

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

19 – 29 September 2023

1 November 2023

GAVI ALLIANCE

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List of acronyms

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

1. Executive Summary

The Gavi Independent Review Committee (IRC) met in Geneva from 19 to 29 September 2023. A total of 30 countries in five World Health Organization regions had submitted 64 applications for support from Gavi. These were from the African Region (22), East Mediterranean Region (3), European Region (2), South East Asian Region (2) and Western Pacific Region (1). Seven Full Portfolio Planning (FPP) applications, 13 Cholera diagnostics and the 3 IPV2 introduction grant requests were reviewed remotely and summary findings and recommendations were presented to the full IRC. There were 13 NVS applications (1 for Oral Cholera Vaccine, 1 for HPV, 3 for IPV2, 3 for Malaria vaccine, four for Measles/Measles-rubella (M/MR) campaigns and one MCV2 introduction. The FPP applications from 7 countries incorporated 2 for Innovation Top Up (ITU), 4 for Cold Chain Equipment Optimization Platform (CCEOP), 6 for Equity Accelerator Fund (EAF), 6 targeted Country Assistance (TCA) and 7 Health Systems Strengthening (HSS). The remaining 26 applications were 1 standalone TCA, 2 standalone ITU, 2 standalone CCEOP, 4 Middle Income Support (MICS), 4 standalone EAF and 13 Cholera Diagnostics.

A total of 23 IRC members with a wide range of expertise participated in the meeting. Two IRC members conducted in-depth financial and budget reviews of the applications (excluding RTS,S malaria applications) and two others on the supply chain, logistics, vaccine management and waste management. The IRC focussed on the following; (a) Review of countries' funding requests and supporting documentation for vaccine introductions and campaigns to support national efforts to improve immunisation coverage and equity; (b) Production of country-specific review reports and recommendations; (c) Development of a consolidated report of the review round, including recommendations for improving funding requests and strengthening routine immunisation; and (d) Provision of recommendations to the Gavi Board and Alliance partners on improving processes relating to Gavi policies, governance, and structure. Review modalities included an independent desk review of each application by two designated members and discussion in plenary with the participation of the full committee. During this round, the IRC was engaged in a newly established meeting and discussion with EPI team members and core partners from countries that had applied for support for M/MR follow-up campaigns. This offered an opportunity to clarify concerns that IRC reviewers had regarding the application.

Results

The IRC recommended 62 of the 64 applications for approval. Two applications were recommended for re-review (ITU application within the Burundi FPP, application from Mali for Malaria vaccine (RTS,S) introduction). The Burundi application was recommended for re-review because the request for proposed scale-up of an innovation lacked a narrative and timeline and there were major uncertainties in relation to the budget and high level of HR costs. For Mali, which requested support for a hybrid 5 dose schedule for the malaria vaccine, the IRC recommended a re-review because the plan of action did not take into consideration operational and logistic implications of a five-dose strategy spanning over three years, and lacked a chronogram of activities that covers the entire introduction period. The IRC noted NVS applications provided more complete analyses of measles epidemiology supported by sub-national data and information from outbreaks, use of equity data to identify bottlenecks, and use of differentiated strategies to reach unvaccinated and under-vaccinated children. One country, Nepal had a robust analysis of the subnational data to justify an expanded age group in selected districts. Overall, the IRC noted that the unavoidable effect of non-selective campaigns in the presence of relatively high coverage of MCV1 and MCV2 is that vaccine will mostly be administered to those who are already immune, rendering the strategy inefficient. The IRC also for the first time approved a series of cholera preventive campaigns targeting 19.7 million people in DR Congo,

but noted that implementation of the campaigns over a three-year period had a high potential to disrupt routine services. As regards gender, equity and zero dose children, the IRC noted 16 countries included gender analyses and of these 12 relied entirely of DHS or previous coverage surveys. In general, despite some improvement in equity reporting, data analyses remain limited and therefore it is difficult to ensure effective strategies will be implemented. For Zero dose children, countries use various size estimation methods including administrative data which do not provide appropriate estimates. The IRC notes that there is no standard recommended method for this and should be given priority by Gavi and the technical partners and consideration should be made to use for estimating zero dose children well established or similar approaches such as the ones used in HIV/AIDS programmes for estimating target population size. For the supply chain, there is clear improvement in the CCEOP applications reflecting systematic use of data for planning. The challenges however remain in the area of CCE selection and in particular, CCE decommissioning for which countries do not have guidelines with reference to international environmental regulations. As regards budgets, the overall quality was satisfactory although countries do not present adequate disaggregation by cost input. This needs to be addressed to ensure transparency and accurate financial management. The IRC also noted that in the FPP applications, service delivery activities which made up a significant share of the budget, were budgeted by cost inputs, such as the number of districts and health facilities without clear linkage with coverage targets, thereby creating challenges in assessing the reasonableness of the estimates. Furthermore, HSS applications still had a high dependence on external support as countries continue to request funding of operational costs for the program from donors and there are no viable transition plans presented. Finally, the IRC noted that requests for Innovation Top Up (ITU) funding were generally weak and countries did not provide details on digital innovations that are proposed, their relevance, inter-operability, scalability, and sustainability.

2. Methods and Processes

Methods

The meeting agenda, allocation of countries for review, country applications, supporting documents and briefing materials were shared with the IRC on 9 September 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 chaired the meeting and was supported by Dr Benjamin Nkowane, Vice Chair of the IRC.

The meeting was opened by Mr Johannes Ahrendts, Director SFP, who welcomed the IRC members and outlined the expectations for the review. Updates were provided on the Gavi Civil Society Organization Policy, Middle Income Country support, Oral Cholera vaccine, HPV vaccine, Measles/Measles-Rubella vaccine, and Gavi Gender Policy.

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 does not instead request the in-depth finance review for malaria applications. FPP applications reviews were presented to the IRC. The review process depended on country categorization (Core, High Impact. Fragile and Conflict). The

review of the FPP proposals started remotely before the IRC and had additional interactions with the country and the secretariat through briefing and clarification calls. All the country reports were individually presented and recommendations were discussed in plenary. The Gavi Secretariat and Alliance partners supported the plenaries by providing information and clarifications when needed on country-specific issues and context.

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

Criteria for review

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

Decisions

There were two decision categories:

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

Table 1. Summary of requests, IRC Meeting September 2023

Types of support requested

13 NVS applications from 9 countries	25 types of FPP applications from 7 countries	26 other applications from 17 countries
<ul style="list-style-type: none"> • 1 for OCV • 1 for HPV • 3 for IPV • 3 for malaria vaccine • 5 for measles campaigns 	<ul style="list-style-type: none"> • 2 ITU • 4 CCEOP • 6 EAF • 6 TCA • 7 HSS 	<ul style="list-style-type: none"> • 1 standalone TCA • 2 standalone ITU • 2 standalone CCEOP • 4 MICS • 4 standalone EAF • 13 Cholera diagnostics

Outcomes of the September 2023 IRC Meeting

The recommendations of the September IRC reviews are summarized in Table 2a, 2b, 2c, 2d, below. In summary, the IRC recommended 62 out of 64 applications for approval and two applications were recommended for re-review by the IRC (one ITU application within the Burundi FPP application and one application for Malaria vaccine introduction from Mali).

