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

11 – 22 March 2024

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List of acronyms

2YL	Second year of life (platform)
AACVS	African Advisory Committee on Vaccine Safety
AEFI	Adverse event(s) following immunization
CCE	Cold-chain equipment
CCEOP	Cold-chain equipment optimization platform
COVID-19	Coronavirus disease 2019
CRS	Congenital Rubella Syndrome
CSO	Civil society organization
EAF	Equity Accelerator Fund
EPI	Expanded Programme on Immunization
FCA	Fragile and conflict-affected
FED	Fragilities, Emergencies and Displaced (policy)
FPP	Full portfolio planning
GACVS	Global Advisory Committee on Vaccine Safety
GNI	Gross national income
HPV	Human Papillomavirus
HR	Human resources
HSS	Health Systems Strengthening
ICC	Inter-agency coordinating committee
IPV2	Inactivated Polio Vaccine 2nd dose
IRC	Independent Review Committee
MAC	Multi-Age Cohort
MCV	Measles-containing vaccine
MICs	Middle-income country support
NITAG	National Immunization Technical Advisory Group
NVS	New and underused vaccine support
PCCS	Post-campaign coverage survey
PCV	Pneumococcal conjugate vaccine
PQ	Prequalified
RCV	Rubella-containing vaccine
RI	Routine immunisation
RVV	Rotavirus vaccine
SAGE	Strategic Advisory Group of Experts on Immunization
SIA	Supplementary Immunization Activity
USAID	United States Agency for International Development
VIG	Vaccine introduction grant
WUENIC	WHO and UNICEF estimates of national immunization coverage
YF	Yellow fever

1. Executive Summary

The first meeting of the Gavi Independent Review Committee (IRC) for 2024 was held in Geneva, Switzerland, from 11 to 22 March 2024. A total of 22 IRC members organised in 3 review panels (see Annex 1 for list of members and expertise) reviewed 19 applications from 15 countries in three World Health Organization (WHO) regions (13 from the African Region, one from the Eastern Mediterranean Region, and one from the European Region).

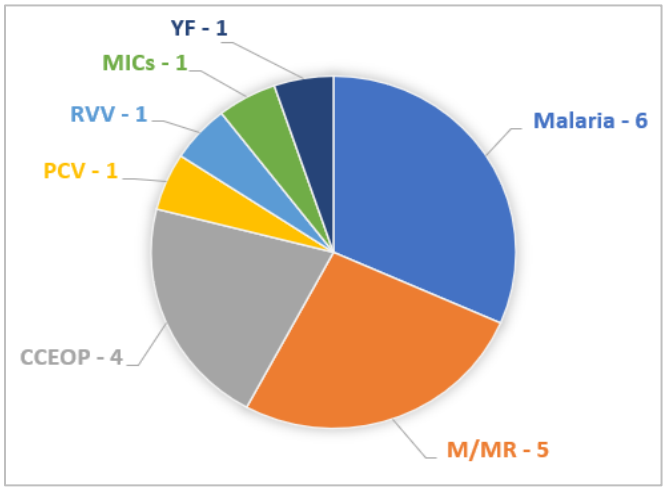

Figure 1:
Distribution of applications by support types reviewed at the March IRC

Applications reviewed at the meeting included four proposals and requests for Cold Chain Equipment Optimization Platform (CCEOP), 1 for middle-income country support (MICs), and 14 for new and underused vaccine support (i.e. 6 for Malaria vaccine, 1 for Pneumococcal Conjugate Vaccine (PCV), 1 for Rotavirus vaccine (RVV), 1 for Yellow Fever vaccine (YF), and 5 for Measles/Measles-Rubella (M/MR) support). All proposals were recommended for approval, and the countries were requested to address the critical concerns by responding to action points. IRC further requested that countries strongly consider additional comments and recommendations to strengthen their interventions and programmes.

Previously conducted remote reviews, finalised at the time of the meeting, included applications from 4 countries in the African WHO region (1 IPV2 introduction grant request and three full-portfolio planning applications with a total of 10 funding requests) and from one country in the South-East Asian WHO region (HPV). All were recommended for approval (see Tables 1a and 1b below for detail on requests from countries and review outcomes).

The IRC recognises an increasing focus on reaching zero-dose children and a higher emphasis on the engagement of civil society organisations (CSO), particularly in full portfolio planning (FPP) applications, and commends the continued efforts by countries and the Alliance in the improvement of the quality of proposals submitted. This is reflected in the 100% approval. The IRC also recognises the efforts of the Secretariat and Alliance Partners for their technical support in the preparation of country applications.

The IRC further recognises and commends the efforts of the Gavi Secretariat in continuing to modify and improve the meeting structure and processes, achieving more focused review presentations and discussions while increasing engagement with country teams.

2. Review methods and processes

2.1 Review methods

Review methods included independent review of applications by assigned primary and secondary reviewers, plus cross-cutting finance and supply chain reviewers where required. They presented their initial findings within the respective panels, followed by focussed discussions, consolidation of the draft report with findings, outcomes, and decisions, post-plenary fact-checking by the Secretariat, and quality and consistency checks by editors and vice-chairs before the formal sign-off.

Decisions were made according to two categories: 1) recommendation for approval with action points to address the identified issues, and 2) recommendation for re-review with outstanding issues and action points to be addressed by the country during revision of the application, prior to a new submission to the IRC.

Criteria for review remain the same as in previous review windows and are guided by IRC Terms of Reference and key criteria in line with Gavi's mission. This includes the extent to which applications meet mandatory requirements and principles of Gavi support, along with contribution to achieving Gavi's mission and strategy. The proposals need to demonstrate justification for the proposed activities, soundness of approach, country readiness, feasibility of plans, contribution to systems strengthening, programmatic and financial sustainability, value for money, and public health benefits of the investment. The IRC continues to strictly adhere to the guidelines to ensure the integrity, consistency and transparency of funding decisions.

2.2 Focus of IRC review

Across the panels, the IRC members focussed on the following specific tasks:

a) individual review of assigned funding requests and all other supporting documentation, which for M/MR applications also included virtual meetings with country EPI managers, country teams and core technical partners;

b) production of country-specific review reports with evaluation and accompanying recommendations provided to the Gavi Secretariat; and

c) development of a thematic report per panel review and cross-cutter groups with recommendations to Gavi and Alliance partners for improvement of funding requests, strengthening of national immunisation programmes, and processes related to Gavi policies and governance.

2.3 Review process

The meeting agenda, the initial allocation of countries for review, and the country applications with supporting documentation were shared with the reviewers on 1 March 2024. The 22-member committee included reviewers with a wide range of expertise, of which 4 were cross-cutters for financial and budget reviews of applications excluding malaria, and another 4 were supply chain, logistics, and waste management cross-cutters for NVS applications excluding malaria and review of CCEOP applications. Nine (9) new members joined this IRC meeting (3 cross-cutters for supply chain, logistics and waste management, 2 finance cross-cutters, and 4 NVS reviewers).

The reviewers were organised into three panels: for reviewing CCEOP applications, malaria applications, and M/MR, PCV, RVV, YF, and MICs applications. The chairing roles were assigned to IRC Vice Chairs Dr Benjamin Nkowane, Pierre Corneille Namahoro, and Dr Bolanle Oyeledun, who also chaired the final plenary session and the debriefing/closing session.

Process and technical briefings and updates were provided to the IRC reviewers prior to the review meeting (4 and 11 March 2024). The dialogues between country EPI teams and the IRC about M/MR applications, held with the support of the FD&R team on 11 and 12 March 2024, were followed by country responses in writing, which facilitated their consideration and inclusion in the IRC review. Gavi Secretariat continued piloting the meeting structure and process changes, including an improved report form for M/MR applications and new report forms for PCV/RVV, CCEOP, and MICs applications.

Review meetings within panels occurred from 12 to 19 March 2024, with reporting back to the full plenary on 20 March and final debriefing on 22 March 2024. All issues requiring resolutions were solved within panels. The IRC members of the NVS review panel availed themselves of two additional closed sessions for one application (i.e. Guinea Bissau re-submission for MR catch-up campaign and rubella introduction support, first reviewed in November 2023), to further discuss identified issues and balance recommendations, and adjourned their decision until they received technical partners' explicit confirmation and acceptance to provide a clear accountability framework to ensure sustained high-quality support, tailored to the applicant country. Despite some disagreement of technical partners expressed online during discussions including at the debriefing session, the IRC remains consistent in fulfilling its mandate in the best interest of countries and Gavi, and welcomes better collaboration with technical partners and better alignment on the guidance, policy and practices.

Remote reviews of FPP, IPV2, and HPV proposals started before the IRC meeting and were conducted independently from the panel review work. The issues identified by reviewers for each proposal were summarised and included in the debriefing presentation.

2.4 Key review outcomes

The main outcomes of country applications reviewed during the March meeting and outcomes of remotely reviewed proposals are summarised per country in Tables 1a and 1b below. All applications were recommended for approval. IRC recognises the continued improvement of the quality of proposals and the efforts of Secretariat and Alliance partners for their technical support and commends continued efforts to improve the process.

