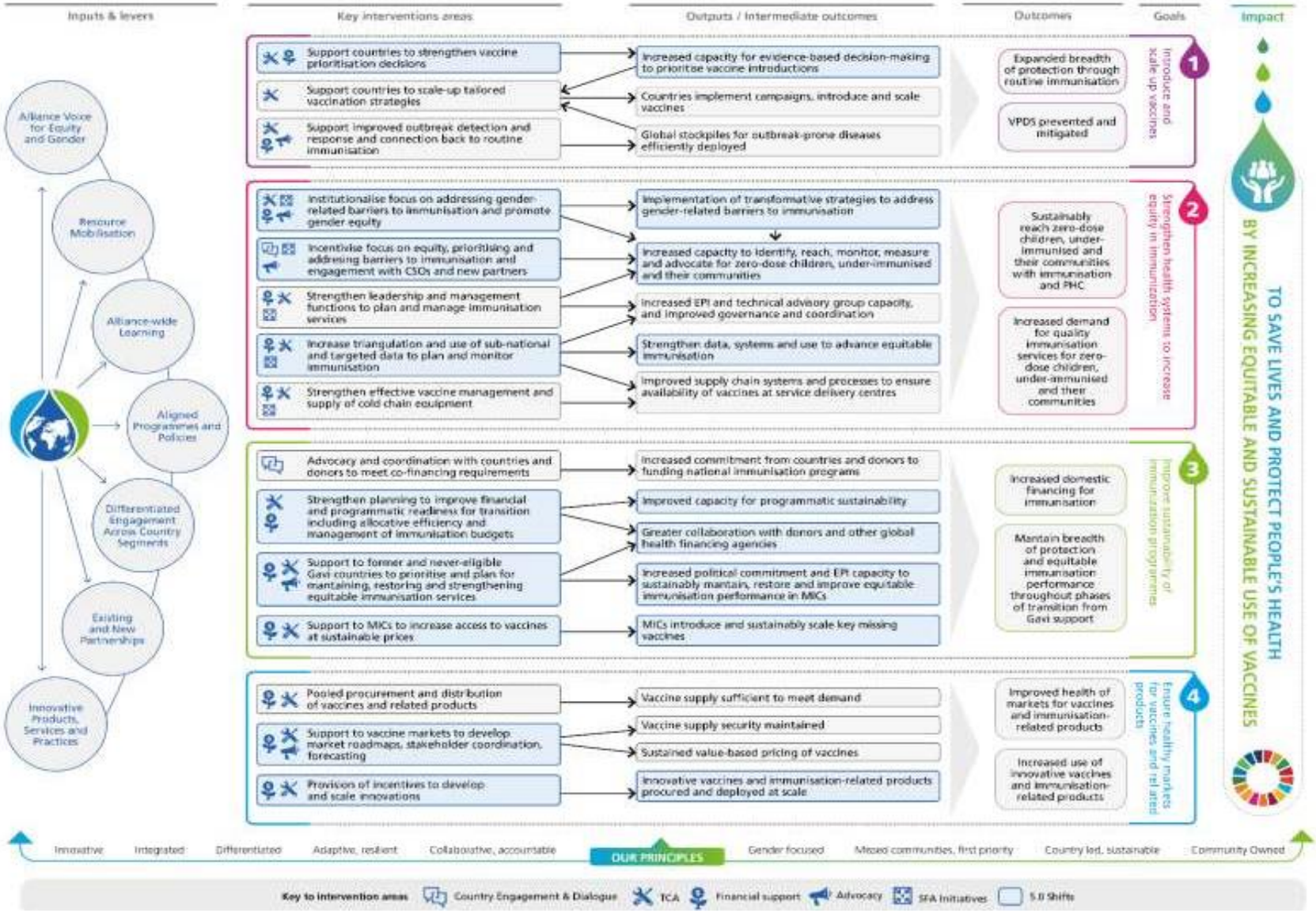


Figure 2: Strategy operationalisation evaluation theory of change

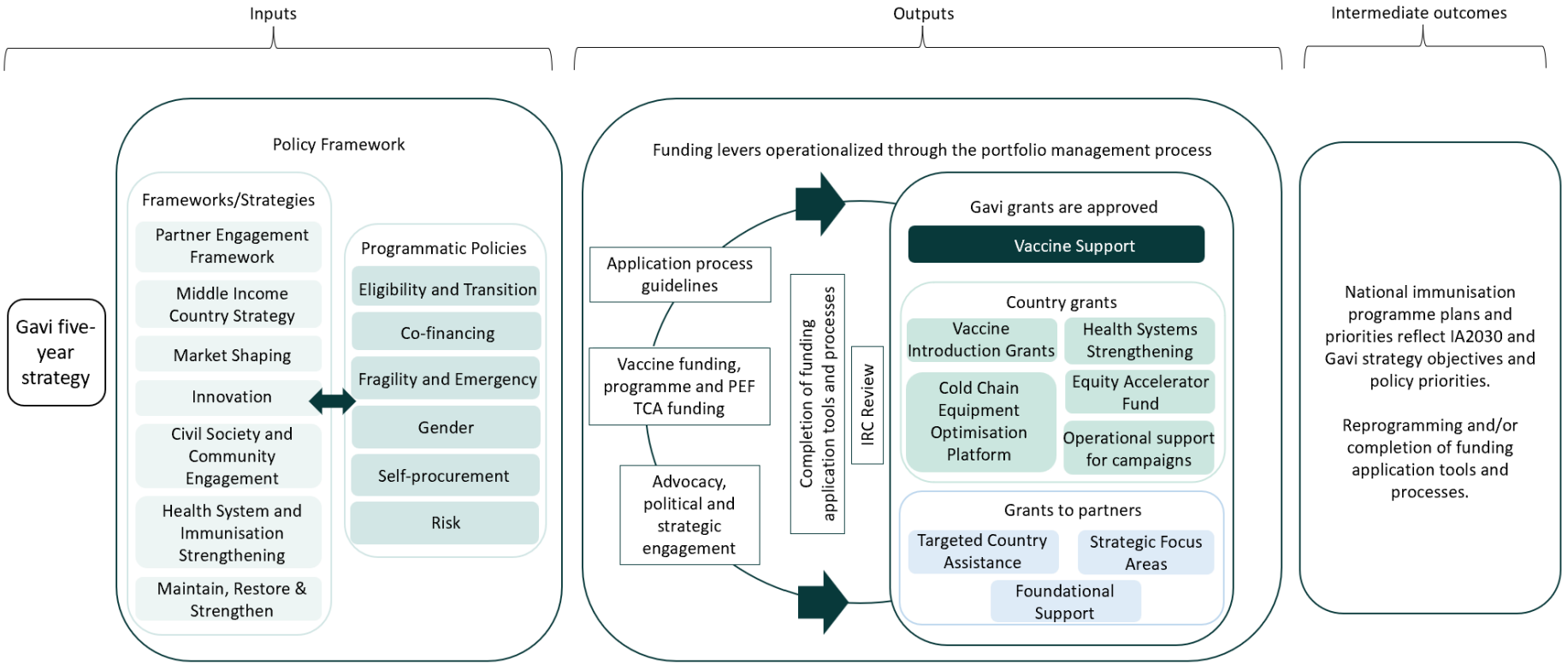


Figure 3: Zero Dose evaluation theory of change

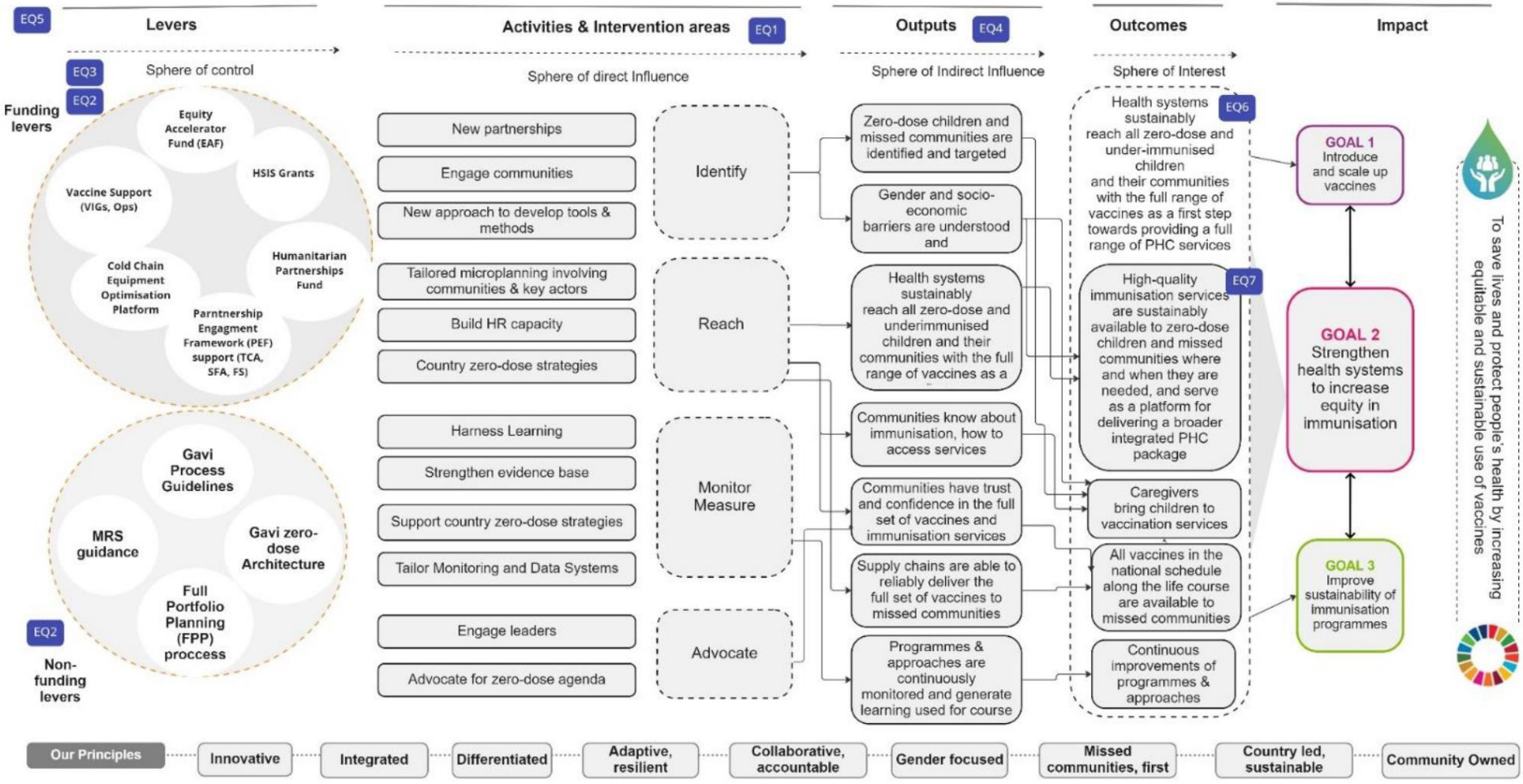
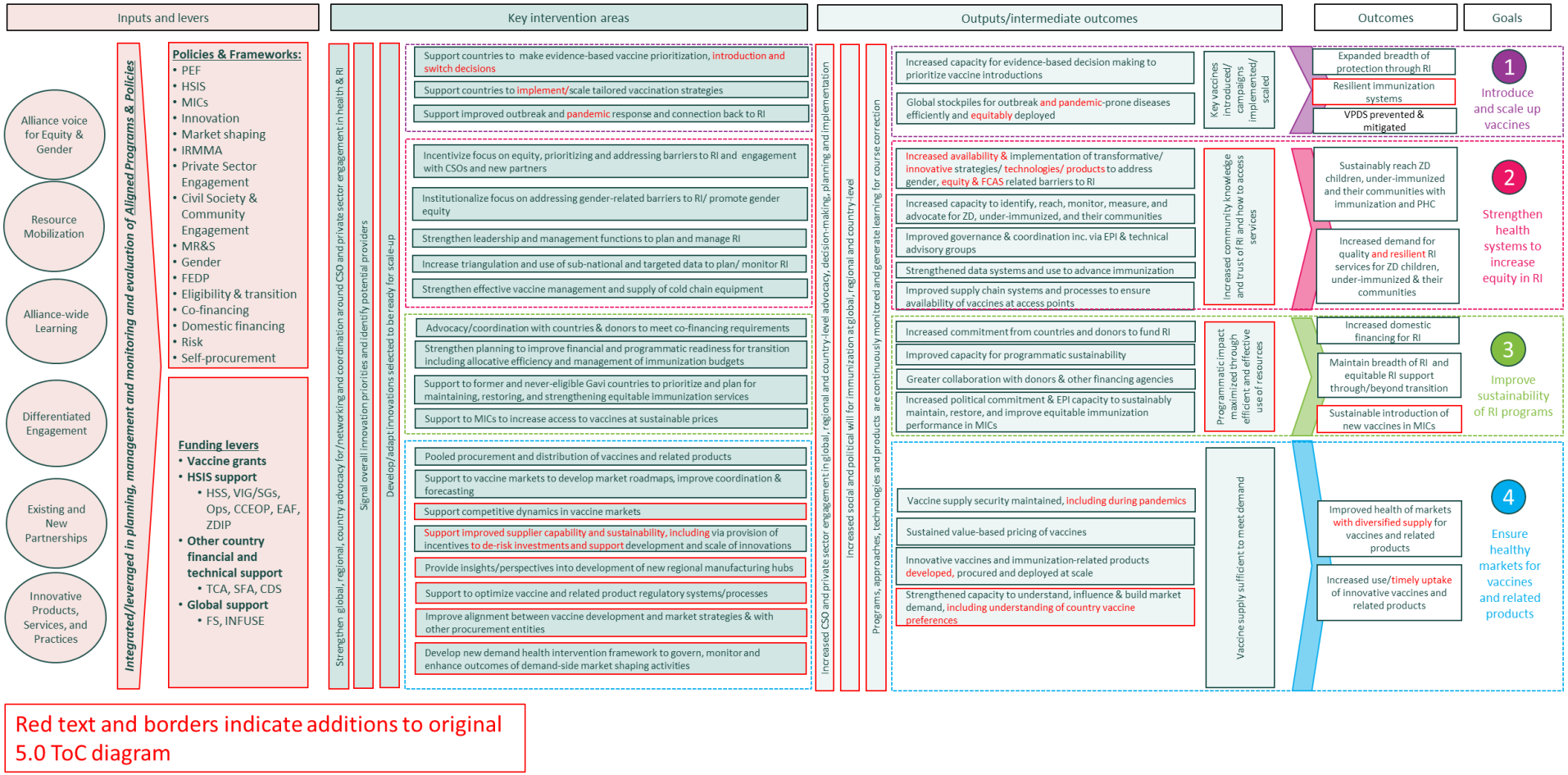


Figure 4: Elaborated Gavi 5.0 ToC for the MTE (additions highlighted in red text/outlines)



Red text and borders indicate additions to original 5.0 ToC diagram

Please note that we have not included the Impact statement on the right hand-side of the ToC for space reasons. It remains unchanged. We have also not included arrows indicating individual causal pathways in the diagram. The broad direction of causality is left-to-right. The narrative previously presented provides more details on individual pathways.

Table 1: 5.0 MTE ToC Assumptions

Inputs-> Levers	Levers-> Interventions	Interventions->Outputs		Outputs-> Outcomes		Goal
		Goal-Specific	Cross-cutting	Goal-Specific	Cross-cutting	
Resource mobilization: • Financial/ economic situation of donor governments/ private sector facilitates sufficient resource mobilisation to support funding levers. **Alliance Voice for Equity and gender:** • Gavi Secretariat, supported by partners, has capacity to conduct advocacy and political and strategic engagement around strategic priorities. **Partnerships:** • Relevant new partnerships can be developed. • Existing and new partners have capacity to fulfil anticipated roles, including development and operationalisation of agreed priorities. **Alliance-wide learning:** • Data can be and is captured on overall Gavi Strategy and policy framework and thus supports learning across all Levers and Goals **Differentiated engagement:** • The portfolio management process supports constructive negotiation of mutually agreeable	1. Sufficient overall in-country financial resources. 2. Appropriate agility of Gavi support in place. 3. Sufficient in-country capacity/ bandwidth exists to apply for/ implement Gavi support. 4. Gavi processes facilitate strategy operationalisation. 5. Gavi processes facilitate interventions supportive of priorities including ZD. 6. Sufficient Gavi capacity/ bandwidth exists.	1. RI-related global supply chain issues can be sufficiently mitigated by pandemic/ emergency response interventions. 2. Country capacity is sufficiently resilient to shocks (related to COVID-19, FCAS contexts etc.) To support evidence-based decision making.	1. Sufficient CSO and private sector interest/ willingness and capacity to engage in development of quality, innovative solutions, inc. In fragile contexts. 2. Current Gavi interventions are/ continue to be relevant, adaptable and able to reach children in changing contexts. 3. Stakeholders (alliance partners, government and beyond) commit to provide coherent support in line with Gavi priorities, which is adopted into national policies and plans. 4. Continuity of and demand for basic health care services is maintained at current levels or better in order to provide a foundation for RI service. 5. Monitoring and data systems (in-country and strategy level) are functional and used, including for learning and course correction.	1. Impact of vaccine misinformation/ hesitancy is not significant enough to reduce overall uptake.		1: Introduce and scale up vaccines.
		3. Root causes of ZD children and missed communities are/can be identified. 4. Effective ZD interventions exist and can be implemented with Gavi support. 5. Sufficient capacity (hr, data, analysis) is available to map/ identify ZD children/ communities.		2. Sufficient in-country approaches are designed to reach ZD children and missed communities and are effective and sustainable.		2: Strengthen health systems to increase equity in RI.
		6. Interventions will be designed to strengthen health systems and be sustainable. 7. Countries are willing and able to prioritise RI, including the ZD agenda, amidst the ongoing impact of the COVID-19 pandemic. 8. Countries will continue to meet co-financing obligations in spite				3: Improve sustain-ability of RI programmes.

priorities between Gavi and national programs i.e. that respect country ownership. **Innovation:** • PENDING. **Aligned programs and policies** • The components of the policy framework, including linked guidelines templates and tools, are mutually coherent, and aligned with Gavi strategic priorities. • The policy framework is internally efficient and aligned with Gavi's operational principles and rules • Gavi Leadership, Culture and political will are supportive of strategic priorities and associated shifts.		of COVID-19 related or other economic contraction. 9. Countries have demand and fiscal capacity to work towards vaccine introduction and co-financing to maintain the vaccine programme. 10. Market shaping activities create the desired market dynamics, related to demand, supply and innovation, that enable implementation of the strategy operationalisation model and desired results.				4: Ensure healthy markets for vaccines and related products.

Annex 3: Key aspects of MTE methodology

Our methodology was set out in full in our inception report (February 2023), with additional detail included in our progress report (06 June 2023). We highlight below selected key elements in our approach, intended to facilitate interpretation of MTE findings, conclusions and recommendations, including:

- Purpose objectives and scope
- Intended audiences.

Purpose, objectives, and scope of evaluation

The primary purpose of the MTE was to support learning to inform the development of Gavi 6.0 through a **summative component,** which looked at implementation and progress to date against the Gavi 5.0/5.1 strategic goals and objectives, capitalizing as much as possible on a synthesis of existing evidence from four key evaluations and one internal review.[13] In addition, a **formative component**, which focussed on emerging themes which could impact on the remainder of Gavi 5.1 and inform Gavi 6.0. We note that, given time lags between strategy, implementation, and visible results for Gavi 5.0 caused e.g., by COVID-19, we de facto looked mainly at how Gavi 4.0 implementation helped countries reach Gavi 5.0/5.1 targets.

The **temporal scope** of the MTE covered **2021 to the end of December 2023**, and the **geographic scope** included **all Gavi-eligible countries in 2023**.

Evaluation of Alliance partners was out of scope, however we did plan to interview key Alliance partners, including WHO and UNICEF and review relevant documents to ensure that we understood the participation of key partners in the 5.0/5.1 strategy formulation and implementation, and could document any cases coming to light where it appeared that these partnerships (including WHO/UNICEF) did not yield the desired outcomes and highlight any emerging partnership issues which may impact Gavi 6.0.

Intended audiences.

We expect findings, conclusions, lessons, and recommendations generated to be of interest and relevance to the following stakeholder groups and processes.

Primary audiences

- The Gavi Board (including appropriate standing Board committees) and Secretariat: for operational learning about the implementation of Gavi 5.0/5.1 and to help the Gavi Alliance develop the Gavi 6.0 policy framework; and
- Gavi EvLU/Measurement and Strategic Information teams: to provide a robust evidence base and synthesis on lessons learned during the implementation of Gavi 5.0./5.1.

Secondary audiences

- Alliance partners, CSOs and countries: to inform on implementation of Gavi 5.0/5.1 and lessons learned for the development of Gavi 6.0; and
- Networks with links to Gavi: those with an interest in learning about responsive strategy development and implementation.

Overall evaluation approach

Our evaluation approach to the MTE is summarised in Figure 5 below, which includes five main aspects:

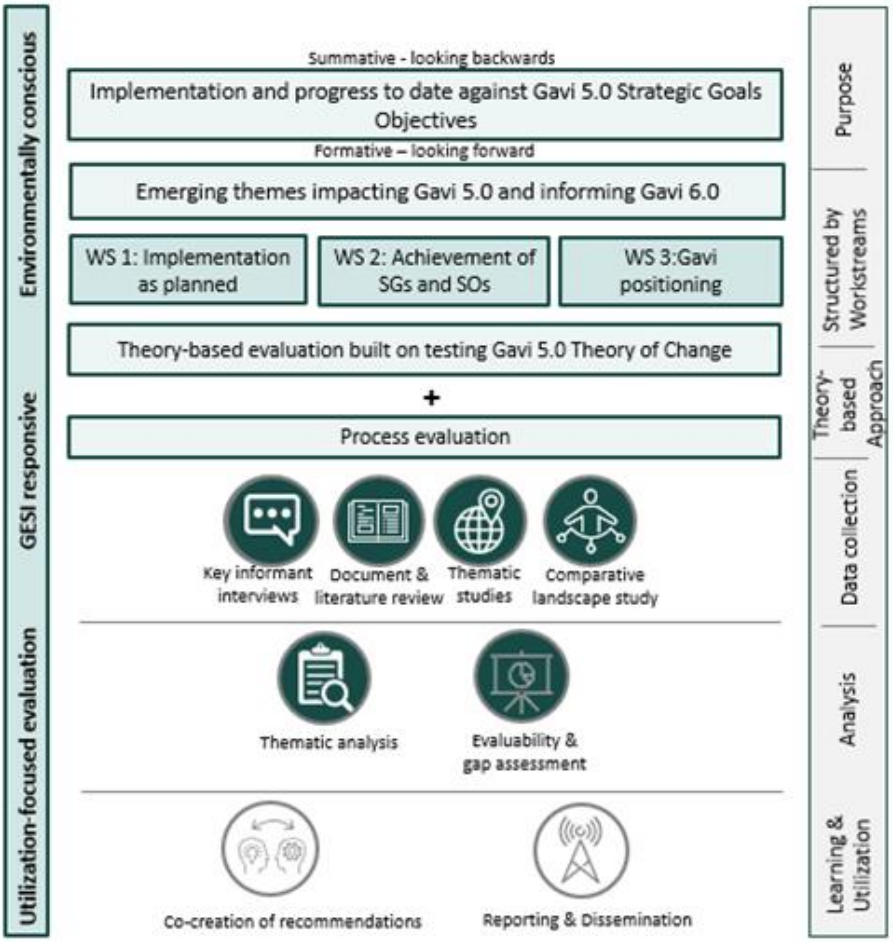
1. The articulation of **three strategic workstreams** that are based on the identification of the three 'high level MTE strategic questions' that should be answered under this assignment.

2. The clustering of **15 EQs** around **five analytical modules** which, we believe, helped us focus enquiry around the priority issues outlined in the RfP, provide a framework for efficiency, and effectively organise our analysis and synthesis work.
3. An analytical approach that blends **theory-based evaluation** based on the Gavi 5.0 theory of change (ToC), **and process evaluation** to identify the enablers and barriers to further progress and any corrective measures needed**.** We used the Gavi 5.0/5.1 as a conceptual framework to understand how and why' progress toward the Gavi strategic goals and objectives is being achieved. A key part of this approach was to look at the underpinning assumptions for the Gavi 5.0/5.1 ToC in order to understand whether these hold or not. A full list of assumptions identified in our work to elaborate the 5.0/5.1 ToC is set out in Annex 2, Table 1 above.
4. **Three core cross-cutting principles** of the evaluation: utilisation-focus, gender, equity, and social inclusion (GESI) responsiveness, and environmental consciousness.
5. A mix of carefully selected **analytical methods to identify and fill gaps in information from other ongoing or recently completed evaluations and reviews** to generate technically robust findings. The findings informed conclusions and lessons on which useful and actionable recommendations could be co-created with the primary intended users.

Our approach centred on maximising the utility of both existing data sources and previously conducted and ongoing evaluations and reviews, to minimize transaction costs and "evaluation fatigue" for Gavi and its partners. We have strived to make the best possible use of findings and observations generated and analysed in the four key evaluations highlighted above. We were already familiar with two of them as a company and a team, as various MTE team members were members of the COVID-19 and strategy operationalisation evaluation teams. We were able to use the early November 2022 meeting in Geneva to form links with the ZD evaluation team and we have shared information and data on potentially overlapping EQs to the extent possible. We have combined this with analysis of Gavi's routine monitoring under the monitoring and performance management (MPM) and against the strategic indicators to identify any gaps we needed to fill through limited primary data collection.

We are satisfied that this approach provided the evidence needed to inform any proposed changes to the business model, contributing to our recommendations on future positioning in Gavi 6.0.

Figure 5: Evaluation approach overview



Sampling strategies

Document selection

We received and reviewed more than 1,000 Gavi and external documents. These were identified by Gavi secretariat staff and other key informants as relevant to the MTE scope and objectives. In some cases, this was following specific requests from the MTE team.

Of these 450 were analysed (including through thematic coding). Choices on which documents to code were made following initial review by the co-team leads or by the module 3 lead (who also led on defining the coding tree and oversight of the research assistant team's coding of documentation).

We also analysed WUENIC data up to July 2023 reporting.

Global KI selection

Our sampling of global KIs was done to ensure a balanced range of perspectives inform the MTE:

- We understand the importance of hearing **country-perspectives** and expect to generate evidence from this category of stakeholders through the following means:
    - To avoid evaluation fatigue of country personnel, we agreed with EvLU to use existing data from the country case studies completed by the COVAX, COVID-19, strategy operationalisation, and ZD evaluations, rather than conducting additional country case studies. The four evaluations had or would collectively cover 20 out of 74 (27%) of Gavi's portfolio, encompassing a range of categories and ZD identification and grant application

statuses (see Annex 15, Vol. II). As the strategy operationalisation and ZD evaluations were still ongoing, we discussed this approach with both teams. They were open to adapting their data collection tools to facilitate us, as far as possible. We kept this under review through monthly coordination meetings with the strategy operationalisation and ZD teams. Where we had concerns whether this approach would deliver what was needed for the MTE, we considered whether MTE team members could join the other teams during their data collection; - this, however, did not take place.

  - We supplemented case study data with perspectives of civil society organisations (CSOs) and Gavi country governments, facilitated through interactions with Gavi board representatives. We worked with Board members to agree and facilitate a process of engagement with their constituents to ensure the breadth of constituent views is reflected appropriately.
- **Secretariat staff** provided important perspectives, in particular feeding our process evaluation.
- Interviews with other key stakeholder categories – such as **Gavi board members, Alliance partners, regional institutions for cross country observations, CSOs, private sector, think-tanks** – ensured our balanced view of Gavi's performance and of the factors that have and will enable and constrain further efforts on 5.1 and during 6.0.
- We strived to maintain the following broad split across global KIIs, as a means to gauge the balance of views – recognizing that this might differ for each EQ. This enabled us to be flexible, within resources allowed, in terms of the broad number and type of global KIIs to undertake:
  - 50% internal: Secretariat and Alliance staff
  - 30% connected: country governments, Board members, donors, CSOs
  - 20% external: private sector, academia, think tanks.

Thematic study selection

We initially proposed to conduct up to five thematic studies (deep dives), to look deeper into specific issues to more comprehensively answer certain EQs. Informed by our KIIs and document review during the inception phase, we developed decision criteria relevant to selecting the topics and shortlisted some topics which meet those criteria (Table 2). We refined this list, informed by findings from the strategy operationalisation and ZD evaluations, as well as further consultations with Gavi and partners, to make adaptations to the five studies originally identified in the IR.

Table 2: Criteria for topics for thematic case studies

Criteria for selecting thematic studies	Topics potentially meeting the criteria
Gaps not covered by other evaluations for which we need additional data to answer EQs.	• SG4 (see Box below).
Ability to inform areas of potentially challenging progress under 5.0.	• HPV relaunch (implementation of 4 strategic shifts). • ZD agenda, including comparator study on other organisations' enablers/challenges in prioritizing equitable access and reaching the most vulnerable.
Ability to inform learning relevant to Gavi 6.0.	• MICs, including comparative study on how other similar organisations deal with transitioning countries. • Challenges in supporting conflict/fragile countries which will become a larger proportion of Gavi's portfolio over time (including comparator study). • Considerations for Gavi's positioning in Pandemic preparedness and response. • Considerations for Gavi's positioning in life course immunisation.
Topics that may have shifted significantly since earlier evaluations were completed.	• Documentation of results of the M&R&S immunisation. responses to COVID-19 from second quarter 2022 onwards

	• Changes in HSS and TCA programming guidance.

Note that thematic studies were initially intended as internal products, to strengthen the evidence base against specific Evaluation Questions. However, in response to demand for the analysis undertaken for specific studies – notably on Resource Mobilisation, SG4, MICs, innovation – we have included write ups of these studies in Annex 9-12. Studies not included (drivers, plausibility, horizon scanning) have corresponding EQs.

Country selection

The criteria that we used for country selection are shown in Table 3. The selection of countries reflected our best judgement of country relevance across the breadth of our criteria and accessibility of information and data and follows discussions with Secretariat staff on challenges and constraints to our selection.

Table 3: Country focus for Thematic Studies

Thematic Study	MTE Lead	Country selection	Rationale for country selection[9]
Sustainability: Domestic financing & resource mobilisation	Julian Schweitzer & Jenna Bates	Ghana, Zambia, Ethiopia	Debt distressed, or countries at high-risk of debt distress as recently identified by the IMF[10]. Majority of interactions likely with country offices of WHO, World Bank etc. to obtain data.
Innovation	Giada Tu Thanh	Madagascar	Only country with application for innovation top up fund to date.
MICs	Ruth Sherratt	Angola, Indonesia Kosovo, Philippines, Sri Lanka	Criteria based selection, including region, segment (HI/ FCAS/ core/ standard), RI performance, target antigen introduction.
SG4	Cheri Grace	No country-level data collection planned	N/A
Horizon scanning	Cheryl Brown	No country-level data collection planned	N/A
Plausibility	Giada Tu Thanh	• HI: Ethiopia • FCAS: Mali • Core priority: Burkina Faso, Ghana, Kenya, Madagascar, Zambia • Core standard: Kyrgyzstan	Criteria based selection focusing on: • countries with FPP application underway/completed. • Spread across different country segments. • +ve and -ve RI trends.
Drivers and incentives of Gavi model	Tim Shorten/ Julian Schweitzer	Same countries as listed for plausibility study	As for plausibility study.

Table 3 includes 12 countries that are specific to the MTE (i.e., countries not covered by strategy operationalisation or ZD) - five for the MIC study and seven for the remaining studies. Strategy operationalisation and ZD looked at 10 countries. In total this means the MTE was able to draw on country perspectives in 22 countries.

Strength of evidence

In our reporting, we used a strength of evidence rating (see below) for findings under each EQ to orient the reader to the strength of each finding based on the level of triangulation that was possible. Assessing the **strength of evidence** requires considering the underlying "quality" of the evidence as

well as the triangulation/ "quantity" of evidence. We applied the robustness rating shown in the table below for our findings, as shown in Section 2, Vol. I of the report:

Table 4: Robustness rating for main findings

Rating	Assessment of the findings by 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 difference sources, e.g., document review and KIIs or multiple KIIs of different stakeholder categories), which are generally of good quality.
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 of KIIs of one stakeholder category) of decent quality.
Limited (3)	• Evidence comprises few data sources across limited stakeholder groups (limited triangulation) and is perception-based, or generally based on data sources that are 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.

Ethical considerations

As set out in the inception report, our aim was to provide credible and useful evidence, to strengthen accountability for development results and contribute to learning processes in conformity with 2020 United Nations Evaluation Group (UNEG) Ethical Guidelines for Evaluation[6] of integrity, accountability, respect and beneficence.[7] To that end, we adhered to the professional, ethical and quality standards highlighted in Table 5.

Table 5: Professional and ethical standards

PROFESSIONAL & ETHICAL STANDARDS	
Objectivity	The team will undertake the evaluation objectively. All efforts will be taken to avoid and dismiss any preconceptions so as not to bias the assessment process or final analysis.
Confidentiality	The team will commit to complete confidentiality during and after the evaluation process. Any information or data provided in confidence will be kept as such. KIIs will be confidential, information from KIs will not be quoted/presented in a way that is traceable to the exact individual. We will delete all Gavi docs from our laptops/systems once the evaluation is over and will not disseminate any findings from the evaluation without Gavi's consent.
Open Communications	The team will commit to maintaining open and frequent communications with the evaluation management team at Gavi. Specifically, any issues that come up during the evaluation that may affect timing or outcome of the reporting will be communicated to Gavi in a timely manner.
Integrity	The team will commit to complete integrity of the evaluation process in line with EHG business integrity systems. Should there be any actual or perceived conflict of interest, it will be brought immediately to attention of Gavi.
Thoroughness	The team will commit to obtaining sufficient information needed to make professional judgments.
Incorporate Feedback	The team will allow sufficient time for the Secretariat to review all draft documents, consider the implications and provide any feedback. From the feedback and questions received, the team will incorporate all valid changes and clarifications requested.

[6] http://www.unevaluation.org/document/detail/2866

1. Evaluation matrix

The following tables set our Evaluation Questions alongside our analytical and data collection methods, including the judgement criteria that we will use to make transparent judgements for each question, and the data sources that we will draw on. Judgements can be made using different approaches. We have listed below five categories of judgements that we are using and show how these apply to each individual judgement criteria in italicised brackets after each.

A) before and after comparisons
B) whether implementation has happened as intended
C) whether implemented has happened as intended but without expected results
D) whether interventions are/are not following what is considered good practice or what broader evidence says works
E) triangulated views/opinions across key stakeholder groups.

WS1: Implementation status *High level strategic question 1: What is the status of implementation of Gavi's fifth strategy by end 2023? What are the drivers and barriers that explain that status?*						
	Sub-Evaluation questions (Sub-EQs)	**Approach**	**Analytical methods**	**Data collection**	**Judgement criteria**	**Data sources (docs/ KI category)**
dule	**Use of levers (Alliance voice, resource mobilisation, learning, programmatic and policy alignment, differentiated engagement, partnership and innovation)**					
	1. (2.f)[8] 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?	• Theory-based evaluation • Process evaluation	Thematic analysis including against ToC assumptions, coherence mapping table (see Annex 6.3)	• Doc review • Global and country KIIs • Thematic studies	• Evidence that implementation mechanisms (Policies, Frameworks, funding levers/programme support) align with 5.0 TOC (colour-rated – see coherence table) *(B, E).* • Evidence that implementation mechanisms are designed to use relevant operational levers[9] (colour-rated – see coherence table) *(B, E).*	Doc review: • Available KII notes, reports etc. from Gavi Strategy operationalisation, COVID-19, COVAX and ZD evaluations (particularly strategy operationalisation). • Board & PPC reports, including Mission and Strategy Indicator Dashboard update reports • Policy documents.[10] • Framework documents.[11]
	2. (1.g) To what extent is there **alignment across key Alliance partners on Gavi's approach** to				• Evidence that operationalisation processes (application guidance and	

[8] Numbers in brackets refer to question numbering in evaluation RfP / ToR (Annex 1)
[9] Alliance Voice, Resource Mobilisation, Learning, Partnership, Differentiated Engagement, Innovation
[10] Co-financing, Fragility, Emergencies and Displaced Populations (FEDP), Gender, Risk, Prioritisation, Self-Procurement, Transparency and Accountability, Vaccine Donation
[11] Health System and Immunisation Strengthening (HSIS), Partners' Engagement Framework (PEF), Healthy Markets Framework (HMF

WS1: Implementation status *High level strategic question 1: What is the status of implementation of Gavi's fifth strategy by end 2023? What are the drivers and barriers that explain that status?*						
	Sub-Evaluation questions (Sub-EQs)	**Approach**	**Analytical methods**	**Data collection**	**Judgement criteria**	**Data sources (docs/ KI category)**
	implementation of the current strategy? Are there **challenges for partners** in playing their expected roles and are these being effectively addressed?				processes and review/approval processes) are clear to core partners (WHO, UNICEF and to less extent World Bank and BMGF) and support timely implementation (colour-rated – see coherence table) *(B, E).* • Evidence that implementation mechanisms utilize (in practice) relevant operational levers and partner experience of their use [14] (colour-rated – see coherence table) *(B, E).* • Extent of challenges experienced by partners and degree to which these have been successfully addressed *I*	• Programme support documents[12] for Full Portfolio Planning (FPP) and standalone support.[13] • Programme guidelines including general Funding Guidelines and Application Process Guidelines, and also specific funding guidelines for Zero Dose (ZD), Maintain, Restore and Strengthen (M&R&S), Demand Generation, Gender, Supply Chain, Cold Chain Equipment and Data. • PEF activities and reports. • ACT minutes. • IRC ToR and reports. • IA2030 and other partner strategy documentation. • Country Grant documents (from countries included in Strategy operationalisation and ZD evaluations as well as from countries included in MTE thematic studies). • Multi-Stakeholder Dialogue (MSD) reports. KIIs: • KIIs will be targeted to fill gaps once review of relevant notes from Strategy operationalisation and other evaluations is complete, and/or probes will be "fed" into KII guides for other evaluations. The following KI categories are relevant:
	3. (1.f) What have **country level stakeholders' experiences** been of the implementation under the current strategy, including use of key operational levers such as differentiated engagement?				• Evidence that operationalisation processes (application guidance and processes and review/approval processes) are clear to in-country stakeholders[15] and support timely implementation (colour-rated – see coherence table) *(B, E).* • Evidence that implementation mechanisms utilize (in practice) relevant operational levers and country stakeholders' experience of their use [16] (colour-rated – see coherence table) *(B, E).*	

[14] From the far left of the original and elaborated 5.0 ToC – namely Alliance Voice, Resource Mobilisation, Learning, Partnership, Differentiated Engagement, Innovation

[12] Including most of those found here Gavi Support Guidelines

[13] Vaccine, Equity Accelerator Funding (EAF), Targeted Country Assistance (TCA), Cold Chain Equipment Optimisation Platform (CCEOP), COVAX, COVID-19 vaccine Delivery Support (CDS) support

[15] Including MoH/EPI/NITAG representatives, in-country CSO stakeholders, in-country private sector stakeholders

[16] From the far left of the original and elaborated 5.0 ToC – namely Alliance Voice, Resource Mobilisation, Learning, Partnership, Differentiated Engagement, Innovation

WS1: Implementation status *High level strategic question 1: What is the status of implementation of Gavi's fifth strategy by end 2023? What are the drivers and barriers that explain that status?*						
	Sub-Evaluation questions (Sub-EQs)	**Approach**	**Analytical methods**	**Data collection**	**Judgement criteria**	**Data sources (docs/ KI category)**
						• Gavi secretariat inc. Senior Country Managers (SCM). • Global level Alliance partners • Regional and In-country stakeholders (EPI managers).
	Efficiency					
	4. (1.h) 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?	• Theory-based evaluation • Process evaluation		• Doc review • Global and country KIIs • Thematic studies	• <u>Intended consequences:</u> Evidence of level of implementation progress based on: ○ review of Strategy. Implementation Indicators in 5.0. Measurement Framework updates *(A)*. ○ Evidence of to what extent causal pathways (including assumptions) from input to output level have played out as anticipated (red-amber-green rated based on level of fidelity of each pathway and assumption) *(C, E)*. • <u>Unintended consequences:</u> Evidence of unintended consequences (those not outlined in the ToC) with green-red-grey rating indicating whether these have supported (green), constrained (red) or had neutral (grey) impact on results *(C, E)*.	Doc review: • Available KII notes, reports etc. from Gavi Strategy operationalisation, COVID-19, COVAX and ZD evaluations (particularly Strategy operationalisation). • Board & PPC reports, including Mission and Strategy Indicator Dashboard update reports. • Policy documents.[17] • Framework documents[18] • Programme support documents[19] for Full Portfolio Planning (FPP) and standalone support.[20] • Programme guidelines including general Funding Guidelines and Application Process Guidelines, and also specific funding guidelines for Zero Dose (ZD), Maintain, Restore and Strengthen (MR&S), Demand Generation, Gender, Supply Chain, Cold Chain Equipment and Data. • PEF activities and reports. • ACT minutes. • IRC ToR and reports.
	5. (2.g) Was the TOC undermined during the initial phase of the				• Evidence of to what extent causal pathways (including assumptions)	

[17] Co-financing, Fragility, Emergencies and Displaced Populations (FEDP), Gender, Risk, Prioritisation, Self-Procurement, Transparency and Accountability, Vaccine Donation
[18] Health System and Immunisation Strengthening (HSIS), Partners' Engagement Framework (PEF), Healthy Markets Framework (HMF
[19] Including most of those found here Gavi Support Guidelines
[20] Vaccine, Equity Accelerator Funding (EAF), Targeted Country Assistance (TCA), Cold Chain Equipment Optimisation Platform (CCEOP), COVAX, COVID-19 vaccine Delivery Support (CDS) support

WS1: Implementation status *High level strategic question 1: What is the status of implementation of Gavi's fifth strategy by end 2023? What are the drivers and barriers that explain that status?*						
	Sub-Evaluation questions (Sub-EQs)	**Approach**	**Analytical methods**	**Data collection**	**Judgement criteria**	**Data sources (docs/ KI category)**
	COVID-19 pandemic or by another significant contextual shift? Is the TOC and assumptions underpinning the TOC still relevant as countries build back from the pandemic?				from input to output level have played out as anticipated (red-amber-green rated based on level of fidelity) of each pathway and assumption *(C, E)*. • Where pathways/ assumptions have not played out as anticipated, red-amber-green rating indicating to what extent COVID-19 impacted these pathways/assumptions (red = significant impact; amber = some impact; green = no impact) *(C, E)*. • Extent to which ToC is aligned with challenges and priorities expressed by countries in building back from COVID-19 *(C, E)*.	• IA2030 and other partner strategy documentation. • Country Grant documents (from countries included in Strategy operationalisation and ZD evaluations as well as from countries included in MTE thematic studies). • Multi-Stakeholder Dialogue (MSD) reports. KIIs: • KIIs will be targeted to fill gaps once review of relevant notes from Strategy operationalisation and other evaluations is complete, and/or probes will be "fed" into KII guides for other evaluations. The following KI categories are relevant: • Gavi secretariat inc. Senior Country Managers (SCM). • Global level Alliance partners. • Regional and In-country stakeholders (EPI managers).
Module 2: Adaptation	**Adaptation to COVID-19** 6. (1.d) To what extent did Gavi effectively and efficiently implement approaches to safeguard routine immunization programs and support recovery in countries from COVID-19 disruption? Were these flexible enough to allow rapidly adapting programmatic, administrative, or financial processes to be implemented in a timely fashion? Which approaches were most/least effective and efficient?	Process evaluation	Thematic /content analysis gap analysis, evaluability analysis	Global and country KIIs, Thematic studies, Doc review	• Evidence that flexibilities under R&P and M&R&S were implemented in a timely manner (as planned) and with intended results (in terms of protecting RI coverage, comparing 2019-23 data) *I.* • Evidence of programmatic (incl. financial) and administrative adaptation (and enablers and constraints to these) *I.* • Evidence that flexibilities achieved intended outputs/outcomes *I.*	• COVID-19, Strategy operationalisation, ZD, COVAX evaluation reports and supporting evidence (KII notes) and analysis. • KIIs with Gavi secretariat, Alliance partners and external stakeholders. • Relevant board and PPC papers and other internal Gavi data – e.g. CPMPM • WUENIC data 2019-23.

WS1: Implementation status *High level strategic question 1: What is the status of implementation of Gavi's fifth strategy by end 2023? What are the drivers and barriers that explain that status?*						
	Sub-Evaluation questions (Sub-EQs)	**Approach**	**Analytical methods**	**Data collection**	**Judgement criteria**	**Data sources (docs/ KI category)**
	7. (1.e) 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? Has operationalization of the recalibrated priorities positioned the Gavi Alliance for success by 2025?				Extent to which recalibrated priorities have altered Gavi's expected activities, outputs etc. and impacted on Gavi's ability to achieve its Gavi's strategic goals: *I* • Maintaining, restoring, and strengthening RI, • Reaching ZD children and missed communities. • Supporting delivery of COVID-19 vaccines to priority populations, • Safeguarding domestic financing for immunisation. Extent to which recalibrated priorities have been implemented, and expected contribution to strategic goals.	
	Adaptation to other barriers **8.** (1.f) How/to what extent did Gavi mitigate against and respond to failures in the TOC causal pathway and other significant barriers to operationalisation?				• Evidence that Gavi has responded to failures (TBD) in the TOC causal pathway. • Evidence that Gavi has responded to barriers to operationalisation (TBD) • Extent to which these challenges are commonly held (beyond Gavi) and to which Gavi responses are aligned with good practice (where it is possible to identify) *(D).*	

WS2: Achievement of 5.0 strategic goals and strategic objectives *High level strategic question 2: To what extent will implementation of Gavi's 2021-2025 strategy on its current trajectory plausibly result in achievement of the prioritized Strategic Goals and objectives? Which areas are important for course correction?*						
	Sub-Evaluation questions (Sub-EQs)	**Approach**	**Analytical methods**	**Data collection**	**Judgement criteria**	**Data sources (docs / KI category)**
Module 3: Effectiveness toward 5.0 strategic goals	**Towards 5.0 strategic goals – General** 9. (1.a) To what extent do Gavi's strategy performance indicators show recovery to 2019 baseline levels in 2021? To what extent will implementation of Gavi's 2021-2025 strategy on its current trajectory plausibly result in achievement of the prioritized SG1, 2, 3 and related objectives?	Theory based evaluation	Thematic / content analysis	Global and country KIIs, Thematic studies, Doc review	• Quantity and quality of evidence against assumptions between outputs and outcomes (to assess plausibility that progress at the output level will lead to progress at the outcome level) (A). • Evidence that strategic targets are/aren't likely to be met (based on progress to date – A – and evidence against assumptions – E) by end of 2025. • Evidence that strategic targets have/haven't been met (based on progress to date – A). • Evidence that strategic targets are/aren't likely to be met (based on progress to date/trajectories – A) by end of 2025.	• Available KII notes, reports etc. from Gavi Strategy operationalisation, COVID-19, COVAX and ZD evaluations (particularly Strategy operationalisation and ZD but also the COVID-19 related evaluations as contextual information to understand impact of COVID-19, including related public health measures and vaccine roll out, on prospects for achieving targets in 2025). • JRF/WUENIC data and other relevant external data sources such as aggregated country admin data and other still to be identified. • Gavi documents in particular Board & PPC reports (5.0 Measurement Framework/strategy progress update twice per year) and CPMPM data. • KIIs and thematic case studies to fill in gaps.
	10. (1.c) 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?		Forcefield analysis Current reality tree	Global and country KIIs, Thematic studies, Doc review	• Factors that are likely to have affected targets (positively or negatively) such as for example: COVID-19 related disruptions, other exogenous factors e.g. (conflict, natural disasters, macroeconomic situation, other country priorities); internal factors such as quality of country engagement, quantity and quality of partnerships *I.*	
	11. (2.b) How/to what extent has Gavi influenced countries to adjust their immunisation programming intentions related to Strategic Goals 1, 2 and 3?				• Evidence that countries have adjusted their immunisation programming intentions in line with SG 1, 2, 3 *I.* • Evidence that Gavi played a role in this adjustment *I.*	

WS2: Achievement of 5.0 strategic goals and strategic objectives *High level strategic question 2: To what extent will implementation of Gavi's 2021-2025 strategy on its current trajectory plausibly result in achievement of the prioritized Strategic Goals and objectives? Which areas are important for course correction?*						
	Sub-Evaluation questions (Sub-EQs)	**Approach**	**Analytical methods**	**Data collection**	**Judgement criteria**	**Data sources (docs / KI category)**
	Towards 5.0 strategic goal 4 12. (1.i) What progress has been made against strategy goal (SG) 4 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? (2) To what extent will implementation of Gavi's 2021-2025 strategy on its current trajectory plausibly result in achievement of the prioritized SG4 and related objectives? 13. (2.d) What has been the contribution to SG4 in relation to the following key Market Shaping Strategy 5.0 pillars? – Healthy Demand, Partnership Optimization, Regulatory Environment, Future Supplier Base 14. (2.e) Is SG4 as originally articulated still relevant in a post-COVID context?	Theory based evaluation	Thematic /content analysis	Global and country KIIs, Thematic study, Doc review	EQ 12 (first question) Whether the activities foreseen in the market shaping strategy have been implemented as intended. *(JC = B).* EQ 12 (second question) as well EQs 13 & 14. *(JC includes A, C, D & E)* Whether the activities are delivering expected results/a plausible trajectory to achieve results. +/- factors that have affected progress, evidence that Gavi played a role in progress. (Noting challenges with attribution to the GAVI Alliance with all these indicators in terms of analysing Gavi's contribution/influence): - Progress against MPM and SG4 corporate performance indicators: **M.26: Number of routine introductions completed over number of targets set for the calendar year** - And **I.17: Percentage of Gavi-approved vaccine doses delivered** **- SG4.1 Number of markets exhibiting sufficient levels of healthy market dynamics** **1.3 Number of innovative products within the pipeline of commercial-scale manufacturers**	• Available KII notes, reports etc. from Gavi Strategy operationalisation, COVID-19, COVAX and ZD evaluations (particularly Strategy operationalisation) • evaluations already conducted on the pandemic's impact on security of supply and supply chains. • GAVI market shaping roadmaps (14) • Board & PPC reports (strategy progress update twice per year) • Evaluation of the Cold Chain Equipment Optimization Platform Endline Evaluation Report Jan 2022 • Evaluation of the Gavi Supply and Procurement Strategy Nov 2020 MPM reporting including SCM qualitative supplement to quant indicator reporting. Data which informs indicator 4.1: vaccine procurement data: UNICEF SD MoU reports. Market intelligence data: Gavi MS roadshows, Alliance partner industry engagements. Data which informs indicator 4.2: Market intelligence data: Gavi MS roadshows, Alliance partner industry engagements VIPS: TBD, pending Board decision on VIPS phase 2. Data which informs indicator 4.3: Gavi-UNICEF Supply Division Memorandum of Understanding reports and key performance indicators.

WS2: Achievement of 5.0 strategic goals and strategic objectives *High level strategic question 2: To what extent will implementation of Gavi's 2021-2025 strategy on its current trajectory plausibly result in achievement of the prioritized Strategic Goals and objectives? Which areas are important for course correction?*						
	Sub-Evaluation questions (Sub-EQs)	**Approach**	**Analytical methods**	**Data collection**	**Judgement criteria**	**Data sources (docs / KI category)**
					and **4.3. Number of vaccines and immunisation-related products with improved characteristics procured by Gavi as compared to the baseline year.** EQ14 How might COVID be impacting SG4 choice of activities (EQ12) and plausibility of achieving results (second part of EQ12, as well as EQ13) *(JC = B, C, E).*	(Reference: Appendix 1: Gavi 5.0 Measurement Framework 05 – Appendix 1 Performance Indicator Reference Sheets). KIIs: • KIIs will be targeted to fill gaps once review of relevant notes from Strategy operationalisation and other evaluations is complete. The following KI categories are relevant: • Demand health: Gavi secretariat inc. Senior Country Managers (SCM), vaccine programming team, In-country stakeholders (EPI managers). • Market shaping team.

WS2: Achievement of 5.0 strategic goals and strategic objectives *High level strategic question 2: To what extent will implementation of Gavi's 2021-2025 strategy on its current trajectory plausibly result in achievement of the prioritized Strategic Goals and objectives? Which areas are important for course correction?*						
	Sub-Evaluation questions (Sub-EQs)	**Approach**	**Analytical methods**	**Data collection**	**Judgement criteria**	**Data sources (docs / KI category)**
						• Global level Alliance partners incl. "The Square"[21] and possibly industry (if necessary); • Market shaping comparator organisations (UNITAID, Global Fund, CEPI).

WS3: Gavi positioning *High level strategic question 3: What are the major, lessons learned and recommendations that can inform development of Gavi 6.0 (2026 – 2030)?*						
	Sub-Evaluation questions (Sub-EQs)	**Approach**	**Analytical methods**	**Data collection**	**Judgement criteria**	**Data sources (docs / KI category)**
Module 5: Lessons	15. (3.b) What new and emerging themes or drivers/factors could impact Gavi's mission, and are critical to inform Gavi 6.0?	Builds on other workstream approaches	Thematic/ content analysis Builds on findings from WS1 and 2	Global KIIs Thematic studies Doc review	Extent to which assumptions/evidence on which the strategy was based are upheld or challenged by emerging themes or drivers/factors *I.*	• **Global survey data** from organisations such as Ipsos and Deloitte[22] • **Delphi panel reports**[23] • **WB reports/data** (on e.g. climate, econ. Prospects, poverty and income inequality, HSS, health financing. • **IMF reports/data** (on e.g. global and country economies, indebtedness, fiscal space). • **WHO data** (health data, health financing. • Financial and health news providers and journals, e.g. including FT and NYT.[24]

[21] Partnership of Gavi market-shaping partners: Gavi Secretariat, UNICEF-SD, WHO-IVB, & BMGF-VDCP (Gavi's Market Shaping Strategy 2021-2025).
[22]For example: https://www.ipsos.com/en/ipsos-global-predictions-2023 and https://www2.deloitte.com/us/en/insights/focus/human-capital-trends.html#read-the-introduction
[23] https://www.nature.com/articles/s41586-022-05398-2?utm_medium=affiliate&utm_source=commission_junction&utm_campaign=CONR_PF018_ECOM_GL_PHSS_ALWYS_DEEPLINK&utm_content=textlink&utm_term=PID1612532&CJEVENT=7c088270a2f811ed808e00460a18b8f7&countryCode=de
[24] E.g. https://www.nytimes.com/2023/02/01/health/covid-vaccines-covax-gavi-prepayments.html

Annex 4: Bibliography and list of key informants

1. List of key informants

We list below (Table 6) the people that we have spoken to since the inception phase.

