REPORT OF THE INDEPENDENT REVIEW COMMITTEE TO THE GAVI ALLIANCE ON THE REVIEW OF APPLICATIONS

19 – 29 June 2023

23 AUGUST 2023

GAVI ALLIANCE

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List of acronyms

ACSM	Advocacy, Communication and Social Mobilization
AEFI	Adverse event(s) following immunisation
bOPV	Bivalent oral polio vaccine
CCE	Cold-chain equipment
CCEOP	Cold-chain equipment optimization platform
CEO	Chief executive officer
COVID-19	Coronavirus Disease 2019
cIP	comprehensive Improvement Plan(s)
EAF	Equity Accelerated Funding
EPI	Expanded Programme on Immunisation
EVM	Effective Vaccine Management
FED	Fragility, Emergencies and Displaced Populations Policy
FPP	Full Portfolio Planning
GACVS	Global Advisory Committee on Vaccine Safety
GEM	Global Equity Marker
HPV	Human papillomavirus
HR	Human resources
HRH	Human resources for health
HSS	Health Systems Strengthening
ITU	Innovation Top Up
IRC	Independent Review Committee
LLIN	Long-lasting Insecticide Treated Nets
MCV	Measles-containing vaccine
MEL	Monitoring, Evaluation and Learning
MR	Measles-Rubella
NMP	National Malaria Programme
NVS	New and underused Vaccine Support
Ops	Operational Support
PCCS	Post-Campaign Coverage Survey
Penta	Pentavalent vaccine (DTP, Hib, HepB)
PMI	Partnership for Market Implementation
PoA	Plan of Action
RCM	Rapid Convenience Monitoring
RI	Routine Immunisation
SAGE	Strategic Advisory Group of Experts on Immunisation
SIA	Supplementary immunisation activity
TA	Technical assistance
TCA	Targeted Country Assistance
TCV	Typhoid conjugated vaccine
TOC	Theory of change
TRP	Technical Review Panel
WUENIC	WHO and UNICEF estimates of national immunisation coverage
ZDC	Zero Dose Children

1. Executive Summary

The Gavi Independent Review Committee (IRC) met virtually from 19 to 29 June 2023. A total of 20 countries had submitted applications for support from Gavi and of these, three countries requested support for Malaria (RTS,S) vaccine which has been made available recently. Other applications were for Measles/Measles-rubella (M/MR), yellow fever (YF) vaccine, yellow fever diagnostics, typhoid conjugated vaccine (TCV), Japanese Encephalitis (JE), Cold Chain Optimization Platform (CCEOP), Equity Accelerator Fund (EAF) and Full Portfolio Planning (FPP) incorporating HSS, EAF, CCEOP, TCA, ITU, a MR follow-up campaign (Eritrea). A total of 21 IRC members with a wide range of expertise participated in the review meeting. Three IRC members conducted in-depth financial and budget reviews of the applications (excluding RTS,S malaria applications) and two others on the supply chain, logistics, vaccine management and waste management. The IRC focussed on the following; (a) Review of countries' funding requests and supporting documentation for vaccine introductions and campaigns to support national efforts to improve immunisation coverage and equity; (b) Production of country-specific review reports and recommendations; (c) Development of a consolidated report of the review round, including recommendations for improving funding requests and strengthening routine immunisation; and (d) Provision of recommendations to the Gavi Board and Alliance partners on improving processes relating to Gavi policies, governance, and structure. Review modalities included an independent desk review of each application by two designated members and discussion in plenary with the participation of the full committee.

Results

The IRC recommended approval for the new and under-used vaccine support (NVS) applications for Malaria RTS,S Vaccine for all three applicants (Central African Republic (CAR), Nigeria, South Sudan). Six countries with M/MR follow up campaign requests targeting children 9 months to 59 months (Cambodia, Eritrea, Lao PDR, Liberia, Rwanda, Sierra Leone) were also recommended for approval. However, the MR request from Mauritania, which targeted children aged 9 months to 14 years, was approved only for standard follow-up campaign age group of 9 to 59 months and the IRC noted that it would be more impactful if the country concentrated on reaching high coverage in the standard age group and reaching zero dose and under-vaccinated children. The TCV requests (Bangladesh, Burkina Faso) and the YF campaign (Niger), YF diagnostics (Sierra Leone) and the remaining stand-alone EAF requests (Congo, Haiti, Niger, South Sudan) and the CCEOP (Rwanda) were all also recommended for approval. For the FPP requests, Mali, Tajikistan, Togo and Zambia were recommended for approval for all requested components. For the remaining two FPP countries, Cameroun and Eritrea, the HSS and EAF requests in both countries and the ITU request for Eritrea were recommended for re-review. The key reasons for these re-reviews were the lack of strategic approaches to health systems strengthening and insufficient alignment between the Theory of change (TOC) and resource allocations.

The IRC noted that NVS applications had a stronger focus on increasing MCV2 coverage with strategies for catch up and integration of interventions in the 2YL platform. However, these activities were often not reflected in the work plans. On the other hand, two high performing countries (Rwanda, Eritrea) used Gavi operational funding flexibility for their MR applications based on a careful measles outbreak and immunity analyses across districts. The IRC also noted that although all applications referred to vulnerable groups that need targeting, only Bangladesh and Niger adequately mapped and quantified these groups while the rest planned to do so at the campaign microplanning stage, which based on the chronograms provided is in all applications late for strategic planning. The estimation of zero-dose children remains a challenge for the countries and no countries use other data sources such as EPI outreach, checking of vaccination status during

campaigns for triangulation. Efforts were also made in the applications to provide gender and equity analyses, but no applications provided rigorous strategies that were gender transformative and equity issues from the analyses were not fully integrated. Furthermore, countries requesting or had recently received other Gavi support (EAF, HSS, TCA, ITU) were not leveraging analyses (e.g. epidemiological, gender, equity) from these support requests into the campaign plans. Another important finding was that three countries (Eritrea, Mauritania, Rwanda) presented recent data (2017-2022) from their case-based measles/rubella surveillance that showed 27%-30% of their cases aged 15 years and above, reflecting residual susceptibility to measles in older cohorts. None of the countries commented on the importance of this and the need to call for exploring options for school vaccinations, adolescent and adult immunisation.

For the supply chain, although updated EVMs were provided by all countries, the key challenges were delays in preparation of the comprehensive Improvement Plans (cIPs), the lack of waste management standard operation procedures and lack of updated national policies. As regards budgets submitted with the applications, the IRC noted improvements in overall quality of campaign planning with alignment of activities and proper use of Gavi budget templates and calculations. The major issues (which have been identified in previous IRC reviews) are the high HR associated costs that appear to be related to the inconsistencies in the number of vaccinators and workloads which are not in line with WHO recommendations and details such as rationale for the estimates which are not provided or sufficiently explained.

The IRC noted that the FPP applications allowed a better understanding of the country immunisation strategy as most programme components were included. However, for low coverage countries, there was clear tension between targeting zero dose children and health systems strengthening as several countries were targeting HSS support to the few districts with large numbers of zero dose children and leaving out all the others with no support for essential EPI activities. It will be essential therefore to revise the guidance so that strengthening of the system remains a priority. The FPP reviews also lacked clarity on contributions by other partners in support of immunisation. In addition, key findings from the FPP applications were related to ITU funding which was not used strategically but treated as extra resources. The TCA strategy, though aligned with the key FPP priorities was not always linked to specific activities and often, the numbers and positions requested not always justified in the country context. Finally, the IRC noted that two countries (Mali, Tajikistan) indicated climatic change as a factor affecting their programmes but overall countries had not developed strategies to address this. It is therefore essential that Gavi and Alliance partners provide guidance to countries on strategies beyond solarization of CCE.

2. Methods and Processes
Methods

The meeting agenda, allocation of countries for review, country applications, supporting documents and briefing materials were shared with the IRC on 9 June 2023, 10 days before the start of the meeting. IRC members reviewed the applications and prepared individual draft reports of their assigned countries. Additional documentation or clarifications were provided by the Secretariat prior to the meeting. Dr Benjamin Nkowane, Vice Chair of the IRC, chaired the first week of the meeting and Professor Rose Leke, Chair of the IRC, chaired the second week of the meeting. Both were supported by Dr Sandra Mournier-Jack, the other Vice Chair of the IRC.

The meeting was opened by Mr Johannes Ahrendts, Director SFP, who welcomed the IRC members and outlined the expectations for the review. Updates were provided on the FED policy, the Gavi Gender Policy,

malaria vaccine, TCV vaccine, JE vaccine and measles-rubella vaccine. The IRC was also briefed on the Gavi focus on a revised "risk appetite and approach" for supporting measles supplementary immunisation activities. For the applications for measles and rubella vaccines support the country program managers made presentations to the IRC outlining the key issues in the requests for support were followed by questions and answers. Bangladesh, which submitted a revised application for TCV and JE vaccine also made a presentation to the IRC.

