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

MARCH 2023
GAVI ALLIANCE

Table of Contents

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 Immunization
EVM	Effective Vaccine Management
FED	Fragility, Emergencies and Displaced Populations Policy
FPP	Full Portfolio Planning
HPV	Human papillomavirus
HR	Human resources
HRH	Human resources for health
HSS	Health Systems Strengthening
ITN	Insecticide-treated nets
ITU	Innovation Top Up
IRC	Independent Review Committee
IRMMA	Identify – Reach – Monitor – Measure – Advocate
LLIN	Long-lasting Insecticide Treated Nets
MCV	Measles-containing vaccine
MEL	Monitoring, Evaluation and Learning
MR	Measles-Rubella
NMCP	National Malaria Control 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 Immunization
SAGE	Strategic Advisory Group of Experts on Immunization
SIA	Supplementary immunization 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 immunization coverage

1. Executive Summary

The Gavi Independent Review Committee (IRC) met in Geneva, Switzerland from 13 to 24 March 2023. This session was particular because it was the first-time review of applications on the newest tool in the fight against malaria - the RTS,S/AS01 (hereinafter referred to as RTS,S) vaccine- from non-pilot countries. Out of 18 applicant countries, 12 applied for support for malaria RTS,S vaccine introduction. Other applications were for Measles- Rubella vaccine (MR), Yellow Fever (YF), Cold Chain Optimization Platform (CCEOP), Equity Accelerator Fund (EAF), and Full Portfolio Planning (FPP) incorporating HSS, EAF, as well as Targeted Country Assistance (TCA), a Measles-rubella (MR) follow-up campaign and CCEOP (Côte d'Ivoire). A total of nineteen 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[1] 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 immunization 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 immunization; 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 applications for Malaria RTS,S Vaccine for eleven countries (Benin, Burkina Faso, Burundi, Cameroon, DRC, Liberia, Mozambique, Niger, Sierra Leone, Sudan, Uganda), Measles-Rubella (Burkina Faso, Tanzania), YF (Tchad), EAF (Côte d'Ivoire, Guinea Bissau, Sao Tome & Principe), CCEOP (Afghanistan), There was a partial approval of the FPP application for Côte d 'Ivoire (approval for MR and TCA requests, re-review for HSS, EAF, and CCEOP). The HSS proposal did not reflect the transitioning status of Côte d 'Ivoire and the need to address systems challenges faced by the program. For the EAF, the application did not provide a differential strategy for the categories considered as hard-to-reach. Recommended for re-review was one RTS,S malaria application (Ghana) requiring a further analysis for the high vaccine coverage targets, additional elaboration related to the schedule and ways to address the malaria vaccine dropout rate from 3rd dose to 4th dose, and further analysis on how the issues with the insufficient resources for vaccine introduction will be overcome. There was also one CCEOP application recommended for re-review (Burundi) because of unclear needs assessment and lack of prioritization of equipment deployment.

As regards the malaria vaccine, the IRC was requested to assess whether vaccine coverage targets proposed by countries are based on evidence in terms of actual performance of the programme. With the roll-out of the RTS,S vaccine, Gavi recommended vaccine coverage targets for the four doses based on a set of standard reference points, but countries could adjust to suit their immunization program. However, when providing targets different from the Gavi recommended ones, the countries did not provide reasoning behind their proposed estimates. Further, countries tried to integrate the first three

[1] excluding RTS,S malaria applications

doses into their existing immunization schedules, but reaching the high coverage for the 4th dose remains one of the main concerns as the countries yet need to strengthen a comprehensive 2nd year of life platform (2YL). In addition, the countries will need to follow up on the potential changes of malaria vaccine schedule recommendations (i.e. 3rd to 4th dose interval), and adjust as needed. The IRC requests that Gavi and technical partners support countries to closely monitor the introduction of the malaria vaccine and review progress on vaccine coverage targets for each dose of the RTS, S vaccine schedule, adjust coverage targets and the vaccination schedule as needed, and encourage countries to identify national tailored mitigation strategies to prevent or reduce the 4th dose dropout.

While Malaria applications' supply chain and waste management planning and budgets, classified as moderate or not critical issues for IRC review consideration by Gavi, were not reviewed by dedicated CCL and financial crosscutters, these topics were considered and addressed by IRC reviewers.

The attention on zero-dose children was a priority area of focus: all applications had an objective to reach and identify zero-dose and under-vaccinated children. It is evident in malaria applications, that most countries will take the RTS,S vaccine introduction as an opportunity to identify zero-dose and under-vaccinated children, and strengthen the health systems. It should be re-emphasized that most countries use administrative coverage data to tailor interventions. The IRC noted that these estimates of numbers of zero-dose children are often biased because of discrepancies between administrative and WHO/UNICEF estimates. Thus, the IRC calls for technical partners to strengthen the utilization of triangulation guidance to support countries in their efforts to estimate zero-dose and under-vaccinated children using the best available data. Regarding applications for MR follow-up SIA support, IRC continues to highlight areas of progress, and recommends that Gavi and technical partners encourage countries to provide a strong evidence-based rationale for subnational MCV follow-up campaigns, especially where measles is endemic, while ensuring equity in immunization.

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 the 3rd of March 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. Professor Rose Leke, Chair of the IRC was supported by Vice Chair Dr Benjamin Nkowane and deputy vice chair Dr Bolanle Oyeledun. The meeting was opened by Mr Johannes Ahrendts, Director SFP, who welcomed the IRC members and outlined the expectations for the review. The IRC was updated on Measles applications and Gavi Monitoring, Evaluation and Learning (MEL) requirements. The update on Malaria vaccine applications had been given at the previous meeting, as well as online before this meeting (28th February 2023), so we had a discussion on malaria applications among reviewers, with emphasis on the review criteria calibration. For the applications for measles and rubella vaccines support (Burkina Faso and Tanzania), the programme managers' presentations to the IRC outlining the key issues in the requests for support were followed by questions and answers.

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 specialized 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 segmentation (Core, High Impact. Fragile and Conflict). Ethiopia and DRC had earlier been reviewed using the in-country review mechanism whilst Côte d'Ivoire was reviewed remotely. All three 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. Since this was the first-time non-pilot countries applications were being reviewed, the malaria team in WHO and at Gavi along with two Global Fund Technical Review Panel (TRP) observers were always present and took part in discussions. 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.

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 March 2023 IRC reviews are summarized in Table 1, and the outcomes of in-country reviews are summarized in Table 2 below.

Table 1: Summary of requests from countries and review outcomes

Country		Types of support		
		NVS requests	Other requests	Recommendation outcomes
1	Afghanistan		CCEOP	Approval
2	Benin	Malaria		Approval
3	Burkina Faso	Malaria		Approval
		MR follow-up campaign		Approval
4	Burundi		CCEOP	Re-review
		Malaria		Approval
5	Cameroun	Malaria		Approval
6	Chad	Yellow fever campaign		Approval
7	Côte d'Ivoire	MR follow-up campaign		Approval
			HSS	Re-review
			EAF	Re-review
			TCA	Approval
			CCEOP	Re-review
8	DRC	Malaria		Approval
9	Ghana	Malaria		Re-review
10	Guinea Bissau		EAF	Approval
11	Liberia	Malaria		Approval
12	Mozambique	Malaria		Approval
13	Niger	Malaria		Approval
14	Sao Tome & Principe		EAF	Approval
15	Sierra Leone	Malaria		Approval
16	Sudan	Malaria		Approval
17	Tanzania		MR follow-up campaign	Approval
18	Uganda	Malaria		Approval

Table 2: Summary of requests and review outcomes from in-country reviews

Country	Review modality	Support	US$ Amount (cash support)	Recommendation
Ethiopia	In-country	FPP: HSS, EAF, TCA, IPV2	159 M	Approval
DR Congo	In-country	EAF	59.7 M	Approval
Total:			218.7 M	

Thematic areas sub-committees

During the review, IRC members were organized into eight 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); Full Portfolio Planning; and Governance. 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 24 March 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. Mr Johannes Ahrendts, Director SFP, closed the meeting after providing recommendations. He further thanked the IRC members for participating in the review of the country applications.

3. Key Findings and Recommendations

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

RTS, S Malaria vaccine introduction

Twelve (12) countries submitted applications for the introduction of the RTS, S malaria vaccine: Benin, Burkina Faso, Burundi, Cameroon, DRC, Ghana, Liberia, Mozambique, Niger, Sierra Leone, Sudan, and Uganda. Only four countries Sudan, Niger, Sierra Leone, and Burkina Faso followed Gavi Alliance guidance. Countries showed the efforts to integrate the first three doses into schedules with vaccination encounters and/or other child health interventions (vaccines/ Vitamin A) and to leverage the malaria vaccine to improve MCV2 coverage and other child health interventions within the second year of life platform (2YL). Ghana included the plan for active sentinel surveillance for AEFI/AESI and reported the data from their AEFI surveillance in their submission.

Sudan and Niger presented a thorough analysis of the readiness of the cold chain to receive additional vaccine doses. Others such as Mozambique and Cameroon showed synergies with Malaria program partners such as the Global Fund but also with the World Bank and Partnership for Market Implementation from the President Malaria Initiative (PMI). Cameroon and Niger had well analysed and integrated equity and communication strategies into their applications.

However, a number of priority issues were the focus of IRC discussions which are deserving further analysis: (a) vaccine coverage targets, (b) schedule and the second year of life platform (2YL), and malaria vaccine dropout rates (3rd dose to 4th dose), (c) resources for vaccine introduction, and (d) synergies with other programmes and identification of zero-dose and under-vaccinated children.