Table 1a: Outcomes of country requests by country category and type of support reviewed at the March meeting

Country segment		Country	Support request	Recommendation outcome
PANEL 1-CCEOP	Core priority	Sierra Leone	CCEOP	Approval
	Core standard	Tajikistan	CCEOP	Approval
	Core standard	Mozambique	CCEOP	Approval
	Core priority	Liberia	CCEOP	Approval
PANEL 2 - NVS Malaria	High impact	DR Congo	Malaria	Approval
	Fragile and conflict	Mali	Malaria	Approval
	High impact	Nigeria	Malaria	Approval
	Core priority	Uganda	Malaria	Approval
	Core priority	Kenya	Malaria	Approval
	High impact	Ethiopia	Malaria	Approval
PANEL 3 – NVS excl. malaria, MICs	Core priority	Guinea Bissau	Yellow fever campaign	Approval
	Core priority	Guinea Bissau	MR 1st and 2nd dose with catch-up campaign	Approval
	Fragile and conflict	South Sudan	RVV and PCV introduction with catch-up campaign	Approval
	Core priority	Kenya	MR follow-up campaign	Approval
	Core priority	Senegal	MR follow-up campaign (9 months to 15 years)	Approval (age-range 9-59 months)
	High impact	Ethiopia	M follow-up campaign	Approval
	Fragile and conflict	Somalia	M follow-up campaign	Approval
	MIC	Angola	VCF HPV and one-off costs (OOC)	Approval

Table 1b: Remote review outcomes

Country segment	Country	Support request	Recommendation outcome
Core Standard	Gambia	FPP (HSS, TCA, EAF)	Approval
Core Standard	Zimbabwe	FPP (HSS, TCA, EAF)	Approval
Core Priority	Benin	FPP (HSS, TCA, EAF, HPV)	Approval
Core Priority	Congo	IPV2	Approval
High Impact	India	HPV	Approval

2.5 Good practices observed

The IRC notes that some country applications included practices and activities which present or have a potential to make positive impact, especially if they, where applicable, will be duly implemented and evaluated. These include:

- study on sustaining vaccine funding conducted with the support of Gavi in **Nigeria**;
- use of data from the functional case-based surveillance system with systematic follow-up and tracking of measles outbreaks in **Ethiopia**;
- planning community engagement for the MR follow-up campaign, leveraging the work of 'village godmothers' in **Senegal**; and
- development of gender-specific workplan activities based on evidence (i.e. study findings, gender norms, roles, values, and beliefs) in **Gambia**.

It is important that the Secretariat and Gavi Alliance partners track and evaluate these practices and activities to quickly scale up and share lessons learned across other countries.

3. Key Findings and Recommendations

3.1 New and underused vaccine support (NVS) and campaigns and MICs applications

Measles and Rubella vaccines

The IRC panel for review of NVS requests excluding malaria reviewed five applications for MCV support. Of these, four were for measles follow-up campaigns: from Ethiopia and Kenya for the age range 9 to 59 months, from Somalia for 6 to 59 months, while Senegal requested support for a wide-age range follow-up campaign from 9 months to 15 years. Guinea Bissau re-submitted the measles and rubella catch-up campaign application with a rubella introduction, first reviewed in November 2023. All applications were recommended for approval. However, Senegal's request was approved for the standard follow-up age range (9 to 59 months). Guinea Bissau's request was recommended for approval only after the technical partners' acceptance to provide a clear accountability framework to ensure sustained, high-quality, tailored support to the country in order to enable strengthening of the EPI programme and reaching ≥80% MCV coverage. Total funds requested amounted to about US$ 31.65 million.

While countries generally continue to improve epidemiological justifications for their requests, in this round only Ethiopia and Kenya provided robust analyses of measles epidemiology which included subnational data and information from outbreaks. Of concern remains reluctance of countries to remove age eligibility limit for measles vaccination, which contributes to missed opportunities for vaccination. In this context, Somalia should be commended for addressing this IRC action point. However, the imperative for all countries remains improving the reach of un- and under-vaccinated children through multiple opportunities of the routine programme and through campaigns. Other issues observed are the following.

Issue 01: Lack of precision in WHO/SAGE recommendations and Gavi funding guidelines empower countries to apply for rubella vaccine introduction despite their weak routine immunisation programmes.

Rubella infection in early pregnancy can lead to foetal death or congenital rubella syndrome (CRS) with multiple disabilities. Vaccination against rubella can prevent CRS, but inadequate coverage may increase the average age of infection and consequently lead to an increase in CRS ('paradoxical effect'). Therefore, the introduction of rubella-containing vaccine (RCV) into an immunisation programme implies a long-term commitment to achieving and maintaining sufficient immunisation coverage to ensure sustained population immunity for rubella. This is reflected in the WHO/SAGE recommendation, which states that 'countries that are planning to introduce RCV should have ≥80% coverage with the first dose of measles vaccine during routine immunization and/or campaigns', with careful consideration related to the sustainability of maintaining high routine immunisation coverage into the future. The IRC notes with unease that countries consider rubella vaccine introduction, with support from the Alliance partners, despite countries' weak routine immunisation programmes and without looking beyond the initial catch-up campaign.

In this round Somalia's ICC/NITAG meeting minutes revealed the decision to introduce RCV based on the coverage of the most recent nationwide measles preventive campaign (86% coverage by survey), and not considering consistent routine coverage under 50% (WUENIC) and 2022 MCV1 coverage by study of 64.5%. Yet, Somalia did not apply for Gavi's support to introduce RCV.

Guinea Bissau re-submitted a request for RCV introduction with the strong support of partners, providing more data to support the proposal, but with no clear consideration for the declining MCV coverage, long stagnating routine coverage across all vaccines, suboptimal national and subnational coverage achieved for the last measles campaign conducted in 2019, and system problems such as challenges with staff retention, data quality, suboptimal surveillance, and funding. In addition, the country has age eligibility limit for measles vaccination at 2 years of age, and the 2YL platform has not been legislated yet, therefore is not functional.

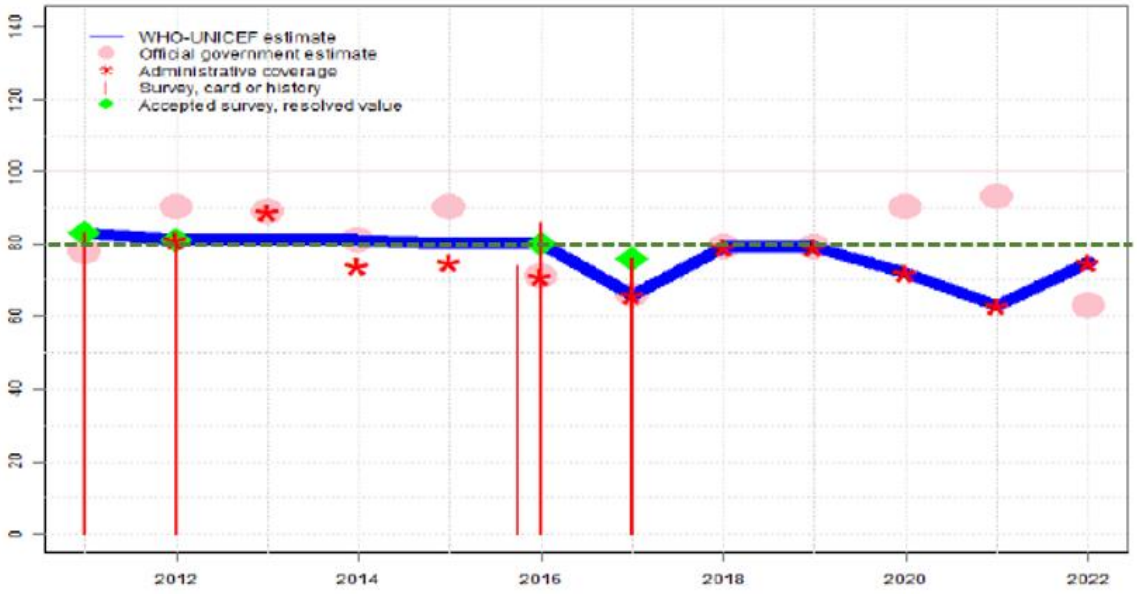

Figure 2: MCV1 coverage in Guinea Bissau 2012-2022 (source: WUENIC, March 2024)

Guinea Bissau's justification rests only on 83% coverage (interestingly the same figure administratively and by survey) achieved nationally more than four years ago, in the 2019 measles campaign. Information from the survey showing coverage below 80% in some regions and well below the threshold in several sectors or the programme context does not seem to have been comprehensively considered. While it is difficult to disregard the programme reality, if looking broadly and superficially, a country with 83% coverage achieved nationally in the last measles campaign appears eligible for rubella vaccine introduction. Of note, the WHO/SAGE guidance currently does not specify recency, number, and frequency of MCV campaigns that countries should consider when deciding on RCV introduction in the absence of sustained ≥80% MCV coverage in the routine programme for each birth cohort. However, knowing that for countries with high birth rates the routine coverage of 80% may not remove the risk of CRS, this will eventually result in country's dependency on campaigns, which is not a sustainable solution. In order to avoid inaccurate interpretation of current recommendations and programmatic decisions potentially guided by funding opportunities, higher precision of WHO/SAGE recommendations and Gavi funding guidelines is warranted.

Recommendations:

- Gavi and partners to encourage the countries to apply for RCV introduction in line with WHO/SAGE recommendations and Gavi guidelines, when MCV coverage in the routine is sustained at 80% or above, and with consideration of overall programme performance and sustainability.
- Technical partners to clarify recency, number and frequency of MCV campaigns in the decision process for RCV introduction, in the absence of sustained ≥80% MCV coverage in the routine programme for each birth cohort, and issue apposite formal recommendation.
- Gavi Secretariat to clarify and align the requirements for RCV introduction in the funding guidelines with clear technical recommendations: if campaign coverage should be considered alone, the most recent timing, and the number and frequency of MCV campaigns to be considered.