Review process

Each country proposal was reviewed independently by a primary and a secondary reviewer, each preparing an individual report. Cross-cutting issues (budgets, financial sustainability, supply chain and waste management) were reviewed in each application (except for malaria applications) by one financial crosscutter and one IRC member specialised in supply chain management. Gavi did not request the in-depth finance review for malaria applications. FPP applications reviews were presented to the IRC. The review process depended on country categorization (Core, High Impact, Fragile and Conflict). The review of the FPP proposals started remotely before the IRC and had additional interactions with the country and the secretariat through briefing and clarification calls. All the country reports were individually presented and recommendations were discussed in plenary. The Gavi Secretariat and Alliance partners supported the plenaries by providing information and clarifications when needed on country-specific issues and context.

For each application, action points, or issues to be addressed, were agreed upon during the plenary, and the IRC agreed on recommendations of either approval or re-review, based on consensus. The first reviewers then consolidated their reports with the reports from the secondary and cross-cutting reviewers in line with the outcomes of the plenary discussion, including decisions and recommendations. The reports were finalized after editing, fact and consistency checking, and quality review. Where a country submitted more than one request for support, a single report was provided with relevant recommendations for each request. The IRC was in addition also presented, for information only, a completed full in-country review FPP report for Papua New Guinea done since the last March IRC meeting.

Criteria for review

Review of the applications was guided by the IRC Terms of Reference and key criteria in line with Gavi mission. These include justification for the proposed activities, soundness of approach, country readiness, feasibility of plans, contribution to system strengthening, programmatic and financial sustainability, value for money and public health benefits of the investment. The IRC adhered strictly to these guidelines to ensure the integrity, consistency, and transparency of the funding decisions. In addition to the above, the IRC assessed the extent to which countries are adapting the applications to focus on identifying and vaccinating zero dose children and how resources will support this.

Decisions

There were two decision categories:
1) **Recommendation for Approval** when no issues were identified that would require re-review by the independent experts.
2) **Recommendation for Re-review** when there were critical issues that require a new review by the independent experts which entails detailed revision of application and a new submission to the IRC.

The recommendations of the June 2023 IRC reviews are summarized in Table 1, and Table 2 below.

Table 1: Summary of requests from countries and review outcomes for NVS and Malaria

RECOMMENDATION OUTCOMES (NVS AND MALARIA –IRC, JUNE 2023

	Countries	Types of support			
		NVS requests	Malaria	Other stand-alone requests	Recommendation outcomes
1	Bangladesh	TCV			Approval
		JE			Approval
2	Burkina Faso	TCV			Approval
3	Cambodia	MR f-u campaign			Approval
4	CAR		Malaria		Approval
5	Congo			EAF	Approval
6	Haiti			EAF	Approval
7	Lao PDR	MR f-u campaign			Approval
8	Liberia	Measles f-u campaign			Approval
9	Mauritania	MR f-u campaign			Approval *(for reduced age range)*
10	Niger	YF campaign			Approval
				EAF	Approval
11	Nigeria		Malaria		Approval
12	Rwanda	MR f-u campaign			Approval
				CCEOP	Approval
13	Sierra Leone	MR f-u campaign			Approval
		YF diagnostics			Approval
14	South Sudan		Malaria		Approval
				EAF *(portion)**	Approval

* Re-review of a portion of EAF from June 2022

Table 2: Summary of requests from countries and review outcomes for FPP applications

RECOMMENDATION OUTCOMES (FPP APPLICATIONS) IRC, JUNE 2023

	Countries	Types of support	
		FPP proposals	Recommendation outcomes
15	Cameroun	HSS, EAF TCA CCEOP	Re-review, Re-review Approval Approval
16	Eritrea	HSS, EAF TCA Innovation top-up MR follow-up campaign CCEOP	Re-review, Re-review Approval Re-review Approval Approval
17	Mali	HSS, EAF TCA FED	Approval, Approval Approval Approval
18	Tajikistan	HSS, EAF TCA Innovation top-up	Approval, Approval Approval Approval
19	Togo	HSS, EAF TCA CCEOP	Approval, Approval Approval Approval
20	Zambia	HSS, EAF TCA Innovation top-up CCEOP	Approval, Approval Approval Approval Approval

Table 3: Summary of IRC review outcomes (including in-country FPP reviews since March 2023 IRC

Country	Support	US$ Amount (cash support)	Recommendation
Papua New Guinea	HSS TCA - portion TCA - portion	30.9 M 7.0 M 2.3 M	Approval * Approval * Re-review .

Includes full approval for July 2023 - Dec 2025 and programmatic approval from Jan 2026 - Dec 2027, subject to approval of PNG Strategy extension by the Gavi Board.

Thematic areas sub-committees

During the review, IRC members were organized into six sub-Committees: RTS,S Malaria Vaccine Introduction; other New and under-used vaccine support (NVS) and Campaigns; Gender, Equity, and Zero-dose; Supply Chain, cold chain, logistics and waste management; Budget, Financial Management, Sustainability; Data – Monitoring, Evaluation and Learning (MEL); and Full Portfolio Planning. Each sub-committee identified issues in the applications that would be of general interest for Gavi and partners to include into the consolidated global report.

Gavi Senior Management, Secretariat and Alliance partners debriefing and closing session

The debriefing of the Gavi Secretariat and partners was held on 29 June 2023. A summary of the IRC meeting's outcomes and key issues and recommendations were presented by each thematic group, and a conclusion by the chair of the IRC. This was followed by in-depth discussions, questions, comments, and responses from the Gavi management, Secretariat and technical partner representatives. It was an opportunity for the IRC to say goodbye to Dr. Seth Berkley, CEO, Gavi, and this was done by the IRC Chair. Dr Berkley thanked the IRC for their work and commitment over the years in participating in the review of country applications, provided some comments and closed the meeting.

3. Key Findings and Recommendations

New and under-used vaccine support (NVS) and campaigns

During this session, IRC reviewed applications from 10 countries for campaign operational support. Seven countries requested support for MCV follow-up campaigns: of these, six targeting children 9 to 59 months (MR – Sierra Leone, Liberia, Rwanda, Cambodia, Eritrea, measles only – Lao PDR), and one targeting 9 months to 14 years (MR – Mauritania). One country applied for yellow fever (YF) mass prevention campaign support, targeting wide age range from 9 months to 60 years (Niger), one for Typhoid conjugate vaccine (TCV) catch-up campaign followed by routine introduction (Burkina Faso), and one for TCV and Japanese encephalitis (JE) catch-up campaigns followed by routine introductions (Bangladesh). The requests for catch-up campaigns included the standard target age group for that SIA type, i.e. 9 months to 14 years. All applications had national geographical scope except Bangladesh's JE campaign subnational scope targeting only 3 divisions (i.e. Rangpur, Rajshahi, and Chattogram). Of ten countries, applications from nine were fully approved, while Mauritania's MR campaign operational support request was approved for the standard follow-up campaign age range (i.e. 9 to 59 months) but not for the age range requested (9 months to 14 years). IRC concluded that it would be more impactful for measles control if the country concentrated on reaching a very high coverage in the standard follow-up campaign group 9 to 59 months and reaching zero-dose and under-vaccinated children. Total funds requested for campaign support amounted to about US$ 59.3 million (M/MR

US$ 4.6 million, YF US$ 16.3 million, TCV US$ 28.7 million, and JE US$ 9.7 million), while vaccine introduction grant requests amounted to about US$ 3.6 million.

Overall, countries continue to strive to provide subnational data and identify zero-dose and under-vaccinated children. The analyses of measles epidemiology are more complete and of better quality, and IRC is particularly pleased to note some countries reporting on AEFI surveillance performance in their applications (Eritrea, Rwanda, Sierra Leone, Lao PDR).

Consistency between country workplans and campaign/new vaccine introduction plans of action

Seven countries (i.e. Lao PDR, Mauritania, Cambodia, Rwanda, Sierra Leone, Liberia, Eritrea) applied for operational support for M/MR follow-up campaigns to provide another opportunity for measles vaccine to children who missed their second dose in the routine programme. Except Rwanda, all applicant countries have suboptimal MCV2 coverage which is between 13 percentage points (Cambodia) and 23 percentage points (Lao PDR, Liberia) lower than MCV1, making MCV1/MCV2 drop-out rates from 15% (Cambodia) to 30% (Lao PDR, Sierra Leone), or the countries have only recently introduced MCV2 like Liberia (2019) or Mauritania (2023). The IRC notes a stronger focus on increasing MCV2 coverage in applications. Countries describe various strategies in their plans of action to catch up with missed doses, such as PIRIs in selected areas or integration with other interventions as a part of the 2YL platform (e.g. growth monitoring, nutritional assessment, mebendazole administration, birth registration, etc.), as experience has shown that mothers are more likely to present their children for vaccination when other services are co-administered. However, the activities mentioned in plans of action do not translate in countries' annual EPI workplan (see Table 1), making it difficult to assess how these and planned campaign activities can be complemented or leveraged. Some operational challenges persist, including but not limited to coordination and collaboration between the vaccinators and other service providers and suboptimal outreach services for the 2YL interventions.