Table 2a: Summary of requests from countries and review outcomes, IRC, September 2023

Countries		Types of support requested			Recommendation Outcomes	# Support types
		NVS request	FPP	Others		
1	Benin	MR 1+2			Approval	1
		MR f-u campaign			Approval	2
2	Burundi		HSS		Approval	3
			EAF		Approval	4
			TCA		Approval	5
			ITU		Re-review	6
			CCEOP		Approval	7
3	Cameroon			Cholera Diagnostics	Approval	8
4	Central African Republic (CAR)		HSS		Approval	9
			EAF		Approval	10
			TCA		Approval	11
5	Chad	Malaria			Approval	12
6	Comoros		HSS		Approval	13
			TCA		Approval	14
			CCEOP		Approval	15
7	Cote d'Ivoire		HSS		Approval	16
			EAF		Approval	17
			CCEOP		Approval	18

Table 2b: Summary of requests from countries and review outcomes, IRC, September 2023 (Cont.)

Countries		Types of support requested			Recommendation Outcomes	# Support types
		NVS request	FPP	Others		
8	DRC	OCV			Approval	19
				Cholera Diagnostics	Approval	20
9	Ethiopia			CCEOP	Approval	21
				Cholera Diagnostics	Approval	22
10	Ghana			EAF	Approval	23
				CCEOP	Approval	24
		Malaria			Approval	25
		MR f-u campaign			Approval	26
		IPV2			Approval	27
11	Indonesia			MICS	Approval	28
12	Kenya		HSS		Approval	29
			EAF		Approval	30
			TCA		Approval	31
13	Kosovo			MICS (VCF) HPV	Approval	32
				MICS (VCF) PCV	Approval	33
				MICS (VCF) Rota	Approval	34
14	Kyrgyzstan			Innovation top-up	Approval	35

Table 2c: Summary of requests from countries and review outcomes, IRC, September 2023 (Cont.)

Countries		Types of support requested			Recommendation Outcomes	# Support types
		NVS request	FPP	Others		
15	Lesotho	IPV2			Approval	36
16	Madagascar	Measles follow-up			Approval	37
17	Malawi			Cholera Diagnostics	Approval	38
18	Mali	Malaria			Re-review	39
19	Mozambique			Cholera Diagnostics	Approval	40
20	Nepal	HPV			Approval	41
		MR follow-up			Approval	42
				Cholera Diagnostics	Approval	43
21	Pakistan			Cholera Diagnostics	Approval	44
22	PNG			TCA Re-submission	Approval	45
23	Sao Tome	IPV2			Approval	46
24	Senegal		HSS		Approval	47
			EAF		Approval	48
			CCEOP		Approval	49
			TCA		Approval	50
			ITU		Approval	51

Table 2d: Summary of requests from countries and review outcomes, IRC, September 2023 (Cont.)

Countries		Types of support requested			Recommendation Outcomes	# Support types
		NVS request	FPP	Others		
25	Sierra Leone			EAF	Approval	52
				Cholera Diagnostics	Approval	53
26	Somalia			Cholera Diagnostics	Approval	54
27	Syria (DAM)			EAF	Approval	55
				Cholera Diagnostics	Approval	56
*	Syria-NWS			EAF	Approval	57
				ITU	Approval	58
				Cholera Diagnostics	Approval	59
28	Uganda		HSS		Approval	60
			EAF		Approval	61
			TCA		Approval	62
29	Zambia			Cholera Diagnostics	Approval	63
30	Zimbabwe			Cholera Diagnostics	Approval	64

Thematic areas sub-committees

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

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

The debriefing of the Gavi Secretariat and partners was held on 29 September 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.

3. Key Findings and Recommendations

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

During this session, IRC reviewed applications from seven countries for NVS support: three for malaria RTS,S vaccine introduction (Chad, Ghana, Mali), one for series of cholera preventive mass campaigns with oral cholera vaccine (DRC), and four for measles/measles and rubella (M/MR) support (Benin, Ghana, Madagascar, Nepal). Total funds requested were about US\$ 32,9 million.

Of malaria vaccine requests, amounting to about US\$ 0.47 million, Ghana's and Chad's applications were approved. The preventive cholera mass campaigns in DRC will target all population older than 1 year of age across 62 endemic and epidemic health zones, for which the approved operational cost estimate amounts to about US\$21.5 million. Of M/MR requests, all countries applied for national, non-selective MCV follow-up campaigns targeting children aged 5 to 59 months. In addition, Benin applied for support of MCV2 introduction, and Nepal for support of rolling subnational campaigns targeting children aged 5 to 14 years of age in 24 selected districts which was backed by robust data and adequate epidemiological justification. The total M/MR operational costs and introduction grant were about US\$ 10.92 million, and all applications were approved. IRC is pleased to see that countries continue to provide more complete analyses of measles epidemiology supported by subnational data and information from outbreaks. They also continue to include steady, data-grounded differentiation of strategies and focus on reaching the un- and under-vaccinated, although zero dose analyses still lack clear methodology. These efforts build into IRC's maintained position that, to be recommended for approval, applications should show a solid epidemiological justification hinged on robust data, a strong focus on reaching consistently missed children with appropriate differentiated strategies, feasible linkages and synergies with routine immunisation strengthening, and continued programme ownership and political commitment.

Issue 01: Implementation challenges specific to OCV, with high potential to disrupt routine immunisation activities, are not fully considered in the planning phase.

DRC's application for the preventive use of oral cholera vaccine (OCV) was the first such application that IRC reviewed. Cholera, killing the poorest and most vulnerable people, is a highly specific indicator for extreme poverty and harsh living conditions. This disease of inequity indicates that a population does not have access

to basic water and sanitation and points to areas in urgent need of WASH investment. In this respect, OCV proved to be a game-changer for cholera control by not only averting cholera cases and deaths during outbreaks and in cholera hotspots, but also by providing the time to governments to implement the sustained WASH solutions and health system strengthening that are necessary for long term cholera control. As a short to medium term measure to control cholera, DRC requested support to conduct a series of preventive vaccination campaigns with OCV in 2024, 2025 and 2026, targeting about 19.7 million people in 13 provinces. The prioritization of areas to target is based on epidemiological criteria (i.e. endemicity, severity, persistence of disease), and on top of this analysis, DRC uses a series of criteria to further prioritize campaigns in a resource constrained environment. Some of these criteria, such as risk of transmission, risk of spread or risk of importation, may be hard to quantify, complex to estimate given the vulnerability of population, and non-discriminant due to poor WASH conditions. However, the prioritization based on epidemiological data should be sufficient as it is easier to quantify and measure progress over time.

Compared to routine or supplementary immunisation activities within EPI, OCV preventive campaigns have a number of challenges which need to be considered in planning. OCV, unlike other EPI vaccines, come in single dose presentation in plastic tubes, and the schedule requires two vaccine doses administered two weeks apart. The target population goes beyond standard EPI age as all population older than 1 year is targeted. The fact that a large population needs to be vaccinated twice in a short period of time and in very harsh conditions presents an additional burden that appears underestimated. As this has a high potential to disrupt routine activities, it must be considered in the planning phase. Further, OCV as single-dose tubes are bulky, and large scale OCV campaigns require a very large volume of cold chain within a short period of time. Finally, integration of OCV campaigns with other EPI interventions and with classic cholera control measures remains limited in scope. Given that coordination mechanisms across sectors and levels of the system are often lacking, OCV campaigns are rarely used to promote or implement other relevant health activities, and marginally used to promote WASH.