Issue 02: Countries apply for expanded age range in MCV follow-up campaigns, i.e. above 59 months of age, without basing their request on solid epidemiological evidence and programmatic feasibility.

As a result of suboptimal measles coverage in routine programmes and in campaigns, susceptibles accumulate in children above 5 years of age. Gavi funding guidelines allow the flexibility to support a follow-up campaign targeting a wider age group than standard 9 to 59 months if countries provide epidemiological evidence to justify this for measles control. IRC has noted in the past that countries generally base their requests for wide age campaigns mostly on the disease burden and age distribution of cases at national level which can lead to spurious inferences, and with little consideration of marginal benefit and cost-effectiveness of such wide age campaigns.

In this round of review, Senegal requested support for the MR follow-up campaign to target 9 months to 14-years-old to interrupt the transmission of measles which was not stopped by the last 2021 selective campaign. The post-campaign coverage survey (PCCS) report is still not available, outbreaks do not seem to have been investigated and critical information is not used for programme planning. Further, data on confirmed cases in all age groups showing clustering in a religious pilgrimage site, are not considered. There is no information on age-specific disease severity, but no deaths have been recorded in 2023. Overall, the epidemiological evidence provided was not compelling to justify the request for wide age

campaign. While the immunity gap in older cohorts inevitably exists and can be estimated to 10-15%, it is unlikely that it would be efficiently addressed with a national wide age campaign without considering subnational data and locally driven strategies to reach older susceptibles in a cost-effective manner, especially in presence of school-based and adolescent vaccination platforms within reasonably well-performing routine vaccination programme.

In order to more sustainably control measles, also in terms of both human and financial resources, a broader variety of interventions beyond campaigns is needed. Campaigns are expected to strengthen the routine programme, not become its alternative. However, IRC strongly reiterates its position that applicant countries should support their requests for wide age-range campaigns with robust epidemiological evidence and programmatic feasibility.

Recommendations:

- Gavi and Alliance partners to support the countries to base their requests for wide age-range measles campaigns on robust epidemiological analysis that includes and triangulates relevant data sources and information including from outbreaks, geographic and demographic changes, etc.
- Gavi and technical partners to propose a set of interventions for cost-effective reach of older susceptibles beyond wide age-range campaigns, and encourage and assist countries in development of sustainable strategies for measles control.

Issue 03: Countries applying for RCV introduction generally do not consider establishing CRS surveillance.

WHO recommends an integrated case-based surveillance for measles and rubella in order to monitor measles and rubella epidemiology. Given the progress toward rubella control and elimination, WHO recommends strengthening integrated measles and rubella case-based surveillance of fever and rash and introduction of CRS surveillance. Generally, acute rash and fever surveillance is less sensitive for rubella than for measles, as rubella is clinically mild or presents without visible symptoms and therefore is less likely to reach medical attention. On the other hand, CRS is evident at or shortly after birth, making it easier to identify and quantify infants infected in utero, even when rubella infection in the mother was inapparent. Given that prevention of CRS is the primary reason for rubella vaccination, CRS surveillance should complement integrated case-based rubella surveillance and be linked to national goals for rubella vaccination. CRS surveillance is needed to, among other objectives, demonstrate the impact of vaccination. For countries without routine CRS surveillance, WHO recommends that active surveillance, including case detection and investigation, should be implemented during and immediately after a rubella outbreak. While the proposals for RCV introduction mention rubella outbreaks, no active surveillance or other methods for assessing the burden of CRS are described.

The vast majority of countries that applied for support to introduce RCV in the past did not have CRS surveillance and most countries did not include establishing it in their plans. This can be explained by the fact that Gavi funding guidelines do not pose this as one of the key requirements to countries, despite clear WHO recommendation. Guinea Bissau, applying for RCV introduction in this round, provided a very high-level outline of their plan to establish CRS surveillance, and while work on elaboration of a protocol and establishment of sentinel sites is planned to be included in the 2024-2025 PEF TCA, the plan of action

mentions that there are no plans to establish CRS surveillance. The IRC therefore requested Gavi and Alliance partners to support the country in establishing the CRS surveillance.

Recommendations:

- Gavi Secretariat to align the vaccine funding guidelines requirements with WHO recommendation and include the plan for CRS surveillance establishment with accompanying budget in the key requirements for RCV introduction.
- Gavi and Alliance partners to support the countries without routine CRS surveillance in establishing active surveillance or advise on other appropriate methods for assessing the burden of CRS after rubella outbreaks.

Malaria vaccines

The panel for review of applications for malaria vaccine support reviewed six applications. Of these, two were for vaccine introduction from Ethiopia and Mali, and four were malaria vaccine scale up applications from DRC, Kenya, Uganda and Nigeria. Two prequalified vaccine products are currently available: RTS,S/AS01 and R21/Matrix-M vaccine. All countries presented convincing applications with robust epidemiology and programmatic rationale for the malaria vaccine introduction or at scale levels, and all applications were approved.

The IRC note some examples of good practice identified in country proposals, and include the following.

- Detailed analysis of lessons learned from post-introduction evaluation were used to inform the application for the malaria vaccine introduction in Uganda. Appropriate mitigation approaches to address anticipated bottlenecks were described.
- Mali presented an innovative approach for introducing the malaria vaccine in a seasonal malaria prevention setting based on WHO recommendations and experiences piloted in the country.
- Inclusion of operational research in the application in Mali and Uganda.
- Demonstrated collaboration between the malaria program and the EPI program in Uganda.
- Uganda presented an economic and impact analysis to inform the application, and a TA activity is planned to prepare an investment case for malaria vaccine funding while quantifying the gains made or expected to be made by investing in the malaria vaccine.
- Many applicants, such as Uganda, Kenya and DRC, underlined how the malaria vaccine administration will be integrated into the routine immunisation program, primary health services (PHC), and community services to mitigate the lack of EPI human resources and maximise impact toward coverage.
- Ethiopia and Uganda's applications demonstrate the adoption of human-centred design methodologies to better address malaria vaccine access barriers.

Issue 04: No consideration of sentinel surveillance of adverse events following immunisation (AEFI) or enhanced passive AEFI surveillance for malaria vaccine introduction in country planning.

IRC has repeatedly expressed a strong recommendation to plan sentinel surveillance when introducing new vaccines, or at least enhanced passive AEFI surveillance with active follow up and causality

assessment of AEFI of special interest. This has been a standing recommendation of the WHO Global Advisory Committee on Vaccine Safety (GACVS) and of the African Advisory Committee on Vaccine Safety (AACVS) for all new vaccine introduction, and malaria vaccines are not an exception. However, none of the applicant countries included such plans in their applications. Five of six countries (i.e. Ethiopia, Uganda, DRC, Mali and Nigeria) describe their plans to apply only passive surveillance systems for monitoring malaria vaccine safety post-introduction. Also, there was no mention in the plans of the need to strengthen the training of staff at the health facility level. This could be accomplished with the use of carefully developed practical Job Aids which would contain information on AEFI detection and reporting processes, along with other necessary information for health workers about the malaria vaccine.

Recommendations:

- Gavi and Alliance partners to encourage countries to align with global recommendation for AEFI surveillance and consider sentinel surveillance or at least enhanced passive surveillance with active follow up and causality assessment of adverse events of special interest following vaccination with malaria vaccine.
- Gavi and Alliance partners to assist countries in developing/adopting simple reference materials about malaria vaccine for health workers, i.e. Job Aids, and include in planning and budget.

Issue 05: Lack of specific strategies to strengthen efforts to improve uptake of the fourth dose of malaria vaccine

Data from Ghana's malaria vaccine introduction show that the uptake of the fourth dose of malaria vaccine improved when it was decided to co-administer it with the second dose of measles vaccine (MCV2) at 18 months of age. Ethiopia and Kenya have requested NITAG recommendation to add the fourth dose of malaria vaccine with MCV2. While this may boost the uptake of malaria vaccine fourth dose, the second year of life platform (2YL) needs to be strengthened to further increase the MCV2 coverage. However, no activities are described or budgeted to this effect despite suboptimal coverage and high drop-out rates.

Recommendation:

- Gavi and Alliance partners to encourage and support countries to devise strategies to improve uptake of the 4th dose of malaria vaccine, including co-administration with MCV2 and strengthening of 2YL.

Issue 06: Previous VIG doses not accounted for in malaria vaccine scale up

In previous rounds, the IRC observed that countries forecasted malaria vaccine needs without applying realistic, or in some instances, any drop-out rates, which may have resulted in many unutilised doses. DRC and Uganda applied to move to scale the malaria vaccine from the initial introductory phase. However, there is no clarity in their requests on how the initially approved doses will be accounted for or deducted from the current vaccine forecast expressed in applications.

Recommendation:

- Gavi and Alliance partners to assist countries to ensure that VIG and approved malaria vaccine doses are accounted for in forecasting when applying to shift from the introductory to scaling up phase.

Issue 07: Lack of clear strategies to ensure that vulnerable groups are reached with malaria vaccine

Plans of action contain scarce information about vulnerable groups despite the existence of data from equity assessments. This is noted in the Ethiopia, Uganda, and Kenya applications. It is of concern that the existing information is not used for developing specific strategies and activities to reach hard-to-reach populations. In addition, in fragile contexts there should be close collaboration with humanitarian agents to support effective strategies for reaching vulnerable communities.