Table 4: Inclusion of 2YL strategy and activities in plans of action for MCV follow-up campaigns and countries' EPI annual workplans (source: country applications)

MCV follow-up SIA	Description of 2YL strategy/activity
Lao-PDR	Mentioned in strategies No specific activities in EPI annual work-plan
Mauritania	None mentioned
Cambodia	Mentioned in strategies No specific activities in EPI annual work-plan
Rwanda	Described in strategies and lessons learnt No specific activities in EPI annual work-plan
Sierra Leone	Described in PoA No specific activities in EPI annual work-plan
Liberia	Described in PoA No specific activities in EPI annual work-plan
Eritrea	Described in PoA No specific activities in EPI annual work-plan

Issue 01: While 2YL strategy and activities are mentioned in the campaign plans of action, they are not translated into activities in countries' EPI annual workplans.

Recommendations:
- Gavi and technical partners to encourage countries to identify key contextualized activities that promote the 2YL attendance beyond advocacy communication and social mobilisation, to be included in the work-plans and budget.

- Gavi to encourage countries to invite all stakeholders that directly or indirectly affect the 2YL attendance to participate in the inter-agency coordination committee (ICC) meetings, to encourage monitoring of progress and feedback.
- Gavi to explore guidance on giving priority to 2YL activities in the situation analyses of the strategic plans for immunisation, Malaria, Nutrition, and Maternal and Child Health, to allow better contextualisation of interventions.

Reaching vulnerable populations during campaigns and routine immunisation

In most applications countries mention vulnerable groups but often do not quantify them, and the adaptation or refinement of strategies are not properly addressed. In MR follow-up campaign applications, we continue to see special groups mentioned but not included in campaign strategies, for example large refugee populations from neighbouring countries such as about 92,000 Malian refugees in Mauritania, or 149,000 refugees in Rwanda. The commendable exceptions in this review round are inclusions of Forcibly Displaced Myanmar Nationals in Bangladeshi TCV and JE campaign plans of action, and refugee/immigrant populations in Niger, who are all well-quantified and included in the target population. Further, in most applications, mapping of hard-to-reach communities or areas and strategies' adaption are left to microplanning phase. Microplanning, when indicated in the campaign workplan/chronogram, is often too close to the campaign implementation (Eritrea, Burkina Faso), or sometimes not even presented in the POA (Niger). However, the Bangladesh application, which was a re-review, showed improvements in campaign planning, with a timely bottom-up microplanning and specific and time-bound activities.

Finally, IRC notes that countries do not leverage analyses from other Gavi support requests when submitted, in their campaigns' POA. Even when vulnerable populations have been identified, differentiated strategies are not well described and do not address all aspects of inequity identified in situation analyses from Equity Accelerator Funding (EAF), Zero dose Immunisation Programmes or TA requests. For example, Niger's proposed strategy for zero-dose and under-vaccinated children in the EAF application was not integrated into the YF campaign POA.

Issue 02: Despite improvements in identification, characterisation and mapping of zero-dose, vulnerable, and hard-to-reach populations, the differentiated strategies proposed do not leverage analyses from EAF support requests and remain weak.

Recommendations:
- Gavi and partners to support countries to develop comprehensive strategies for promptly reaching all vulnerable populations.
- Gavi to request countries to present a summary of EAF into campaign POA.
- Gavi to include information on ongoing or upcoming EAF applications for each country in pre-screening documentation.

Residual susceptibility to measles in older cohorts

The IRC notes with pleasure that two high-performing countries in this round of review, Eritrea and Rwanda, used Gavi operational funding flexibility for their MR campaign applications. Eritrea, given its sustained high coverage, permissible national vaccination policy with school entry checks, and high retention of vaccination cards, opted for a national selective follow-up campaign which would include screening of 9- to 59-month-old children nationally and vaccination of only those with missed doses of measles vaccine. Rwanda, which

identified gaps in coverage based on outbreak and immunity analysis across districts, opted for a subnational non-selective follow-up campaign targeting all 9- to 59-month-old children in areas of low coverage while keeping the intensified demand generation activities in excluded districts. In the analysis of confirmed measles cases, most confirmed cases in both Eritrea and Rwanda were older than 5 years (Table 1). Interestingly, in Eritrea, the age-based analysis of the crude incidence rate per 100,000 revealed that measles cases were higher in adolescents and adults, indicating an epidemiological shift to older cohorts. Operationally, a follow-up SIA would likely miss a large proportion of individuals with residual susceptibility in Eritrea, as would other current programme options. However, despite overall high MR coverage, there are spatial inequalities in vaccination coverages and surveillance which should be addressed through the routine strengthening of microplanning, reporting and monitoring, and management of outbreaks.

On the other hand, Mauritania, which only recently introduced MR2, with suboptimal MR1 and high-quality measles campaigns by survey, applied for an MR follow-up campaign but with an extended age range (i.e. 9 months to 14 years). Although Mauritania has a high proportion of confirmed measles cases in children 5 to 14 years of age (Table 1), given that the relative rate of infection for measles remains highest among children under 5 years of age, if the country reaches more than 95% coverage in the follow-up campaign with standard age range (i.e. 9 to 59 months), the measles immunity gap in older children will not make much difference in measles control. It remains critical that the country focuses on achieving high routine immunisation coverage and strengthens measles vaccination in the second year of life and beyond while developing operational strategies to identify zero-dose and under-vaccinated children and targeting hard-to-reach populations.

Table 5: Confirmed measles cases (%) by age in applicant countries and campaign type and geographical scope (Source: country applications)

Country/period	Age distribution of confirmed measles cases (%)					Campaign type / scope
Eritrea (2018-22)	<9m **15%**	9-24m 7%	25-59m 22%	5-14yr **25%**	>15yr **31%**	National selective follow-up
Rwanda (2017-22)	<9m **8%**	9-24m 12%	25-59m 18%	5-14yr **35%**	>15yr **27%**	Sub-national non-selective follow-up
Mauritania (2019-22)	<11m **5%**	12-23m 28%	25-59m 18%	5-14yr **20%**	>15yr **30%**	National non-selective follow-up

Issue 03: Current programme options (routine or campaigns) have no effect on residual susceptibility to measles and rubella in older cohorts.

Recommendations:
- Gavi and partners to further encourage countries to make data-supported context-specific campaign type and scope choices, considering feasibility and expected impact.
- Gavi, partners, and countries to explore options for school vaccinations, adolescent and adult immunisation.

AEFI surveillance
Functional national AEFI surveillance and response systems remain key components which contribute to maintaining public confidence in vaccines and vaccination programmes while monitoring and ensuring the safety of vaccines. Therefore, strengthening technical capacity for AEFI surveillance systems in countries and reporting on AEFI surveillance system performance as a part of joint appraisal report/multi-stakeholder dialogue, have been standing IRC recommendations.

Upon analysis of AEFI surveillance in 13 countries reviewed in this round, IRC notes with pleasure that almost all countries as shown in Figure 1 (12/13 countries: Bangladesh, Burkina Faso, Cambodia, CAR, Eritrea, Lao PDR, Liberia, Mauritania, Niger, Nigeria, Sierra Leone and South Sudan) demonstrate capacity of AEFI reporting in 2022 (i.e. have more than 10 reported cases per 100,000 surviving infants per year).