Recommendations:

- Gavi to request from countries to include in planning the challenges for implementation of large-scale OCV preventive campaigns and propose concrete activities, adapted to local context
- Gavi and partners to support countries to develop practical strategies and activities to use the opportunity of OCV campaigns for supporting other health related and cholera control activities
- Gavi and partners to encourage countries to document findings and experience from mass preventive campaigns for lessons sharing

Issue 02: Operationalization of hybrid schedule option for malaria vaccination not planned beyond the primary series

Countries that applied for malaria vaccine introduction have so far opted for age-based 4-dose schedule, however, with a variable interval between doses 3 and 4 (i.e. seldom considering SAGE recommended interval between doses 3 and 4 of 12 to 18 months after the third dose to prolong duration of protection).

Mali is the first country that opted for the hybrid 5-dose schedule in which the primary series (i.e. first three doses) of RTS,S vaccine is age-based, and doses 4 and 5 are seasonal, to be delivered through campaign mode annually. Mali's schedule would include primary series administered at health clinics throughout the year at monthly intervals starting from 5 months of age, but preferably from April to June, before the peak transmission season in July. The 4th RTS,S dose would be given in the subsequent year between April and

June, with a preferable 12-month interval between doses 3 and 4 but also allowing the minimum of 6 months so that more children would receive the dose 4 prior to high transmission season. Of note, any recommendation to provide the RTS,S 4 in less than 18 months after RTS,S3 is an off-label recommendation, however, the reduction of this interval to minimum 6 months between RTS,S doses 3 and 4 is a flexibility advised by WHO SAGE as a part of March 2023 recommendations on schedule options in areas with highly seasonal malaria transmission. Finally, dose 5 of RTS,S would be administered minimum 12 months after the 4th dose, in June of the third year to all those who were vaccinated in two previous years, to complete the series. Therefore, three years are needed to complete the proposed schedule and for this, a new vaccination contact needs to be established in the third year of a child's life. For the EPI programme, the implementation of this schedule would also require that along with primary RTS,S vaccination throughout the year, from the 3rd year on, an annual RTS,S campaign in June is organized, to increase protection of recipients of 3 or 4 RTS,S doses before the next peak transmission season.

While aligned with WHO SAGE guidance, this schedule is complex, relies on a well-functioning immunisation programme and health system, and requires advance planning across all programme components to reach those most in need and reduce in particular RTS,S3/RTS,S4 and RTS,S4/RTS,S5 drop-outs. Operational and logistic implications of this schedule beyond the first year of introduction are not reflected in the programmatic components that Mali's plan of action describes only in general terms and bases on outdated information and data. The hybrid schedule, stretching through three years and engaging annually extra resources (human and financial), needs careful, comprehensive, context-based, and time-bound planning to minimize its disruptive potential and reduce added stress to fragile systems.

Recommendations:

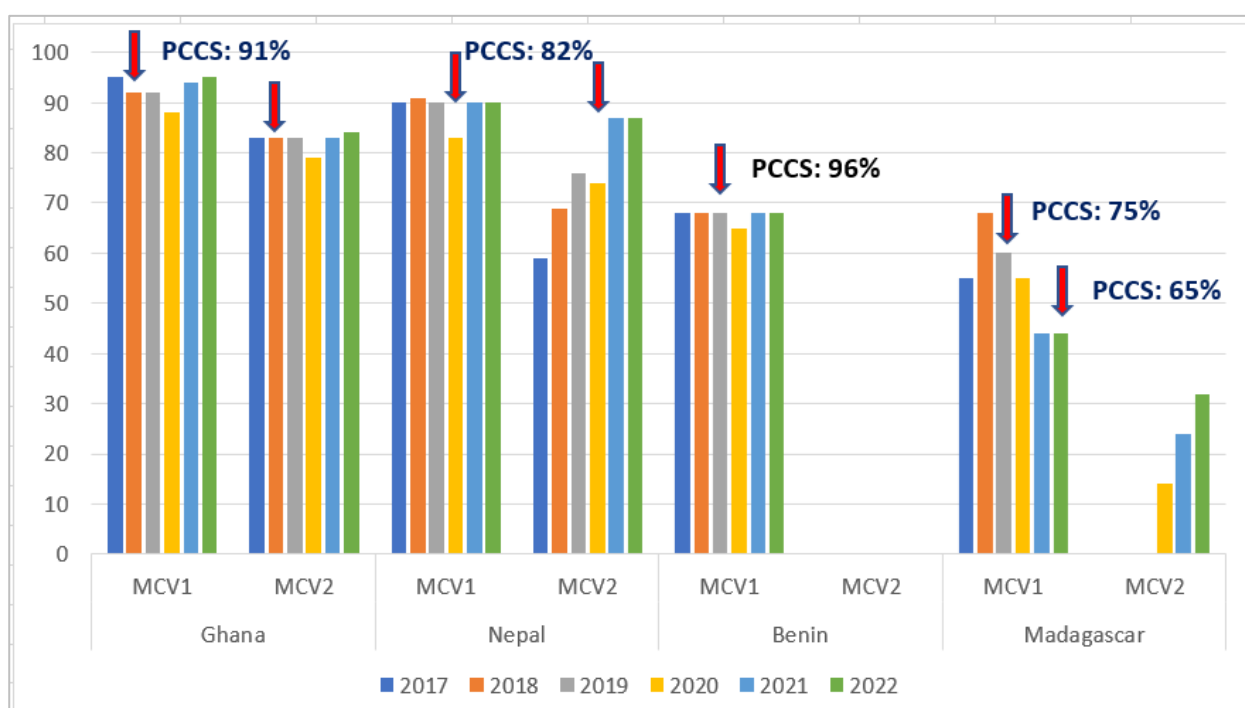
- Gavi to request from countries multi-year plan for malaria vaccine introduction when hybrid approach is applied
- Gavi to request from technical partners to develop practical guidance for operationalization of hybrid schedule for countries where malaria transmission is highly seasonal
- Gavi to request countries to document challenges and solutions applied during the introduction.

Issue 03: Continued reliance of countries on national non-selective campaigns to control measles

Following previous recurrent IRC recommendations, countries continue to provide solid data and analyses to justify the scope of their campaigns, nationwide and non-selective for all. IRC is pleased to see the use of equity lens and available data to identify bottlenecks in reaching un- and under-vaccinated children and propose differentiated strategies. We also note cross-sectoral collaboration in order to leverage resources and ensure better campaign outcome, such as cross-sectoral collaboration with the Ministry of Education and Malaria Control Programme in Ghana, and collaboration with Ministry of Education and Ministry of Gender, Child and Social Protection in Nepal. We further note, again in Ghana and Nepal, documentation of regular ICC and NITAG meetings with detail in the aspect of programme oversight and application of science. The 2YL integrative platform is described in Benin, though in the context of MCV2 introduction, and in Ghana, while in Nepal that is a 'platform for stronger primary health care'. While the quality of campaign applications is indeed increasing, irrespective of countries' performance, they all report outbreaks and all continue to rely on non-selective campaigns to control measles. Figure 1 summarizes WUENIC coverage for MCV1 and MCV2 (where introduced) in applicant countries, along with coverage achieved in previous campaigns. We note that well performing countries such as Ghana and Nepal had suboptimal SIA implementation (Ghana 2019: 91%, Nepal 2020: 82%), but we are confident that with solid plans both countries will conduct quality campaigns

and achieve higher coverage among never-reached. However, an unavoidable effect of non-selective vaccination campaigns in the presence of sustained relatively high coverage for both MCV1 and MCV2, is that many vaccine doses will be administered to those who are already immune, either from previous vaccination or disease, rendering such strategy inefficient. Therefore, the success of non-selective campaigns in well-performing countries will be in the high reach of un- and under- vaccinated children. This goes beyond zero-dose children, defined as those who do not receive a single dose of DTP vaccine, and includes children who may have received doses of DTP vaccine but have not received or completed two-dose measles vaccination. Failing to reach previously unreached with measles vaccine, such campaign will have limited impact on population immunity for measles.