Recommendation:

- Gavi and Alliance partners to support countries in ensuring that the available data on equity and vulnerability are analysed and translated into explicit relevant strategies, specific activities and interventions within the plan of action and related budget.

Issue 08: Lack of visibility of potential linkages across approved Gavi grants (CCEOP, CDS, HSS, EAF)

Applications do not include sufficient information on already approved or ongoing grants in HSS, CCEOP and EAF. Therefore, it is difficult to establish if any potential linkages or duplications have occurred across these grants. This information would be particularly important in crosscutting areas for Malaria vaccine introduction like CCE, HR, data management, gender, equity and on budget.

Recommendation:

- Gavi Secretariat to ensure that plans include linkages with existing grants and that relevant documentation is provided to IRC to inform the review.

Other vaccines and MICs

There was one application for RVV and PCV introduction with PCV catch-up campaign targeting children 12 to 59 months from South Sudan, one application for preventive yellow fever (YF) campaign targeting individuals from 9 months to 60 years from Guinea Bissau, and one MICs application for HPV introduction with additional multi-age cohort (MAC) campaign from 9 to 12 years from Angola. While South Sudan and Guinea Bissau applications were recommended for approval as requested, Angola's application was approved for the standard recommended MAC range (i.e. 9 to 14 years). The following issues were observed.

Issue 09: Lack of comprehensive guidance for vaccination of pregnant women during yellow fever preventive campaigns

Preventive mass vaccination campaigns against yellow fever remain the most efficient approach to rapidly increase population immunity levels. Guinea Bissau introduced YF vaccine in the routine immunisation schedule in 2008, as a single strategy, without a preventive mass campaign. The coverage has been ≤80%, mostly in the range of 60-80%. As a single approach, YF routine vaccination could not have reached the level of sufficient population immunity since introduction. This, couples with the absence of a vector control programme in the country, recent YF outbreaks in neighbouring Guinea, and population movements, puts Guinea Bissau at a significant risk of a YF outbreak. Therefore, the country plans to

prevent it with the implementation of a mass campaign that will target all individuals from 9 months to 60 years of age. This aligns with WHO recommendation for YF preventive campaigns. Further, the application mentions that high-risk groups, including pregnant women will also be targeted on the basis of a risk-benefit assessment, with the justification that the benefits of vaccination outweigh the risks of virus transmission during outbreaks.

Noting that YF is a live vaccine, WHO indeed recommends that a risk-benefit assessment be performed for all pregnant women for whom YF vaccine is being considered, indicating that in areas where YF is endemic or during outbreaks, the benefits of YF vaccination are likely to far outweigh the risks of adverse pregnancy or infant outcomes. Counselling is then advised so that pregnant women may make an informed decision about vaccination. While there is no explicit recommendation for such practice during preventive campaigns, WHO position paper does not list pregnancy as a contraindication for YF vaccination unlike all WHO prequalified (PQ) YF vaccines' product information inserts where pregnancy is listed as a contraindication for YF vaccination, except under epidemiological emergency circumstances.

Although YF vaccine is generally regarded as safe, limited safety data are available on its use in pregnant women. Since this is a preventive campaign and not a response to an outbreak, the IRC strongly reiterates its previous recommendation on additional guidance.

Recommendations:

- Gavi and technical partners to provide comprehensive guidance and clear recommendations for vaccination of pregnant women and other special population subgroups during YF preventive campaigns
- Gavi and technical partners to encourage and support countries to evaluate the feasibility of checking for pregnancies and recording the findings during preventive YF campaigns

Issue 10: Differing target age range for HPV MAC campaigns from NITAG and WHO recommendations

Angola requested support for a national HPV introduction through the Middle-Income Countries (MICs) Vaccine Catalytic Financing (VCF) and One-off Costs (OOC). The proposed HPV vaccination introduction plan presents a two-stage approach, with first a catch-up campaign targeting girls between 9 and 12 years of age and then the introduction of the national immunisation programme targeting nine-year-old girls. The country provided the NITAG meeting minutes of 16 October 2023, recommending targeting girls between 9 and 14 in the campaign as recommended by the WHO guidelines. However, the letter from the Ministry of Health dated 29 January 2024 requested support only for a catch-up campaign targeting age groups from 9 to 12 years. Except for a mention of close collaboration with the NITAG and partners in developing the HPV vaccination introduction plan, the application lacks clarity on the reasons for not complying with NITAG and WHO recommendations. Recognising this as a gap, the IRC raised an ethical and equity issue, considering that girls aged 13 or 14 are excluded without substantial justification from programmatic or financial aspects.

Recommendation:

- Gavi and Alliance partners to work with countries to ensure the faithful implementation of current WHO recommendations regarding catch-up campaigns or MAC for HPV introduction.

3.2 CCEOP

Issue 11: Applicant countries not applying for their full Gavi ceiling due to country contribution requirements and their budgetary limitations.

Two of four CCEOP requests from Tajikistan and Liberia were submitted below the Gavi ceiling. Tajikistan applied for 65% of the ceiling, whereas Liberia applied for 54%. While Tajikistan cited financial constraints for requesting below the approved ceiling, Liberia cited the commitment of in-country partners to bridge the immediate storage capacity gap of 537 units of CCE, some of which have started arriving in the country.

Requests below the Gavi ceiling risk programme performance, may compromise future vaccine introductions, and lead to sub-optimal supply delivery systems, unless alternatives like the case of Liberia exist. In addition, not executing the full Gavi ceiling under the CCEOP would risk the inclusion of cold-chain equipment in other applications where country contribution is not required, such as the HSS window.

Recommendations:

- Gavi and technical partners to ensure the Gavi ceiling is used to meet cold chain capacity gaps identified during the CCEOP application process.
- Gavi and technical partners to work with countries to ensure optimal vaccine cold chain equipment, regardless of CCE funding source.

Issue 12: Discrepancies in population figures within and across documents

Discrepancies were observed in population figures between levels in the inventory gap analysis tool and across documents submitted. For example, Liberia and Sierra Leone had discrepancies in population figures between the various levels of the supply chain. The comprehensive cold chain needs for Sierra Leone indicated that the 2030 projected population figure was used to estimate needs but no figure was provided, making comparison with the figures in the inventory gap analysis tool and the assessment of needs difficult. Application of different population figures will affect the gap analysis at various levels and may lead to under- or over-estimation of required cold storage capacity. This may result in inequity since the required volume of vaccines may not be secured due to inadequate cold storage capacity and contribute to missed opportunities for vaccination.

Recommendation:

- Gavi to ensure that the CCEOP applicant countries cross check, revise and align population figures at various levels and across all documents submitted for review, for correct gap analysis and determination of CCE requirements.

Issue 13: Safeguarding cold-chain equipment from theft in conflict zones and damage from climate disasters is not included in the plans.

Mozambique requested the replacement of 83 prequalified CCE units under 5 years old. This equipment was reported damaged or destroyed by cyclones or internal conflict. While prioritising the procurement of these units, no information was provided as to how the equipment installed in internal conflict areas would be safeguarded despite its potentially high value. Also, no contingency plans are proposed to respond effectively in such events.

Recommendation:

- Gavi to request the countries applying for CCE replacement in conflict zones to include information as to what safeguards and contingency plans are in place to secure the equipment, with designated accountability for their operationality and access.

Issue 14: Requests for spare-part kits below Gavi's recommended guidance may affect corrective maintenance.

Spare parts are essential for CCE repair and maintenance. The Gavi guidance recommends that for every 10 CCE requested, there should be one set of spare parts. If the number of CCE units is between 1 and 9, one set of spare parts must be requested. Sierra Leone, Tajikistan and Mozambique miscalculated the number of spare part sets requests in their applications. For example, Sierra Leone requested ten spare part sets for 103 CCE units instead of 11, which may affect the corrective maintenance of CCE. An adequate quantity of spare part sets is important as it enables quick response to unexpected breakdowns and ensures that the immunisation programme provides potent vaccines.

Recommendations:

- Gavi and Alliance partners to ensure that the countries comply with guidance and request an adequate number of CCE spare part sets in relation to the number of requested CCEs.
- Gavi to request the countries to justify additional spare part sets for existing equipment as required.

Issue 15: Decommissioning guidelines for the safe disposal of CCE not used

Decommissioning cold chain equipment has been a persistent challenge for most countries. Out of the four CCEOP applications submitted in this review window, only Sierra Leone provided a decommissioning guideline for the safe disposal of faulty/obsolete CCE. Guidelines are crucial as they provide information on how to dispose of defective or obsolete CCE in an environmentally friendly manner, preventing the release of ozone-depleting substances and reducing environmental threats. By decommissioning, more storage space can be available for cold chain needs. Even in countries with documented plans, poor coordination between different health system levels and lengthy administrative procedures often delay the implementation of CCE decommissioning. Liberia, Tajikistan, and Mozambique should have included or referred to decommissioning guidelines for CCE in their applications.

Recommendations:

- Gavi and technical partners to support the countries to develop decommissioning guidelines aligned with international environmental standards and regulations
- Countries to develop and implement eco-friendly decommissioning guidelines, disseminate them to relevant stakeholders and monitor adherence.
- Gavi to require CCE decommissioning guidelines as a mandatory document as a part of country applications.