Figure 1: AEFI reporting rates in 13 countries discussed in IRC plenary session (source: JRF 2022)
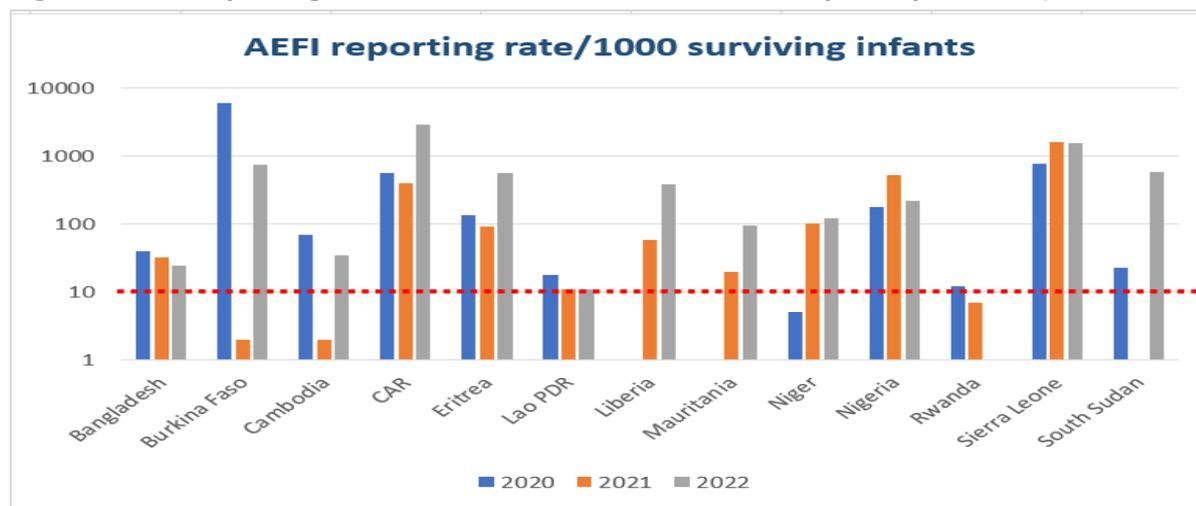
However, progress with case-based serious AEFI reporting remains slow. The case-based serious AEFI indicator rate is introduced with the IA 2030 and is required for monitoring progress in AEFI surveillance in all age groups. In this round, only 5/13 countries (CAR, Eritrea, Lao PDR, Nigeria, Sierra Leone) meet the initial target of at least 1 serious AEFI case reported per 1 million population per year (Figure 2). While many countries may find it challenging to transfer case-based information to higher administrative levels without electronic tools, serious AEFI must be documented.

Figure 2: Rate of case-based serious AEFI in 13 countries (source: JRF 2022)
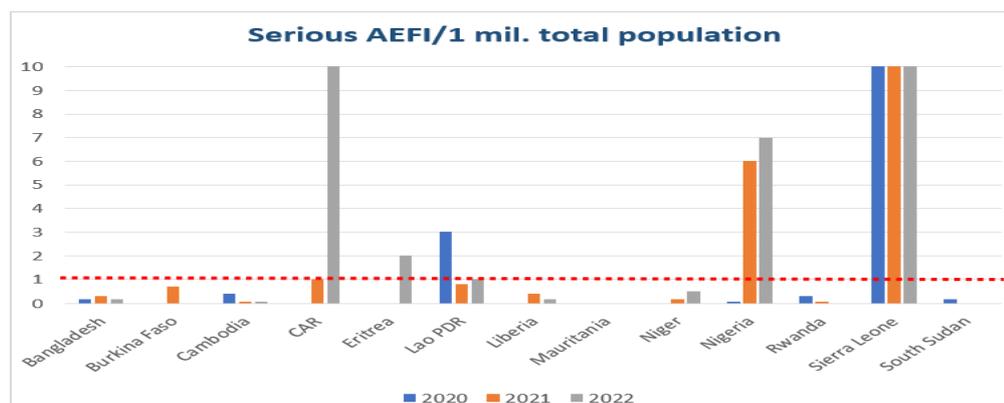
Despite repeated IRC requests, only 4 of 13 applicant countries reported on performance of their AEFI surveillance system of which two only from campaigns (Eritrea, Rwanda from campaigns, Sierra Leone, and Lao PDR for RI), however, it is limited to quantitative information, with no qualitative analysis. Although 6 countries will be introducing new vaccines (malaria, JE, TCV, YF) none of them plan sentinel surveillance or at least enhanced passive AEFI surveillance. It is unclear why for new vaccine introductions countries and partners rely on passive AEFI surveillance and do not align with Global Advisory Committee on Vaccine Safety (GACVS) recommendations. Unlike passive surveillance, active vaccine safety surveillance activities are less

affected by underreporting or inappropriate reporting, and can be used to estimate rates when the size of the population is known. Various methodological approaches can be used that are appropriate for monitoring vaccine safety post introduction in resource limited settings (e.g. self-controlled case series techniques), especially regarding hospitalized outcomes. This can provide important data on the risk of a particular adverse event among vaccinated individuals, especially for new vaccines that have not been used in countries with mature AEFI surveillance systems, and boost the credibility of immunisation programmes in general and their acceptance by population.

Issue 04: Slow progress in reporting on AEFI surveillance system performance and no consideration of active vaccine safety surveillance methods for new vaccine introductions.

Recommendations:
- Gavi to request countries to report on AEFI surveillance system performance.
- Gavi and partners to encourage countries to consider sentinel surveillance for all new vaccine introductions, especially malaria and TCV or at least enhanced passive surveillance with active follow-up and causality assessment of AEFI of potential interest (GACVS recommendation).

RTS,S Malaria vaccine introduction

Three malaria vaccine applications were reviewed in this round from Nigeria, South Sudan and the Central African Republic (CAR). All applications were recommended for approval. The reviewers found that all three applications were aligned with the Gavi Alliance guidance provided, and efforts were made for an effective coordination between the EPI and the National Malaria Programme (NMP). High-level support was provided from both the Ministry of Health and Finance, demonstrating technical and financial commitment to the malaria vaccine introduction.

Integration of other childhood interventions during introduction of the malaria vaccine

It was observed that all three countries are planning to associate the Malaria vaccine with other interventions, including administration of Vitamin A (at 6 months CAR and Nigeria), and/or Mebendazole (South Sudan). However, for South Sudan, children aged younger than 12 months were targeted to receive Mebendazole and children less than 6 months were targeted for Vitamin A.

Issue 05: Appropriate age indications are not always observed when integrating malaria vaccination with other high childhood impact childhood interventions.

Recommendation:
- Gavi to require countries explicitly follow WHO recommendations on appropriate age, to avoid potential side effects jeopardizing introduction success when planning to include other childhood impact interventions during malaria vaccine introduction.

Timeframe for the 3rd and 4th dose of malaria vaccine

The IRC noted that 2 out of 3 countries applying for support to introduce malaria vaccine considering age-based schedule, diverged from the recommended 12-18 months interval between the 3rd and the 4th dose (WHO position paper, March 2022), making use of the WHO-proposed flexibility to optimize vaccine delivery. Table 6 shows the vaccination schedule and the intervals between the 3rd and the 4th dose chosen by applicant countries. For South Sudan and CAR, the IRC also noted that these countries opted for off-label use

of RTS,S vaccine (i.e. interval between the 3rd and 4th dose is shorted than 12 months). It is unclear why these countries adopted this approach.

Table 6: Proposed vaccination schedules for Malaria vaccine, Nigeria, South Sudan, CAR

Country	Vaccine Schedule	3rd to 4th dose interval
Nigeria	5, 6, 7, 20 months	13 months
South Sudan	5, 6, 7, 18 months	11 months
Central African Republic	6, 7, 9, 16 months	7 months

Issue 06: Flexibility in the vaccination timeframe for the 3rd and 4th dose

Recommendations:
- Gavi and Alliance partners to encourage countries to reflect on options to achieve the highest impact and effectiveness when determining their country malaria vaccine schedule (in particular referencing the 3rd to 4th dose interval).
- Partners to guide and support countries to monitor safety and efficacy of malaria vaccine in particular when off-label options are applied and document the findings.

Contribution of partners to workplans for introduction of malaria vaccine
It was noted that while the Vaccine Introduction Grant (VIG) is meant to cover a share of the RTS,S vaccine introduction activities, countries indicate in the applications that they are leveraging existing financial resources mostly from Alliance partners. However, the submitted plans are not comprehensive and do not specify all the partners' contributions (GF, PMI, WB others) for the Malaria vaccine introduction.

Issue 07: Programmatic workplans not reflecting partners contribution.

Recommendations:
- Countries leveraging existing partner financial support (from GF, WB, PMI and others) should reflect these contributions in the budget/workplan.
- Gavi to closely collaborate with the Global Fund in support of malaria and EPI programmes so that funding and resources are leveraged and potential synergies capitalised. This would help strengthen health system key elements such as National Health Information Systems (NIHS), the supply chain and human resources for health (HRH).

Vaccine wastage rates for malaria vaccine
During this round, the IRC noted that CAR and South Sudan submitted vaccine wastage rates of 5% and 7%, which were withing the acceptable WHO recommended rate of 7%. Nigeria submitted a wastage rate of 9% without providing justification or context for the high wastage rate. The IRC noted that in its previous reviews of malaria vaccine applications, countries applied a 5% wastage rate reflecting effective vaccine management by keeping wastage to a minimum particularly when the global supply is limited.

Issue 08: Wastage rates for the malaria vaccine introduction.

Recommendation:
- Gavi should continue to request countries to provide a strong justification for their malaria wastage rate, particularly if higher than that recommended by WHO.

- Where high wastage rates are submitted, Gavi and Alliance partners should support effective vaccine management.