(a) RTS, S malaria vaccine coverage targets

With the roll-out of the RTS, S malaria vaccine and limited previous experiences on the performance of this new programme, Gavi has recommended vaccine coverage targets for the RTS, S malaria vaccine dose 1, 2, 3 and 4 based upon a set of standard reference points for coverage targets and wastage rates. The standard references draw on globally recognized publicly available datasets and tools, developed by United Nations and other partners: UN World Population Prospects (UN WPP) data, and WHO and UNICEF Estimates of National Immunisation Coverage (WUENIC), and dose-requirement calculation tool.

For the 4-dose RTS, S malaria vaccine, the projected vaccine coverage targets for each malaria dose, recommended by Gavi and based upon program performance is:

- Dose 1 - using Gavi HLRP approved coverage for DTP3
- Dose 2 - based on DTP1 - DTP3 drop out (Gavi HLRP coverage, see explanation below)
- Dose 3 - using Gavi HLRP approved coverage for MCV1
- Dose 4 - using Gavi HLRP approved coverage for MCV2.

The rationale for this proposed vaccine coverage targets for the 4 doses of the RTS, S malaria vaccine is based on evidence of the past programmes' performance relating to DTP, MCV1 and MCV2 in each country. Gavi advised countries to utilize these vaccine coverage targets or make any adjustments that are best suited to their immunization program, when a strong justification and supporting evidence is provided for any adjustment made to these assumptions.

The IRC was requested to assess whether vaccine coverage targets proposed by countries are aligned with actual performance of the programme to date (see above) or whether the country provided strong justifications for any adjustment made to these assumptions.

IRC notes that 6 out of the 12 countries provided initial application materials with missing information on malaria vaccine coverage targets, or the information was not aligned with program performance, or the proposed coverage targets varied across their application materials. As an example, initially a few countries proposed 100% coverage target for the 1st dose of the malaria vaccine, or 80% coverage across all 4 doses. Subsequently upon receiving inputs, the finalized application materials incorporated revised projections for the malaria vaccine doses aligned with past programme performance.

Secondly, a few countries such as DRC, Sudan and Burkina Faso proposed projected malaria vaccine coverage rates that are higher than the Gavi HLRP standard references. For DRC and Sudan, justification and additional background for the increase of the coverage targets was not available in the application materials; whereas Burkina Faso projected coverage targets that are higher than the Gavi HLRP standard references, and provided justification based upon administrative vaccine coverage data reported in 2021.

Last, in a few cases, IRC observed that the past program performance dictated that the 4th dose of malaria vaccine coverage target is as low as 30% (based upon Gavi HLRP approved coverage for MCV2) and there were no proposed adjustments for the 4th dose coverage target. The IRC debated whether the 4th dose vaccine coverage target is too low or not ambitious enough, for ensuring the successful introduction of the malaria vaccine in the immunization program.

Issue 1: The projected Gavi HLRP standard reference vaccine coverage targets may not be well understood across all countries.

Recommendation:

- Gavi and technical partners to share with countries information regarding the HLRP standard reference vaccine coverage rates, their applicability to the malaria RTS, S vaccine coverage rates, and the rationale, in cases where this methodology is utilized by countries.

Issue 2: Countries presented adjusted malaria vaccine coverage targets (different from the Gavi standard references and past programme performance) without solid justification or evidence for the adjustments.

Recommendation:

- Gavi and partners to support countries to review the deviance for vaccine coverage targets from past performance and help ensure the adjustments are based upon evidence.

Issue 3: The malaria 4th dose coverage target may be low in some cases per Gavi HLRP 4th dose approved coverage.

Recommendations:

- Gavi and partners to review 4th dose coverage targets per Gavi HLRP approved coverage for MCV2, and if lower that a certain threshold, potentially recommend a more ambitious way forward for the successful introduction of the RTS, S vaccine.
- Gavi and technical partners to support countries to closely monitor the introduction of the malaria vaccine and review progress on vaccine coverage targets for each dose of the RTS,S vaccine schedule, and adjust coverage targets as needed going forward.
- Gavi and partners to support countries in preventing or mitigating the dropout rates between each malaria vaccine dose.

(b) Schedule and malaria vaccine dropout rate from 3rd dose to 4th dose

Regarding the vaccination schedule, WHO guidance (Malaria vaccine position paper March 2022) recommends that the first dose of vaccine be administered from 5 months of age. There should be a minimum interval of 4 weeks between the first three doses. The vaccine should be administered in a 3-dose primary schedule, with a fourth dose provided approximately 12–18 months after the third dose to prolong the duration of protection. However, there can be flexibility in the schedule to optimize delivery, for example, to align the fourth dose with other vaccines given in the second year of life.

Data from the pilot countries that introduced Malaria vaccine showed that a key challenge they experienced in implementing the recommended schedule is the high dropout with the 4th dose. IRC appreciated that most of the applications reviewed have considered the lessons learned from pilot countries on the potential dropout risk between the 3rd and 4th dose and noticed that most of them included mitigation strategies to some extent. However, many applications and relevant Malaria introduction national plans did not refer to a comprehensive to strengthen supply and demand approaches aiming to align the RTS,S 4 to 2nd year of life (2YL) interventions. Most of the applications, moreover, did not consider elements of gender or equity barriers to access in designing their mitigation strategies.

Sierra Leone and Sudan applications provided good examples of comprehensive mitigation strategies. In particular, IRC has appreciated how Sudan application has highlighted that malaria vaccine will serve as an additional contact point to catch up with missed measles second dose vaccinations. Sudan also plans to integrate other child health services related to the 2nd year of life, such as growth monitoring, vitamin A and deworming, and to strengthen messages for promoting other Malaria prevention interventions like the use of insecticide-treated nets (ITNs) and prompt seeking behaviour for diagnosis and treatment of fever. On the demand side, inter-personal communication and demand generation activities have been included to ensure utilization and acceptance for the needed additional visits. Defaulter tracing system will be strengthened in collaboration and coordination with the National Malaria Control Programme (NMCP) to reduce missed opportunities for vaccination by checking the child vaccination status whenever they seek health care. Similarly, Sierra Leone application highlighted that Malaria vaccine will be provided in routine immunization services alongside other maternal and child health interventions: e.g. the first dose will be given at 6 months with Vitamin A, growth monitoring of the child, TD for lactating mothers, family planning counselling and exclusive breast-feeding sensitization, and at 18 months with the fourth dose of the malaria vaccine, deworming and vitamin A will be provided along with proposed ITNs distribution.

Issue 4: While the countries are aware of the potential dropout risk between the 3rd and the 4th dose, mitigation strategies are not detailed, do not refer to strengthening 2YL platform, and do not consider gender and equity barriers.

Recommendations:

- Gavi and technical partners to encourage countries to identify national tailored mitigation strategies to prevent the 4th dose dropout, looking at both supply and demand potential approaches and consider gender and equity barriers.
- Gavi and technical partners to continue supporting the countries to identify and implement comprehensive packages for the 2nd year of life platform drawing from local and other relevant lessons learnt (e.g. comprehensive package of primary health care interventions in 2YL).
- Gavi and partners to support countries in documenting the modalities of implementing the recommended schedule to build evidence and models of successful vaccine uptake.

(c) Resources for Malaria vaccine introduction

The Vaccine Introduction Grant (VIG) is meant to cover a share of the RTS, S vaccine introduction activities, however countries have “struggled” to leverage identified existing financial resources from The Global Fund (GF), the World Bank, the American Government (USG) and others. When additional resources have been identified, other than Government allocations (identified in Benin, Burkina Faso, Cameroon, Ghana, Mozambique, and Sierra Leone), applications were less specific in identifying the funding source. here resources would be identified for the vaccine introduction. Some countries assume that funding applications yet to be submitted will be successful and aligned with the Global Fund in time to support the malaria vaccine introduction (Mozambique, Sudan, and Tanzania). On the other hand, Ghana identified the Government as the sole funder for the vaccine introduction gap, while Uganda identified a significant gap without resource allocation from Government or partners. Only DRC, Ghana and Sudan mentioned existing or future Gavi grants to cover some of the introduction costs (see Table 3 for more detail). A financial analysis can be found on the Finance section of this report.

Table 2: Financial resources to support the RTS, S vaccine introduction.

Country	VIG % of intro-duction costs	Leverage Gavi grant	Contribution from			
			Government	Technical partners	Global Fund	World Bank/USG
Benin	20%		US$26,700	US$438,318 from partners WHO, UNICEF, USAID; allocations unspecified.		
Burkina Faso	21%		US$36,783	US$741,651		
Burundi	97%			Undefined partner allocations.		
Cameroun	74%		US$35,995	Partners not specified but allocated tasks and costs.		
DRC	41%	Intend to leverage HSS funds. Unspecified.		Partners mentioned but not specified.		
Ghana	16%	HSS for incinerators	The rest of introduction costs		Through NFM4*	
Liberia	39%		VIG not catalytic as CDC and PMI are shown as VIG grant recipients	Not specified how the US$155,000 will be resourced from partners		
Mozambique	27%		Specified US$28,872	UNICEF US$95,513 WHO US$42,183	Expected new NFM contribution of US$352,385	USG expected to contribute
Niger	42%		Unspecified funding source. Budget shows funding gaps for TA.	Unspecified partner(s)		
Sierra Leone	70%		US$12,341 for supply chain consumables	Partners are unspecified	Reprogramme NFM3 funds, NFM4 expected to contribute	

Sudan	31%	Training in HSS3 2024. Service delivery from existing HSS/EAF.		UNICEF and WHO committed to support PIE	Probable funds for surveillance through NFM	
Uganda	5%	Showing funding gap with no allocation to Government or any donor or technical partner.				