Table 6: People interviewed throughout the evaluation

GLOBAL LEVEL KIs (n=104)			
Abdallah Bchir	Former Head Gavi Evaluation Unit	Gavi	Internal
Alex De Jonquieres	Director, HSIS	Gavi	Internal
Alice Ma	Senior Manager, Strategy (market dynamics team)	Gavi	Internal
Amy La Trielle	Director, Fragile and Conflict Countries	Gavi	Internal
Annamaria Bejar	Director, Public Policy Engagement	Gavi	Internal
Anne Cronin	Former Head, Partners' Engagement Framework. Current: SCM	Gavi	Internal
Aurelia Nguyen	MD, Office of the COVAX Facility, Ex-MD, Vaccines & Sustainability current: Chief Programme Strategy Officer	Gavi	Internal
Benjamin Loevinsohn	Director, Immunisation Financing and Sustainability	Gavi	Internal
Bertrand Pedersen	Senior Manager, Private Sector Partnerships and Innovation	Gavi	Internal
Beth Evans	Acting Senior Programme Manager, Vaccine Programmes (former CHAI)	Gavi	Internal
Brenda Killen	Director, Governance	Gavi	Internal
Cassandra O'Farrell	Market shaping team	Gavi	Internal
Charles Bleehan	Innovation finance	Gavi	Internal
Ciara Goldstein	Former Manager, Partners Engagement – Now. Manager, Crisis Management, Operations	Gavi	Internal
Clara Rudholm	Senior Manager, Communities & CSOs	Gavi	Internal
Dan Hogan	Head, Measurement & Strategic Information	Gavi	Internal
Daniel Oyaole	Senior Manager, Digital Health Information	Gavi	Internal
David Marlow	Chief Operating Officer | Acting CEO	Gavi	Internal
David Powell	Head, Portfolio Financial Management (High Impact Countries)	Gavi	Internal
Derrick Sim	Managing Director, Office of the COVAX Facility	Gavi	Internal
Dominic Hein	Head, Market Shaping	Gavi	Internal
Dita Mocova	Senior Manager, Finance Business Partnering, allocation ceiling	Gavi	Internal
Ed Baker	Lead, Markets and Tender Strategy (market dynamics team)	Gavi	Internal
Gurleen Hans	Head, Portfolio Finance Management	Gavi	Internal
Homero Hernandez	India Senior Country Manager	Gavi	Internal
Hope Johnson	MD, Director Measurement, Evaluation and Learning Unit	Gavi	Internal
Jean Munro	Senior Manager, Gender	Gavi	Internal

Jessica Crawford	SCM for Nigeria but also country rep in the Innovation WG	Gavi	Internal
Johannes Ahrendts	Director, Strategy, Funding, and Performance	Gavi	Internal
Karan Sagar	Head, Comprehensive Vaccine Management	Gavi	Internal
Kim Harper	Head, Middle Income Countries Strategic Engagement	Gavi	Internal
Lindsey Cole	Head, Funding Design and Review	Gavi	Internal
Manjari Shankar	Manager, Programme Support Team. HSS allocation method HSS allocation methods	Gavi	Internal
Marion Menozzi-Arnaud	Innovation (market dynamics team)- Senior Projects specialist	Gavi	Internal
Marumbo Ngwira	Head, Programme Support Team|SFA	Gavi	Internal
Matt Blakley	Head, Vaccine Forecasting & Grant Operations. vaccine allocation methods	Gavi	Internal
Paolo Sison	Director, Innovative Finance	Gavi	Internal
Pascal Barollier	Managing Director, PEIS	Gavi	Internal
Quentin Guillon	Head, Strategy	Gavi	Internal
Ranjana Kumar	Head health system planning	Gavi	Internal
Raphael Ferry	Senior Manager, Innovative Finance	Gavi	Internal
Richard Mihigo	former EPI regional adviser Afro, now Gavi staff	Gavi	Internal
Riswana Soundardjee	Senior Manager, Equity Data, HSIS	Gavi	Internal
Sam Muller	Acting Director, Middle Incomes Countries	Gavi	Internal
Samya Mandal	Manager, Vaccine Forecasting & Grant Operations (forecasting)	Gavi	Internal
Santiago Cornejo	Former Director, IF&S (Country engagement?)	Gavi	Internal
Seth Berkley	Outgoing CEO	Gavi	Internal
Thabani Maphosa	Managing Director, Country Programmes Delivery	Gavi	Internal
Tiziana Scarna	Senior Manager, Innovation and special projects	Gavi	Internal
Tokunbo Oshin	Director, High Impact Countries	Gavi	Internal
Veronica Denti	Senior Programme Manager, Vaccine Implementation	Gavi	Internal
Aamer Ikram	CEO, Board member Implementing countries, Pakistan & Somalia	National Institutes of Health, Pakistan	Gavi Board
Awa Marie Coll Seck	Independent individual Board member	Ministre d'Etat, Présidente CN-ITIE, Comité Scientifique du Forum Galien Afrique	Gavi Board
Bounfeng Phoummalaysith	Implementing countries Board member; India & Lao PDR (alt)	MoH	Gavi Board
Bvudzai Magadzire	Senior Technical Advisor, Research & Advocacy, VillageReach, South Africa Board member representing CSOs	Village Reach	Gavi Board
Eduardo Humberto Retes	Implementing countries Board member; Armenia & Honduras (alt)	MoH	Gavi Board

José Manuel Barroso	Chairperson Gavi Board; independent individual Board member	Gavi	Gavi Board
Juan Pablo Uribe	Global Director, Health, Nutrition and Population | Director, Global Financing Facility (GFF)	World Bank	Gavi Board
Mohamed Jama	Implementing countries Board member; Pakistan & Somalia	MoH	Gavi Board
Rafael Vilasanjuan	Dir. Policy and Global Development, ISGloab| CSOs	ISGlobal, Institute PH, Barcelona	Gavi Board
Sarah Goulding	Donor gov rep. Board member (US, Australia, Republic of Korea Vice Chair Gavi Board	Dept Foreign Affairs and Trade, Australia|	Gavi Board
Takeshi Akahori	Donor Gov. rep Board member (Japan/ Italy/ New Zealand/ Spain)	Director-General and Ambassador for Global Issues, MOFA Japan	Gavi Board
Violaine Mitchell	BMGF Gavi Board member. Director Immunization/ Health Funds and Partnerships	Bill & Melinda Gates Foundation (BMGF)	Gavi Board
Adrien de Chaisemartin	Former Head, Strategy at Gavi Deputy Director for Gavi, Immunization Partners, and Special Initiatives	BMGF	Alliance
Chris Wolff	Deputy Director, Country Partnerships	BMGF	Alliance
Gaurvika Nayyar	Senior Program Officer, Access & Market Dynamics	BMGF	Alliance
Greg Widmeyer	Senior Advisor, Global Development Division	BMGF	Alliance
Helen Matzger	Deputy Director, Vaccine Programmes	BMGF	Alliance
Ann Ottosen	Epidemic prone vaccines	UNICEF	Alliance
Celestin Traore	Senior Immunization Specialist, UNICEF WCARO	UNICEF	Alliance
Ephrem Lemango	Associate Director, Health, Chief of Immunization	UNICEF	Alliance
Gunter Boussery	Senior Health Specialist, Immunization, UNICEF ROSA	UNICEF	Alliance
Jean-Pierre Amorij	Vaccine technology specialist – Innovation	UNICEF	Alliance
Kristina Grace Lorenson	Strategic management of procurement services to LMICs	UNICEF	Alliance
Oluwaseun Ayanniyi	Contracts manager – HPV vaccines	UNICEF	Alliance
Oya Zeren Afsar	Health specialist, new vaccines – Vaccine uptake | HPV & malaria	UNICEF	Alliance
Ulla Griffiths	Senior Advisor, Immunisation Financing and Health Systems Strengthening	UNICEF	Alliance
Amos PETU	IST East and Southern Africa (IST ESA), VPD Team Leader/Sustainable Immunization Financing Officer for ESA countries	WHO	Alliance
Anna Lea Kahn	WHO. CTC	WHO	Alliance
Baran Hiito Sillo	Regulation and Safety, Department of Regulation and Prequalification	WHO	Alliance
Carmen Rodriguez Hernandez	Vaccines assessment, WHO Prequalification	WHO	Alliance
Jenny Walldorf	New vaccine introduction	WHO	Alliance
Paul Bloem	Senior officer immunisation – HPV	WHO	Alliance

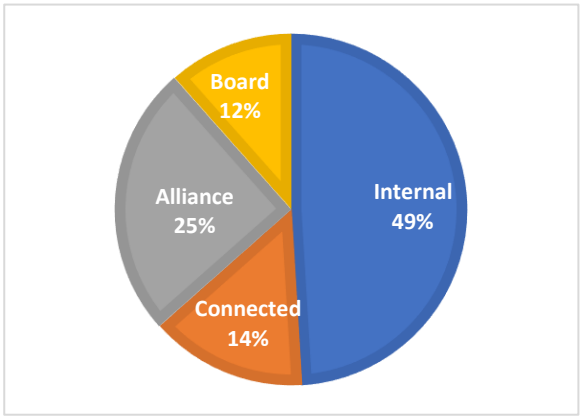
Peter Cowley	Director Health Systems Division	WHO	Alliance
Quamrul Hasan	EMRO	WHO	Alliance
Shalini Desai	WHO - rotavirus, and pneumococcal vaccine	WHO	Alliance
Xu Ke	Lead, monitoring health expenditure	WHO	Alliance
Anurag Kumar	Economist, Health	World Bank	Alliance
Christoff Kurowski	Global Lead, Health Financing	World Bank	Alliance
Shingai Grace Machingaidze	Senior science officer	Africa CDC|Africa Union	External
Janeen Madan Keller	Deputy Director of the Global Health Policy Program and a Policy Fellow	Center for Global Development (CDG)	External
Richard Hatchett	CEO	CEPI	External
Frauke Uekermann	Director, Vaccine Markets	CHAI	External
Rajinder Suri	CEO, Developing Countries Vaccine Manufacturing Network	DCVMN	External
Ademola OSIGBESAN	Technical Manager, Strategic Sourcing and Supply	UNITAID	External
Robert Matiru	Director, Programme Division, UNITAID	UNITAID	External
Anuradha Gupta	President Global Immunization -- former Gavi Deputy CEO	Sabin Vaccine Institute	Connected
Benjamin Nkowane	IRC chair (WHO<2014) Medical Epidemiologist, PH consultant Senior Lecturer in Community Health, UNZA	IRC	Connected
Zeenat Patel	Former Head, Vaccine Implementation		Connected
Miranda Bodfish	Associate Vice President for Infectious Disease Programs	CDC	Connected
Ellie Marsh	Senior Manager, Strategy, Procedure and Innovation, Supply Operations	The global fund (TGF)	Connected
Jacqueline Bataringaya	Strategy, Investment & Impact Division	TGF	Connected
Olga Bornemisza	Senior Specialist, Health Systems Strengthening	TGF	Connected
RK Suri	Developing Countries Vaccine Manufacturers Network		Private Sector
COUNTRY LEVEL Interviewed for thematic studies (n=80)			
Alice Abou-Nader	SCM Indonesia|temp SCM Angola	Gavi	Internal
Dr Antoinette E. D. Awaga	SCM Burkina Faso	Gavi	Internal
Billie Jean Nieuwenhuys	SCM Kenya	Gavi	Internal
Inga Savin	Lead on MICs learning agenda	Gavi	Internal
Jamilya Sherova	SCM Zambia	Gavi	Internal
Jan Castilhos Franca	SCM Kosovo	Gavi	Internal
Jemimah Eitokpah	PM (consultant) Angola	Gavi	Internal
Dr Jorge Mariscal	Gavi Focal Point, Angola	Gavi	Internal
Martin Iputu	Financial Management Agent, Angola	Gavi	Internal
Masafumi Funato	SCM Sri Lanka	Gavi	Internal
Miriam Faid	SCM Angola	Gavi	Internal
Pietro Di Matteir	Regional head eastern and southern Africa / Former SCM Angola	Gavi	Internal

Sam Muller	Acting Director, Middle Incomes Countries	Gavi	Internal
Sara Menzies	Programme Officer Angola (former)	Gavi	Internal
Smita Singh	SCM for Kyrgyzstan – previously senior manager Demand	Gavi	Internal
Sophie Chadwick	SCM Philippines	Gavi	Internal
Ralph Midy	UNICEF LAC RO	UNICEF	Alliance
Frederico Brito	Child Survival & Development Chief, Angola	UNICEF	Alliance
Felix Osei-Sarpong	Health Specialist, Ghana	UNICEF	Alliance
Dr Mrunal Shetye	Chief of Health, Indonesia	UNICEF	Alliance
Dr Kenny Peetosutan,	Health Specialist, Immunization, Indonesia	UNICEF	Alliance
Rustini Floranita	Health Officer EPI, CO Indonesia	UNICEF	Alliance
Sugiarto Hiu	Immunisation Officer, CO Indonesia	UNICEF	Alliance
Artan Sadiku	Health Officer, CO Kosovo	UNICEF	Alliance
Bekë Veliu	Health Officer, CO Kosovo	UNICEF	Alliance
Ms Sajeda Atari	CO Kosovo	UNICEF	Alliance
Kubanychbek Monolbaev	Immunization specialist, Child Survival and Development, Kyrgyzstan	UNICEF	Alliance
Rima Imarova	Programme officer (supply chain), Kyrgyzstan	UNICEF	Alliance
Galina Solodunova	Communication for Development Specialist, Kyrgyzstan	UNICEF	Alliance
Dhammica Rowel	Health and nutrition officer, CO Sri Lanka	UNICEF	Alliance
Kasun Madhusanka Senevirathne	Immunisation consultant, CO Sri Lanka	UNICEF	Alliance
Monjur Hossain	Chief Health and HIV/AIDS, CO Zambia	UNICEF	Alliance
Francis Mwansa	CO Zambia	UNICEF	Alliance
Svetlana Stefanet	Immunization Specialist, ECA RO	UNICEF	Alliance
Gerald Sume	Technical Officer for Immunisation, MENARO	WHO	Alliance
Fred Osei-Sarpong	Technical Officer Immunization, Ghana	WHO	Alliance
Dr. Olivi Silalahi	National Professional Officer, Routine Immunization, Indonesia	WHO	Alliance
Dr. Paba Palihawadana	Medical Officer EPI/RI, Indonesia	WHO	Alliance
Momoe Taekuchi	Deputy Res Rep, CO Indonesia	WHO	Alliance
Dieter Eckhart	Technical Officer (partnerships), CO Indonesia	WHO	Alliance
Dr. Rodri Tanoto	National Professional Officer (New Vaccine), Indonesia	WHO	Alliance
Dr. Stephen Chacko,	Team Leader, IVD, Indonesia	WHO	Alliance
Kibet Sergon	Epidemiologist, WHO FP, Kenya	WHO	Alliance
Ms Edita Haxhiu	Immunisation, CO Kosovo	WHO	Alliance
Zhanara Bekenova	Technical Officer Immunization, Kyrgyzstan	WHO	Alliance
Osman Niyazi Cakmak	Group Lead, Vaccine-preventable Diseases and Immunization Unit, EMRO (Kyrgyzstan)	WHO	Alliance
Preshila Samaraweera	National Professional Officer, Communicable Disease Unit, Sri Lanka	WHO	Alliance

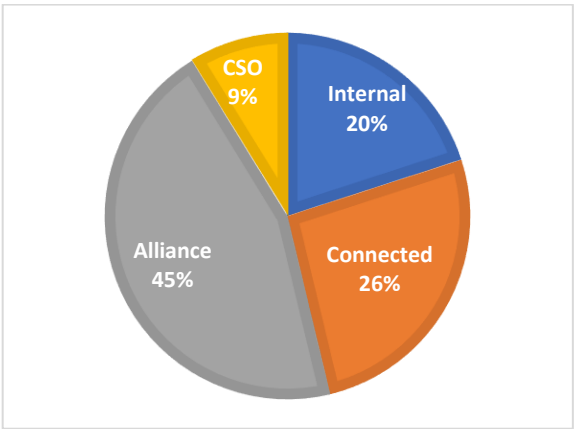
Dr. Thiraj Haputhanthri	CO Sri Lanka	WHO	Alliance
Dr. Penelope Kalesha Masumbu	National Professional Officer - Routine Immunisation, Zambia	WHO	Alliance
Tseganeh Amsalu Guracha	Senior Health Economist, Ethiopia	World Bank	Alliance
Elisha Kipkemoi Ngetich	Health Specialist, Ghana	World Bank	Alliance
Alison Morgan	Senior Health Specialist, Zambia	World Bank GFF	Alliance
Amina Ismail	EPI focal point, Kenya	PATH	Connected
Vidia Darmawi	SMILE Project Manager, Indonesia	UNPD	Connected
Tina Rosalina,	SMILE Project Officer, Indonesia	UNDP	Connected
Agus Soetianto	SMILE, Indonesia	UNDP	Connected
Dr Abdramane Sawadogo	Secretary general NITAG, Burkina Faso	NITAG	Connected
Issaka Ouedraogo	EPI manager for the Centre region, Burkina Faso	MoH/ EPI	Connected
Seydou Kabore	Head of logistics, Burkina Faso	MoH/ EPI	Connected
Bakouan Réné Didace	Service planning, monitoring and evaluation, Burkina Faso	MoH/ EPI	Connected
Some Vouandas	communication department, social mobilisation in favour of vaccination, Burkina Faso	MoH/ EPI	Connected
ZONGO Amidou	Responsible for routine vaccination, Burkina Faso	MoH/ EPI	Connected
ZONGO isabelle	Monitoring and management of vaccination data, Burkina Faso	MoH/ EPI	Connected
Dr C. NEYA Ouedraogo	Directrice de la Prévention par les vaccins, Burkina Faso	MoH/ EPI	Connected
Prof Fred Were	Chairman NITAG, Kenya	NITAG	Connected
Fetije Fetaj	Immunization Manager/NIPH, Kosovo	MoH	Connected
Gulbara Satygulovna Ishenapysova	Republican Center for Immunoprophylaxis (RCI), Kyrgizstan	MoH/ RCI	Connected
Gulnara Zhumagulova	Republican Center for Immunoprophylaxis (RCI), Kyrgizstan	MoH/ RCI	Connected
Dr. Nurmuhammed Babadjanov	NITAG Chair, Kyrgizstan	MoH/ RCI	Connected
Dr Janis Cbunoanmacazo	Department of Health, Philippines	MoH	Connected
Lakshmi Somatunga	Additional Secretary (Public Health), Sri Lanka	MoH	Connected
Bianca Chifwelu Hibweengwa	Directorate of PH and Research, Child Health and Nutrition Unit (EPI Secretariat), Zambia	MoH/ EPI	Connected
Jacob Sakala	EPI Manager, Zambia	MoH/ EPI	Connected
E. Bakouan	Gavi HSS contracted	SPONG	CSO
Cecilia Senoo	Executive Director, Advocacy, resource mobilisation and accountability, Ghana	Hope for Future Generations (HFFG)	CSO
Putri Herliana	Vaccines Regional Manager, Indonesia	CHAI	CSO
Atiek Anartati	Country Director, Indonesia	CHAI	CSO
Asel Toktomambetova	Red Crescent Society, Kyrgizstan	Red Crescent Society	CSO

Friday Nkhoma	Advocacy, Zambia	Churches Health Association of Zambia	CSO
Yoram Siame	Director Advocacy, Planning and Development, Zambia	CHAZ	CSO

Global-level interviews (104)



Country-level interviews (80)



2. List of key documents

Table 7 below lists the documents that we have drawn on during our document review.
In addition, we have used the Gavi website (www.gavi.org) to supplement our document review and to enrich our understanding of how Gavi operates and communicates with its stakeholders.
Examples of documents accessed through the website are listed below:

- Guidance for Gavi Grant Performance Frameworks – 2019
- Responding to COVID-19
- COVID-19: Gavi steps up response to pandemic
- Targeted country assistance
- Gavi support guidelines
- The Zero Dose child explained
- Gender Policy

During the implementation phase we have used a structured method to extract and code relevant data for each Evaluation Question.

Table 7: Documents reviewed and used for reference in the report

	Documents coded and|or thematically reviewed for reference in the report	
Country Programmes	Country Programmes quarterly report, 01 August - 30 November 2020	2020
	Country Programmes quarterly report, 01 December 2020 - 31 March 2021	2021
	Country Programmes quarterly report, 01 April - 30 June 2021	2021
	Country Programmes quarterly report, 01 July - 30 September 2021	2021
	Country Programmes quarterly report, 01 October - 31 December 2021	2022
	Country Programmes quarterly report, 01 January 2022 - 31 March 2022	2022
	Country Programmes quarterly report 01 April 2022 - 30 June 2022	2022
	Country Programmes quarterly report 01 July 2022 - 30 September 2022	2022
	Country Programmes quarterly report 01 January 2023 - 31 March 2023	2023
	Country Programmes quarterly report 01 April 2023 - 30 June 2023	2023
Governance	Board Decisions 2020-21-22	2022
	Board Retreat - Summary FINAL	2023

	Policy Team needs for 6.0 prep	2023
Board 2019	Board meeting 4-5 Dec.2019: Minutes	2019
	Board meeting 26-27 June 2019: Minutes	2019
	Board meeting 19 July 2019: (Teleconference): Minutes	2019
Board papers	Report to the Board, 2016-2020 Strategy: Progress, challenges and risks	2019
	Report to the Board, Annex A: Implications/ Anticipated impact	2019
	Report to the Board, Annex B: Paragraphs referenced in decision points for Eligibility & Transition and Co-financing Policies	2019
	Report to the Board, 2016-2020 Strategy: Progress, challenges and risks	2019
	Gavi 5.0_The Alliances 2021-2025 Strategy	2019
	Gavi 5.0_Operationalising the Alliances 2021-2025	2019
	Report to the Board: Annex E, Gavi 5.0 MICs Approach and COVID-19	2019
Board 2020	Board meeting 30 July 2020: Minutes	2020
	Board meeting 24-25 June 2020: Minutes	2020
	Board meeting 19 March 2020: Minutes	2020
	Board meeting 11 May 2020: Minutes	2020
	Board meeting 15-17 December 2020: Minutes	2020
Board papers	Report to the Board, 2016-2020 Strategy: Progress, challenges and risks	2020
	Report to the Board, Annex A: Zero-dose & equity approach to immunisation: best practices	2020
	Report to the Board: Recalibrating Gavi 5.0 in light of COVID-19 and successful replenishment	2020
	Report to the Board: Report of the Chief Executive Officer	2020
	Report to the Board: Strategy and implications of COVID-19: Gavi 4.0 progress, challenges and risks and update on Gavi 5.0 operationalisation	2020
	Report to the Board: Strategy, programmes and partnerships: Progress, risks and challenges (for guidance)	2020
	Report to the Board: Accelerating efforts to reach Zero-dose children and missed communities in Gavi 5.0	2020
	Report to the Board, Annex B: Areas highlighted by the PPC to be further addressed in the Board paper and/ or during operationalisation	2020
	Report to the PPC: Accelerating efforts to reach Zero-dose children and missed communities in Gavi 5.0	2020
	Measurement framework Annex A-Implications and anticipated impact	2020
	Measurement framework Annex C Gavi 5.0 strategy indicator dashboard	2020
	Measurement framework Annex D Summary of Gavi 5.0 strategy indicator	2020
	Measurement framework Annex E Draft Gavi 5.0 Theory of Change and Learning Priorities	2020
	Measurement framework Appendix 1 - Gavi 5.0 indicator reference sheets	2020
	Measurement framework Appendix 2 - Draft Gavi 5.0 Learning System	2020
	Measurement framework Gavi 5.0_Measurement Framework	2020
	SPP Annex A - Updated Alliance KPI dashboard	2020
	SPP Annex B - Strategy indicators reported as originally defined	2020
	SPP Annex C - AR implementation of the gender policy	2020
	Reaching ZD Annex A - Toc reaching ZD children and missed comm	2020
Board 2021	Board meeting 22 March 2021: Minutes	2021
	Board meeting 23-24 June 2021: Minutes	2021
	Board meeting 28 September 2021: Minutes	2021
	Board meeting 30 November 2021: Minutes	2021
Board papers	Report to the Board: Report of the Chief Executive Officer	2021
	Report to the Board: Strategy, programmes and partnerships: Progress, risks and challenges (for guidance)	2021
	Report to the Board: Strategy, programmes and partnerships: Progress, risks and challenges (for decision)	2021
	Annex B - Proposed baselines and targets for Gavi 5.0 mission	2021

	Annex C - Gavi 5.0 strategy indicators dashboard	2021
	Strategy, Programmes and Partnerships	2021
Board 2022 Board papers	Board meeting 06 April 2022 minutes	2022
	Board meeting 22-23 June 2022 minutes	2022
	Report to the Board: Report of the Chief Executive Officer	2022
	Report to the Audit and Finance Committee: Risk Management Update	2022
	Report to the Board: Strategy, programmes and partnerships: Progress, risks and challenges (for guidance)	2022
	Report to the Board: COVAX: key strategic issues	2022
	Report to the Board: Review of Fragility, Emergencies, Refugees Policy	2022
	Report to the Board, Annex A: Implications/ Anticipated impact	2022
	Report to the Board, Annex B: Paragraphs referenced in decision point (b) on the MICs Approach, as amended by discussions at the PPC	2022
	Report to the Board, Annex C: Paragraphs referenced in decision point (d) on the rules under which support could be provided to fragile MICs	2022
	Report to the Board: Report of the Chief Executive Officer	2022
	Report to the Board: Strategy Programmes and Partnerships Progress Risks and Challenges	2022
	Report to the Board, Annex A: Risk & Assurance Report 2022	2022
	Report to the Board, Annex B: Gavi's future role in Pandemic Preparedness and Response	2022
	Report to the Board: Gavi 5.1 (including Pandemic Preparedness and Response)	2022
	Report to the Board: Human papillomavirus (HPV) Vaccine Programme relaunch	2022
	Report to the Board: Gavi's role in a future COVID-19 Vaccine Programme	2022
	Report to the Board, Annex A: Framework for Gavi Funding to Countries	2022
	Decision language for co-financing flexibilities	2022
	Gavi 5_0 dashboard and update on key metrics	2022
	Strategy, Programmes and Partnerships: Progress, Risks and Challenges (by Deputy CEO)	2022
	Financial Update including Forecast	2022
	Supporting Considerations for a Future COVAX-Supported Paediatrics Programme and Risks and Trade-offs	2022
	COVAX Key Strategic Issues	2022
	Gavi Alliance: an end-to-end approach, delivering PPR through core functions, leaving no one behind	2022
	Gavi's potential role in pandemic preparedness response	2022
	Fragility Emergencies and Displaced pops policy	2022
	Partnerships for African Vaccine Manufacturing (PVM) Framework for Action (African Union; Africa CDC)	2022
	Gavi Expanding Sustainable Vaccine Manufacturing in Africa 2022: priorities for support	2022
	Update on Malaria Vaccine Programme	2022
	Gavis Approach to Engagement with Former & Never-Eligible MICs	2022
	GC Chair Report to Board - June 2022	2022
	IFFIm Chair Report to Board	2022
	Investments Committee Chair Report	2022
	PPC Chair Report to Board	2022
	Gavi 5.0 Mission and Strategy indicator dashboard and Strategy Implementation Indicators update	2022
	Gavi 5.1 operationalisation and financial considerations	2022
	Rationale for initial illustrative vaccine product prioritisation	2022
	A new financial instrument to incentivise African vaccine manufacturers post EO	2022
	Gavi's Role in Regional and African Vaccine Manufacturing	2022
	Annex B - Looking Ahead and Uncertainties	2022
	Annex B - Health System and Immunisation Strengthening Policy	2022

	Funding Policy Review - Context and HSIS Policy	2022
	Co-financing Policy	2022
	Eligibility and Transition Policy and Co-Financing Policies	2022
Board 2023 Board papers	Board and Committee minutes	2023
	Report of the Chief Executive Officer, report to the Board	2023
	Gavi Balanced Scorecard June 2023 Beta	2023
	Report to the Board: Gavi Human Papillomavirus Measurement Framework	2023
	Report to the Board, Annex C: Gavi 5.0/5.1 dashboard and update on key metrics	2023
	Report to the Board, Strategy, Programmes and Partnerships: Progress, Risks and Challenges	2023
	Report to the Board, Gavi's Role in Pandemic Prevention, Preparedness and Response	2023
	Embarking on the Gavi 6.0 journey and Gavi's raison d'etre	2023
	Opportunities for impact and enablers underpinning Gavi 6.0	2023
	Gavi 6.0 Board Retreat: Pre-read [part 1]	2023
	Gavi 6.0 Board Retreat: Pre-read [part 2]	2023
	Gavi 6.0 Board Workshop: Summary of main outcomes	2023
	Virtual deep dive on eligibility, co-financing & transition model and MICs in Gavi 6.0	2023
	Health Systems Strategy deep dive: pre-read	2023
PPC 2019	Programme and Policy Committee Meeting 8-9 May 2019: Minutes	2019
	Report to the PPC, appendix 4: HPV supply and programmatic analysis	2019
	Report to the PPC: Gavi 5.0: Operationalising the Alliance's 2021-2025 Strategy (for guidance)	2019
	Programme and Policy Committee Meeting 23-24 October 2019: Minutes	2019
	Report to the PPC: Gavi 5.0: Funding Policy review (for decision)	2019
	Report to the PPC: Gavi 5.0: Operationalising the Alliance's 2021-2025 Strategy (for guidance)	2019
PPC 2020 PPC papers	Programme and Policy Committee Meeting 26-27 May 2020: Minutes	2020
	Programme and Policy Committee Meeting 28-29 October 2019: Minutes	2020
	Report to the PPC, Annex B: Draft Gavi 5.0 Indicator dashboard	2020
	Report to the PPC, Annex C: Summary of Indicator Definitions	2020
	Report to the PPC: Accelerating efforts to reach Zero-dose children and missed communities in Gavi 5.0	2020
	Report to the PPC: Strategy, programmes and partnerships and recalibration of Gavi 5.0	2020
	Report to the PPC: Vision for Civil Society and Community Engagement in Gavi 5.0	2020
	Updated Alliance KPI dashboard	2020
	Strategy indicators reported as originally defined	2020
	SOP for repurposing meningococcal vaccines	2020
	Strategies for repurposing meningococcal vaccines	2020
	Implications Anticipated Impact	2020
	Gavi 5.0 Strategy one-pager - Oct 2020	2020
	Draft Learning Priorities - Oct 2020	2020
	SPI reference sheets	2020
	Gavi 5.0 Learning System	2020
	Gavi 4.0 eval, targeted assessments	2020
	Gavi 5.0 Measurement Framework	2020
PPC 2021	Programme and Policy Committee Meeting 19-20 May 2021 (virtual): Minutes	2021
	Report to the PPC, Annex C: IRC/HLRP recommendations	2021
	Report to the PPC: The Vaccine Alliance Risk & Assurance Report 2021, draft	2021
	Report to the PPC, Annex E: Yellow fever diagnostics and laboratory capacity	2021

	Report to the PPC, Annex F: Malaria Vaccine Implementation Programme: two years on	2021
	Report of the Independent Review Committee	2020
	Report of the Independent Review Committee	2021
	Report to the PPC: Strategy, Programmes and Partnerships: Progress, risks and challenges	2021
	Report to the PPC, Annex A: Update on Health Systems and Immunisation Strengthening (HSIS) Support Framework	2021
	Report to the PPC, Appendix 3 – Annex D to the May 2020 PPC Paper with update on the Funding Policy Review	2021
	Report to the PPC: Appendix 4: Further details on the economic impact of COVID	2021
	Report to the PPC: Appendix 5: Implementation of exceptional COVID-19 co-financing waivers	2021
	Report to the PPC: Gavi 5.0: Operationalisation - funding policies	2021
	Report to the PPC, Gavi 5.0 Innovation Strategy	2021
	Report to the PPC, Annex A: Updated Alliance KPI dashboard	2021
	Report to the PPC, Annex B: Strategy indicators as originally defined	2021
	Report to the PPC, Annex G: ToR of the Partnerships Team	2021
	11 - Appendix 6 - Co-financing implications for the introduction of malaria vaccine	2021
	Report to the PPC, Annex D: Proposed baselines and targets for Gavi 5.0 mission	2021
	PPC May/21 Appendix 1: Gavi 5.0 indicator Reference Sheet	2021
	PPC May/21 Appendix 2 – Draft Gavi 5.0 Strategy Implementation Indicators	2021
	Report to the PPC: GAVI 5.0: Measurement Framework (May 21)	2021
	Report to the PPC, Annex D: Summary of approved and proposed baselines/targets for Gavi 5.0 indicators	2021
	Report to the PPC, Annex E: Monitoring & Evaluation Update	2021
	Report to the PPC, Gavi 5.0: Measurement framework (Oct 21)	2021
PPC 2022	Programme and Policy Committee Meeting 31 October – 1 November minutes	2022
	Programme and Policy Committee Meeting 18-19 May 2022 minutes	2022
	Programme and Policy Committee Meeting 8 June 2022 minutes	2022
	Report to the PPC, Annes G: IRC/HLRP report	2022
	Report to the PPC: Strategy Programmes and Partnerships Progress Risks and Challenges (including update on Gavi 5.1)	2022
	Report to the PPC: COVAX - key strategic issues	2022
	Report to the PPC, Annex A: Update on the Vaccine Investment Strategy (VIS)	2022
	Report to the PPC, Annex B: Overview of the potential additional future role of Gavi in Pandemic Preparedness and Response	2022
	Report to the PPC, Annex C: Vaccine Alliance Risk and Assurance Report 2022 - Draft	2022
	Report to the PPC, Annex C: Risks to the Immunisation Landscape and Other Gavi 5.1 Priorities	2022
	Report to the PPC: Strategy Programmes and Partnerships Progress Risks and Challenges (including update on Gavi 5.1)	2022
	Report to the PPC: Gavi's role in a future COVID-19 Vaccine Programme	2022
PPC 2023	Partnerships' Team March meeting summary and action plan	2023
	High level review panel (HLRP) report	2023
	IRC progress report	2023
	June 2021 Gavi Board Risk Appetite Statement	2023
	Vaccine Investment Strategy 2018	2023
FPP general docs	FPP step-back: streamlining, differentiating and ensuring strong country plans - synthesis document	2022
	M&L FPP Simplification Changes	2022
	Introduction to Gavi's Revised Application Process & key portfolio management shifts	2021

FPP applications Burkina Faso	FPP step-back: streamlining, differentiating and ensuring strong country plans - synthesis document	2022
	FPP step-back: streamlining, differentiating and ensuring strong country plans - presentation at meeting (Thabani)	2022
	FPP step-back: streamlining, differentiating and ensuring strong country plans - presentation at meeting (Assietou)	2022
	Country M&L Update: Application Kit Changes Following FPP Step Back Recommendations	2022
	ToC detail soutien Gavi 4_Burkina Faso	2022
	Argumentaire TDC	2022
	Burkina Faso commentaires FPP-23.09.22_Réponses	2022
	Burkina Faso IRC Report Final Nov	2022
	Préscreening Burkina Faso commentaires August 2022	2022
	Préscreening Burkina Faso commentaires July 2022	2022
Ethiopia	Ethiopia FPP Developmment Process Documentation	2022
	Ethiopia FPP Pre-Screening	2022
	FPP Situational Analysis	2023
	TOC Narrative final	2023
	TCA Summary Narrative	2023
	TOC Consolidated with workplan	2023
	TCA Ethiopia Activity Planning	2023
	IRC Report Ethiopia FPP final report	2023
	IRC Debriefing Addis Ababa final slides for presentation	2023
Kenya	Kenya TOC Gavi Format	2021
	Programme Support Rationale	2021
	Programmatic Only Gavi Consolidated Feedback FPP Application	2023
	Kenya FPP Screening Template	2022
Kyrgyzstan	Part A Programme Support Rationale KGZ	2021
	Parts B and C, situation analysis, KGZ	2021
	Kyrgyzstan Theory of Change	2021
	KGZ IRC Report 15 June - FINAL	2021
	PSR Screening Kyrgyzstan	2020
	KGZ Screening template NVS IRC	2021
	Budgeting and Planning HSS3 KGZ	2021
Madagascar	Madagascar Argumentaire ToC	2022
	MDG-Consolidated IRC report Final	2023
	FPP Pre-Screening Template	2022
	Madagascar TdC Détail du Soutien Gavi	2023
Mali	Mali TOC narrative – report in preparation for requesting Gavi support	2023
	Pre-screening Comments and Action Tracker	2023
	TOC Narrative	2023
Zambia	Gavi Support Detail Zambia final	2023
	TCA Narrative 2023 to 2025_Zambia	2023
	Zambia FPP IRC Report, HSS, EAF, TCA, ITU, CCEOP	2023
WUENIC	WUENIC July 2019 technical brief	2019
	WUENIC old vs new plots2019	2019
	WUENIC19 calculated file	2019
	WUENIC July 2020 technical brief	2020
	WUENIC old vs new plots	2020
	WUENIC20 calculated file	2020
	WUENIC July 2021 technical brief	2021

	WUENIC old vs new plots	2021
	WUENIC to share 2021-07	2021
	WUENIC initial briefing 18 July draft	2023
	WUENIC old vs new plots	2023
	WUENIC to share 2023-07	2023
SGs Cross-cutting	Partnerships Team meeting: March pre-read	2022
	Call for Humanitarian Partnerships	2021
	Report to the Board on Partners Engagement Framework (PEF)	2016
	Private Sector Partnerships Highlights	-
SG2-4	~200 specific SG documents, including ZD analysis for **58** countries for 2022 and 2023	
HLRP	High-Level Review Panel: Records of proceedings and recommendations, 2016 – 2022 ***27 docs**	2020-2022
VPO	Brown-bag presentations on Vaccine Portfolio Optimization ***5 docs**	2023
CPMPM	Specifically downloaded results from the CPMPM dashboard ***11 docs**	2023
IRC	Debriefing from 5 meetings plus meeting recording	2020
Angola country docs	Angola grant management request	2022
	Angola proposal incl ZD	
	National plan for Human Papillomavirus vaccine introduction 2023-2024	2023
	Monitoring agent services for Gavi grants in Angola Q2 progress report	2023
Ghana country docs	CCEOP BM Budget Template_09082023	
	GHA CCEOP Single Document B Medical	
	Situational Analysis Checklist	2023
	TOC_TEMPLATE_Gavi_ToC	2023
	Strategic Narrative_ENG_Ghana_21_08_2023	2023
	TEMPLATE EAF application background	2023
	Gavi-Budgeting-Reporting EAF	2023
	EAF APPLICATION EXECUTIVE SUMMARY	2023
	IPV budgeting reporting	2023
	IPV Switch form	2023
	Workplan malaria	2023
	Response to IRC report Ghana MVI	2023
	NVIP malaria application	2023
	NVS application form round 3	2023
	Final MR 2024	2023
	Pre-screening docs for malaria, MR, IPV2, CCEOP, EAF	2023
Indonesia	Indonesia MICs TI Narrative - FINAL	2023
	IRC Indonesia MICs Sept 2023	2023
Kosovo	IRC Report Kosovo VCF Sept 2023	2023
	Kosovo Ang. Vaccination Plan final	2023
	Kosovo Concept Note TA 4 Sep 2023	2023
	Kosovo New Vaccine Introduction Plan pdf	2023
	Kosovo Recommendation of NITAG	2023
	Kosovo Concept note 29 June	2023
Kyrgyzstan	IRC Report_15 June – FINAL	2021
Sri Lanka	Sri Lanka MICs Fragility Application	2023
Zambia	Resource mapping report for Zambia 2023-2027 (draft report)	2023
	National Health Accounts 2017-2021 (WB)	2021
	Costs of introducing pneumococcal, rotavirus and a second dose of measles vaccine into the Zambian immunisation programme: Are expansions sustainable? (Griffiths et al.)	2016
MICs regional	EMR Gavi middle income countries approach: Supporting Narrative for Technical Assistance and Political Will Building to Mitigate Backsliding and support New Vaccine Introductions Theory of Change	
	Gavi MICs approach – regional TA (UNICEF)	2023

	Overview for linked MICs regional TA	2023
	WHO EURO activities, regional TA for evaluation sharing	
	WHO PAHO activities, MICs regional TA for evaluation sharing	2022
MICs other	Report to the PPC Oct 2023: Annex A: MICs approach progress dashboards	2023
	Report to the PPC Oct 2023 Update on Middle-Income Countries Approach	2023
	Update to PPC on Middle-Income Countries Approach	2023
	MICs Approach ME framework	2023
	MICs MEL learning agenda	2023
	Board June 2022 Gavi's approach to engagement with former and Never-eligible middle-income countries (MICs)	2022
Gender	AR implementation of the gender policy	2021
	AR implementation of the Gender Policy	2022
Other evaluations and reviews	Evaluation Management Response: COVAX Facility and COVAX Advance Market Commitment (AMC) Formative Review and Baseline Study, including Gavi EMR	2023
	Evaluation of Gavi's Initial Response to COVID-19: final report including Gavi management response	2022
	Evaluation of the operationalisation of Gavi's strategy through Gavi's policies, programmatic guidance, and use of funding levers: Final report, including EMR	2023
	Strategy operationalisation Country Case Study – Cambodia + summary	2023
	Strategy operationalisation Country Case Study – Djibouti + summary	2023
	Strategy operationalisation Country Case Study – DRC + summary	2023
	Strategy operationalisation Country Case Study – Ethiopia + summary	2023
	Strategy operationalisation Country Case Study – India + summary	2023
	Strategy operationalisation Country Case Study – Nigeria + summary	2023
	Strategy operationalisation Country Case Study – South Sudan + summary	2023
	Strategy operationalisation Country Case Study – Yemen + summary	2023
	ZD evaluation Inception Report	2023
	ZD evaluation year one annual report	2023
	Mid-Term Review Report 2021-2025 - Raising Generation Immunity	2023
	EVOLVE As Is Report v2.0 fully signed	2023
	EVOLVE Booklet Template Inspiration Day	2023
	EVOLVE Lessons Learnt from previous projects	2023
	EVOLVE overview	2023
Other Gavi documents	Gavi 5.0 Measurement Framework	
	Countries and Partners Retreat: Summary by Johannes Ahrendts	2020
	Countries and Partners Retreat: Closing remarks by Thabani	2020
	Countries and Partners Retreat: Gavi 5.0 key discussion points	2020
	Need to Know (June 2020 - July 2022), digital newsletter	2022
	Partnerships Team meeting: Key takeaways	2021
	Gavi TOC narrative for Fragile, Conflict and Displaced Populations (FED) policy	2022
	Gavi TOC narrative for Funding Policies Framework	2022
	Gavi TOC narrative for Health Systems Immunisation Strengthening (HSIS)	2021
	Expanding sustainable vaccine manufacturing in Africa: Priorities for support (requested by AU and G7)	2022
WHO	Immunisation Agenda 2030	2022
Center for Global Development	Gavi's Approach to Health Systems Strengthening: Reforms for Enhanced Effectiveness and Relevance in the 2021–2025 Strategy	2009
NY Times	Can Africa get close to vaccine independence	2023
IMF	Patterns and drivers on health spending efficiency	2022
Lancet	Countdown on health and climate change: health at the mercy of fossil fuels	2022
	A new era of vaccine manufacturing in Africa	2022
WB	From double shock to double recovery - Implications and Options for health financing in the time of COVID-19	2022

CGD	A New Playbook for Gavi: Advancing Equitable and Sustainable Immunization in an Evolving Global Landscape	2024
FGHI	The Lusaka Agenda: Conclusions of the Future Global Health Initiatives Process	2023

Annex 5: Supporting evidence for HLQ1

Evidence supporting Report Vol. I Section 2.1.1

The following text provides detail to support the findings presented in Vol. I, section 2.1.1, and the following EQ:

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. Aligned Programmes & Policies

We note that the Strategy operationalisation evaluation and the EVOLVE process have reviewed how *aligned programmes and policies* have supported 5.0 implementation, and that both processes have highlighted the perceived complexity of Gavi's programs and policies. Additional MTE data collection and analysis does not provide any entirely new insights, but underlines the significant negative impact these process-side challenges have had "on the ground". A summary of the main insights that emerge in both Strategy operationalisation and EVOLVE is provided in Table 8, along with insights from MTE data collection that complements are adds nuance to these insights.

Table 8: Summary of strategy operationalisation evaluation and EVOLVE insights related to alignment of programs and policies, and complexity of processes, with MTE nuance

Insight	MTE Nuance
Despite efforts to coherently translate and operationalise strategic priorities, misalignment of processes resulted in various issues, including conflicting messages for partners and countries and thus perceptions of complexity.	Operationalisation processes were not fully fleshed out/tested in advance for MICs support, which led to significant frustrations and delays for initial countries to apply, and resulted in new vaccine introductions progressing without Gavi MICs support.
Despite the FPP process, there continue to be separate grant application processes and proliferation of funding levers with varying management arrangements.	Kenya and Zambia MTE case studies highlight the impact of these issues, with the FPP to disbursement timeline in Kenya taking over three years. Internal stakeholders are optimistic that EVOLVE will improve things moving forward
Progress has been made in streamlining grant application, grant-making, and grant management processes. However, challenges remain, linked to the underlying complexity of Gavi, IT rigidities during the strategy operationalization phase and known issues with Secretariat capacity, operational management, and culture.	The design and operationalisation of differentiated engagement to date has compounded these issues, with larger and/or complex core countries (for example) not receiving adequate Gavi support with application processes despite burdensome requirements, and with internal Gavi processes/requirements not being fully accounted for in the initial roll-out of support to MICs countries.
Gavi's policy framework, systems, processes, and ways of working are highly complex and challenging to communicate.	

2. Alliance voice for equity and gender

Equity through the ZD framing is consistently integrated into the design of 5.0 funding levers and is strongly filtering through to the interventions included in applications for Gavi support. Gender however is not reflected as clearly or consistently in the design of funding levers, and is not well-represented in applications for Gavi support.

The ZD and equity agenda is a key component of the Immunization Agenda 2030,[25] and, as noted by the strategy operationalisation evaluation, this agenda has received greater focus than the other 5.0 SGs. This is clearly reflected in the extent to which ZD and equity are reflected in the design and

[25] A Global Strategy to Leave No one Behind (IA2030), adopted by the World Health Assembly in 2020

operationalisation of the various funding mechanisms. The inclusion of "Alliance voice for equity and ZD" as a cross-cutting bubble in the ToC further reflects the overall importance placed on this area.

3. Differentiated engagement

Evidence strongly indicates a need to refine the design of differentiation so that application and review processes better account for the actual Secretariat resources needed to effectively manage countries, the relative risk of working with and the capacity/need of different countries. Learning from the MICs approach in terms of simplifying processes provides some insights into how processes can be refined moving forward.

Differentiated engagement is designed to work in line with defined country segments, namely Core (priority and standard), High Impact, Fragile, with Middle Income Countries (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 Table 9 for summary). [26, 27]

[26] This outline is based on further refinements made to differentiation within FPP made in mid 2022. Prior to this, the same level of detail was in principle expected of countries across country segments.

[27] KIIs – SCM x 5, Secretariat x 7, Country x 4, Core partner x 3; 11a - Annex A - Framework for Gavi Funding to Countries, Strat-Ops Final Report, EVOLVE Report, CPMPM dashboard, IRC Evaluation Report, 20220620 FPP step back final; FPP Overview Presentation (1); M&L FPP Simplification Changes_July2022; 20220603 FPP MD CP mtg_vF.

Table 9: Overview of FPP process for different country segments – design (D), perceived reality (R), perceived need (N)[28]

<table>
<tr><th></th><th rowspan="2">Owner-ship</th><th colspan="3">Application detail</th><th colspan="3">Timeline (in months, m)</th><th colspan="3">IRC Review</th><th colspan="3">Secretariat Engagement</th></tr>
<tr><th></th><th>D</th><th>R</th><th>N</th><th>D[29]</th><th>R</th><th>N</th><th>D</th><th>R</th><th>N</th><th>D</th><th>R</th><th>N</th></tr>
<tr><td>High Impact</td><td>SCM driven via FPP</td><td>National and subnational NIS
Detailed ToC</td><td rowspan="4">Seen as too detailed, complex and/or burdensome, with limited in-country understanding of ToC etc.</td><td rowspan="4">Overall simplification needed for all segments and/or in line with country size/allocation/capacity</td><td>Prep: 3-6m
Process: 5m</td><td>10.3m[30] (FPP -> IRC)
11m[31] (IRC-disbursement)</td><td rowspan="4">Within intended timeframes as a minimum. Expedited when (additional) fragility or emergency such as disease outbreak, natural disaster, conflict occurs</td><td rowspan="4">Standard – No differentiation</td><td rowspan="4">Some: Gavi flags to IRC if more detailed review needed</td><td rowspan="3">Based on risk level in line with context</td><td>VH</td><td>VH</td><td>H</td></tr>
<tr><td>Core Priority</td><td>Country and partner driven</td><td>National NIS
Detailed ToC</td><td>Prep: 3-6m
Process: 3m</td><td>14m[32] (FPP- IRC)
7.8m[33] (IRC-disbursement)</td><td>M</td><td>L-M</td><td rowspan="2">In line with risk, size, need</td></tr>
<tr><td>Core Standard</td><td>Country driven</td><td>National NIS
High-level ToC</td><td>Prep: 3-6m
Process: 3m</td><td>7m (FPP- IRC)
9.7m[34] (IRC-disbursement)</td><td>L</td><td>L</td></tr>
<tr><td>Fragile</td><td>Country and partner driven</td><td>National NIS
ToC not required[35]</td><td>Prep: 3-6m
Process: 5m</td><td>12.5m (FPP- IRC)
11.8m[36] (IRC-disbursement)</td><td>Limited/ none</td><td>H</td><td>L-M</td><td>H</td></tr>
<tr><td>MICs design comparison</td><td>Country driven</td><td colspan="3">NIS not required
High-level ToC Narrative (not required for Fragile MICs)</td><td colspan="3">No specific timelines laid out</td><td colspan="3">No IRC for Fragile MICs or for TA delivered entirely by Core partners</td><td colspan="3">Variable across country population/ MICs priority</td></tr>
</table>

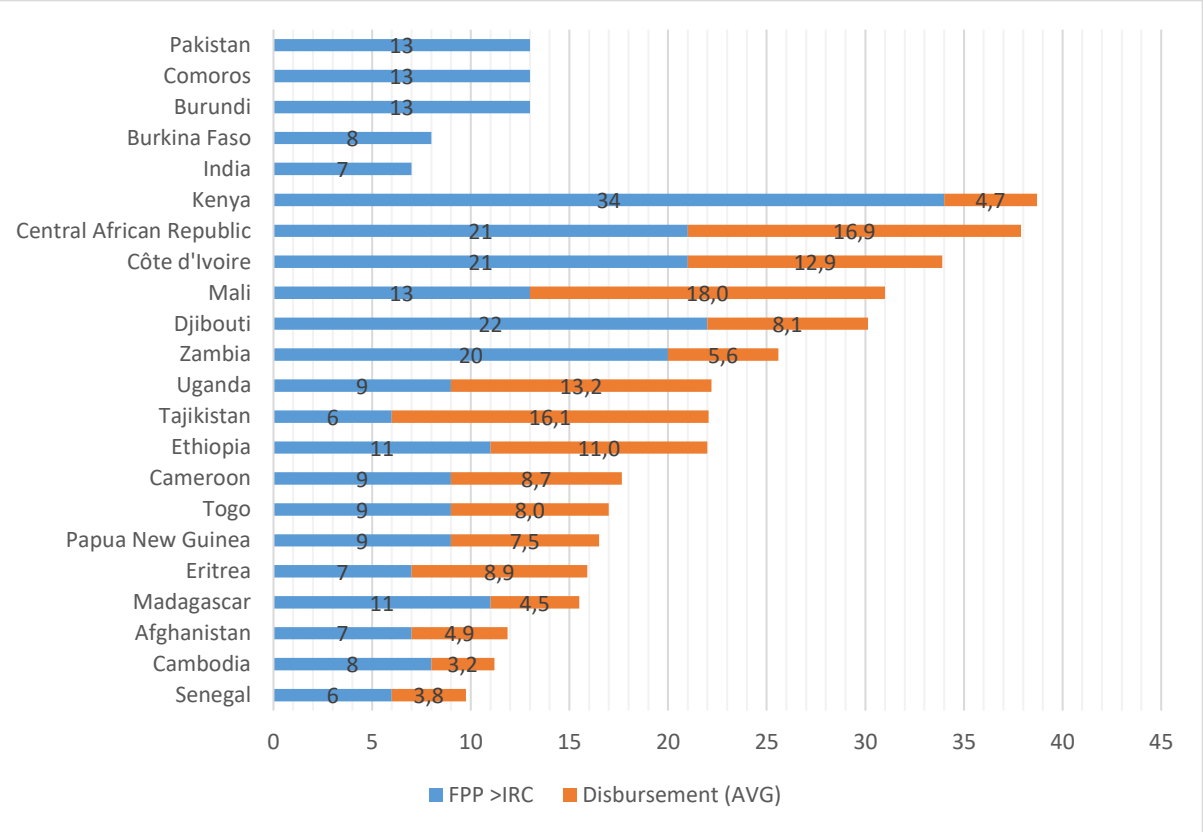
VH = very high; H = high; M = medium, L = limited

Stakeholders within Gavi perceive limited to no differentiation in practice in terms of relative effort required from countries, and partner and country government informants generally confirmed that FPP processes are too burdensome and complicated, and inflexible to unforeseen emergencies (see EQ3 for more discussion). [37] In some cases, this is compounded by lack of familiarity with segments (on the part of the IRC),[38] or some Gavi staff not adhering to segment-specific guidance due to individual concerns about risk.[39,40]

[28] Ibid
[29] Excluding final ICC review and submission
[30] Average across three HI countries
[31] One HI country
[32] Average across 13 Core Priority countries
[33] Average across 10 Core Priority countries
[34] Both averaged across 2 Core Standard countries
[35] Plan focussed on operational results
[36] Both averaged across 4 Fragile countries
[37] KIIs – SCM x III
[38] KIIs x II, EVOLVE Report; IRC Evaluation Report
[39] For example, Cambodia, as a core (standard) country is not required to complete a full budget template, but this was still requested by the SCM due to concerns about risk.
[40] CCS Cambodia summary

This application/process burden is reflected in the extended timelines from the start of the FPP process to IRC approval and then disbursement (see Figure 6 and Table 9), which show no evidence of prioritisation or improved efficiency across different segments or countries. Almost all stakeholders agree on the need to further simplify processes and improve timelines, and the outcomes of the EVOLVE process are expected to address many of the specific "pain points" identified. One of these relates to the FPP IRC review processes, which to date have not been differentiated by segment, but which is seen as important moving forward.[41]

Figure 6: Average time from FPP start to IRC approval and then disbursement (months)



Secretariat engagement does seem to be higher in high impact countries, but overall, the allocation of Secretariat resources across segments is perceived by multiple Gavi informants as being mismatched in terms of the effort needed, resulting in bottlenecks for larger and more complex Core countries in particular, but also for smaller countries where one SCM is expected to cover multiple countries, which may still require extensive engagement.[42] Overall, there is an emerging picture that Secretariat engagement levels need to reflect the relative effort required in each country to ensure processes move forward within the target timeframes, and thus reflect individual country context (risk to Gavi, size, complexity, country capacity etc.), as reflected by the "Needs" columns in Table 9.[43] The ongoing EVOLVE process has also highlighted the lack of differentiation in terms of processes

[41] KIIs – SCM x 5, Secretariat x 7, Country x 4, Core partner x 3; 11a - Annex A - Framework for Gavi Funding to Countries, Strat-Ops Final Report, EVOLVE Report, CPMPM dashboard, IRC Evaluation Report, 20220620 FPP step back final; FPP Overview Presentation (1); M&L FPP Simplification Changes_July2022; 20220603 FPP MD CP mtg_vF.

[42] KIIs – SCM x III, Secretariat x III, IRC x I, CCS DRC_hybrid_summary.docx, Gavi EVOLVE Report, Zero Dose Evaluation Draft Report, Strat-Ops Evaluation Report

[43] KIIs – SCM x III, Secretariat x III, IRC x I, CCS DRC_hybrid_summary.docx, Gavi EVOLVE Report, Zero Dose Evaluation Draft Report, Strat-Ops Evaluation Report

as an issue, and proposes a move towards end-to-end differentiation in accordance with country context (performance, capacity, risk and potential for Gavi impact).

The experience under the MICs approach offers some insights into how alternative ways and levels of engagement, application requirements and review processes could be integrated into revised FPP processes moving forward: the MICs approach has been designed to be lighter-touch, more country driven and less prescriptive from Gavi's side, and have differentiated review processes, with further simplifications for Fragile MICs (see Annex 10). As highlighted in Annex 10, allowing for some teething issues, most stakeholders agreed that MICs application and review processes are less burdensome, faster and more responsive.

4. Partnerships

"New and existing partnerships" are seen as key to the success of 5.0, but evidence indicates that the Secretariat has not sufficiently mitigated the inherent tension between these two types of partners, or the complexity of contracting country CSOs. This has affected progress in development of new partnerships, and also may affect the coherence and harmony of Gavi's relationship with core Alliance partners.

Under 5.0, inclusion of CSO partners has in effect been mandated via a minimum 10% threshold for HSS, EAF and TCA funds allocated to CSO partners, including within that, 30% of funds to local (i.e., in-country) partners.[44] Updated SFA focus areas also programme CSO engagement, and additional COVID-19 Vaccine Delivery Support (CDS) funding allocated at least 25% for CSOs.[45] EAF funding of around US$1 million has also been allocated for Multi-Country Partnerships, which again aim to bring new partners to the table to help overcome cross-border challenges such as conflict.[46]

Several challenges to the formation of new partnerships have surfaced, a key one being administrative. Despite integrating the 10% CSO requirement into 5.0 funding processes, Gavi systems and requirements are not supportive of direct contracting of smaller and/or local CSOs,[47] leading to sub-contracting by core partners.[48] This latter point links to a challenge in expansion of partnerships and the inherent tension (primarily at country level) between an Alliance traditionally reliant on and funding core partners while aiming to bring on new partners in a constrained financial environment (explored further under EQ2 and EQ3). Review of Board minutes and risk review documents suggests that this risk was not explicitly foreseen or mitigated against. The risk of competition between governments and civil society was raised by a participant at a Board meeting, with a response that "this approach will need to be carefully integrated with internal Gavi processes and aligned and coordinated with partners for this to be meaningful. While CSOs already work with the core partners and some have large capacity, all Alliance partners will need to buy in to the new approach for this to work".[49] Our review of available evidence does not indicate if any work has been done to mitigate this risk and ensure Alliance consensus.