Gender, Equity and Zero-dose Children

Gender analyses inclusion and incorporation in proposed activities

All applications of this round made efforts to provide some, though primarily descriptive, analysis of gender. This continues to be primarily in terms of sex-related differences in immunisation coverage and associations between coverage and maternal education, with some countries indicating that gender did not appear to be a major equity concern within immunisation programming (e.g. Cambodia, Rwanda). However, few applications used gender analysis to explicitly inform planning and no applications provided rigorous strategies or policy-level engagement in gender responsive and transformative approaches within immunisation. The latter is perhaps unsurprising, as it can be challenging to consider gender responsive/ transformative action within NVI or campaign requests but there should be scope for this in FPP applications. While several FPP applications noted that gender issues would be addressed, this often appeared as an afterthought. For example, while Tajikistan noted in its TCA report from June 2023 that addressing gender inequities should be ensured during TCA planning, in its FPP application gender analysis is included in a "demand generation and barriers to vaccination study" that will thus miss gender-related concerns beyond these issues (e.g. to service delivery, data disaggregation, reporting and monitoring). Finally, introduction of gender markers in workplans activities was noted, but decisions about which activities would be most crucial seems largely subjective, with limited to no rationale provided.

Advancing gender equity is not only about funding applications or activities but instead is an approach that should be applied across everything Gavi does and supports, e.g. by ensuring development and implementation of gender-responsive/transformative strategies that are monitored using evidence-based indicators in all funding windows (e.g. inclusion in national policies, women's socioeconomic status, decision-making power, women's rights adherence, education levels, vaccination access). In terms of projection (e.g. capacity building in countries, especially for those where with significant gaps or bottlenecks), a Gender Equity Marker (GEM) could provide a baseline, with low scores to be met with support approach that aims to build capacity and strengthen approaches to gender equality.

Issue 09: Gender analyses do not explicitly inform planning and rigorous strategies or policy-level engagement in gender responsive and transformative approaches within immunisation are not included or remain weak.

Recommendations
- Gavi to consider working with partners to ensure standardised and holistic gender analyses are conducted in countries and to help countries to consider gender responsive and transformative approaches.
- Gavi to follow-up recommendations by the IRC that gender analyses should provide the foundation for gender-responsive and transformative strategies in any application, by ensuring development and implementation of gender-responsive/transformative strategies and are monitored using evidence-based indicators.
- Gavi to consider developing a Gender Equity Marker (GEM) to track the extent to which all Gavi financing supports gender equity.

Equity analyses adequacy and incorporation of lessons learnt

Some good examples in applications (e.g. Cambodia MRfu, Nigeria Malaria, Sierra Leone MRfu) incorporated specific equity lessons from previous introductions and SIAs. However, equity issues are still not fully integrated into applications, sometimes appearing as an afterthought, or planned after development of activities (e.g. Congo). Some applications (e.g. South Sudan EAF, Niger EAF, Mauritania MRfu, Haiti EAF, CAR malaria) only aggregated quantitative data on parameters that are of limited use programmatically in addressing equity and gender in immunisation, e.g. infant sex, parental educational level, household income, geographical location (rural vs urban), that may hide sub-national divergences and miss group-specific vulnerabilities (e.g. mobile populations, ethnic minorities). Additionally, equity analyses generally focused on vaccination demand without considering delivery and thus did not consider elements such health centre/district resources or gender-based violence (i.e. Cameroon HSS/EAF, Mauritania MRfu, Haiti EAF).

Issue 10: Equity issues are still not fully integrated into applications and generally focus on vaccination demand without considering delivery.

Recommendations

- Gavi and partners to consider supporting countries in including root-causes in equity and gender analyses by triangulating data from surveys and other research.
- Gavi and partners to consider requesting countries to include matrices within equity and gender analyses that show identified challenges and proposed solutions.

Capacity of proposed strategies to address coverage inequities and reach zero-dose children

Applications in this round described approaches to developing ZDC strategies, but sometimes before the relevant analyses were available (e.g. gender analysis for Congo EAF) and mentioning details to be elaborated later. Despite some general improvements in equity reporting, data collection and analyses are still limited and may be sub-nationally focused on areas being funded (e.g. Mali). Without general and gender equity being explicitly included in applications, TOCs, and MELs, it is difficult to ensure that strategies will address coverage inequities and effectively reach un/under-immunised children.

Most equity-relevant strategies were fragmented across or within different funding windows (e.g. HSS and EAF for Eritrea), resulting in partial and disjointed action in terms of activity packages, geographic coverage, time sequencing, and stakeholder involvement. Therefore, activities may have limited impact and even unintentionally increase disparities. Best practice examples for countries could thus be useful along with effective MEL follow-up. Issues requiring improvement include development of tailored equity guidance for immunisation, streamlined among international partners based on the RED/REC approach. This should include development of streamlined guidance for community engagement integrated into stakeholder mapping, microplanning, and other activities) using linguistically and socio-culturally adapted communication tools and approaches. Additionally, periodic implementation of equity-focused mapping and characterization, bottleneck analysis, tailored service delivery with adapted tools and activities, and measurement of bottleneck reduction in target geographic locations could be helpful to incorporate in a comprehensive package of equity-focused activities.

Issue 11: Despite general improvement in equity reporting and equity-relevant strategies to address coverage inequities, effectively reaching zero-dose children remain fragmented across or within different funding windows.

Recommendations

- Gavi and partners to consider supporting a comprehensive package of equity-focused activities, including equity-focused mapping and bottleneck reduction, to leverage HSS/EAF/TCA/FPP funding and synergies with partners addressing gender inequities.

Cold Chain, Logistics and Waste Management

Cold chain readiness for NVS (MRfu, TCV, YF, Malaria)

NVS can create additional pressure on a strained supply chain system in countries with limited storage capacity. All countries provided updated EVM assessment records and had sufficient storage capacity. This was due to timely investments by the Gavi Alliance and other partners in Cold Chain Equipment through the CCEOP applications and the recent COVAX facility. While countries continue to face supply chain challenges, the IRC noted that Cambodia, Rwanda, Nigeria, and Niger were the best performers in EVM assessment (EVMA) records and in organising their supply chain systems. However, for the remaining countries in this review, comprehensive improvement plans (cIP), were not prepared on time (delays of more than 6 months) and three countries (Eritrea, Liberia and Lao-PDR) used cIP templates that did not follow Gavi guidelines. These factors make it difficult to align the proposed activities in the five-year National Immunisation Strategies (NIS) and compromise implementation of suitable corrective and preventive actions.

Issue 12: Countries prepare comprehensive Improvement plans (cIPs) more than 6 months after EVMs and fail to integrate the cIPs in their National Immunisation strategy (NIS).

Recommendation:

- Gavi to ensure countries provide timely cIPs, using Gavi recommended templates, following EVM assessments, and quickly integrate the cIPs into the NIS so that coordinated corrective and preventive actions are taken.

Waste Management

Supplementary immunisation activities will inevitably increase the volume of immunisation waste. In this review, Lao-PDR, Mauritania, and Zambia did not have adequate waste management systems as reflected in the lack of robust standard operating procedures (SOPs), especially at the health service delivery points or health facilities. In addition, the countries reviewed did not adhere to the WHO waste management guidelines and key information such as an inventory of available incinerators and status was not available.

Issue 13: Lack of waste management standard operating procedures and updated national waste management policies.

Recommendation:

- Gavi and partners to ensure supported countries establish/update national waste management policies and SOPs, along with updated incinerator mapping, so they align with WHO recommendations.

CCEOP

Five CCEOP applications were reviewed, and all of them were approved. The IRC however noted that decommissioning and rehabilitation plans were not adequately and consistently documented. Where the plans were documented as in Eritrea (FPP) and Rwanda (CCEOP), implementation of activities was often

delayed due to lengthy national administrative procedures for disposal of obsolete equipment. Rehabilitation and decommissioning plans for these two countries did not consider cold rooms in central vaccine stores. Additionally, some countries are engaged in solarisation initiatives of health facilities (HF) that could impact the selection of CCEs, without involving supply chain professionals or integrating these projects into the cold chain (CC) rehabilitation plans. Furthermore, although key strategic partners were highlighted in the applications (World Bank, Global Fund, Gavi, UNICEF, USAID, JICA), there was still a certain level of fragmentation in the supply chain technical support.

Issue 14: Implementation of rehabilitation and decommissioning of CCE and solarization initiatives for the cold-chain remains a challenge for countries.

Recommendations:
- Gavi and in-country partners to advocate for changes in procedures at country level to facilitate speedy decommissioning of obsolete CCE equipment as there is a high risk of this equipment being sold on the black market.
- Countries and partners to ensure active involvement of supply chain professionals in the process of piloting solarisation projects to ensure that they fit the purpose and are compliant with cold chain standards.