*Applications to be reviewed in April, July or September 2023

Issue 5: Identification of synergies and available funding sources other than VIG to fund the identified gap for malaria vaccine introduction and their clear representation in the budget is lacking.

Recommendations:

- Governments to Identify synergies and complementarities to fund the identified vaccine introduction funding gap by leveraging additional resources from the Global Fund, the World Bank and PMI.
- Countries to include in the budget all funding identified sources to support the introduction of the malaria vaccine, and indicate how the gap (if any) will be funded.
- Countries to focus on resourcing for activities related to introduction of the Malaria Vaccine into the routine immunization program. This should be delineated from routine immunization strengthening activities that require wider stakeholder involvement and contribution.
- With immediate effect, Gavi to assist countries applying for the June 2023 window to identify HSS and other grant resources potentially available to support vaccine introduction.

(d) Synergies between the RTS,S malaria vaccine introduction and other programmes and identification of zero-dose children and the under-vaccinated

Most countries will take the RTS,S vaccine introduction as an opportunity to identify zero-dose children and the under-vaccinated and strengthen their health systems, however Benin and to a lesser extent Ghana had scant narrative on how these children will be identified. Countries such as Cameroon, Sierra Leone and Sudan have presented comprehensive strategies for reaching zero-dose children despite some mentioned challenges such as geographical remoteness or scarcity of financial resources. Benin, Burundi and Mozambique discussed the zero-dose children population in Category 1 areas noting that a percentage of these Category 1 areas contain significant zero-dose children and under-vaccinated. See Table 4 for details.

Table 3: Strategies to reach zero-dose children and synergies with the RTS,S vaccination

Country	Synergies between RTS,S vaccine introduction areas and zero-dose children and the under-vaccinated	Strategies to reach zero-dose children
Benin	Yes, 4 out of 8 Category 1 departments are identified as having the highest population of zero-dose children	Not specifically mentioned.
Burkina Faso	Not specified but during Immunization intensification days to administer the 4th dose, the series of the first three doses will be administered as well as for zero dose and under vaccinate to help to minimize vaccine losses.	For the catch-up of zero-dose or under-vaccinated children, intensification days are planned before the period of high malaria transmission (March to May). Also, the integration of vaccination with other health interventions will be an opportunity to vaccinate children.
Burundi	Yes. Out of the 25 districts in Category 1, 11 have a high number of zero-dose children	The use of CHWs and other community relays to trace zero-dose children and take them to the vaccination sites. Intense awareness campaigns will be organized in favour of the new vaccine and zero-dose children and under vaccinated who will come for the antimalarial vaccination will also be caught up for the missed vaccines.
Cameroon	Not specifically described but zero-dose children will be reached through community relays used during seasonal malaria chemoprevention in northern regions, mass distribution of mosquito nets and other community-based activities. Chronically missed communities will be identified during micro-planning at health facility level.	2021-2025 plan to reach zero-dose children. The plan has taken existing evidence-based approaches into consideration and best practices to sustainably improve access to vaccination and other primary health care communities and it is aligned with the vision of "leaving no one behind" and is based on the IRMMA conceptual framework.
DRC	Not specified however the EPI will take the opportunity to improve its performance through the malaria vaccine introduction to target zero dose and the under-vaccinated, improving vaccination coverage of other vaccines in the first and the second year of life. Geographical access is noted as a challenge.	DRC notes that guidance is required for health providers on monitoring vaccination status, service delivery, and recording doses administered, as part of routine immunization and periodic intensification activities, to be included, in national policies, practical manuals, training and supervision as every opportunity is important target children to administer the malaria vaccine particularly to zero-dose children.
Ghana	Not specified. The application mentions the location of zero-dose children but is not linked to the 43 districts.	Digital micro-planning in 8 districts but 43 are the focus of the application.
Liberia	Not specified though it is expected that the introduction of the malaria vaccine will improve routine immunization services (increased attendance, reduced zero- dose	The EPI works through the Public-Private Partnership (PPP) in the effective management and delivery of vaccination services, to increase vaccination uptake and ensure that zero-dose

	children, increased uptake of other vaccines).	children and underserved populations are fully vaccinated, irrespective of their status in society.
Mozambique	Yes, Zambezia has the second largest zero-dose children population.	Through PIRI funded by CDS3 in operation in various regions including Zambezia.
Niger	Not specifically though the introduction of vaccination against malaria is an opportunity to further reduce the number of zero-dose children and to strengthen the vaccination programme.	Several strategies (Periodic Intensification of Immunization PIRI activities, catch-up activity for inter-district children, opportunity for mass campaigns, integration of services, etc.) are implemented to map zero-dose children.
Sierra Leone	The malaria vaccine introduction will be an opportunity to increase access and reach zero-dose children in hard-to-reach communities.	Zero-dose children will be identified at health facility level based on target of their catchment population and on health facility administrative and survey data.
Sudan	Using zero-dose children as an entry point to deliver a wider PHC and MNCH package of service in the identified priority localities.	Comprehensive strategy to reach zero-dose children through the EAF grant Interventions proposed under EAF s application, will leverage the malaria vaccine accessibility and utilization.
Uganda	Not specified for the Category 1 area as zero-dose children will be reached according to immunisation policies.	Existing policies of integration of immunisation services with a focus on zero-dose children and partnerships with the for-profit sector.

Issue 6: While most of countries describe strategies to reach zero-dose and under-vaccinated children in their priority areas, they do not specifically identify synergies between RTS,S malaria vaccine and other programmes for that purpose.

Recommendations:

- Gavi to request applicants to identify the zero-dose children and under-vaccinated population in their priority categorisation.
- Countries to elaborate on their strategies to reaching zero-dose children and the synergies between the RTS, S malaria vaccine introduction and other programmes in their priority categorization.

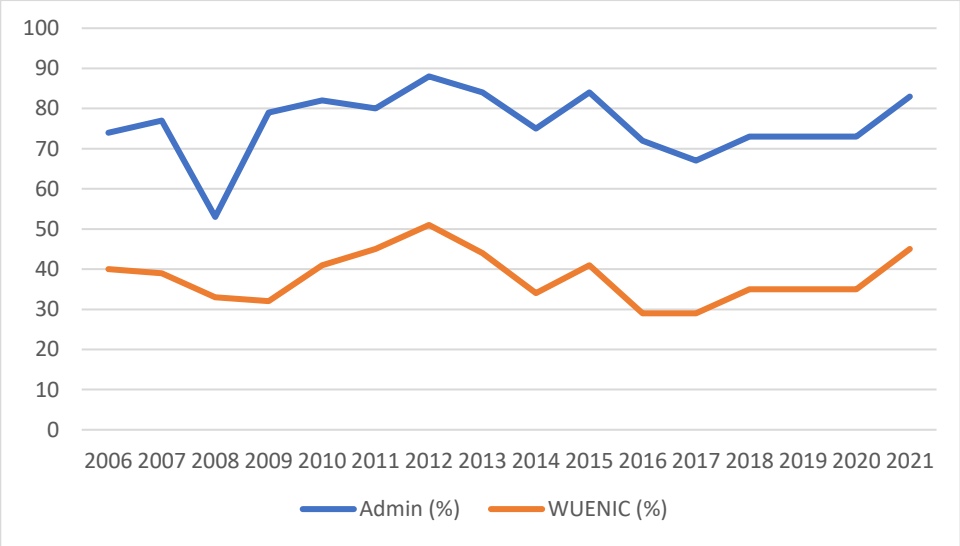
Measles-Rubella follow-up and Yellow Fever mass preventive campaigns

During this session, the IRC reviewed applications from three countries for campaign operational support: two for measles-rubella (MR) follow-up campaigns targeting children aged 9 to 59 months (Burkina Faso and Tanzania), and one for yellow fever (YF) mass prevention campaign (Chad), targeting wide age range from 9 months to 60 years. Both MR requests were for a subnational campaign using operational cost flexibility, with well-aligned plans and budgets. While lacking a solid rationale for such geographic scope, the countries presented thoughtful differentiation of strategies and a strong focus on reaching consistently missed children. The IRC was particularly pleased to see Tanzania's analysis of gender-related issues in immunization and its consideration in design of strategies. Funds requested for MR follow-up campaign operational costs were US$6.36 million, which with YF campaign operational costs of US$10,93 million amounted to a total of US$17.29 million. All three applications were approved.

(a) Yellow fever mass preventive campaign

Aligned with the WHO and AFR TAG recommendations to control yellow fever, the yellow fever vaccine, administered at nine months of age with the measles vaccine, has been introduced in the Chad routine immunization schedule since 1985. However, as shown in Figure 1, WUENIC estimates, significantly lower than the administrative ones, have been at the values insufficient to confer population immunity (at minimum 80%), with recognized subnational disparities.