5. Alliance learning

Alliance learning has been integrated into the 5.0 monitoring framework and there are multiple examples of where Gavi has made efforts to integrate ongoing learning into its policies and processes. Zero Dose and MICs have established dedicated communities of practice, with

[44] KI (Gavi Secretariat); 20220322_March PT 2-day pre-read_VF presented; 05 - Annex A - Risk & Assurance Report 2022.pdf; 1a - Annex A - Framework for Gavi Funding to Countries.pdf; Strategy Programmes and Partnerships-Progress Risk.pdf

[45] KIs (Gavi Secretariat)

[46] 20220322_March PT 2-day pre-read_VFpresented; 03 - Annex G - IRC-HLRP report.pdf; 05 - Annex A - Risk & Assurance Report 2022.pdf

[47] KIs (Gavi Secretariat); CCS Djibouti_desk_summary.docx; 20220322_March PT 2-day pre-read_VFpresented

[48] CCS Djibouti_desk_summary.docx; CCS Yemen_desk_summary.docx

[49] Board-2021-Mtg-02-Minutes.pdf

anecdotal evidence of the MICs regional Linked Immunisation Action Network (LINKED) providing valuable learning which is expected to improve the effectiveness of HPV introduction in Kosovo.

Alliance learning has been integrated into the design of overall support and specific funding levers. A draft Gavi 5.0 Learning System was shared at the December 2020 Board meeting, outlining a plan for how data across the 5.0 portfolio would be captured, collated, analysed and used.[50] This included creation of "Learning Hubs" in a subset of countries to identify and share best practices. To ensure evidence from learning is used, the Learning System proposed the introduction of a Utilisation Framework to "help organise, access and facilitate management of evidence generation across the Learning Priorities and enhance utilisation". The Learning System has since been iterated, with the last update in 2022, and with learning reportedly used to feed into Gavi 6.0 planning, ZD and country programming, vaccine investment strategy, and risk and audit activities.[51] A large number of agency-wide external evaluations have been conducted since 2021 or are in process of being contracted, as well as a large number of country and/or vaccine specific evaluations and studies.[52]

In addition to these, a ZD learning agenda has been established, with an accompanying ZD Learning Hub website, which acts as a resource for ZD evidence, and a ZD Community of Practice. Neither the MTE nor the ZD evaluation has identified evidence of the impact of the ZD learning agenda to date, but the 2023 Learning Agenda report shared in the MEL update to the PPC indicates that four countries included in the ZD Learning Hubs ((Bangladesh, Mali, Uganda and Nigeria) are making some progress, with Bangladesh having completed a rapid assessment which has helped to identify ZD communities.[53]

Similarly, under the MICs approach, a dedicated learning agenda has been established, with a set of MICs specific learning questions, and a Gavi-funded regional Linked Immunisation Action Network (LINKED) website and network for MICs stakeholders to share learning. Several stakeholders across the Secretariat, country teams, core partners at regional and country level felt that LINKED was already proving valuable information. For example, it facilitated sharing and troubleshooting of problems experienced by Indonesia during the MICs application process and prevented these from reoccurring in Vietnam, and in Kosovo, it led to the government in Kosovo choosing to do full national HPV rollout rather than sub-national pilot, based on evidence shared by core partners in the EURO region about sub-national roll-out increasing vaccine hesitancy and misinformation.

In addition to the above, there are multiple other avenues for individual countries (governments and partners) to share learning through, for example, sharing successes and challenges during partnership team meetings.[54] Some examples of learning across the portfolio at global and country level include adaptation of processes to support increased focus on zero dose, folding of the CCEOP into HSS to reduce fragmentation and improve planning,[55] discontinuing the Performance Payments Mechanism[56] and ongoing attempts to simplify application processes such as the FPP.[57]

Despite the multitude of evaluations, studies, theme specific learning agendas and other opportunities for learning to be captured, some stakeholders question whether learning is driving decision-making and thus real improvement and change. On a more granular level, Gavi monitoring systems are not yet supporting efficient tracking of progress against Strategy 5.0 as outlined in the 5.0 Theory of Change.

[50] Appendix 2-Draft Gavi 5.0 Learning System.
[51] Gavi (2033), Report to the Programme and Policy Committee, October 2023, Learning Agenda
[52] Gavi (2033), Report to the Programme and Policy Committee, October 2023, Learning Agenda
[53] Gavi (2033), Report to the Programme and Policy Committee, October 2023, Learning Agenda
[54] 20220322_March PT 2-day pre-read_VFpresented
[55] 11 - Annex A - Updates on HSIS Support Framework.pdf
[56] 11 - Annex A - Updates on HSIS Support Framework.pdf
[57] Strategy Programmes and Partnerships-Progress Risk.pdf; Johannes Ahrendts KII notes.docx

While it is clear that Gavi has a strong focus on learning, there is a perception among some stakeholders that the learning focus is not being sufficiently well translated into actual improvements on the ground, partly due to the sheer volume of "learning" that is happening at any one time, but without sufficient focus on operationalising it.[58] For example, findings and recommendations from previous evaluations conducted in 2016 highlighted many of the same issues and made similar recommendations as in the recent strategy operationalisation evaluation, but improvements were not successfully operationalised in the intervening time since the first evaluation. There are however some key actions have been put in place to address this, for example the EMR follow-up system has been established with inclusion of an indicator to track whether recommendations/actions from evaluations is being incorporated into the GBS. These are important steps to ensure the organisation is using evidence for decision making/course correction.

On a more granular level, the process of conducting the MTE has also highlighted various challenges with the current monitoring systems within Gavi. This includes the systems used to monitor progress against the overall strategy. For example, CPMPM dashboard, which has recently been updated, appears to be displaying some data incorrectly (for example, for time from FPP start to approval, it is adding together the periods for two separate processes in one country, actually making the average period longer than in reality); partner milestone monitoring frameworks are structured around "programmatic areas" rather than components for the ToC; several MPM indicators are still to be integrated into the dashboard (and it is not clear if data is being collected via other systems).

EVOLVE has also highlighted challenges in tracking and reporting accurate financial, including disbursement data, which the MTE has also experienced as a significant challenge.

Evidence supporting Report Vol. I Section 2.1.3

The following text provides detail to support the findings presented in Vol. I, section 2.1.3, and the following EQ:

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?

The following charts provide evidence in support of Finding 1.6 on PEF TCA/SFA milestones:

[58] KIs (Gavi Secretariat)

Figure 7: TCA milestones (number and proportion) mapped against focus SG, 2021-mid 2023[59]

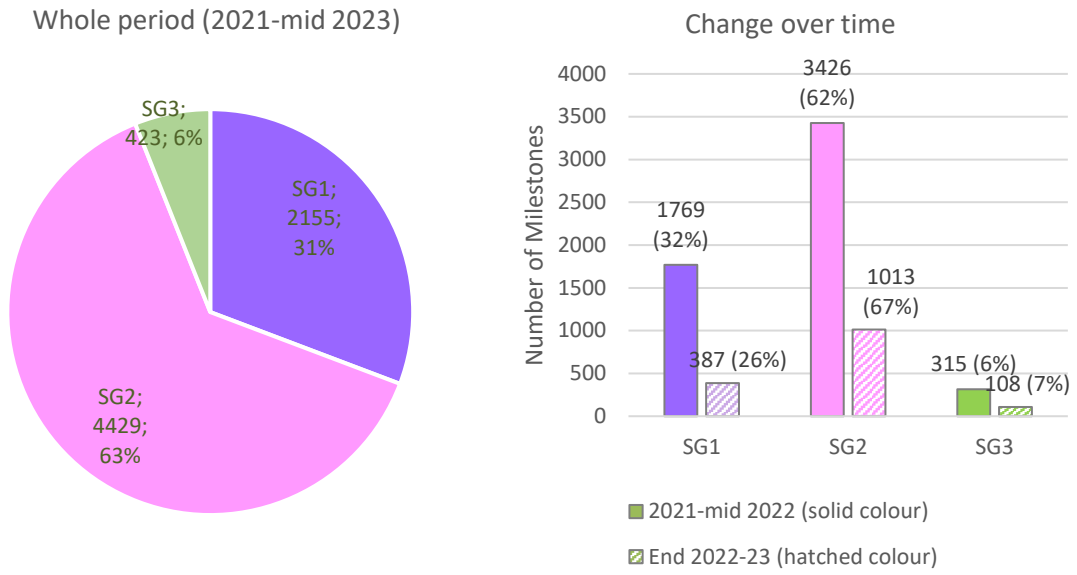


Figure 8: Status of TCA Milestones 2021 - mid 2023 against SG

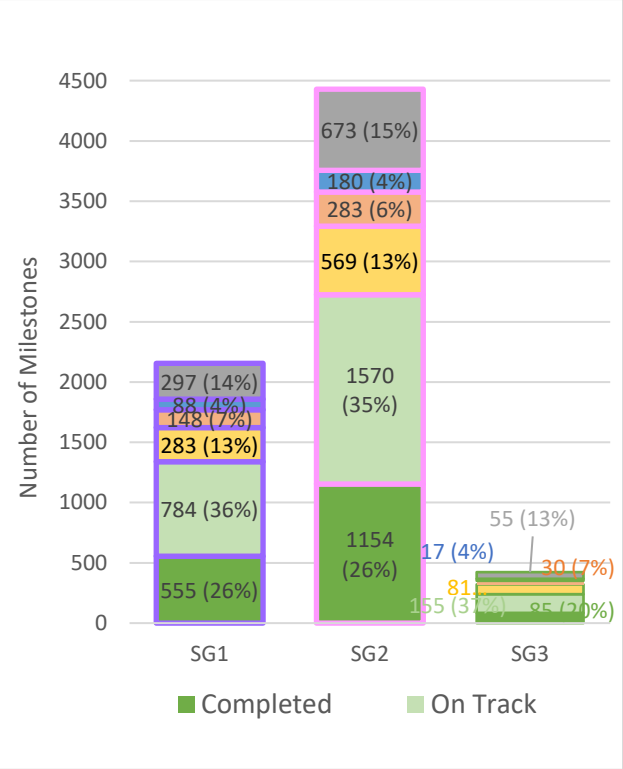
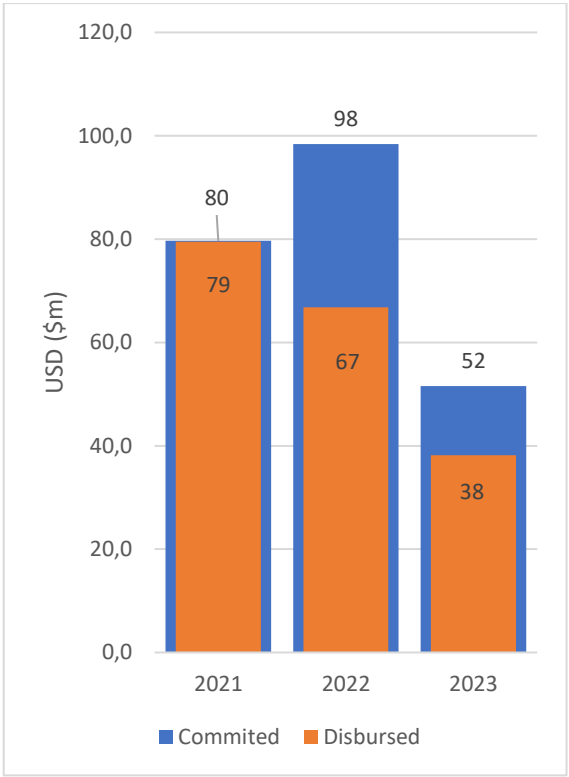


Figure 9: TCA Committed vs. disbursed, 2021-July 2023



[59] Gavi (2023), PEF TCA Milestones Report

Figure 10: TCA milestones mapped against ToC intervention and SG, 2021-mid 2023

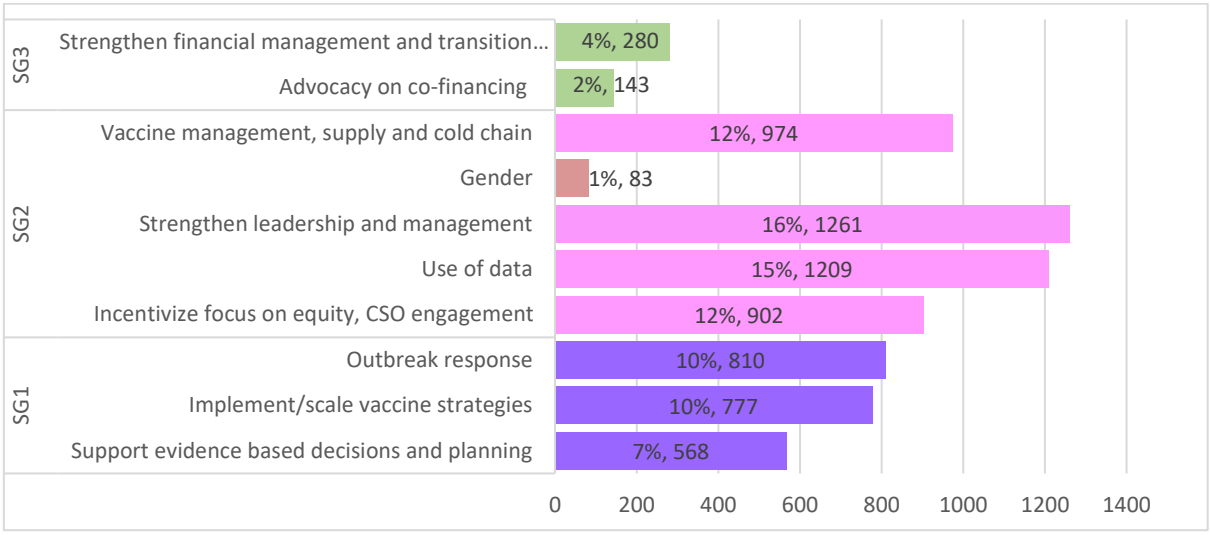


Figure 11: SFA milestones against focus SG, 2021-mid 2022.

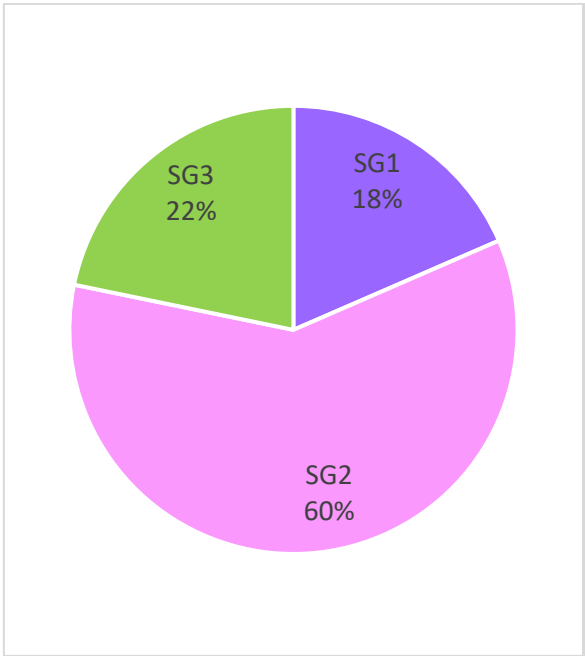


Figure 12: SFA Milestone Status 2021 -mid 2022 against SG

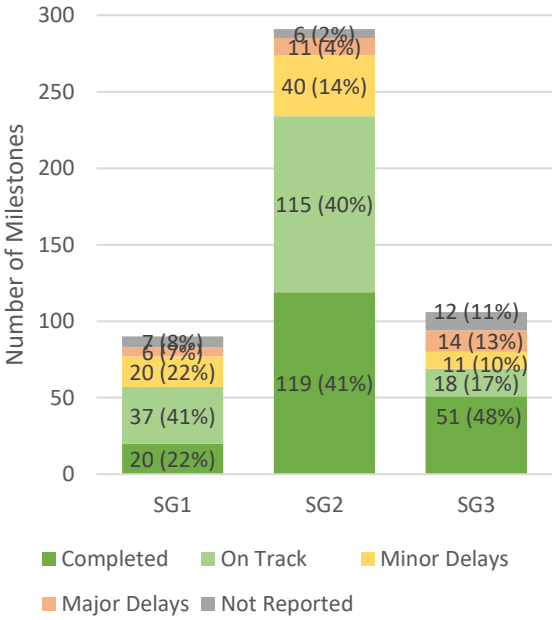


Table 10: SFA disbursement data 2022-23, up to Oct 2023[60]

SFA	Budget		Committed		Disbursed	
	Value	% of total	Value	% of total	Value	% of total
CSCE strategic indictor	$2,000,000	1%	$655,026	1%	$487,873	1%
Demand	$12,909,552	8%	$8,136,220	8%	$4,075,844	11%
Gender	$8,941,050	6%	$4,977,393	5%	$2,225,787	6%

[60] Gavi (2023) SFA Progress report, Oct 2023

Leadership	$5,800,000	4%	$1,196,724	1%	$184,045	0%
MEL	$31,491,895	20%	$21,349,631	22%	$8,490,907	22%
Supply Chain	$15,589,408	10%	$14,067,762	14%	$6,009,339	16%
Sustainable RI financing	$16,090,628	10%	$11,843,630	12%	$1,759,886	5%
Vaccination targeting	$24,200,000	15%	$15,298,281	15%	$5,749,705	15%
Zero Dose	$24,815,253	16%	$21,656,366	22%	$8,756,911	23%
HPV launch	$15,000,000	10%	$0	0%	$0	-
TOTAL	$156,837,786		$99,181,033		$37,740,298	

Table 11: Detailed summary of evidence against ToC interventions

			PEF milestones evidence	Evidence from relevant indicators	Evidence from narrative reports and interviews	Summary assessment
SG1		Support countries to make evidence-based vaccine prioritization, introduction and switch decisions	Significant number of relevant milestones, which are mostly complete/ on-track	• Improvement in timeliness of vaccine launches, expected increase in HPV application approvals, improvement in number of new HPV launches, and improvement in number of malaria vaccine introduction applications approved. • **Minor deterioration** in annual NVIs, and off-track towards cumulative target of 82 by end 2025.	Moderate evidence of medium volume interventions e.g. of TA provided to support NVIs etc. Also moderate evidence of TA being planned to support malaria vaccine introduction in countries which have had applications approved. But evidence of challenges with supply of malaria vaccine, inhibiting roll-out beyond pilot and high priority areas for countries who have applications approved.[61]	
		Support countries to implement/scale tailored vaccination strategies	Significant number of relevant milestones, which are mostly complete/ on-track	• Improvement in % of measles applications approved on first IRC review, improvement in measles campaign reach • Small and stable incidence of stockouts and understock.	Moderate evidence of significant volume of interventions to e.g. scale vaccine roll-out[62]	

[61]KIIs – Gavi staff x 2, 04 - Appendix 4 - Malaria programme detailed update.pdf, Gavi (2021), December Board Minutes/Papers, 04 - Strategy Programmes and Partnerships_Progress Risks and Challenges (2023), 20220322_March PT 2-day pre-read_VFpresented (004)

[62] KII – Gavi Core partner x 1, Gavi staff x 1, 04 - Strategy Programmes and Partnerships_Progress Risks and Challenges (2023), 20220322_March PT 2-day pre-read_VFpresented (004) , 20230731 CPD-PPDDS Quarterly Report April - June 2023

				• Deterioration in number of annual vaccine campaigns conducted		
		Support improved outbreak and pandemic response and connection back to RI	Significant number of relevant milestones, which are mostly complete/ on-track	• Almost 100% of C19 vaccine doses allocated over 2022-23 • Stable number of outbreak responses supported by Gavi, and on target • Deterioration in timely outbreak detection.	Strong evidence of significant volume of interventions to e.g. improve diagnostic tools, support VPD surveillance, monitor adverse reactions to vaccines, deliver vaccines rapidly via stockpiles in response to outbreaks etc. [63]	
SG2		Incentivize focus on equity, prioritizing and addressing barriers to RI and engagement with CSOs and new partners	Significant number of relevant milestones, which are mostly complete/ on-track	• Significant increase in EAF and FPP grants allocated to ZD in 2023. % of funds allocated to CSOs above target, but deterioration from 2022 2023. • Significant improvement in number of immunisation sessions • Deterioration in % of HSS, EAF and TCA allocated to CSOs from 2022-23 and **marginally below target** at mid 2023. • Deterioration in % of countries implementing tailored plans to overcome demand barriers. • **Stable but small %** of PEF funds allocated to local partners. • **Slight deterioration** in number of health facilities providing RI services. • **Stable but off-track** number of EAF and FPP applications approved	Strong evidence of significant volume of interventions to improve demand, of efforts to track CSO contribution to ZD efforts, to increase outreach efforts to reach ZD children etc.	
		Institutionalize focus on addressing gender-related barriers to RI/ promote gender equity	Very limited number of relevant milestones and relatively small SFA budget	• Lack of trend data, but in 2023 67% of countries who submitted applications included activities to address gender-related activities (compared to 5% under Gavi 4.0)	Strong evidence of limited focus on gender overall. IRC reports, gender policy update, SFA reports and other report narratives and KIIs indicate that while there is progress increasing the focus on gender since Gavi 4.0, there is still need for increased focus in this area	

[63] Gavi (2023), SFA Success Stories Presentation, 04 - Strategy Programmes and Partnerships_Progress Risks and Challenges (2023), Gavi (2022) December Board Minutes/Papers

					with only 23% of applications in 2023 including a robust gender analysis[64]	
		Strengthen leadership and management functions to plan and manage RI	Significant number of relevant milestones, which are mostly complete/ on-track	• Deterioration in EPI management capacity from 2021-22.	Strong evidence of significant volume of interventions to e.g., improve PHC governance, support capacity building of key management levels etc.[65]	
		Increase triangulation and use of sub-national and targeted data to plan/ monitor RI	Significant number of relevant milestones, which are mostly complete/ on-track	• Significant increase in CDS3 applications approved from 2022-23 (**partial relevance**)	Strong evidence of significant volume that funds are being used to support data-focussed activities, including FPP applications and e.g. SFA funds being used support use of innovative sources of population data in DHIS2[66]	
		Strengthen effective vaccine management and supply of cold chain equipment	Significant number of relevant milestones, which are mostly complete/ on-track	• Significant increase in CDS3 applications approved from 2022-23 (**partial relevance**)	Strong evidence of significant volume of interventions are proceeding to e.g. improve vaccine forecasting, cold chain capacity, vaccine transportation capacity etc., including in MICs eligible countries that received CDS support[67]	
SG3		Advocacy/coordination with countries & donors to meet co-financing requirements	Very limited number of relevant milestones, but mostly complete/ on-track	• Deterioration in % of countries with co-financing obligation met	Limited evidence, but examples include advocacy e.g. with Ministry of Finance as part of Gavi country team mission visits, of engaging CSOs to advocate	

[64] KIIs – Gavi staff x 3, 20220630 CP Quarterly Report April - June 2022, EHG (2023) Strat-Ops Evaluation Report
[65] 02b - Appendix 2 - NSIPSS Mid-Term Review Report.pdf, 04 - Strategy Programmes and Partnerships_Progress Risks and Challenges (2023),
[66] Gavi (2023), SFA Success Stories Presentation, EHG (2023) Strat-Ops Evaluation Report
[67] KIIs – Country Teams x 5, Gavi Secretariat x 3, core partners x 8, country government x 4; Gavi (2023), SFA Success Stories Presentation, 02b - Appendix 2 - NSIPSS Mid-Term Review Report.pdf, EHG (2023) Strat-Ops Evaluation Report

					on PHC financing etc.[68]	
		Strengthen planning to improve financial and programmatic readiness for transition including allocative efficiency and management of immunization budgets	Limited number of relevant milestones, but mostly complete/ on-track	• No relevant indictor with data over period 2021-23	Limited evidence, but examples include e.g. TCA support to develop transition roadmaps, SFA supported testing of conditional/non conditional cash/non-cash transfers to increase use of RI services in DRC, Cameroon, Nigeria, Lesotho and Afghanistan[69]	
		Support to former and never-eligible Gavi countries to prioritize and plan for maintaining, restoring, and strengthening equitable immunization services	N/A	• Significant increase in RI coverage in former-eligible/post transition MICs. • Increase in % of MIS countries engaged with backsliding and/or NVI support	Strong evidence of planned support approved/ in process of being reviewed, but no/ very limited implementation to date[70]	
		Support to MICs to increase access to vaccines at sustainable prices	N/A	• No relevant indicator	Support in progress to UNICEF's MICs Financing Facility (MFF) is and HPV Market Shaping Roadmap incorporates MICs demand. However limited impact on vaccine markets due to MICs approach/ procurement related support through the MFF to date[71]	

[68] Gavi (2023), SFA Success Stories Presentation, 02b - Appendix 2 - NSIPSS Mid-Term Review Report.pdf, 20230430 CPD-PPDDS Quarterly Report January - March 2023, EHG (2023) Strat-Ops Evaluation Report, 04 - Strategy Programmes and Partnerships_Progress Risks and Challenges (2023), 20230731 CPD-PPDDS Quarterly Report April - June 2023, 20220630 CP Quarterly Report April - June 2022, 04 - Annex B - Annual Risk Report 2023

[69] Gavi (2023), SFA Success Stories Presentation, 20230731 CPD-PPDDS Quarterly Report April - June 2023, 20221031 CP Quarterly Report July - September 2022, 20220630 CP Quarterly Report April - June 2022, 04 - Annex B - Annual Risk Report 2023

[70] KIIs – Country Teams x 5, Gavi Secretariat x 3, Core Partners x 8, Country government x 3, 11 - Update on Middle-Income Approach.pdf; 11 - Annex A - MICs Approach Progress Dashboards, 20230731 CPD-PPDDS Quarterly Report April - June 2023, 20221031 CP Quarterly Report July - September 2022

[71] 11 - Update on Middle-Income Approach.pdf, 20221031 CP Quarterly Report July - September 2022, 20220630 CP Quarterly Report April - June 2022

Table 12: Summary of Process/Output related indicators (incl. SII and MPM indicators) against SGs[72]

SG	Indicator (Italics have no specific target)	Source	2025 Target	2021	2022	Mid 2023	Trajectory
SG1[14]	Timeliness of vaccine launches (median time in days)[15]	SII A1.1/ Balanced scorecard	N/A	328	288	N/A	Improvement
	New vaccine introductions (cumulative)	S1.4l/ Balanced scorecard	82 *(cumulative)*	13	16 (29)	7 (36)	Deterioration
	% Gavi-approved vaccine doses delivered (Core)	SII A1.2/ Balanced scorecard	?	95%	99%	93%	Deterioration
	%age Annual Vaccine Requirement (AVR) consumed	SII A1.3/ Balanced scorecard	N/A	82%	N/A	N/A	N/A
	Number of vaccination campaigns conducted[16]	SII A1.4/ Balanced scorecard	N/A	26	23	9	Deterioration[73]
	Approved measles applications upon first IRC	SII A1.5/ Balanced scorecard	N/A	N/A	55%	100%	Improvement
	Campaigns achieving target coverage	MPM dashboard	N/A	N/A	0%	N/A	N/A
	Measles campaign reach	S1.6/ Balanced scorecard	50%	37.3%	70.2%	N/A	Improvement
	MPM Antigens stockout (Core)	MPM dashboard	N/A	N/A	2 (Q4 only)	1	Stable
	MPM Antigens understock (All)	MPM dashboard	N/A	N/A	3 (Q4 only)	3	Stable
	C19 doses allocated vs. requested	Balanced scorecard (other)	?	N/A	100%	99%	Stable
	Outbreak response campaigns supported by Gavi	MPM dashboard	?	N/A	38	19	Stable
	Timely outbreak detection	PS1.7/ Balanced scorecard	37.5%	27.6%	18%	N/A	Deterioration
	HPV applications approved	Programmatic goals/ Balanced scorecard	N/A	N/A	2	2	Improvement
	New HPV launches (cumulative 2021-25)	HPV scorecard	N/A	3 routine 3 multi-age cohort	5 routine 3 multi-age cohort	10 routine 4 multi-age cohort[17]	Improvement
	HPV coverage in Gavi 57	HPV scorecard	N/A	9%	10%	N/A	N/A
	Girls fully immunized with HPV (cumulative)	HPV scorecard	N/A	14.7m	1.6m (16.3m)	N/A	Improvement
	Malaria applications approved	Programmatic goals/ Balanced scorecard	N/A	N/A	3	16	Improvement
SG2[18]	A2.1 EAF and FPP applications approved (cumulative)	SII A2.1/ Balanced scorecard	N/A	2	8 FPP 7 EAF	8.5[19] FPP 14 EAF	Stable

[72] CPMPM data from October 2023 download. Balanced scorecard data from June 2023.

[73] We note that it can be argued that more campaigns is not necessarily better – as the ultimate vision of success is no follow-up campaigns needed due to strong RI systems in place. However, our rating reflects the "amber" rating given in the June 2023 Balanced scorecard

	A2.2 Approved EAF and FPP grants allocated to ZD	SII A2.2/ Balanced scorecard	N/A	$20.8m	$20.8m	$331,393m (46%)	Improvement
	A2.3 % funds allocated to CSOs	SII A2.3/ MPM dashboard	10%	N/A	29%	18%	Deterioration (but above target)
	A2.4 Cash disbursement vs. forecast	SII A2.4/ Balanced scorecard	?	79%		108%	Improvement
	A2.5 % of grant funds utilised (CDS & HSS)	SII A2.5/ MPM dashboard	N/A	71.4%* (HSS 76.8%; CDS 32.8%)	76.0%* (HSS 80.9%; CDS 58.8%)	77.9%* (HSS 83.6%; CDS 62.2%)	Improvement
	CDS3 applications approved	Balanced scorecard/ Other	N/A	N/A	31	65	Improvement
	HSS, EAF, TCA allocated to CSOs	Balanced scorecard/ Other	20%	N/A	28%	17.5%	Deterioration
	PEF (TCA, FS, SFA) allocated to Local/Expanded Partners	Balanced scorecard/ Other	N/A	2%/24%		2%/23%	Stable
	Health facilities providing RI services	MPM dashboard	N/A	90.5%	87.1%	N/A	Deterioration
	Number of immunisation sessions	Strategy Indicator S2.4/ PPC Report October 2023	N/A	6.4	17.2m	N/A	Improvement
	% countries implementing tailored plans to overcome demand barriers	Strategy Indicator S2.7/ PPC Report October 2023	N/A	86%	86%	69%	Deterioration [74]
	% countries addressing gender-related barriers with Gavi support	Strategy Indicator S2.8/ PPC Report October 2023	N/A	N/A	N/A	67%	N/A
SG3	% of countries with increasing domestic PHC expenditure per capita	SII A3.1/ Balanced scorecard	N/A	82% (2020)	N/A	N/A	N/A
	% of countries with co-financing obligation for current year met	SII A3.2/ MPM dashboard	N/A	84%	75.5%	28.8%	Deterioration
	RI coverage in transitioned countries	SII A3.3/ Balanced scorecard	N/A	47%	75%	N/A	Improvement
	% MICs countries engaged with introducing new vaccines/ mitigating backsliding	SII A3.4/ Balanced scorecard	?	N/A/ 71%	10%/76%	N/A	Improvement
SG4	A4.1 Sufficient and uninterrupted availability of vaccine products that meet programmatic needs	SII A4.1/ Balanced scorecard	10	11	10	N/A	Stable
	A4.2 Alliance health markets activities.	SII A4.2/ Balanced scorecard	?	81%	82%	N/A	Improvement

[74] In the Annual Performance Review, it was indicated that the reporting of this indicator in JRF has been significantly changed since 2021, so these values are not comparable from year to year.

Cross-cutting	A5.2 Cash going through government systems (Core)	SII A5.2/ Balanced scorecard	55%	38%	20%	N/A	Deterioration
	A5.3 Time taken from IRC to disbursement (TCA, HSS, EAF, VIGs, Ops, VSGs)	SII A5.3/ Balanced scorecard	9 months	9.9 months	9.96 months	8.9 months	Improvement
	PEF (TCA, FS, SFA) utilisation vs. disbursement	Balanced scorecard/ Other	N/A	88%		N/A	N/A
	A5.1 Partner TCA milestones achieved (all partners)	SII A5.1/ Balanced scorecard	75%	68%	60%	69%	Improvement
	Average time from FPP to IRC review decision	MPM A1.1	N/A	12.6 months (HI = 10; FCAS = 13, CORE = 13)			N/A
	% disbursement through each funding channel	MPM B4	N/A	NOT YET CLEAR			N/A

Table 13: Support for Finding 1.7: Detailed summary of progress against intervention areas by SG

	Intervention Area	Progress			Summary Progress Assessment
		PEF milestones evidence	Evidence from relevant indicators	Evidence from narrative reports and interviews	
SG1	Support countries to make evidence-based vaccine prioritization, introduction and switch decisions	Good	Moderate	Moderate	Moderate
	Support countries to implement/scale tailored vaccination strategies	Good	Good	Good	Good
	Support improved outbreak and pandemic response and connection back to RI	Good	Good	Good	Good
SG2	Incentivize focus on equity, prioritizing and addressing barriers to RI and engagement with CSOs and new partners	Good	Moderate	Good	Good
	Institutionalize focus on addressing gender-related barriers to RI/ promote gender equity	Limited	Good	Limited	Limited
	Strengthen leadership and management functions to plan and manage RI	Good	Limited	Good	Good
	Increase triangulation and use of sub-national and targeted data to plan/ monitor RI	Good	Moderate	Good	Good
	Strengthen effective vaccine management and supply of cold chain equipment	Good	Moderate	Good	Good
SG3	Advocacy/coordination with countries & donors to meet co-financing requirements	Moderate	Limited	Limited	Limited
	Strengthen planning to improve financial and programmatic readiness for transition	Moderate	N/A	Limited	Limited
	Support to former and never-eligible MICs to prioritize and plan for maintaining, restoring, and strengthening equitable immunization services	N/A	Good	Moderate	Moderate
	Support to MICs to increase access to vaccines at sustainable prices	N/A	N/A	Limited	Limited

SG4	Pooled procurement and distribution of vaccines and related products	N/A	Good	Good	Good
	Support to vaccine markets to develop market roadmaps, improve coordination & forecasting	N/A	Good	Good	Good
	Support competitive dynamics in vaccine markets	N/A	Good	Good	Good
	Support improved supplier capability and sustainability, including via provision of incentives to de-risk investments and support development and scale of innovations	N/A	Moderate	Moderate	Moderate
	Provide insights/ perspectives into development of new regional manufacturing hubs	N/A	Good		
	Support to optimize vaccine and related product regulatory systems/processes	N/A	Moderate	Moderate	Moderate
	Improve alignment between vaccine development and market strategies & other procurement entities	N/A	Moderate	Moderate	Moderate
	Develop new demand health intervention framework to govern, monitor and enhance outcomes of demand-side market shaping	N/A	Moderate	Moderate	Moderate

Table 14: Detailed summary of progress against SG outputs

	Intervention Area	Evidence from narrative reports and interviews	Strength of Evidence	Summary Progress Assessment
SG1	Increased capacity for evidence-based decision making to prioritize vaccine introductions	• India was cited as an example of a country where immunisation infrastructure and human resource capacity has improved,[75] although this was not linked to decision-making capacity specifically. • Counter: Countries pausing vaccination because their preferred vaccine product is out of stock, even though an effective alternative is available;[76, 77]	**Limited**	**Moderate**
	Global stockpiles for outbreak and pandemic-prone diseases efficiently and equitably deployed	• Gavi support to yellow fever diagnostics and supplies, supporting Ghana with rapid confirmation of an outbreak through in-country molecular testing. As a result, Ghana could detect and respond in a little over half the time that WHO considers acceptable, thereby facilitating containment of the outbreak. [78]	**Limited**	**Moderate**
SG2	Increased availability & implementation of innovation to address gender, equity barriers to RI	Our innovation case study indicates that implementation to date is limited, although there are some examples of innovation being leveraged in some countries	**Limited**	**Limited**
	Increased capacity to identify, reach, monitor, measure, and advocate for ZD, under-immunized, and their communities	• ZD evaluation provides evidence of regional planning and assessments supporting local needs • There is evidence of increased understanding of coverage in some countries such as India. [79] • In some countries such as Indonesia, recruitment of addition HCW, training of HCW and middle/sub-national	**Moderate**	**Good**

[75] CCS India_desk_summary.docx – Strat-Ops report Volume II
[76] Although this may not reflect lack of capacity, but other reasons
[77] KIIs (Gavi Secretariat)
[78] 02 - CEOs report.pdf
[79] September 2022 HLRP; CCS India_desk_summary.docx; 03 - Annex G - IRC-HLRP report.pdf

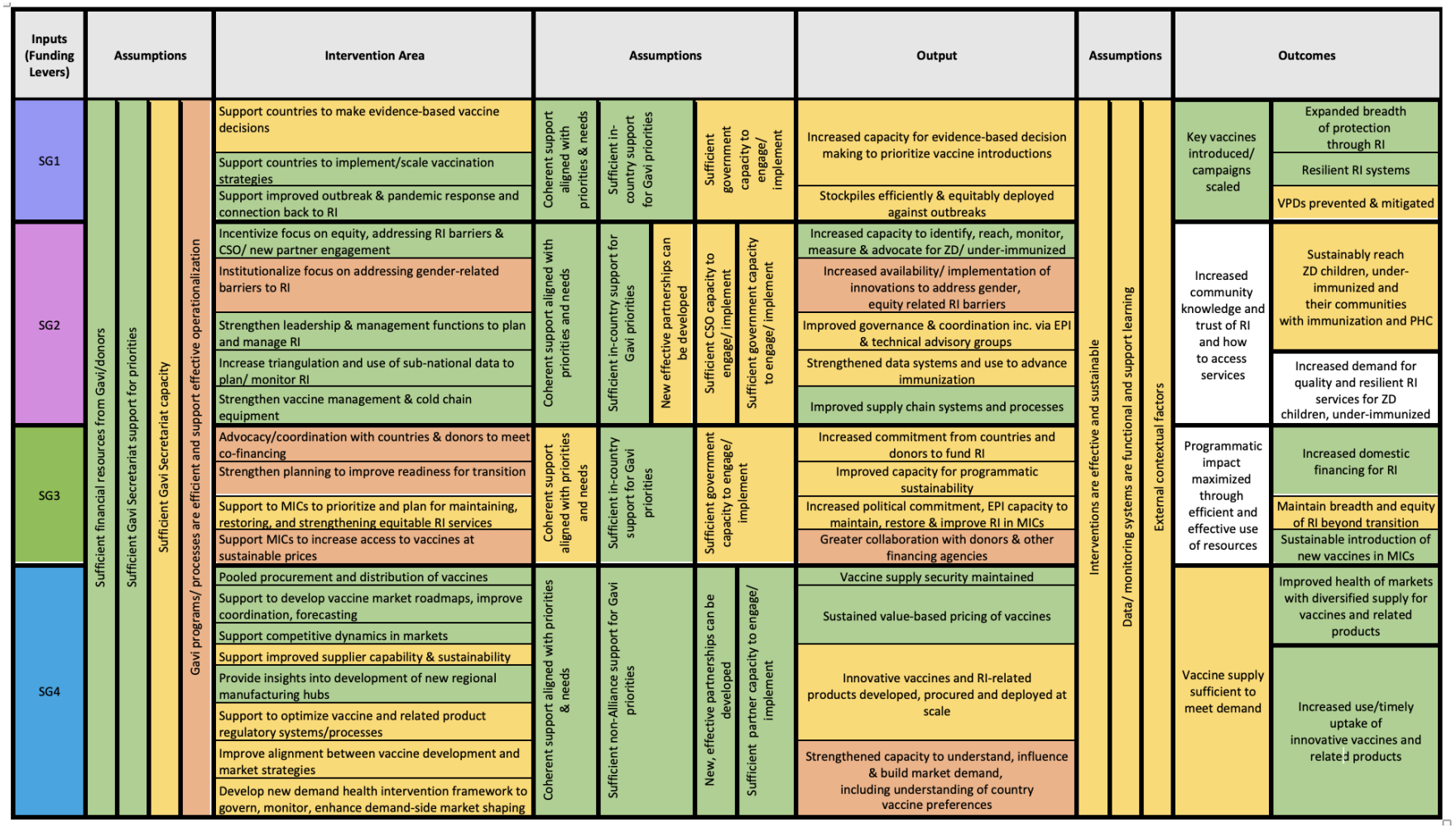
		level managers has reportedly improved capacity to identify ZD[80] • In countries such as Zambia – investment in the capacity require to conduct a campaign pre registration process for HPV reportedly helped to get 100% coverage[81] • In other countries including Ghana, Gavi support enabled the development of ZD micro plans, which reportedly held to identify and reduce ZD children[82] • In countries such as Kyrgyzstan, CSOs have reportedly successfully helped to reach additional ZD[83] Counter: • Deterioration in EPI management capacity (Strategy Indicator S2.6) from 2.73 in 2021 to 2.51 in 2022. • Evidence that countries entering transition do not always have sufficient institutional capacity[84]		
	Improved governance & coordination inc. via EPI & technical advisory groups	• Some examples of improved governance and coordination in-country were cited, leading to improved vaccination coverage, e.g. in Afghanistan and Pakistan related to polio eradication[85]	**Limited**	**Moderate**
	Strengthened data systems and use to advance immunization	• Some examples of improved use of innovate data collection and analysis technologies were cited.[86] • In Indonesia, the SMILE electronic vaccine management system[87] • In Kosovo, CDS support also supported improved data systems [88]	**Limited**	**Moderate**
	Improved supply chain systems and processes to ensure availability of vaccines at access points	There are some examples of improved vaccine management and forecasting[89], including specifically • In Indonesia, the SMILE electronic vaccine management system[90] • In Kosovo, CDS support also supported improved data systems [91] • In Sri Lanka, CDS support had improved cold chain capacity, vaccine transportation systems, trained HCW, which had ensured vaccine accessibility and quick recovery from COVID-19[92] • In Kyrgyzstan, the EVM assessment score reportedly increased and CDS support to cold chain capacity was seen as essential[93]	**Limited**	**Good**
SG3	Increased commitment from countries and donors to fund RI	• See resource mobilisation study	**Limited**	**Moderate**

[80] KIIs – Country teams x 2, Core partners x 3
[81] KIIs – Country government x 2, Core partner x 1
[82] KIIs – Core partner x 2, 20220322_March PT 2-day pre-read_VFpresented (004)
[83] KIIs – Expanded/CSO partner x 2, country government x 1
[84] Gavi (2019) Gavi 5.0 Funding Policy Review
[85] Annex F AFC Update on Risk Management.pdf; PPC-2021-Meeting 04; CCS India_desk_summary.docx
[86] CCS India_desk_summary.docx; 01e - Annex C - Proposed innovation approach for Gavi 5_0 (1).pdf
[87] KIIs – Country team x1, Core partners x 4
[88] KIIs – Country teams x 1, Core partners x 3, Countyr government x 1
[89] September 2021 Vaccine HLRP; CCS India_desk_summary.docx
[90] KIIs – Country team x1, Core partners x 4
[91] KIIs – Country teams x 1, Core partners x 3, Country government x 1
[92] KIIs – Core partners x 2, country government x 1
[93] KIIs – Core partners x 2, Expanded/CSO partner x 1

	Improved capacity for programmatic sustainability	• In Angola, the use of subnational consultants to produce monthly programmatic and financial reports[94] • Increased capacity and thus efforts to track vaccine expenditure[95] • In Kyrgyzstan, an increase in the ability to structure VIS and overall planning for sustainability[96] • In Indonesia, the SMILE electronic vaccine management system has reportedly reduced waste rates and improved the return on investment of funds spent on vaccines by a factor of 2.77, as HCW no longer have to travel to clinics on weekends to monitor fridge temperatures etc.[97] Counter: • Resistance to Gavi feedback on budget errors, inconsistencies and inefficiencies in countries s such as Yemen[43]	**Limited**	**Moderate**
	Greater collaboration with donors & other financing agencies	• Kyrgyzstan – FPP makes it easier to bring together partners	**Limited**	**Limited**
	Increased political commitment & EPI capacity to sustainably maintain, restore, and improve equitable RI performance in MICs	• Indonesia – influencing of policy making via UNICEF staff HO etc.) – advocacy at national and sub-national level, bringing in religious leaders – helped to restore RI • Strong political commitment in Kosovo to NVI	**Limited**	**Moderate**

[94] KIIs – Country government x 1, Country teams x 2
[95] KIIs – core partner (regional) x 1
[96] KIIs – country partner x 1
[97] KIIs – core partners x 3, expanded/CSO partners x 1

Figure 13: Summary of progress against the ToC



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?

Funding to CSOs is well above the 10% minimum threshold across EAF, HSS and TCA levers, but progress developing new partnerships at country level appears to be slower than hoped, with various inhibiting factors including contracting challenges and the limited number of potential CSO partners in some countries.

Qualitative data confirms that new partnerships are being formed at global, regional, and country levels, though several informants noted that progress is slower and harder than anticipated.[98] Data on the effectiveness of these partnerships was not available. Some examples of new partnerships include:

- Under the EAF, new multi-country partnerships have been formed in the Sahel (led by World Vision) and Horn of Africa (led by International Rescue Committee).[99]
- New partnerships with the International Federation of the Red Cross, the International Organisation for Migration (IOM), United Nations High Commissioner for Refugees (UNHCR), United Nations Office for Project Services (UNOPS) and Save the Children UK, Partnership for Maternal, Newborn and Child Health, the CORE group, Internal Vaccine Access Center and AMREF.[100]
- A new partnership with African Union/Africa CDC on regional vaccine manufacturing, to advance Zero Dose policies, operationalise vaccine manufacturing and to handle regulatory aspects.[101]
- Existing CSO /expanded partnerships continue to operate in many countries, with new partners added to the mix.[102]

At a country level, in some countries CSO partners are seen by other in-country stakeholders as valuable,[103] for example in Kyrgyzstan, CSOs are seen as valuable for demand generation activities, especially in for example religious communities and some other communities were vaccine hesitancy is more common.[104] It is important to note that despite the tensions between core partners and increased CSO engagement highlighted earlier, some in-country core partners did reference the importance of this, and in some countries such as Afghanistan, there is support and acceptance that CSOs actually play the majority of the role in terms of service delivery.[105]

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?

[98] KI (Gavi Secretariat); Partnerships Team meeting: March pre-read (March 2022)
[99] 03 – Annex G – IRC-HLRP report.pdf
[100] Strategy Programmes and Partnerships-Progress Risk; 05 – Annex A – Risk & Assurance Report 2022
[101] 2023 Board Retreat Pre Read.pdf; 05 – Annex A – Risk & Assurance Report 2022
[102] CCS Ethiopia_desk_report.docx– Strat-Ops report Volume II
[103] KIIs – country government x 2, expanded/CSO partner x3, core partner x 2.
[104] KIIs – country government x 1, expanded/CSO partner x 1.
[105] KIIs – core partners x 4

Table 15: Timeline of FPP applications (as of October 2023)

	2020				2021				2022				2023				2024				2025			
Country	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Kyrgyzstan	*Q1*		*Anticipated IRC*		*Disbursement*																			
Syria - Northwest	Mar	*Anticipated IRC*			*Disbursement*																			
Syrian Arab Rep.	Mar	*Anticipated IRC*			*Disbursement*																			
South Sudan		May									IRC July		*Disbursement*											
DPR Korea		Q2			Q1	*Disbusement*																		
Kenya				Q4								*Anticipated IRC*			*Disbursement*									
Djibouti				Nov					IRC May		*Disbusement*													
Pakistan				Nov							IRC Dec		*Disbursement*											
Zambia						Jun							IRC Feb + Jun		*Disbursement*									
Benin							August						*Anticipated IRC*		*Disbursement*									
CAR								Dec				IRC March		*Disbursement*										
Cambodia									Q1		IRC Oct		*Disbursement*											
Burkina Faso									Mar			23/01/2023		*1st disbursement 16/08 2023*										
Ethiopia									Mar			IRC Feb		*Disbursement*										
Madagascar									Mar			IRC Jan		*Decision ltr Sept*										
Afghanistan										April	IRC Nov		*Disbursement*											
Burundi											Q3	*ticipated IRC*		*Disbursement*										
Comoros											Aug	*Anticipated IRC*		*Disbursement*										
Côte d'Ivoire											Aug	IRC March		*Disbursement*										
Cameroon											Sept			*June*	*Disbursement*									
PNG											Sept	in-ctr review April		*Disbursement*										
Togo											Sep			*June*	*Disbursement*									
Eritrea												Q4		*June*	*Disbursement*									
India												IRC Oct			*Disbursement*									
Tajikistan												Dec		*June*	*Disbursement*									
Uganda												Dec		*Q2*	*Disbursement*									
Zimbabwe													Q1	*Anticipated IRC*		*Disbursement*								
Rwanda													Jan		Q3	*Disbursement*								
Somalia													Jan		Q3	*Disbursement*								
Lao													Q1		Q3	*Disbursement*								
Niger													Mar		Q3	*Disbursement*								
Congo DRC														Q2						*Q3*	*Disbursement*			
Mauritania														Q2		Q4	*Disbursement*							
Nepal														Q2	Q3	*Disbursement*								
Mali														June	*Disbursement*									
Nigeria														Apr			Q1	*Disbursement*						
Gambia																Q4		Q2	*Disbursement*					
Liberia																Q4		Q2	*Disbursement*					
Senegal																Q4		Q2	*Disbursement*					
Sierra Leone																Q4		Q2	*Disbursement*					
Guinea																	Q1	Q2	*Disbursement*					
Haiti																	Q1			2025	*Disbursement*			
Guinea-Bissau																		Q2		Q4	*Disbursement*			
Congo, Brazzaville																			Q3	Q4	*Disbursement*			
Malawi																				Q4				
Mozambique																				Q4				
Myanmar																				Q4				
Tanzania																				Q4				

Mid-point 5.0

full information given, ending with IRC meeting

Start date known, *IRC anticipated*

assumed both start and stop

anticipated disbursement, average 9.9 months as per CPMPM data

Annex 6: Supporting evidence for HLQ2

Table 16 and Table 17 provide our assessment for Mission Indicators (MIs) and Strategy Indicators (SIs), based on the most recent WUENIC data[106] as well as the latest Secretariat report to the Board[107] as to whether:

1) Indicator values were back to pre-COVID-19 levels in 2021 ('Diff 21 vs. 19' columns).[108]

2) Indicator values were back to pre-COVID-19 levels in 2022 ('Diff 22 vs. 19' columns).

3) Indicator values were on track in 2022 assuming linear progress from baseline (2019 or 2021 depending on the indicator) to 2025 ('Diff with 22 on track value' column).

The green font indicates values that are (back) on track and red font indicates values that are not on track.

We note that targets are of different types (increases, decreases, cumulative, values to be achieved in the last year, benchmarks to be achieved every year – see key at the top of Table 4). Values/differences that could not be calculated because of missing data points are marked "not applicable" (n/a). Our quantitative analysis is followed by a discussion on the plausibility that Gavi will achieve its 5.0 goals based on evidence to date.

The presentation of this data, assembled at speed following the publication in July 2023 of 2022 WUENIC data, will be improved in our final report to maximise accessibility for our target audience.

Table 16: Indicator analysis (2021 and 2022 cf. 2019) based on data reported in Oct 2023 to the PPC

ID	Indicator name	Unit	2019	2020	2021	2022	Difference 2021 cf. 2019	Difference 2022 cf. 2019
M.1	Under-five mortality rate	deaths per 1,000 live births	59.2	57.5	55.7	n/a	-3.5	n/a
M.2	Number of future deaths averted	millions	n/a	n/a	1.2	2.4*	n/a	n/a
M.3	Number of future DALYs averted	millions	n/a	n/a	60	121*	n/a	n/a
M.4	Reduction in number of ZD children	millions	9	11.6	12.4	10.2	3.4	1.2
M.5	Unique children immunized through RI	millions	n/a	n/a	65	133*	n/a	n/a

[106] https://immunizationdata.who.int/ (accessed in July 2023)
[107] Gavi. 2023. Report to the Board 26-27 June
[108] Question 1.a in the RfP (now part of EQ9) explicitly asked the evaluators to assess whether Gavi strategy performance indicators showed recovery to 2019 baseline levels in 2021.