Figure 1: Summary of WUENIC MCV1/MCV 2 coverage and survey coverage in applicant countries (Source: JRF)



On the other hand, given the drop in the routine programme and suboptimal implementation of recent SIAs, Madagascar has been advised to continue with non-selective nationwide SIAs every two years. While SIAs have an important role in filling immunity gaps, it will likely not be sufficient to achieve or sustain measles control in the presence of low MCV1/MCV2 coverage. Furthermore, it carries a risk to become a strategy that would attempt to compensate for weak routine immunisation and not interrupt transmission. Other approaches, easier to plan and implement in given topography, could be more effective (e.g. PIRIs). However, the choice of strategy will have to consider feasibility, cost and impact, while the efforts to strengthen the routine will remain priority.

Recommendations:

- Gavi and partners to support countries in RI strengthening beyond EPI activities, and link with other departments and programmes in and outside of health sector

- Gavi and partners to support countries in identifying and reaching un- and under- vaccinated children for measles, as they may also be outside of the pool of zero-dose children.

Gender, Equity and Zero-dose Children

Issues related to adequacy of equity and gender analyses and incorporation of lessons learned in proposed interventions

Sixteen countries (i.e. excluding those applying only for CCEOP or ITU support) included gender/equity analyses while 3 (i.e. Cote d'Ivoire FPP, DRC OCV, Indonesia MICS) provided none. Twelve of these 16 relied entirely on DHS or previous coverage survey data, while 4 provided more in-depth purposeful analyses supported by TA (i.e. Comoros FPP, Sierra Leone EAF, Uganda FPP, Syria DAM EAF). However, as there is no standard tool used for the analyses, there is limited comparability of the findings.

Table 3. Gender and Equity Analyses in country applications

Country	Support requested	Gender issues identified	Other vulnerable groups identified	Gender analysis in the report	Interventions identified to address inequities
Benin	MR2 NVS + MRfu	No differences in coverage by sex of the child, low maternal education correlated with low coverage.	Low socioeconomic status, certain geographies.	Analysis of coverage by sex (DHS data); refers to an equity analysis that has been done but no findings in the report	None
Burundi	CCEOP, EAF, HSS, ITU, TCA	Limited decision-making power of mothers, high female illiteracy, 15% home births i.e. low health care utilisation.	Certain geographical groups	Analysis mentioned by data source and details unclear	Enhanced engagement of fathers/men
CAR FPP	EAF, HSS, TCA	Male headed households had higher coverage	None specifically reported	Analysis of coverage by sex (admin data)	Involving communities in microplanning
Chad	Malaria	No difference in coverage by sex of the child, low literacy among women, male vaccinators have limited access to homes in some communities, decision making power lies with father.	Nomads, refugees, households in zones of insecurity	Analysis of coverage by sex (DHS data)	Training for HCWs on equity, tailored messages, additional mobilisation activities, female vaccinators.
Comoros FPP	CCEOP, HSS, TCA	None specifically reported	Urban areas and geographical	ADB and UNICEF gender equity analysis	Tailored communication strategy; community dialogue sessions among action groups for women and men; additional study on gender barriers to better inform decision and planning.
Cote d'Ivoire	CCEOP, HSS, TCA	None	Geography, migrants/ refugees, low socioeconomic status groups	None	Gender analysis to inform interventions.
DRC	OCV	None		None	Zero dose children identified during door-door campaign will be referred to health facilities

Ghana	CCEOP, EAF, Malaria, MR	No differences in coverage by sex, women have limited decision-making power	Geography	Analysis of coverage by sex (DHS data)	Enhanced social mobilisation targeted at women in informal employment, camp-out activities (outreach) in remote areas, container clinics at markets, additional weekend sessions, community meetings, women's and men's groups engagement.
Indonesia	MICS TI	None	Geography	None	None
Kenya	HSS, EAF, TCA	No difference in coverage by sex, lack of autonomy of women	Geographies, urban, refugees, arid and semi-arid lands people, IDPs	Analysis mentioned by data source and details unclear	Engaging community opinion leaders, CSOs and CHVs; tailored messages; engaging both male and female caregivers; conducting sensitization meetings with fathers.
Kosovo	MICS NVI (PCV, Rota, HPV)	Female children have lower vaccine coverage	Specific ethnic groups: Roma, Ashkali and Egyptian	Analysis of coverage by sex (administrative digital coverage data)	Training modules for health care workers on equity and gender related barriers, recurrent analysis of coverage by gender through introduction to target interventions (unspecified)
Madagascar	MRfu	Female children have lower vaccine coverage, low literacy among women, women have low decision-making power.	Low socioeconomic status, households in zones of insecurity, households at distance from health centres	Analysis of coverage by sex (PCCS data)	Sensitization of fathers, tailored messages, door-to-door mobilisation, outreach services, geo-location of overlooked communities.
Mali	Malaria	No difference in coverage by sex of child, low maternal education is correlated with low coverage.	Low socioeconomic status, certain geographies.	Analysis of coverage by sex (MICS, DHS data)	None
Nepal	HPV, MRfu	No difference in coverage by sex or school attendance by sex, women are the decision makers in most households	Geographic barriers (hard to reach areas)	A gender analysis is mentioned (data source and details unclear)	Female vaccinators, outreach, enhanced social mobilisation
Senegal	CCEOP, EAF, HSS, ITU, TCA	Limited decision-making power of women, inconvenient times, lack of knowledge, female health-workers have difficulty accessing remote areas and certain communities	Low socioeconomic status	Analysis mentioned but data source and details unclear	Amended opening hours of vaccination sites, capacity building and trainings for the health staff, communication strategies to create demand, engagement of women's groups and of men.
Sierra Leone	EAF	Female children have lower vaccine coverage, low maternal education correlates with low coverage.	Low socioeconomic groups, certain ethnic and religious groups	Detailed quantitative and qualitative equity analysis by Jhpiego	Engagement of women's groups/ mother-support groups, CSO-supported programme to instigate income-generating activities and/or village-level savings initiatives to overcome mother's time, financial, and literacy constraints, promotion and advocacy for women's rights and their inclusion in the decision-making on healthcare utilization, parent champions, engagement of male caregivers and men's groups, promotion of female healthcare workers.

Syria DAM	EAF	Low literacy among women and general low access to information on vaccines means messages often miss mothers; mothers are principal decision-makers on vaccination; mothers take children to the facility but face barriers travelling long distances to functional facilities alone due to insecurity, cultural barriers, and financing. No evidence of difference in coverage by sex of child. Most health-workers (88%) are female.	Geography, insecurity	Several equity studies referenced including 55 qualitative discussions in 13 out of the 14 governorates of Syria, discussions with key partners and health workers.	Tailored messages, training to reduce missed opportunities, extension of opening hours of facilities, increased outreach, integration of outreach with other services, increased social mobilisation.
Syria NWS	EAF, ITU	Mothers take children to the facility but face barriers travelling long distances to functional facilities alone due to insecurity, cultural barriers, and financing; no difference in coverage data by sex, low education and literacy levels among women, discriminatory attitudes towards women among healthcare workers.	Geography, insecurity	Analysis of coverage by sex (PCCS data)	Recruitment of female community mobilisers, involvement of community members in designing engagement strategies
Uganda FPP	EAF, HSS, TCA	Limited involvement of males in childcare, male dominance in decision making around travel to clinics and financial resources required (which is mostly an issue for mothers of low education), cultural barriers in some groups in accessing care from male healthcare workers	Certain religious and geographically dispersed groups, hard to reach areas, urban populations	In-depth analysis of equity of 2YL programme (CDC), previously published work, and DHS data. A Nice analysis of the reach of different mass communication channels by gender - to inform communication methods.	Focus on community engagement and educational entertainment in communities, given that mass communication methods disproportionately mobilise men.