Figure 1: Yellow fever vaccination coverage estimates (administrative and WUENIC) in Chad by year 2006-2021 (Source: WHO Immunization Data portal)



The administrative and WUENIC estimates for YF vaccine remain about 10 percentage points lower than for MCV1 in the country, without clear reasons for this difference and the overall low coverage. Generally cited reasons include supply insecurity, limited age eligibility, programmatic restrictions (i.e. unwillingness to open a multi-dose vial for only one child), and priority given to outbreak response. As responses to outbreaks, Chad has conducted outbreak response immunization campaigns, including in 2022 when 17 affected districts were covered. However, Chad has undertaken a risk analysis which considered data from the 2017-2019 period, population immunity, and risk factors for yellow fever epidemics in the country. This resulted with classifications of districts by risk level: 11 districts were classified as very high risk, 30 as high risk, 66 as medium risk, and no low-risk districts were identified. Based on these results, the low routine coverage, and frequent stock-outs of YF vaccine, Chad proposes to conduct a broad age-range nationwide preventive campaign, targeting 9 months to 60 years population in all risk areas, which represents 95% of the total Chadian population.

While the best way to maintain high levels of population immunity is to ensure high vaccination coverage in the routine programme, the most efficient way to rapidly increase population immunity on a short-term basis is achieving high coverage in a wide age-range preventive mass vaccination campaign. The global strategy to eliminate yellow fever epidemics (WHO EYE) indeed recommends preventive mass vaccination campaigns to rapidly reduce the risk of outbreaks, though in areas at high risk of YF virus transmission and inadequate population-level herd immunity. Noting that a single dose

of YF vaccine is sufficient to confer sustained life-long protective immunity against YF disease, that the vaccine has been in the routine system for nearly four decades, and that there is also a herd immunity from wild YF infection, it is likely that half of the targeted country population may already be immune to yellow fever. This context may lead to lower efficiency and performance of the proposed resource-intensive approach.

Issue 7: Need for further refinement of guidance on strategic options for yellow fever immunization in countries where the vaccine has been included in the routine programme long term.

Recommendations:

- Technical partners to refine the guidance and recommendations on strategic YF immunization options for countries considering nationwide mass preventive vaccination campaigns, where there are different yellow fever risk level areas and where the vaccine is included in the routine immunization programme long term.
- Gavi and technical partners to encourage and support countries with low or stagnating YF vaccination coverage to monitor, analyse, and address the reasons for insufficient coverage, when YF vaccine is administered with measles-containing vaccine.
- Gavi and technical partners to support countries in case based YF surveillance with laboratory confirmation and data quality improvement, and to assist the countries in the analysis and interpretation of programme data to guide the design of interventions.

(b) Geographically targeted MR follow-up campaigns

The IRC has repeatedly called on the use of flexibility for the Gavi operational funding of MCV campaigns as it allows countries to innovate and progress toward reaching consistently missed children. This is particularly applicable to high-performing countries, with stable high vaccination coverage both in the routine programmes and previous campaigns, with low measles susceptibility in children younger than 5 years of age, and in which the nationwide non-selective campaigns would not likely result in programmatic improvements. Similarly, WHO SAGE (Strategic Advisory Group of Experts on immunization) recommends that countries with medium disease incidence and periodic outbreaks, inadequate immunity in some populations and moderate programme capacity (i.e., MCV1 coverage of 85-90% and MCV2 coverage of 80-90%) can conduct targeted subnational campaigns according to the epidemiological profile of the subnational areas concerned, if high-quality data and accurate subnational analysis are available.

Tanzania and Burkina Faso applied in this round for subnational MR SIA operational support using operational cost flexibility. Figures 2 and 3 show suboptimal WUENIC estimates for MCV1 and MCV2 in the 2017-2021 period, with neither of the countries reaching MCV2 coverage to meet SAGE criteria for subnational campaigns.

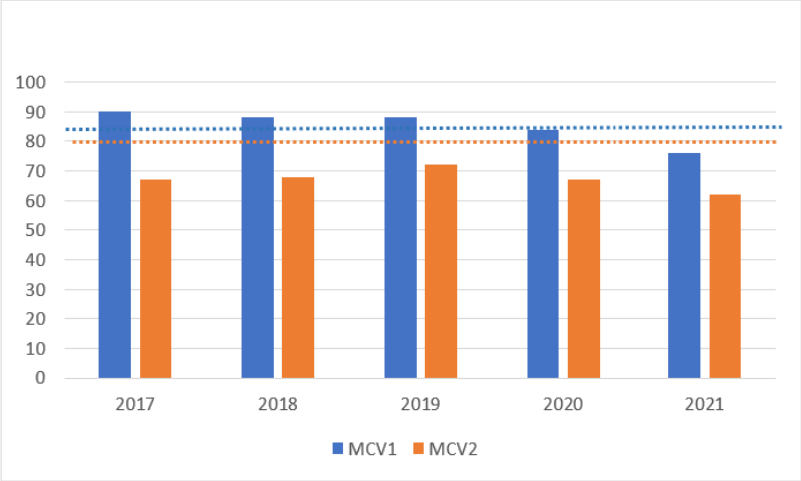


Figure 2: MCV1 and MCV2 coverage estimates (WUENIC) in **Tanzania**, 2017-2021 in relation to SAGE subnational campaign minimum criteria for MCV1 and MCV2
(Source: WHO Immunization Data portal)

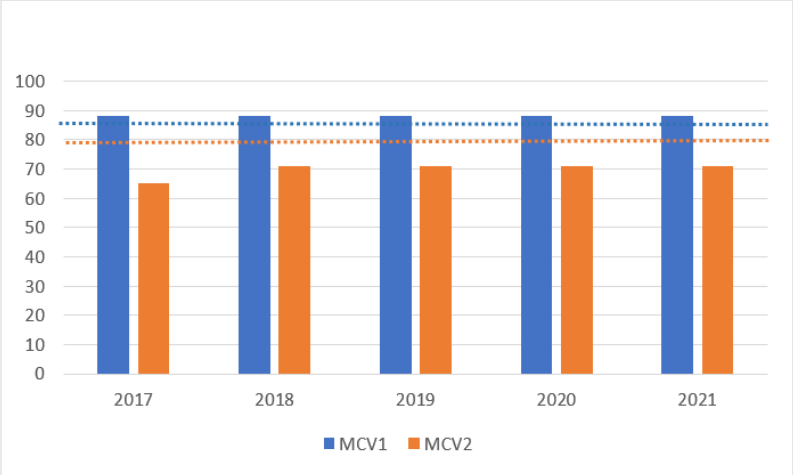


Figure 3: MCV1 and MCV2 coverage estimates (WUENIC) in Burkina Faso, 2017-2021 in relation to SAGE subnational campaign minimum criteria for MCV1 and MCV2
(Source: WHO Immunization Data portal)

Both countries note higher administrative than WUENIC coverage, Burkina Faso about 10 and Tanzania about 15 percentage points, signalling persisting uncertainties about data quality. In addition, both countries conducted a nationwide SIA in 2019, but neither achieved the expected high coverage by post-campaign coverage survey (Table 1). In their applications for subnational campaigns, both countries provided justifications for prioritization of targeted areas which overall lacked robust evidence-based rationale. This is because the countries used unreliable administrative data, did not leverage available data from outbreak investigations, and/or measles zero dose analyses were either lacking or when performed, used unclear methodology.

The IRC notes with pleasure a good presentation of carefully thought-through and well-developed differentiated strategies, but these were presented only for targeted districts. Finally, the decisions relied on the measles risk assessment tool rather than on structured analysis and triangulation of the available and most appropriate data.

Table 5: Coverage by survey in previous MR SIA and proportion of targeted districts planned SIA in applicant countries

Country	Previous national MR SIA coverage (By post-campaign survey)	Targeted area in the planned SIA
Tanzania	2019: 88.2%	63% of all districts
Burkina Faso	2019: 84.4%	65% of all districts

In addition, the rationale for excluding districts from the MR SIA lacked clarity. In Burkina Faso, although almost 73% of the targeted 9–59-month cohort live in the districts prioritized for the campaign, the increasing political insecurity, potential population displacements, and suboptimal immunisation programme performance, could result in an accumulation of many susceptible children in the 24 excluded districts. For Tanzania, while a significant drop in coverage is noted during the COVID-19 pandemic, the application does not provide granular information on programme performance, population characteristics, or measles cases in the excluded districts, to provide better understanding for their exclusion. Finally, differentiated tailored strategies presented in the applications will be used in targeted districts in both countries, while reaching un- or under-vaccinated children in excluded districts will rely on usual routine immunization activities: PIRIs in Tanzania and regular defaulter tracking in Burkina Faso, both poorly performing as shown by the high MR1/MR2 drop-out rates (18% in Tanzania and 19% in Burkina Faso in 2021).

While it is difficult to conclude if planned subnational approaches would be feasible, they certainly raise equity issues and diverge from the IA 2030 strategic priority 3 of enhancing coverage and equity to achieve universal health coverage. The IRC acknowledges the development of focused strategies for reaching specific populations of children who have continuously been missed by the routine immunization services and by previous campaigns. This effort should continue and be data-driven and equitably applied.

Issue 8: Need for a strong rationale for geographically targeted MCV follow-up campaigns.

Recommendations:

- Gavi and technical partners to encourage countries to provide a strong evidence-based rationale for subnational MCV follow-up campaigns, especially where measles is endemic, while ensuring equity in immunization.
- Gavi and technical partners to continue supporting countries to develop strategies based on epidemiological evidence, including outbreak and surveillance data and surveys, and to decrease reliance on tools.
- Gavi and technical partners to continue to support countries in boosting their capacity for data quality review, analysis and improvement.