M.6	Economic benefits generated	Billions USD	n/a	n/a	18.1	35.8*	n/a	n/a
S1.1	Breadth of protection	%	48%	50%	51%	56%	3pp	8pp
S1.2	Vaccine coverage [DTP3]	%	83%	79%	78%	81%	-5pp	-2pp
S1.2	Vaccine coverage [MCV2]	%	58%	60%	60%	64%	2pp	6pp
S1.2	Vaccine coverage [PCV3]	%	56%	56%	56%	70%	0pp	14pp
S1.2	Vaccine coverage [HPV2]	%	7%	8%	9%	10%	2pp	3pp
S1.3	Rate of scale up of newly introduced vaccines - PCV	%	n/a	n/a	98%	98%	n/a	n/a
S1.3	Rate of scale up of newly introduced vaccines - RotaC	%	n/a	n/a	96%	90%	n/a	n/a
S1.3	Rate of scale up of newly introduced vaccines - YF	%	n/a	n/a	91%	88%	n/a	n/a
S1.3	Rate of scale up of newly introduced vaccines - MCV2	%	n/a	n/a	78%	86%	n/a	n/a
S1.4	Number of vaccine introductions	Absolute number	n/a	n/a	13	29*	n/a	n/a
S1.5	Country prioritisation of vaccines	n/a	n/a	n/a	n/a	n/a	n/a	n/a
S1.6	Preventive campaign reach (measles)	%	n/a	n/a	37%	70%	n/a	n/a

S1.7	Timely outbreak detection and response		%	25%[109]	28%	18%	n/a	n/a
S2.1	Geographic equity (DTP3 coverage)	%	67%	66%	62%	62%	-5pp	-5pp
S2.2	DTP drop out	%	6%	7%	7%	6%	1pp	0pp
S2.3	MCV1 coverage	%	81%	79%	77%	79%	-4pp	-2pp
S2.4	Number of immunisation sessions	millions	n/a	n/a	6.4	17.2	n/a	n/a
S2.5	Stock availability at facility level	%	n/a	n/a	72%	n/a	n/a	n/a
S2.6	EPI management capacity	Average score	2.73	2.7	2.51	n/a	-0.22	m.i.
S2.7	Percentage of countries implementing tailored plans to overcome demand barriers	%	n/a	n/a	86%	n/a	n/a	n/a
S2.8	Percentage of countries addressing gender-related barriers with Gavi support	%	n/a	n/a	n/a	67%	n/a	n/a
S3.1	Co-financing commitment	%	100%	100%	100%	100%	0pp	0,00
S3.2	Preventing backsliding in routine immunisation coverage in Gavi-transitioned countries	Absolute number	n/a	n/a	8	8	n/a	n/a
S3.3	(If applicable) Vaccine introductions (HPV, PCV, Rota) catalysed in Gavi-	n/a	n/a	n/a	n/a	n/a	n/a	n/a

[109] Average 2018-2020

	transitioned and never-Gavi eligible countries							

Key

	Back to or increased in comparison to pre-COVID-19 levels
	Not yet recovered to pre-COVID-19 levels
m.i.	Measurement issues related to how S2.6 EPI management capacity is measured and reported (testing and piloting new approaches was initially paused but has resumed in 2023 (reporting for this indicator to begin 2024)
n/a	Not available (as a data point was missing) or not applicable (as the baseline is not 2019)
*	Cumulative values

Table 17: Indicator analysis (plausibility) based on data reported in Oct 2023 to the PPC

ID	Indicator name	Unit	2022	Back to 2019 in 2022	2025 target	Difference with on track in 2022 (linear)	Difference with on track in 2022 (non-linear)	Plausibility
M.1	**Under-five mortality rate**	deaths per 1,000 live births	n/a	n/a	53.28	n/a	n/a	Cannot predict (2022 value not yet available)
M.2	**Number of future deaths averted**	millions	2.4	n/a	7	-0.4	0.1	Likely
M.3	**Number of future DALYs averted**	millions	121	n/a	320	-7	6.7	Likely
M.4	**Reduction in number of ZD children**	millions	10.2	1,2	6.75	2.325	1.8	Unlikely
M.5	**Unique children immunized through RI**	millions	133	n/a	300	13	10	Highly Likely
M.6	**Economic benefits generated**	Billions USD	35.8	n/a	80	3.8	3,.8	Highly Likely
S1.1	Breadth of protection [BOP]	%	56%	8%	64%	0%	3%	Highly Likely
S1.2	Vaccine coverage [DTP3]	%	81%	-2%	87%	-4pp	-3pp	Unlikely
S1.2	Vaccine coverage [MCV2]	%	64%	6%	71%	0pp	-3pp	Highly Likely
S1.2	Vaccine coverage [PCV3]	%	70%	14%	79%	3pp	5pp	Highly Likely
S1.2	Vaccine coverage [HPV2]	%	10%	3%	24%	-5pp	3pp	Somewhat likely

ID	Indicator name	Unit	2022	Back to 2019 in 2022	2025 target	Difference with on track in 2022 (linear)	Difference with on track in 2022 (non-linear)	Plausibility
S1.3	Rate of scale up of newly introduced vaccines - PCV	%	98%	n/a	90%	8pp	Target to be achieved every year	Highly Likely
S1.3	Rate of scale up of newly introduced vaccines - RotaC	%	90%	n/a	90%	0pp	Target to be achieved every year	Highly Likely
S1.3	Rate of scale up of newly introduced vaccines - YF	%	88%	n/a	90%	-2pp	Target to be achieved every year	Likely
S1.3	Rate of scale up of newly introduced vaccines - MCV2	%	86%	n/a	90%	-4pp	Target to be achieved every year	Likely
S1.4	Number of vaccine introductions	Absolute number	29	n/a	82	-3.8	1	Likely
S1.5	Country prioritisation of vaccines	n/a	n/a	n/a	n/a	n/a	n/a	Cannot predict (Indicator has been in abeyance given the pause on rolling out the VIS 2018 vaccines during the COVID-19 pandemic)
S1.6	Preventive campaign reach (measles)	%	70%	n/a	50%	20pp	20pp	Somewhat Likely
S1.7	Timely outbreak detection and response	%	18%	n/a	42%	-14%	-14%	Unlikely
S2.1	Geographic equity (DTP3 coverage)	%	62%	-5%	74%	-9%	n/a	Unlikely
S2.2	DTP drop out	%	6.0	0,00	5.0	0.5	n/a	Likely
S2.3	MCV1 coverage	%	79%	-2%	85%	-4%	-3%	Unlikely
S2.4	Number of immunisation sessions	millions	17.2	n/a.	not specified	n/a	n/a	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 level	%	n/a	n/a	not specified	n/a	n/a	Cannot predict no target specified. Only value available is for 2021)

ID	Indicator name	Unit	2022	Back to 2019 in 2022	2025 target	Difference with on track in 2022 (linear)	Difference with on track in 2022 (non-linear)	Plausibility
S2.6	EPI management capacity	Average score	n/a	m.i.	not specified	n/a	n/a	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 2024)
S2.7	Percentage of countries implementing tailored plans to overcome demand barriers	%	n/a	n/a	not specified	n/a	n/a	Cannot predict (no target specified. Indicator has been significantly changed since 2021 so values are not comparable)
S2.8	Percentage of countries addressing gender- related barriers with Gavi support	%	67%	n/a	not specified	n/a	n/a	Cannot predict (no target specified. Indicator has been significantly changed since 2021 so values are not comparable)
S3.1	Co-financing commitment	%	100%	0,00	100%	0%	Target to be achieved every year	Highly Likely
S3.2	Preventing backsliding in routine immunisation coverage in Gavi-transitioned countries	Absolute number	8	n/a	no decline	0%	Target to be achieved every year	Likely
S3.3	Vaccine introductions catalysed in Gavi-transitioned and never-Gavi eligible countries	n/a	n/a	n/a	not specified	n/a	n/a	Likely

Key

	Back to or increased in comparison to pre-COVID-19 levels / on track compared to projection
	Not yet recovered to pre-COVID-19 levels / not on track compared to projection
m.i.	Measurement issues related to how S2.6 EPI management capacity is measured and reported (testing and piloting new approaches was initially paused but has resumed in 2023 (reporting for this indicator to begin 2024)
n/a	Not available (as a data point was missing) or not applicable (as the baseline is not 2019 or projections are not available)

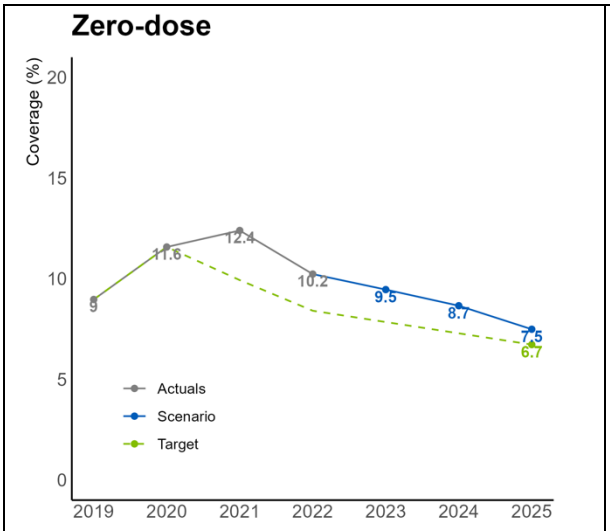


Figure 14: Ambitious ZD plausibility scenario (Gavi projections)

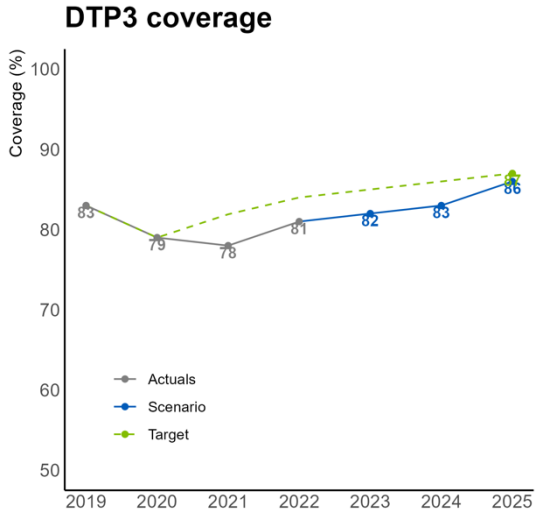


Figure 15: Ambitious DTP3 coverage scenario (Gavi projections)

Source: Gavi (MEL/MSI). 2023. 5.0 target plausibility scenarios. September

Annex 7: Use of Forcefield Analysis and Current Reality Tree

This Annex provides an overview of how we have used Forcefield Analysis (FFA) and Current Reality Trees (CRT) to support our work understanding drivers of observed results. This is to address EQ8 and EQ10.

Forcefield Analysis

Forcefield Analysis is a tool used in change management, developed by Lewin[110] to describe the status of an organisation in relation to a desired change and where efforts could be prioritised to move things further or faster. Lewin advised that rather than invest further efforts into driving forces (those working in favour of the desired change), it is more effective to focus on reducing constraining forces (those pushing against it) which is why we are using FFAs in our root cause analysis, to diagnose what is working against the changes required by 5.0/5.1 and those relevant for 6.0. An FFA diagram illustrates the driving forces and the constraining forces and their level of influence, from weak to strong. Rating the influence of each force allows us to calculate the sum of the driving and constraining forces.

An FFA diagram does not show the relationship between the forces or explain what the root causes of each force are, which is why we also use CRTs to get a more nuanced picture and help Gavi identify what is within and outside of its control to influence for the future.

Current Reality Trees

The purpose of a CRT is to help organisations identify the root causes ('core problems') of negative experiences ('undesired effects'). The process results in a directed graph that makes explicit the relationships between undesired effects and identifies core problems that account for most of the undesired effects. Alternatively, a CRT might identify that the root cause of the undesired effects is a conflict between two neutral factors e.g., focusing on what is known to work vs. trying new things.

Another way of understanding a CRT is to think of it as an analysis of an organisation's ToC. The CRT is read from bottom to top, instead of from left to right and illustrates where assumptions are not holding.

How we used Forcefield Analysis and Current Reality Trees in the MTE

We prioritised analysing six Gavi 5.0/5.1 indicators that are of particular interest for the evaluation, being off-track and areas in which Gavi is investing substantial resources; we informally checked our selection with the secretariat. For each of these, we produced a small number of FFAs and CRTs to gain insights into how the drivers and their influences differ between countries within the set of Gavi 57.

Table 18: Summary of FFAs and CRTs produced

Indicator	# FFA	Countries (CRT in bold)
DTP3 coverage (S1.2)	3	Ghana, **Kyrgyzstan, Madagascar**
HPVc coverage (S1.2)	2	Zambia, **Sri Lanka**
# vaccines introduced (S1.4)	2	Burkina Faso, **Angola**
Reduction in ZD (M4)	3	Ghana, **Burkina Faso, Indonesia**
Geographic equity (S2.1)	3	Kenya, Zambia **Philippines**
DTP1 drop out (S2.2)	2	Kenya, **Madagascar**

[110] https://www.ifm.eng.cam.ac.uk/research/dstools/force-field-analysis/

Countries for FFA were selected as being illustrative of above or below average achievement among the Gavi 57 for each indicator while ensuring that no country is used for more than two FFAs.

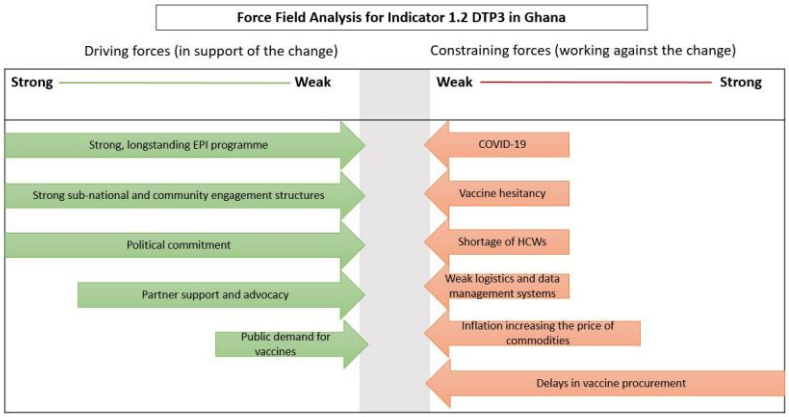
A basic CRT was also produced for each country with FFAs focused on understanding below average achievement for an indicator. This is because a CRT is used to analyse situations where the results are undesirable.

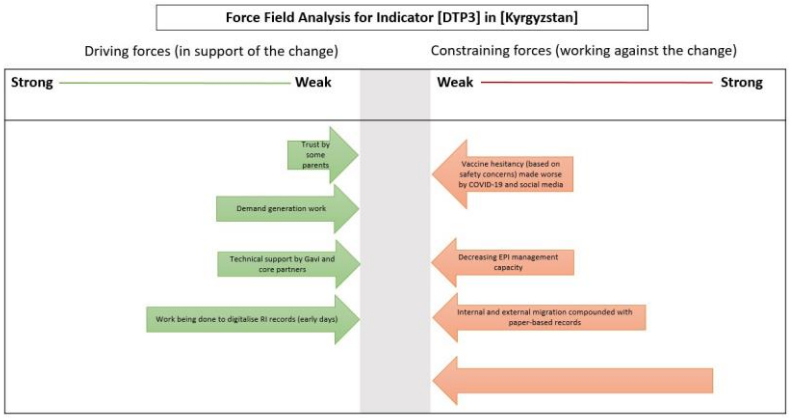
FFAs and CRTs drove selection of KII topics as per Table 18 above. Information gathered in interviews was used to develop detailed FFAs and ratings. These were then reviewed by the 'drivers' thematic study lead including to seek a degree of standardisation in the way ratings and language were applied in order to enable read-across countries. This reflected on the work done at the end of wave 1 data collection, which identified a long list of potential drivers – as noted in our update report (September 2023).

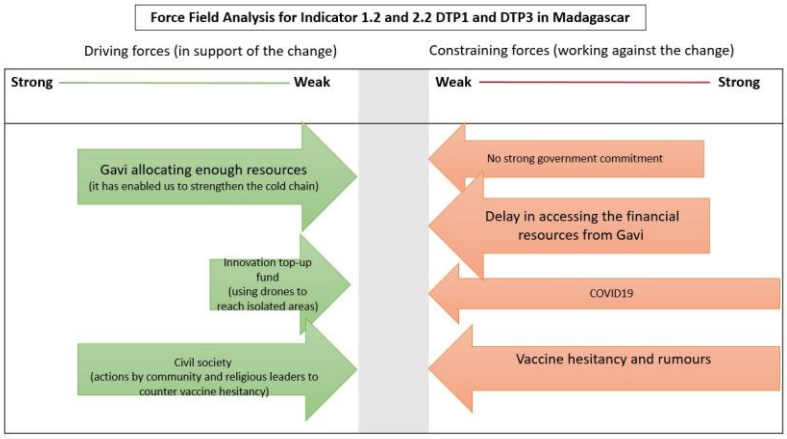
The 'drivers' thematic lead then analysed FFAs and CRTs to identify trends (repeat occurrence) across identified drivers.

All FFAs and CRTs are reproduced below.

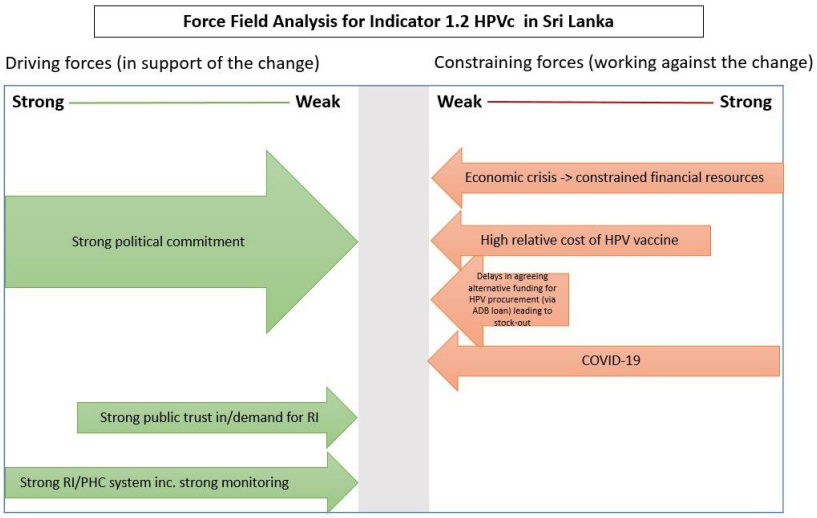
Indicator 1.2 DTP3

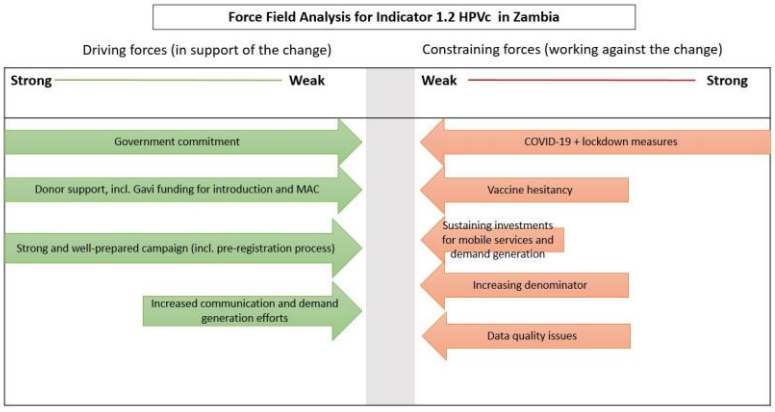




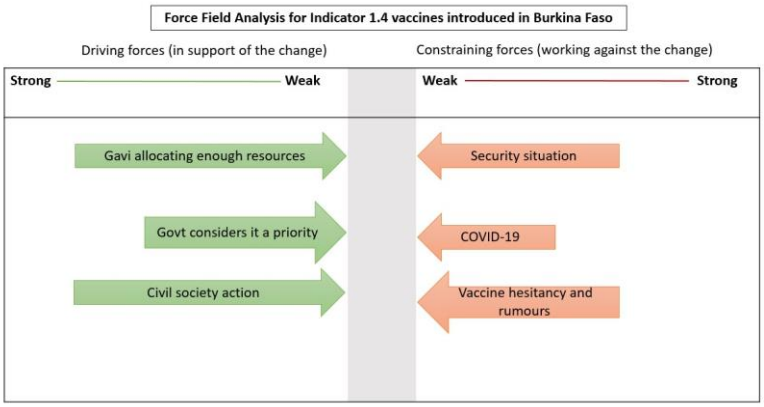


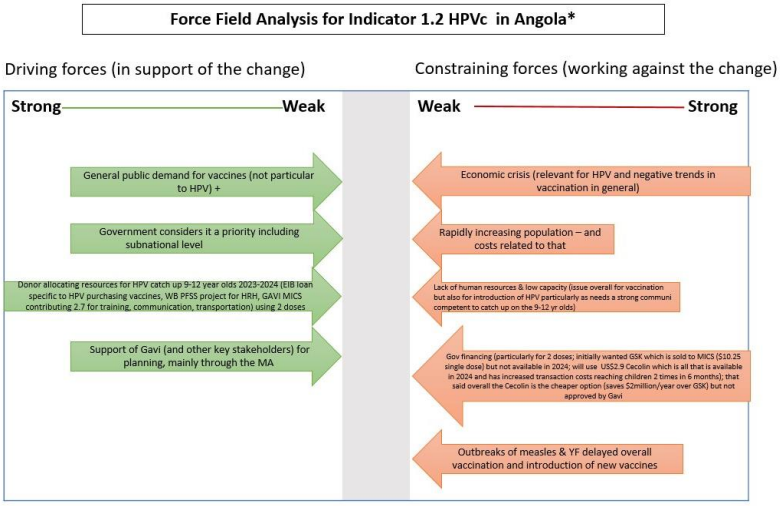
Indicator 1.2 HPVc



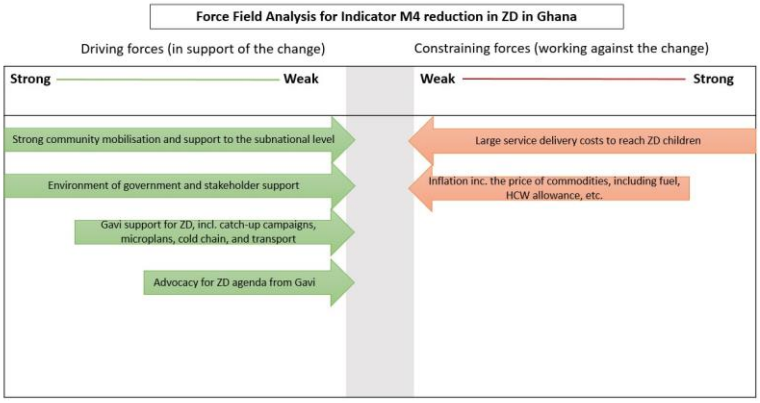


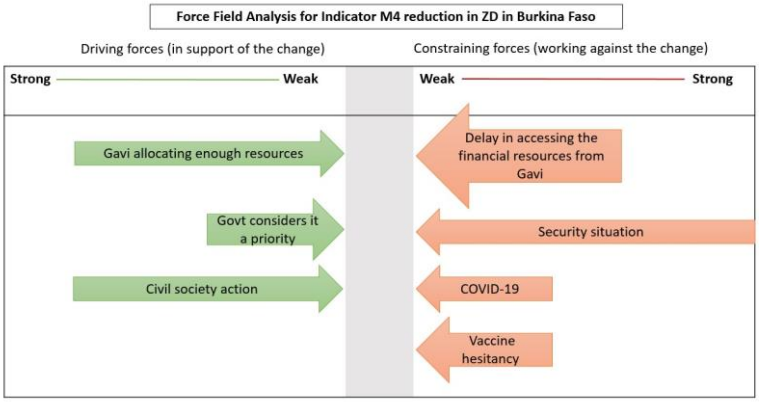
Indicator 1.4 Vaccines introduced

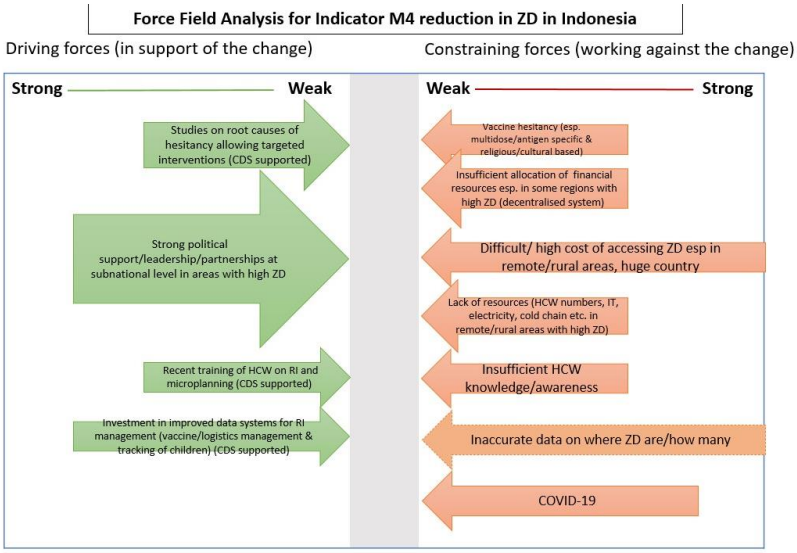




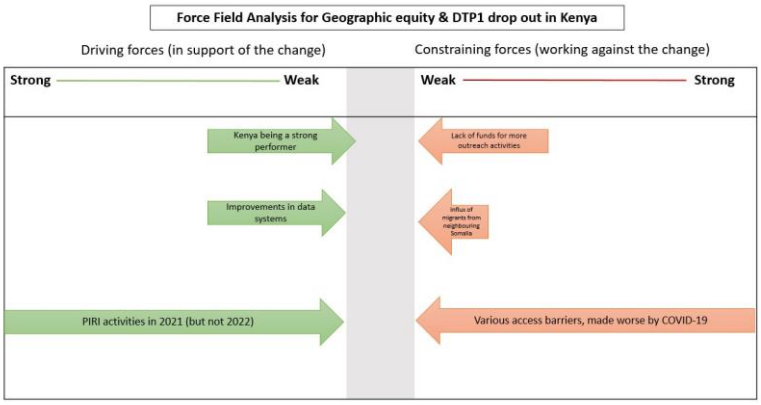
Indicator M4 Reduction in ZD

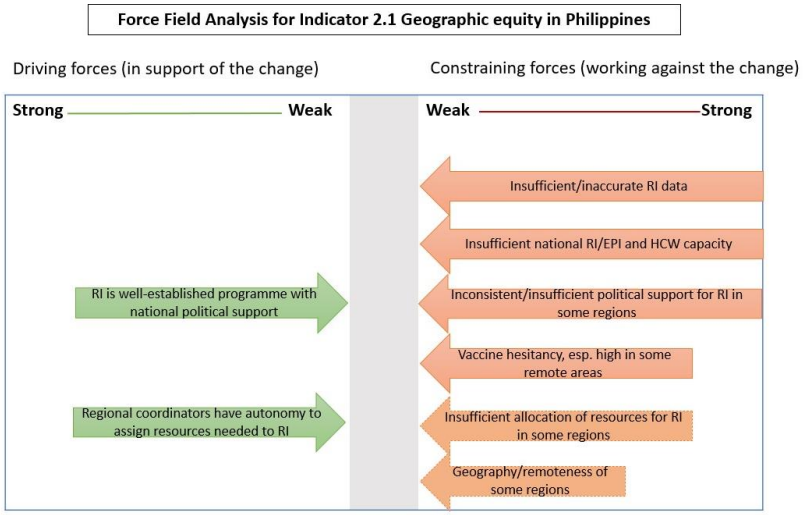


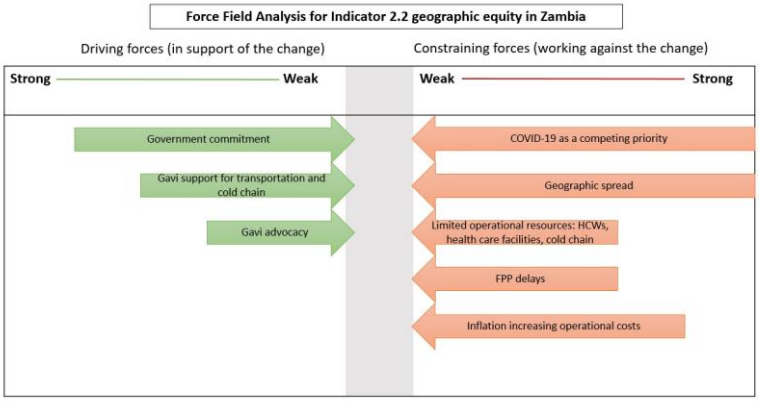




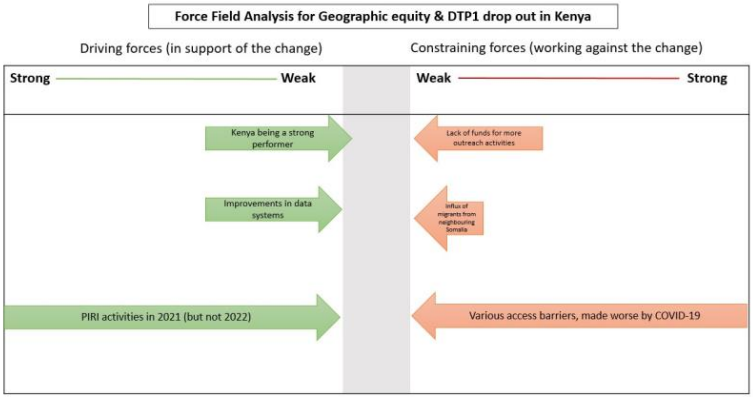
Indicator 2.1 Geographic equity

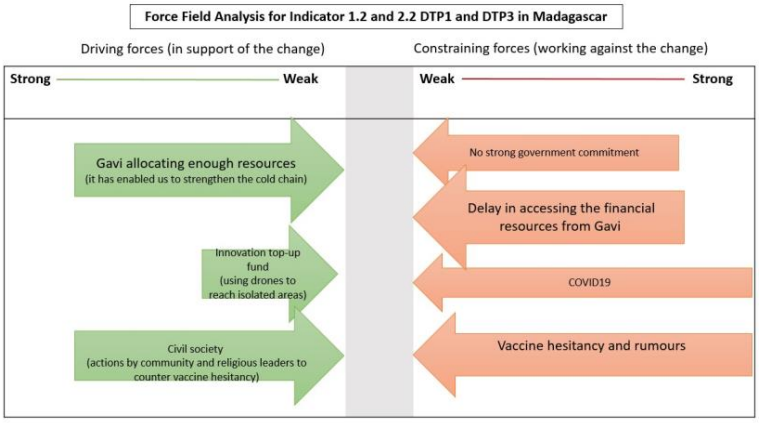






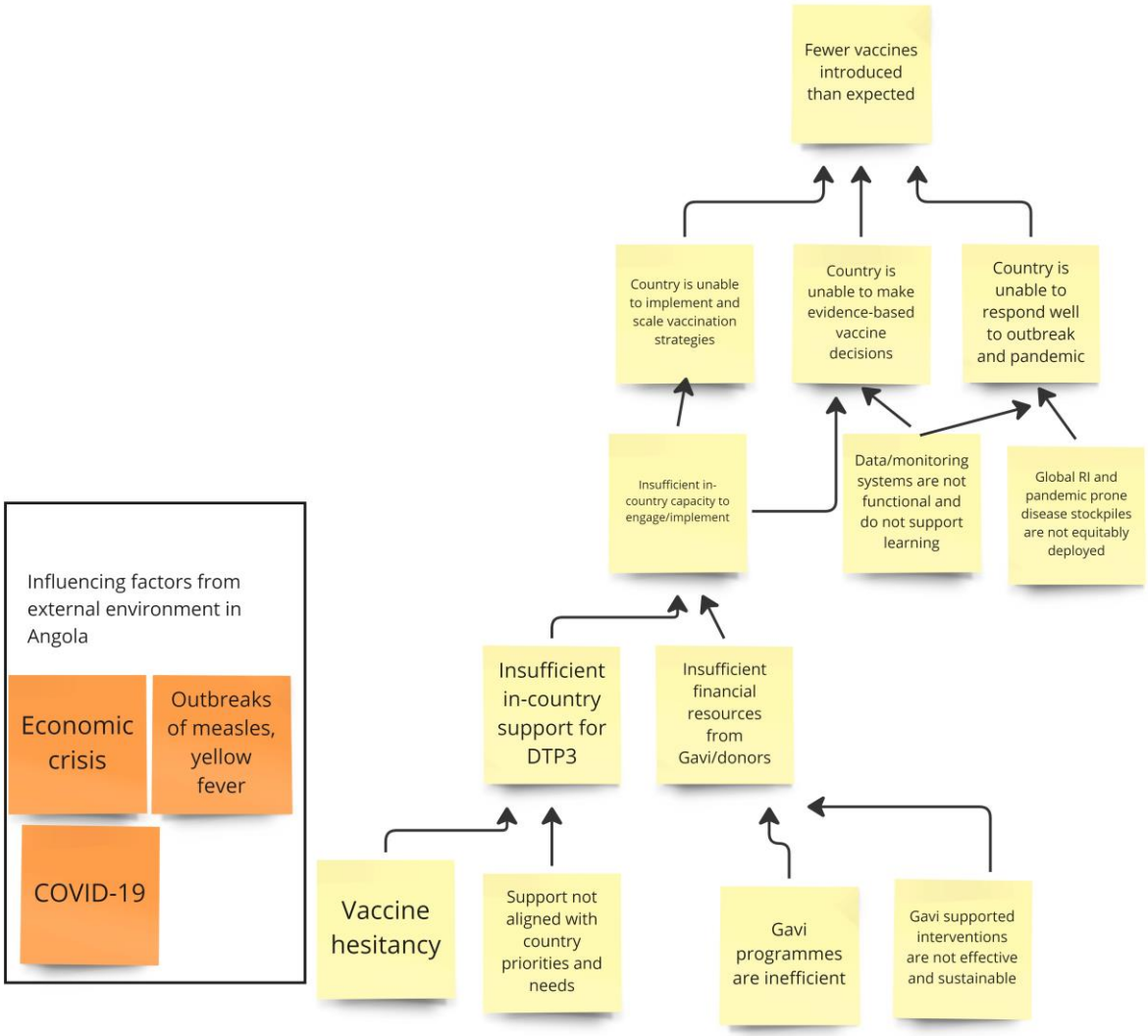
Indicator 2.2 DTP1 drop out



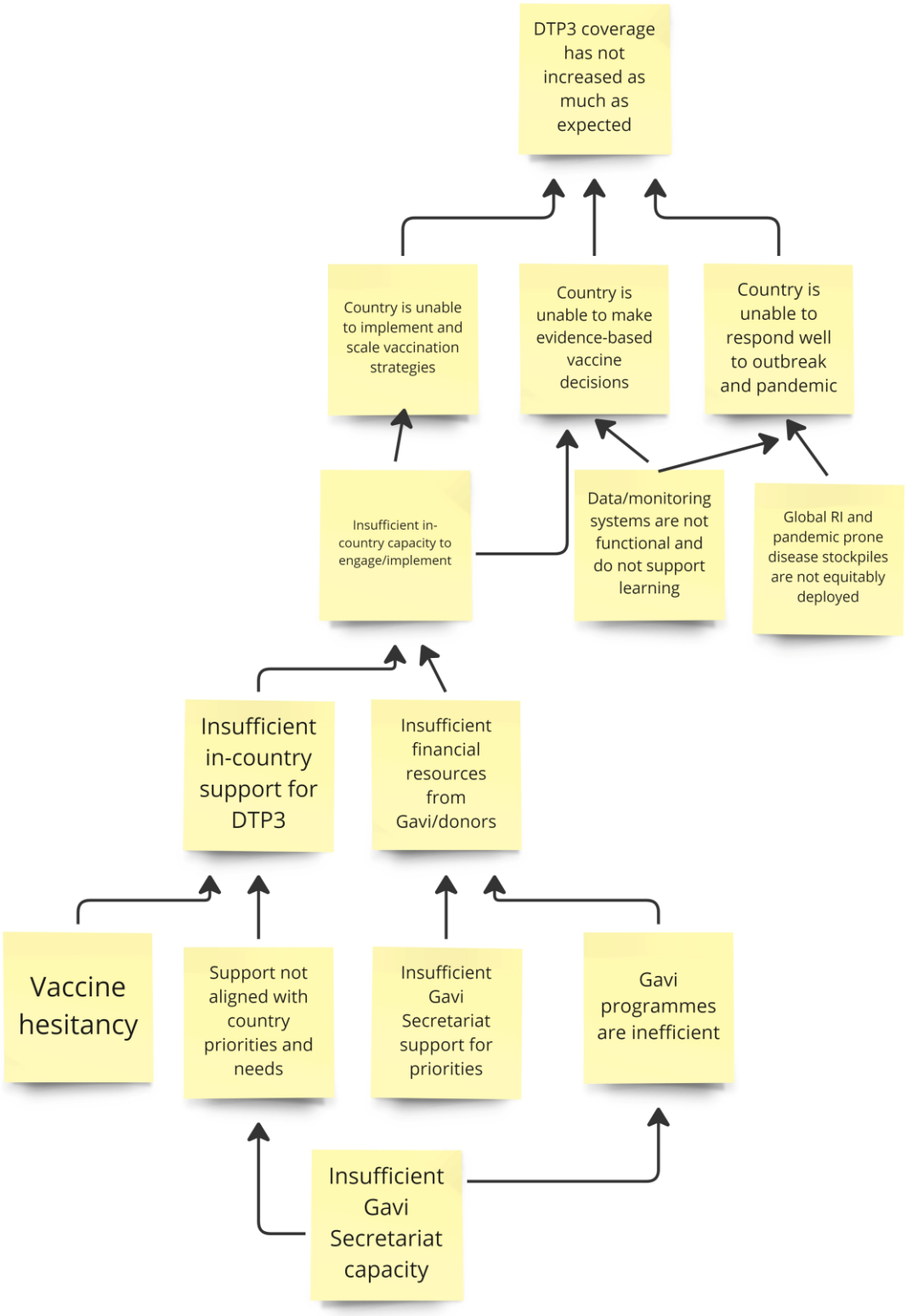


Current reality tree diagrams

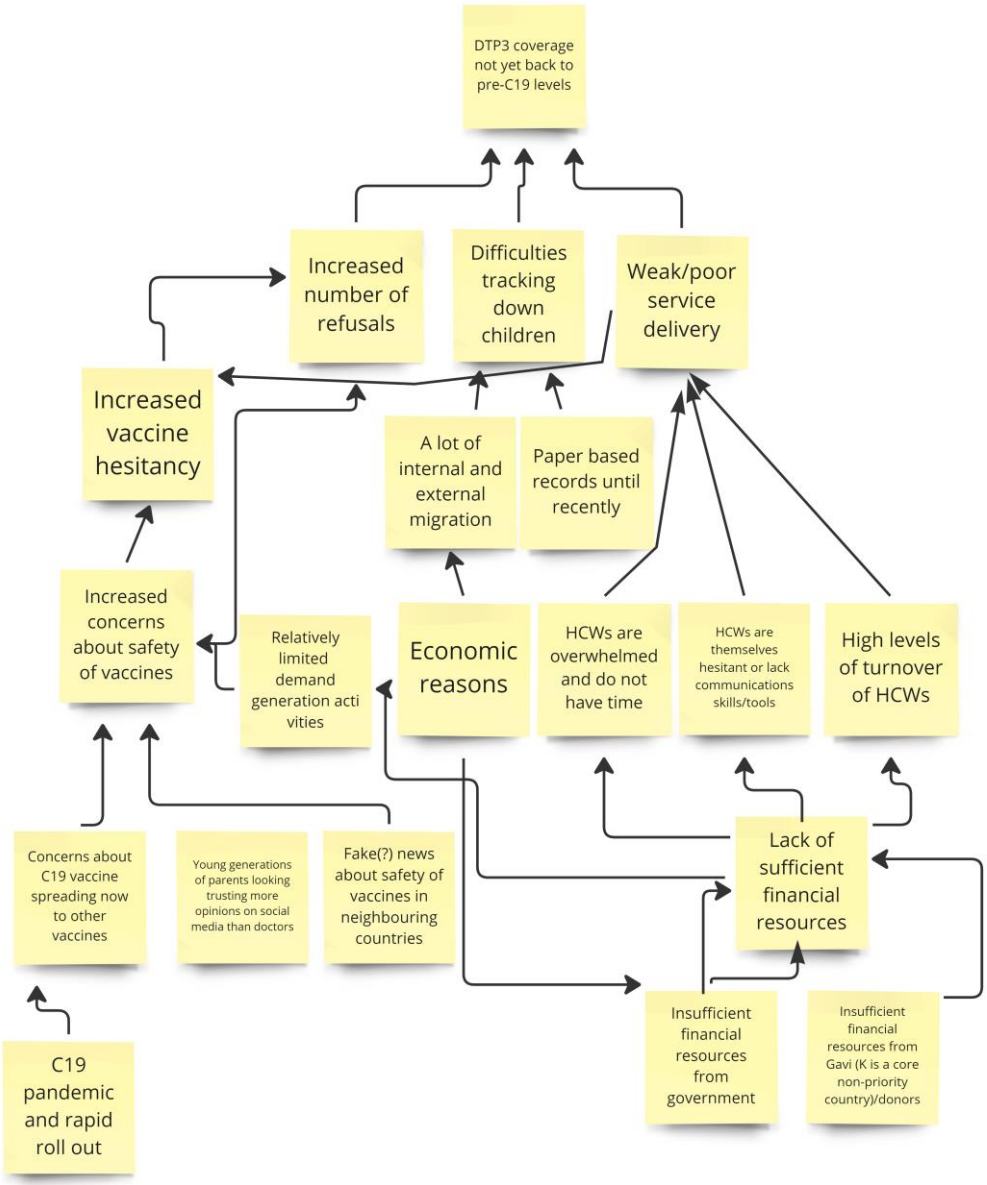
Angola, S1.4, # vaccines introduced



Kyrgyzstan, SG1.2, DTP3



Madagascar, S1.2, DTP3



Annex 8: Summary of questions for MTE arising from strategy operationalisation evaluation analysis and other key evaluations.

In our September 2023 interim report, we noted a range of questions that we were keen to explore through our second wave of data collection. We include here a summary overview against each question for the EAC's benefit.

Table 19: Emerging Questions from the COVAX, COVID-19 and the final strategy operationalisation evaluation reports[111]

Questions	Summary of findings
1. *What is/are root cause(s) of the proliferation of ToCs, funding levers and processes? Why is there a lengthy and complex application process and extensive guidelines that frequently change? Why are systems and ways of working seemingly difficult to communicate? Since coverage has plateaued over the past decade (i.e., starting prior to COVID-19), what has this apparent profusion of ToCs, funding levers and processes achieved*?	• EVOLVE highlights complex processes and stakeholder involvement in decision making, reflecting weak internal operational structures and capacity including a complex decision-making hierarchy with multiple layers of management reporting, IT system rigidities and an unclear relationship between risk appetite and processes, resulting in excessive checks and balances, and transaction costs. • KIIs note potential drivers, including resource mobilisation efforts (new products), donor accountabilities, need to drive programming (e.g. CSO earmark), lack of flexibilities, inadequate internal systems for management of resources.
2. *What are the drivers of these long-standing issues and why has it proved difficult to address them? What are the drivers of the reported low appetite for risk, the complex decision-making hierarchy and multiple layers of management reporting? Which of these drivers are internal (from management) or external (from stakeholders). What are possible solutions?*	• No systematic Board oversight of Gavi responses and actions in response to evaluations. • Insufficient oversight by Board on programme implementation • Heavy Secretariat transaction costs associated with governance structures. • Board interest in minimising fiduciary risk linking to risk averse culture. • Rapid increase in staff numbers with many off-book consultants resulting in HR and morale issues. • EVOLVE and operational excellence initiatives offer some potential solutions
3. The PHC agenda is reported to be a secondary priority at both the global and country levels, with evidence suggesting that management processes and incentives may not be facilitating partner synergies at the country level. *What are the reasons for this?*	Strong primary health care systems will be crucial to the achievement of the ZD agenda. In 2020, there was a strong push to align Gavi's planning processes and ToC with other global development partners on health systems strengthening, so that governments could plan holistically and ensure that Gavi support is complementary to overall Primary Health Care (PHC) efforts. However, these efforts were delayed by COVID-19 and Gavi is only now embarking on a health system strengthening strategy, which inter alia will need to address the long-standing issue of coordination with partners.
4. *What are the reasons for inconsistencies of implementation across the portfolio and the difficulties in tackling systemic challenges?*	Covered in module 1 under HLQ1. Inconsistencies linked to complex Gavi application and guidance, differences in Gavi support at country level (incl. SCMs, Alliance, CSOs),

[111] We do not yet have any data from the ZD evaluations but expect to be able to use the first round of ZD data and findings in our second wave of KIIs to start in September).

Questions	Summary of findings
	differentiation between segments. Plus, a range of exogenous and contextual factors such as COVID-19, health system strength, political commitment, availability of resources. Competing priorities mean that not all countries place same value on Gavi programmatic priorities (as per EQ1/EQ11).
5. *Why has there been less progress on gender-responsive and transformative interventions in Gavi grant designs across the portfolio?*	See Vol. I, Section 2.1.2. Similar issues highlighted to those under Q4 (previous row).
6. *Why was there so little opportunity for reprogramming several years into Gavi 5.0?*	This is a feature of the Gavi model. Grants are programmed for five years. Adjustments fall into two categories: reallocation and reprogramming. One is relatively easy to do as it is within the SCMs delegated authority, but must be less than 25% of the grant value or below a financial limit of $10 million. The other requires sign off by the IRC, MD or HLRP,[112] which is time consuming in terms of resources required to apply and time taken to get a decision.

EQ	What we still need to understand (August 2023)	Update (December 2023)
EQ1 – design of implementation mechanisms	• How/to what extent innovation "bubble" has been integrated into design of relevant funding mechanisms (via Innovation mini thematic study). • How/to what extent resource mobilisation "bubble" has been considered in design of Gavi support (via resource mobilisation/sustainability thematic study).	See thematic studies on resource mobilisation (Annex 11) and on innovation (Annex 12).
EQ2 – Alliance partner alignment & experiences	• KIIs with Alliance partners (core partners at all levels and expanded/CSO partners at regional and global level) to strengthen evidence on how they are experiencing and supporting implementation of Gavi funding levers, including their experience of the ToC "bubbles" and probing on relevant key drivers identified in this report.	125 KIIs conducted in wave 2, including with Alliance and extended partners. Insights incorporated into the report.
EQ3 - country experiences	• KIIs with in-country stakeholders (government and country level expanded/CSOs partners) to strengthen evidence on how they are experiencing and supporting implementation of Gavi funding levers, including their experience of the ToC "bubbles", and probing on relevant key drivers identified in this report.	125 KIIs conducted in wave 2, including with country stakeholders. Insights incorporated into the report.
EQ4 and EQ5 - progress against ToC interventions and outputs	• Retrieval and quantitative analysis of updated/additional PEF milestone data (if made accessible) and any other milestone data available. • Retrieval and analysis of updated CPMPM data at output level (Strategy Implementation Indicators and other relevant operational indicators). • KIIs and document review under MICs thematic study to understand progress against SG3 MICs related ToC interventions, outputs, and outcomes.	See Vol. I, section 2.1, and Annex 5. Milestone and CPMPM data received 18 Oct. MICs thematic study completed. See Box 4 and Annex 10.

[112] Gavi Operational Guideline: 3.14 Reprogramming, Reallocating and No-cost Extensions of HSS grants (2017)

	• KIIs and document review under resource mobilisation/sustainability thematic study to understand progress against SG3 related ToC interventions, outputs and outcomes. • Resources: Gavi contribution compared to overall budget.	RM thematic study completed. See Box 7 and Annex 11. Disbursement data received on 28 Nov.
EQ6 – COVID-19	• Any available updates on M&R&S uptake • How and to what extent COVID-19 Vaccine Delivery Support (CDS) was expected to protect and support recovery on RI, and effective doing so. • Better understanding of disbursement issues and actions to address these issues. • Understand links between risk and progress on COVID-19, and actions to address these.	Country case studies highlighted contribution of CDS to HSS. EVOLVE report provides insights. Some insights on drivers of risk appetite from KIIs.
EQ7 – recalibration	• Update co-financing performance. • Confirm which mechanisms were key for taking forward recalibrated priorities. • RI performance in MICs. • Reflections from Gavi Secretariat on pros/cons of recalibration. • Was implementation of other key shifts for 5.0 affected?	Oct 23 PCC docs and CPMPM data received. Recalibration mainly a signalling exercise. See MICs thematic study (Annex 10) and section under HLQ2/ Annex 6 on results. See Vol. I, section 2.1.7 for effects of pausing.
EQ5 and EQ8 – ToC failure/ barriers to ops	• KIIs with Alliance partners (country, regional and global), Secretariat, country teams, in-country stakeholders to fill gaps in data on key assumption around effectiveness of Gavi interventions and strengthen data on other ToC assumptions. • Fill gaps in structure of report for each of the key drivers. • Undertake systematic root cause analysis for selected drivers.	Country case studies generated FFAs and CRTs for selected indicators (Vol. I, section 2.2.3). Analysis of these has fed into findings under EQ8 and EQ10.
EQ9-11	• Further analysis needed (from ZD evaluation) on ZD integration into country applications. • Analysis of additional indicator reporting ahead of the next PPC meeting when available. • Analysis of updates of and historical CPMPM data to look at trends since 2021 when/if available. • Further analysis of Independent Review Committee (IRC)/ High Level Review Panel (HLRP) reports (incl. those received after the last data collection cut-off point). • Access qualitative analysis on the extent to which priorities are reflected in HSS by the Health system and immunisation strengthening (HSIS) team once completed. • If resources allow, internal analysis of a subset of FPP documents (Plausibility TS sample: Ethiopia, Mali, Burkina Faso, Kenya, Madagascar, Zambia, Ghana and Kyrgyzstan). • Explore with countries, which were the main enablers and barriers that explain current performance and Gavi's contribution to those drivers.	Review of FPP docs, PEF milestone data, ZD report has generated insights on integration of programmatic priorities. Latest analysis and underlying data on indicator reporting received from Gavi. Analysed separately by MTE. CPMPM data received 18 October. Analysed by MTE team. Additional document review completed, incl. IRC and HLRP reports. Analysis received and incorporated under EQ11 write up. Analysis of FPP docs completed by MTE team. Reflected in EQ11 write up.

	• Explore further the link between vaccine hesitancy and plausibility. • More work to be done internally on mapping evidence against ToC and assumptions based on wave 1 and 2 data collection. • Data on which countries are using donor fundings to fulfil co-financing commitments and whether that number/proportion has increased since 2019 from the Immunisation Financing & Sustainability (IFS) team. • Data on what proportion of total co-financing has been covered by waivers in 2021. • Incorporate information from TSs focused on plausibility, MICs and innovation. • Integrate findings from next ZD report if this is received in time.	Key focus of country-level KIIs in 12 focus countries. Mapping evidence against ToC completed – see Vol. I, section 2.1. Thematic studies completed and incorporated in analysis. Separate write ups of four key studies included in Annexes 9 - 12. Draft ZD report received (informally) 9 November and incorporated in MTE analysis.
EQ12-14	Confirm results from phase 1 with further data review, country and global KIIs, specifically: 1. With regard to COVID-19 impact on plausibility of achieving SG4 objectives, phase 2 will require further interviews, especially with UNICEF, in order to understand seemingly divergent data on COVID-19 supply side impact. 2. Further KIIs with MST as well as M&E teams are required, to better understand the i) process for choosing performance indicators and ii) corporate requirements for workplan level M&E. 3. Under "Future Supplier Base", phase 2 will focus on the content and utility of the antigen roadmaps (as outlined in the SG4 thematic study plan). 4. Re: "partnership optimisation" and "regulatory environment" pillars, we will in phase 2 circle back to MST to get further information on these two workstreams and to ask for their help in securing interviews with UNICEF and WHO. 5. Will continue to refine and triangulate data on the "demand health" pillar work being done under 5.0. 6. Further triangulation is needed to understand Gavi's role in the innovation space (in the vaccine development to access continuum). 7. As Gavi's regional manufacturing strategy plans become more detailed during 2023, we will be in a better position to discuss probable impact.	1. Five interviews conducted with UNICEF during Phase 2. This, combined with industry interviews, informed findings. 2. During Phase 2, further information on M&E process was requested. No further information was provided. Therefore, finding SoE was rated as medium and findings are based on interviews with Square partners and evaluators review of previous evaluation recommendations, market shaping strategy plans, and TPMs provided during Phase 1. 3. KIIs with WHO and UNICEF largely relied on. Only one full antigen map was provided, due to restricted/ confidential nature. 4. We were able to independently secure 5 UNICEF interviews and 7 WHO interviews. We also had interviewed relevant persons from MST. 5. Done with 33 additional interview hours during Phase 2. 6. Done with 33 additional interview hours during Phase 2. 7. Review of more developed proposal submitted by MST in Oct 2023.
EQ15	• Review of experience from other organisations or in published literature against selected drivers as identified in Section 4. An outstanding question is the Alliance's capacity to respond to the next pandemic. • If resources permit, comparisons across all shortlisted drivers. For example, on governance,	See Vol. I, section 2.3.1.

	we will look to undertake a more detailed, systematic comparison of key elements of Gavi governance with other comparable organisations during phase 2. Illustrative examples might include IAVI, the Global Fund, GFF and the World Bank.	

Annex 9: Thematic study – SG4

Introduction

Euro Health Group (EHG) has been commissioned by Gavi to undertake a Mid-Term Evaluation (MTE) of Gavi 5.0. The objectives of the MTE are 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 prioritized 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).

During the MTE inception phase, we assessed the evaluability of our key evaluation questions (EQs), listed in Annex 1. We identified the need to strengthen our evidence base in specific areas including SG4, given the fact that there have not been other recent evaluations on this topic, upon which we can draw and more specifically EQs 12-14. Data collection against the scope set out here took place from March to November 2023.

As indicated in our Inception Report, the primary purpose of this case study is to strengthen Theory of Change (ToC) focus and the evaluability of some MTE EQs, in particular EQs 12-14.

Scope

This case study provides findings that address the following agreed study areas of inquiries:

- status of implementation of the 5.0/5.1 SG4 interventions, enablers and constraints to implementation;
- status of the achievement of the prioritised SG4 and related objectives, enablers and constraints to achievement;
- description of the mechanisms/ levers/ tools at Gavi's disposal to deliver on SG4, including Secretariat effort from various teams;
- manufacturer prioritisation decisions as they relate to the 14 "Supply and Procurement" roadmaps (Gavi's long-term market ambition for each vaccine or immunisation product);
- deeper dive into 2 or 3 roadmaps focused on those technologies where the pandemic brought about tensions around manufacturer prioritisation and/or handling of raw material supply chains;
- unpack assumptions behind roadmaps and how the pandemic might have affected those assumptions;
- degree to which the recommendations from the evaluation of Gavi's previous Supply and Procurement Strategy 2016-2020 have factored into changes in Gavi;
- emerging changes in the external environment (e.g. rise in vaccines developed/produced by/ in China, growing political momentum to build capacity for African vaccine manufacturing and procurement, and evolving implications of these changes on manufacturer prioritisation and raw material supply chains); and
- how do other comparable organisations incentivise healthy markets and innovation and how was their market shaping progress affected by the pandemic?

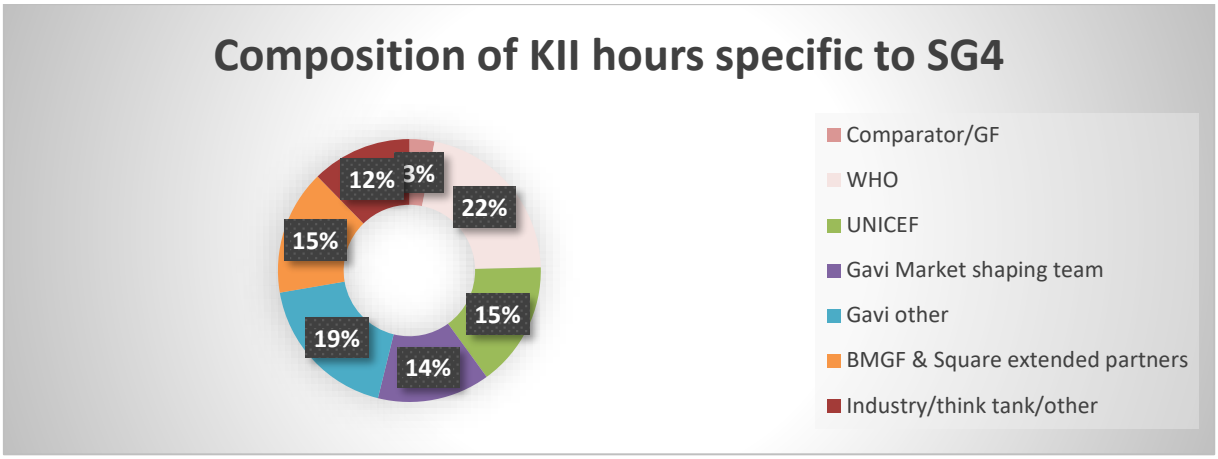
Methods and limitations

The evaluation team relied primarily on publicly available data and key informant interviews as data sources. In comparison with other interview groups, we had rather limited opportunities for interaction with the Gavi market shaping team, and limited access to confidential data and to internal team documentation of operational activity taking place during the 5.0/5.1 period. These

factors reduce evaluability and therefore most of the SG4 findings have been rated as moderate on the strength of evidence rating.

The SG4 specific evaluation was conducted between March and November 2023 and is primarily based on publicly available documents and key informant interviews with market shaping stakeholders (See Figure 16 for composition). Limited internal documentation was available to explain what activity had taken place relative to market shaping strategy operational plans;[113] answering the questions on contribution was therefore heavily reliant on KIIs. The Secretariat market shaping team had limited availability for consultation, therefore we supplemented information based on interviews with other Gavi teams, Alliance partners, and market shaping stakeholders. Given these limitations, most of the strength of evidence ratings are graded as moderate.

Figure 16: Composition of Key informant interviews for SG4



Findings

The findings for this thematic study have been organised into three sections:

i. Right design: This section describes the relevance of what Gavi set out to do as outlined in its Market Shaping Strategy 2021-2025, considering whether the design was strategically focused on potentially high impact activities aligned with market shaping needs, and taking into account the recommendations coming from the November 2020 evaluation of the Supply and Procurement Strategy.

ii. Right results: This section considers the plausibility that the SG target will be met. It maps to the MTE evaluation question 13: *"What progress has been made against SG 4 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?"*

iii. Right way: This section describes the market shaping implementation activity during Gavi 5.0, including observations on the enablers and constraints to activity progress. This section maps to the MTE evaluation question 13: *"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".*

[113] The Vaccines & Sustainability Team Priority Matrix in Excel, a summary of progress against milestones for the three SG4 indicators, the aggregated partner scores for 2022 supporting the market health SG 4.1 indicator, and the methodology explanation for how SG4.1 is evaluated by partners. Full antigen roadmaps are confidential. One was provided to evaluation team after the official cut-off date of data collection.

Evaluation question 14 *"Is SG4 as originally articulated still relevant for the second half of the 5.0/5.1 Strategy period?"* is answered by bringing together the findings under all sections to arrive at concluding observations and recommendations.

1. Right Design

2 **Finding 1.1: Gavi's Market Shaping Strategy (MSS) 2021-2025 design is comprehensive, setting 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 evaluation of the previous market shaping strategy 2016-2020,[114] except for plans to support market health in transitioning and never-eligible/ MICs countries and to develop a detailed M&E framework to be used internally to monitor progress.**

The **demand health** pillar was given increased priority under the new MSS, given i) the increasing complexity of country decisions related to programme or product choice (23 product presentations on the Gavi menu in 2015, expected to increase almost threefold by 2025) and the consequent impact of this complexity on market dynamics, and ii) Gavi's increasing engagement in markets with unpredictable and/or volatile demand characterised by peaks and troughs linked to campaigns and reactive use, markets with uncertainties on vaccination strategies, schedules, or uptake. The expected outputs from this pillar included that Gavi's market strategy (Roadmap) development process would define market-specific demand health outcomes – considering demand materialisation, demand predictability, the balance of demand of appropriate products, and timing of uptake of new innovative products.[115]

The **future supplier base** pillar recognised a need to consider and monitor supplier health/ sustainability, cross-cutting challenges, and opportunities across the current and future supplier base more deeply. It was recognised that vaccine markets increasingly require cross-cutting and manufacturer-centric views in addition to the individual vaccine market views, around which Alliance partners had traditionally been organised.[116] This work was expected to lead to setting target outcomes for the overall supplier base and to tailored manufacturer strategies, strengthening the specific vaccine market shaping strategies (antigen roadmaps) by ensuring that cross-market interdependencies would be more comprehensively considered and addressed. The main difference between the Gavi 4.0 and 5.0 future supplier base approach was thus supplementing the in-depth vertical vaccine markets work of Gavi 4.0 with a cross-cutting market (geographic and vaccine market) and supplier portfolio view to have a more nuanced approach to the diversity of supplier profiles.