Issue 16: New malaria vaccine product (R21) not included in the WHO sizing tool

Countries use the WHO sizing tool to conduct the CCE gap analysis to establish cold storage requirements for vaccines. However, the WHO sizing tool has not been updated to include the new R21 malaria vaccine. It is crucial for countries to be able to monitor CCE capacity and provide an updated gap analysis after factoring into the equation the estimated R21 vaccine CCE requirements in a specific timeframe. Moreover, malaria applications lack evidence on cold chain and dry storage capacity to accommodate for vaccine introductions or scale up.

Recommendations:

- Gavi and Alliance partners to accelerate the update of the WHO sizing tool for the new malaria R21 vaccine.
- Gavi to require from countries information on cold storage capacity along with information on dry storage capacity or on actions to be taken to identify the necessary dry storage for immunisation ancillary supplies.

3.3 Gender issues

IRC has repeatedly emphasised that one of the key aspects countries should consider when applying to Gavi for funding support is understanding and addressing gender-related barriers to ensure equitable access to immunisation services. Countries are required to articulate gender-related barriers in their applications, as understanding these barriers can help immunisation programmes adapt their strategies. Nevertheless, despite countries' efforts to comply with the requirement, they seldom succeed in translating this into effective measures to address gender inequities through detailed, targeted, and budgeted gender-responsive and transformative strategies.

Issue 17: Despite some progress in including gender barriers in their applications, countries rarely devise efficient gender-responsive and gender-transformative strategies.

Often described gender-related barriers that stand in the way of high routine coverage and successful campaigns are mothers' lack of decision-making power, inadequate time, lack of funds to access services, lack of information or misinformation, and poor treatment by health workers. Ideally, countries should conduct their own analyses before developing strategies, before including related activities in their workplan and budget. However, countries sometimes plan to undertake gender barrier studies during the execution of the grant without considering the possibility of identifying issues that may require the inclusion of previously unforeseen strategies.

In this round, Guinea Bissau and South Sudan did not carry out gender studies prior to tailoring strategies and developing a work plan and budget. DRC, Senegal, and Somalia mentioned some gender barriers and equity issues, but only a few strategic gender-responsive activities were developed and budgeted. In contrast, Kenya and Gambia developed strategies and gender-responsive activities based on their existing gender analyses.

Recommendation:

- Gavi and Alliance partners to assist countries in identifying gender barriers and equity issues to develop strategic gender responsive and gender transformative activities to be included in the theory of change, work plan, and budget.

Issue 18: Failure to use existing gender and equity data may result in less impactful intervention.

Countries sometimes omit utilising existing gender and equity data available in the country from studies in the field of immunisation or HSS conducted by technical partners such as UNICEF or The Global Fund. Uganda and Ethiopia malaria vaccine applications did not include a gender analysis or activities despite an already approved Equity Accelerator Fund (EAF) grant, risking to make the vaccine introduction or campaign less efficient and impactful by lack of applying available information and data on zero-dose children and missed communities.

Recommendation:

- Gavi and Alliance partners to encourage countries lacking detailed gender analyses to link gender issues across all their grants beyond the EAF and use data from related studies by partners in the country where available to ensure that efficient gender-responsive and transformative strategies are developed and included in all applications.

3.4 CSO engagement

Within the new Civil Society and Community Engagement approach approved in December 2021, the Gavi Board approved a requirement for all countries to allocate at least 10% of their combined funding ceilings (HSS, EAF, TCA) for CSO implementation, as they submit their new applications through full portfolio planning (FPP) processes. For non-adherence to this mandate, the countries must provide a detailed rationale as to why this is not appropriate in their context. Also, Gavi has introduced a new fund management mechanism to increasingly shift resources and implementation authority to CSOs. With this new fund management mechanism, Gavi has signed agreements with two organisations to serve as CSO Fund managers.

IRC is pleased to note that all three FPP reviews reported back to the IRC in this round (Zimbabwe, Gambia, and Benin) successfully met the Board mandate (Figure 3). Also, all three countries will utilise the new fund management mechanism for CSO engagement. For example, in the Zimbabwe FPP application, 16 CSOs have been identified and will be coordinated via the fund manager.

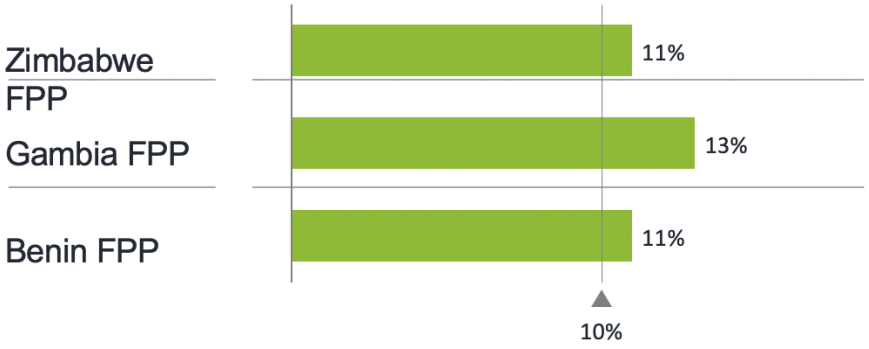

Figure 3: Percentage of the combined funding ceilings (HSS, EAF, TCA) allocated for CSO in FPP applications

Issue 19: Emphasis on local partners missing in the requirement for CSO allocation

Per Gavi guidance, civil society engagement encompasses the full range of formal and informal, non-governmental and not-for-profit organizations that represent interests of the communities. These include community-based organisations, faith-based organisations, international NGOs, civil society networks, local professional associations, and not for profit advocacy organizations. IRC observed that countries generally do not include comprehensive descriptions of CSO engagement in the narrative of their applications, and it is not always easy to differentiate local CSOs from international NGOs in the application materials, especially considering the broad definition of civil society engagement.

Recommendations:

- Gavi Secretariat to require prioritisation of local partners in CSO allocations and limit the CSO allocation to local partners where appropriate.
- Gavi Secretariat to provide a clear definition of local partners and ensure that countries utilise it in their applications and implementation.
- Gavi Secretariat to require that countries include in their applications the names of local partners and the focus and capability of these organisations.

Issue 20: The Board mandated allocation to CSOs not required for all Gavi applications

Inclusion of CSO is an important step towards sustainability of programs. Currently, only the FPP applications (HSS, EAF, TCA) are required to have combined funding of 10% allocated to CSOs. IRC notes that the FPP funding for 2022-2023, since the implementation of the Board mandate, represented 47% of the total amount approved by Gavi while 53% of the non-FPP funding in the same time period was not required to have an CSO allocation. Whilst the IRC note that it might not be feasible to always allocate a a minimum 10% of budget for non- FPP funding, it is imperative that these budgets also recognise and maximise the roles of CSO in reaching children especially in highly constrained environments. IRC notes that the global health community has experience and lessons learned on local partner engagement. Gavi could potentially adopt a model to absorb the lessons learned from these engagements.

Recommendations:

- Gavi to strongly consider ensuring that beyond the mandatory CSO allocation for FPP, other support type applications must have reasonable earmarks defined within their budgets for CSO with emphasis on local partners.
- To actualise above recommendation, it is imperative that Gavi identify a minimum range of appropriate allocation percentage for the non-FPP applications, and specifically intended for local partners.

Issue 21: CSOs not utilised to the full extent of their expertise

In the narrative of applications, CSO engagement was mainly described for activities regarding demand creation, advocacy and community engagement. Gambia FPP and Uganda malaria applications included CSO engagement for advocacy and community engagement activities. Very few applications mentioned service delivery and none described CSO engagement for driving innovation and for providing technical expertise.

Recommendation:

- Gavi and technical partners to encourage the utilisation of local partners to their full capability, including in integrated service delivery and to drive innovation as appropriate.

Issue 22: Alignment between CSO narrative and budgets not always present

The IRC notes that countries often describe the engagement of CSO in their plans of action, but this is seldom followed by the appropriate allocation in the budget. For example, YF application of Guinea Bissau and DRC malaria application indicate that CSO will be involved in demand generation activities. However, the budget presented has no allocation for this purpose. Similarly, in the Ethiopia MR application, the narrative includes a good summary of engaging local NGOs that have the capability and experience working on immunization programs, but it is not clear if their engagement is budgeted for.

Recommendation:

- Gavi to request that countries include CSO activities in the budget and make this evident in the budget presentation.

3.5 Fragile and conflict-affected countries

The fragile and conflict-affected (FCA) countries segment includes countries classified as fragile according to the Gavi Fragilities, Emergencies and Displaced (FED) policy. The IRC applies the standard review process and the same levels of scrutiny for all applications, regardless of the country segment. However, to achieve effective implementation of Gavi support in challenging and volatile environments, often in humanitarian crises and in complex political contexts, further scrutiny is needed to understand factors and their interaction with the implementation and outcome of planned interventions. Leveraging all the support from UN and humanitarian organisations engaged in the field becomes critically important in ensuring

their engagement at every stage during the planning, implementation, monitoring and evaluation of interventions. As the issues may vary greatly by context in each country of interest, the following IRC observations relate to FCA countries' applications reviewed in this round. These include malaria vaccine application from Mali, MCV follow-up campaign application from Somalia and PCV and RVV introduction from South Sudan.