Most proposed interventions involved general outreach and social mobilisation, while a few were more innovative, for example, (a) CAR FPP engaging communities in microplanning, (b) Chad Malaria and Nepal HPV recruiting more female vaccinators, (c) Madagascar MR follow-up and Ghana EAF establishing father-to-father and spouse support groups/ sensitisation, and, (d) Sierra Leone EAF proposed using a package of interventions to address distal determinants of gender inequity (e.g. income-generation, village-level savings initiatives, literacy, in collaboration with CSOs) and promoting women's rights/inclusion in health decision-making. The Sierra Leone EAF application was a good example of good practice, using in-depth equity analysis to propose a package of interventions. The application also included activities to promote and advocate for engagement of male caregivers and men's groups.

Despite some improvements in equity reporting, data and analyses are still limited. Without general and gender equity being explicitly included in applications, TOCs, and MELs, it is difficult to ensure that strategies will effectively reach un/under-immunised children. Best practice examples for countries could thus be useful along with effective MEL follow-up.

Issue 04: There is lack of streamlined guidance for community engagement integrated into microplanning, equity-focused research and bottleneck analysis, tailored equity-focused activities

Recommendations:

- Gavi and partners to consider implementation of a standard equity and gender analysis tool (e.g. UNICEF Practical Guide to Integrating a Gender Lens into Immunisation Programmes) by all eligible countries to increase clarity and comparability of national efforts to identify challenges and develop solutions.
- Gavi to consider longer-term gender-specific TA support to countries to help them use existing and adapted tools to generate, consolidate, and interpret gender-related data and develop contextualized and pragmatic responsive/transformative interventions across all support applications.

Coverage of zero-dose children

All 19 countries requesting vaccine support used various methods to estimate numbers of zero-dose children (e.g. administrative coverage WUENIC estimates and PCCS coverage). Administrative coverage is often unreliable as often higher than true coverage and leads to underestimates. WUENIC coverage estimates probably provide the most accurate number nationally but do not allow for sub-national estimates. Zero-dose children were generally characterised as concentrated in a few specific communities/sub-populations, such as (a) urban informal settlements, (b) displaced (refugees/IDPs), (c) Conflict-affected areas, (d) low social economic status, (e) hard-to-reach areas, and (f) marginalised ethno-religious groups. Interventions generally included enhanced microplanning, with some applications proposing satellite imagery and GIS software to identify previously overlooked communities.

Issue 05: There is no standardised method for the countries to use in calculating zero dose children and use of administrative coverage data is inappropriate.

Recommendation:

- Gavi and partners to consider developing, or ensuring use of, standardised methodology for countries to calculate national and sub-national estimates of zero-dose children and circulating best practice examples of how to identify, mobilise, and access these groups for vaccination.

Cold Chain, Logistics and Waste Management

The IRC reviewed 6 CCEOP applications (Burundi, Ethiopia, Comoros, Ghana, and Côte d'Ivoire), 6 HSS applications, and 4 measles containing vaccine introduction or campaign applications.

CCEOP

Of the 4020 refrigerators required for financing by the platform, 3,266 (81%) are intended to equip non-equipped sites (extension). This high proportion likely indicates that the basic need to replace malfunctioning or obsolete equipment has been met thanks to the support provided by previous CCEOP grants and other partners, notably for COVID-19 vaccination. Thus, all 6 countries that submitted a CCEOP application are considering extending their cold chain to increase vaccine access in underserved areas.

Overall, the IRC found that the CCEOP applications have improved significantly with the systematic use of data for planning thanks to comprehensive cold chain inventories. Among the best practices and lessons learned by countries, using private service providers for bundled services come up regularly, as developing comprehensive deployment and deviation plans and setting up a project management team. However, several issues may have a negative impact on the implementation of CCEOP. They are related to CCE selection, partners' coordination and information sharing on CC strengthening, CCE decommissioning, temperature monitoring and temperature-related data use for management.

Issue 06: Coordination and information sharing on CCE procurement at the country level is inadequate and may lead to overlapping supports provided by various partners (Senegal, Burundi), or the procurement of equipment does not correspond to the country's needs (Comoros).

Recommendation:

- Support coordinating mechanisms should be ensured among partners for CC and SC-related information sharing (from National LWG to Regional LWG or Global LWG). Country-level coordination should be strengthened through acceleration of strengthening leadership and management capacities.

Issue 07: Temperature monitoring data is not used for planning.

Temperature monitoring systems are not appropriately addressed and none of the countries used temperature data for planning of CC rehabilitation and expansion nor for maintenance activities. Challenges face by countries in the development of temperature monitoring systems may include the multiplicity of models/manufacturers with poor system interoperability, the lack of Standard Operating Procedures and poor integration of temperature data in a computerized management system, the lack of capacity of EPI logistics team and the high capital and running costs with poor visibility on subscription cost and funding.

Recommendation:

- Routine Temperature Monitoring Devices should be included in an overall temperature monitoring policy ensuring deployment of RTMDs is adapted to country capabilities, capacity, and context; update the temperature monitoring system guideline and develop capacity of logistics personnel in country through training and TA.

Issue 08: CCE Selection and CCE decommissioning

CCE selection is in some cases based on invalid, questionable or imprecise criteria and sometimes driven by manufacturers rather than technical specifications which leads to selecting equipment that does not meet country needs (Ghana, Burundi). The performance of the local service providers in resolving installation problems or equipment malfunctions can have an impact on the equipment functionality, and may lead countries to exclude equipment from the manufacturer linked to the service provider (Ghana). CCE decommissioning remains a challenge, although some countries have succeeded in developing guidelines and plans (Ethiopia, Ghana, Burundi). However, plans are sometimes incomplete and not operational, or financing is not specified (Ghana, Burundi). Other countries (Côte d'Ivoire, Comoros, Senegal) did not provide decommissioning plans.

Recommendations:

- Foster the use of the total cost of ownership tool for CCE selection through updated guidelines and TA to ensure that selection criteria include economic data.
- Countries and UNICEF Supply Division should closely monitor service provider performances to enable prompt and effective actions for rectifying any shortcomings.
- Alliance partners to provide guidelines with reference to international environmental regulation, technical solutions, funding solutions, case studies, and TA for the development of the CCE decommissioning plan. Integration of CCE decommissioning with other biomedical equipment should be promoted.

Issue 09: Use of HSS funds for CCE needs

Some countries (Uganda, Kenya, Burundi) use HSS funds to procure CCE, because CCEOP support cannot cover all CCE needs in term of quantity, and not all CCE types are eligible for CCEOP funding (e.g. cold rooms, refrigerated vehicles). The amount allocated to this equipment may limit funding for other key interventions.

Recommendations:

- Priority should be given to immunisation supply chain strengthening interventions including LMIS, strengthening leadership and management, CC maintenance, temperature monitoring system, SC design, decommissioning, and immunisation waste management, funding of comprehensive improvement plan
- Foster integration of Gavi HSS support with other partners' support for health system strengthening (TGF, WF, USAID, GIZ, Expertise France, AfCDC) with a specific focus on supply chain management.

Issue 10: Delays in the development of ciP following EVM assessments

A number of countries delay the development or endorsement of comprehensive improvement plans and these are not linked to the HSS application.