The **innovation** pillar held the key assumption that vaccine product innovations as prioritised by Gavi's Vaccine Innovation Prioritisation Strategy (VIPS) were critical to supporting Gavi 5.0's vision to "leave no-one behind with immunisation", by overcoming stubborn immunisation barriers. Some of the work envisaged included to: develop integrated, end-to-end strategies for the VIPS priorities

[114] Evaluation of the Gavi Supply and Procurement Strategy 2016-2020, 25 November 2020. See: https://www.gavi.org/programmes-impact/our-impact/evaluation-studies/gavi-supply-procurement-strategy-2016-20

[115] The addition of the demand health pillar (as well as the addition of demand health to the antigen roadmaps and demand health focused changes to tools and processes) maps to the 2020 evaluation's recommendation to "build up the Strategy to be truly a "market" strategy, reflecting both demand and supply aspects".

[116] This reorientation addressed several of the recommendations from the 2020 evaluation of the previous market shaping strategy, to: "Evolve from a vaccine by vaccine approach to consider the manufacturing portfolio as a whole and how this may impact individual vaccine markets" and "integrate approaches within the Strategy that more closely consider the wider ecosystem within which Gavi's market shaping strategy work functions."

across immunisation partners through the development/update of the roadmaps; generate evidence to assess the programmatic and public health impacts of priority innovations across potential use cases through in-country implementation research, modelling studies and/or demonstration pilots; support Full Vaccine Value Assessments to assess the full value that a vaccine-product innovation offers in terms of broader public-health and socioeconomic gains; support testing of Preferred Policy Profiles by the WHO (non-binding guidance, aiming to specify the anticipated recommendation for use to inform late-stage product development programmes regarding expected evidence) and explore new and integrated policy, procurement/financing and introduction mechanisms to de-risk investment and bridge between the value of an innovation and willingness to pay.[117]

The strategic enabler **optimising market shaping partnership**[118] was to be designed around the core market shaping partners' synergistic organisational mandates, capabilities, and capacities and reinforced by the integration of other market shaping actors within the Alliance. The "Square" group was formalised as the Alliance's market shaping leadership structure and roles and responsibilities were to be defined as a function of the partnership model and the Square group's terms of reference. The outputs of this enabler were expected to be harmonised information sharing, market analysis and market reporting. Specifically, the MSS spoke about the need to i) harmonize market reporting across core partner publications by building a common reporting framework and reference guide of market reports produced by UNICEF, GAVI, and WHO and to ii) explore creating common information sharing platform(s) between partners, particularly market intelligence information across partners and standardizing data sets from market analyses between partners (Gavi Roadmaps, UNICEF market analyses, BMGF market analyses, WHO market analyses, market information data, assumptions).

The strategic enabler **improving regulatory efficiencies**[119] that contribute to enabling vaccine access, recognised that Gavi 4.0 supported activities to improve the regulatory landscape were ad-hoc, and proposed that the new market shaping strategy would redefine its approach to more deliberately support targeted initiatives in the regulatory landscape, which have the most direct impact on all aspects of SG4 (i.e. supply, costs and innovation) in the mid to long-term, ensuring complementarity to existing and planned partners' support. Continued support to the WHO Prequalification Team was foreseen as well as help to manufacturers to navigate the process and Gavi would also support efforts to raise awareness of existing and future mechanisms and guidelines aimed at optimising regulatory systems and their relevance for vaccine access as well as supporting their implementation. The market shaping strategy proposed that Gavi could also explore the possibility to support efforts to strengthen national regulatory systems, in particular if they focus on vaccine-producing countries accounting for an important part of the Gavi-supported vaccines supply with national regulatory authorities of maturity level 3. For new delivery technologies such as those prioritised by VIPS, there were plans to engage global regulators, WHO PQ as well as regional and local regulators early on regulatory pathways and data requirements to ensure alignment and avoid unnecessary delays between the end of phase 3 and a market authorisation.

[117] This pillar of work maps to the 2020 evaluation recommendation to "adopt a more consolidated, joined-up and long-term approach to innovations in the next strategy".
[118] This enabling work maps to the 2020 evaluation's recommendation to: "build on current successes in partnerships with key stakeholders, while expanding coordination with other market shaping stakeholders where relevant".
[119] This enabling work maps to the 2020 evaluation's recommendation to: "move away from approaching vaccines as a vertical intervention, with better coordination with other global partners on key cross-cutting issues particularly with regards to the challenges posed by country regulatory requirements".

Under the strategic enabler **implement updated strategic tools and processes,** there were plans to update the M&E framework structure and definitions, to ensure adequate progress measurement.[120] The Healthy Markets Framework was to be updated as well, to align with the new market shaping strategy focus areas and bring greater emphasis to long-term market views.[121] Specifically, the roadmap update was to focus on increasing efficiencies, and better aligning to partner needs through both process and content solutions. The intensity of roadmap creation had "often led to tender misalignments in timelines and unmatched target objectives to procurement agendas" and thus an effort was to be made to "significantly streamline the roadmap creation process in drafting, editing, and capturing partner feedback". It was also recognised that Gavi's roadmaps initially filled a critical gap in the market by providing a consolidated analysis for each vaccine. However, an increase in partner publications providing similar analysis (i.e., UNICEF's market notes, WHO's MI4A market studies)[122] were offering a wide lens perspective on market dynamics. To reduce redundancies and streamline efforts, the Gavi roadmaps would aim to better synchronize and rely on market analysis with partners.[123] Other areas for work envisaged under this enabler included a demand health toolkit (tools, information provision and targeted technical support), development and deployment of financial tools to meet market needs, and product portfolio management.

2 **Finding 1.2: Areas of weakness in the design of the market shaping strategy, and where the 2020 evaluation's recommendations were not adequately actioned, include 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.**

1. In relation to the recommendation to "Consider additional processes and metrics to improve the monitoring and evaluation of the activities and results of the Strategy", the MSS proposal in this area does not fully align with the recommendation. The MSS contains a ToC (as recommended), however the ToC is not linked to "a series of more detailed indicators that pick up the scope of the strategy, (including centrally/systematically tracking interventions set out in the roadmaps) and then ultimately linking with a smaller set of strategic indicators for Gavi's overall market shaping goal (SG4). That is, we specifically recommend that the market shaping team include a detailed M&E framework to be used internally to monitor progress, recognising that the SG4 indicators are high-level and do not cover the full scope of the Strategy." Instead, the MSS only provides what are referred to as "driver-level indicators" (Table 20) as means to monitor operational performance. These indicators are high level (percentage of planned Alliance activities on track), and do not link to the ToC nor to the antigen roadmaps; they were also not shared with the evaluation team, with the rationale that the denominator of activity plan is constantly changing.

[120] This maps to the 2020 evaluation recommendation to "Consider additional processes and metrics to improve the monitoring and evaluation of the activities and results of the Strategy" (NB: However, the MSS plans in this area do not fully align with the recommendation – see below).

[121] This maps to the 2020 evaluation recommendation to "incorporate key updates to the next iteration of the HMF" as well as "long term considerations should be a guiding principle across all aspects of the Strategy, including planning for vaccine and non-vaccine markets and the operationalisation of the VIPS initiative".

[122] Market Information for Access Initiative (MIforA) collects data from countries through their joint reporting form of UNICEF and WHO on an annual basis. Data collected include volume procured, prices paid per dose, contract length and whether they pay VAT on the product, amongst other data.

[123] This maps to the 2020 evaluation recommendation to "incorporate suggestions for improvements in the development of roadmaps".

Table 20: Driver level indicators linking to the SG4 objectives

SG4 Objectives		Objective level indicators	Driver level indicators
4.1	Ensure sustainable healthy market dynamics for vaccines and immunization-related products at affordable prices	Number of markets exhibiting acceptable market dynamics	Sustainably competitive future supplier base: Number of markets with supply interruptions and insufficient supply that cannot meet demand
			Sustainably competitive future supplier base: % of planned Alliance activities on track to ensure business sustainability of suppliers/ competitive market dynamics
			Healthy demand: % of planned Alliance activities on track to address unbalanced demand for appropriate products
4.2	Incentivise innovation for the development of suitable vaccines	Number of innovative products within the pipeline of commercial-scale manufacturers	Enabling environment for transformational innovations: % of Alliance activities on track to support innovations
			Enabling environment for transformational innovations: % of Alliance activities on track to develop new approaches and tools to demonstrate the full value of an innovation from the perspectives of countries and funders
4.3	Scale up innovative immunisation-related products	Number of vaccine and immunisation-related products with improved characteristics procured	Enabling environment for transformational innovations: Number of products with improved characteristics added to the Gavi-menu
			Healthy demand: Time from prequalification to first country adoption

2. Addressing risks of vaccine procurement failure in **countries nearing transition** has been on Gavi's radar since at least 2018. The "Country-owned decisions in vaccine procurement roadmap" paper[124] describes procurement risk and vaccine access challenges experienced by countries on the transition pathway, what was being done (in 2018) to address those challenges, and what were the remaining gaps. The document ends with "An Alliance working group prioritised those gaps and defined target outcomes and associated interventions to address them." It is not clear how the working group's recommendations were followed up and what is being done now to address the risk of vaccine procurement failure, and to systematise differential pricing access for countries nearing transition. In relation to **transition countries,** the MSS notes that significant transitions would start from 2026, and therefore that during 2021-2026, countries would need support to prepare for transition. There is nothing in the MSS that speaks to actions to address this, apart from one mention of "strengthening local capabilities to use market resources for self-sustainability, helping to support supply and procurement performance after transition" however no actions were identified underneath any of the pillars in support of this. Therefore, although the management response to the 2020 evaluation (under Finding/Recommendation number 8) states that there would be "capacity building for transitioning countries" it seems that the following recommendations from the 2020 evaluation were not adequately actioned:

- Consider relevant approaches for price stability for transitioning countries alongside wider coordination with MICs, to better reflect country contexts within the market shaping function. At a minimum this would entail ensuring better/regular communication around market shaping developments with countries, ensuring greater predictability and consistency (rather than ad hoc) approaches across transitioning MICs.

[124] https://www.gavi.org/sites/default/files/document/country-owned-decisions-roadmap---public-summarypdf.pdf dated March 2018

- Work with wider Secretariat teams and partners to more effectively engage with and build country understanding of and ability to input into the Alliance's market shaping work, especially for transition countries.

Furthermore, the 2020 evaluation recommendations related to **never-eligible and MIC countries** were not adequately actioned either. Gavi had previously commissioned work[125] on an "externalities" framework that would be used periodically to assess whether Gavi's market shaping activities have resulted in any unintended consequences, or "externalities", particularly for countries, manufacturers or other key partners.[126] At the conclusion of that work, Gavi concluded that the next steps would be to: instigate regular monitoring of the 2018 findings; continue alertness to potential manufacturer exits; and improve input data in particular with regards to MIC vaccine pricing (in conjunction with WHO/Market Information for Access (MI4A)), global supply & demand dynamics and "country preference" analysis with partners. Under recommendation 7 of the 2020 Supply and Procurement Strategy evaluation, the following was recommended in relation to this work: "In terms of monitoring externalities, we recommend that this practice is continued under 5.0, with a greater effort to link up with the overall strategy in terms of incorporating learning from the monitoring to inform future directions and actions (in line with Recommendation 4), define indicators and data sources clearly upfront, and include qualitative assessments where beneficial." In Gavi's management response, the recommendation was agreed to, although the proposed actions are unclear, stated as: 1. Gavi 5.0 MIC engagement and 2. Future supplier base MSS workstream. It is logical that the prioritisation given to supporting transitioning countries and MICs was likely reduced given the overall Gavi 5.0 pandemic "recalibration", which led to a delay in implementing the MICs strategy, however it now seems very timely to reprioritise an across-Secretariat and Alliance wide effort to look at i) differential pricing access throughout the continuum of Gavi and post Gavi support ii) addressing risk of vaccine procurement failure[127] and improving market intelligence data related to MICs and never-eligible Gavi countries.

2. Right results

2 **Finding 2.1: The SG4 composite indicator target of 10/14 for "healthy markets" has already been achieved in 2021 and 2022. The 4.2 innovation-focused indicator with a target of eight products in the R&D pipeline was also met, as of 2022. The 4.3 indicator "products with improved characteristics procured" has a target of eight by 2025 and currently stands at two. Indicators 4.1 and 4.2 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 (4.1), or if some products are culled from the R&D pipeline. Nonetheless, with the information available, it seems likely that indicators 4.1 and 4.2 will be met. Indicator 4.3 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 new product introductions, and therefore it may be met.**

[125] https://www.gavi.org/sites/default/files/document/the-monitoring-of-gavi-market-shaping-externalities---public-summarypdf.pdf

[126] Examples: reduced investment in vaccine R&D with a low-income countries (LICs) focus; compromised supply security for Gavi and non-Gavi-funded vaccines in Gavi and non-Gavi geographies; dwindling product & manufacturer diversity; price increases in ex-Gavi and non-Gavi geographies to compensate for lower Gavi prices, including price volatility.

[127] The Global Fund is dealing with the same issues, as explained in the Strategic Review 2020, and Gavi might reach out to Global Fund for lessons learned and mitigating strategies.
https://www.theglobalfund.org/media/10498/terg_strategicreview2020_report_en.pdf

The SG4.1 indicator is "the number of markets exhibiting sufficient levels of healthy market dynamics" with a target of 10 (out of a denominator of 14)[128] total by the end of the strategic period. The data for the indicator comes from the Healthy Market Framework ratings of all Gavi markets. Each market is scored for healthy market "attributes" – three demand side attributes, five supply side attributes and one innovation attribute; and scored based on consensus views of market shaping partners. Antigen markets are scored into one of four categories: i) acceptable and sustainable ii) acceptable with risks iii) unacceptable with conditions for improvement, and iv) unacceptable and requires further intervention. In 2021, Gavi reported that 11 vaccine markets demonstrated acceptable levels of market health,[129] meaning that they were scored under the first two categories. In 2022, 10 out of Gavi's 14 markets were judged as having acceptable levels of market health, while four vaccine markets were graded in the two unacceptable categories (Rota, malaria, HPV, and Cholera).[130] The Rotavirus (Rota) market regressed between 2021 and 2022 due to unforeseen manufacturing issues.

The SG 4.2 indicator is "the number of innovative products within the pipeline of commercial scale manufacturers" with a target of 8 by the end of the strategic period. For 2021, Gavi reported the addition of several products in the R&D pipeline: two Measles-Rubella Micro-Array Patch (MAP) Phase 1 studies were initiated and preparations for a clinical trial launch in 2022 were underway for several flu and COVID-19 vaccine candidates on MAPs.[131] The most recent PPC paper from Oct 2023 states that five MAP pipeline candidates made progress in R&D in 2022 and two new vaccines received approval for controlled temperature chain qualification since 2022. The 2022 progress brought the overall achievement to 9, meeting the 2025 target well in advance of schedule.

The SG 4.3 indicator is "the number of vaccines and immunisation related products with improved characteristics procured by Gavi as compared to baseline years" with a target of 9 by 2025. The PPC October 2023 paper reported that two new products with improved characteristics were procured in 2022: a liquid Rota vaccine, improving the ease of delivery for healthcare workers, and a new presentation for a yellow fever vaccine, changing from ampoule to vial containers, improving its cold chain footprint. Regarding the plausibility of an additional seven products coming to market by the end of the strategic period, there is a risk that this will not be achieved, since innovative product development and market entry, culminating in product procurement, may have a longer timeframe than a Gavi strategic period. However, the market shaping team reports that the target for this measure was derived from a scan across all the antigen roadmaps and the timing of expected introductions, the majority of which are anticipated during 2024 and 2025. Therefore, according to the market shaping team, the indicator will likely be met.

[128] The 14 antigens assessed (the denominator) include penta, rota, pneumo, HPV, IPV, YF, MR, Measles, MenA, JE, Cholera, TCV, Hexa, and Malaria. Partners also assess market health of vaccines for Ebola, COVID-19, as well as cold chain equipment (CCE). VIS antigens approved in 2018 but put on hold during the pandemic "recalibration" are not scored at present.
[129] Page 31 MTR as well as Report to PPC Annex D Dec 2022
[130] Page 34 MTR
[131] Report to PPC Annex D Dec 2022

Table 21: Summary of achievement against SG4 targets to date (as reported by the market shaping team, noting 'unmet' for future periods for which for which data will be available in the year following each reporting year)

SG 4.1	2020 baseline	2021	2022	2023	2024	2025
Actuals	10	11	10	0	0	0
Perfromance against target	N/A	Met	Met	Unmet	Unmet	Unmet
	N/A	110%	100%			

SG 4.2	2020 baseline	2021	2022	2023	2024	2025
Actuals	0	2	9	9	9	9
Perfromance against target	N/A	N/A	N/A	N/A	N/A	Met
	N/A	N/A	N/A	N/A	N/A	113%

SG 4.3	2020 baseline	2021	2022	2023	2024	2025
Actuals	0	0	2	2	2	2
Performance against target	N/A	Met	Met	Met	Unmet	Unmet
	N/A	N/A	200%	100%	29%	22%

2 Finding 2.2: The pandemic did affect RI supply performance for some antigens. However, there was less immunisation activity happening in countries during the pandemic, so the Alliance was able to effectively manage demand and supply alignment. The exception to this was with Rota; several factors including the pandemic affected Rota vaccine production, several countries had multi-month stock-outs and have yet to catch up the cohorts that were missed during the pandemic due to supply disruptions. In conclusion, COVID-19 induced supply disruptions were not material in affecting acceptable levels of market health (indicator 4.1) except for Rota. There is no evidence to suggest that the pandemic influenced R&D effort (with implied impact on 4.2 and 4.3).

In relation to Gavi's innovation related work, several interviewees theorised that vaccine R&D for Gavi's core portfolio was likely to have been affected by the pandemic, since researchers were pulled into COVID-19 R&D. However, there were no specific instances cited and it is beyond the resourcing of the evaluation to collect primary data needed to determine the situation. Regarding COVID-19's effect on RI vaccines and coverage, it has been widely documented that RI coverage decreased during the pandemic, due to issues within countries – lockdowns, vaccine hesitancy and health care workers being redirected to work on COVID-19.

On the supply side, Gavi Secretariat included on their risk map the possibility that COVID-19 would lead to diversion of capacity from the production of routine vaccines to more lucrative COVID-19 vaccine production. Gavi initiated conversations with manufacturers at the beginning of the pandemic, to enquire about whether manufacturing capacity was being shared across COVID-19 and RI vaccines and to express that COVID-19 vaccines were important but should not be manufactured at the expense of other vaccines. Nonetheless, there were several cases of RI production availability being reduced due to repurposed manufacturing,[132] unforeseen issues with staff sickness and other

[132] "OPV, repurposed their building line to fill COVID-19 vaccine instead of BOPV vaccines. So that's a very clear competition…… we saw that also I believe in Indonesia there was also a shift in production to produce COVID-19 vaccine…..we saw that in quite a few places actually" (KII)

manufacturing issues.[133] In all cases except for Rota, the reduced capacity did not have a material effect on supply needed to meet demand, due to demand being reduced and effective management by Alliance partners.[134] The exception was with Rota; although KIs report that the initial driver of Rota supply shortages was a commercial decision, unrelated to COVID-19, of the main Rota vaccine manufacturer to reduce supply, this supplier's capacity reduction was exacerbated by a "perfect storm" of issues with other suppliers – e.g. a fire in one facility, COVID-19-induced delays in production with other manufacturers, staff not being able to show up or infecting another group, action plans being continually revised, shifting shipment plans due to not being able to ship in the usual frequency.

Other contributing factors were slow processes at GAVI "*sending mixed messages to countries as to the need to switch to a different product, how to switch, what administrative information was needed for the switch*" (KI). This exacerbated the challenges and KIs opine that if countries had switched immediately they would not have had a stock out, but "*because those switches took such a long time for various reasons there were about five countries that were affected with stock outs, and Kenya was affected for five months*". Those cohorts who missed Rota still need to be caught up, however Rota is not included in Gavi's "big catch up"[135] so KIs express some concern.

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

i. At the strategic reporting level, there is not appropriate weighting/emphasis of the three SG4 indicators, given the higher proportion of Secretariat and Alliance LOE going into the components of indicator 4.1. and demand health (folded into the aggregated SG 4.1 indicator) does not receive the visibility aligned with the increased emphasis it was supposed to have had during Gavi 5.0.
ii. At the operational level, there is a market-shaping strategy operational plan (MSS OPs) with six components including activities, working groups associated with each, process, and operational indicators, but the market shaping team (MST) reports that these plans are not being used and monitored, as priorities have changed. Consequently, internal activity reporting linked to market shaping strategy workplans is currently weak and some of the Square[136] partners are recommending that a refresh to operational plans and targets is needed.
iii. The coherence between Gavi 5.0 strategic imperatives and realisation of market shaping objectives (as measured through SG4 indicators and MSS M&E respectively) may be challenged due to the differing timeframes upon which results can be observed, as well as

[133] As noted in the MST teams 2020 Team Priority Matrix, the COVID-19 outbreak threatened manufacturing continuity with producers of TCV, PCV and Rota, and KIIs report that polio vaccine production was affected as well.
[134] The SG4 team priority matrix notes that a diverse supply base was an existing mitigation across all markets, that UNICEF SD was in constant contact with existing suppliers, that Gavi participated in WHO-led COVID-19 impact workshops and VFGO was engaged on generous safety/buffer stock assumptions for renewals.
[135] A new Gavi initiative allowing preferential co-financing arrangements for certain antigens in order to enable missed cohorts to catch up on their missed RI.
[136] Partnership of Gavi market-shaping partners: Gavi Secretariat, UNICEF-SD, WHO-IVB, & BMGF-VDCP (Gavi's Market Shaping Strategy 2021-2025).

the largely parallel strategy operationalisation processes of the Market Shaping Strategy and the 5.0 Strategy.[137]

iv. The combination of weaknesses in the relevance of SG4 strategic reporting as well as operational level M&E systems may 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 and the transparency of decisions about relative effort (including those of Alliance partners) given to different initiatives, at the outset and during implementation.

3. Right way: Market shaping implementation activity during Gavi 5.0, including enablers and constraints to activity progress

2 **Finding 3.1: Gavi's market shaping levers are being effectively deployed on an ongoing basis.** Gavi's main market shaping influence relies on the demand signal that Gavi offers suppliers, given assured financing, a tendency for countries to remain with the same product, predictable birth cohorts and regular, credible forecasts. At the same time, competition is facilitated through several enablers, including WHO Prequalification and national regulatory authority (NRA) support, as well as UNICEF procurement tenders. 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 constant interaction with UNICEF and with manufacturers. Risk sharing through pre-payments or volume guarantees are exceptional levers Gavi has also used when it is determined necessary with a new entrant at a particular time with a particular product. A 2019 study showed that Gavi's market shaping produces wider benefits beyond Gavi countries, because it increases market transparency, enhances competition and promotes a stable supplier base.[138] 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 SG4.1 indicator on healthy markets is meeting its target, suggests that market shaping levers are being effectively deployed. Misalignment between demand and supply is the reason why some antigens do not meet the criteria for market health; this alignment could be improved if certain limitations could be removed, and efforts expanded (see further discussion below).

2 **Finding 3.2: Under the MSS strategic enabler "implement updated strategic tools and processes" changes were proposed to the antigen roadmap drafting process in order to align the level of effort with its potential impact and to maintain relevance. Eight of 15 roadmaps have been updated during 5.0, some of which have been with the new, more agile format.** Antigen roadmaps reflect the bulk of the market shaping team's work, and according to KIIs, a large basis of tangible success or failure in Gavi's market shaping efforts. In the past, the antigen roadmaps have been long and detailed, taking example 4-6 months to draft and involving many consultant days. As of 2021, a new process was proposed – supplementing the detailed roadmap with a sub-section to be updated annually, to maintain relevance. Table 22 provides the status of antigen roadmap updates under Gavi 5.0.

Table 22: Vaccine programme updates

Updated during 5.0		Not yet updated during 5.0	
Year updated	Vaccine programme	Year updated	Vaccine programme

[137] EHG. 2023. Evaluation of the operationalisation of Gavi's strategy through policies, programmatic guidance, and the use of funding levers; pg. 22.

[138] 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.

2023	HPV vaccine	2020	Yellow fever laboratory diagnostic capacity
2023	Oral cholera vaccine		
2022	Typhoid conjugate vaccine	2019	Meningococcal vaccines for outbreak response
2022	Rotavirus	2018	Japanese encephalitis vaccine
2022	Pneumococcal	2017	Yellow fever vaccine
2022	Malaria vaccine	2017	Measles-rubella vaccine
2022	Covid 19 vaccine	2017	Ebola vaccine
Reported as "piloted early version of updated format":	Pentavalent, IPV, Hexavalent and DTP boosters during 2nd year of life	2015	Meningococcal vaccine

2 **Finding 3.3: Some partner misalignment remains around the appropriate frequency and format of Gavi roadmaps, including how they synergise with procurement cycles and tactics. Partners suggest that the timing, scope, and utility of roadmaps could be further improved.**

Dynamic markets need to have more frequent updates, and roadmap timing and content needs to be aligned with procurement cycles and tactics. The confidential full antigen roadmaps were not made available to the evaluation team; thus, the source of the following comments is restricted to Square[139] partners' feedback and the publicly available roadmap summaries. Several KIs suggested that the timing of roadmaps needs to be tailored to the procurement cycle and to the antigen typology; where the market is changing frequently including due to manufacturer entry/exit, where there is high demand volatility (outbreak prone diseases), or for antigens that are highly influenced by geopolitics, there should be more frequent interrogation of possible interventions to resolve challenges, documented in updated roadmaps. However, it was noted by market shaping colleagues that this request is contrary to partner feedback that they would like less burdensome roadmap updates. As an example, there was a huge shift in the HPV market and consequently Square partners opine that there should have been an updated HPV roadmap several years ago. The urgency for an up-to-date roadmap also increases prior to a procurement round because the roadmaps bring alignment amongst the partners around procurement tactics. The malaria roadmap timing and content was faulted in this respect, as it was developed at the same time as UNICEF was launching tenders, it became too operational and overlapped with the tender strategy, rather than serving as a longer-term strategic vision document. The evaluation team was able to access older roadmaps from the 4.0 strategic period and one observation is that they are entirely future orientated; there is no evidence of a post hoc analysis process to determine what went well/less well (lessons learned) during previous roadmaps periods to inform future market influence tactics. However, the market shaping team noted that when a new roadmap is created, it invariably analyses outcomes under the previous roadmap of the same vaccine.

2 **Finding 3.4: Gavi's "criticality/capabilities" analysis within the "future supplier base" strategic pillar has been delayed due to partner misalignments. Some interviewees suggest that reconsideration should be given whether the input, or the approach being taken is in proportion to the time available and to what ultimately the analysis is meant to achieve.**

Several Square KIs report that the future supplier base workstream "criticality/capabilities" analysis was protracted with the Square partners continuing to suggest new ways to approach the analysis and a "perfect-the-enemy of the good" situation resulting. Alliance partners could not come to an agreement on the actual indicators that needed to be tracked and the confidentiality of data

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

inputting to those indicators. The work consequently got pushed into the implementation stage of the market shaping strategy instead of informing risk mitigation or Alliance actions to be taken during the strategy to try and influence supplier decision-making. *"I think at some point we need to think through what's maybe less scientific but a more pragmatic approach that can still deliver outputs on time"* (Square KI). Now that the assessments are complete, the utility is under question, as "*previous brainstorms on how to leverage these analyses have been slow to yield new ideas*" (market shaping team KI).

2 **Finding 3.5: The focus of the "partnership optimisation" enabling workstream has been to improve the efficiency of data sharing amongst the Square partners and clarity of roles and responsibilities; the former has been challenging, hindered by confidentiality restrictions in sharing pricing data and/or differences in assumptions and use case for the forecasting data**. A platform has already existed with data on suppliers, their pipelines their plans, their business strategy. Pre-2019, this was in the form of an internal data SharePoint which was haphazard and difficult to search. A consultant was hired to improve it to provide a better shared view about the information held on Gavi vaccine suppliers, to inform tender and procurement strategies. According to one Square KI: "*I think it has progressed a little bit, but not tremendously from what I see. The focus has been on what data points are relevant for which audience and how can they be shared in a better coordinated and an easier to navigate way, rather than each organisation sharing their pieces of information and updating them on whatever cycle*." Despite good communication and good intent, another Square partner opined that the attempt to find ways to streamline partner data sources has not gone very well, due to each partner being tied to their own data or there being confidentiality restrictions on data e.g. on pricing and forecasting. WHO has pricing data from non GAVI-eligible countries, BMGF has confidential information on cost of goods, certain UNICEF contracting terms might be confidential. Similarly, assumptions driving demand forecasts differ across partners, depending on the data sources and the main audience e.g. suppliers or financers. Anchoring on one forecast, or one price, has been challenging for partners. The Gavi market shaping team offered the option of building a shared platform to improve data sharing and alignment, but partners opted against it. So now the alternative is ad hoc sharing, and that is dependent on all partners actively uploading and forwarding data (market shaping team KI)**.**

2 **Finding 3.6: 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 to hasten market entry of new supply, including through the WHO Pre-qualification process.** Supply for certain antigens carries a risk of being dependent on the National Regulatory Authority of a concentrated number of countries, such as India. Therefore, to minimize this risk, Gavi funds WHO to strengthen country regulatory capacity in priority countries. A global benchmarking tool is being deployed, to identify regulatory weaknesses and develop plans to address these. WHO is also promoting reliance[140] for efficiency and speed of regulatory review processes. Gavi is also supporting the WHO Pre-qualification team and is in frequent contact to understand the status of applications and expected timelines for approval. The inclusion of this enabling work is an essential tool in Gavi's market shaping armamentarium, as it supports supply security and competitive pricing.

2 **Finding 3.7: Although the need for increased attention to demand health/portfolio optimisation was recognised as a major shift in 5.0, country appetite for new vaccine uptake and product switches has been less than expected.** Historically, Gavi's market shaping had

[140] Regulatory reliance can take many forms and encompasses a broad array of regulatory practices that can involve two or more regulatory bodies or authorized third parties. In addition, it can be limited to a discreet regulatory process or function or include the entire life cycle of a medical product. Regulatory reliance is actively promoted by organizations such as the WHO as a way for NRAs to better manage resource capacity and focus on core national activities.

focused on the supply side, however the need for increased attention to demand health started to emerge as a priority in 2019/2020 due to the increase in number of products and presentations available and soon to be available, as well as the need to mitigate risk of supply insecurity (as a function of insecure demand materialisation or demand skewed to one presentation). Examples of the types of challenges encountered via the latter include: 1) Gavi launches a programme, the supplier base scales up to expected volumes but the introduction appetite is lacklustre (e.g. typhoid, HPV) and the Gavi Alliance loses credibility; 2) when the demand from Gavi supported countries skews to one favoured product,[141] for which there is insufficient supply; 3) in markets with high demand volatility due to outbreaks – the need to manage the supply side through stockpiling or creating preventive or more routinized markets.

Gavi 1.0 had three products and three presentations and until recently, impact was realised mainly by countries introducing new vaccines, like PCV, Rota, HPV. However, under Gavi 5.0, there are now 19 antigens on the menu with over 50 vaccine presentations (e.g. going from two to 12 Rotavirus options, four options for PCV presentations and two schedules, plus HPV options) and another 6-12 antigens will be considered in the next vaccine investment strategy. Now there is an opportunity to realise further impact and savings by thinking through how countries can optimise their vaccine portfolios. Optimisation is relevant to all countries. Given Gavi's current co-financing policy, countries nearing transition, or those facing severe fiscal constraints have greater incentives to switch to vaccines which are equivalent, but lower priced, to do more with the immunisation budget. Portfolio prioritisation – consideration of which vaccines can have the highest health impact if taken up in the immunisation schedule – is another priority in Gavi 5.0. "*Success in market-shaping under 5.0 is more dependent on whether demand will materialise than it was back in 3.0 or 4.0…… back then it was a question of when a product will be taken up; now it's a question of whether to introduce, i.e. 'Is Typhoid enough of a problem in my country to merit the investment that it's going to require?*'." (Alliance KI)

However there has been much less uptake activity than anticipated so far during this strategic period. As per December 2020 reporting to the Board, 15 out of 26 new vaccine introductions planned for 2020 were delayed due to COVID-19.[142] And switch activity has been limited as well, although with increasing interest; Secretariat KIs report that approximately a dozen countries during this strategic period have requested or have been prompted by the Secretariat to consider optimisation options for either saving costs or increasing coverage. However, most country decision-making has been "forced" (due to unpredictable supply events, particularly in the Rota space since 2018, where options increased but supply-security decreased unexpectedly). "Forced" switches are unusual for Gavi, which under normal circumstances operates on the principle of leaving vaccine choice entirely to country decision-making. One Secretariat KI hypothesized that the less than anticipated appetite for vaccine portfolio optimisation may be due to countries not having the tools, or capacity to do evidence-based assessments and/or due to the pandemic absorbing country attention away from new vaccine introductions. However, as covered in Finding 3.12, Gavi policies are likely to be a key constraint to portfolio optimisation as well.

2 **Finding 3.8: There is a gap in the vaccines market shaping space in terms of downstream/country support to evidence informed decision making around vaccine uptake and switches; this gap is only partially filled by limited resource in the Secretariat and external partners.** Countries need to assess new product introduction options and switches in terms of different vaccine effectiveness relative to disease burden, cold-chain requirements, cost,

[141] E.g. Rotavirus, HPV, PCV, malaria. Tendency to prefer higher valency and/or multi-national company source leading to constrained supply for preferred product and consequently delayed introductions.
[142] Strategy, Programmes and Partnerships: Progress, Risks and Challenges Report to the Board December 2020, as quoted in the strategic operationalisation evaluation report 2023.

programmatic/ operational requirements. Given gaps in the current architecture for supporting such assessments, the Secretariat has consequently been expanding its resources. "*There's a balance between supply and demand that I feel Gavi was comfortable with in the earlier phases. But that cracked in 5.0 and we realised we needed to rework it. So, our teams between market shaping and vaccine programmes have come together very strongly to deal with this*." (Secretariat KI) The MST has dedicated a resource more at the strategic supply coordination level to support demand health; a framework has been created, with a common language on how to compare a new vaccine option; Secretariat capacity has been increased with the appointment of healthy demand lead on MST and more work from the vaccine programmes team (one person at 30%), supported by 25% of an additional full time equivalent. Roadmaps are being updated to ensure that the target outcomes include demand side targets as well.

At the partner level, it is reported that WHO does not support the level of analysis required to support evidence informed decision making towards uptake and switches – that is, not only informing countries of their vaccine options but helping them understand the value (cost, supply, security, ease-of-use, coverage, cold-chain impact etc) of these options; this is partly due to capacity and partly due to seeing it as outside their normative guidance remit. Interviewees suggest that the gap in supporting countries to assess options may leave a country open to influence from multi-national companies and their marketing materials. CHAI supports evidence informed decision-making in some countries, primarily with FCDO or BMGF funding. Furthermore "*WHO's CAPACITI team works on a number of tools supporting country decisions and the CHOICES team works off a grant from Bill & Melinda Gates Foundation. And then our goal is to formalise this group into a cross-Alliance demand health working group*." (Secretariat KI) But Square partners close to this work are of the view that there is not yet a good enough mechanism for providing support to NITAGs for such assessments.

2 **Finding 3.9: Secretariat internal capacity and processes to support healthy demand have strengthened, especially during 2023 and there is scope for further strengthening.** Demand health is where the market shaping goals and the introduction and delivery goals come together so it is an important area to have shared goals and to break out of siloed working. Links between the vaccine portfolio and market shaping teams have already been well established at the antigen level, e.g. with the vaccine portfolio team looped into the antigen roadmap development process. But the Secretariat's approach to looking at demand health from an across-portfolio and country engagement perspective, as well as strategic implementation co-creation is a newer, still developing area. Internal Secretariat siloed working means that roles and responsibilities are fragmented – vaccine portfolio team, SCMs, MST, sustainability and the forecasting team, the latter whose primary mandate has shifted to focus primarily on internal financial forecasts, to be able to project Gavi spending on vaccines. According to a Secretariat KI "*we're starting to harmonise how we are supporting countries in the decision-making across vaccine optimisation options and across vaccine programme prioritisation… do I invest first in malaria or Rabies or Hexavalent? We're just starting there, but it is definitely on the radar of the work that is progressing.*" A significant development is the "Brown bag" webinars initiated by the vaccine programmes team. Three have been conducted since May 2023 supporting an evidence-based review of e.g. serotype relevance, cold chain requirements, and programmatic implications of portfolio optimisation.

Square partners acknowledge that this newer area of work is likely to require new forums for communication across the programmatic and market-shaping teams, new policies related to how the market-shaping and programmatic teams work together, more cohesive targets that are collectively created across the two teams; remapping of roles and responsibilities and better ways of

communicating vaccine choices to countries.[143] And conversations are still to happen around other more systemic areas e.g. the influence of GAVI policies on eligibility, co-financing and VIS on country vaccine uptake and switch decision making processes and outcomes.

2 **Finding 3.10: Gavi's proposal to do more market shaping prior to final Board approval of vaccines on the pre-VIS longlist has potential to address gaps in the vaccine market shaping value chain**. As has been shown for over a decade by UNITAID and others,[144] in sectors other than vaccines, a wide variety of push and pull levers can be tailored to address the specific market shortcomings. The vaccines sector in comparison is relatively weak in that part of 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 coincide only once there has been a Board decision to fund and begin the design of a vaccine programme.

However, there is a current proposal in development for a larger investment to be considered for Gavi 6.0, acknowledging that pre-VIS market shaping can have a positive impact on averting a 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. As rationale for the proposal, the Secretariat's points to evidence of exceptional, early risk-sharing interventions it was able to make for Ebola, malaria and hexavalent vaccines prior to a Gavi programme. And – we suggest – the case for such interventions can also be evidenced by historic examples where Gavi did not enter into well designed (i.e. early enough or sizeable enough) bilateral risk-sharing agreements. Due to limitations on the tools at Gavi's disposal to enter into well-designed bilateral risk-sharing agreements, capacity investments on many antigens have been delayed relative to unconstrained demand. Even though there have been examples where the Gavi Alliance, including with support from Bill & Melinda Gates Foundation, has used innovative pull contracting mechanisms with intent to accelerate R&D, maintain supplier interest and/or stabilise prices, these deals have been critiqued as either coming too late, being too small to have the required incentive effect or not being explicit enough about the rules by which the money would be allocated.[145] However, these deals are the exception while the norm is to rely on UNICEF "good faith agreements" whereby UNICEF communicates (a non-obligatory) intent to buy specific quantities at certain prices to a range of manufacturers. As eloquently analysed in a working paper from Center for Global Development, UNICEF's approach is fine for established vaccine programmes and vaccines at a more mature lifecycle stage, but tighter bilateral firm contracting may be needed to incentivise capacity investments and price reductions otherwise.[146]

The Secretariat, in collaboration with partners, is consequently proposing to conduct a 'long-horizon market shaping assessment' for each vaccine on the VIS 2024 longlist and global health security epidemic living assessments.[147] Such an evolution in Gavi's market shaping would support Gavi intervening earlier with market shaping pull mechanisms than has traditionally been the case and would require some revisiting of roles and responsibilities between Gavi Secretariat teams (Policy/ vaccine investment strategy, global health security, market shaping) and externally (e.g. CEPI, BMGF),

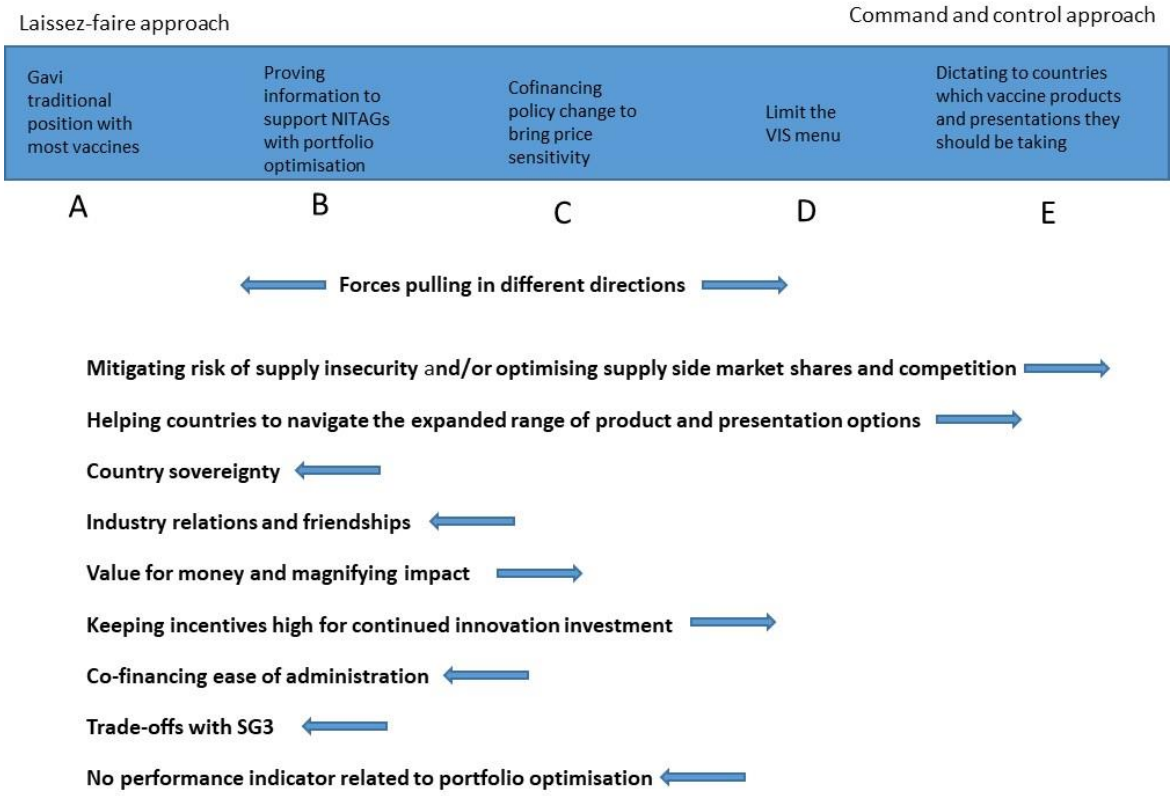
[143] For example, the Gavi website communicates the antigen offering, eligibility and the application for each. Whereas the communication could alternatively be structured more along the lines of, for example, 'Because of the high impact of these antigens, we highly recommend these four first. After those, here is a menu depending on the region you are in'. Countries could click and see the implication for their fiscal space, and the potential health impact it could have.
[144] https://2017-2020.usaid.gov/sites/default/files/documents/1864/healthymarkets_primer_updated_2019.pdf
[145] E.g., pp 115-135 of Evaluation of the International Finance Facility for Immunization (IFFIm) 2011
[146] Owen Barder and Ethan Yeh, Centre for Global Development Working Paper No 80, January 2006 *"The Costs and Benefits of front-Loading and Predictability of Immunization"*
[147] Vaccine Investment Strategy 2024: Longlist and Evaluation Frameworks, Report to the Programme and Policy Committee 16-17 May 2023

as well as care not to undermine the objectivity of the VIS process by pressures to validate Gavi's pre-VIS investments.

1 **Finding 3.11: On an imaginary continuum, with a "laissez-faire" approach to Gavi's role in shaping country portfolio optimisation decisions and a "command and control" approach at the other end, Gavi has traditionally taken a laissez-faire approach, although this has shifted slightly during Gavi 5.0, and some partners are of the view that it needs to shift to an even more directive role.** There is a fundamental tension under this strategy: how to get an efficient global market while serving country-level needs, i.e. balancing country autonomy and demand health in a way that is more sustainable for the market and of better service to the countries.

Consider an imaginary continuum (see Figure 17) where on the left-hand side (position A), doing nothing at all and leaving decision making entirely to countries as to which products and presentations to take up within the approved product menu (Gavi's approach prior to 5.0). Slightly further to the right (position B) is providing the information to facilitate evidence informed decision making on product introduction and switches (the approach Gavi has started to take with a few countries during 5.0). Further to the right (position C) is changing the co-financing policy to increase price sensitivity. Even further right (position D) is increased limitation of the product menu/limiting the options of which products/presentations of those VIS-approved products Gavi will fund. The most directive end of the continuum (point E) is to dictate to countries which vaccine they must take, e.g. saying "for optimum market health, we need the ratio of X product to Y product to be 60/40 and, and given your size, we need you to take X product". This was in fact the approach adopted with CCEOP products and with Rota "forced" switches, due to supply disruptions.

Figure 17: Imaginary continuum



In CCEOP markets, there were strong divides between equivalent products with price differentials and an agreement that Gavi could be more directive (point E) with non-medical products, in the case

of equivalent products with large price differentials (same product, half the price). In vaccines, the view has been that it is harder to show equivalency in terms of product features, programmatic use, costs etc, therefore countries should have complete autonomy to choose. This was easier traditionally due to the limited product and presentation menu, so the matter was left entirely to country choice (position A). Given the expanded range of offering under this strategy and some unexpected supply disruptions, there have been a dozen instances where Gavi has shifted to provide the very best technical information about vaccine product specificities for informed choices (position B) and in the case of supply disruptions, has had to dictate to countries which products they will be offered (position E).

There is no agreement amongst Alliance partners as to which position Gavi should be taking generally, and for different products. Some KIs note that working with each country to provide information to make better decisions – as Gavi has started to do under Gavi 5.0 – is an improvement but as an approach, it takes longer, is more inefficient/incremental and is a more expensive way to do things, whereas according to one KI "*Gavi was created to be able to make big swooping decisions with partners and countries in mind, which could have dramatic impact quickly. If a country like Nigeria, in the space of this, can save US$ 1 million by switching their PCV products and there are groups within Gavi that say we cannot talk to them about that, then that does not seem correct to me."* (Alliance KI)

"In most cases, you could say that it is a country decision. But there is a threshold, because if you have eight products and they are all the same or interchangeable, then why are they all on the menu? They are not all the same for Rota but in cases when there are three or four products which are interchangeable and it is just a brand conversation, this feels unnecessary. This is not a true choice that a country is making, but more confusion is added. It is nuanced: it should be country-led but there should be value-for-money built into that." (Alliance KI)

1 **Finding 3.12: Gavi's demand health influence faces limitations due to Gavi's current co-financing policy, the country finance allocation methodology and country control over the vaccine supplier and product presentation. Several developments – e.g. rise in number of Gavi supported vaccines, higher prices of newer vaccines and larger price differentials between vaccines with similar biological and programmatic profiles, distortions relating to the co-financing policy – warrant a reconsideration of Gavi policies, to positively influence demand materialisation, portfolio optimisation and overall market health going forward.** There are several challenges on the horizon which will make continuation with Gavi's current country allocation methodology, product menu and co-financing policy problematic:

- As mentioned, growing numbers of programmes and presentations, some vaccine presentations having large price differentials bearing no meaningful programmatic or biological benefit above the less expensive alternative.
- Tendency for countries to prefer higher valency vaccines, including in cases where the higher valency is substantially higher priced but offers no real biological benefits.[148]
- Tendency for countries to prefer vaccines produced by multi-national companies, even in cases where an alternative exists with a superior biological or programmatic profile.

[148] As an HPV expert explained: *"There is a clear tendency by countries to go for higher-valent products because they are perceived to have more benefits and therefore the market is now nearly 80% in the hands of the 4-valent HPV product, not in the 2-valent HPV product and so it's a very skewed market. And now if the 9 valent product is approved for Gavi funding, it's pretty easy to see where countries' preference would go, particularly where it does not cost them anything additional, even if it costs GAVI $4 rather than $2 per dose to purchase that product."* And as a PCV expert explained *"The extra three valences you get from the Pfizer product relative to the Serum product are not great value for money for the dollar that you save….so the cost-effective thing to do is to adopt the Serum PCV product."*

- Higher-priced vaccines increasingly included on Gavi's product menu, e.g., malaria and HPV, and VIS shortlist which might threaten inter-country equity and/or allocative efficiency if certain large countries absorb a disproportionate amount of Gavi's budget.

Sub point 1: There is no VfM incentive linked to the co-financing policy, except for countries in the preparatory and accelerated transition phases. For the initial self-financing countries, Gavi's current co-financing model is a fixed price irrespective of the vaccine price – 20 cents/dose whether it is a US$ 3 or a US$ 2 vaccine. These countries therefore have no price sensitivity. Co-financing policy changes were discussed around the start of Gavi 5.0 that would encourage countries to trade off the profile of the vaccine with its price, however the comprehensive funding policy review[149] was paused due to the COVID-19 pandemic and the co-financing policy review was not revisited, "*due to a feeling that this was one too many changes.*" (Secretariat KI)

However, for countries in preparatory and accelerated transition, there is price sensitivity because the co-financing share borne by these countries progressively increases over time and as GNI increases. Therefore, co-financing requirements from those countries decrease if they opt for more cost-effective alternatives. KIs report anecdotally the benefit of rising co-financing obligations contributing to increase the attention of countries on VfM. The disadvantages of the current co-financing policy, however, include a disincentive for preparatory and accelerated transition countries to take up newer expensive vaccines; recognition of this has led to the design of a tailored co-financing approach for malaria, including mitigating the risk of low uptake for countries approaching transition.

Sub point 2: Until recent work begun by the vaccine programmes team related to the demand health pillar, there has been *weak attention to encouraging uptake of lower priced vaccines or reduced dosing schedules* (where comparable options exist). If countries opt for less expensive vaccines, or lower dose schedules from 2 dose to 1 dose for example,[150] two things could happen: i) co-financing contributions may reduce.[151] If the reduction applies to a vaccine which represents a large portion of the country's vaccine budget, this could signal a move away from vaccine investments, unless the government invested the same resources in a new vaccine programme to maintain co-financing amounts. ii) Gavi could spend less on vaccines. Gavi's investment cases are based on projections of vaccine introduction and support at country level. Gavi was successful in its 5.0 fund raising, receiving US$ 1 billion more than the investment case request of US$ 9.4 billion. There is now an implied mandate to spend the funds raised – for example, if large volume countries opt for cheaper PCV vaccines (currently representing approximately 16% of Gavi's vaccine budget),[152] Gavi's budget utilisation could decline, unless there is a compensating (unanticipated) rise in expenditure elsewhere.

Sub point 3: There are no limitations posed by Gavi's country or vaccine allocation formula. The allocation formula for HSS, EAF, CCEOP, and TCA has a ceiling defined by several criteria.[153] However,

[149] In June 2020, the Board made a deliberate (and appropriate) decision to pause the Funding Policy Review, given the uncertainties engendered by the pandemic (Strat-Ops report).

[150] E.g. SAGE recommendations to reduce the number of vaccine doses e.g. for HPV, essentially cutting the programme cost in half and reducing the country's co-financing contribution towards Gavi's finance raising ability as well as reducing overall Gavi expenditure.

[151] If a lower priced vaccine is chosen, the co-financing level will reduce only for those countries on the transition pathway, because they are paying a larger proportion of the vaccine price. In the case of dose reduction, co-financing would reduce for all countries, because the volume of vaccine procurement halves.

[152] Page 39 Gavi 5.0 Investment Strategy.

[153] The formula gives equal weight to population in need, measured by the birth cohort, ability to pay, measured by 3-year rolling average of GNI per capita defined by the World Bank, calculated using the Atlas method, strength of RI programme, measured by number of children under-immunised for DTP-3; and equity of immunization, measured by the number of children that receive DTP1 (ZD children).

there is no country allocation formula for vaccines support. Gavi-eligible countries apply for vaccine support as justified by epidemiological considerations and cohort size, but level of support is not impacted by whether other vaccine programmes are supported by Gavi. 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 vaccines eligible to Gavi support. Therefore, in theory, a very large volume country could introduce several vaccines at once, including expensive malaria vaccines, and absorb a disproportionate percentage of the overall Gavi budget.[154] 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. (see Box 1 for an illustration of this latter point, which would be analogous to undifferentiated Gavi product markets or vaccine markets where the differentiation offers no real biological benefits).

Box 1: How Global Fund's country allocation formula incentivizes VfM in product choice decisions

The Global Fund to Fight AIDS, TB and Malaria provides countries with a budget ceiling for each of their disease grants, and co-financing is raised as a sum proportionate to the overall grant amount, rather than being linked to health commodities. The presence of a disease fixed envelope results in prioritisation conversations about how to achieve required intervention and prevention coverage levels within a limited budget, and the best VfM health products to achieve that. In malaria grants, countries choose LLINs based on their resistance patterns, however subsequently countries can, for example, choose LLINs that are 180 cm tall vs 150 cm tall, with the taller net being priced 50 cents more for the extra 30 cm. The Global Fund's market shaping goal in this case is to consolidate demand around heights to create manufacturing efficiencies and make the grant funds go further in coverage levels with lower priced, comparable nets. In the Global Fund, there is a health product specialist as well as disease specialist assigned to a country team, and they are involved in funding request review and negotiating best VfM in product choice as well as in accelerating adoption of new, improved innovation ("Next generation market shaping"). For a country to be able to procure the more expensive LLIN height, the country is required to justify the request and it needs to be approved by the head of grant management as an exception. (KI Global Fund) In contrast, there is no comparable budget constraint at Gavi incentivizing countries to choose a less expensive product (unless the country is nearing transition and paying a larger share of the price); the only Gavi constraints to introduction and scale up include supply constraints for certain antigens, constraints in the process of achieving programming quality and/or the speed of the Gavi application to disbursement to implementation process.

Sub point 4: With a few exceptions,[155] *countries have complete control over the choice of vaccine supplier and product presentation.* Historically, Gavi policy is for countries to have complete freedom of choice, and this has led to difficulties in aligning supply with demand for the preferred product, and consequently slow introductions when the preferred supplier's capacity 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 3-5 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 would likely occur with the malaria vaccine. WHO SAGE has already recommended the second malaria vaccine and its WHO pre-qualification is anticipated by the end of Q1 2024. Several countries are already approved for the first vaccine and have started to request preference for one or other vaccine (even though experts agree there is no meaningful biological or programmatic difference between the two). How to allocate both products is still being discussed with the goal to respect current Gavi policy of country choice, whilst keeping both vaccines in the market. Some principles have been proposed for how to allocate and KIs suggest that some countries may have to proceed with a vaccine different from their first choice, since the first supplier

[154] A prioritisation mechanism exists at Gavi but has not been used since 2009, as there have been no funding constraints: https://www.gavi.org/programmes-impact/programmatic-policies/prioritisation-mechanism.

[155] 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.

only has capacity of 18 million while the second has capacity of 100 million. This would be a departure from Gavi's ways of working historically.

2 **Finding 3.13: Gavi's entry into supporting regional manufacturing and African manufacturing was responsive to global imperatives[156] and a four-pronged strategy was approved by the Board in 2022.** In December 2022, following calls from the African Union for Gavi to support their goal to produce more than 60% of the vaccine doses required on the continent by 2040 and the G7's call for Gavi to present their strategy in support, the Gavi Board approved a new regional manufacturing strategy with a particular focus on Africa. The strategy involves close partnership with the African Union, including Africa CDC, to help analyse and provide assurance on future levels of demand and sets out a set of recommended actions that local, regional, and international partners will need to take to develop a sustainable vaccine manufacturing ecosystem. A four-pronged strategy was approved by the Board including: 1) advisory support for antigen and platform selection, 2) evolution of GAVI market-shaping, 3) seeking demand assurances and 4) new financial instruments for Africa. According to KIs and implied by documents submitted to the Gavi Board, the African Union and Africa CDC had already been calling for support for regional manufacturing, and the pandemic brought further attention and a political imperative for Gavi to respond.

2 **Finding 3.14: The details of Gavi's regional manufacturing strategy have taken further shape during 2023; an African Vaccine Manufacturing Accelerator (AVMA) proposal recently submitted to the Board defined the incentive amounts, their duration and structure, eligibility requirements (antigens and value chain stage) and specified that further work would take place during the first half of 2024. Risks identified include impacts on the broader market and prices, impacts from the broader enabling environment, manufacturer production risk and risks inherent in AVMA design choices. These details will determine its ultimate impact.** A capitalisation fund of up to US$ 1 billion is proposed to support time-limited incentive payments. This would come from the US$ 2.6 billion remaining funds from COVAX.[157] The aim is for a legacy of at least four African Vaccine Manufacturers (AVMs) operating sustainably into international markets, delivery of more than 0.8 billion doses over ten years; localisation of three drug substance antigen platform technologies; and support to 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.