Issue 23: Scarce information about implementation plans for interventions in administrative regions and areas with compromised security or out-of-government control

All three FCA countries applying in this round, Mali, Somalia and South Sudan, are vast in geography, weak in health infrastructure, and inadequate in system capacity, and all present difficulties to achieve equitable immunisation services and to reach zero-dose children and underserved remote communities. In situations of conflict, when massive population displacements leave large administrative areas beyond the control of the government, this further aggravates the situation, as it leads to moving out of health workers and abandonment of health facilities. Such interruption of already meagre services creates fertile ground for outbreaks of vaccine-preventable diseases. Given the inherent political sensitivities and due considerations, countries usually seek an all-round assistance and help from UN and other international humanitarian organizations, to alleviate immediate problems and to extend primary health care and immunisation services where they are critically needed. All three applications from FCA countries reviewed in this round, show the intent to engage UN and humanitarian agencies on the ground during implementation of the respective proposed interventions. While this support should be broader and coordinated, countries provide little or no detail on how this engagement is to be applied in practice.

Recommendation:

- Gavi to request the FCA countries to include in their applications' plans of action detailed mapping of partnerships with specific roles and responsibilities, logistical, transport and distribution of vaccines and supplies, and monitoring of activities in all areas with compromised security, including those not controlled by the government.

Issue 24: Leveraging and integration of different interventions not considered in FCA countries' applications

The plan of action for the measles follow-up campaign presented in Somalia's application included integration with the polio campaign, with implications of synergy and resource optimisation. At the same time, the potential integration or leverage of activities and resources within the PCV and RVV introduction approved in the previous IRC review was not mentioned or explored. While the benefits of integrating activities during campaigns should be carefully weighed, integration and optimisation of resources in FCA countries will likely translate to greater value in improving access and efficiency as more life-saving interventions are made accessible to communities most in need.

Recommendation:

• Gavi to make mandatory for countries to reflect implementation activities and potential synergies of interventions of different support windows, included those funded by non-Gavi sources.

Issue 25: High cost of post-campaign coverage surveys leading to their exclusion from the plans in FCA countries

WHO guidance on the implementation of campaigns recommends conducting a post-campaign coverage survey (PCCS) to assess the coverage reached, the effectiveness of planning and implementation activities and their impact on immediate outcomes and the routine immunisation programme, and to gather lessons learned that can inform subsequent campaigns. The levels to which campaigns reach the target is a key determinant of impact, but surveys often exclude conflict-affected areas. In this round, justifying it with high operational costs surpassing the Gavi ceiling, South Sudan opted to drop out of PCCS after the planned PCV catch-up campaign. Gavi recognises that fragility and conflict settings often experience excessively high operational costs due to prohibitive transport costs and high per diem rates, and its FED policy allows the increase of permissible budget limits subject to adequate justification. This enables countries to comply with WHO recommendations and Gavi requirements.

Recommendations:

• Gavi and Alliance partners to provide technical and material assistance to FCA countries to meet the requirements of a complete application, along with guidance on how to identify funding sources and technical input on other possible cost-effective options.

• Gavi and Alliance partners to advise and assist countries to present a more detailed budget with costs for PCCS in order to identify cost drivers.

3.6 Budget, financial management and sustainability

Lack of visibility of non-Gavi funding contributions

IRC financial cross-cutters reviewed 14 applications from 10 countries, which included one PCV, one RVV, one YF, five M/MR and six Malaria applications. The applications had a total budget of US$ 65,333,436 out of which Gavi funding accounted for US$ 39,079,337 (60%), Government funding for US$ 4,422,687 (7%), Technical Partners funding for US$ 7,754,930 (12%), other sources of funding for US$ 1,430,554 (2%), with a funding gap of US$ 12,645,931, representing 19% of the total budgets submitted (Figure 4). The financial cross-cutters also reviewed 3 FPP applications remotely from Benin, Gambia, and Zimbabwe. Figure 5 below shows the budgets by country and by funding source.

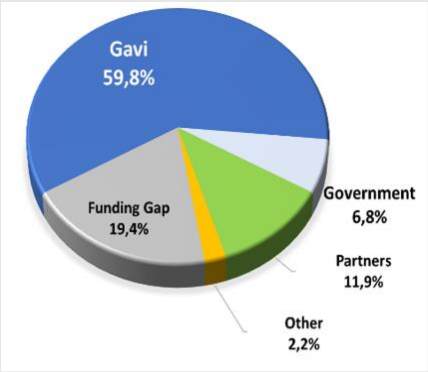

Figure 4: Overall budget by funding source

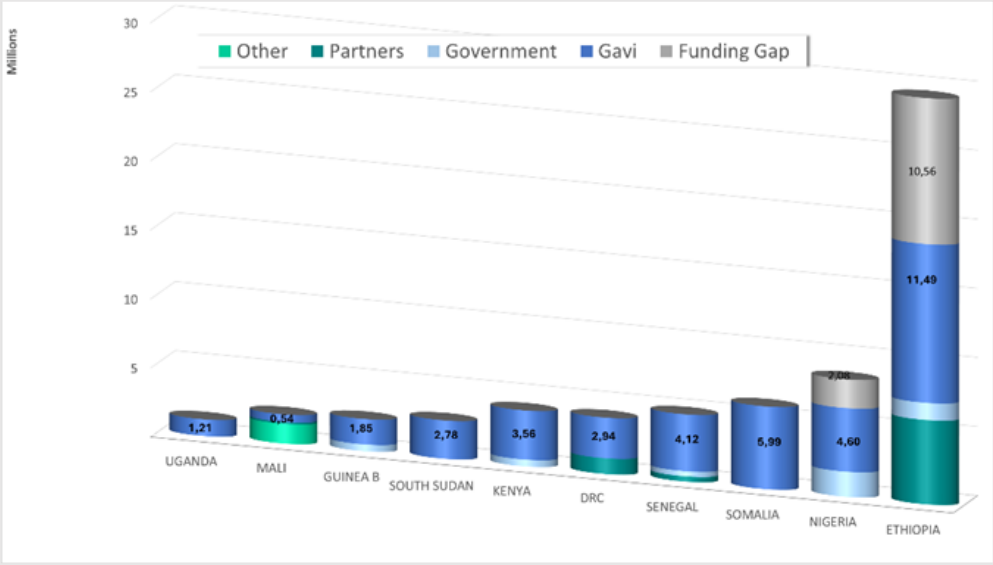

Figure 5: Budgets by country and by funding source

Gavi's contribution across budgets is much lower than in recent rounds (between 82% and 98%)[1]. Only 5 out of 14 budgets reviewed allocated 100% of the costs to the Gavi funding contribution, which could indicate that countries submitted comprehensive budgets that considered the full range of interventions. However, IRC has identified several issues related to the presentation of other sources of funding, both in the Gavi Excel template and the Plan of Action. These issues were observed in all grants but to a higher extent in malaria grants. Figure 6 illustrates the issues related to sources of funding for malaria grants.

[1] Gavi contribution was respectively 98%, 85%, 95%, 82% and 94% for 2023 IRC rounds (February, March, June, September and November).

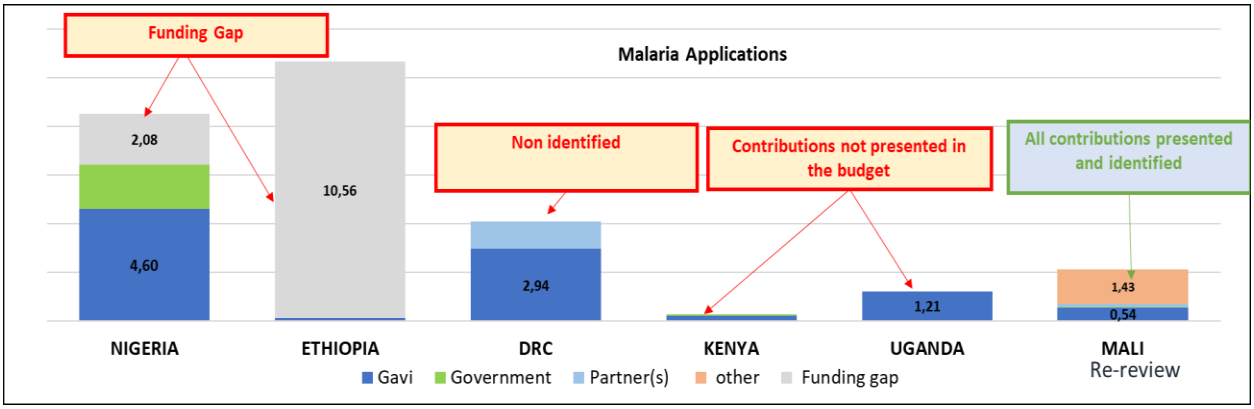

Figure 6: Budgets for malaria applications by country and by funding source and related issues

Malaria vaccine funding support as vaccine introduction grants (VIG) and are meant to cover a share of malaria vaccine introduction activities. Of the six malaria budgets, five (5) presented issues related to identifying non-Gavi funding sources. Ethiopia presented a US$ 10.6M budget with only US$ 99,937 from Gavi corresponding to the ceiling and the remaining US$10.5M as a funding gap with no proposed or identified funding source. This means that there is a high risk that essential vaccine introduction activities will not be implemented due to the lack of funding. The analysis of the activities with a funding gap indicated that Gavi financing will only be utilised for capacity development, and demand creation, supply chain, and governance and strategy activities are budgeted within the funding gap. Other applications showed several overestimations or duplicated activities with other fundings.