Budget, Financial Management and Sustainability

Budget overview and quality of budget information
Thirteen budgets from 9 countries were reviewed, for a total proposed amount of US$ 63,656,337. Of this, US$ 60,332,004 (94.8%) was requested from Gavi, US$ 1,740,606 (2.73%) from government, US$ 1,351,632 (2.12%) from partners, and US$ 42,637 (0.07%) from other[1], leaving a US$ 189,457 (0.3%) funding gap[2]. Three countries requested 100% Gavi contribution (Liberia, Rwanda and Bangladesh) while two requested 50% Gavi contribution (Cambodia and Mauritania). The lowest Gavi contribution request (26%) was from Laos PDR. Of total requested Gavi contributions, US$ 33,274,943 (55%) was to Bangladesh, US$ 15,377,384 (26%) to Niger, and US $7,356,649 (12%) to Burkina Faso. The remaining US$4,323,727 (7%) were for Mauritania, Cambodia, Sierra Leone, Lao, Rwanda, and Liberia. Budget by vaccines were US$19,700 412 for M/MR (7 budgets), US$29,905,657 for TCV (4 budgets) and US$10,725,935 for JE (2 budgets). Of the total Gavi contribution, 94% related to Campaign Operational Support (Ops) and 6% for Vaccine Introduction Grants (VIGs).

Figure 3: Overall budget by funding source   **Figure 4:** Budgets by country and funding source

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[1] Corresponding to PSC costs of UNICEF and WHO which will be funded by Gavi FMRA facility in the Sierra Leone budget.
[2] Funding gap was presented in the Lao budget.
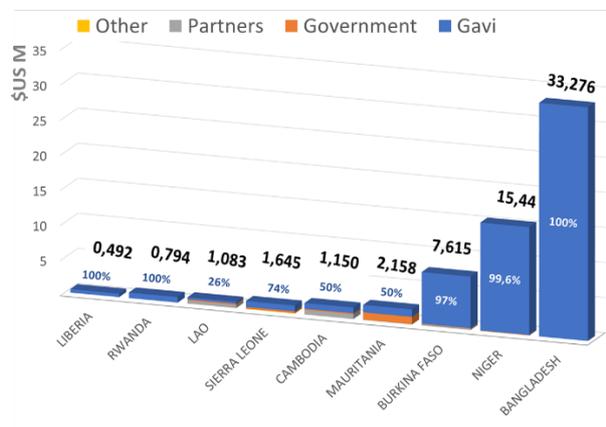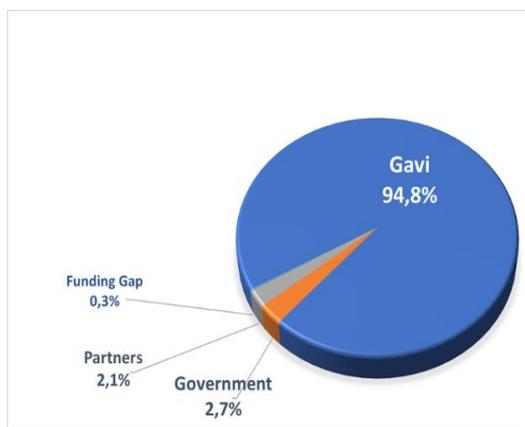
Issue 15: Despite improvements, countries still do not present comprehensive funding landscapes.

Recommendations:
- The IRC re-iterates its recommendation to request countries to present the full funding landscape for all campaign applications.

Compliance with budget presentation guidelines

Improvements in the overall quality of vaccination campaign planning and budgeting have been observed, with proper use of budget templates and adequate calculation details provided. However, one exception is Cambodia, in which the budget does not provide sufficient calculation details. Except for Liberia, budgets appropriately reflected activities outlined in the POAs. Several recurring issues identified across the vaccination campaigns that require attention and resolution include unit costs associated with various inputs are not easily identified in budgets, creating challenges in cost analysis and tracking. For example, Mauritania's budget has 31 budget lines for 31 activities, presenting several different cost inputs in single budget lines and significant misclassifications, with 11% of total budget allocated to "Human resources" including transport costs. Similarly, Sierra Leone presented a detailed budget comprising 121 budget lines for 25 activities, making overall summary analysis difficult.

Issue 16: Despite improvements, countries do not present adequate activities disaggregation by cost input. These issues need to be addressed to ensure transparency and accurate financial management.

Recommendations:
- Gavi secretariat to ensure that budget items are adequately aggregated during pre-screening and require revisions before submission to IRC.
- Gavi to analyse common budget classification errors (especially in events, supervision, and transport costs classification) and clarify guidelines to avoid common errors in budget activities disaggregation.
- Gavi to improve the budget template to add a special tab for all unit costs assumptions.

Staffing and Vaccinator workloads

The main issue identified is the recurring one in applications in that the budgets for campaigns show inconsistencies in the workload of staff and vaccinators and the assumptions were not detailed and the estimates varied across the countries. Two countries (Niger, Cambodia) did not provide this information.

Table 7 presents HR-related costs in Gavi contribution, average workload per vaccinator per day, average number of team members, and number of vaccinators per team across reviewed budgets.

Table 7. HR related costs and vaccinator workload for TCV and MR campaigns

Country budget	HR-related cost share of budget	Average workload per vaccinator/day	Average number of team members	Average vaccinators per team
Bangladesh TCV	49%	125	4	1
Burkina Faso TCV	60%	58	4-5	**2**
Rwanda MR	21%	199	**6-8**	1
Cambodia MR	30%	-	-	-
Niger MR	30%	-	-	-
Sierra Leone MR	41%	131	4	1
Liberia MR	55%	88	4	**2**
Lao PDR MR	60%	113	**2-3**	1
Mauritania MR	88%	98	3.32	1

The HR related costs (per diems/allowances for travel-related activities) are high for most countries (Bangladesh, Burkina Faso, Liberia, Lao PDR, Mauritania). Mauritania presented the highest rate of 88% and this was due to the low share of the Gavi contribution of 50% which was allocated to DSA while other activities are allocated to Government funding. However, the Mauritania HR rate calculated for the grant was still high (63%). The number of vaccination team members varied across the countries. In Mauritania, the teams consist of 3 to 4 persons, in Lao from 2 to 3 while in Rwanda it was 6 to 8 individuals. Mauritania included Vitamin A administrator which was to be supported by other sources.

As regards vaccinators on the teams, most countries have one vaccinator except for Burkina Faso and Lao which planned to have 2 vaccinators. This assumption leads normally to a reduction of the number of teams but because these two countries used low workload rates, they presented high HR costs comparable to other countries with one vaccinator. The average vaccinator workload levels among the countries show variations, with Burkina Faso having the lowest (58) and Rwanda the highest (199) experiencing the lowest workload and Rwanda facing the highest workload. In Burkina Faso, the workload is low due to the fact that almost 59% of the target population was assumed to be in Hard to Reach (HTR) areas using a low workload of 50 children per day per vaccinator, which is justified, but for the fixed strategy, country used a workload of 75 children per day per vaccinator which is below WHO guidelines (100-150).

In addition, several inconsistencies were observed with respect to the implementation of the Plan of Action (POA) in different countries which impact on the budget. These include:

1. Sierra Leone: The duration of the vaccination campaign is not adequately reflected in the workload calculation, indicating a discrepancy between the actual campaign duration and the calculated workload.
2. Mauritania: Different workloads are presented but the specific reasons are not mentioned in the documents provided and the targets for rural/urban strategies is not adequately reflected in the budgets for Mauritania and Sierra Leone, suggesting a misalignment between the targets and the allocated resources.
3. Rwanda: The large team sizes were not adequately justified however Gavi funding was for delivery cost involving transport and related allowances.

4. Liberia: The total number of vaccinators are aligned between the budget and the Plan of Action but the breakdown by strategy is not clear making it challenging to compare figures.

Issue 17: Despite improvements, countries still present budgets with inadequate assumptions and inconsistencies with the Plans of Action resulting in high levels of HR related costs.

Recommendations:
• Gavi and partners to ensure that clear justification for HR requirements for e.g., target groups, delivery strategies, vaccination team composition(s) are provided and aligned with WHO requirements.
• Gavi and partners to reinforce controls to ensure alignment of budgets with POA assumptions and calculations.

Health Information Systems and Monitoring and Learning (MEL)

Use of available case based epidemiological data
Nine of the 10 country NVS applications (i.e. MR, YF, TCV, JE) provided appropriate and adequate subnational epidemiological analysis of burden of disease and risks to justify the vaccination strategies proposed. Two high performing countries (Cambodia and Rwanda) demonstrated appropriate use of available data to decide on a selective sub-national approach (Rwanda) or a non-selective nationwide approach (Cambodia). In one country (Mauritania), adequate data and analyses were presented to justify the need for a measles follow-up campaign but there was insufficient justification for targeting an expanded age-group (9 months – 14 years) for the campaign. The issues for consideration of an expanded age group for MR follow-up campaigns do not currently address rubella epidemiology even though several countries have introduced rubella-containing vaccines.