Recommendations:

- Gavi and technical partners should ensure Comprehensive Improvement Plans should be timely (within 6 months after the EVMA) and be directly linked with country immunisation strategies and plans.
- Countries should ensure the HSS budget covers ciP.

Waste management

Waste management continues to be insufficiently addressed across applications for supplementary immunisation activities and health system strengthening. Failure in developing plan or strengthening waste management in HSS applications (Burundi, Comoros, Cote d'Ivoire, Senegal). Ghana and Madagascar did not provide a waste management plan in the MR follow-up campaign PoA. Nepal has to adapt to new national policy banning burning of immunisation waste, without presenting alternative for the planned MR follow-up campaign.

Issue 11: Countries will progressively adapt their regulation to international environmental regulations banning burning, although alternative solutions are often not available within the public health sector in Gavi-eligible countries.

Recommendations:

- Countries should consider the outsourcing of waste management and disposal, including the search for and selection of service providers, contractual arrangements, performance monitoring, and identification of resources.
- Gavi and technical partners to support countries in assessing and planning for waste management, including review of national regulations, mapping of stakeholders (MoH, private sector) involved in waste management and identification of technical solutions.

Budget, Financial Management and Sustainability

Budget overview and quality of budget information

Seven budgets from four countries were reviewed, with a total requested amount of US\$ 41,263,305. Of this, US\$ 33,974,827 (82.34%) was requested from Gavi, US\$ 2,488,634 (6.03%) from government, US\$ 4,501,249 (10.91%) from partners, and US\$ 298,594 (0.72%) from other sources. All countries presented a budget with different contributors. The lowest Gavi request was from Nepal (68%) where the Government was proportion high (32%) representing 90% of all Government contributions presented. Of total the requested Gavi contributions, US\$ 21,490,336 (63%) was for DRC, US\$ 4,756,701 (14%) for Nepal, US\$ 3,068,501 (9%) for Madagascar, US\$ 2,290,495 for Benin (7%) and US\$ 2,368,794 for Ghana (7%). These are shown in Figure 3 and 4 below.

Budget request by vaccines were US\$ 21,490,336 for OCV (1 budget from DRC), US\$ 10,886,433 for M/MR (5 budgets), and US\$ 1,598,058 for HPV (2 budgets) and of the total Gavi contribution, 96% related to Campaign Operational Support (Ops) and 4% for Vaccine Introduction Grants (VIGs).

Figure 3: Overall budget by funding source

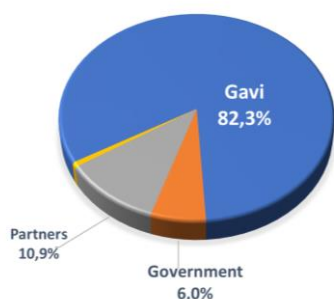
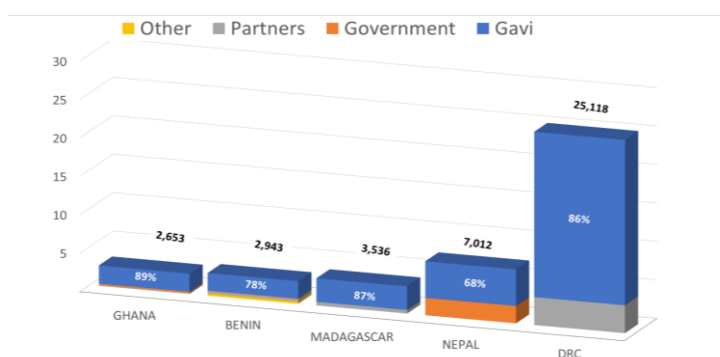


Figure 4: Budgets by country and funding source



There were five FPP budgets reviewed by financial reviewers and presented in this round (Uganda, Cote d'Ivoire, Senegal, CAR and Kenya). The overall quality of budgets presented was satisfactory. Countries used the budget templates properly and provided adequate calculation details. Madagascar, DRC and Ghana presented a separate tab for main budget assumptions linked with all other calculations which ensured consistency and facilitated simulations and review. It is a good practice to be commended and it is easier than having assumptions in separate excel files which was the case in Nepal. There are still some issues in grouping budget items by activities: Madagascar presented a budget that was dispersed across too many budget lines (125 budget lines less than US\$1,000 out of 231 budget lines). DRC also presented their budget dispersed across 159 budget lines for only 25 activities. Kenya had recurrent issues with related activities spread between budget (HSS, EAF, TCA) and issues related to activities proposed that were deemed to be low-value for money (i.e. advocacy to parliament, tracking mechanism for defaulter tracing etc) and high meeting costs.

Issue 12: Despite improvements, countries do not present adequate activity disaggregation by cost input, needed to ensure transparency and accurate financial management.

Recommendations:

- Gavi secretariat to ensure that budget items are adequately aggregated during pre-screening and require revisions before submission to IRC.
- Gavi to improve the budget template to add a special tab for all unit costs assumptions.

HR related costs assumptions and calculations

HR related costs (per diems and transport allowances) represents the highest share of budget which is often the case. For Benin, they represent 78% for OPC and 57% for VIG, for Ghana 61%, for Nepal HPV 58% and for Madagascar they are at 57%. Despite these levels, the costs appeared to be justified. We observed significantly less issues related to HR costs assumptions and calculations for this round especially in the MR applications.

Some issues were observed due to missing or unclear assumptions: countries present different teams' workloads for different delivery strategies without a providing justification. DRC and Benin used a distribution ratio between urban and rural of 60%-40% which was not explained. This may have a material impact on the number of teams as the workload for in urban and rural areas can be significantly different (in DRC the Urban workload is double the rural). Benin budgeted for additional 320 special vaccinations teams (in addition to 3,022 standard teams) to be deployed in the areas with high zero-dose areas but did not provide any detail on calculation neither a link to target population. In Madagascar, there were unclear assumptions related to the number of community Health Workers (CHW) that creates a discrepancy between PoA assumption (4,256 CHW) while the budget used 36,000 (people or 2 per FKT). Nepal also had unclear assumptions with the number of vaccinators required and workload.

Another issue contributing to inflating HR costs is a large number of "DSA related activities" like trainings, workshops, and meetings. Countries tend to budget for a high number of activities, to include large number of participants, or to inflate the number of days. This issue is mainly observed in FPPs but was also observed in DRC OCV application. For example, DRC budgeted for a community leader sensibilization for US\$1.2M (6% of the budget) due to quantities as they included 5 leaders per Health Area (9,625 persons). Also, in DRC planned pre-campaign trainings totalling US \$972k to be organized before each dose administration while the period between the two doses is 2 weeks. For Uganda FPP, Workshops, trainings, and meetings represents at least 20% of the budget with different activities with similar targets and objectives that can represent duplicates or can be merged. Kenya had meetings for US\$2m with unclear objectives. There were also unclear assumptions in transport calculations (ie motorbike hire in Kenya). Figures were given but it was not stated how the quantities were derived and what the HRH usage of these bike would be.

Issue 13: Despite improvements, countries still present budgets with inadequate assumptions and inconsistencies with the Plans of Action resulting in high levels of HR related costs, particularly when budgeting for vaccinators.

Recommendations:

- Gavi and partners to ensure that clear justification for HR requirements for e.g. target groups, delivery strategies, vaccination team composition(s) are provided and aligned with WHO requirements.
- Gavi and partners to show details on transport requirement calculations (i.e. motorbikes and HR).
- Gavi and partners to ensure that the level of events activities are reasonable and explore possibilities of merging activities.