(c) Rapid Convenience Monitoring (RCM) in campaigns

The IRC has reiterated the importance of using RCM during and immediately after campaigns in finding missed children to vaccinate them and identify reasons for non-vaccination. The IRC acknowledges that all countries applying for campaigns now consistently include RCM in their plan of actions and budgets. However, the IRC notes that RCM is often referred to as a rapid survey to assess coverage

during campaign and that countries use 95% coverage as a trigger for mop-ups (Chad, Tanzania), or base mop-ups on LQAS coverage (Burkina Faso) without adequate explanation.

The IRC reiterates that RCM cannot produce valid vaccination coverage estimates as it is not a probability-based survey. Rather, it is a simple pass/fail assessment which provides supervisors with information on the general performance during or shortly after the campaign. It can be used to refine strategies to reach hardest-to-reach in rapid corrective action and improve the routine programme. These are the obvious benefits of RCM, and its use should be restricted to that of a supervisory tool to improve operational performance during and immediately after the campaign.

Issue 9: RCM remains often referred to as a rapid survey to assess coverage during campaign instead of supervisory tool.

Recommendation:

- Gavi and technical partners to reinforce to countries that RCM is used as a supervisory tool during and immediately after the SIA to improve operational performance, and that it is not referred to as a survey or used as an estimate of vaccination coverage.

Gender, Equity and Zero-dose Children

Equity analyses in applications

Increasing equity in immunization delivery is a priority of Gavi's support with a high ambition to reduce the number of under-immunized children and an intensified focus on reaching the unreached, especially zero-dose children. These tend to be clustered in communities without any basic health services.

The equity analysis observed in this round of proposals continues to present challenges in correctly selecting the target population. Despite considering the common dimensions of inequality such as geographical accessibility, economic status, parental education level (especially maternal), place of residence, sex, mother's age, the equity tool continues to miss out to monitor on activities for vulnerable, marginalized and underrepresented populations such as displaced population, illegal migrants, sex workers or ethnic minorities that have access issues to health services.

Nevertheless, the IRC acknowledges some best practices in this context, which are exemplary for future applications. Tanzania presented well developed differentiated strategies based on very well thought through equity and gender analyses with clearly costed interventions reflected in the operational plan and budget. Cameroon included an Equity Framework for malaria control measures and immunization to reduce the disease burden, maximize the reach of those not yet reached by prioritizing and including health districts with a high drop-out rate that are the most vulnerable in terms of health and socio-economic status (located in Adamaoua and East Regions). The applications of Cameroon, Burkina Faso, Chad and Burundi further included reaching those economically disadvantaged groups (refugees, conflict-related internally displaced persons, nomads, and hard-to-reach and indigenous communities). In addition, Chad commendably presented differentiated strategies for the YF campaign with well-defined and quantified vulnerable groups.

Issue 10: Equity and zero-dose children analysis in all applications are rare, except in EAF, and lack vulnerability elements affecting access to immunization to marginalized communities such as internally displaced people, stateless persons, illegal migrants, people affected by conflict, children of sex workers or ethnic minorities.

Recommendation

- Gavi and partners to support countries in including equity and vulnerability analyses dimensions in EAF, HSS and vaccine introduction applications, with special attention to marginalized groups and forcibly displaced populations.

Gender equity analyses in applications

Concerning gender, as in previous rounds the IRC notes that most of the proposals use data from a former equity analysis to show that male and female children have equal access to immunization services. We make the recurrent observation that whilst women responsible for bringing children to health services, the decision-making remains with men. In some countries, sexual harassment of female health workers by supervisors has been observed to be a cause of absenteeism and quitting, leading to a demotivated and reduced workforce. Little efforts are engaged by countries to address this cultural gender imbalance, with some notable exceptions, i.e. São Tomé and Principe EAF addressing demand barriers by "Targeting mothers and fathers in communication campaigns using the image of a father with a baby".

Issue 11: Countries are supposed to use evidence, evaluations, and improved data for their programs, but do not apply this rule to measure and address gender barriers.

Recommendations:

- Gavi to consider including a mandatory section on gender indicating country-specific challenges and strategies how to overcome them, in HSS, EAF and vaccine introduction applications.

Cold Chain, Logistics and Waste Management

Cold chain readiness for Malaria vaccine introduction

With a volume per dose of 9,9 cm^3 and a cost of € 9.30 per dose, the Malaria RTS,S vaccine is the bulkiest, costliest, and scarcest vaccine in the immunisation schedule so far. Some countries estimated that RTS,S vaccine may represent about 46% of vaccine volume currently used and would increase the total vaccine volume by 32% at service delivery level. It would be inaccurate to think that countries, thanks to the support provided to strengthen their cold chain through CCEOP, COVAX, CDS and other funding, have sufficient storage capacity for the RTS,S vaccine. Malaria application review showed that all countries identified gaps at certain levels of the supply chain, most gaps are to be addressed with CCE procurement already funded, some yet to be funded and some countries plan to reduce vaccine delivery intervals. Cold storage gap analysis is facilitated by existence of CCE inventory in all countries as a requirement for previous CCE support applications. Two countries (Niger and Sudan) conducted comprehensive and well documented gap analysis in areas target for the Malaria vaccine introduction, and described how gap will be addressed. Lack of cold storage gap analysis and mitigation action might cause Malaria vaccine stock out or wastage likely leading to high vaccine drop-out and poor coverage, loss of vaccine efficacy and efficiency, and mistrust in this new vaccine.

Issue 12: Most countries are not using existing data and tools such as cold chain inventory and gap analysis tool to analyse their cold storage capacity in area identified for Malaria vaccine introduction, and inadequately describe how storage capacity will be enhanced.

Recommendations:

- Countries to conduct cold storage gap analysis using updated CCE data, considering sites targeted for the vaccine introduction.
- Gavi and its Alliance partners to move from Excel tools towards digital or technology solutions.
- Countries to describe how storage capacity will be enhanced in places with identified gaps to ensure safe storage of the Malaria vaccine at the time of the introduction, with timeline and indication of funding source.
- Partners to continue supporting countries in evidence-based planning using appropriate and updated data and tools.

CCEOP

Three CCEOP applications were reviewed, including Côte d'Ivoire that was reviewed as part of the remote FPP application. One was recommended for approval (Afghanistan) and two for re-review (Côte d'Ivoire, Burundi). The reasons for recommendation for re-review were, (a) Incorrect documentation of cold chain inventories, cold chain capacity and gap, (b) Lessons from previous CCEOP implementation were not properly documented. and (c) one application came without narrative presenting the Theory of Change (TOC) and technical requirements (Burundi).

Issue 13: Inaccurate needs requirement (type and number of CCE) may lead to underestimation or duplication of CCE and poor efficiency.

Recommendations:

- Countries to always submit their updated inventories and gap analyses using the WHO gap analysis, sizing tool or equivalent for all CCEOP applications.
- Countries to demonstrate how CCEOP support will contribute to improving supply chain efficiency and achieving program objectives through a TOC.
- Gavi secretariat to provide clear guidance/tool for CCEOP application development (single document).

Waste Management

New vaccine introduction and supplementary immunization activities increases the volume of immunization waste. In Sudan, the malaria vaccine waste will represent 40% of other EPI waste; and will increase immunization waste volume by 30%. The Measles follow-up campaign in Burkina Faso and Tanzania will generate in 7 days 6,9 million and 2.8 million of syringes and needles respectively.

Waste disposal relies mostly on burning in pits, sometime with incinerators. When incineration is used, there is no clear information on incinerators, their volume capacity, status (functioning or out of use), maintenance plan, and sources of funding for repair or procurement. Health and Environmental hazard are not properly addressed with clear policies and approved SOPs. An example of good practice is

Burkina Faso which, as in previous vaccination campaign plans to outsource transportation and elimination in smelters of waste generated by the measles follow-up campaign; included the cost in the operational budget with government funding.

However, there remain long-term risks to health and the environment, along with reputational, legal and financial risks to Gavi if waste management policies and SOPs are not properly documented and endorsed by local governments.

Issue 14: Increase in immunization waste volume has not been considered, nor budgeted for, in malaria applications, although significant, and solutions to enhance waste management are poorly described and not properly funded. Health and environmental and legal risks involved in current policies and procedures are not addressed.

Recommendations:

- Gavi and partners to support countries in implementing sustainable, cost-effective and eco-friendly waste management systems by:
  - Supporting the development of national policies and SOPs;
  - Enhancing collaboration of multiple governmental and non-governmental institutions;
  - Developing innovative funding mechanisms;
  - Providing guidance for affordable efficient technical solutions.
- Gavi to engage an external immunization waste management and risk evaluation to assess all the risk and issues (environmental, legal, financial and reputational) and comprehensive mitigation strategies.

Budget, Financial Management and Sustainability

Budget overview and quality of budget information

Three budgets presented by 3 countries were reviewed by financial crosscutters with a total proposed amount of US$20,277,265. Of this amount, proposed contributions comprised US$ 17,293,884 (or 85.3%) from Gavi, US$ 2,478,225 (or 12.2%) from governments and US$ 505,156 (or 2.5%) as partners' contributions. Chad proposed 100% Gavi funding, while Burkina Faso and Tanzania included contributions from governments and partners.