Mali budget, which was a re-review, was the only malaria budget with adequate presentation of all funding sources, including non-Gavi resources (USAID, Government). Nigeria presented a budget with a US$2M funding gap representing 24% of the total budget, which is material. The gap is related to essential vaccine introduction activities such as microplanning and formative research. DRC presented a budget with a high share of funding from partners (US$1,136,092) without identifying the funding sources. Kenya and Uganda should have presented other funding sources for activities mentioned in their work plans. For Kenya, contributions from the Government and technical partners are mentioned in the vaccine introduction plan as complementary sources of funding to the Gavi VIG, but the allocations are not defined. Uganda presented a budget within the ceiling of US$ 1.2M, which was misaligned with the work plan budget of US$3.2M.

Similar issues were also identified in the M/MR applications for Somalia and Ethiopia, which presented material gaps. Ethiopia, for instance, had a US$6,104,588.00 funding gap but still presented a different budget from the aggregate budget and POA. Somalia presented a budget which was US$ 3,958,019 above the Gavi ceiling. The IRC approved the total amount requested as it was in line with the most recent Measles follow-up budget approved for the 2022 campaign that achieved good coverage, verified by the PCCS. However, inconsistencies leading to overestimation of the number of supervisors was an important issue. Kenya did not disclose the non-Gavi contributions in either application, the malaria vaccine introduction or the MR follow-up campaign.

Issue 26: Fully costed budgets with material funding gaps or with non-identified funding sources for critical vaccine introduction or campaign activities present a risk for implementation of vaccination campaigns or for introduction of new vaccines.

Recommendations:

- Gavi and Alliance partners to ensure that countries disclose all other non-Gavi committed resources by including in the budget template the sources of funding for the aggregate budget of all activities needed for the successful implementation of intervention.
- Gavi and Alliance partners to support countries to develop a budget that maximises expected outcomes, particularly FCA countries with budgets above the ceiling.

Missed opportunities to create efficiencies across ongoing Gavi grants

As in the previous round, the IRC observed several potential duplications or lack of integration of activities between the budgets presented in this round or with other ongoing Gavi support. While the plan of action for the Senegal MR application indicated that no other activities will occur during the campaign preparation, the IRC has just approved an FPP grant, including HSS and EAF support, which include different training activities and are opportunities for integration. Trainings and meetings in the campaign are budgeted at US$682K and include several events (workshops of implementation, final report writing, launching and training at different levels) which could be integrated with some FPP activities. Kenya MR application mentioned synergies with IPV and CDS3, and the action plan referred to integrating MR follow-up campaign activities with Vitamin A supplementation. However, there is no budget information provided to support this alignment and/or integration with other funding streams at the country level. Ethiopia malaria and MR applications, despite the US$10.5M and US$6.1M resource gap, have not identified other programmes to draw programme efficiencies and related linkages, despite the ongoing FPP approved in 2023.

Integration of activities leads to important savings that can be allocated to underfunded activities. It also prevents adding supplementary burden and stress on health actors and disrupting routine immunisation activities.

Issue 27: Countries do not consider integration of activities, notably demand generation, training, and vaccine distribution costs, with other ongoing or planned Gavi funding, in particular through FPP and CDS.

Recommendations:

- Gavi and Alliance partners to support applicant countries to better align budgets with ongoing Gavi or other donor-supported initiatives at country level.
- Gavi Secretariat to prepare details of ongoing Gavi support to the country (especially FPPs), and support countries to identify areas of integration, and share with IRC reviewers during pre-screening.
- Gavi Secretariat to prepare a landscape of funding from other donors (especially GF for malaria grants) and share with IRC reviewers.

Lack or misalignment of budget assumptions between plans of action and budgets

Overall, IRC observed that activities described in the plans of action are budgeted. Budget requests are generally linked to target populations indicated in the plan of action, but with several exceptions due to lack of information or inconsistencies. Some plans lack details on cost drivers (e.g. number of activities, number of persons involved, frequency) which prevents ensuring alignment, as was the case in MR follow-up application from Senegal, and malaria applications from DRC, Nigeria, and South Sudan. Malaria applications from Uganda and Ethiopia Malaria had inconsistencies in the number of regions, teams' composition, and DSA rates, which were not verified. The Somali measles follow-up application introduced costs and activities not defined in the POA.

Further, in the South Sudan application, the plan of action is not aligned with WHO guidelines, and would benefit from eliminating duplications and ensuring that the narrative is aligned with objectives, activities in the chronogram, and budget.

In addition, when provided in the plan of action, costing assumptions are inconsistent with budget calculations. For example, the Senegal MR follow-up application presents an inconsistent distribution of the target population between the plan and the budget that can increase the number of teams by 8%. Other inconsistencies are noted in the numbers of vaccinators and can lead to an extra cost of US$207K or in the team composition with an impact of US$319K. Nigeria's malaria plan presented several inconsistencies with the budget related to the distribution of target states between phases of implementation, the implementation timeline, and the target population for low transmission areas. Guinea Bissau rubella application budget did not change after re-review, but the vaccinators' workload did. In Ethiopia's malaria application, the differentiation of strategies was described in the plan, while the teams' calculations and costs were standard for all strategies. Uganda's malaria application presented data variations on targets, geographical regions and human resources involved, as well as duplication in the role of TA.

Issue 28: Countries still present plans of action with few details on main costs drivers (i.e. number of activities, number of persons involved, frequency, etc.) or with major inconsistencies with budgets.

Recommendations:

- Gavi to explore mechanisms to enforce countries' responses on pre-screening observations/findings before tabling applications for IRC review.
- Gavi to encourage countries to better align budget and population target figures between the plan of action and the NVS application to facilitate IRC review checks.

Co-funding issues and transition

Gavi Eligibility and Transition Policy is based on thresholds depending on the country's Gross National Income (GNI). It defines the transition pathway through which Gavi support is phased out when countries reach higher GNI per capita following three phases: initial self-financing, preparatory transition and

accelerated transition. In this round, countries in the accelerated transition phase, Nigeria and Kenya, and Angola as a middle-income country, revealed some challenges in financing their EPI needs. Nigeria has difficulties meeting its co-financing obligations. A World Bank loan was used to pay co-funding commitment in 2023. Kenya is expected to fully self-financed by 2030 but noted funding gaps to achieve national malaria strategy targets. Angola, which has transitioned, presented a sustainability plan, but this was limited by several gaps.

Other countries are in the initial self-financing phase, but some trends raise concerns. For example, Benin and Gambia FPPs present high recurrent costs (25% for Benin), which leave little fiscal space for other key EPI interventions. These two countries did not explain in their applications how to sustain these expenses. Also, EPI spending levels in Zimbabwe are low to achieve transition objectives (HR, infrastructure, vaccines).

Issue 29: Due to the loosely applied Gavi Eligibility and Transition Policy, countries in early stages are not encouraged to develop and institute well-articulated transition plans that reflect their current financial and programmatic situation.

Recommendations:

- Gavi to systematically support countries in transition planning at an early stage and monitor its implementation.
- Gavi and Alliance partners to support countries to increase EPI spending as they transition from donor support.
- Gavi to provide more clarity for sustainability requirements for countries in early stages of transition.

3.7 Cross-cutting issues

The IRC observed several recurring cross-cutting issues highlighted below.

Issue 30: Post-campaign coverage surveys heavily delayed or not conducted

Post-campaign coverage surveys are time and resource-intensive and require detailed planning, organisation, logistics, and specialised professionals. Countries applying for campaign operational support are required to conduct a PCCS immediately after the campaign, while the finger marks are still visible and to minimise the recall bias. For this, timely planning is essential, as emphasised in the WHO guidance. While in the past years IRC has seen more PCCSs being conducted, we also observe that the countries do not always do so despite PCCS being included in the budget and funded by Gavi, or that PCCS reports are heavily delayed. This undermines the use of the survey in understanding who was missed, where and why, and does not provide useful lessons that can inform subsequent planning and activities. For example, Senegal applied for MR follow-up campaign without the benefit of information from the 2021 national selective MR campaign due to implementing partner's excessive delay in submitting the survey report. This information could have additionally informed the country in development of differentiated strategies which are key for campaign reach and impact. Another example mentioned earlier is of South Sudan,

which opted to drop out PCCS after PCV catch up campaign due to high operational costs imposed by fragility and conflict settings.

Recommendations:

- Gavi to reinforce PCCS as mandatory for all Gavi applications for campaigns.
- Gavi and Alliance partners to support countries in identifying other resources and/or other cost-effective options in case costs are above budget ceiling.
- Gavi to assist the countries in identifying a reliable partner for timely conducting and delivery of the PCCS.

Issue 31: Stagnating routine immunisation programme underperformance

Not discounting the impact of the COVID-19 pandemic to immunisation programmes, the IRC notes the concerning lack of planning and strategies to achieve optimal routine immunisation programme performance and sustain it. This is partly evident in the frequent requests for preventive vaccination campaigns such as for measles, the frequency of which is dictated not only by suboptimal routine but also by suboptimal performance of previous campaigns. While campaigns can address deficiencies in routine delivery, they are not meant to address the failures of previous campaigns and become the alternative for routine immunisation programme strengthening.