- Gavi and partners to reinforce controls to ensure alignment of Budgets with PoA assumptions and calculations.

Service delivery in FPP applications

FPP applications include service delivery activities with a significant budget share in most cases. These activities are budgeted by cost inputs (number of districts, health facilities, regions) without clear linkage with coverage targets. This creates challenges in assessing the reasonableness of estimations and therefore calculating value-for-money. Uganda FPP budgeted for bi-annual Integrated Child Health Days for US\$4M (8,5% of the budget) or quarterly island to island vaccination for US\$588k (1% of the budget) including outreach vaccination services but did not present the targets to be reached. The same with Central African Republic (CAR) which budgeted for outreach services in 23 districts for US\$414k and PIRIs in priority districts for US\$515k. The budget was calculated based on assumptions of days and frequency per district, but no link was provided to the target population to validate these assumptions.

Issue 14: The service delivery activities are budgeted in FPP applications by cost inputs without a link with target populations which prevents from assessing the reasonableness of assumptions.

Recommendation:

- Gavi and partners to ensure that service delivery activities budgeted in FPP applications are linked to target population.

Allocation of resources between funding streams

Gavi funding can be provided to countries through different funding streams (NVS, TCA, HSS, EAF, ITU, CCEOP, etc.) and allows, with conditions, to use funds from a stream to fund other needs. During this review, we observed several examples of allocations of expenses that should be funded by another funding stream (or Gavi grant type). In most situations, countries use this allocation when they reach the ceiling of the adequate funding stream. For example, HSS funding was used for US\$7M of cold chain expenses out of US\$36M Uganda budget. A large share of this investment was eligible for a CCEOP grant however they reached their ceiling. Similarly, Kenya included cold chain in their HSS for US\$2.1M. Uganda also included technical assistance for US\$105k under HSS while these items are usually covered by the TCA funding stream. Campaign funding was used in the case of DRC OCV for items that overlaps with other streams: Technical assistance of WHO/ UNICEF TA for US\$486k usually under TCA was requested in the OCV budget and recurrent management costs for US\$287k that usually falls under HSS. While these allocations are aligned with guidelines, these examples can indicate that there is a need to adjust ceilings or funding streams guidelines and processes to align with country's needs.

Issue 15: Countries use different funding streams for the same or similar activities.

Recommendation:

- Gavi and partners to consider reviewing ceiling criteria and allocation of different streams guidelines.

Civil Society Organizations (CSOs)

Countries are required to allocate at least 10% of combined HSS, EAF and TCA ceilings for CSO implementation, as they submit new funding requests to Gavi. However, the CSO allocation by country is not always visible to IRC reviewers in the budget. In other instances there is often a discrepancy in what is reported in the budget vs what is reported in the pre-screening. The budget has a column where countries can indicate if the funds are for a CSO - (Uganda reported pre-screen - 8.6% vs Uganda budget document: 7.3% and Kenya reported pre-screen: 2.2%; Kenya budget:0%). In addition, applications consider activities such as mapping of CSOs as CSO allocations. Such activities should not be considered as CSO implementation activities as CSOs do not receive the funding. There are also instances of CSO allocation where 100% is allocated to a partner (MOH) for capacity building and no other funding to that CSOs for implementation.

Applications also have little or no details on where/how they plan to engage with CSOs. One country (Indonesia) in this round invited CSOs to the consultation of the application. There was however no engagement in terms of addressing challenges – which could be around gender and equity, or in service delivery and demand creation. The budget template has a column for a sub-recipient, however only one country (Ghana) gave any details. In addition, the narrative seldom describes any role that CSOs could/would provide.

Issue 16: CSOs receive little to no funding and their role is not clearly indicated.

Recommendations:

- Gavi should require all applications to indicate in both the narrative and the budget template what resources will be allocated to CSOs.
- Allocation of funds to CSOs should be a requirement at the submission.

Health Information Systems and Monitoring and Learning (MEL)

Estimating the number of zero-dose children

Issues with estimating the number of zero dose children (ZDC) are recurrent. In the applications reviewed by the IRC, several sources of estimates were used by different countries, including administrative data, Institute for Health Metrics and Evaluation (IHME), and WHO/UNICEF National Immunisation Estimates (WUENIC). In the case of Uganda, the above-mentioned methods for estimating ZDC were used in addition to data from measles/rubella surveillance, polio risk analysis and polio campaigns. While this shows that several options are available to countries for estimating ZDC, it reveals the need for support by technical partners in analysing various data sources. As part of routine EPI and disease control programs, several countries organize activities that entail door-to-door visits by vaccination teams or community health volunteers. Malaria chemoprophylaxis and vaccination campaigns are examples of activities involving home visits.

Issue 17: Countries applying for support from Gavi should include in their application data from all sources used for estimating zero dose children.

Recommendations:

- Gavi and technical partners should support countries in analysing data from multiple sources to improve estimates of ZDC.
- Technical partners should consider advising countries in adapting methods such as those used for estimating prevalence, incidence and population size estimates of HIV.

Issue 18: Countries regularly conduct door-to-door activities which are often missed opportunities for estimating ZDC.

Recommendation:

- Gavi and technical partners should support countries in developing strategies that take advantage of the opportunity offered by home visits or door to door campaigns in obtaining estimates of ZDC.

Post campaign coverage surveys: guidance for counties applying for Gavi support

There is some misalignment between the requirements for a post-campaign coverage survey (PCCS) between Gavi and the World Health Organization (WHO) resulting in countries submitting applications with different timelines for conducting PCCS. The Gavi funding guidelines indicate that a PCCS should be conducted as soon as feasible, within three months, whereas the WHO reference manual for cluster coverage surveys recommends that the PCCS, field work should start no later than a month after the campaign.

Issue 19: Misalignment of guidance from Gavi and WHO on the conduct of PCCS.

Recommendation:

- Gavi and WHO should align the requirements for PCCSs so that the countries have a unique and clear understanding of the timelines for conducting PCCS.

Use of available case-based epidemiological data

It is encouraging to see that countries are conducting comprehensive analysis of available epidemiological data in their applications. However, data analysis should be accompanied with appropriate interpretation of the results such that the chosen vaccination strategies align with the data. Benin, Madagascar and Nepal submitted proposals for measles follow-up campaigns and presented appropriate analyses of currently available data, including outbreaks. On the contrary, Ghana presented analyses of measles data, but the interpretation of the results was inaccurate and therefore, could not justify the strategy proposed for the measles follow-up campaign.

Issue 20: There is a need to strengthen the analysis and interpretation of epidemiological data analyses in country applications.

Recommendation:

- Technical partners should support countries to do a thorough analysis and interpretation of the data supporting justification and vaccination strategies.

Middle Income Countries (MICs)

Two countries applied for support for this window. Kosovo was a new review of a never-eligible country for US\$ 1,064,392 in one-time vaccine catalytic funding to introduce PCV, Rota vaccine and HPV vaccines into the routine immunisation programme. While the Kosovo proposal was of a very good standard, it is worth noting that inclusion of up to three new vaccine support proposals in one application only allowed a high-level review as the application did not have sufficient detail on operationalisation and sustainability.

Indonesia was a re-review of a formerly eligible country applying for US\$11,457,013 for a 2-year period. This was a revised application linking technical partners to activities to address vaccination back-sliding and

un/under-immunised children and improving national capacity in planning, implementation, and monitoring catch-up vaccinations. The revised proposal largely addressed re-review issues, but remained unclear as to how government will sustain gains when funding ends.