Figure 4: Overall budget by funding source

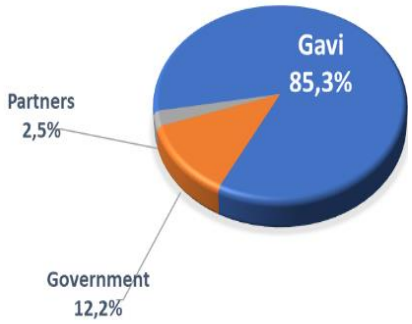
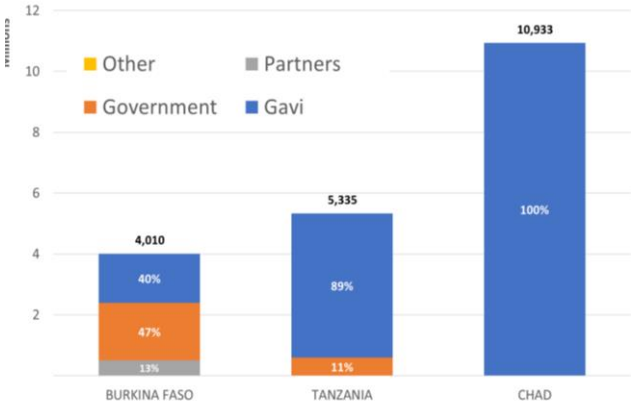


Figure 5: Budgets by country and funding source



Budget by vaccines included US$10,932,602, for Yellow Fever (YF) and US$6,361,281 for Measles-Rubella. All requested budgets are for Campaign Operational Support (Ops). Other budgets were presented during this IRC round but not reviewed by financial crosscutters: 2 Equity Accelerator Funding (EAF) budgets for a total of US$1,381,274 (100% Gavi contribution) and 12 malaria budgets totalling US$8,696,731 with US$2,017,275 Gavi contribution (23%).

IRC noted an improved focus and effort by countries and Gavi Country teams and Secretariat in pre-screening applications for validity and consistency and to ensure compliance with mandatory requirements. All budgets reviewed this round properly used budget templates and provided adequate calculation details. We noted that all 3 countries presented their plans of action (PoA) with adequate information on main budget assumptions (HR quantities based on specific delivery strategies linked with target populations). This resulted in fewer identified issues than in previous IRC rounds. The main issues are described in the following sections.

(a) Teams' estimations and calculation

The level of HR related costs (per diems/allowances for travel-related activities) in the reviewed budgets is high according to previous approved budgets (e.g. 84% for Tanzania, 78% for Burkina Faso and 51% for Chad). Guidelines no longer include a recommended threshold for these items but requires that the level of these costs be technically justified. Some inadequate assumptions and calculations were identified and may have led to the observed high rates of HR related costs.

Table 6. The level of HR related costs in Gavi contribution, the average workload per vaccinator per day and the average number of team members across the three reviewed budgets

Budget / country	HR related costs share of the budget	Average workload per vaccinator per day	Average number of team members
Tanzania (MR)	84%	110	3
Burkina Faso (MR)	78%	69	4
Chad (YF)	51%	95	5,6

The high level of HR related costs in Tanzania budget is mainly driven by activities of which training was dominant. Burkina Faso presented high number of staff as it planned to mobilize 20,644 persons for the campaign compared to 2019 MR campaign that mobilized 8,030 persons with a higher target population (3.2M in 2019 against 2.4 M in this application) which represents an increase of 156%. Country allocated the special strategy with the lowest workload (50 per day/team) to 74% of teams and 54% of the target population with no clear explanation for that ratio. Also, the method used to obtain this differentiation is to classify districts by "difficulty" and then apply only one strategy for each district. This further contributed to an increase in the number of teams. Moreover, Burkina Faso used the same number of team members (2 health workers and 2 community workers) to all delivery strategies without differentiation. All these inadequate assumptions explain the lowest average workload. Tanzania also used the same number of team members for all strategies (3 teams' members across all strategies), but the number is lower.

Like Burkina Faso, Chad did not provide enough rationale to the distribution of target population per delivery strategy (50% for fixed, 45% for outreach and 5% for mobile). Chad has the highest average number of team members (5.6 person per team) but presented the lower HR related costs. It can be partly explained because they used 50% of teams on fixed strategy which has the lowest unit cost regarding other strategies. Chad budget presented inconsistencies with the PoA which indicates a ratio of 125 vaccination per team (and per vaccinator) per day while the budget calculations used an average of 95 (31% difference). In other pages of the same PoA, a ratio of 150 vaccination per day per vaccinator for outreach strategy was presented against 100 in calculations.

Chad also presented high supervision costs (estimated to US$1.58M at all levels representing 14% of the budget) with several identified like inconsistency in supervisors' assumptions between the PoA (1 supervisor for 5 teams) and calculations (an average of 1 supervisor for 3 teams). This leads to an extra 2,000 supervisors than PoA assumptions. In addition, the country inadequately budgeted for team supervisors in mop-up activities by using a ratio of 1 supervisor for each team while the standard used was 1 supervisor for 3 teams for other activities.

Issue 15: Despite improvements, countries still present budgets with insufficient or inadequate staffing assumptions and inconsistencies between calculations and PoA which leads to high level of HR related costs.

Recommendations:

- Gavi Secretariat to:
  - Continue to focus efforts on pre-screening of applications to ensure improved information, assumptions, unit costs, quantities as well as overall budgets before submission for IRC review.
  - Continuously improve budgeting guidelines (this could include ongoing feedback from each IRC round).
- Gavi Secretariat and partners to:
  - Ensure WHO recommended standards are applied for estimating HR related cost inputs.
  - Provide technical support to selected countries in planning and budgeting including involving fiduciary agents to support budget pre-screening.

(b) High Transport costs

The transport costs (vehicle rent + fuel) must be under 10% of the budget for OPC according to Gavi guidelines. Burkina Faso and Chad presented a rate under the threshold, but after the correction of misclassifications, the rates exceed the limits. Burkina Faso presented a rate of 9% while it amounts to 13% after correction of misclassifications. Chad presented a 10% rate while it is 15% after correction. Chad presented rental costs embedded in budget items including different cost inputs, like for transportation of technical assistants (act 27, US$227k), motorbike rental (act 28, US$648k and act 50, US$190k). Burkina Faso and Chad presented the vehicles to be leased based on overall needs, which is not justified when the available vehicles are considered: for example, Burkina Faso has a purchase plan of refrigerated trucks and vehicles under ongoing FPP but presented a budget for leasing these vehicles.

Issue 16: Due to several errors and misclassifications, the 10% of the budget threshold for vehicles rent and fuel is not met by countries, yet they presented a compliant rate.

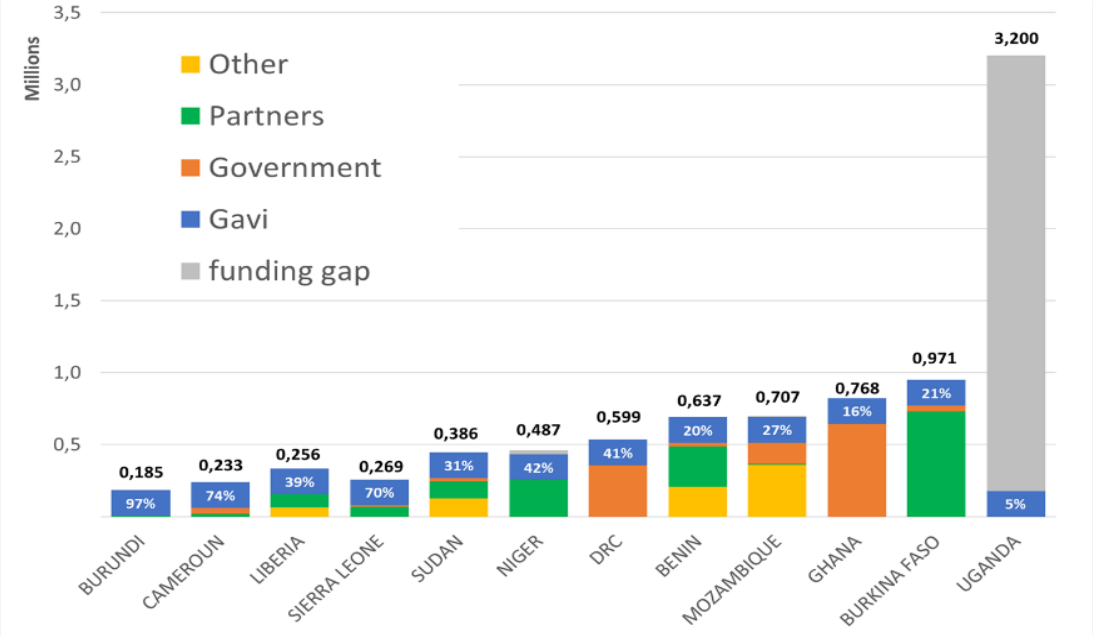
Recommendations:

- Gavi Secretariat to:
  - Continue to focus the effort on pre-screening applications by reviewing the classification of all transport costs before submission, to ensure that countries present the actual rate of transport costs.
- Gavi Secretariat and partners to:
  - Ensure that the presented need for leased vehicles is compared to available vehicles in countries, to avoid unnecessary rental and inflated transport costs in the budget.
  - Provide technical support to selected countries in planning and budgeting, including by involving fiduciary agents to support budget pre-screening.

Lack of information on funding landscape in malaria budget requests

As noted above, malaria applications budgets were not reviewed by financial crosscutters. Below is an analysis-based on the budget summary.