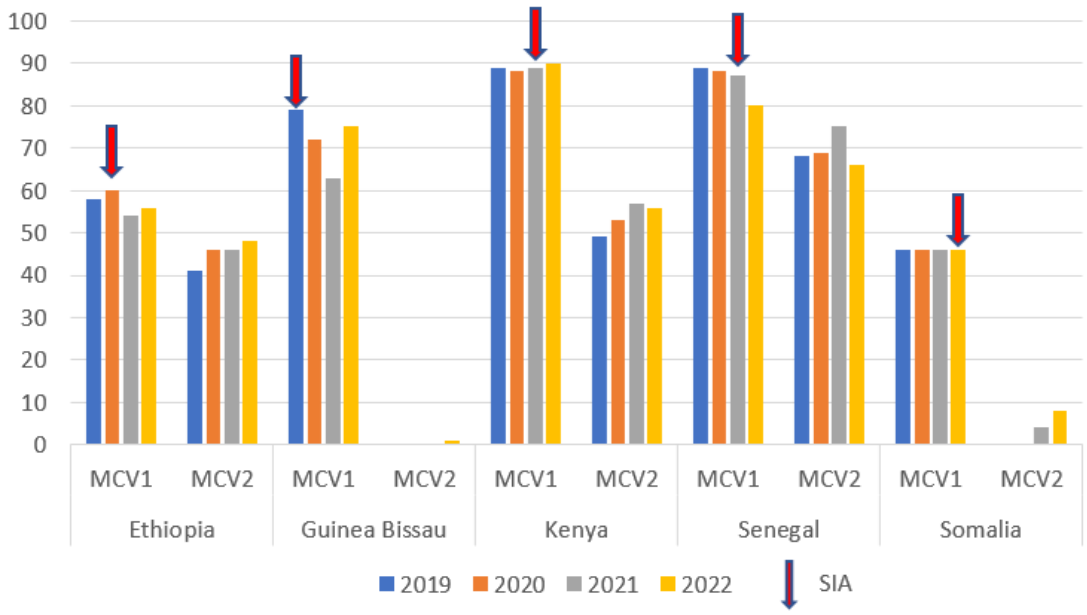

Figure 7: Stagnating suboptimal routine coverage for MCV1 and MCV2 in M/MR support applicants, with year of last SIA (Source: WUENIC 2024)

Recommendation:

• Gavi and Alliance partners to support the countries in developing roadmaps for improving routine immunisation programmes.

Issue 32: Gap in governance mechanisms

Independent, transparent, evidence-based, and timely recommendations from technical bodies such as NITAGs are of paramount importance for a well-functioning immunization programme. Governments rely on this expertise to inform their decisions. However, in this review window, the IRC notes a gap in governance mechanisms. This relates to endorsement of applications by ICC before the decision and recommendation of NITAG, as was the case in Senegal where the application was already endorsed when it arrived to NITAG. In the case of Somalia, ICC and NITAG met at the same time to endorse the application for MR introduction and catch-up campaign, although that was not the intervention for which support was requested. Somalia applied for MCV follow-up campaign but without separate recommendation or endorsement by NITAG and ICC.

Country	ICC endorsement	NITAG meeting/validation
Senegal	17 January 2024	25 January 2024
Somalia	Joint ICC and NITAG meeting on 17 August 2023	

Table 2: Gap in governance practices observed during March 2024 review

Recommendations:

• Gavi and Alliance partners to ensure that countries adhere to governance practices.

• Gavi Secretariat to ensure that countries provide adequate endorsement for their requested support type.

4. Conclusions

During March 2024 IRC meeting, all 30 applications (19 applications reviewed across 3 panels and 11 in previously started remote reviews), were approved, of which 2 (7%) with amendments. This indicates a continued improvement of applications and a joint effort of countries and the Alliance. While the IRC commends Gavi and Alliance partners for their strides toward new vaccine introductions, notably rubella-containing vaccine, it is critical to maintain the focus on strengthening routine immunisation programmes and ensure clear technical guidance so that the risk of inaccurate interpretations of current recommendations is minimised (e.g. eligibility for RCV introduction, vaccination of pregnant women during preventive YF campaigns).

The IRC remains concerned that countries seem to be proceeding with extending the age range of MCV campaigns and/or with shortening the interval between campaigns without deep consideration of solid epidemiological and clinical evidence, programmatic feasibility, or other programmatic and delivery

options. The IRC reiterates that while campaigns undoubtedly provide protection to many children, they cannot replace a strong routine immunisation system. Therefore, countries and technical partners should put additional effort to develop roadmaps for improving routine immunisation programmes, with attention to programmatic and financial sustainability.

The IRC notes many good practices in malaria introductions, particularly collaboration of malaria and EPI programmes. However, there is still a need to increase the use of available data, particularly on vulnerable populations and gender inequity, in the development of strategies that would reach those most in need and improve the uptake of the important fourth dose of malaria vaccine.

Further, the IRC would like to see better budget alignment with ongoing Gavi or other donor-supported initiatives and urges Gavi and partners to support the countries in creating efficiencies across ongoing grants. The IRC also deems it important that Gavi determines the extent to which FCA countries can enhance their budgets to cover the costs related to their contexts.

Finally, the IRC commends the Secretariat's and, in particular, the FD&R team's ongoing efforts to introduce structure and process changes that will increase review differentiation and efficiency.

5. Acknowledgments

The IRC would like to thank the Gavi Executive Team for their continued support of its work and the FD&R team for organising the meeting.

The IRC also thanks the Gavi Secretariat, SCMs, VPs, HSIS, and PFM team members for their continued important input during pre-review screenings and clarifications on country-level perspectives during review sessions.

The IRC also acknowledges the contribution of the Alliance partners in supporting country applications and their participation in sessions during the IRC's deliberations.

Annex 1: IRC members participating in the March 2024 meeting

#	Name	Nationality	Profession/Specialization	Sex	Review language	Expertise
1	Abdul-Aziz Garba Mohammed	Nigeria	Pharmacist/Supply chain management, Ministry of Health Yobe State, Nigeria	M	EN	Health supply chain management, immunization supply chain, vaccine and cold chain logistics
2	Zenaw Adam	Canada	Independent consultant	M	EN	Routine immunization, SIAs and NVS, HSS and PHC services, fragile and underserved communities
3	Juliana Amanyi-Enegela	Nigeria	Senor Programme Manager/ Knowledge Management Lead - NTDs	F	EN	HSS, programme management and M&E of health programs, mass vaccination campaigns, research
4	Beatriz Ayala-Öström	UK, Sweden, Mexico	Independent consultant	F	EN, SP, PT	Health system strengthening, supply chain management, pandemic preparedness
5	Sabine Beckmann	Germany	Independent consultant	F	EN, FR	HSS, public health policy advisor, gender & equity, conflict and fragile settings, vaccination campaigns
6	Aleksandra Caric	Croatia	Independent consultant	F	EN, FR	Measles, SIAs, AEFI surveillance and vaccine safety, programme management, primary health care
7	Rochika Chaudhry	USA	Advisor, Johns Hopkins Medical Institution	F	EN	Immunization services, global health security, outbreak response, HSS, health finance and policy, malaria, HIV
8	Emmanuelle Espié	France	Regional technical advisor in Global Health, French Embassy, Ivory Coast	F	EN, FR, SP	Epidemiology, epidemic preparedness, surveillance, outbreak responses, vaccine effectiveness and safety, vaccinology
9	Henry Katamba	Uganda	National Facilitator, GF at the Ministry of Health in Uganda	M	EN	Epidemiology, M&E of health projects, health research and advisory
10	Wassim Khrouf	Tunisia	Auditing and Consulting Worldwide, Partner	M	EN, FR	Financial and budget analysis, audits, project assessment
11	Viviana Mangiaterra	Italy	Associate Professor, SDA School of Management, Bocconi University, Milan	F	EN, FR	HSS, Maternal and Child Health, Malaria, HIV and TB
12	Tony Mugasia	Kenya	Independent Consultant	M	EN	Malaria, HSS
13	Mutuku Stephen Mutinda	Kenya	Health economist and health financing specialist	M	EN	Economic modelling, expenditure and costing analysis, efficiency and productivity, Value for Money -VfM analysis, Return on Investment (ROI) and Impact analysis
14	Pierre-Corneille Namahoro – VICE CHAIR	Rwanda	Director of Public Health, Global Supply Chain & HSS, Fascinans Ltd.	M	EN, FR	HSS, Supply Chain Management and Cold-Chain Logistics
15	Villyen Nkengafac Motaze	Cameroun	Associate Professor of Epidemiology, Medicine Usage in South Africa (MUSA), Noth West University, South Africa	M	EN, FR	Vaccinology, epidemiology, systematic reviews, evidence-based practice

16	Benjamin Nkowane - VICE CHAIR	Zambia	Independent consultant	M	EN, FR	Measles epidemiology, mass vaccination campaigns, technical support for field operations in risk areas
17	Chioma Nwuba	Nigeria	Independent consultant	F	EN	Supply chain management and cold-chain logistics
18	Bola Oyeledun – VICE CHAIR	Nigeria	Chief Executive Officer at Centre for Integrated Health Programs (CIHP), Nigeria	F	EN	HSS, MNCH, immunisation, adolescent reproductive health & HPV, programme assessment and evaluations
19	Sehrish Tehreem	Pakistan	Independent consultant	F	EN	Health and immunization system strengthening, vaccine management, disease surveillance
20	Ousmane Amadou Sy	Senegal	Independent consultant	M	EN, FR	Grant management, financial management and internal control mechanisms.
21	Pierre de Vasson	France	Independent consultant	M	EN, FR	Supply chain management and cold-chain logistics
22	Kondwani Msampha	Malawi	Deputy Global Director for Corporate Services & Human Resources Director at the World Scout Bureau Global Support Centre	M	EN	Finance & budget management