The MTE suggests that the plausibility of achieving positive impact with Gavi's strategy is highly dependent on two main factors:

- Whether the broader enabling environment will effectively de-risk African supplier investments: The AVMA proposal operates under the assumption that "If sufficient demand-side support can be mobilised to help manufacturers through early years of investment (where debt servicing costs are at their highest), they have the potential to be able to bid at competitive global prices as they achieve economies of scale, and debt servicing on capital costs and imported labour costs decline". Linked to this is an assumption in the AVMA ToC that "Increased financial capacity due to early payments upon attaining WHO PQ certification" will help address early capitalization needs. The proposal does not address the issue of whether other partners will be providing "push" funds earlier in the R&D process. The risk of waiting for PQ to provide a first "prize" reward is that African firms with limited

[156] Source: External KIs and implied in Board documents written by Sanne Wendes.
[157] https://www.reuters.com/business/healthcare-pharmaceuticals/covid-19-vaccine-scheme-poorest-has-26bn-left-spend-pandemic-recedes-2023-06-26/

access to financial markets may not have the ability to fund R&D all the way to the PQ stage.[158]

- The management of potential unintended consequences, notably other suppliers raising their prices as a response to the subsidy: By paying a subsidy to higher priced African vaccine manufacturers, this may have the unintended consequence that other non-African suppliers raise their prices in response to reduced market share or cartel like behaviour.
- Whether demand materialises for African vaccines: there are many unknowns and concerns in relation to this, e.g. scepticism as to how influential supplier geography would be relative to other considerations (pricing, co-financing, epi/disease burden, health economics, programmatic/ operational aspects) and therefore the likelihood that e.g. a country would prefer to buy a vaccine because it is made in South Africa. The African Union is reportedly trying to create demand pacts for African products and there has been political pressure for Gavi to provide offtake agreements or volume guarantees; Gavi has resisted this. Instead, Gavi will try to understand what country preferences are, and inform manufacturers of these preferences, to give improved market visibility.

In conclusion, this area of work is entirely new for the market shaping team since the start of 5.0 and is not reflected in the MSS, or performance indicators. The four-pronged plans initially sketched out at a high level are taking further shape, are appropriately within Gavi's 'lane', and have been Board approved. The work is highly visible and politically sensitive. Further design decisions would benefit from economic modelling from the perspective of individual firms targeted with the AVMA, as well as from the overall market perspective of the targeted antigens.

2 **Finding 3.15: Gavi's Vaccine Innovation Prioritisation Strategy (VIPS) work under the innovation market shaping pillar[159] supports Gavi's immunisation coverage and zero dose strategic goals. Under the 5.0 strategy, Gavi was given the mandate to be involved earlier 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, now with clear strategies, clear action plans, clear alignment and collaboration with partners. There are now nine such innovations in development, with two new products having received licensure for controlled temperature chain.**

Although there was work in previous strategies to support innovation in vaccine delivery products, the agenda was given an additional push under Gavi 5.0, with dedicated funding of US$ 7 million under VIPs and increased transparency to prioritise with all Alliance partners and consider how to best accelerate three types of vaccine delivery innovations:

- microarray patches with the intent to improve access by enabling easier administration and delivering;
- Barcodes – enabling improved tracing, management and monitoring of vaccines; and
- thermostability, to enable vaccines to be kept at higher temperatures improving suitability for lower-income countries.

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. For example, a trained nurse must give an injection, limiting reach, but a patch would enable task shifting to lower cadres, with potential to increase vaccination coverage rates.

[158] For a discussion of the respective roles and push and pull in bringing neglected disease technologies to market, see Grace, C. and Kyle, M. Global Forum Update on Research for Health Volume 6: efaidnbmnnnibpcajpcglclefindmkaj/https://www.margaretkyle.net/PushPull.pdf

[159] Although the MTE EQ 13 doesn't list innovation as one of the market shaping pillars, it is one. Therefore, we include it.

Partners refer to VIPS as a catalyser, with Gavi being given the mandate to be involved earlier on in the development pathway with a clear plan and role to coordinate partners to advance these prioritised innovations. The Innovations group within the market shaping team began by working with partners to prioritise VIPs interventions and to build a VIPS strategy, considering the most appropriate antigens to benefit from the delivery innovations. Five-year road maps have been drafted to outline what would be needed per innovation, identifying a series of activities to accelerate development and partner roles; this included clarifying the regulatory pathway (WHO), providing grants for R&D (BMGF), thinking about market incentives (Gavi and UNICEF). The value of the coordinated approach is to bring the end-to-end view. Gavi is engaging in advocacy with manufacturers around the roadmap, facilitating pathways to licensure, and confirming use cases (impact at country level and scale of need). See Box 2 for details of how Gavi is adding value within the thermostability innovation work.

Box 2: KI description of how Gavi adds value in supporting CTC work under VIPS

Controlled temperature chain (CTC) is a subset of the thermostability work. The Alliance has different levers with CTC. Supporting pre-qualification, studies to determine new vaccine use cases, and communicating the value proposition to countries and to manufacturers to show that the technology is worth investing in. Informants report that these levers worked successfully with the Meningitis A vaccine; SII found it a compelling case to get CTC licensure.[160] The Secretariat has been funding implementation research to show evidence on potential benefit at country level of CTC (e.g. HPV study in Cote d'Ivoire to show the impact of CTC on coverage). For various reasons, making a case for CTC with HPV and Hep B has been more challenging to date.

Initial momentum in VIPs work was weakened, due to the individuals involved in the innovation sub-team being pulled into COVAX. This was a logical 'recalibration', given innovation has longer timeframes. Project kick offs also happened later than planned due to issues related to application of Gavi processes for VIPS operationalisation; this has now been resolved and the innovation work is reported to be going well – with clear strategies, clear action plans, clear alignment and collaboration with partners. And as reported under SG4.2, several products are in the R&D pipeline: five MAP pipeline candidates made progress in R&D in 2022 and two new vaccines received approval for controlled temperature chain qualification since 2022. Nonetheless, a Square partner stated that, *"We were expecting more out of it by now, the pandemic is part of that. We always knew MAPS would be longer term but with CTC and barcoding we thought these were low hanging fruits. VIPS has prevented initiatives from dying out though. In the next year, we hope to see CTC for pentavalent. And on reflection, we know that vaccine vial monitors took longer than expected and so did Uniject (15 years)."*

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

Gavi's market shaping pillar work scope has been altered since the outset of the 5.0 strategy, with some new areas added, and differential levels of urgency and pace applied to different pillars. Given the pandemic, it is difficult to imagine a counterfactual scenario whereby a different level of emphasis would have been taken to prioritisation of the market shaping pillars. However, some of the areas that have received less attention to date will now require a major uplift during the remainder of Gavi 5.0/5.1.

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 has been the African manufacturing initiative, an important new area of work not foreseen

[160] The cholera vaccine has also been CTC licensed but this is reported to be due to influence of other actors, not VIPS.

at the outset of the 5.0 strategy, which has required continuing Gavi Secretariat 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 were delayed but have been making impressive recent gains. There has been more delayed progress on demand health partly because it was a newer area of emphasis under Gavi 5.0 and has taken some time to operationalise, but also because supply constraints as well as the pandemic have led to delayed vaccine introduction and switch activity, to which this pillar is linked. For many reasons detailed earlier, work to improve demand health, and optimise vaccine portfolios, is urgent. Alliance efforts to support countries to make evidence informed decisions are increasing as of late, but the full range of Gavi levers is not yet being deployed to bring about VfM based prioritisation. This has implications for delivering on MSS 5.0 objectives and implies the need for increased emphasis during the second half of Gavi 5.0/5.1. Yet, this pillar is outside the control of the market shaping team and requires cross-Secretariat collaboration and evolution of wider Gavi policies, which affect demand materialisation, portfolio optimisation and overall market health.

It is also relevant to reemphasize that the SG4 chosen indicators do not fully reflect the emphasis of the MST's work, neither do they reflect shifts that have happened within this strategic period, particularly the new emphasis on African manufacturing. There is also an issue of relevance; market shaping interventions often have a longer lead time to show results than Gavi strategic reporting cycles, hence whether the original SG4 targets – which capture market snapshots in time – will be met is less relevant.

Our focus has therefore been on whether the market shaping strategy is being delivered as intended and what can be done to remove some of the current limitations to mitigating risks or to allowing Gavi to have even greater market shaping impact. Importantly, there is no corporate performance indicator on portfolio prioritisation and optimisation, which would be appropriate from both a SG3/ sustainability and value for money lens as well as a SG4/market shaping lens. Since there is no indicator, there are reduced incentives to track it and deliver on it, and the imperative to spend the budget and raise co-financing may also work against this, incentive-wise. As mentioned, there is a gap in the vaccines market shaping space in terms of support to evidence informed decision making around vaccine uptake and switches; this gap can only be partially filled by limited resources in the Secretariat and external partners; such limitations imply that the demand health side objectives (however loosely defined) under the MSS may not be delivered under Gavi 5.0/5.1. Gavi can continue to take a transaction heavy committee approach to allocating scarce supply and to influencing countries' optimisation decisions, however it is suggested that evolving more central level policies to incentivise supply and demand alignment and a VfM-focus might enable greater traction.

Similarly, Gavi's market shaping work is constrained in terms of what it can achieve upstream under the current business model. A more cogent and rounded discussion may be required 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.

Recommendations arising from the thematic study:
T**he overarching recommendation is to 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)**. Specifically:

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 NRAs, 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, 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]**
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]**

Annex 10: Thematic study – MICs

Introduction and primary purpose

Euro Health Group (EHG) was commissioned by Gavi to undertake a Mid-Term Evaluation (MTE) of Gavi 5.0. The 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 prioritized 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).

During the MTE inception phase, we assessed the evaluability of our key Evaluation Questions (EQs), see final EQs in Vol.1, Table 1. We identified the need to strengthen our evidence base in specific areas, including our understanding of Gavi's work under the MICs approach to date and thus identify any emerging themes from this work, which should inform development of 6.0.

This study aimed specifically to examine the MICs approach related Theory of Change (ToC) pathways (which primarily led to Strategic Goal 3, Improved sustainability of RI programmes) in more detail and strengthen our understanding of how the MICs approach is contributing to relevant ToC outputs and outcomes. This study provided more complete answers to multiple MTE EQs, on the broader implementation of the MICs approach under 5.0/5.1, and key insights into how the MICs approach should be adapted and integrated into 6.0 (and thus supported EQ15 in particular).

Scope

As a result of the amended, phased MICs approach, implementation to date has been limited, and limited data is available against Gavi's MICs approach and implementation indicators. While data for some indicators was anticipated to become available during 2023, it was determined that it would still be limited and provide limited insights into how well implementation of the MICs approach was progressing and whether any course correction is needed prior to or during development of 6.0.[161] This case study provides findings that address the following agreed case study questions:

1. ***Is Gavi's MICs approach providing the right support to facilitate introduction of targeted key vaccines (PCV, rotavirus and HPV) and reduce inter- and intra-country RI inequities?***
    a. *Is the type of support being offered relevant and sufficient to support introduction of the targeted vaccines?*
        i. *Is the support to former-and never-eligible countries taking sufficient account of individual country context and needs (including of fragile and conflict affected states (FCAS) MICs)?*
        ii. *What lessons are there to date about provision of support to never-eligible MICs? Has engagement via COVAX and core Alliance in-country partners provided the necessary foundation for future Gavi engagement with never-eligible countries on an equitable basis?*
2. ***In former-eligible MICs that transitioned during the 4.0 strategic period and have experienced significant RI back-sliding, is the MICs approach to date on track to mitigate/ prevent further backsliding and restore RI as intended?***

[161] Measurement of progress against indicator S3.2 is based on a July 2022 WUENIC (thus no update yet, and first update expected August 2022); and similarly, no progress to be reported against indicator S3.3 until 2023. For the Strategy Implementation Indicators, no data was available on A3.4 (introduce new vaccines) at the end of 2022, and it is not clear from document review to data to what extent substantive engagement with never-eligible countries has started.

   a. *What were the key factors (external, e.g. COVID-19 economic impact; and internal, e.g. Gavi funding model/transition processes) that contributed to backsliding, and how/to what extent has Gavi's MICs support to date addressed these and supported the relevant SGs?*
   b. *Are these key factors likely to persist into the 6.0 strategic period, and if so, what are the implications for Gavi, its transition model, and MICs approach (including for FCAS MICs) moving forward?*
   c. *What unintended consequences (positive and negative) of Gavi's MICs approach with former-eligible countries have emerged to date, and what course-correction is indicated for 6.0?*

3. ***How is MICs approach to date at regional/global level supporting former and never-eligible countries to mitigate/prevent further backsliding and support introduction of targeted key vaccines?***
   a. *Is the approach at this level targeting the right common barriers and challenges? (design focus)*
   b. *How/to what extent has implementation to date helped to mitigate backsliding and supported introduction of new key/target vaccines?*

Methods

This thematic study was conducted through a mixed-methods approach consisting of thematic analyses of documents and KIs triangulated with quantitative data analyses. Data collection consisted of:

- a document review of existing literature and data on MICs design and implementation;
- interviews with 10 global and regional KIs representing the Gavi Secretariat and Alliance Partners including WHO and UNICEF; and
- remote case studies in Indonesia, Angola, Kosovo, Sri Lanka, Philippines with 38 people across government stakeholders, Alliance partners (WHO, UNICEF), expanded partners (CHAI, UNDP).

Findings

Findings are presented against three broad areas – the relevance and appropriateness of the design of MICs, implementation and likely results of MICs, and implications moving forward.

1. Design

The following findings cover case study question 1, including 1a (i and ii) and contribute to EQ1, EQ2 and EQ3.

1 **Finding 1.1: Most stakeholder groups perceive Gavi's MICs lever to be lighter touch than other funding levers, as intended. However, rapid turnover and limited capacity of Gavi country teams, sub-optimal communication of changes to Gavi country team organisation and a lack of sufficient planning at the start of MICs rollout resulted in significant delays and frustrations for early former-eligible MICs applicants. A need for additional support to help never-eligible countries navigate Gavi processes successfully was also flagged.**

Gavi MICs approach was designed to be lighter touch in terms of application and approval processes. For example, application forms are less prescriptive and require far less information and fewer attachments, and requests for support from Gavi fragile MICs and requests for non-cash TA support bypass the IRC and are approved by the CEO.[162] The MICs approach was also intended to be relatively self-contained and not pull Gavi resources away from those needed for Gavi-eligible countries, which

[162] KIs – Country teams x 2, Secretariat x 2; 11 - Update on Middle-Income Approach (PPC23),

also drove the push for tailored processes and decision-making pathways.[163] A majority of stakeholders within Gavi, across Alliance core and extended partners and within Ministries of Health did feel that compared to the main funding levers, the experience of applying for MICs was easier,[164] with some informants stating that it was easier than comparable Global Fund and/or World Bank support processes.[165] However, several stakeholders noted that especially for never-eligible countries, the process can still feel confusing and/or burdensome, as these countries are largely unfamiliar with Gavi's funding processes, often have less core Alliance partner capacity (in terms of number of staff), and have many competing priorities. As a result, it was felt that looking forward, these countries, including priority never-eligible MICs such as the Philippines, may require additional support to apply for and be approved for MICs support.[166] Other specific complications that have arisen include the requirement for the Minister of Finance or equivalent to sign-off on any application for MICs support. While it is understood that this is to ensure political and financial commitment is in place, several stakeholders flagged that this requires parliamentary approval in some countries and can result in considerable delays and is not a standard process for non-cash support in many countries.[167]

For former-eligible MICs, countries that were first to apply (e.g. Indonesia and Angola), they experienced various process-related delays. Initial delays with MICs rollout due to COVID-19 were reportedly compounded by perceived poor communication of the restructuring/reintegration of the Gavi MICs country team (which was previously under COVAX) into the wider country engagement team; regular changes of SCMs and other personnel; limited SCM/country team capacity, and a resultant perception of mixed/ever changing messaging on the scope of and processes for applying for MICs support.[168] This was perceived as further compounded by the fact that no "dry run" of MICs application processes was carried out, and for MICs fragility support, no guidance existed at the time the support offer was made public.[169]

These issues resulted in some significant delays. For example, a lack of clarity and/or awareness around the requirement for MICs country governments to have performance capacity assessments (PCAs) in place to receive direct funding from Gavi, resulted in significant confusion and delays. A valid PCA is a standard Gavi requirement, but even for former-eligible countries, some PCAs had lapsed,[170] and for never-eligible countries, PCAs had not been done. Due to a combination of limited portfolio management team capacity, and also the intention for the MICs approach to not pull resources from Gavi-eligible countries, funds instead had to be channelled through core partners. However, this process was not clear from the start, which led to confusion and delays in some countries .[171,172] While it was intended from the design phase that the majority of MICs approach funding (with exception of some 'targeted intervention' funds and other operational costs) would go through core partners rather than be channelled through government, these process-related delays were reported as having significant on-the-ground impact. For example, despite Indonesia flagging the need for/ interest in MICs New Vaccine Introduction (NVI) support in 2021, the ongoing delays meant the country started with these introductions without Gavi support.[173] The bypassing of IRC approval for fragile MICs appears to have supported significantly faster approval and disbursement

[163] Report to the board June 2022_eng (Board22).pdf.
[164] KIs – country teams x 4, Secretariat x 3, Alliance country/regional partners x 5, country MoH x 2.
[165] KIIs – Alliance country partner x 1; country MoH x 2.
[166] KIIs – Country teams x 3, Secretariat x 1, Alliance country/regional partners x 3, country MoH x 1.
[167] KIIs – Country teams x 2, Secretariat x 2, Alliance country/regional partners x 3.
[168] KIIs - Country teams x 4; Secretariat x 2, Alliance country partners x 5.
[169] KIIs – Country teams x 2, Secretariat x 2.
[170] They are reportedly valid for three years.
[171] One informant also shared a perception that channelling funds ultimately intended for the government through core partners reduced country ownership and unnecessarily increased overhead costs.
[172] KIIs – Country teams x 4, Secretariat x 2.
[173] Indonesia MICs ZD Application; KIIs – Alliance country partners x 3, Country teams x 2.

than is the norm, with support for Lebanon and Venezuela provided within three months of application receipt.[174] For Sri Lanka however, there were delays acting on the initial request from the Minister of Health made directly to Gavi in 2022, with their MICs fragility support only recently approved.[175]

2 **Finding 1.2: The relevance and likely sustainability of NVI support being offered to Gavi MICs countries is constrained by the extent to which these countries have sufficiently strong health systems in place and by the vaccine prices made available and limited transparency of vaccine pricing and availability to these countries.**

MICs support for NVI at country level is available to support relevant TA, to look at for example potential demand-side barriers to successful introduction, relevant one off costs and also vaccine catalytic financing (VCF) which provides support for 50% of the costs of vaccines for the first cohort for vaccination, with procurement through UNICEF SD or PAHO RF.[176] Especially for large MICs eligible countries such as the Philippines, Egypt, and Algeria, the 50% support was noted by several stakeholders as being relatively small, meaning countries may struggle to sustain introductions if they have not identified medium- to long-term financing.[177] In this context, the importance of MICs countries, including those eligible for Gavi MICs support, having access to more affordable and transparent vaccine prices was highlighted.

While former-eligible countries initially may have access to cheaper Gavi prices, stakeholders highlighted that access to Gavi pricing for transitioned countries is not guaranteed and is time limited. Similarly, never-eligible MICs have had less pricing visibility and predictability to date, and multiple informants referenced higher/less affordable prices as a barrier to sustainability and vaccine introductions in these countries.[178] Some stakeholders highlighted that currently it is challenging for countries to access vaccine pricing information, even though in theory it is publicly accessible.[179] Beyond pure financial sustainability, several stakeholders also noted the importance of having a sufficiently strong and resilient RI and broader health system in place to support sustainable vaccine introductions.[180] Some Gavi and Alliance informants noted that in never-eligible countries, the strength of RI systems is highly variable, partly because they have not had significant/long-term Gavi support to put in place standard systems such as NITAG committees or equivalent.[181]

2 **Finding 1.3: In never-eligible countries, the lack of access to MICs back-sliding or other support which can ensure the necessary foundations are in place to support sustainable introduction of new vaccines is further constrained, especially in the context of more limited Secretariat and Alliance partner capacity, limited donor support and competing priorities common in smaller countries that have yet to introduce some of the target vaccines.**

Due to their middle-income status, most never-eligible MICs countries were noted as having limited donor support to the health sector in general and in RI in particular.[182] Under the MICs approach, these countries are currently ineligible for Gavi back-sliding support (which has reportedly acted as broader health system/RI strengthening support, albeit on a relatively small scale, in several former-eligible countries), despite many experiencing significant backsliding (see Table 23). While some Gavi

[174] 11 - Update on Middle-Income Approach (PPC23).
[175] 11 - Update on Middle-Income Approach (PPC23); KIIs x 3.
[176] 11 – Update on Middle-Income Approach (PPC23), KIIs x 3.
[177] KIs x 4.
[178] KIs x 3.
[179] KIs x 2.
[180] KIs x 7 (across Gavi Country Teams, core partners).
[181] KIs x 2.
[182] KIs x 4.

informants felt that it is beyond Gavi's scope or comparative advantage to provide this kind of support in MICs, especially in never-eligible MICs,[183] others noted the importance of ensuring that the health system is sufficiently resilient before offering new vaccine introduction support.[184] It was also noted that MICs that are experiencing health system challenges also often have lower or highly variable Alliance partner capacity, as Alliance partners are reliant on member state contributions in these countries, with smaller countries often having no RI specialists within WHO and/or UNICEF.[185] Country government and partner stakeholders noted the difficulty of navigating multiple health priorities in these countries with limited domestic human and financial resources.[186] Even where never-eligible MICs choose to prioritise new vaccine introductions, the lack of partner capacity to support them in the process is sometimes compounded by lack of Secretariat capacity, where one SCM may be supporting multiple smaller never-eligible MICs countries.[187]

2 **Finding 1.4: The package of support offered under MICs is seen by most as being flexible and thus relevant to the context of countries eligible to apply. However, there are concerns from some around use of GNI data to decide overall eligibility for MICs support and the use of national WUENIC (and primarily DTP3) data to decide eligibility for backsliding support, which makes the support package less relevant to the context of some MICs.**

MICs is seen as being relatively flexible, with countries in theory able to receive any kind of TA (for backsliding/ZD support[188] and/or NVI[189]) once their application successfully demonstrates how it will be high impact and lead to the intended results and aligns with Gavi's priority areas, including equity, gender and innovation. [190.191] Applications submitted to date reflect this, and exhibit a wide range of requested TA support. Most stakeholders however felt that the relevance on the support on offer to MICs in general was limited by the overall eligibility criteria used to define overall MICs eligibility, and/or for eligibility for backsliding/ZD support.

Currently, overall MICs eligibility is based on being a former Gavi i.e. post-transition country, being a World Bank defined LMIC (GNI below approximately US$ 4 000 per capita) or being an IDA MIC. On this basis, 46 countries are currently included on the MICs eligibility list, including special cases such as Venezuela. In 2022, the Board considered also including UMICs with GNI below US$ 6 000 per capita on the MICs list, but it was decided that for the rest of the current strategic period, eligibility would remain the same, albeit also including MICs which had experienced drops of income and thus now classified as LMIC.[192] Several stakeholders however felt that use of GNI data to decide the eligibility of never-eligible MICs for support is too narrow and is no longer a fit-for-purpose proxy of where most support is needed and that other criteria such as burden of disease should also be considered.[193,194] The rationale cited was that MICs are incredibly diverse, and some may have higher income but be burdened with issues including extremely high poverty rates, health system accessibility constraints, high ZD numbers, geographic inequities and/or additional constraints

[183] KIs x 2.
[184] KIs x 3.
[185] KIs x 4.
[186] KIs x 3.
[187] KIs x 3.
[188] For former-eligible countries only.
[189] For all MICs approach elibible countries.
[190] KIIs – country tams x 4, Secretariat x 2, Alliance country/regional partners x 5, country MoH x 2.
[191] 2023.30.06 IDN MICs TI Narrative – FINAL.pdf; IRC Indonesia MICs Sept 2023_Cleared by V Chair.docx, Angola Proposta MICs - Zero dose versão Rev final.docx; IRC Report Kosovo VCF Sept 2023.pdf; Kosovo Concept Note TA 4 Sep 2023.pdf; Kosovo_Concept note_29 June.pdf.
[192] Report to the board June 2022_eng (Board22).pdf.
[193] The ongoing ELTRACO review is reportedly considering including more than GNI per capita as an indicator, with presumably implications for MICs eligibility also.
[194] KIs x 2.

accessing vaccine markets due to their location and/or small population. At the same time, several partner stakeholders believe that MICs eligibility should not be too broad, and that focussing on impact in terms of children's lives saved is key.[195]

The issue of eligibility for backsliding/ZD support was also raised as a concern by several stakeholders. Concerns that never-eligible countries are ineligible for this kind of support were raised by several stakeholders, especially while there is a perceived push from Gavi for new vaccine introductions in countries with major backsliding and thus higher priorities than new introductions.[196,197] Concerns about relying on DTP3 national WUENIC data as the sole data point to decide eligibility for backsliding support were also raised, as it was noted that in some countries, DTP coverage may be high, but e.g. IPV coverage may be substantially lower, as a result of multi-dose and specific antigen vaccine hesitancy, pushing health care workers to choose the vaccine which offers the broadest protection (e.g. penta), but deprioritising single-antigen vaccines such as IPV.[198]

2 Finding 1.5: Alliance learning is strongly integrated into the MICs approach, with a dedicated MICs MEL framework and learning agenda, and integration of a regional Alliance partner community of practice which has already supported valuable learning in support of new vaccine introductions.

When the MICs approach was first approved by the Board in late 2020 with a phased approach, it was identified as a key area for learning, and as such, a dedicated ToC and "Learning Agenda" were also integrated from the start. The purpose of this learning focus was to drive sustainable new vaccine introductions and prevent RI backsliding, and thus create great impact. Even more broadly, given that the MICs approach approval was initially for 5.0/5.1 only, any continuation of the MICs approach into 6.0 was reliant on the robust capture of progress and lessons as implementation progressed.[199] Since 2020, an even more comprehensive MICs approach MEL framework has been designed, incorporating the ToC, learning agenda, ongoing measurement and analysis against outcomes and indicators framed against the ToC, and data use and dissemination.[200] In addition to the overall MICs MEL framework and learning agenda, a Gavi-funded regional Linked Immunisation Action Network (LINKED) website and network for MICs stakeholders to share learning has been established.[201] Several stakeholders across the Secretariat, country teams, core partners at regional and country level felt that LINKED was already proving valuable.[202] For example, it facilitated sharing and trouble-shooting of problems experienced by Indonesia during the MICs application process and prevented these from reoccurring in Vietnam, and in Kosovo, It led to the government in Kosovo choosing to do full national HPV rollout rather than sub-national pilot, based on evidence shared by core partners in the EURO region about sub-national roll-out increasing vaccine hesitancy and misinformation. Learnings from LINKED is in turn fed into the MICs learning agenda, along with data from other sources such as a recent internal MICs review exercise, and ongoing CPMPM. monitoring.[203]

[195] KIs x 3.
[196] Kis x 3.
[197] Informants did acknowledge that ultimately it is a country's choice whether to proceed with a vaccine introduction, but a small but significant number of informants did refer to a perceived pressure to go ahead especially in MICs approach eligible countries seen as key to achievement of MICs approach and overall strategic goals
[198] IPV was used as an illustrative example by stakeholders representing two case study countries, and in one case-study country, increased cases of vaccine-derived polio were noted, and it was hypothesized that this could be at least partly due to this issue. However, the overall point can apply to other antigens also.
[199] KIIs x 2, Report to the board June 2022_eng (Board22).pdf, MICs Approach_MEL framework_9th of August.pdf.
[200] MICs Approach_MEL framework_9th of August.pdf, MICs Learning agenda_ 9th of August FV.ppt.
[201] KIIs x 5, MICs Approach_MEL framework_9th of August.pdf, MICs Learning agenda_ 9th of August FV.ppt.
[202] KIIs x 6.
[203] MICs Approach_MEL framework_9th of August.pdf, MICs Learning agenda_ 9th of August FV.ppt.

2 **Finding 1.6: Global and regional MICs support channelled through core Alliance partners is seen as valuable, with examples of regional support being successfully leveraged (both in terms of improving application processes and sharing of valuable technical insights between countries), and examples of how regional level support has helped to support countries with backsliding and/or new vaccine introductions. There is also evidence of the key role that expanded partners can play. There is however limited regional/global level support for never-eligible countries in the Americas region, and integration of CSO partners is seen as challenging in never-eligible MICs.**

The MICs approach design includes a dedicated "Foundational building blocks" component at regional/global level, working with core partners in four regions to advocate and provide TA support for new vaccine introductions and to address RI backsliding and ZD.[204] This support includes activities to assess cost effectiveness and/or vaccine impact to demonstrate the value of the vaccines in the local context and provide evidence to guide decision-making, mapping country capacity for NVI, and strengthening NITAGs to support evidence-based decision-making.[205] Regional level core partners are in turn working with country level offices to encourage MICs applications and provide necessary support. In most regions, support from regional level included support for both former and never-eligible countries, but in the Latin America and Caribbean region, support for never-eligible countries through core partners is more limited, even though six out of seven never-eligible countries in the region have at least two of the three target vaccines not yet introduced (see Table 27).[206] It was not clear from the documents reviewed why this was the case, and the picture from the limited number of informants questioned about or with knowledge of the rationale for this was unclear: some reported that this was due to a focus from regional partners on prioritising backsliding and ZD over NVIs, but others felt that this was a gap in support.[207] More generally, a small number of informants representing Americas and Pacific countries said this may reflect a lack of focus on smaller MICs, which would not significantly contribute to Gavi's SGs.[208]

In addition to leveraging the core partners, the MICs approach application forms also encourage use of a "wide selection" of partners. Evidence on use of expanded partners was limited based on MICs approach case studies, but are playing a key role in some countries such as Indonesia, where CHAI and UNDP are working closely along with core partners and the government.[209,210] Some stakeholders across core partners and country governments however referenced the challenge of including wider/non-core partners in MICs, especially in never-eligible MICs, where CSO capacity (in terms of number and/or experience and expertise) is generally lower than in LICs.[211] In the bigger former-eligible countries such as Indonesia and Angola, expanded partners are already more established, and were thus seen as valuable contributors.[212] In one former-eligible country a core partner informer was unaware of why Gavi pushes for wider partner involvement, suggesting a need for more sensitization of core partners in MICs.[213] One area of partner support which some

[204] 11 - Update on Middle-Income Approach (PPC23).docx, 11 - Update on Middle-Income Countries Approach (PPC23).ppt, MICs regional TA for Linked - Jan 2023.pdf.
[205] 11 - Update on Middle-Income Approach (PPC23).docx, 11 - Update on Middle-Income Countries Approach (PPC23).ppt, MICs regional TA for Linked - Jan 2023.pdf.
[206] Gavi MICs TA_UNICEF First Technical Review Meeting for sharing.pdf; WHO PAHO activities, MICs regional TA, for Evaluation sharing.pdf; MICs regional TA for Linked - Jan 2023.pdf.
[207] KIs x 3.
[208] KIs x 3.
[209] Since the time of writing, two expanded partners have reportedly been engaged focusing on engaging CSOs and local communities to strengthen demand; health worker training in immunisation; identification of missed communities; and NITAG strengthening. These activities are being deployed in the Asia Pacific and European regions (KI x 1).
[210] KIs x 7; 2023.30.06 IDN MICs TI Narrative – FINAL.pdf; IRC Indonesia MICs Sept 2023_Cleared by V Chair.docx.
[211] KIs x 5.
[212] KIs x 4.
[213] KIs x 1.

stakeholders referenced as being especially promising was a partnership with World Bank supported initiatives in Indonesia and Honduras focussed on nutrition and early years support for children. Several Indonesia stakeholders saw that MICs support, which is by nature limited in scope, is more sustainable and far-reaching.[214]

2 **Finding 1.7: Gavi's other cross-cutting priorities such as gender, equity, and innovation are explicitly integrated into the application process, but levels of actual integration vary across countries. ZD is explicitly part of backsliding support, and there are some countries where, for example, potentially valuable innovations are planned, for example in use of geospatial tools to improve RI planning. Gender however is not well reflected to date.**

Gavi's other cross-cutting levers such as gender and equity and innovation have also been integrated into the design of MICs support. Backsliding support for former-eligible MICs is explicitly focused on reaching areas with more and/or higher proportion of ZD children, with application forms requiring countries to justify the choice of which areas to focus on. Countries are also encouraged to consider gender and other equity considerations, however in applications to date there is very limited evidence of this being explicitly considered, a point also noted by the IRC.[215] There are some examples of gender and broader equity being considered however, for example in Kosovo's application for NVI, which considers Roma/traveller populations and how to reach girls within these populations who are often not in school, and gender has reportedly been integrated into the contract of one of the expanded partner contracts.[216]

Innovation is one of the "guiding principles" which MICs technical support applications are expected to be aligned with. The concept of innovation within Gavi is not well defined (as outlined in our spotlight on Gavi's approach to innovation, Annex 12), but the MICs approach asks countries to "try new approaches and methods, e.g. to find ways to have meaningful engagement of subnational government and local level organisations where effective relationships can be established". In country applications to date, some examples of innovations are making use of geospatial tools to support improved planning of RI; the use of electronic vaccine management information systems; and integration of AI into ZD monitoring systems.[217]

2. Implementation and likely results

The following findings cover case study question 2 (including 2a), and case study question 3 including 3a and 3b) and contribute to EQ1, EQ2, EQ3, EQ5, EQ6, EQ9, EQ10, and EQ11.

1 **Finding 2.1: Stakeholders in MICs case study countries were broadly optimistic about mitigation of backsliding and meeting vaccine introduction targets. Strategic Goal 3.2 has officially been met, with eight former-eligible countries maintaining or increasing coverage. Four MICs countries that did backslide recovered DTP3 backsliding to pre COVID-19 levels by end of 2022, notably all without MICs support in place. At the time of data collection, coverage levels of HPV in Sri Lanka are expected to be fully restored with MICs fragility support, but only partial recovery is expected in other countries. For introduction of targeted vaccines, at least 10 national vaccine introductions are expected across five countries with Gavi support by the end of 2025, with**

[214] KIs x 3; 11 - Update on Middle-Income Approach (PPC23).pdf
[215] 2023.30.06 IDN MICs TI Narrative – FINAL.pdf; IRC Indonesia MICs Sept 2023_Cleared by V Chair.docx, Angola Proposta MICs - Zero dose versão Rev final.docx.
[216] KI x 1, IRC Report Kosovo VCF Sept 2023.pdf; Kosovo Concept Note TA 4 Sep 2023.pdf; Kosovo_Concept note_29 June.pdf.
[217] KIIs x 3, MICs regional TA for Linked - Jan 2023.pdf; 2023.30.06 IDN MICs TI Narrative – FINAL.pdf; IRC Indonesia MICs Sept 2023_Cleared by V Chair.docx.

a further seven across four further countries possible, thus likely exceeding the target of 8-10 vaccine introductions.

While there was significant backsliding in several MICs countries over the period 2019-2021, 2022 WUENIC data indicates that four MICs eligible countries which had significant DTP3 backsliding in 2020 and/or 2021 had restored coverage to pre COVID-19 levels by the end of 2022.[218,219] An additional four former-eligible countries maintained or increased coverage despite the challenge of COVID-19,[220] helping Gavi to meet Strategic Indicator 3.2. Gavi's contribution to this is however unclear, as Gavi MICs support has not (to date) been delivered to any of these countries, although there is some possible contribution from COVID-19 Vaccine Delivery Support (CDS) support in some of these countries, which several stakeholders referenced as valuable to broader RI.

Eighteen MICs countries have not yet caught up significant DTP3 backsliding,[221,222] though it is notable that eight of these were experiencing backsliding even before the advent of COVID-19.[223] Of the MICs former-eligible countries with the most significant ongoing levels of DTP3 and DTP1 (zero dose) backsliding – namely Angola, Azerbaijan, Bolivia and Honduras – all of these have either already applied for or expressed interest in MICs backsliding targeted intervention (TI) and/or ZD support.[224] Indonesia has also applied, but 2022 WUENIC data indicates that they have already recovered DTP3 coverage and have halved the number of ZD children from 2021 to 2022.[225] See Table 23 for a summary of DTP3 backsliding and ZD magnitude along with MICs application status in former-eligible countries.

Stakeholders familiar with sampled case study countries felt that by the end of 2025:[226]

- For mitigating backsliding in former-eligible MICs with MICs support
    - Angola was unlikely to fully catch-up on backsliding
    - Even though Indonesia have caught up on DTP3 coverage in 2022, there were doubts over whether backsliding in other antigens would fully catch-up
    - Sri Lanka is likely to restore HPV coverage to pre-COVID-19 and economic crisis levels (the only antigen where coverage has not already recovered most losses)[227]
- For introduction of targeted vaccines with MICs support:[228]
    - Kosovo will introduce all three target vaccines
    - Indonesia will expand PCV and HPV introduction from subnational and introduced RV nationally,[229] although the contribution from MICs is not as significant as it could have been due to delays with MICs being approved[230]

[218] 2 former-eligible – Indonesia, Viet Nam and 2 never-eligible – eSwatini and Philippines
[219] WHO (2023), Country WUENIC estimates, DTP3.
[220] Armenia, Guyana, Cuba, Bhutan
[221] 7 former-eligible and 11 never-eligible countries
[222] WHO (2023), Country WUENIC estimates, DTP3.
[223] 4 former-eligible: Angola, Azerbaijan, Bolivia, Honduras, Indonesia; 4 never-eligible: El Salvador, St. Lucia, Venezuela, Jordan
[224] Gavi (2023), 11 - Annex A - MICs Approach Progress Dashboards (PPC23); 11 - Update on Middle-Income Approach (PPC23); 11 - Update on Middle-Income Countries Approach (PPC23) PowerPoint.
[225] WHO (2023), Country WUENIC estimates, DTP3.
[226] KIIs: Country Teams x 4, Gavi Secretariat x 2, Alliance country/regional partners x 6, Country MoH x 2; Gavi (2023), 11 - Annex A - MICs Approach Progress Dashboards (PPC23); 11 - Update on Middle-Income Approach (PPC23); 11 - Update on Middle-Income Countries Approach (PPC23) PowerPoint.
[227] This was considered the status at the time of data collection, but may evolve again between now and end of 2025
[228] KIIs: Country Teams x 2, Gavi Secretariat x 2, Alliance country/regional partners x 4, Country MoH x 3; Gavi (2023), 11 - Annex A - MICs Approach Progress Dashboards (PPC23); 11 - Update on Middle-Income Approach (PPC23); 11 - Update on Middle-Income Countries Approach (PPC23) PowerPoint; 04 - Appendix 1 - HPV Operationalisation Update.pdf
[229] These introductions have all already started without MICs NVI support yet being disbursed but MICs support is still expected to contribute to the successful introduction of these three vaccines.
[230] KIs x 4

- Azerbaijan will introduce RV and possibly also HPV
- Cuba will likely introduce PCV and possibly also HPV
- Iran will introduce RV and PCV
- Jordan will likely introduce PCV
- Grenada will likely introduce HPV
- Ukraine may introduce all three vaccines[231]
- Tunisia may introduce HPV
- Philippines may scale up HPV to national level (medium-high likelihood)[232]

Several never-eligible countries also continue to experience significant backsliding, with El Salvador and Venezuela still experiencing low DTP3 coverage and high numbers of ZD. The Philippines has recovered DTP3 coverage from 2021-2022 and has cut the number of ZD by around 40%, but still has high ZD burden.[233] Some never-eligible countries (as well as former-eligible countries) such as Venezuela and Lebanon are eligible for and have received MICs fragility support, which has a different scope to other MICs support, on the basis of their fragile state.

2 **Finding 2.2: Common factors that contributed to backsliding in MICs countries included COVID-19, vaccine hesitancy/demand, limited accessibility of RI, perceived inaccuracy of RI data, and insufficient resources for RI (financial and human) – most of which are broader health system constraints. MICs backsliding applications target these issues, but implementation is limited to date, and many stakeholders raised concerns about the ability of MICs support, which is designed to be targeted and catalytic, to address these factors in contexts where broader system strengthening is not taking place.** COVID-19 was the most cited reason for backsliding in MICs case study countries. This and other commonly cited factors included vaccine hesitancy/demand issues, data issues and insufficient resources/capacity were reportedly issues in both former- and never-eligible countries.[234] Some former-eligible i.e. post transition MICs struggled to maintain RI even before COVID-19, with insufficiently strong RI and broader health systems and inadequate financial resources and management in place to sustain RI performance.[235] In this context, Gavi CDS funding was seen as especially useful in both former and never-eligible MICs in supporting some broader RI/health system functions such as cold-chain infrastructure, health care worker training and RI data systems.[236] Some stakeholders however raised concerns that in some contexts, for example Angola, that health system strength and capacity is not sufficient and that MICs support as currently designed is insufficient to mitigate where transition from regular Gavi support has in essence been unsuccessful.[237]

[231] Although it is acknowledged the volatile and evolving context makes this hard to judge for certain.
[232] KIs x 4, 04 - Appendix 1 - HPV Operationalisation Update.pdf.
[233] WHO (2023), Country WUENIC estimates, DTP3 and DTP1.
[234] KIs x 12.
[235] WHO (2023) WUENIC data; KIIs x 4.
[236] KIs x 6.
[237] KIs x 3.

Table 23: Backsliding and ZD summary and MICs application status, former-eligible MICs[238]

Region	Country *(Bold = case study country)*	>5pp backsliding (>5+/>5- DTP3 change)				Zero Dose (>10,000 or 10%)			TI*/ ZD Application Status (Applied/ Not Applied/ Interested)
		'15-'19	'19-20	'19-21	'19-'22	2021 Number	2022 Number	2022 %	
Africa	**Angola**	**-2**	**-6**	**-12**	**-15**	**553,309**	**614,172**	**47%**	**Disbursed**
Europe	Armenia	-2	-1	+1	+1	1,337	1,293	4%	
	Azerbaijan	-2	-15	-5	-11	10,019	12,188	10%	
	Georgia	0	-6	-9	-9	1,502	2,438	5%	
	Moldova	0	-5	-4	-3	4,906	4,020	11%	
	Ukraine	+57	+1	-2		30,104	72,071	22%	
	Uzbekistan	-3	-1	+2	+3	7,986	7,684	1%	
Americas	Bolivia	-14	-7	-5	-6	64,400	64,555	25%	Disbursed
	Cuba	0	0	0	0	1,001	993	-	
	Guyana	+4	0	-1	-1	321	316	2%	
	Honduras	**-10**	**-8**	**-11**	**-10**	**38,537**	**43,031**	**20%**	**Disbursed**
	Nicaragua	0	-6	-11	-6	16,677	8,260	6%	
SE Asia	Bhutan	-2	-2	+1	+1	95	189	2%	
	Indonesia	**+1**	**-8**	**-18**	**0**	**1,149,784**	**570,969**	**13%**	**Disbursed**
	Timor-Leste	+10	-4	-4	-4	4,164	4,184	13%	
Western Pacific	Mongolia	-1	-2	-3	-3	2,126	2,068	3%	
	Viet Nam	-8	+5	-6	+2	187,315	113,843	8%	With IRC
	Kiribati	+19	-7	-5	-6	68	136		

** Only the following countries are eligible for TI support: Angola, Indonesia, Honduras, Bolivia and Vietnam*

[238] KIIs: Country Teams x 4, Gavi Secretariat x 2, Alliance country/regional partners x 6, Country MoH x 2; Gavi (2023), 11 - Annex A - MICs Approach Progress Dashboards (PPC23); 11 - Update on Middle-Income Approach (PPC23); 11 - Update on Middle-Income Countries Approach (PPC23) PowerPoint.

Table 24: Backsliding/ZD summary, never-eligible MICs (not eligible for backsliding/ZD support) [239]

Region	Country *(Bold = case study country)*	>5pp backsliding (>5+/>5- DTP3 change)				Zero Dose (>10,000 or 10%)		
		'15-19	'19-20	'19-21	'19-'22	2021	2022	
						Number	Number	%
Africa	Algeria	-7	-4	-7	-11	74,807	81,904	9%
	Cabo Verde	+3	-3	-3	-3	691	294	3%
	Eswatini	0	-7	-13	+7	3908	275	1%
Europe	**Kosovo**	*	*	*	*	*	*	*
Americas	Belize	+4	-19	-15	-14	1211	642	9%
	Dominica	+1	-3	-7	-7	48	48	5%
	El Salvador	-4	-14	-12	-15	22,102	23,868	24%
	Grenada	+2	-22	-17	-17	315	407	21%
	St Lucia	-7	-6	-12	-11	225	161	8%
	St Vincent	-2	0	-5	-5	40	39	3%
SE Asia	Maldives	-1	+1	-2	+1	219	72	1%
Eastern Mediterranean	Iran	+1	0	-1	0	23,858	11,622	1%
	Egypt	+2	-1	+1	+2	72,910	72,577	3%
	Tunisia	0	-1	-1	-1	1950	1905	1%
	Morocco	0	0	0	0	6417	6346	1%
	Jordan	-22	-12	-	+3	47,450	14,189	22%
Western Pacific	Marshall Isl.	-6	+3	+7	+7	24	30	4%
	Micronesia	+6	+5	-6	-9	116	186	8%
	Fiji	-2	+2	+2	+2	176	175	1%
	Philippines	**-3**	**0**	**-14**	**+1**	**1,047,996**	**637,202**	**26%**
	Samoa	-12	+21	+17	+8	238	178	3%
	Tonga	+3	0	0	0	24	24	1%
	Tuvalu	-4	+3	+2	-1	3	3	1%
	Vanuatu	+10	-12	-28	-22	2676	1582	17%

Table 25: MICs Approach Countries eligible for Fragility MICs support Overview

Region	Country *(Bold = case study country, NE = never-eligible; FE = former-eligible)*	>5pp backsliding (>5+/>5- DTP3 change)			Zero Dose (>10,000 or 10%)				Fragility MICs Application Status (Applied/ Not Applied/ Interested)
		'15-19	'19-20	'19-21	'19-'22	2021	2022		
						Number	Number	%	
Americas	Venezuela (NE)	-23	-10	-8	-8	120306	116825	27 %	
Eastern Med.	Lebanon (NE)	0	-12	-16	-16	10,079	9685	12 %	
	Occ. Pal. Terr. (NE)	0	-1	-4	-1	1433	1436	1%	
SE Asia	**Sri Lanka (FE)**	**0**	**-3**	**-3**	**-1**	**12,175**	**5,999**	**2%**	**Approved**

[239] KIIs: Country Teams x 4, Gavi Secretariat x 2, Alliance country/regional partners x 6, Country MoH x 2; Gavi (2023), 11 - Annex A - MICs Approach Progress Dashboards (PPC23); 11 - Update on Middle-Income Approach (PPC23); 11 - Update on Middle-Income Countries Approach (PPC23) PowerPoint.

Table 26: Former-eligible country past, current and likely status of vaccine introductions by the end of 2025, with MICs application status[240]

Region	Country *(Bold = case study country, F = fragile)*	Antigens introduced/ not introduced/ possibly introduced[241] *(2025 based on stakeholder predictions; G indicates with Gavi MICs support)*									NVI Application Status (Applied/ Not Applied/ Interested)	
		RV			PCV			HPV				
		'21	'23	'25	'21	'23	'25	'21	'23	'25	TA	VCF
Africa	**Angola**									G		
Europe	Armenia											
	Azerbaijan			G						G		
	Georgia											
	Moldova											
	Ukraine (F)			G			G			G		
	Uzbekistan											
Americas	Bolivia											
	Cuba						G			G[242]		With IRC[238]
	Guyana											
	Honduras											
	Nicaragua											
SE Asia	Bhutan											
	Indonesia		**G**	**G**	*****	**G**	**G**	*****	**G**	**G**	**Approved**	
	Sri Lanka (F)											
	Timor-Leste					G[243]				G[244]		
Western Pacific	Mongolia									G[245]		
	Viet Nam									G		
	Kiribati											

** HPV was introduced in Indonesia at sub-national level in some provinces in 2017. Full coverage (two doses) has remained very low, but first dose coverage reached 29% nationally in 2022.*

[240] KIIs: Country Teams x 2, Gavi Secretariat x 2, Alliance country/regional partners x 4, Country MoH x 3; Gavi (2023), 11 - Annex A - MICs Approach Progress Dashboards (PPC23); 11 - Update on Middle-Income Approach (PPC23); 11 - Update on Middle-Income Countries Approach (PPC23) PowerPoint.

[241] New and underutilized vaccines introduction (who.int)

[242] Cuba reportedly intend to apply for HPV support; so far they have applied for PCV support

[243] With Gavi Post-transition, not MICs support; 04 - Strategy Programmes and Partnerships Progress Risks and Challenges (2023)

[244] With Gavi Post-transition, not MICs support; 04 - Appendix 1 - HPV Operationalisation Update.pdf

[245] 04 - Appendix 1 - HPV Operationalisation Update.pdf

Table 27: Never-eligible country past, current and likely status of vaccine introductions by the end of 2025, with MICs application status[246]

Region	Country *(Bold = case study country, F = fragile)*	Antigens introduced/ not introduced/ possibly introduced[247] *(2025 based on stakeholder predictions; G indicates with Gavi MICs support)*									NVI Application Status (Applied/ Not Applied/ Interested	
		RV			PCV			HPV				
		'21	'23	'25	'21	'23	'25	'21	'23	'25	TA	VCF
Africa	Algeria											
	Cabo Verde											
	Eswatini								G		Approved	
Europe	**Kosovo**			**G**			**G**			**G**	**Approved**	**Approved**
Americas	Belize											
	Dominica											
	El Salvador											
	Grenada									G		
	St Lucia											
	St Vincent											
	Venezuela (F)											
SE Asia	Maldives											
Eastern Medi-terranean	Iran			G			G					Approved
	Egypt											
	Tunisia									G		
	Morocco											
	Jordan						G					
	Lebanon (F)											
	Occ. Pal. Terr.											
Western Pacific	Marshall Isl.											
	Micronesia											
	Fiji											
	Philippines							*	*	G		
	Samoa											
	Tonga											
	Tuvalu											
	Vanuatu											

** HPV was introduced in the Philippines at sub-national level in some provinces in 2015. Full coverage (two doses) has remained very low, but first dose coverage reached 23% nationally in 2020 based on roll-out in target provinces, but dropped down to 4% in 2021 and 0% in 2022.*

2 **Finding 2.3: While MICs implementation is making good progress, there are concerns about the sustainability of these results, and the risks of pushing countries to introduce new vaccines when financial and systems sustainability is not in place and prices of vaccines are not clear.** As outlined in Table 23 and Table 24, MICs approach implementation against targets is broadly on track. Implementation from the perspective of budget approval and disbursement is also viewed as on track given delays to roll-out, 44% of US$ 301 million budget programmed by the end of September 2023 and 21% disbursed.[248] Maintaining approval and disbursement levels is likely, however dependent on successfully engaging with and disbursing funds to additional large population countries with MICs NVI support, such as Philippines, Angola, Venezuela and Tunisia. There are however potential implications of this, particular in the context of some stakeholder

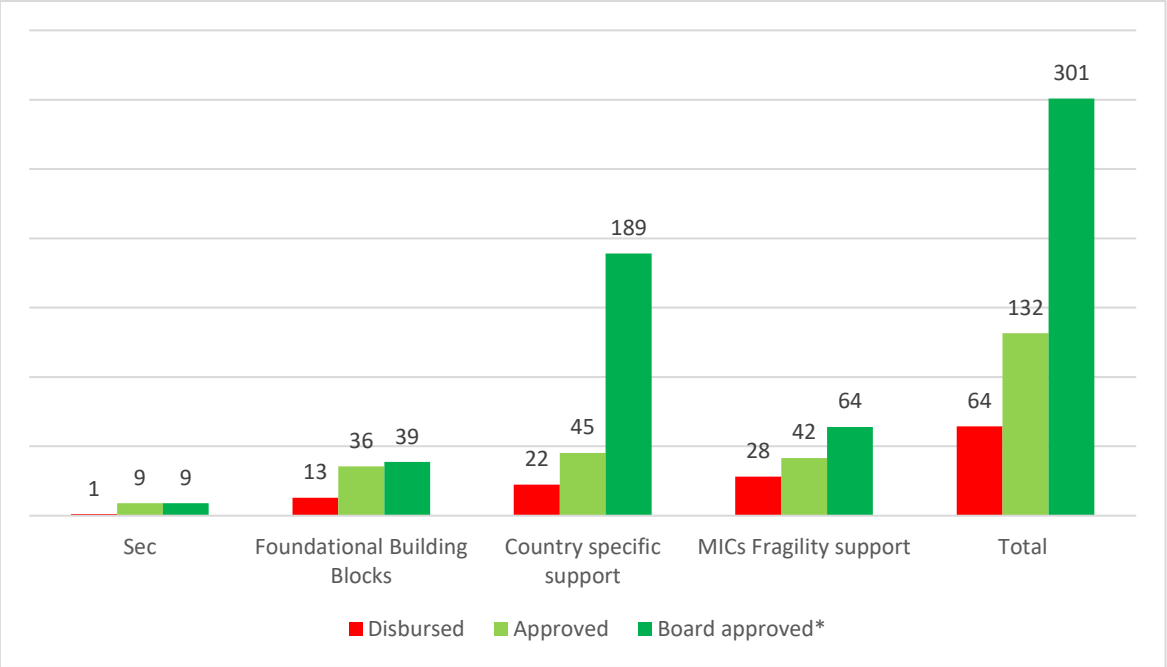
[246] KIIs: Country Teams x 2, Gavi Secretariat x 2, Alliance country/regional partners x 4, Country MoH x 3; Gavi (2023), 11 - Annex A - MICs Approach Progress Dashboards (PPC23); 11 - Update on Middle-Income Approach (PPC23); 11 - Update on Middle-Income Countries Approach (PPC23) PowerPoint.

[247] New and underutilized vaccines introduction (who.int)

[248] 11 - Update on Middle-Income Countries Approach (PPC23) PowerPoint, 11 - Update on Middle-Income Approach (PPC23)

concerns about overall prioritisation of countries with bigger populations over those with larger proportion of ZD and/or bigger issues with child mortality, and of the risks around NVIs in fragile countries (Venezuela) and those with weak health systems (Angola and Philippines).

Figure 18: MICs approach budget utilisation by August 2023 (US$ million)



One critical area of work which is delayed is the planned MICs related support to UNICEF's MICs Financing Facility (MFF). The MFF was established in 2022 by UNICEF SD, the aim of which is to "allow countries [including MICs] to benefit from UNICEF's procurement, scale, access, market expertise, and affordable pricing". MICs approach support was intended to leverage the MFF to support Gavi's overall MICs objectives, but there have been delays to finalising this engagement. This has been acknowledged as an area of concern, with the recent MICs PPC report noting that "*questions about pricing visibility for former-Gavi countries continue to arise…[and] never-eligible Gavi countries are experiencing more barriers related to limited price visibility and affordability*".[249]

Multiple stakeholders also raised this as a concern given a perceived lack of easily available vaccine pricing and product availability information preventing countries from making evidence-based decisions about NVIs, and the relatively high prices of vaccines particularly for never-eligible countries of particular concern.[250] The lack of certainty and potential high cost of sustaining new vaccine introductions was the sustainability concern cited most, but broader concerns about the sustainability of MICs support were also raised. These predominantly focussed on concerns about lack of sufficient health system strength/resilience in terms of having the financial and human resources to maintain an ever-broader RI schedule.[251] Some stakeholders were particularly concerned about the push for new vaccine introductions in large never-eligible countries such as the Philippines, where health system capacity was acknowledged as limited by all in-country stakeholders.[252] For fragile MICs, there were also specific concerns about whether these countries really would be able to revert to more sustainable (ideally domestic) support for their RI programs in

[249] 11 - Update on Middle-Income Approach (PPC23).docx, 11 - Update on Middle-Income Countries Approach (PPC23).ppt
[250] KIs x 5.
[251] KIs x 7.
[252] KIs x 3.

the medium term,[253] and IRC reviews of several MICs proposals also identified concerns around sustainability.[254]

3. Looking forward/implications

The following findings cover case study questions 2b and 2c and contribute to EQ2, EQ5, EQ9, EQ10, EQ15.

3 **Finding 3.1: Broader health system challenges within both former and never-eligible MICs are seen as likely to persist into the 6.0 strategic period. Overall financial sustainability of RI in MICs in the face of high/uncertain vaccine pricing is seen as particular challenge.**

As previously outlined, broader health system challenges are already seen as a key barrier to addressing backsliding and supporting sustainable vaccine introductions. Several stakeholders felt that this barrier is likely to remain a key one moving into the 6.0 strategic period, especially as more countries move towards transition.[255] The lack of clarity around vaccine prices for transitioned countries beyond 2025 is seen as a risk not just for individual countries, but also as a potential reputational risk for Gavi If successful transition is affected.[256] Never-eligible countries were referenced as having even less certainty, having to pay up to five times Gavi prices for vaccines, making the VCF support offered under the MICs approach relatively insignificant, and the importance of countries having strong political commitment and health system resilience key.