Figure 6: Summary of malaria budgets in applicant countries



Twelve malaria budgets with a total of US$8.7M were presented. These budgets were distributed by funding source as follows: Gavi contribution US$2M (23%), partners US$1.58M (18%), governments US$1.29 (15%), others US$0.75 (9%), and "Funding Gap" (35%). The funding gap is related to Uganda budget which presented a gap of US$3,025,135 out of a total budget of US$3,199,613. The Uganda budget is far higher than other budgets and was unclear whether it concerns all 4 phases of vaccine introduction or not. The Gavi Country Team mentioned that there are funds earmarked to fill the gap but are not yet approved. Budgets presented different level of detail on all non-Gavi-funded activities which prevents having a broad analysis and to ensure that all activities planned in the PoA have secured budget.

Issue 17: Malaria budgets present different level of detail, and lack clarity on funding sources and how funding gaps will be covered.

Recommendation:

- Gavi Secretariat and partners to ensure that budgets for malaria vaccine introduction cover all PoA activities at high level, with clear indication of funding sources.

Health Information Systems and Monitoring and Learning (MEL)

Use of available case based epidemiological data

Countries applying for NVS often include outcomes of modelling such as the WHO tool analysis to determine areas for differentiated strategies and prioritization. However, despite repeated IRC recommendations, analysis of available data from the case-based surveillance is not done or the analysis is inadequate. Most countries carry out surveillance for vaccine-preventable diseases and report this data annually to WHO via the joint reporting form (JRF). In addition, more detailed case-

based data, not reported to WHO, are often available at the country level through the well-developed Integrated Disease Surveillance and Response (IDSR) systems. This data is a source of valuable insights into disease epidemiology which can direct vaccination activities. While it is commendable that the countries applying for Gavi support make use of recommended tools, further analysis of available surveillance data will complement the output of the tools and better inform vaccination strategies. This is particularly useful since there is always some degree of heterogeneity at subnational level.

Issue 18: Countries are not using all available data and often do not conduct appropriate epidemiological analysis of information from case-based surveillance and outbreaks in development of differentiated strategies for routine EPI and supplementary immunization activities.

Recommendations:

- Gavi and technical partners to ensure that all NVS applications have appropriate epidemiologic analysis (at a minimum: geographic and sub-national distribution of confirmed cases, age, vaccination status) and distinction of whether cases are outbreak or endemic cases.
- Countries to conduct robust epidemiologic analysis and detailed investigation of all outbreaks to determine if the cases are "preventable" or "non-preventable".

Use of administrative coverage data

Countries continue to use administrative coverage data for determining risks for measles transmission and occurrence of outbreaks, despite inconsistencies between WUENIC estimates that are often lower by 10 to 15 percentage points. Interestingly, WUENIC estimates in 2021 for MCV1 were higher than administrative estimates for Afghanistan and Burundi, which is contrary to the usual pattern. Using administrative data therefore may lead to under-estimation of risk at sub-national level and, as a result, a lower estimate of zero-dose children. Other than data on routine coverage, data from post-campaign coverage surveys (PCCS) can also be used. When done according to the design, these PCCS produce estimates of coverage that better reflect the reality at the sub-national level where they are conducted. Given that these resource-intensive PCCS are funded, it would be important to do them properly and consequently make use of their findings in planning subsequent vaccination activities, which goes even further to justify such an investment.

Issue 19: Reliance only on administrative coverage data for determining strategies and assessing subnational risks for disease.

Recommendation:

- Countries to demonstrate that they have included in their risk assessments methods all available coverage data including from recent PCCS and other coverage surveys, to determine risks at sub-national (e.g. district) level.
- Countries to prioritize conducting EPI coverage surveys to obtain robust estimates of vaccine coverage.
- Gavi and partners to support EPI coverage surveys as a matter of priority.

Data quality

There is an absence of data quality review and/or data quality improvement plan in country applications. Data quality assessments are currently not a requirement for countries applying for Gavi support. When reviewing country applications, it rapidly becomes clear that there are data quality issues. For example, there is a disconnect between reported vaccination coverage figures and occurrence of outbreaks. Other key aspects related to the EPI programs such as surveillance, EVM and cold chain capacity cannot be adequately assessed if data quality is poor at national and sub-national level. Consequently, planning of vaccination activities based on poor quality data will inevitably compromise countries' (and eventually Gavi's) ability to achieve the expected outcomes of the immunization activities.

Issue 20: Data quality reviews and data improvement plans are not being given priority by country immunization programmes.

Recommendations:

- Countries to plan and include periodic data quality reviews alongside EPI program reviews or effective vaccine management assessments.
- Gavi and partners to provide technical support to countries and put more emphasis on data quality improvement.

Capacity at country level to conduct analysis and triangulation of data for programme purposes

Inadequate analysis to inform vaccine introduction and immunization campaigns remains a challenge for countries applying for NVS support. In this round, there was some variation in the analysis performed by countries applying for support to conduct similar vaccination activities. It is not clear to what extent the EPI teams within countries are able to conduct robust epidemiological analyses, as there are countries providing inadequate analyses and those conducting robust epidemiological analysis, even with inclusion of mathematical modelling techniques.

Issue 21: Data analyses accompanying NVS support requests remain insufficient.

Recommendations:

- Gavi and technical partners to provide further support for data analysis to countries when preparing applications.

Electronic data collection and management tools

The Plans of Action for proposed intervention do not systematically mention the use of electronic data collection tools (e.g. ODK) for recording vaccine administration data or reporting of adverse events following immunization (AEFI). Electronic data collection tools can be easily installed on mobile devices, either owned by health care personnel or purchased specifically for the purposes of implementing vaccination activities. The use of electronic data collection tools provides real-time data, easy to analyse and therefore support evidence-based decision making. In addition, these electronic tools can also be used for subsequent mass vaccination activities and for other public health interventions (e.g. mass treatment or LLIN distribution).

Issue 22: Available electronic tools are not optimally used for EPI programme management.

Recommendations:

- Gavi and partners to encourage the countries to make use of electronic platforms for data collection (e.g. ODK) that have been developed and are in use in other Gavi-supported countries.
- Countries to prioritize electronic platforms for handling data on activities that involve vaccination and other aspects of healthcare provision (e.g. logistic management and adverse event reporting).

Governance

The Immunization Coordination Committee (ICC) and National Immunization Technical Advisory Group (NITAG) both play a crucial role in national immunisation governance and decision-making. However, engagement of and endorsement by both ICC and NITAG differed across applications, with only some countries including details of discussions or endorsement by one or both governance bodies. Of 17 submissions this round, 14 provided ICC endorsement.

While ICC engagement appears unchanged from other application rounds, previously strong NITAGs (e.g. Uganda) appear to have weakened due to loss of funding. All applicants have NITAGs, except Chad and Sao Tome & Principe, according to the latest JRF data. However, not all are fully functional and only 10 provided NITAG endorsement of applications. Where endorsement from NITAGs was provided, supporting documentation such as meeting minutes was not always included. Some applications provided incomplete or outdated ICC or NITAG endorsement (e.g. Ghana), making it unclear if applications remained aligned with country needs. Financing for NITAGs is an ongoing issue globally and can be recognised as a reason for reduced functioning of many NITAGs.

Issue 23: Countries increasingly lack or provide outdated ICC or NITAG endorsements, often not supported by meeting minutes.

Recommendations:

- Gavi to reinforce requirements for ICC and NITAG endorsement of all applications.
- Gavi to work with partners to support countries in developing and strengthening NITAGs, to ensure they are sufficiently functional to provide needed technical governance and guidance to national immunisation programmes.

Full Portfolio Planning reviews (FPP)

Review Process

Two FPP applications were reviewed in this round. Ethiopia, as a high impact country, was reviewed using an in-country process while Côte d'Ivoire was reviewed remotely and presented to the main IRC. Both applications had multiple funding windows (See Table 7). Decisions for the FPP applications were approval for Ethiopia and for Côte d'Ivoire the decisions were re-review for the HSS/EAF and CCEOP components and approval for TCA and MR follow-up campaign. Key reasons for this re-review are described in Table 7 and include the lack of alignment between the theory of change (TOC) and resource allocation, a lack of emphasis on systems strengthening in a Gavi transitioning context, while reasons for CCEOP re-review involved a lack of comprehensive documentation that consolidates all CCE needs for a CCEOP submission as required.

Table 7: FPP by type of support and review modality

Country	Support	US$ Amount Requested	Recommendation	Review modality	Key Rationale
Ethiopia **High Impact Country**	**HSS**	**$99,947,139**	Approval	***In country Review***	***Strong consolidated response to rebuild and rapidly reinstate*** *quality immunization services to conflict and other affected zones across the country;* ***Sustainability:*** *Continued government support for staff salaries and allowances across all tiers of service delivery across the country;*
	EAF	**$44,180,347**	Approval		*Data driven, well triangulated approach to quantify, prioritise and differentiate ZD children by selected Woredas for defined and contextualised packages of intervention.*
	TCA	**$15,000,000**	Approval		
	IPV2	**$ 902,488**	Approval		
Cote d'Ivoire	**HSS/EAF**	**14,315,378**	**Re-review**	***Remote review***	*Lack of alignment between TOC and resources allocation; lack of emphasis on systems strengthening in a Gavi transitioning context. Lack of differentiated strategies targeted at ZDC; multiple budget issues and duplication between windows.*
	TCA	**3,315,765**	Approval		
	MR f-up campaign	**3,080,724**	Approval		*No comprehensive documentation that consolidates all CCE needs for a CCEOP submission as required; Inadequacy in CCE inventory tool settings; Failure to justify some CCE needs; Gaps in the budget.*
	CCEOP	**3,415,108**	**Re-review**		

Key findings

There were multiple findings from this FPP review rounds. Both countries demonstrated strong country led FPP development processes. Ethiopia showed a strong consolidated response to rebuild and rapidly reinstate quality immunization services to conflict and other affected zones across the country. It also demonstrated a remarkable sustainability approach with continued government support for staff salaries and allowances across all its tiers of service delivery. Côte d'Ivoire FPP provided a sound analysis of supply side factors for poor uptake, and offered innovative interventions tailored to these challenges. Examples of these approaches include the use of mobile medical units for routine care in large cities positioned in places frequented by women and increased coverage through collaboration with faith-based private health facilities. However, despite these strengths, one important finding revolved around the persisting siloing of individual applications within the full portfolio planning. Others include the limited leveraging of HSS in some cases to support the delivery of other funding windows such as campaign support and cold chain investments. Activities such as training and supervision lacked an integrated approach (Côte d'Ivoire, Ethiopia) leading to duplication of activities, cost-ineffectiveness and poor scheduling of foundational activities that could for example benefit campaign performance – activities such as population enumeration, microplanning and the development of a national immunisation policy. Budgeting often did not integrate support across activities in different funding windows leading to inefficiency and missed opportunities, as well as resulting in multiple training and workshop activities that would draw staff multiple staff from facilities and potentially undermine routine systems. For example, it was suggested to use the annual microplanning workshop and add one additional day for the MR campaign rather than plan two specific such activities.