Issue 18: The recurring issues raised by the IRC of countries not using available data or appropriate analyses for design of proposed intervention including the age groups to target in designing MR follow-up campaigns.

Recommendations
• Gavi to share the analyses done by Rwanda and Cambodia with other countries as best practices.
• For countries proposing interventions that include a wider age-group target for follow-up campaigns, Gavi should require technical partners to provide an in-depth review of the data supporting the strategy.

Estimating the number of zero-dose children
It was encouraging to see that in the action plans of several countries, estimation of zero-dose children was done based on the number of surviving infants who had not received DTP1 based on coverage data. This method often leads to negative numbers of zero dose children. However, other opportunities exist for identifying and quantifying zero-dose children, including checking for vaccination status during vaccination campaigns or routine EPI outreach activities. These alternative methods do not seem to be used, which could allow for triangulation of data that results in a more precise estimate.

Issue 19: Lack of triangulation of different methods for estimating zero dose children in the estimations in applications.

Recommendation

- Gavi to support countries in analysing data from multiple sources to better estimate zero-dose children in countries that are supported rather than relying on coverage data which is often unreliable.

Estimating population denominators for vaccination

Some countries lack recent census data which renders vaccination targets inherently inaccurate. For example, South Sudan had a census in 2018, implying that the target population for malaria vaccination in 2023 is likely to be substantially different from the actual population figures.

Issue 20: Estimating population denominators for vaccination targets is a challenge for many countries.

Recommendation

- Gavi and partners to support countries to conduct regular population-based surveys, which can be combined with other EPI activities such as immunisation coverage surveys and enumeration of zero-dose children.

Post campaign coverage surveys: Vaccination cards and finger marking for coverage estimates

Bangladesh requested US$5.7 million for one time vaccination cards for TCV and JE campaigns and at same time requested US$800,000 for finger markers. PCCS is planned for 2 or more months after each campaign (not in line with WHO guidelines). In addition, for the introduction of JE and TCV in routine, there is a request for vaccination cards, which are for a portion of the Home Based Record cards for routine EPI, for US$1.05. Investment of US$5.7 million is not appropriate value for money and these resources could be better used for programme activities. If WHO guidelines are followed, and the PCCS is done immediately following the campaign, finger markers and history of vaccination would be adequate. Furthermore, vaccination cards for routine should already be available and not be stand-alone.

Issue 21: Questionable value investments in one time vaccination cards for the purpose of PCCS.

Recommendation

- Countries to adhere to WHO guidance and timely plan so that PCCS implementation follows immediately after the campaign in order to use appropriate and cost-effective methods such as finger marking and recall for assessing coverage.
- When countries are producing new vaccination cards for routine EPI, consideration should be made to include spaces for new vaccines that may be introduced.

Full Portfolio Planning reviews (FPP)

Six FPP applications reviewed this round include Cameroun, Eritrea, Mali, Tajikistan, Togo, and Zambia. PNG was reviewed in country in April 2023 and presented to the IRC for information. All applications had multiple funding windows (Table 2). Decisions for the FPP applications were approval for all countries except Cameroun and Eritrea, for which decisions on HSS and EAF were re-review and the decision for ITU (Innovation Top-up) in Eritrea was also re-review. Key reasons for re-reviews were linked to the lack of strategic approach to health systems strengthening and insufficient alignment between the theory of change (TOC) and resource allocation. Decision for PNG FPP HSS and TCA was approval for the years 2023 to 2025.

For 2025 to 2027, the IRC provided programmatic approval but required the Gavi Board to approve an extension to the accelerated transition phase until 2027. A supplementary TCA request of $2.3 M for the 2023-25 was granted a re-review.

Key findings

There were multiple findings from this FPP review round. First, because FPP now incorporate most components, reviewers found this allowed a better understanding of the overall country strategy and how the previously siloed applications interlink and complement each other. The IRC found this holistic approach facilitates the evaluation of the portfolio support and contributes to strengthening aid coherence and efficiency. However there remained some areas of progress in terms of additional integration such as for example better training activities/plan across applications through a comprehensive training plan, better strategic approaches to ensure gender responsive interventions and more creative focus and/or test of new ideas through the Innovative Top Up Fund Allocation (e.g. Zambia). Whilst recognizing the possible limitation of adequate and real time information, it is critical that applicants endeavour to map out funds from other sources to ensure complementarity and reduce duplication of activities to enhance judicious use of scarce resources.

Strategic targeting and health systems strengthening

The reviewers noted that in this round several countries with low coverage across most districts strategically targeted a small number of districts not only with EAF but also with HSS funds. This tension between the requirement to target districts with high number of ZDC and the use of resources to improve immunisation systems across the country was apparent for countries such as Zambia, Mali and Cameroun and Togo to a lesser extent as highlighted in Table 8.

The restriction of HSS funds to a limited number of geographical areas is problematic in countries where all districts have insufficient coverage as it may mean important activities such as outreach services, communication and microplanning may not be properly funded in the non-targeted districts. Several countries in this situation acknowledged that coverage is low in these non-targeted districts. However these were not able to provide evidence on how the non-targeted districts will be supported either though government or partners resources. The risk is that large resources are concentrated on finding and vaccinating a finite number of zero dose children while non targeted districts may have insufficient resources further maintain or improve their already low coverage. This could also result in limiting investment in national systems such as health information systems and supply chain improvement. In addition, the selection of districts with a high number of ZDC may itself be fraught, because of multiple challenges around data quality and the limitations of modelling and triangulating assumptions (such as the removal of all districts with >100% coverage and removal of districts with negative zero dose children).

Table 8. FPP geographical targeting strategies

Country	Number of estimated ZDC for 2021 cohort	WUENIC DPT3 (2021)	Number of targeted districts for EAF	Number of districts targeted for HSS	Total districts whole country	FPP funding (HSS+ EAF)
Cameroon	253,413	69%	49 (65% of the ZDC)	80	200	$27M
Eritrea	2,036 ZD	95%	30 sub-zobas (80% of the ZDC)	All	58	$8,5M
Mali	114,476	77%	15 (46% of ZDC)	44	75	$31.4M
Tajikistan	7,638	97%	15 (62% of the ZDC)	All	66	$2.1M
Togo	31,838	83%	12 (92,3% of the ZDC)	18	39	$9M
Zambia	344,352	65%	23 (52% of the ZDC)	23	70	$14M

In conclusion, whilst we agree that EAF should be aimed to reach ZDC and under vaccinated children, the whole FPP portfolio investment should be more focused at improving coverage with the HSS resources further aiming to strengthening systems and programmatic sustainability for the whole country. This would involve providing essential support to all districts (e.g. microplanning, outreach strategies, etc.). Hence, Gavi guidance to countries on targeting should be recalibrated for countries, particularly for countries with universally low coverage.

Issue 22: Tension between strategic targeting and the need for Health Systems Strengthening.

Recommendations:
- Gavi to consider using HSS to strengthen national systems and ensure all districts have resources to conduct essential EPI activities, and reserve EAF funding for targeting ZD and under vaccinated children in selected districts.
- Gavi to consider revising guidance for low-coverage countries to emphasise systems strengthening and targeting un/under-immunised children.
- Gavi and partners to consider evaluating early implementation of FPP strategy in a selected low-coverage country and small number of targeted districts and assess level of operational funding for non-targeted districts and changes in coverage rates.
- Gavi and technical partners (both Gavi- and non-Gavi) to ensure all immunisation and systems-focussed investments in countries are reported to maximise resource use and reduce duplication whilst ensuring maximum coverage (e.g. this information could be provided as annexes to FPP applications).

Innovative Top-up Funding
The IRC noted a lack of innovative and strategic focus in the elaboration of the ITU requests which tend to be digital in their nature. In some cases, we identified a lack of country ownership for innovations. "e-platforms and tools" are mostly not situated within the broader HIS strategy and often appear as 'patching up' of information systems. The lack of creativity and strategic thinking behind ITU investment decisions points to ITU being seen as 'extra resources' to spend on digital platforms. In one case in Zambia, a large funding request was submitted to finance the currently disused LMIS system Logistimo while Eritrea requested ITU funding for interventions that were misaligned to objectives and not programmatically

justified (e.g. GIS to track people movements). The risk resulting from the absence of an overarching health information strategy and the untested interoperability with existing systems may also lead to more systems fragmentation, and the unsustainable multiple parallel systems and poor lack of country ownership.

Issue 23: Need for more strategic use of ITU funds (Innovative Top-Up Funding).