3 **Finding 3.2: Some MICs are more interested in local vaccine production over procurement from UNICEF SD. The potential consequences of MICs choosing to produce their own vaccines, at least partly due to concerns around/limited visibility of vaccine pricing, rather than use Gavi/UNICEF pooled vaccines has implications for Gavi's overall focus and model moving forward.**

Some larger former- and never-eligible MICs with existing vaccine manufacturing capacity are reportedly more interested in domestic manufacturing of the vaccines targeted by the MICs approach rather than procurement through UNICEF SD/ VCF support.[257] Government views on this were not directly available, but core partners and country teams referenced this being behind some delays or lack of applications for MICs support from some countries.[258] Similarly the rationale for such decisions could not be established through interviews. Some stakeholders felt it may be considered more sustainable given the lack of transparency/clarity over vaccine pricing, particularly for never-eligible MICs, and also in the wake of the experience of COVID-19, where vaccine nationalism affected the flow of vaccines between countries,[259] while others felt that it may be due to individual countries' industrial/manufacturing policies or regulations, or laws around procurement.[260]

3 **Finding 3.3: Increased vaccine hesitancy in some contexts, such as concerns around lack of halal vaccines in Muslim countries, and around specific antigens (e.g. dengue as a result of the Philippines experience) is a factor which may need more attention moving forward.**

[253] KIs x 3.
[254] 09 - Appendix 4 - IRC Review September 19-29_DEBRIEFING_Final.
[255] KIs x 6.
[256] KIs x 4; 11 - Update on Middle-Income Approach (PPC23).docx.
[257] KIs x 4.
[258] KIs x 3.
[259] KIs x 4.
[260] KIs x 2.

Vaccine hesitancy/demand was seen as a key driver of backsliding in all MICs case study countries, but specific reasons for this were identified in some contexts. Specifically in Indonesia, concerns around the use of porcine products in vaccines meaning they are not halal was seen as driving increased hesitancy, with a risk of this increasing further through the actions of religious lobby groups. Broader multi-antigen hesitancy was also identified as a driver of increased overall hesitancy, with implications for the use of DTP3 as a measure of coverage. In the Philippines, the Dengvaxia scandal was also seen as driving broader hesitancy, making any new vaccine introductions in that context seen as particularly risky.

3 **Finding 3.4: Overall eligibility for and design of MICs backsliding support has pushed focus on countries and provinces with higher numbers of ZD. This risks increasing inequities by neglecting under-served hard-to-reach communities with lower numbers but higher proportions of ZD and under-vaccinated children.**

MICs support is limited and thus intended to be catalytic, and as a result backsliding support is limited in geographic scope, and countries are asked to prioritise and target subnational regions.[261] Several stakeholders raised a concern that this pushes countries to prioritise the areas with the highest numbers of ZD children, in order to maximise value for money and the number of ZD children reached.[262] An unintended consequence of this is that ZD children in the most remote and hard-to-reach areas are likely to be left out due to the relative high costs of reaching them. Because of the high costs, these children are also unlikely to be reached through existing government efforts. Some stakeholders saw this as in effect working against Gavi's equity principles.[263]

[261] Report to the board June 2022_eng (Board22).pdf
[262] KIs x 5
[263] KIs x 5

Annex 11: Thematic study – Domestic Resource Mobilisation and Sustainability

Introduction

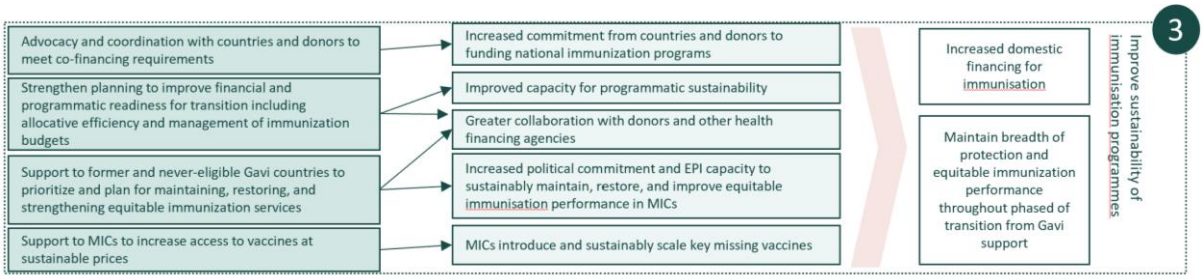
Euro Health Group (EHG) was commissioned by Gavi to undertake a Mid-Term Evaluation (MTE) of Gavi 5.0. The objectives of the MTE were to:

- 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 prioritized strategic goals (SGs) and objectives and identify areas for course correction; and
- 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).

During the MTE inception phase, we assessed the evaluability of our key Evaluation Questions (EQs), listed in Annex 1. We identified the need to strengthen our evidence base in specific areas, including resource mobilization and sustainability. Data collection against the scope set out here took place in September-October 2023.

The third strategic goal of Gavi 5.0/5.1 is to improve sustainability of immunization programmes through the following objectives: (1) strengthen national and subnational political commitment to immunization, (2) promote domestic public resources for immunization and primary health care to improve allocative efficiency, and (3) prepare and engage self-financing countries to maintain or increase performance (see Figure 19). The success of this strategic goal is measured through the percentage of countries that fulfil co-financing commitments by the end of the calendar year, prevention of backsliding in RI coverage in Gavi-transitioned countries, and vaccine introductions (HPV, PCV, and Rota) catalysed in Gavi-transitioned and never-Gavi eligible countries). The following analysis will highlight the status of this strategic goal and assess whether the current model of reaching sustainability is fit for purpose.

Figure 19. Theory of Change for Strategic Goal 3



Rationale

To date, Gavi has largely relied on country co-financing of RI and other vaccines as a proxy for the sustainability of its vaccine investments. Starting at US$ 0.20 per dose in initial self-financing countries, low-income countries (LICs) entering preparatory transition pay an increasing proportion of procurement costs (starting at 10% and rising with country income level) until graduation. Co-financing has been a core Gavi policy since 2008 and has generally been a success story, holding up well during the pandemic. Co-financing ensures that all Gavi countries have some financial ownership of vaccine procurement and helps to protect the vaccine budget against reallocation. However, we argue in this paper that it is an insufficient proxy of country capacity to maintain, accelerate or sustain vaccine investments.

A recent World Bank paper[264] notes that globally, real per capita central government health spending generally soared during the first two years of the pandemic and in 2021, it stood at 25% above 2019 levels. However, in 2022, real per capita government health spending contracted on average, from its peak of 25% to only 13% above the 2019 level, close to its pre-pandemic trajectory. The reversal was even starker in the priority that governments gave to health. On average, the central health share in general government spending tumbled, from its maximum of 17% to only 5% above the 2019 baseline, falling back to its pre-pandemic trajectory. Hence, it was no longer the prioritization of health, but growth in general government spending that primarily helped bolster 2022 central government health spending above the 2019 level. The rapid decline of real central government health spending may have been a risky and costly retreat, and the World Bank notes that the stark reversal in the priority given to health in government spending does not bode well for global health security and progress toward the health-related Sustainable Development Goals (SDGs), especially in countries where the macroeconomic outlook remains concerning, and limited capacity to increase government spending. Overall, the World Bank projects that 41 governments (mainly LICs) will spend less on health between now and 2027 than they did in the pre-pandemic period; in 69 countries, spending will remain almost on par with pre-pandemic levels.

The post-COVID-19 de-prioritisation of health has occurred as the fiscal and economic conditions in many of the Gavi-57 and MICs countries have deteriorated markedly. Heavy indebtedness, supply shortages, inflation and other economic shocks have placed a large burden on many Gavi countries. As of August 2023, 26 countries (many in sub-Saharan Africa) were in, or at high risk of debt distress (unable to meet financial obligations/in default) leading to loss of market access and higher borrowing costs, and many of these countries are Gavi recipients (see Annex 1 of this study).[265] Some former-Gavi-eligible MICs such as Sri Lanka and never-eligible MICs such as Grenada, are also in debt distress, or default. Debt distress, together with stalled debt restructuring negotiations, appears to have implications for co-financing capacity in pre-transition Gavi countries, as well the capacity to maintain basic health infrastructure in support of RI, vaccination of ZD children and the introduction of new vaccines in current Gavi countries, as well as former- and never-eligible MICs (see Findings).

Turning specifically to vaccines, deteriorating economic conditions are not necessarily a prelude to falling vaccine investments and some KIs noted that since total domestic vaccine expenditures are only about 2% of total public health expenditures and these investments have very high returns, governments will protect these investments against cuts. However, since a large proportion of government health expenditures in LICs (US$56 p.c. in Zambia, one of our focus countries) are non-discretionary (salaries, equipment, essential drugs etc.), discretionary costs such as vaccine spending are vulnerable to cuts, particularly for the resources needed to deliver vaccines (e.g. transport, fuel).

Focusing specifically on ZD children, where Gavi has set a target of reducing the numbers by 25%, or 3.5 million children by 2025, the Gavi 2022 Risk and Assurance Report notes that there is a very high risk that "*Many countries may have insufficient EPI capacity and capabilities to maintain, restore and strengthen immunisation programmes and reach zero-dose communities"*. One aspect of this risk (supported by our country interviews, see below) is financial. ZD programme costs appear to have been largely estimated in terms of vaccine procurement costs, without considering the additional, relatively high in-country costs of reaching the ZD children – of the circa 14 million children

[264] Kurowski C, Evans DB, Tandon A, Eozenou PHV, Schmidt M, Irwin A, Cain JS, Pambudi ES & Postolovska I. From Double Shock to Double Recovery – Implications and Options for Health Financing in the Time of COVID-19; Technical Update 2: Old Scars, New Wounds. The World Bank Group. September 2022.
[265] IMF. List of LIC DSAs for PRGT-Eligible Countries. 31 August 2023. https://www.imf.org/external/pubs/ft/dsa/dsalist.pdf

unvaccinated for DTP1 (2022),[266] many are in hard to reach or in conflict-affected locations, raising considerably the marginal cost per dose.[267]

To date, we have been unable to find in the literature, or Secretariat documentation, any estimates of these additional in-country costs (e.g., for equipment, vehicles, fuel, campaigns, HR) to achieve the 25% reduction, but evidence from our country KIIs suggests that the lack of financial resources to meet these costs is impacting the ZD agenda. This may also be an issue in Gavi-eligible and former-eligible MICs,[268,269] which may need to weigh spending the additional resources on the "final mile of ZD" rather than on new, but relatively expensive vaccines, such as malaria.

Finally, we note that Gavi has been very successful in mobilizing donor resources, not least to support COVID-19 vaccines. But according to the above cited Risk and Assurance Report, confirmed by our interviews with Board members, there is a high likelihood that this favourable scenario may not continue in the next funding cycle, as donor countries face economic headwinds and multiple competing priorities. This could clearly impact Gavi 6.0.

In this context, Gavi is actively exploring approaches to improve financing and capacity to respond to future pandemics. These include partnering with the international financial institutions (World Bank, regional development banks, EIB)[270] and Development Finance institutions such as the US Development Finance Corporation, the IFC and Med Access, as well as continuing the successful IFFim initiative. One other important initiative is to find mechanisms to frontload Gavi commitments to enable liquidity of pledges without compromising the Gavi balance sheet. There is also a cohort of countries entering post-transition and recognition during the preparation of Gavi 6.0 that these countries will need assistance to ensure sustainability during the period of economic downturns and disruptions.

Methods

The study was conducted through a mixed-methods approach consisting of thematic analyses of documents and KIs, triangulated with quantitative data analyses. Data collection consisted of:

- analysis of existing literature and data on resource mobilization and sustainability;
- interviews with 21 global KIs representing the Gavi Secretariat, Board members and Alliance Partners including WHO, UNICEF, and the World Bank; and
- remote case studies in Ethiopia, Ghana, Zambia, and Sri Lanka, consisting of document reviews and 16 KIIs.

[266] Gavi. Zero dose children: almost 14 million get no vaccines. 28 April 2022. 'Zero dose' children: almost 14 million get no vaccines | Gavi, the Vaccine Alliance

[267] USAID & Momentum. Routine Immunization Transformation and Equity. October 2022.

[268] As of September 2022, the Gavi MICs approach offers support for: (1) targeted interventions to prevent backsliding in former Gavi-eligible countries that have seen significant reductions in coverage, and (2) new vaccine introductions of HPV, PCV, and RV in former- and never-eligible countries through TA, flexible funding for one-off costs of introduction such as campaigns, and financing for half of the first birth (or target) cohort.

[269] Gavi. Gavi's approach to engagement with middle-income countries. September 2022. *Gavi-MICs-Approach-Overview.pdf; accessed 17 November 2023.

[270] We note however that countries will have multiple priorities for concessional financing so that there may be limited additional funds from these sources.

Findings

1. Trends in health and immunization financing

1 **Finding 1.1: Gavi-eligible countries are expected to experience fiscal challenges and declining health expenditures in upcoming years, due to increased debt distress and macroeconomic shocks since 2020, including COVID-19.** Since 2020, countries have faced macroeconomic shocks including COVID-19, food prices and commodity inflation, wars, increasing public debt and interest payments, and strained health resources due to the pandemic.[271]

Kurowski et al. (2022) reported that without historically high prioritisation of health spending, in 41 general government expenditure (GGE) contraction LICs and LMICs,[272] per capita government health spending is projected to decline annually from 2019 to 2027 (see Annex 1 of this study for a full list of Gavi countries, GGE status, and risk of debt distress).[273] In another 69 GGE stagnation countries,[274] GHE per capita is expected to grow slowly.[275] Impacts of contraction will be greater impact for LICs and LMICs, increasing inequalities in health financing. In addition, while LMICs in the expansion group[276] will be able to spend more on health than those in stagnation and contraction groups, they also have the largest absolute impact of increased public debt service and are therefore, also likely to have a constrained fiscal space.

While trends in immunisation expenditures are not generally available, negative trends in general and in health expenditures are likely to impact the sustainability of immunisation programmes in Gavi countries. Notably, despite meeting increasing co-financing payments, countries in accelerated transition are facing increased financial challenges: 20% are in contraction, 50% are in stagnation, and 60% are at high risk, or in debt distress (see

[271] Kurowski C, Evans DB, Tandon A, Eozenou PHV, Schmidt M, Irwin A, Cain JS, Pambudi ES & Postolovska I. From Double Shock to Double Recovery – Implications and Options for Health Financing in the Time of COVID-19; Technical Update 2: Old Scars, New Wounds. The World Bank Group. September 2022.
[272] Contraction countries: projected to have a decrease in spending capacity through 2027, with per capita GGE in 2027 below pre-COVID-19 levels.
[273] Kurowski C, Evans DB, Tandon A, Eozenou PHV, Schmidt M, Irwin A, Cain JS, Pambudi ES & Postolovska I. From Double Shock to Double Recovery – Implications and Options for Health Financing in the Time of COVID-19; Technical Update 2: Old Scars, New Wounds. The World Bank Group. September 2022.
[274] Stagnation countries: projected to have positive but relatively slow growth in GGE per capita, with an average annual rate of growth from 2019 to 2027 below the average growth rate of countries in its income group in the ten years before COVID-19 hit.
[275] Ibid.
[276] Countries projected to have relatively strong growth in GGE per capita, exceeding the average annual growth rate of the relevant income group in the ten years prior to COVID-19.

Table 28). Interviewees noted that despite success in maintaining RI and new vaccine introductions in previous graduating countries, the upcoming set of countries transitioning from Gavi support face unique financial challenges. In the context of constrained fiscal space, it is possible that short-term priorities may take precedence over priorities with long-term gains such as vaccines.

Table 28. Government expenditures and debt distress in accelerated transition countries

	DTP3 Coverage (2022)[277]	Co-Financing / GGHE-D (2023)[278]	GGE (2022)[279]	Risk of Debt Distress (2023)[280]
Newcomers				
Bangladesh	98%	0.69%	Expansion	Low
Ghana	99%	0.69%	Expansion	In debt distress
Kenya	86%	0.24%	Stagnation	High
Cote d'Ivoire	76%	0.79%	Expansion	Moderate
Djibouti	59%	0.20%	Stagnation	High
Urgent				
Solomon Islands	89%	0.61%	Contraction	Moderate
Sao Tome	97%	0.69%	Stagnation	In debt distress
Lao PDR	80%	1.58%	Stagnation	In debt distress
Tailored				
Nigeria	62%	1.88%	Stagnation	-
Papua NG	36%	-	Contraction	High

2. Measuring sustainability of immunization financing

1 **Finding 2.1: Gavi currently very largely bases its measure of sustainable immunisation financing on Gavi countries meeting co-financing requirements, which is not reflective of the overall sustainability of immunisation programmes, including the costs of traditional vaccines and delivery. Gavi does not study the overall costs of immunisation in low- and lower middle-income countries beyond the procurement costs.** Despite its appearance in Gavi documents, we could not find a Gavi definition of sustainable immunisation financing. We therefore use the World Bank definition: *spending needs versus the availability of funding in the medium-term (five to ten years), also considering possible improvements in the efficiency of funding*.

While sustainability is one of Gavi's four strategic goals, current tracking of immunisation financing is limited to the fulfilment of co-financing obligations. Co-financing has largely been a success, with nearly all countries meeting co-financing obligations despite recent financial challenges. The highest performance in five years was noted on 30 June 2023, with 65% of co-financing paid, despite total co-financing obligations being 36% higher than in 2022.[281] In addition, most co-financing obligations are covered by domestic resources (90.9% in 2021 and 96.3% in 2022), with the World Bank and UNICEF occasionally providing loans.[282]

[277] WUENIC data, 2022.
[278] Co-financing of Gavi vaccines as a percentage of domestic general government health expenditures
[279] Kurowski C, Evans DB, Tandon A, Eozenou PHV, Schmidt M, Irwin A, Cain JS, Pambudi ES & Postolovska I. From Double Shock to Double Recovery – Implications and Options for Health Financing in the Time of COVID-19; Technical Update 2: Old Scars, New Wounds. The World Bank Group. September 2022.
[280] IMF. List of LIC DSAs for PRGT-Eligible Countries. 31 August 2023. https://www.imf.org/external/pubs/ft/dsa/dsalist.pdf
[281] Gavi Immunisation Financing & Sustainability Team. Co-financing presentation for FCDO. Gavi. September 2023.
[282] Ibid.

> *"It's been puzzling me for a while, but I have yet to see a Gavi study that estimates the costs of immunizing children and adults in all LICs and LMICs (both vaccine and delivery costs), current spending and financing (including Gavi's role). I think this will be critical for a future strategy, including fundraising. We have been tempted to do this, but of course, Gavi should take this on."*
>
> - Alliance KI

However, global data on general vaccine procurement and delivery expenditures is highly limited and of questionable quality. The most recent immunization expenditure report is WHO's 2021 Situation Analysis of Immunization Expenditures, which utilised data collected annually through the WHO-UNICEF Joint Reporting Form.[283] However, the quality and subsequent utility of the data has been criticized for low response rates and inconsistencies when triangulating against other data sources.[284, 285] It is particularly pertinent to collect data on expenditures due to low health budget credibility[286] in many contexts, as expenditures are often found to vary significantly from what is budgeted.[287] For example, health budget credibility was negative in Zambia from 2014-2020, with underspending of 40.7% in 2019 and 26.7% in 2020 and overspending on health by 30.5% in 2021.[288]

Anecdotal evidence from country case studies indicates that, despite timely co-financing payments, traditional immunisations are not always well-funded and may experience stock-outs. While data is limited, traditional immunisations appear to be partially, or fully funded by donors in multiple countries. For example, a UNICEF survey found that in 2016/2017, 56.25% of Gavi-eligible countries in East and Southern Africa and 35% of Gavi-eligible countries in the West and Central Africa region did not fully pay for traditional vaccines and received funding from the World Bank, UNICEF, EU, DFID, and other bilateral donors.[289] KIs and literature have suggested that some countries prioritise payment of Gavi vaccines to the detriment of traditional vaccine funding. In addition, some literature has speculated that Gavi funding may have contributed to a crowding-out of traditional vaccines by increasing resource needs through new vaccine introductions with no significant additional domestic budget allocations.[290, 291]

Box 3: Examples from country case studies

Zambia: While the government has consistently paid co-financing over the years, there have historically been stock-outs of traditional vaccines, that are not fully funded by the government. Anecdotal evidence from interviews suggests that UNICEF has been involved in resource mobilization and these vaccines are now funded by numerous external donors.

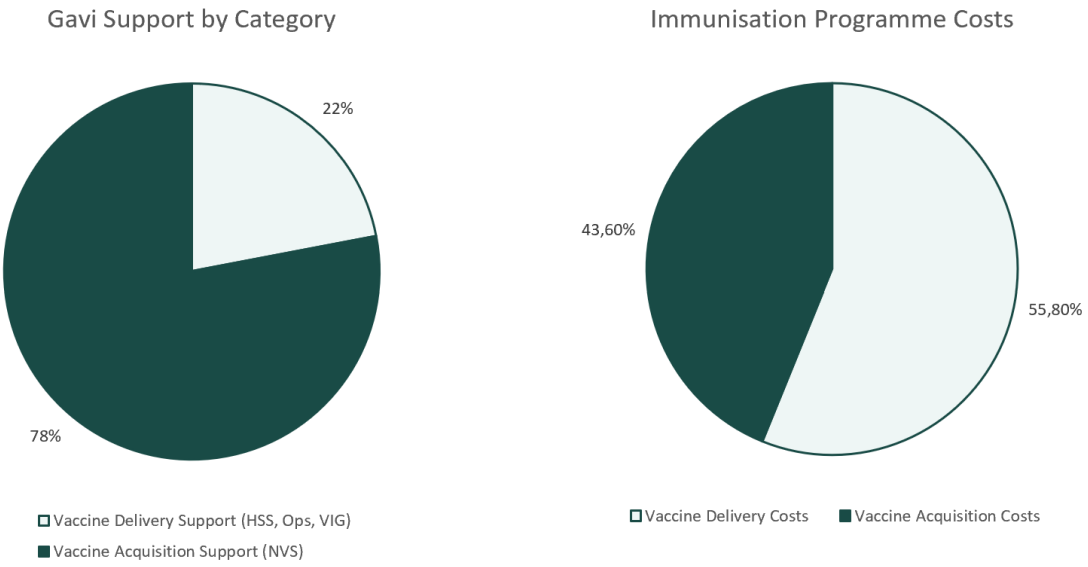
Ghana: The country has experienced delays in co-financing payments and stockouts of traditional vaccines in recent years. While coverage has remained high thus far due to a strong EPI programme, KIs expressed concerns that resulting service disruption would impact coverage and lead to increased outbreaks of vaccine-preventable diseases.

[283] World Health Organization. Situation Analysis of Immunization Expenditures: Key Facts, 2021.
[284] KIs close to the process
[285] UNICEF. WHO-UNICEF Joint Reporting Form: Immunization Financing Indicators Revision Proposal. n.d.
[286] Budget credibility refers to a deviation of government spending from approved budgets.
[287] Griffiths UK, Asman J, Adjagba A, Yo M, Oguta JO & Cho C. Budget line items for immunization in 33 African countries. Health Policy and Planning, 1-12. 2020. doi: 10.1093/heapol/czaa040.
[288] UNICEF Zambia. Health Budget Brief: Key Messages and Recommendations. 2022.
[289] Adjagba A & Griffiths UK. Sources of financing for traditional vaccines used in routine immunization in ESARO and WCARO. UNICEF. February 2018.
[290] Kwesiga B. Sustainable Financing for Traditional Vaccines. UNICEF. July 2023.
[291] Country & Global Partner KIIs

Sri Lanka: Sri Lanka has historically maintained high coverage of routine immunisations since transitioning from Gavi support in 2016. However, due to the ongoing economic crisis, Sri Lanka has been relying upon buffer stocks of routine immunisations for the past year. This resulted in a stock-out of HPV, which had a lower buffer stock, and contributed to a dip in coverage (82% in 2019 to 49% in 2022).[292] The country has now received an Asian Development Bank loan to procure HPV through UNICEF at prices below market value. They have also received Gavi MICs Emergency and Fragility support for the procurement of vaccines for the National Immunization Programme from 2023-2025.

Expenditures on vaccine delivery, which constitute an estimated 55.8% of immunisation programme costs versus 43.6% for vaccine acquisition,[293] are not being systematically tracked by Gavi. This is an area consistently receives less funding from Gavi (constituting approximately 22% of funding in 2023)[294] and other donors, while essential to maintain coverage (see Figure 20).

Figure 20: Immunisation programme costs vs. Gavi support



3. Gavi support for domestic resource mobilisation

3 **Finding 3.1: There is evidence that there may be a funding gap for immunisation programmes, without significant increases in domestic immunisation financing.** Sriudomporn et al. (2023) used projections of immunisation programme costs based on historical data and expected trends in Gavi support to estimate an increasing funding gap of US$ 38.4 billion from 2011-2030 (US$ 8.3 billion from 2011-2017 and US$ 30.0 from 2018-2030).[295] Delivery costs were found to contribute to 86% of the gap.[296] As this only included development and demographic changes and did

[292] WUENIC estimates, HPV Vaccination programme coverage, last dose, females. 2019-2022. https://immunizationdata.who.int/pages/coverage/hpv.html?CODE=LKA&ANTIGEN=&YEAR=; accessed 6 November 2023.
[293] Sriudomporn S, Yoon Sim S, Mak J, Brenzel L & Patenaude BN. Financing and Funding Gap for 16 Vaccines Across 94 Low- and Middle-Income Countries, 2011-30. Health Affairs 42, No.1: 94-104. 2023. doi:10.1377/hlthaff.2022.00343
[294] Kolesar RJ, Spruk R & Tsheten T. Evaluating Country Performance After Transitioning From Gavi Assistance: An Applied Synthetic Control Analysis. 2023.
[295] Sriudomporn S, Yoon Sim S, Mak J, Brenzel L & Patenaude BN. Financing and Funding Gap for 16 Vaccines Across 94 Low- and Middle-Income Countries, 2011-30. Health Affairs 42, No.1: 94-104. 2023. doi:10.1377/hlthaff.2022.00343
[296] Ibid.

not factor in COVID-19-related disruptions and recent financial shocks, it may be an underestimate of the additional funding needed to maintain immunisation programmes.

The Sriudomporn study also projected that domestic funding is expected to increase at a slower rate relative to the decrease in external funding such as Gavi support. Domestic funding is threatened by the projected trends in general government expenditures and debt distress described previously.[297]

2 **Finding 3.2: Gavi supports domestic resource mobilization and sustainability through several funding levers (including PEF-TCA and SFAs), but documentation of impact is limited, and it appears to receive less prioritization than other strategic areas.** Evidence suggests that Gavi's promotion of domestic resource mobilisation has been centred around timely fulfilment of co-financing in initial self-financing and preparatory countries, with increased support for transition planning in accelerated transition countries. Sustainable financing for immunization is a priority area under PEF grants, including strategic focus area (SFA) and foundational support (FS) funding for global/regional partners and targeted country assistance (TCA) funding for in-country partners. Examples of support at the global level are detailed in Box 4 and examples of support at the country level are in Box 5.

Box 4. Examples of Gavi's efforts to support resource mobilisation at the global level[298, 299]

Foundational Support –
UNICEF has supported a limited group of countries with:

- the Gavi 5.0 Domestic Financing Learning Agenda;
- assessing financial sustainability of zero dose through EAF and FPP;
- avoiding stock-outs through pre-financing; and
- preventing default on co-financing obligations.

WHO has received FS funding to:

- conduct, analyse, and strengthen data quality of the electronic Joint Reporting Form on immunization;
- review changing fiscal landscapes in Lao PDR and PNG and identify options for more sustainable financing in the context of donor transition;
- support immunisation financing reviews as part of planned EPI programme reviews in Cambodia and Solomon Islands;
- validate and publish data on PHC spending by funding source on Global Health Expenditure Database 2023;
- technical support to Gavi countries to increase financing for immunization in SEARO; and
- support to Kyrgyzstan and Tajikistan to calculate vaccine resource requirements.

Strategic Focus Areas – Funding used to engage CSOs for advocacy on immunization and PHC financing in Nigeria, Ghana, Madagascar, Kenya, and PNG and testing conditional and/or unconditional (non-) cash transfers to increase use of immunization services in DRC, Cameroon, Nigeria, Lesotho, and Afghanistan.

However, sustainability and domestic resource mobilisation initiatives comprise a relatively small amount of Gavi support compared to other strategic goals and priorities. As of October 2023, support for sustainability comprises 3.93% of SFA disbursements from 2022-2023 (compared to 19% for monitoring and learning and 13.4% for supply chain).[300] Activities related to SG3 comprised

[297] Ibid.
[298] Gavi. SFA progress report – (commitments &disbursements). October 2023.
[299] Gavi. WHO and UNICEF FS Mid-Year Reports. 2023.
[300] Gavi. SFA progress report (commitments &disbursements). October 2023.

approximately 5% of activities under PEF-TCA[301] from mid-2021 to 2022 and 5.9% of activities planned under FS[302] in Gavi 5.0.

Box 5. Examples of Gavi's efforts to support resource mobilisation

In **Zambia**, Gavi has reportedly been involved in generating domestic commitment through high-level advocacy to ensure that co-financing was paid earlier, with an improvement in the timeliness of co-financing payments from December in 2022 to June in 2023.[303] CIDRZ, a local CSO, has also previously received PEF-TCA support to conduct a desk review and workshop for immunisation financing.

In **Ghana**, a country in accelerated transition, there have been more activities aimed to secure domestic resources for immunization. At the time of data collection (October 2023), the Ghanaian government and partners, including Gavi, the World Bank, and UNICEF, had just begun meetings for a National Roadmap for Gavi Transition funded by PEF-TCA support from Gavi. The roadmap is aimed to provide tangible steps to ensure that the government assumes costs for programmatic activities and procurement for transition by 2030. KIs have stated that transition planning will consider the financing of the immunization programme in its entirety, including traditional vaccines. Gavi has also previously partnered with the World Bank and UNICEF for immunization financing activities, including a situational analysis of vaccine financing in Ghana and the costs of introducing new vaccines, published in May 2023. Gavi has also partnered with Hope for Future Generations, a local CSO, for increased immunization funding at the parliament level and commitment for the introduction of new vaccines such as HPV.

There is also documentation of Gavi's efforts to secure domestic funding for immunisations in **Nigeria** (which has an extended 10-year accelerated transition period from 2018-2028), where Gavi has engaged with government and external partners to develop a three-pronged approach consisting of (1) a transition assessment of context, financing trends, and capacities, (2) transition planning targeting immunization coverage and PHC strengthening metrics, strategies and resource requirements, and accountability between government donors and partners, and (3) monitoring and accountability, including development of an accountability framework, political commitment for financing, and a resource mobilization strategy. [304] As a result, there have been increased allocations to vaccine financing in the Service-Wide Votes and secured immunization financing as a first-line charge in the National Budget.[305]

While there are efforts to advocate for increased and sustained domestic financing for resource mobilization and prepare countries for transition, KIs have expressed the need for increased systematic support for evidence-based budgeting and execution to maximise immunization programme sustainability. KIs in initial self-financing countries also expressed a desire for increased support to mobilise domestic financing for immunization programmes beyond co-financing, including support for advocacy to the Ministries of Health and Finance.

[301] Gavi. PEF-TCA milestone data; mid-2021-2022. 2022.
[302] WHO and UNICEF FS Mid-Year Reports. 2023.
[303] Gavi. CP MPM data. 2022-2023. Accessed 28 November 2023.
[304] Lambo K, Salau G, Wiwa O, Daradara K, Unogu S, Mbogu A, Mngemane S, Ilomuanya S, Crawford J & Atuhaire B. Mapping the Pathway Towards Sustainable Immunization Financing: Insights into Nigeria's Continued Vaccine Financing in Light of Transition from Gavi's Support. IHEA & Immunization Economics.org. July 2023.
[305] Ibid.

In addition, even if there is government commitment for domestic resources for immunization, as previously mentioned, transitioning countries face a context of declining fiscal capacity to support immunization programmes. For example, in Sri Lanka there is reportedly a budget line for the immunization programme within the Ministry of Health,[306] but there is insufficient funding due to the economic crisis. In this context, advocacy will likely not be sufficient as the sole method of increasing or maintaining domestic allocations to immunisation financing and will likely require an integrated approach leveraging the skills of core Alliance partners and CSOs.

> *"In my view, advocacy and accountability alone will not do the trick… given the general macro-fiscal outlook, we believe that a multi-pronged approach is necessary."*
> - Alliance KI

In the absence of systematically collected and robust data on immunization programme expenditures, it will also be challenging to monitor any impacts of domestic resource mobilization efforts. In general, monitoring of results of PEF-TCA, FS, and SFA support is limited.

3 **Finding 3.3: While not a major focus of Gavi programming, health spending inefficiencies are also a consideration when advocating for increased domestic health financing in a constrained fiscal space.** A study published by Garcia-Escribano et al. (2022) reported that emerging markets have the most to gain from improving health spending efficiencies, as they could save 1.4% of their GDPs on average, and that low-income developing economies could save 1% of their GDPs by reducing inefficiencies.[307] The study also found that there are several determinants of health spending inefficiencies, including universal health coverage, income inequalities, and corruption.[308] This is not currently a major focus of Gavi programming, although in light of the constrained fiscal spaces and large financial needs faced by many Gavi countries, it is increasingly relevant to consider funding interventions and technical assistance to maximise potential gains in immunisation spending efficiency.

2 **Finding 3.4: Immunisation delivery is at-risk in the context of high inflation and declining domestic resources.** Increasing costs of fuel and human resources (per diems and payment) associated with high inflation) were reported as key barriers to immunisation delivery by key informants in Zambia and Ghana. Kis in Zambia also suggested that annual health expenditures had not adequately adjusted to account for inflation. While data on the costs of immunisation service delivery are limited, a ThinkWell study on campaign costs in Sierra Leone and Nigeria found that per diems and transport costs constituted the majority (64-69%) of costs.[309]

KIs found that this was particularly relevant to reaching ZD children, often located in remote and hard-to-reach areas. An Alliance KI based in a Gavi-eligible country in accelerated transition stated that "*costs are a big challenge, as operational costs for ZD children are more expensive. In general, operational costs are an issue -- inflation has been a challenge, and operational costs such as fuel and motorbikes needed to cover a successful immunization programme have not yet been provided. Inflation has compounded this over the last 2-3 years*."

[306] Gamage A, Kapuge Y, Abeysinghe N, & Peiris S. Country Case Study: Lessons Learned from Sri Lanka's Experience Transitioning from Gavi Support. Learning Network for Countries in Transition & Institute for Health Policy. September 2021.
[307] Garcia-Escribano M, Juarros P, & Mogues T. Patterns and Drivers of Health Spending Efficiency. IMF. March 2022.
[308] Ibid.
[309] ThinkWell. Findings from Immunization Campaign Costing Studies: Policy and Program Implications. March 2022.

Table 29. Annual percent change in inflation rates in case study countries 2019-2023

Country	2019	2020	2021	2022	2023
Ghana	7.1	9.9	10	31.9	42.2
Zambia	9.2	15.7	22	11	10.6
Ethiopia	15.8	20.4	26.8	33.9	29.1
Sri Lanka	4.3	4.6	6	45.2	-
Global	**3.5**	**3.2**	**4.7**	**8.7**	**6.9**

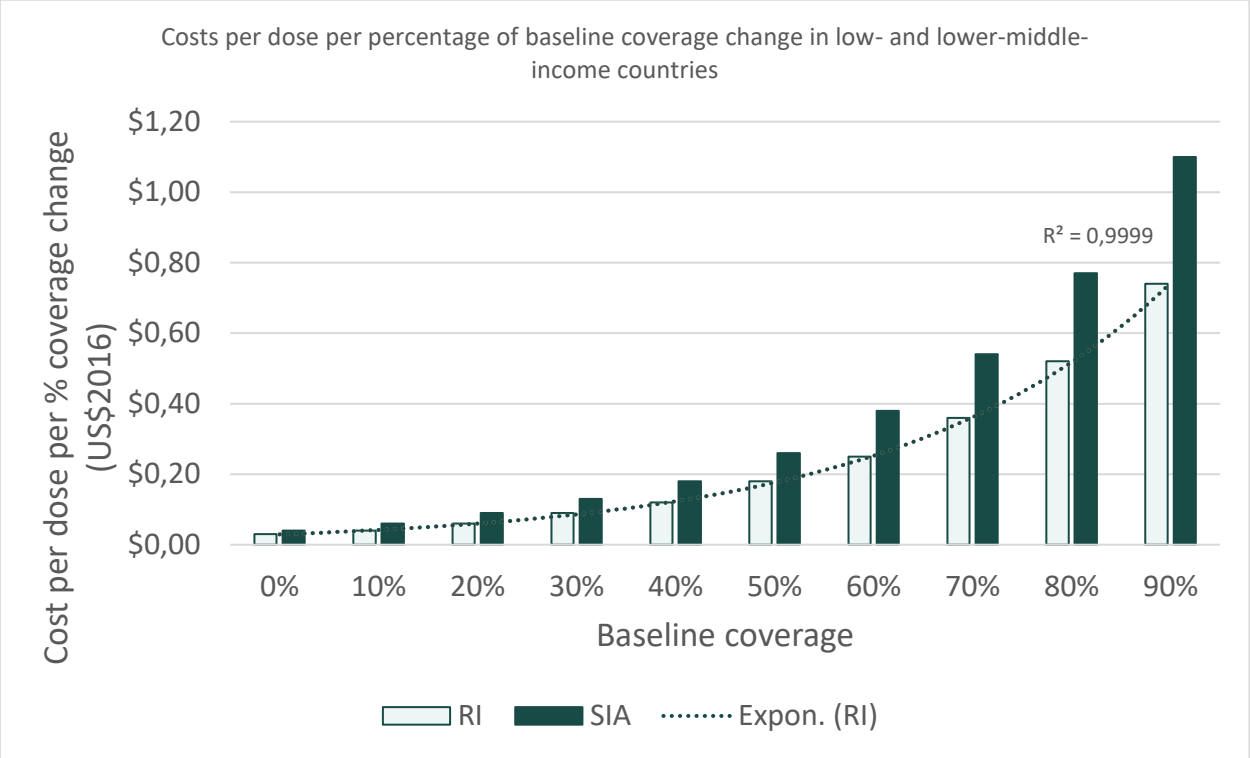
KIs identified high immunisation delivery costs as a driver of negative WUENIC trends including decreasing DTP3 coverage, increasing ZD children, and decreasing geographic equity in Zambia,[310] where a sparse population is spread over a wide geographic area. On the contrary, coverage has remained high in Ghana and Sri Lanka despite high inflation – in Ghana, this was attributed to a well-developed EPI programme and vaccine delivery integrated into a well-developed primary health care system.

While Gavi does offer support for transport and HR costs through immunization system support grants including HSS, EAF, Innovation Top-Up, VIGs, Ops, and PSG, recent IRC reports have noted higher costs than for previous approved budgets in some countries, with inadequate justification, and subsequently have recommended revision.[311] In Zambia, KIs noted transport and HR allocations were reduced in response to IRC comments, but feared that it would impact the feasibility of conducting immunisation programmes. Maximum HR-related costs including salaries and wages, incentives, and per diems for travel and events range from 20-40% of the total grant depending upon the grant, and maximum transport costs including vehicle procurement/rental, fuel for vehicles, and maintenance are 10% of the total grant for HSS, VIGs, OPS, and Switch and 20% for EAF.[312] Notably, due to sustainability concerns, these are also flagged as recurrent costs that should be reduced to zero before countries transition from Gavi funding.

2 **Finding 3.5: Recent data on the costs of reaching ZD children is limited.** However, Ozawa et al. (2017) conducted a meta-analysis that found that costs per dose increased significantly and exponentially with higher baseline coverage and were furthermore higher for supplemental immunization activities versus routine immunization, suggesting that it costs much more to vaccinate hard-to-reach populations (see Figure 21).[313] As many countries are currently undertaking efforts to identify ZD children and to create budgets and workplans using Gavi Equity Accelerator Fund support, assessing the domestic costs of reaching ZD children would appear to be very important.

[310] Gavi. WUENIC data, 2019-2022. Accessed August 2023.
[311] Gavi Alliance. Report of the Independent Review Committee to the Gavi Alliance on the Review of Applications. March 2023.
[312] Gavi. Budget Eligibility Guide. March 2022.
[313] Ozawa S, Yemeke TT & Thompson KM. Systematic Review of the Incremental Costs of Interventions that Increase Immunization Coverage. Vaccine; 36(25): 3641-3649. June 2018. doi: 10.1016/j.vaccine.2018.05.030

Figure 21: Cost per dose per % of baseline coverage change314



In the context of the high costs of new vaccine introductions and maintaining RI in a constrained fiscal space, KIs additionally noted the need to evaluate the value for money of reaching ZD children, suggesting that the approach may be more applicable in some contexts (e.g., with high numbers of ZD children and low coverage) than in high-coverage settings.

1 **Finding 3.6: Surprisingly, in view of the high priority attached to the zero-dose programme, we could not find any estimates of the actual costs, beyond the costs of the vaccines themselves, of reaching ZD children. This data would appear to be critical for planning purposes and to assess the sustainability of these investments.** Secretariat and external KIs were not aware of any estimates of the costs of reaching ZD children. KIs in Ethiopia, Zambia, and Ghana confirmed the need to analyse these costs. These countries reflect a variety of settings, with ZD children existing in conflict settings (Ethiopia), rural and remote areas (Zambia), and urban poor and remote areas (Ghana), and exhibit a range of immunisation coverage. This appears to be a crucial analytical gap which may threaten the success of the ZD programme.

4. Sustainability of the co-financing and transition models

1 **Finding 4.1: Considering the increasing availability and costs of new antigens, introductions are reportedly a challenge for some MICs.** Key informants in countries in accelerated transition (Ghana), former Gavi-eligible (Angola) and never-eligible (Philippines) identified fiscal capacity as a barrier to new vaccine introduction. For example, while Ghana has planned to introduce HPV and HepB since 2018, it has not done so due to the implications of increased co-financing payments and upcoming transition. UNICEF Ghana estimated the costs of introducing the malaria vaccine (which has now been introduced), HPV, and HepB, considering the increases in co-financing over the upcoming transition period. The estimates show that in 2034 (after transitioning from Gavi support in 2029), the total cost of the vaccine portfolio would be nearly twice as high with

[314] Ibid.

the new vaccines versus without them (US$ 58 million versus US$ 30 million),[315] not including delivery costs. KIs indicated that given the current context and the country's challenges in meeting increasing co-financing requirements on time, it may be unrealistic to expect more new vaccine introductions beyond malaria.

This is increasingly relevant as new vaccines such as malaria and HPV are costlier and require different service delivery approaches due to shifted target populations. For example, HPV introduction often requires additional implementation measures such as microplanning, school-based delivery, and demand generation, requiring additional human and financial resources.[316] [317]

Continued introduction of new vaccines in transitioning countries may be contingent upon fully self-financing countries being able to access Gavi pricing. Sriudomporn et al. (opus cit.) estimated that a projected immunisation programme funding gap of US$ 38.3 billion from 2011-2030 would increase by US$ 54.6 to US$ 1038.7 billion (42 to 2605%)[318] if fully self-financing countries were no longer able to access Gavi pricing.[319] Notably, this calculation did not include the new malaria vaccination. Fully self-financing countries can no longer access Gavi prices for vaccines. However, some manufacturers have conditionally[320] agreed to give transitioning and fully self-financing countries procuring through UN organisations (e.g., UNICEF and PAHO) access to Gavi prices for Penta, PCV, Rota, and HPV until 2025.[321] Never-eligible MICs are not able to access these manufacturer agreements. Former- and never-eligible countries can also procure via UNICEF Supply Division or access affordable prices through pooled procurement (i.e., PAHO Revolving Fund for Latin America and the Caribbean). In addition, a new pooled procurement mechanism for members of the African Union was spearheaded by the Africa Centres for Disease Control and Prevention and signed off in February.[322]

1 **Finding 4.2: The sustainability of Gavi's model, and of new introductions and sustained routine immunization in MICs in general, is threatened by significantly higher vaccine prices for non-Gavi countries.** For example, in 2017,[323] Gavi prices for PCV ranged from US$2.95 to US$3.30, compared to a range of US$12.57-22.04 for non-Gavi and non-PAHO LMICs (up to four to six times the

> *"Gavi's model and tiered pricing is not equivalent to sustainability – they are pushing for low prices for low-income countries, but they don't pay the full price & don't pay based on the cost. Costs are more relevant for middle-income countries."*
>
> - Alliance KI

[315] Schramm N. Vaccine financing in Ghana. UNICEF & Gavi. May 2023.
[316] Levin A, Wang SA, Levin C, Tsu V & Hutubessy R. Costs of Introducing and Delivering HPV Vaccines in Low and Lower Middle-Income Countries: Inputs for Gavi Policy on Introduction Grant Support to Countries. PLoS One. 26 June 2014; 9(6): e101114. doi: 10.1371/journal.pone.0101114.
[317] Guignard A, Praet N, Jusot V, Bakker M & Baril L. Introducing new vaccines in low- and middle-middle-income countries: challenges and approaches. Expert Review of Vaccines. 2019; 18:2, 119-131. doi: 10.1080/14760584.2019.1574224.
[318] Calculated using the minimum, average, and maximum prices in the WHO MI4A database of vaccine prices.
[319] Sriudomporn S, Yoon Sim S, Mak J, Brenzel L & Patenaude BN. Financing and Funding Gap for 16 Vaccines Across 94 Low- and Middle-Income Countries, 2011-30. Health Affairs 42, No.1: 94-104. 2023. doi:10.1377/hlthaff.2022.00343
[320] Dependent upon certain criteria, e.g., GSK and Pfizer PCV products are only available at Gavi prices if countries satisfy the AMC condition of DTP3 coverage of at least 70%, Merck Rota products are only available to countries with GNI per capita under $3.200, and access to Gavi pricing for GSK and Merck HPV products is dependent upon introduction agreements. This is also dependent upon the countries using the products with manufacturer pricing agreements.
[321] World Health Organization. Vaccine Pricing: Gavi Transitioning Countries. November 2018.
[322] Africa CDC. Africa CDC spearheads bold move to secure Africa's health future by creating a 50 billion dollar medical market. 19 February 2024. Africa CDC Spearheads Bold Move to Secure Africa's Health Future by Creating a 50 billion Dollar Medical Market – Africa CDC.
[323] Vaccine price data is regularly reported in the WHO/UNICEF Joint Reporting Form and results are compiled into the WHO MI4A database (Immunization, Vaccines and Biologicals (who.int)). However, recent results with robust data points are lacking due to the aforementioned low response rates.

price).[324] HPV prices ranged from US$4.50 to US$4.60, compared to approximately US$13.69 for non-Gavi and non-PAHO LMICs (three times the price).[325] In recent years, WHO prequalification of vaccines from India-based manufacturers such as Serum Institute of India and Bharat Biotech have increasingly made less expensive alternatives available (e.g., for Rotavirus).[326]

This has implications for the sustainability of the Gavi transition model, in which Gavi countries gradually assume 100% of vaccine costs according to Gavi prices but would pay significantly higher prices as fully self-financing countries in absence of the current ad hoc, time-limited manufacturer arrangements[327] (see Figure 22 and Figure 23). It also has implications for Gavi never-eligible countries, which are not eligible for the manufacturer arrangements but still face economic distress (see Appendix 1). Particularly, as Gavi now offers catalytic funding to former- and never-eligible countries to pay for half of the first birth cohort for introductions of Rota, PCV, and HPV, it is increasingly relevant to consider the sustainability of these introductions in the context of access to differential vaccine prices.

KIs in former-eligible (Angola and Indonesia), and never-eligible countries (Kosovo) identified the need for Gavi to establish a mechanism to enable access to affordable pricing for vaccines. Multiple high-level KIs have also expressed support for a model in which Gavi considers how to support access to affordably priced vaccines in former- and never-eligible to ensure sustainability and equitable access to vaccines.

As the demand for many vaccines in the 2024 Vaccine Investment Strategy will be most pertinent for MICs (e.g., Dengue in MICs in Central America, South America, and Southeast Asia),[328] it will be especially important for Gavi to consider how the most impacted countries are able to access priority vaccines.[329] Needs will notably vary by country, as large transitioning countries will likely be price shapers on their own, and some may consider local production for some routine vaccines. Others may require assistance with supply and procurement performance in order to enable access.

[324] Ibid.
[325] Ibid.
[326] Glass RI, Tate JE, Jiang B & Parashar U. The Rotavirus Vaccine Story: From Discovery to the Eventual Control of Rotavirus Disease. The Journal of Infectious Diseases. 1 October 2021; 224(Suppl 4): S331–S342. doi: 10.1093/infdis/jiaa598.
[327] Each company has different commitments to post transition countries based on a variety of factors and for different time lengths. See https://www.gavi.org/sites/default/files/document/supply-procurement/vaccine-price-commitments-from-manufacturers.pdf AND https://www.who.int/publications/m/item/factsheet-on-vaccine-pricing-for-gavi-transitioning-countries.
[328] US CDC. DengueMap. DengueMap (healthmap.org); accessed 17 November 2023.
[329] Gavi. Report to the Board: Vaccine Investment Strategy 2024: longlist and frameworks. 26-27 June 2023.

Figure 22. Gavi's co-financing model330

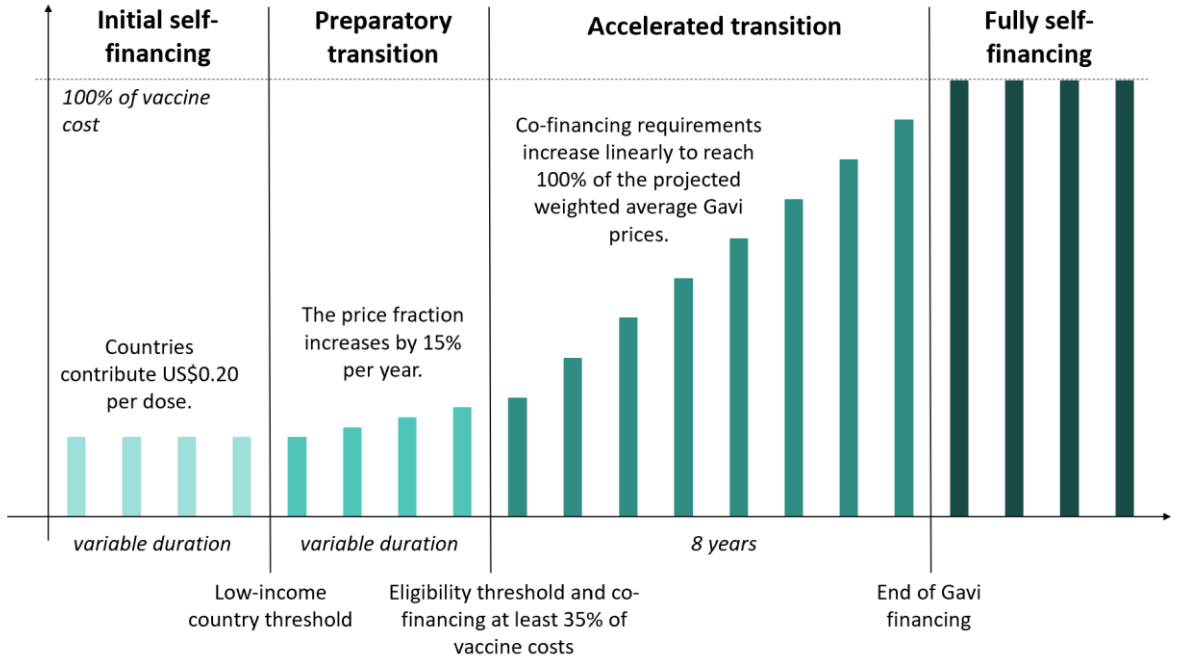
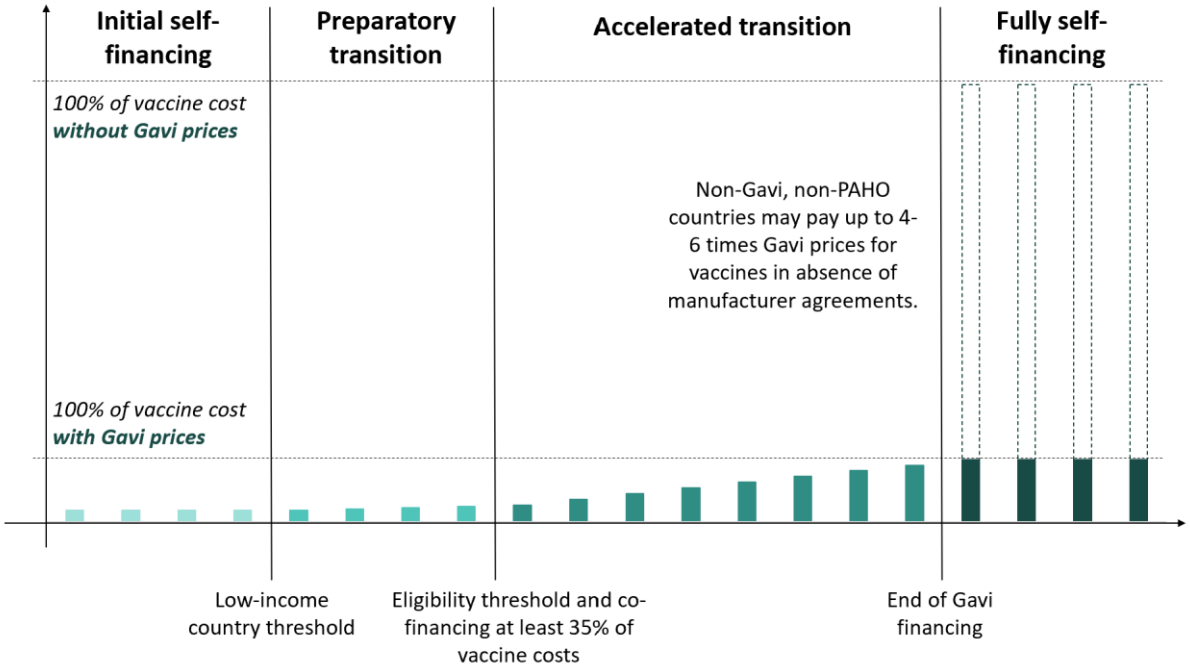


Figure 23. Gavi's co-financing model if Gavi prices are not available to fully self-financing countries[331, 332]



2 **Finding 4.3: Currency depreciation, alongside inflation and debt distress, will likely also threaten the sustainability of Gavi's model.** Currency depreciation in emerging markets poses

[330] Gavi. Co-financing Policy: Version 3.0. 1 November 2022. Board Document Template (gavi.org).
[331] World Health Organization. Vaccine Pricing: Gavi Transitioning Countries. December 2017.
[332] Gavi. Co-financing policy, version 3.0. 1 November 2022.

another threat to sustainability of immunisation programmes.[333] For example, sub-Saharan Africa has been heavily impacted by the appreciation of the US dollar, driving up the prices of imported goods. The IMF reported that the average depreciation against the US dollar was 8% from January 2022 to May 2023.[334] However, this varied by country, as Ghana's Cedi and Sierra Leone's Leone depreciated by more than 45%.[335] This will impact the costs of several imports priced in US dollars which are relevant to immunisation programmes, including vaccines, fuel, and cold chain equipment. In addition, depreciation will also increase inflation (the IMF reports that an increase in the rate of depreciation against the US dollar of 1% led to an increase in inflation of 0.22% in the sub-Saharan Africa region)[336] and external public debt. This is an important threat for Gavi to monitor in its role in not only providing grants but securing accessible vaccine pricing and ensuring sustainability of vaccine programming. These issues are on Gavi's radar – the Board in 2022 decided to expand the accelerated transition phase to consider the challenging macro-fiscal context for these countries and the ongoing ELTRACO review in preparation for 6.0 is also currently looking at this.

1 **Finding 4.4: In this context, there is a need to improve cost-effectiveness of procurement through country portfolio optimization for initial self-financing Gavi-eligible countries.** While Gavi has begun providing more information to facilitate evidence-informed decision-making on product introduction and switches under the 5.0/5.1 strategy, Gavi has generally taken a more "laissez-faire" approach to influencing country vaccine portfolio decisions (see Annex 9).

The co-financing model does not encourage switches to and introductions of more cost-effective vaccines until countries enter preparatory and accelerated transition, during which time the co-financing requirement comprises a steadily increasing percentage of the price of vaccines per year.[337] Prior to this, in the initial self-financing phase, the government contributes a flat amount of US$ 0.20 per dose of any Gavi-supported vaccines.[338] In the context of constrained fiscal space and limited capacity for new vaccine introductions, Gavi's continued and increased engagement in vaccine portfolio optimization could help countries prepare for transition and increase sustainability of immunisation programmes.

Considerations

To inform both fundraising and programming for Gavi 6.0, Gavi should consider working with Alliance partners to carry out comprehensive studies of the costs of immunising children and adults in all LICs and LMICs, including both vaccine procurement and delivery costs.
Gavi has never undertaken such a study, and filling this knowledge gap is critical to informing Gavi's role and strategic direction on sustainability. As many Gavi-eligible and former-/never-eligible countries are currently facing debt distress, inflation, and currency depreciation, this would be important to inform policymakers when determining the trade-offs of financing i) maintenance of RI, ii) reaching ZD children, and iii) new vaccine introductions. WHO, UNICEF, and the World Bank may be consulted as partners with key roles in vaccine procurement, delivery, and health financing to assist with the study.