Issue 24: Missed opportunities by countries to leverage multiple windows provided by the FPP application

Recommendations:

- Gavi to support countries and TCA partners to better leverage the full benefits of holistic and synergetic planning for FPP applications with multiple windows, to include:
  - Supporting countries in developing integrated training plans and integrated supervision plans across windows for better synergy and efficiency;
  - Placing more emphasis on scheduling of activities and ensuring that key foundational HSS activities can be leveraged by campaign/EAF activities (e.g. enumeration, development of national immunisation policy);
  - Providing more support for budget reviews across windows to avoid duplication and minimise multiple meeting/workshop activities that undermine the routine programme;
  - Promoting (and measuring) resource allocation of activities at sub-national level for better ownership and efficiency.

Other findings

Other findings included the lack of evidence-based communication strategies across funding windows, and under investment and scaling up of digital technologies. In particular, it was unclear in the case of Ethiopia how the current demand approaches/activities are strategic enough to address the well-articulated barriers to increase utilization of immunization services within a provider friendly milieu (e.g. IPCC skills building in HCW, 7-Day annual media campaigns; SMS; multiple community dialogues and advocacy meetings across the tiers). TCA was not always sufficiently supporting innovative approaches of the FPP activities and missed opportunities to innovatively catalyse the systems supported beyond business as usual (Ethiopia). In Côte d'Ivoire, TCA was used purposedly to scale up interesting innovative interventions such as the M-Vaccine pilot, which uses SMS to recall parental missed appointments.

There is limited evidence of use of the "science and art" of strategic communication in designing proposed demand creation activities both in Ethiopia and CIV. The strategic approaches remain more of same old story involving the use of posters, TV and radio spots without meaningful consideration of data evidence and nor use of cutting-edge approaches to communication and strategic behaviours changes. There is also limited consideration for use of human centred design approaches and science of social norms, minimal consideration for exploration and use of social media amongst others. Proposed budgets for the activities were often not realistic and a combination of over- and under-budgeting.

Issue 25: Poorly designed Demand creation and Communication Strategies

Recommendations:

- TCA support to focus on supporting countries to:
  - identify and cost appropriate social and communication interventions to create demand and promote behaviour change;

- understand, use, and evaluate emerging media to segment and reach audiences through social media (e.g. content creators, influencers etc.).

Issue 26: Current TCA mechanisms appear focused on "business as usual approaches" rather than on countries' context. This often translates into interventions that appear to also be more like "business as usual" rather than being responsive to the needs of supported countries.

Recommendations:

- All TCA partners to further support countries in strengthening and contextualizing current practices/activities, to include:
  - supporting innovative approaches to capacity building, microplanning, visualization and use of data on vaccine consumption, strategic demand creation/community engagement;
  - consideration of defined mentorship processes to transfer skills;
  - exploration and use of digital innovations especially in creating/supporting the interphases between the IT/innovations hubs across countries to encourage technology use/adaptation to immunization and system strengthening.

4. Conclusions

This IRC session was the first to review applications for the malaria vaccine introduction for non-pilot countries. The world, in particular Sub-Saharan Africa, has been anxiously waiting for this vaccine to help save children from severe malaria. Gavi should be commended for its contribution to the development to the end product and now getting it into countries, in collaboration with and active involvement of WHO and all Malaria program partners.

Gavi and partners should provide further guidance as to the timing between the 3rd and 4th doses, as the 4th dose is critical for improved protection.

Gavi and partners should consider funding implementation research, to learn from early roll-out and make sure that the excitement, the hard work and the momentum are sustained.

IRC would also like to highlight other issues in need of focused attention while noting gradual and steady improvements in the use of Gavi templates and attempts to contextualize proposed interventions.

When designing interventions within NVS/campaigns applications, countries should be further encouraged to triangulate available epidemiological data including from outbreaks, subnational surveillance and surveys, rather than relying on modelling tools. This is important to ensure clear and strong rationale for subnational MR follow-up campaigns while safeguarding equity in immunization. Emphasis should continue to be placed on strengthening routine immunization. In that respect, there should be continuous support of NITAGs, to ensure that they are sufficiently functional and, along with ICCs, providing governance and technical guidance to national immunization programmes.

IRC notes continued improvements in budget presentations and their alignment with plans of action. However, HR related and transport costs remain high and countries should be further encouraged to ensure transparency in budgeting by consistent use of WHO recommended standards for estimation of HR requirements and adequate classification of all transport costs.

IRC reiterates the need of submitting the updated inventories and gap analysis in CCEOP applications. Countries should be further encouraged to demonstrate how CCEOP support will improve supply chain efficiency and achieve programme objectives.

Finally, IRC commends the responsiveness of Gavi leadership, along with the role of technical partners in their commitment to support countries in adopting strategic processes with the aim of raising standards of their national immunization programmes.

5. Acknowledgements

The IRC would like to thank the Gavi Executive Team for their continued support and responsiveness to key IRC recommendations. The IRC expresses its gratitude to FDR team (Lindsey, Verena, Sonia, Anjana) for their excellent organization of the meeting and their availability at all times during the meeting, and for coordination of travel (Noelia).

Our thanks also go to all the Gavi Secretariat, SCMs, VP, HSIS and PFM team members. Their inputs during pre-review screenings and clarifications on country-level perspectives during plenary sessions, were important and useful for final decision-making.

Finally, we recognize the contribution of the Alliance partners who provided support to countries in preparing the applications, attended our sessions and provided insights and clarifications during the deliberations of the IRC.

Annex 1: IRC members participating in March 2023 meeting

#	Name	Nationality	Profession/ Specialization	Gender	Langu-age	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	Aleksandra Caric	Croatia	Independent consultant	Female	EN, FR	Measles, AEFI Surveillance and vaccine safety, programme management, primary health care
4	Rochika Chaudhry	USA	Advisor, Johns Hopkins Medical Institution	Female	EN	Immunization services, global health security, outbreak response, HSS, health finance and policy, malaria, HIV
5	Borja Cuervo Alonso	Spain, Mozambique	Independent consultant	Male	EN, SP, FR, PT	HSS, disaster preparedness and emergencies, challenging operating environments, equity, HIV, malaria
6	Emmanuelle Espié	France	Senior scientist, CEPI	Female	EN, FR, SP	Epidemiology, epidemic preparedness, surveillance, outbreaks, vaccine effectiveness and safety, vaccinology
7	Natasha Howard	Canada, UK	Associate Professor, NUS School of Public Health and LSHTM	Female	EN, SP, AR	HPV, immunisation service delivery, FER settings
8	Philippe Jaillard	France	Director of EpiLinks	Male	EN, FR	Health and immunization supply chain management, training and educational engineering
9	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
10	Wassim Khrouf	Tunisia	Auditing and Consulting Worldwide, Partner	Male	EN, FR	Financial & budget analysis, audits, project assessment
11	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
12	Viviana Mangiaterra	Italy	Associate Professor, SDA School of Management, Bocconi University, Milan	Female	EN, FR	HSS, Maternal and Child Health, Malaria, HIV and TB
13	Nkengafac Villyen Motaze	Cameroon	Associate Professor of Epidemiology,	Male	EN, FR	Vaccinology, epidemiology, systematic reviews, evidence-based practice

			Medicine Usage in South Africa (MUSA), North West University, South Africa			
14	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
15	Benjamin Nkowane **- Vice-chair**	Zambia	Independent consultant	Male	EN, FR	Measles, epidemiology, mass vaccination campaigns, technical support for field operations in risk areas
16	Gavin Surgey	South Africa	Radbound University Medical Centre	Male	EN	Financial and Budget Analysis, Health Economics, Health Financing Strategies, Program M&E
17	Edward Ouko	Kenya	Executive Director of Edrak Associates Limited	Male	EN	Auditing and public financial management, governance, M&E
18	Bolanle Oyeledun **- Deputy chair**	Nigeria	Chief Executive Officer at Centre for Integrated Health Programs (CIHP), Nigeria	Female	EN	HSS, MNCH, immunisation, adolescent reproductive health & HPV, programme assessments and evaluations
19	Erika Wichro	Austria	Independent consultant	Female	EN, FR	Emergency settings, outbreak response, HSS, polio, ebola, measles, COVID-19, surveillance, epidemiology