Recommendations:
- Gavi to request countries to provide a clear rationale for ITU funding and how it is situated within the existing HIS national strategy and a rationale of how this investment may be sustained beyond the Gavi grant. This should include an assessment of interoperability of the new App/digital innovation before the request is submitted.
- Gavi should request that applications for innovation requests, provide should provide evidence-based results from ITU implementation in other comparable countries and/or propose piloting the innovation before scale-up, with implementation research alongside as a standard.
- Gavi to prioritise ITU funding for co-financing to ensure ownership and sustainability of new digital innovations.

TCA investments for programmes

Overall we observed in this review that the TCA strategy was generally aligned with FPP key priorities. However, we noticed that TCA proposed investments were not always clearly linked to specific activities, while the level of investment proposed was not systematically justified. TCA allows investment to support leadership and coordination but sustainability was also often unclear. In particular staff positions were not always linked to specific objectives and applications did not show how these activities supported building of local capacity. In some cases, heavy reliance on full time international and national consultants was not mitigated by a plan explaining how country programmatic sustainability would be built over time. Numbers of the positions requested appear too many given the context of TA need. The IRC also noted that some TCA costs are wrongly placed in HSS allocation beyond the TCA funding period.

Issue 24: Strategic use of TCA needs to be strengthened

Recommendations:
- Gavi and partners to ensure TCA requests are linked to activities and this linkage is part of guidance.
- Gavi to require country applications to state how in-country capacity can be built using TCA.
- Gavi and partners to ensure gaps in management and coordination capacity are addressed through TCA with steps to programmatic sustainability clearly described.
- Technical partners to ensure TCA requests are needs based and follow Gavi guidelines for support so that use of TCA resources is judicious and not to keep positions open.

Partner contributions to FPP activities

The IRC would like to congratulate countries for better coordinating with partners in the design of the FPP strategy, as shown in the case of South Sudan and Mali where CHWs are supported by key partners and modalities of support are aligned. Other vertical funding such as CDS is also increasingly mentioned in CCEOP applications and to some extent in ITU applications where other partners are involved in co-funding the intervention such as USAID in Mali. However we also noted a persistent lack of clarity of how other partners are contributing to common activities especially related ZDC, RI and HSS, as in the case of Cameroon and

Zambia. In some cases, countries stated that essential activities such as operational support to outreach is funded by other partners, but provided limited/no detail on scope, level, and duration of this support.

Issue 25: Contribution by other partners to FPP activities and resources is unclear.

Recommendations:
- Gavi to provide technical support to enable countries to develop well-integrated FPP applications that holistically reflect all partners support towards strengthening the system.

Climate change and impact on programmes
Countries are increasingly mentioning climate change concerns in their applications and a growing number of Gavi countries are reporting being affected such as Mali and Tajikistan. However there is no clear strategic consideration for climate change friendly strategies apart from solarisation strategies.

Issue 26: Climate change is overlooked in programming

Recommendations:
- Gavi and partners to focus on climate friendly strategies and innovations such training/e-learning platforms, digital activities, where appropriate the use of drones as an effective vaccine delivery strategy, and efficient transportation.
- Gavi and partners to encourage countries to better coordinate and to avoid duplication of efforts and resources; using immunisation or other platforms for multiple service delivery, including maternal and child wellbeing interventions.

5 Conclusions

The June 2023 IRC session reviewed a total of 45 requests for Gavi support from 20 countries. Forty (89%) of the requests were recommended for approval. The IRC noted that the quality of the applications was in general good, and the proposed activities were likely to achieve the objectives set by the countries. The areas for improvement in the applications recommended for approval have been clearly outlined and the IRC has recommended to Gavi and Alliance partners the critical actions where technical support is needed. The IRC noted that most of the improvements in the budget applications are due increased efforts by the technical partners and the Gavi secretariat in pre-reviews as well as aligning the activities in the Plans of Action and the budgets. Recurrent challenges are the high human resources costs that are reflected in the budgets for vaccination campaigns which appear to be related to inconsistencies or lack of clear assumptions that are used and often are not aligned with WHO recommendations. Although it is increasingly better use of available epidemiologic data for planning strategy development, use of equity and gender data remains poor and the information is not used to develop strategies. Key takeaways from this review include, (a) how to ensure that HSS has the maximum impact on children, especially when zero dose children are spread geographically across the country, (b) how to ensure that imperfect data and modelling is supported with operational and subnational data which provide clear signals for un/under immunized communities, and, (c) countries-especially well performing ones should look at the residual susceptibility and shift to older age groups in their analysis for which populations to target especially for measles and rubella vaccination.

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Finally, the contribution of the Alliance partners who provided support to countries in preparing the applications, participated in sessions and provided insight and clarifications during the deliberations of the IRC is also acknowledged.

Annex 1. IRC members participating in June 2023 meeting

	Name	Nationality	Profession/Specialisation	Sex	Review language	Expertise
1	Beatriz Ayala-Öström	UK, Sweden, Mexico	Independent consultant	Female	EN, SP, PT	Health system strengthening, supply chain management
2	Sabine Beckmann	Germany	Independent consultant	Female	EN, FR	HSS, public health policy advisor, gender & equity, vaccination campaigns
3	Blaise Bikandou	Congo, France	Independent consultant	Male	EN, FR	HSS, project/program management, Preparedness and response, vaccine preventable diseases, epidemiology
4	Aleksandra Caric	Croatia	Independent consultant	Female	EN, FR	Measles, AEFI Surveillance and vaccine safety, programme management, primary health care
5	Rochika Chaudhry	USA	Advisor, Johns Hopkins Medical Institution	Female	EN	Immunisation services, global health security, outbreak response, HSS, health finance and policy, malaria, HIV
6	Borja Cuervo Alonso	Spain, Mozambique	Independent consultant	Male	EN, SP, FR, PT	HSS, disaster preparedness and emergencies, challenging operating environments, equity, HIV, malaria
7	Emmanuelle Espié	France	Senior scientist, CEPI	Female	EN, FR, SP	Epidemiology, epidemic preparedness, surveillance, outbreaks, vaccine effectiveness and safety, vaccinology
8	Natasha Howard	Canada, UK	Associate Professor, NUS School of Public Health and LSHTM	Female	EN, FR, SP, AR	immunisation service delivery, health policy, HPV, measles, malaria, Covid-19, EAF, FER settings
9	Philippe Jaillard	France	Director of EpiLinks	Male	EN, FR	Health and immunisation supply chain management, training and educational engineering
10	Henry Katamba	Uganda	National Facilitator, GF at the Ministry of Health in Uganda	Male	EN	Epidemiology, M&E of health projects, health research and advisory
11	Wassim Khrouf	Tunisia	Auditing and Consulting Worldwide, Partner	Male	EN, FR	Financial & budget analysis, audits, project assessment
12	Rose Leke - **CHAIR**	Cameroon	Emeritus Professor of Immunology and Parasitology, University of Yaoundé, Cameroon	Female	EN, FR	Malaria. Global Health, HSS, training of the next generation of scientists
13	Viviana Mangiaterra	Italy	Associate Professor, SDA School of Management, Bocconi University, Milan	Female	EN, FR	HSS, Maternal and Child Health, Malaria, HIV and TB
14	Nkengafac Villyen Motaze	Cameroon	Associate Professor of Epidemiology, Medicine Usage in South Africa, North West University, South Africa	Male	EN, FR	Vaccinology, epidemiology, systematic reviews, evidence-based practice
15	Sandra Mounier-Jack - **Vice-chair**	France, UK	Professor in Health Systems and Policy, LSHTM	Female	EN, FR	HPV, measles, immunisation programmes, HSS, health policy and health financing
16	Pierre-Corneille Namahoro	Rwanda	Director of Public Health, Global Supply Chain & HSS, Fascinans Ltd	Male	EN, FR	HSS, Supply Chain Management and Cold-Chain Logistics
17	Benjamin Nkowane - **Vice-chair**	Zambia	Independent consultant	Male	EN, FR	Measles, epidemiology, mass vaccination campaigns, technical support for field operations in risk areas
18	Gavin Surgey	South Africa	Radbound University Medical Centre	Male	EN	Financial and Budget Analysis, Health Economics, Health Financing Strategies, Program M&E.
19	Edward Ouko	Kenya	Executive Director of Edrak Associates Limited	Male	EN	Auditing and public financial management, governance, M&E
20	Bolanle Oyeledun	Nigeria	Chief Executive Officer Centre for Integrated Health Programs (CIHP), Nigeria	Female	EN	HSS, MNCH, immunisation, adolescent reproductive health & HPV, programme assessments and evaluations
21	Erika Wichro	Austria	Independent consultant	Female	EN, FR	Emergency settings, outbreak response, HSS, polio, Ebola, measles, COVID-19, surveillance, epidemiology