[333] IMF. Emerging Market Economies Bear the Brunt of a Stronger Dollar. 19 July 2023. https://www.imf.org/en/Blogs/Articles/2023/07/19/emerging-market-economies-bear-the-brunt-of-a-stronger-dollar
[334] IMF. African Currencies Are Under Pressure Amid Higher-for-Longer US Interest Rates. 15 May 2023. https://www.imf.org/en/Blogs/Articles/2023/05/15/african-currencies-are-under-pressure-amid-higher-for-longer-us-interest-rates.
[335] Ibid.
[336] Ibid.
[337] Gavi. Co-financing Policy: Version 3.0. 1 November 2022. Board Document Template (gavi.org).
[338] Ibid.

Comprehensive monitoring of immunisation programme expenditures should be initiated in all countries receiving Gavi support, including former- and never-eligible MICs, to provide an evidence base for targeted Gavi support, to inform future investments, and to assess sustainability of the investments. This should be coupled with efficiency analyses to increase health for money.

Evidence from documentation, Secretariat and Alliance KIs, and country KIs indicates that payment of co-financing obligations is a poor proxy of sustainability. Monitoring of full immunisation programme expenditures should be prioritised, including acquisition costs of both Gavi and traditional vaccines and vaccine delivery. This would be used to:

- identify potential areas for increased cost efficiencies in immunisation delivery;
- increase awareness of Gavi and traditional immunisation financing and sustainability;
- target the design of Gavi support and budgeting for various funding levers;
- inform introduction of new vaccines, including HPV and malaria; and
- provide a basis for transition planning.

This is especially important considering the context of declining health expenditures following fiscal and economic shocks impacting countries in the Gavi portfolio. This work should be carried out with Gavi's core partners (WHO, UNICEF and the World Bank). Recent developments, such as an agreement with the UNICEF Supply Division to share data about regarding procurement of Gavi-supported and traditional vaccines in consenting Gavi-eligible countries and work with the Global Fund, Global Financing Facility, and the World Bank around resource mapping and expenditure tracking, are a step in the right direction. This work should be continued and prioritised to ensure systematic tracking of immunisation programme expenditures (including both vaccine and programmatic expenditures) in preparation for Gavi 6.0. This work should be coupled with efficiency analyses to increase value for money.

Gavi should support investment cost analyses of reaching zero-dose children and introduction of new vaccines to inform future support and better understand the sustainability of these investments.

Reaching ZD children, as a continued programmatic priority, should be supported with strong evidence regarding the value for money of reaching ZD children in the various contexts in which Gavi works. In addition, as the vaccine portfolio continues to increase in cost due to the inclusion of antigens such as HPV and malaria, it is important to analyse costs of procurement and delivery of proposed new vaccine introductions in transitioning, former-eligible, and never-eligible MICs to ensure sustainability. These analyses should be used to inform country-driven choices of where to allocate limited resources, e.g., in deciding whether to prioritise introduction of malaria vaccines over "reaching the last mile" in countries with high RI coverage, but high morbidity and mortality from malaria.

Gavi should prioritize TA for budget efficacy within PEF grants, especially for transitioning countries.

With the increasing need for domestic resource mobilisation to replace donor funding, it is important to support countries with evidence-based budgeting and execution to maximise spending efficiency and immunisation programme sustainability. This may include the continuation and scaling up of initiatives such as the ongoing use of PEF envelopes to systematically fund "budget monitoring focal points" at country-level to support the MoH in budget planning and execution. Initiatives should be coupled with monitoring of impacts and results.

Advocacy for increased domestic resources for immunisation will likely require an integrated approach, leveraging Alliance partners and CSOs. Ongoing efforts to support CSO advocacy for health and immunisation financing under PEF support should be continued and prioritised in the remainder of Gavi 5.1 and Gavi 6.0.

Advocacy, while important to increase public awareness and support for vaccines, is unlikely to ensure prioritisation of domestic financing for vaccines. Alongside increased accountability through improved monitoring of expenditures, Gavi should continue and increase collaboration with global and country-level partners to influence prioritisation of immunisation through an approach which integrates budgetary analysis and advocacy.

Gavi should consider additional support to increase the sustainability and equity of access to vaccines for former- and never-eligible MICs, to secure long-term, affordable access to vaccines.

As MICs face increasing economic challenges, mechanisms for former- and never-eligible MICs to access vaccines at reduced prices should be considered. While former-eligible MICs currently have access to Gavi prices for a number of years post-graduation, the commitments vary by manufacturer and offer a time-limited solution. In addition, never-eligible MICs do not have access to these agreements, despite facing similar fiscal challenges to former-eligible MICs. Needs may differ by country, as large transitioning countries are likely to be price shapers or to begin manufacturing their own vaccines, whereas smaller countries may need more support to access equitable vaccine prices.

In the likely context of constrained resources throughout the Gavi 5.0/5.1 and 6.0 strategy periods, Gavi should revisit approaches to incentivizing countries to optimize their vaccine portfolios to maximise value for money and adequately prepare countries for transition.

This may be through revisiting the flat co-financing rate of US$ 0.20 per dose for initial self-financing countries, or by offering more targeted and directive assistance to Gavi countries throughout the development of their vaccine portfolios to encourage cost-effective and sustainable product choices. Ongoing vaccine portfolio optimisation efforts should be continued and prioritised in the next strategic period, especially as new and potentially more expensive vaccines enter Gavi's menu.

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Appendix 1

Out of 54 Gavi-eligible countries, 18.5% are projected to exhibit GGE contraction, 40.7% stagnation, and 33.3% expansion from 2019 to 2027.[339] In addition, 48% of Gavi-eligible countries are at high risk of or in debt distress as of August 2023,[340] which may further threaten any potential gains from an expanding economy.[341] In addition, 19.5% of former- and never-eligible Gavi MICs are projected to exhibit GGE contraction and 34.1% are projected to exhibit stagnation. Many are also at high risk of or in debt distress. These rates vary regionally, with low- and middle-income countries in the African and the Western Pacific Regions at higher risk of GGE contraction or stagnation and debt distress.

Table 30: Trends in general government expenditures and risk of debt distress in current, former-eligible, and never-eligible Gavi countries

Country	Transition Status (2023)[342]	GGE (2022)[343]	Risk of debt distress (2023)[344]
African Region			
Algeria	Never Gavi-eligible	Contraction	-
Angola	Fully self-financing	Contraction	-
Benin	Preparatory transition	Expansion	Moderate
Burkina Faso	Initial self-financing	Stagnation	Moderate
Burundi	Initial self-financing	Stagnation	High
Cabo Verde	Never Gavi-eligible	Stagnation	Moderate
Cameroon	Preparatory transition	Stagnation	High
Central African Republic	Initial self-financing	Stagnation	High
Chad	Initial self-financing	Stagnation	High
Comoros	Preparatory transition	Contraction	High
Congo	Preparatory transition	Contraction	In debt distress
Cote d'Ivoire	Accelerated transition	Expansion	Moderate
DR Congo	Initial self-financing	Expansion	Moderate
Egypt	Never Gavi-eligible	Stagnation	-
Eswatini	Never Gavi-eligible	Contraction	-
Eritrea	Initial self-financing	Stagnation	-
Ethiopia	Initial self-financing	Expansion	High
Gambia	Initial self-financing	Stagnation	High
Ghana	Accelerated transition	Expansion	In debt distress
Guinea	Initial self-financing	Expansion	Moderate
Guinea-Bissau	Initial self-financing	Expansion	High
Kenya	Accelerated transition	Stagnation	High
Lesotho	Preparatory transition	Contraction	Moderate
Liberia	Initial self-financing	Contraction	Moderate
Madagascar	Initial self-financing	Contraction	Moderate

[339] Kurowski C, Evans DB, Tandon A, Eozenou PHV, Schmidt M, Irwin A, Cain JS, Pambudi ES & Postolovska I. From Double Shock to Double Recovery – Implications and Options for Health Financing in the Time of COVID-19; Technical Update 2: Old Scars, New Wounds. The World Bank Group. September 2022.

[340] IMF. List of LIC DSAs for PRGT-Eligible Countries. 31 August 2023. https://www.imf.org/external/pubs/ft/dsa/dsalist.pdf

[341] Kurowski C, Evans DB, Tandon A, Eozenou PHV, Schmidt M, Irwin A, Cain JS, Pambudi ES & Postolovska I. From Double Shock to Double Recovery – Implications and Options for Health Financing in the Time of COVID-19; Technical Update 2: Old Scars, New Wounds. The World Bank Group. September 2022.

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[343] Kurowski C, Evans DB, Tandon A, Eozenou PHV, Schmidt M, Irwin A, Cain JS, Pambudi ES & Postolovska I. From Double Shock to Double Recovery – Implications and Options for Health Financing in the Time of COVID-19; Technical Update 2: Old Scars, New Wounds. The World Bank Group. September 2022.

[344] IMF. List of LIC DSAs for PRGT-Eligible Countries. 31 August 2023. https://www.imf.org/external/pubs/ft/dsa/dsalist.pdf

Malawi	Initial self-financing	Stagnation	In debt distress
Mali	Initial self-financing	Stagnation	Moderate
Mauritania	Preparatory transition	Stagnation	Moderate
Morocco	Never Gavi-eligible	Stagnation	-
Mozambique	Initial self-financing	Expansion	High
Niger	Initial self-financing	Expansion	Moderate
Nigeria	Accelerated transition	Stagnation	-
Rwanda	Initial self-financing	Stagnation	Moderate
Sao Tome and Principe	Accelerated transition	Stagnation	In debt distress
Senegal	Preparatory transition	Expansion	Moderate
Sierra Leone	Initial self-financing	Stagnation	High
South Sudan	Initial self-financing	Contraction	High
Togo	Initial self-financing	Expansion	Moderate
Tunisia	Never Gavi-eligible	-	-
Uganda	Initial self-financing	Expansion	Moderate
UR Tanzania	Preparatory transition	Expansion	Moderate
Zambia	Preparatory transition	Contraction	In debt distress
Zimbabwe	Preparatory transition	Expansion	In debt distress
Region of the Americas			
Belize	Never Gavi-eligible	Contraction	-
Bolivia	Fully self-financing	Stagnation	-
Cuba	Fully self-financing	Expansion	-
Dominica	Never Gavi-eligible	Stagnation	High
El Salvador	Never Gavi-eligible	Expansion	-
Grenada	Never Gavi-eligible	Expansion	In debt distress
Guyana	Fully self-financing	-	Moderate
Haiti	Preparatory transition	Stagnation	High
Honduras	Fully self-financing	Stagnation	Low
Nicaragua	Fully self-financing	Stagnation	Moderate
Saint Lucia	Never Gavi-eligible	Stagnation	Moderate
Saint Vincent and the Grenadines	Never Gavi-eligible	Stagnation	High
Venezuela	Never Gavi-eligible	-	-
Eastern Mediterranean Region			
Afghanistan	Initial self-financing	-	High
Djibouti	Accelerated transition	Stagnation	High
Occupied Palestinian territory	Never Gavi-eligible	-	-
Iran	Never Gavi-eligible	Expansion	-
Lebanon	Never Gavi-eligible	-	-
Pakistan	Preparatory transition	Stagnation	-
Somalia	Initial self-financing	-	In debt distress
Sudan	Initial self-financing	Contraction	In debt distress
Syria	Initial self-financing	-	-
Yemen	Initial self-financing	-	Moderate
European Region			
Armenia	Fully self-financing	Expansion	-
Azerbaijan	Fully self-financing	Expansion	-
Georgia	Fully self-financing	Expansion	-
Kosovo	Never Gavi-eligible	-	-

Kyrgyzstan	Preparatory transition	Stagnation	Moderate
Republic of Moldova	Fully self-financing	Expansion	Low
Tajikistan	Preparatory transition	Stagnation	High
Uzbekistan	Fully self-financing	Expansion	Low
South-East Asian Region			
Bangladesh	Accelerated transition	Expansion	Low
Bhutan	Fully self-financing	Expansion	Moderate
DPR Korea	Initial self-financing	Expansion	-
India	Fully self-financing	Expansion	-
Indonesia	Fully self-financing	Expansion	-
Maldives	Never Gavi-eligible	Stagnation	High
Myanmar	Preparatory transition	Stagnation	Low
Nepal	Preparatory transition	Expansion	Low
Philippines	Never Gavi-eligible	Expansion	-
Sri Lanka	Fully self-financing	Stagnation	-
Timor-Leste	Fully self-financing	Contraction	Moderate
Western Pacific Region			
Cambodia	Preparatory transition	Expansion	Low
Fiji	Never Gavi-eligible	Contraction	-
Kiribati	Fully self-financing	Contraction	High
Lao PDR	Accelerated transition	Stagnation	In debt distress
Marshall Islands	Never Gavi-eligible	Stagnation	High
Micronesia	Never Gavi-eligible	Contraction	High
Mongolia	Fully self-financing	Expansion	-
Papua New Guinea	Accelerated transition	Contraction	High
Samoa	Never Gavi-eligible	Stagnation	High
Solomon Islands	Accelerated transition	Contraction	Moderate
Tonga	Never Gavi-eligible	Expansion	High
Tuvalu	Never Gavi-eligible	Expansion	High
Vanuatu	Never Gavi-eligible	Contraction	Moderate
Vietnam	Fully self-financing	Expansion	-

Annex 12: Thematic study – Innovation

Primary Purpose
The primary purpose of this case study was to strengthen our understanding of how innovation contributes (or is intended to contribute) to Theory of Change (ToC) outputs and outcomes and the evaluability of some MTE EQs.

Scope
This thematic case study was to be guided by the following study questions:

1. To what extent is innovation defined as 'new products, practices and services that unlock more efficient and effective ways to accelerate Gavi's mission' (Gavi, 2021) is commonly understood across key stakeholder groups as one of Gavi's key inputs/levers? (Useful for Module 1)
2. What mechanisms/ strategies exist within Gavi to operationalise innovation (with rationale and key assumptions)? How efficient and effective has the operationalization been? (Useful for Module 1)
3. What have country level stakeholders' experiences been of the implementation under the previous and current approach to innovation? (Useful for Module 1)
4. How/to what extent innovation has been used to restore Routine Immunisation? (Useful for Module 2)
5. How plausible is it that Gavi's provision of incentives to develop and scale innovations will result in increased use of innovative products, services and practices contributing to SGs1-3, in particular, SG2 - e.g., identifying and reaching more ZD children/missed communities? Enablers and constraints (useful for Module 3)

In order not to create duplications and higher transaction costs for KIs, Category 2 Innovations (under the Vaccine Innovation Prioritisation Strategy - VIPS) are covered by the SG4 TCS/Module 4 and the future of Innovation is covered by the Horizon scanning TCS/Module 5.

Limitations
As flagged in our Progress Report dated 06 June 2023, the operationalisation of the new Gavi 5.0 Innovation Approach has been delayed by almost two years. Hence, implementation of the new approach at country level had barely started at the time MTE data collection ended in November 2023. This limited the extent to which country perspectives on the Gavi 5.0 Innovation Approach could be gathered. Moreover, given the short time with each global level KI versus the broad range of topics to be covered (especially with Gavi leadership) and turnover among key staff involved in the design of the new approach, Innovation questions were covered in less detail and with a narrower group of KIs than originally designed. This thematic note is mainly based on KIIs with a small subset of Gavi staff who focus on aspects of the Innovation Approach in their daily work, complemented by a handful of perspectives from other Gavi KIs and country-level stakeholders, as well as a review of some excerpts related to Innovation from Gavi documents.

Findings

2 **Finding 1.1**: Gavi 5.0 approach to Innovation approved by the Board in June 2022 is based on six key shifts grounded in learning from previous approaches. A working group (WG) was formed to establish the Gavi 5.0 innovation approach which was presented to the PPC and Board in June 2022. Rather than a radical shift, the approach was meant to be an evolution, based on lessons learned, of Gavi's existing innovation model and was intended to help accelerate progress

towards reaching Gavi 5.0 SGs.[345] According to MTE KIs and documentary evidence, this was the first time Gavi was putting an Innovation Approach on paper.

The six key shifts to the approach include:

- Shift 1: Provide a clear articulation of Gavi's role along the innovation value chain also thanks to a bespoke Theory of Change.
- Shift 2: Ensure country needs guide the identification and prioritisation of innovations through systematic engagement with countries and Alliance partners to surface, understand, and signal country needs including specific innovation asks from countries, leveraging both pre-defined touchpoints such as the FPP process and the annual joint appraisals.
- Shift 3: Focus innovations that support specific programmatic priorities, in line with Gavi's strategic goals, grounded in country needs identified as per Shift 2.
- Shift 4: Establish a mechanism to 'try fast, iterate fast, learn fast' for innovations needing proof of concept (related to category 1 innovations).
- Shift 5: Incentivise countries to accelerate scale-up of proven innovations and improve sustainability of these innovations.
- Shift 6: Improve end-to-end portfolio management of innovations through monitored learning (through a results framework assessing progress of specific indicators at each step of the Theory of Change and an associated learning agenda), coordination and decision making.[346]

Categorisation of the new approach, innovations are categorised into three categories corresponding to the three Intermediary Outcomes in the Innovation ToC:

- **Category 1: Potential 'breakthrough' innovations needing proof of concept/ adaptation at county level to address needs in Gavi- supported countries** (mainly through INFUSE and a sub-set of Private Sector partnership)
- **Category 2: Innovations needing global / regional interventions to enable scale up** (mainly through the VIPS – which has prioritised three innovations based on country needs: micro-array patches, heat stable and controlled temperature chain qualified vaccines, and barcodes).
- **Category 3: Proven innovations ready for scale up at country level** (mainly through the Innovation Top Up – ITU - fund).[347] The ITU fund is a newly introduced funding lever to help countries scaling up proven interventions that respond to country needs[348]. This money is additional to the HSS provision and, as confirmed by KIs, it was meant for countries that do not have enough room in their HSS grants to invest in innovation.

Operationalisation of the approach was, however, delayed and has been hampered by several interconnected factors as seen below.

1. COVID-19, COVAX and de-prioritisation

The new Innovation approach was approved by the Board in June 2022, one and a half years into Gavi 5.0 strategic period.[349] Delays in finalising the approach were attributed by KIs to the pandemic and the related roll out of COVAX which shifted attention and resources within Gavi away from Innovation. According to evidence from KIIs, the ITU approach was only announced to countries at the end of October/early November 2022; INFUSE and the VIPS also suffered from de-prioritisation for the same reasons.

[345] Gavi. 2022. Annex C: Proposed innovation approach for Gavi 5.0 (extract of Section 2 of the May 2022 PPC paper)
[346] Gavi. 2022. Annex C: Proposed innovation approach for Gavi 5.0 (extract of Section 2 of the May 2022 PPC paper)
[347] Gavi. 2022. Annex C: Proposed innovation approach for Gavi 5.0 (extract of Section 2 of the May 2022 PPC paper)
[348] Gavi. Unknown. Innovation Top-Up: explanatory note (received from a KI)
[349] Gavi. 2022. Annex C: Proposed innovation approach for Gavi 5.0 (extract of Section 2 of the May 2022 PPC paper)

2. Weak monitoring and accountability systems

The new approach set out a bespoke ToC, describing how the innovation approach would contribute to Gavi's four strategic goals including access to COVID-19 vaccines and that an 'internal oversight group composed of Gavi leadership team members will guide and coordinate the innovation approach across Secretariat teams. Supported by a small central coordination function […] the group will conduct periodic progress reviews at portfolio level applying the results framework and learning agenda and ensure that the innovation approach is adjusted accordingly. In addition, it will keep track of the consolidated country needs, and review the innovation priorities on an ongoing basis'.[350] Evidence from KIIs, however, points to this not being the case. KIs described how, during the elaboration of the approach, the work of the Innovation WG was effectively coordinated by members of the Strategy team but also reported that, since the approach has been approved, no one has taken ownership, and no central body exists to implement the strategy, monitor progress against the ToC and systematically collate country needs.

According to one KI, the Innovation WG has recently met (after a hiatus) to discuss the role of Innovation in 6.0 but the higher-level Steering Committee on Innovation has not met in a while. The Funding Design and Review (FD&R) team might conduct an internal assessment of ITU fund uptake/use yet that had not happened by end November 2023. INFUSE has benefited from findings from the 2021 Private Sector Engagement evaluation[351] and has reported having taken stock and having make adaptations to their approach accordingly. Some of the Pacesetters have also benefited from external evaluations such as the impact evaluation of Zipline in Ghana commissioned by Bill & Melinda Gates Foundation.[352] A comprehensive assessment of the new Innovation approach as a whole, however, is still to take place and according to multiple KIs, in the meantime each team is left to monitor its own activities against different frameworks (for example against the Digital Health Information (DHI) Strategy[353] but also the PSE strategy).[354]

3. Different understandings of the term 'Innovation' with too much attention to the 'shiny and trendy'

According to the new approach 'Innovation in Gavi 5.0 will be defined as new products, practices and services that unlock more efficient and effective ways to accelerate countries' immunisation objectives in line with Gavi's mission.'[355] While many KIs agreed that Innovation is important and there is 'appetite' for it within Gavi, they also concurred that the term tends to mean different things for different people. While some of these different understandings can be complementary, some views might also be at odds.

'*It's clear that innovation is important, even before the Innovation strategy it was understood as one of the key principles […] innovation is identified as an important area. But what does it mean? Working with the Private Sector? Strengthen Health Systems? Every team would have its own ways of progressing innovation, but they are all complementary*' (Gavi Secretariat KI).

[350] Gavi. 2022. Annex C: Proposed innovation approach for Gavi 5.0 (extract of Section 2 of the May 2022 PPC paper)
[351] Mott MacDonald. 2021. Evaluation of Gavi's Private Sector Engagement Approach 2016-2020. Available at: https://www.gavi.org/sites/default/files/evaluations/Evaluation-Gavi-PSEA-Final-Report.pdf
[352] IDinsight. 2022. Measuring Zipline impact on Health Access, Availability, and Supply chain in Ghana. Available here: https://www.idinsight.org/wp-content/uploads/2022/06/Zipline-Brief-FINAL-Digital-v3.pdf
[353] Gavi. Unknown. Digital Health Innovation Strategy 2022-2025. Available here: https://www.gavi.org/sites/default/files/support/guidelines-2022/Gavi-Digital-Health-Information-Strategy-2022-2025_Eng.pdf
[354] Gavi. 2021. Private Sector Engagement Strategy. Available here: https://www.gavi.org/sites/default/files/board/minutes/2021/30-nov/11%20-%20Private%20Sector%20Engagement%20Strategy.pdf
[355] Gavi. 2022. Annex C: Proposed innovation approach for Gavi 5.0 (extract of Section 2 of the May 2022 PPC paper)

'*It's bitter-sweet. There is high appetite for innovation but not so high understanding of innovation and the prerequisites to have innovation, and what it takes for innovation to be sustainable'* (Gavi Secretariat KI).

'Across the board, there is not a good understanding, not much enthusiasm in bringing innovations specific to the new [innovation] strategy. There are new ways of working and thinking but that's not because of the new strategy. It's because the old way of working is not giving results needed […] Country Teams and partners are innovating in ways to solve big systemic challenges. But Gavi suffers from not recognising those examples as 'innovation'. Would be great to have a cultural shift to celebrate innovation for what it is and use that experience to build from and shift the way they think about innovation. This is already happening with other sources of funding such as HSS, EAF, TCA' (Gavi Secretariat KI).

'What constitutes innovation? Is DHIS or LMIS an innovation? This can be discussed more' (Gavi Secretariat KI).

Reasons for co-existence of different understandings were linked by one KI to 1) a legacy/'hangover' of 'innovation' meaning 'parachuting' down something countries don't want/need. An interesting parallel was also made with the term 'gender' also being misunderstood and creating hesitancy, 2) lack of time and bandwidth, especially within CP. '*Only so much can pushed through this little funnel (the SCMs)*'; and 3) not yet having operationalised the strategy.

Multiple KIs also reported a tendency by some within Gavi to favour the 'new' and 'shiny' as opposed to more cost-effective, sustainable and locally catalysed solutions, such as for example empowering traditional birth attendants to report or register children or improving the way patients queue.

'*Gavi doesn't do health system strengthening, we can do health system support, with potentially opportunity in hand full of countries to make some systematic changes. Yet these require long-term focus, whereas Gavi changes its ambitions too frequently, chasing shiny objects like drones, digital tools, private sector engagement etc, all failing after 1-3 years and then we jump to next sexy topic*' (Gavi Secretariat KI).

'There is a call for digital systems, traction for things 'shiny and trendy'. More attention is being given to new and trendy tools compared to real system strengthening. People […] ask 'What can we do with AI?' […] The problem should determine the solution, not the other way around. Not because it's trendy we should use it. Sometimes could also solve the same problem with an excel' (Gavi Secretariat KI).

4. Not having a centralised home / lack of promised human resources

As mentioned under the point on monitoring and accountability, the operationalisation of the Innovation approach has suffered from not benefiting from additional/dedicated human resources to implement the strategy as well as not having a centralised oversight function. A KI reported that such resources were initially promised but never came. This was attributed to key people leaving and not been replaced and also a de-prioritisation of operationalisation of the Innovation approach linked to the transition in higher leadership within Gavi. This centralised function was to coordinate the activities of various teams that otherwise sit within totally different departments: Category 1 innovation under Resource Mobilisation, Category 2 innovations under Market Shaping and Category 3 Category 3 Innovations with HSIS but they need to be taken up by Country Programmes. Without these additional/dedicated resources, the operationalisation of the approach is reportedly left to the activities of 4-5 staff members within the Secretariat, most of whom have other demanding roles to fulfil within Gavi at the same time. KIs were also usually in agreement that more human resources

are needed to implement the new approach, starting with the replacement of key staff members that were working on innovation and have left.

5. To some extent, financial resources devoted to the implementation of the new approach Opinions were somewhat mixed on whether more financial resources are also needed to implement the approach. While the ITU fund was decreased from US$ 50[356] to 40[357] million for reasons we could not ascertain within this study, it is too early to say whether there will be unmet requests at the end that meet the requirements[358], given that an assessment of uptake and disbursement under the ITU is still to happen. Some KIs expressed, however, that financial resources allocated might not be enough to match Gavi's ambitions.

'*Limited funding if you want to be ambitious*' (Gavi Secretariat KI).

'*Optimistically, will exhaust that fund and still have unmet needs. Many countries are interested in this funding leaver […] there is a mismatch. Don't see appetite or the need for innovations shrinking. Countries are getting more connected in terms of broadband connectivity. With this comes increase in digitalisation, with this comes increase in tools, solutions..*' (Gavi Secretariat KI).

3 **Finding 1.2: As a result of the aforementioned barriers, progress to date has been limited and piecemeal, not based on a country driven approach and done in siloes.**

Progress/implementation to date has been limited and piecemeal – the lack of human resources to implement the strategy has contributed to delays, e.g., to the postponement of the INFUSE cohort 2 selection workshop due to key team members been pulled into Mid-term Review (MTR)-related work, and slower than desirable progress.

'*It has been piecemeal. We are achieving only what could be achieved given the resources available. […] We are all volunteering our time*' (Gavi Secretariat KI).

Teams are still working in silos (despite complementarity of design) with stakeholders expressing their perspectives on how the different components complement each other and there is some early evidence of innovations by INFUSE Pacesetters being scaled up through the ITU fund (e.g. Parsyl – producing remote temperature monitoring device).

'*Category 1 Innovation start with Private Sector funding as there is a high risk associated to it and the Private Sector is willing to fund. So we leverage that capacity. Once an innovation has passed proof of concept, at that stage, it´s private money often until innovation is proven. Then we can leverage HSS or innovation top up funding. […] we are going in right direction in terms of innovation in all funding streams*' (Gavi Secretariat KI).

'*INFUSE generates competitiveness and have know-how from Private Sector, that's fantastic. We have the ITU to scale these innovations that have been proven from INFUSE or initial piloting. The strategy makes sense […] The approach is working as some Pacesetters have been transitioning to being clients of the country, going through the normal FPP process. That's how we want it to be*' (Gavi Secretariat KI).

Nevertheless, given that, as mentioned above, different teams working on other types of innovations sit within different departments and there is no central function to bring their work together. Some

[356] Gavi. 2022. Annex C: Proposed innovation approach for Gavi 5.0 (extract of Section 2 of the May 2022 PPC paper)
[357] TCS KIIs
[358] Gavi. Unknown. Innovation Top-Up: explanatory note (received from a KI)

KIs shared concerns about working still being siloed, despite aspirations for greater coordination expressed in the new approach.[359]

'The *ITU sits within HSIS, INFUSE sits within Resource Mobilisation and sometimes CP and HSIS may not even be aware of details of Pacesetters being supported, we also need to see programmatic contribution and viability of some of those. A lot of work is also going on in the vaccines programme about barcoding. There is a lot of siloed innovation approaches and there is a need for improved communication, collaboration and complementarity*' (Gavi Secretariat KI).

The approach is still not (entirely) country-driven

Through the ITU fund, countries can now apply to scale up proven innovations of their choice,[360] and evidence from KIIs confirms that through the review process Gavi tries to ensure that proposed solutions are really innovative and match country needs in a sustainable way.

Despite aspirations for greater focus on country level needs and demands set out in the new approach[361], however, KIs flagged how, in the absence of dedicated human resources playing a coordination function, country needs are still not systematically collated and conveyed to those in charge of developing and promoting innovative solutions. As a Secretariat KI put it, siloed working can also '*lead to investing in stuff that's not needed/relevant to countries. Doesn't need to be so complex*' (Gavi Secretariat KI).

'*Not sure where they would be getting country level info – as we have not been able to connect those dots. We do know about country needs, but it's not systematic*' (Gavi Secretariat KI).

'*You still have INFUSE & some SFAs that are parachuting interventions to countries. Sometimes this is positive as countries not aware, sometimes ideas that need an opportunity to be piloted to see if they could solve problems. Can't stop shaping the market, engaging the Private Sector. But cannot keep pushing down*' (Gavi Secretariat KI).

2 **Finding 1.3: Given delays in its roll out and challenges with its operationalisation, coupled with the staggered nature of Gavi grant-making processes and the nature of Category 1 and 2 innovations, there is very limited implementation to date of the new/5.0 approach.** This implies that that results will only (fully) materialise after the end of this strategic period. Given delays and challenges mentioned above, implementation/scale up of innovations under Category 3 through the ITU fund has just started (as of November 2023) with a pilot happening in Madagascar for example.[362] More precise information on uptake and disbursement/use of the ITU funds (beyond which countries have applied) could not be gathered as KIs reported that an internal assessment had not been carried out by the FD&R team.

Based on evidence from KIIs, at the beginning of November 2023, Gavi had committed/approved about US$ 14 million of the total US$ 40 million (35%). The following countries were mentioned as having applied for funding: Burundi, Chad, Eritrea, Ethiopia, Kyrgyzstan, Madagascar, Senegal, Syria, Tajikistan and Zambia. Evidence from our country-level KIIs shows that Madagascar is starting implementation of two initiatives under the ITU fund: The first project focuses on transporting medical supplies to hard-to-reach areas. Madagascar, being a very large country with a poorly developed road network with enclaves that are difficult to access during the rainy season, has opted

[359] Gavi. 2022. Annex C: Proposed innovation approach for Gavi 5.0 (extract of Section 2 of the May 2022 PPC paper)
[360] Gavi. Unknown. Innovation Top-Up: explanatory note (received from a KI)
[361] Gavi. 2022. Annex C: Proposed innovation approach for Gavi 5.0 (extract of Section 2 of the May 2022 PPC paper)
[362] Madagascar case study

to use drones, which they tested in pilot districts (with a lot of children).[363] The second project concerns scaling up eLMIS, a computerised logistics management system for immunisation, family planning products, anti-malaria products and other health-related product or input. This would be a single system for all the partners; they are currently recruiting the firm responsible for setting up the programme and providing training. Recruitment should be completed by mid-December 2023.[364]

'*Effect by 2025? Only the low hanging fruits. Still 1 whole year to go so something will be achieved but the real impact will only be felt after this strategic period*' (Gavi Secretariat KI).

As confirmed by KIs, Category 1 and Category 2 innovations are more longer-term endeavours (given their upstream nature) and KIs concurred that effects from those will only likely be reported on after 2025.

2 **Finding 1.4: Due to limited implementation, assessing country experiences of implementing the new approach is not possible. However, early evidence from this case study shows that there is scope for streamlining of funding levers**. Although some country level KIs reported that applying for the ITU fund was comparatively easier than filling in other Gavi applications, the rationale for having the ITU fund as a separate leaver was sometimes questioned. Although country level stakeholders in Kyrgyzstan for example reported that applying for the ITU fund was not that complex as it's 'just a top up', and Gavi KIs confirmed that the application can already be done concurrently with HSS or separately (when the window has been missed) and that complementarity with HSS is always checked when reviewing the ITU applications, multiple stakeholders confirmed that it would make sense to merge the ITU application with the HSS one (especially as bandwidth to monitor it as a separate lever is limited) .

2 **Finding 1.5: Despite challenges with operationalisation of the approach, innovation as a priority is being integrated, albeit only partially, in new applications, making plausible that it will contribute at least to some extent to Gavi 5.0 SGs**. The new approach sets out in a ToC how and through which pathways Innovation is meant to contribute to the 4 strategi goals, in particular through Intermediary outcomes that match the three categories of innovations mentioned above.[365]

'*The key expected outcomes of the innovation approach are to accelerate the restoration of routine immunisation, reach more zero-dose children, and help scale-up COVID-19 vaccination in an integrated way […] Gavi also expects innovations to increase the effectiveness, efficiency, and sustainability of immunisation programmes*' (Gavi Secretariat KI).

According to a recent exercise by the HSIS team, reviewing all HSS and EAF applications approved in 2022 and 2023 under 5.0, the average score (25 countries) for the extent to which scale up of innovation was integrated as a key shift was 2,16 out of 3 (AMBER-partially meets the criteria) – higher than for gender but lower than demand, CSO and ZD. 6 countries did not meet it, 9 partial and 10 meeting it'.[366]

One KI offered a potential explanation of why integration of Innovation as a priority might still be sub-optimal.

[363] Madagascar case study
[364] Madagascar case study
[365] Gavi. 2022. Annex C: Proposed innovation approach for Gavi 5.0 (extract of Section 2 of the May 2022 PPC paper)
[366] HSS 5.0 Key Shifts tracker

'*Innovation is part of the tools we use. It's included in situation analysis, budget template, JA template... but how well integrated? It's an afterthought, like gender, more of a tick box exercise. We are trying to solve very big systemic problems, so many things we are trying to solve, innovation is one thing among many. We have not done a good job in encouraging countries; we are not doing a good job at catalysing innovation at country level*' (Gavi Secretariat KI).

3 **Finding 1.6: Likewise, innovation (under Gavi 4.0) has plausibly contributed to some extent to observable outcomes, although this contribution cannot be quantified.** There are multiple examples of how Innovation has been successfully leveraged in the past, including during the COVID-19 response.

- An example of innovation that has been often quoted is the eVIN platform in India. '*eVIN was designed to record supply chain transactions and collect data on vaccine stock and storage temperatures up to last-mile health facilities and led to significant savings in vaccine utilisation (30%) and reduced stock-outs (by 40%). Building on eVIN and with Gavi support, the Government of India built a new tool, called CoWIN integrating the tracking of COVID-19 vaccine beneficiaries*'[367].
- Another example comes from one of our case study countries, Kyrgyzstan, where part of the CDS funds received from Gavi were used for development of the COVID-19 online vaccination system which was able to generate vaccination certificates. This was used only for COVID-19 vaccinations but KIs confirmed that the idea of having an RI digital solution also came from that experience'.[368]
- As detailed in the MTR, '*Since 2017, in collaboration with the University of Oslo, UNICEF and other partners, and in coordination with donors including NORAD, USAID, and the Global Fund, Gavi has supported more than 40 countries to integrate coverage data into DHIS2 (the world's largest health management information system). This has reduced the use of parallel systems, increased sustainability, and improved data quality and use. […] When the pandemic started, countries needed an agile and easy system to capture and respond to COVID-19 cases, and more than 40 countries chose to use the Gavi- supported DHIS2 module. Gavi also supported countries to further adapt DHIS2 to facilitate the planning, delivery, and monitoring of COVID-19 vaccines to improve stock visibility, track recipients, generate digital certificates, understand demand, and monitor any potential adverse events following immunisation. Gavi is also supporting 20 countries to scale up electronic logistics management information systems (eLMIS)*'.[369]
- Moreover, '*Since many health facilities in Gavi implementing countries lack access to reliable electricity, there has been a particular focus on scaling up climate-friendly solar- powered refrigeration technologies, which account for 60% of all units installed to date*'.[370]
- '*The roll-out of COVID-19 vaccines drove additional investment, with COVAX support from 2020 enabling countries to strengthen higher levels of the supply chain: more than 4,200 units of cold chain and 177 cold or freezer rooms were successfully installed across 53 countries. The Alliance also built on the CCEOP platform to rapidly deploy nearly 500 ultra-cold chain units, installed by UNICEF, given very few immunisation programmes had this capacity prior to the pandemic*'.[371] '*The delivery of COVID-19 vaccines was also made possible by an unprecedented scale up of new Ultra Cold Chain equipment in more than 45 AMC countries, to use mRNA vaccines*.'[372] Contribution to CCE was also recognised by a

[367] Gavi. 2022. Annex C: Proposed innovation approach for Gavi 5.0 (extract of Section 2 of the May 2022 PPC paper)
[368] TCS KIIs
[369] Gavi. 2023. Raising generational immunity. The 2023 Mid-Term Review Report. Available at: https://www.gavi.org/sites/default/files/investing/funding/resource-mobilisation/MTR23_Report_FULL_eng.pdf
[370] Ibid
[371] Ibid
[372] Gavi. 2022. Annex C: Proposed innovation approach for Gavi 5.0 (extract of Section 2 of the May 2022 PPC paper)

number of country level stakeholders as one of Gavi key contributions as highlighted in our MTE report.

Additionally, some successful examples of previous INFUSE projects as reported by KIs include:

- Zipline, that offers a drone delivery system, which is now active in in Rwanda, Ghana, Kenya, Nigeria. This is reportedly a much more efficient way to deliver vaccines in some settings, as vaccines can be delivered everywhere irrespective of road conditions and on a demand basis. According to the impact evaluation of Zipline in Ghana,[373] commissioned by Bill & Melinda Gates Foundation, the county that was reach via drones had a much stronger rebound from the pandemic than the other counties (the county supported had an increase in vaccine delivery, while the others were backsliding due to COVID-19). Impact could also be felt in terms of ZD children being reached with routine immunization.
- Zenysis, a platform to help decision makers bring all the data together and have the insight they need in one platform.
- Khushi Baby, a digital health platform for a community health system in India.
- Simprints, that offers a fingerprint solution to recognize babies that started immunisation in Bangladesh and now is also in Ghana.
- Nexleaf Analytics, offering a remote temperature monitoring system (to reduce the freezing of vaccines) that was rolled out through INFUSE nationwide in Tanzania. Based on this experience, as well as a deeper understanding of the technology and its use-case, it has since been deployed in Kenya and Mozambique. These learnings reportedly enabled INFUSE to support another remote temperature sensor organisation, Parsyl, thereby diversifying the supplier base.[374]
- Logistimo, offering a platform for health, health system management, integrated supply chain for tracking and a tracking platform for all supply chains.

Despite these encouraging examples of innovation bringing about positive change, contribution of Innovation to observed results cannot clearly be quantified, due to the methodological challenges presented in our MTE report.

[373] IDinsight. 2022. Measuring Zipline impact on Health Access, Availability, and Supply chain in Ghana. Available here: https://www.idinsight.org/wp-content/uploads/2022/06/Zipline-Brief-FINAL-Digital-v3.pdf

[374] Gavi. 2022. Annex C: Proposed innovation approach for Gavi 5.0 (extract of Section 2 of the May 2022 PPC paper)

Annex 13: Stakeholder engagement

Background on identifying evaluation stakeholders

The stakeholders for this evaluation encompass all those who have an interest in, and a degree of influence on the MTE. This includes key informants and people who we expected would need to engage with the evaluations' findings, recognising the overlap between the two groups.

During the inception phase, we used initial KIIs and feedback from the Gavi Secretariat and EAC to clarify our understanding of the evaluation's stakeholders and their interest and availability in being involved at different stages in the evaluation process.

For the purpose of **identifying key informants** for the MTE we categorized stakeholders as:

A. **internal** (Gavi Secretariat and Alliance staff),
B. **connected** (country governments, board members, donors) or
C. **external** (private sector, academia, think tanks).

To this list, we added the Zero Dose and strategy operationalisation evaluation teams as **connected** stakeholders, with whom we have been exchanging knowledge for the mutual benefit of all three evaluations and particularly to ensure that this MTE adds value to other evaluations commissioned by Gavi.

Target audiences for disseminating evaluation findings

To inform our approach to **communicating the findings of the evaluation**, we prioritised specific stakeholders as follows:

Primary audiences

- The **Gavi Board** (including appropriate standing Board committees and Alliance Board members): to help the Gavi Alliance develop the Gavi 6.0 policy framework.
- **Gavi Secretariat**: for operational learning about the implementation of Gavi 5.0/5.1 and the design of Gavi 6.0.
- **Gavi EvLU/Measurement and Strategic Information teams**: to provide a robust evidence base and synthesis on lessons learnt during the implementation of Gavi 5.0/5.1.

Secondary audiences

- **Alliance partners, CSOs and countries**: to inform on implementation of Gavi 5.0/5.1, and lessons learned for the development of Gavi 6.0.
- **Other Gavi partner organisations** grappling with similar internal and external challenges.
- **Networks with links to Gavi**: those with an interest in learning about responsive strategy development and implementation.

From EHG's work on the COVID-19 and strategy operationalisation evaluations, we were aware of the communications channels available for reaching the primary audiences. We produced an initial communications calendar that outlined when we expected evidence to be available from the evaluation and the opportunities for sharing these with our audiences, such as Board meetings. We have used regular meetings with the EvLU to review when it would be most timely to share information from the MTE with our primary and secondary audiences.

At this stage in the MTE our engagement has been with internal and connected stakeholders, and sharing of findings has been limited to the primary audiences, as summarised in Table 31. We are reviewing with the EvLU, the most appropriate approach to take to engagement in Q1 of 2024, including delivery of a final report, slide-deck, policy brief and dissemination meetings.

Table 31: Primary audiences and summary of engagement

Stakeholder Group	Summary of engagement to date
Gavi EvLU	EHG has met with EvLU on a bi-weekly basis to review progress with the evaluation. These have been key for raising any issues with data collection, discussing the timing of deliverables and obtaining advice on the information needs of primary audiences and opportunities for communicating with them about the evaluation, particularly with regard to the Board.
Gavi Secretariat and Alliance Staff	KIIs have been carried out with members of the Gavi Secretariat and Alliance Staff during which the purpose of the evaluation and the value it is expected to deliver to Gavi have been communicated. EHG team members leading on thematic case studies have also benefitted from liaising with key focal points in the Secretariat.
Gavi Board including relevant standing committees e.g., EAC	As anticipated, the EAC has played a critical intermediary role for this evaluation, being a conduit between EHG and the Gavi Board. In response to feedback from the EAC, EHG interviewed several Board members to ensure that their concerns are being addressed through the MTE. EHG presented an update on the MTE at the October 2023 EAC meeting. Subsequently, further KIIs have been held with Board, which has enabled EHG to collect valuable data and insights into their requirements for communications of the MTE findings and recommendations.
Zero dose and strategy operationalisation evaluation teams	The MTE team has been in regular communication with the ZD and strategy operationalisation evaluation team leaders, to establish how the MTE can provided most added value to other evaluations commissioned by Gavi. Members of the strategy operationalisation and ZD evaluation teams have contributed updates to MTE analysis workshops and informally reviewed the first MTE draft report.
Other key informants	As described elsewhere in the report.

At the time of writing (December 2023) further engagements with the secretariat and Board are expected in Q1 2024, including:

- Co-creation workshop to discuss implications from MTE findings (February 2024)
- Briefing to the Board ahead of April 2024 Board retreat (March 2024)

Other opportunities may be identified through further discussion with the EvLU.

Annex 14: Line of sight

Conclusion	Supporting evidence (Findings)
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.	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 cash grants for which disbursements are more challenging to predict. 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.
2. Some, but not all, strategic goals (SGs) 1-3 will be met by 2025, while most SG4 targets will be achieved.	Finding 1.2: Most partner engagement framework (PEF) interventions are focused on SG1 and SG2, with limited focus on SG3. 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. Finding 1.6: Progress and assumptions more consistently hold 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. Finding 2.2: Plausibility varies by SG (see Figure 1). The plausibility of reaching targets cannot be calculated for some indicators, mainly because relevant targets have not been set. Finding 2.15: The SG4 indicators are on track, minimally influenced by COVID-19. Finding 2.28: Although the SG4 indicators will likely be met, more emphasis is needed in areas where market health remains weak.
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 effects.	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. 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.

Conclusion	Supporting evidence (Findings)
	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 EAF), the staggered nature of the grant-making process, and lags in reporting. Finding 2.4: The contribution of Gavi 4.0 to current results has been substantial, especially in terms of vaccine introductions, cold chain equipment improvements and helping countries contain pandemic impacts on RI. Finding 2.5: We cannot yet estimate the future contribution that 5.0/5.1 will make to 2025 outcomes and beyond, but early evidence points to positive contributions to reaching an increasing number of children with an ever-expanding number of life-saving antigens. Finding 2.20: Increased attention to demand health was a key shift in 5.0, but lower country appetite for new vaccine uptake/product switches has limited the opportunity to improve demand health.
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.	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. Finding 1.8: Alliance partnerships can work well, but some concerns exist about the inconsistent capacity and accountability of core partners. 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. 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. Finding 1.23: There is a high degree of convergence on a set of key barriers to including timelines for application/disbursement, alignment with country priorities, data quality and weaknesses in Secretariat and partner capacity. Finding 2.21: There is a gap in downstream/country support to evidence-informed decision-making around vaccine uptake and switches, only partially filled by limited available resources available in the Secretariat and the wider Alliance. 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

Conclusion	Supporting evidence (Findings)
	countries, with many fragile countries experiencing very low utilisation during 2021-22, and some fragile and core countries struggling to utilise funds into 2023. 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. 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. 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. Finding 2.11: COVID-19 is recognised as a key barrier to achieving the 5.0/5.1 SGs, but other drivers such as complex systems predate the pandemic. Finding 2.23: Gavi's demand health influence has been limited, partly due to the current co-financing policy, the country finance allocation methodology, and country control over choice of vaccine supplier and product presentation. 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.
5. Vaccine goals are unlikely to be achieved or sustained without resilient and strong health systems and increased attention to vaccine programme sustainability.	Finding 2.6: It is unclear whether 5.0 has the potential to strengthen health systems, or sustainability of immunisation investments. Finding 2.14: Responding to these constraints is often outside Gavi's control, meaning Gavi's contribution is often indirect, and relies on others for its effectiveness. Access and data are 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). Finding 2.15: The SG 4 indicators are on track for achievement, being minimally influenced by the pandemic. Finding 2.16: The SG4 corporate performance indicators are not well aligned to the emphasis of Gavi's market shaping work. Further, operational level SG4 M&E systems are not well-defined and transparent, which may reduce accountability and transparent prioritisation, as well as opportunities for learning and course correction.

Conclusion	Supporting evidence (Findings)
	Finding 2.6: It is unclear whether Gavi 5.0/5.1 will strengthen health systems or sustainability of immunisation investments. Finding 2.9: There is strong stakeholder agreement on a limited set of SG enablers, including health system capacity. 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. Finding 3.1: Gavi's operating environment will likely continue to be marked by turbulence and uncertainty during the remainder of Gavi 5.0/5.1 and 6.0. Gavi needs to ensure that its systems can respond to different country contexts with timely and flexible programming.
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.	Finding 1.2: PEF milestone data shows very limited focus on SG3-related interventions. 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. Finding 2.1: Co-financing remained at 100% between 2019 and 2022, waivers aside. 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. Finding 2.23: Gavi's demand health influence has been limited, partly due to the current co-financing policy, the country finance allocation methodology, and country control over choice of vaccine supplier and product presentation. Resource Mobilisation Finding: Co-financing is insufficient as an indicator of vaccine sustainability. Resource Mobilisation 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. Resource Mobilisation 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. MICs 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.

Conclusion	Supporting evidence (Findings)
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 these barriers depends crucially on the success of current efforts to deal with longstanding barriers to operational efficiency and effectiveness.	Finding 2.12: Our analysis notes the likely influence of a range of exogenous factors over which Gavi has limited control, or even influence, such as the effects of fragility and conflict, an increase in birth cohorts, and difficulties/lack of incentives in accessing the hard to reach, especially in a context of competing priorities. 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. Finding 3.2: International financial support is not assured for Gavi 6.0, with many competing priorities. 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.

Annex 15: Strengths and weaknesses

Table 32 presents strengths and weaknesses impacting Gavi 5.0/5.1 and Gavi 6.0, which were generated to inform lessons learned and recommendations. Connected findings are indicated in parentheses ( ).

Table 32: Strengths and weaknesses impacting Gavi 5.0/5.1 and 6.0

5.0/ 5.1	• Disbursements on track (1.1) • SG1 progress expected Momentum building on SG2 but not translated to results yet (1.3, 1.6, 2.1, 2.2, 2.15, 2.18, 2.27) • SG3 and SG4 broadly on track • The approach set out in 4.0, which is broadly carried forward into 5.0/5.1, is making a substantial contribution; and there are early indications that 5.0/5.1 will continue this trend. (2.4, 2.5, 2.17) • fundamental alignment around key priorities (notably ZD) and partnerships can work well to implement these priorities (1.7, 1.8) • Advocacy and country engagement (2.7) • Awareness of enablers and constraints and plans to address (internal and external) (1.11, 1.13, 1.19, 1.26, 2.22)	• SG2 off track; programming encouraging but won't show till 2025 (2.1, 2.2): *maintain focus* • SG3 lacks programming (1.2, 1.3) • Gavi priorities not being taken forward consistently, notably gender (1.4, 1.25, 2.21, 2.28, 2.29): *prioritise* • Gavi M&E weak in evidencing Gavi contribution, and lag in terms of 5.0/5.1 results will not be verified through WUENIC data until mid-2025 at earliest. (2.3, 1.25, 2.6, 2.8, 2.16): *put warning systems in place* • Implementation of partnership model is patchy (1.7, 1.9, 1.10, 1.13, 1.25) • Lack of country capacity (1.12, 1.25), reliance on partnerships, differentiation not working • EVOLVE will take time and success not guaranteed (1.19, 1.25) • Limits in Gavi influence over exogenous factors (2.12, 2.13, 2.14, 3.1): *requires flexibility*
6.0	• Gavi mechanisms committing/disbursing funds seems to be working (1.1) • Future progress plausible (1.3, 1.6, 2.17, 2.18, 2.22) • Early signs of progress on reforming Gavi internal systems and processes suggest scope for improvement going forward; likely to be mostly felt into 6.0 given planned roll out of work under EVOLVE and other internally-focused reform agendas (1.11) • Recalibration underlines importance of shared, realistic expectations with the Board around priority areas and results. Balanced scorecard and 'must have' list are a step in the right direction, enabling the Board to have more strategic oversight across Gavi's work rather than focusing in on specific policy areas. (1.22) • Gavi is focused on most of the internal and external barriers to progress that the MTE has identified. These represent agendas that will not be delivered/resolved within the 5.0/5.1 period will need to be central to thinking about Gavi's approach and risk identification for 6.0. (1.26, 2.7, 2.9, 3.4)	• 5.0/5.1 programming finalised in second half of strategy period, with knock-on effect for change in early stages of 6.0. • Gavi is trying to take forward too many priorities (c.f. lack of progress on gender). • Gavi faces a perennial challenge to ensure availability of quality data to evidence progress and Gavi's contribution. • Sustainability is not assured going into 6.0, with Gavi's approach to MICs both an important advance and one that needs modification (1.6, 2.21-24, 2.29, 3.4, 3.5) • Lack of clarity around Alliance roles, responsibilities, accountabilities and culture. Broadening partnerships important but comes with risks. • Rationalisation of Gavi tools and systems to ensure faster decision making and change management across the organisation, incorporating culture and ways of working. • Enable Gavi to flexibly respond to changes in their operating context

Annex 16: Supporting information for recommendations

In Table 33, we summarise key reform activities in Gavi which we understand are under preparation in the run up to 6.0, and which appear to be on similar tracks to our own recommendations (see Vol 1, Section 3.2). This provides context about the nature of our recommendations in terms of adapt, continue, or stop, as well as a contextual framing of the recommendations to maximise utility and relevance as Gavi enters the final two years of 5.1 and plans 6.0.

Table 33: Ongoing work related to the recommendations

MTE Recommendation	Activities
Continue strategic focus	Preparatory papers for Gavi 6.0 suggest strong continuity in strategic focus between 5.1 and 6.0. Our recommendation supports this and encourages Board decisions to that effect.
Organisational reform	The Operational Excellence agenda, including EVOLVE, addresses key aspects that fall under this recommendation and will be key to the successful implementation of 6.0. We focus on expectations, scope, implementation, monitoring and reporting to the Board.
Country engagement	EVOLVE incorporates proposals to operationalise differentiation in end-to-end Gavi systems and processes. Some progress has been made on delegating decision making. We focus on ensuring that decisions are made at country level in practice as well as in principle.
Partnerships	We focus on establishing clearer definitions of roles, responsibilities and accountabilities for Alliance Partners, particularly in countries and regions. Discussions around an Alliance reset, including increased knowledge-sharing and defining roles & responsibilities, are ongoing in the Alliance, but details and status were unavailable at the time of issuing this report.
Sustainability	We focus on actions to ensure financial and programmatic sustainability during a period of increased economic, social and political fragility. The ELTRACO policy suite is under review in preparation for Gavi 6.0, in recognition that sustainability is a key area that needs strengthening.
HSS	Gavi's first health systems strategy is under development. We endorse this work, recommending incorporating key aspects of the Lusaka agreement and learning from previous GHI experience in this area.
MICs	An internal review exercise related to MICs was conducted in late 2023, but details and status of any planned adaptations in response to this review were unavailable at the time of issuing this report. From informal conversations held during the February MTE recommendations workshop, it is understood that the our MICs-related implications and related recommendations are in line with the overall direction coming out of the internal review, and that the MTE serves as useful reinforcement.
M&E	The M&E challenges are well understood and Gavi is strengthening internal reporting, including CPMPM and the Balanced scorecard. We focus on consolidating and advancing previous efforts and ensuring that the necessary trade-offs are documented and reviewed.
Market shaping	Our recommendations are broadly consistent with Gavi's direct of travel, including the Market Shaping Strategy 2021-2025. We focus on ensuring better integration of market shaping into Gavi programmes, to promote value for money and programmatic sustainability. We also recommend a greater focus on demand health, noting that Gavi's market shaping roadmap development process is increasingly including demand health outcomes. We support AVMA, while noting some downside risks and we also suggest that Gavi, under suitable conditions, should deepen involvement in pull mechanisms.

In Table 34, we identify implications of each recommendation for 5.1 (course correction) and 6.0. Through this, we note that recommendations are relevant for the current and upcoming strategic periods.

Table 34: Implications of recommendations for Gavi 5.0/5.1 and 6.0 strategic periods

Recommendation	Gavi 5.0/5.1	Gavi 6.0
Continue strategic focus	Incorporate in 6.0 design work, including efforts to operationalise by start of 6.0.	
Organisational reform	Design, pilot, review organisation reforms to ensure they are ready for start of 6.0	Implement revised organisational reforms across the entire organisation. Monitor at board level.
Country engagement	Review and revise country engagement arrangements as per detail in recommendation 3; ready for start of 6.0.	Implement any agreed revisions.
Partnerships	Review and revise partnership working as per detail in recommendation 4; ready for start of 6.0.	Implement any agreed revisions. Monitor at board level.
Sustainability	Review and revise ELTRACO policies and other relevant policies e.g. market shaping as per detail in recommendation 5. Ensure ready for start of 6.0	Implement any agreed revisions.
HSS	Develop new health systems strategy and ensure ready for start of 6.0	Implement HS strategy.
MICs	Review and revise MICs approach for 6.0 and ensure ready for start of 6.0	Implement any agreed revisions.
M&E	Review and revise M&E arrangements as per detail in Recommendation 8 to ensure ready for start of 6.0	Implement any agreed revisions.
Market shaping	Review and revise arrangements to ensure sustainable supply of affordably priced vaccines as per detail in recommendation 9, and revisions that can be implemented from start of 6.0	Implement any agreed revisions.