Issue 21: MICs applications tend to be high level and do not provide sufficient details on operationalization of proposed activities and sustainability after support ends.

Recommendations:

- Gavi to consider clarifying review templates/criteria to consider long-term sustainability for MICs.
- Gavi to consider requesting MICs Targeted intervention support to elaborate sustainability pathways to ensure routine immunisation is strengthened and immunisation backsliding addressed.

Full Portfolio Planning reviews (FPP)

Seven countries submitted FPP applications that incorporated a number of requests. They included Burundi (HSS, EAF, TCA, ITU, CCEOP), the Central African Republic- CAR (HSS, EAF, TCA), Comoros, (HSS, TCA, CCEOP) Cote d'Ivoire, (HSS, EAF, CCEOP), Kenya (HSS, EAF, TCA), Senegal (HSS, EAF, CCEOP, TCA, ITU) and Uganda (HSS, EAF, TCA). All FPP applications were recommended for approval except for the ITU request in Burundi which was recommended for re-review. The primary reason for the re-review was that the request for proposed scale-up of an innovation lacked documentation, the narrative and timeline were lacking and there were major uncertainties in relation to the budget and high level of HR costs

Key findings

Key issues common to applications were: (a) the high dependence on external donors especially related to funding of operational activities without viable transition plans, thereby hampering long-term resiliency and sustainability. This was noted in Comoros, Kenya, Cote d'Ivoire, Madagascar, Senegal and Uganda, (b) Lack of optimal leveraging of the private sector in EAF proposals such as seen in Senegal, which is a missed opportunity to close the loop on zero-dose children. In addition countries like Cote d'Ivoire, resources from EAF were to be used to replace HSS funding instead of focussing on strategies to cover unimmunized and under-immunized children, (c) limited investments in improving immunisation data (CAR, Comoros), (d) Non-alignment of the FPP application with the National Immunisation Strategy (Cote d'Ivoire) and, (e) Countries still struggle to estimate the number of zero-dose children for planning of targeted interventions (Cote d'Ivoire, Comoros). For the application from Burundi, the HSS with the exception of the traveller's building rehabilitation (US\$1.3 million).

For the support window of Immunisation Top Up (ITU) funding, the applications reflected limited or no engagement of the beneficiaries in the country and often, proposals were to support digitalization systems that were often not evaluated for effectiveness, not integrated with existing systems and unsustainable as there were no buy-ins from the country. Justification for proposed interventions were not provided (Burundi).

Recommendations:

- For EAF funding requests, countries should be required to reflect the engagement of the private sector in closing the gap for zero dose and under-immunized children.
- Gavi should stress that the country NIS should inform the preparation of the FPP applications.

- Technical support should be provided to countries requesting ITU funding to ensure proposed innovations are aligned with the existing systems and sustainability considerations are given priority.

4. Conclusions

The September 2023 IRC reviewed a total of 64 requests for Gavi support from 30 countries. Sixty-two (96.9%) of the requests were recommended for approval. The IRC noted that the quality of the applications for NVS and campaigns continues to improve as proposed activities are increasingly based on robust situation analyses and epidemiologic data. The newly introduced discussion between the IRC and the applicant countries requesting MR support was particularly enriching and offered an opportunity for engagement and clarifications for issues not clear to the IRC reviewers. The support for Oral Cholera Vaccine is a game changer in cholera control but the IRC review raised the important issue of ensuring there is limited disruption of routine services as the strategy for vaccination is complex and involves mobilisation of health workers for a prolonged period. For FPP application, the IRC noted that the weakest aspects were Immunisation Top-up funding requests primarily because the proposed activities and innovations were not clearly outlined and not aligned with the needs of beneficiaries in the country and often not sustainable. Finally, the IRC noted that in almost all applications, countries struggle to estimate the number of zero dose children and the methods used are often inappropriate. This calls for urgent action from the Gavi and Alliance partners to advise approaches and develop methods that could be recommended. Exploration of similar methods such as those used in the HIV/AIDS programme for estimating prevalence of HIV could be an appropriate approach.

5. Acknowledgements

The IRC would like to thank the Gavi Executive Team for their continued support of its work, the FDR team for their excellent organization of the meeting and Noelia for coordinating the travel of IRC members.

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

Annex 1. IRC members participating in September 2023 meeting

	Name	Nationality	Profession/Specialisation	Sex	Review language	Expertise
1	Beatriz Ayala-Öström	UK, Sweden, Mexico	Independent consultant	Female	EN, SP, PT	Health system strengthening, supply chain management
2	Blaise Bikandou	Congo, France	Independent consultant	Male	EN, FR	HSS, project/program management, Preparedness and response, vaccine preventable diseases, epidemiology
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	Katherine Gallagher	UK	Assistant Professor of Epidemiology, London School of Hygiene & Tropical Medicine (LSHTM) and KEMRI-Wellcome Trust Research Programme, Kenya	Female	EN	Infectious disease epidemiology (particularly human papillomavirus, ebola, pneumococci, and to some extent SARS-CoV-2) and vaccine delivery
6	Natasha Howard	Canada, UK	Associate Professor, NUS School of Public Health and LSHTM	Female	EN, FR, SP, AR	immunisation service delivery, health policy, HPV, measles, malaria, Covid-19, EAF, FER settings
7	Philippe Jaillard	France	Director of EpiLinks	Male	EN, FR	Health and immunization supply chain management, training and educational engineering
8	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
9	Landry Kaucley	Benin	Director of Logistics, National Agency for Vaccination and Primary Health Care, Benin	Male	EN, FR	Immunization supply chain management, routine immunization, epidemiology and disease surveillance, mass campaign management and health economics.
10	Wassim Khrouf	Tunisia	Auditing and Consulting Worldwide, Partner	Male	EN, FR	Financial & budget analysis, audits, project assessment
11	Stefano Lazzari	Italy	Independent Consultant	Male	EN, FR	Outbreak, epidemic and emergency response, HSS, Prevention and control of infectious, monitoring and evaluation of health programs; capability building
12	Dominique Legros	France	Independent Consultant	Male	EN, FR	Epidemiology of infectious diseases in developing countries, surveillance and early warning systems, vaccinology, operational research, management of outbreaks and of complex emergencies
13	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
14	Viviana Mangiaterra	Italy	Associate Professor, SDA School of Management, Bocconi University, Milan	Female	EN, FR	HSS, Maternal and Child Health, Malaria, HIV and TB
15	Nkengafac Villyen Motaze	Cameroon	Associate Professor of Epidemiology, Medicine Usage, Northwest University, South Africa	Male	EN, FR	Vaccinology, epidemiology, systematic reviews, evidence-based practice
16	Sandra Mounier-Jack	France, UK	Professor in Health Systems and Policy, LSHTM	Female	EN, FR	HPV, measles, immunisation programmes, HSS, health policy and health financing
17	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
18	Benjamin Nkowane - Vice-chair	Zambia	Independent consultant	Male	EN, FR	Measles, epidemiology, mass vaccination campaigns, technical support for field operations in risk areas

19	Gavin Surgey	South Africa	Radbound University Medical Centre	Male	EN	Financial and Budget Analysis, Health Economics, Health Financing Strategies, Program M&E.
20	Bolanle Oyeledun	Nigeria	Chief Executive Officer Centre for Integrated Health Programs (CIHP), Nigeria	Female	EN	HSS, MNCH, immunisation, adolescent reproductive health & HPV, programme assessments and evaluations
21	Abdel Tibouti	Morocco/ Canada	Independent consultant	Male	EN, FR	Financial and Budget Analysis, Health Economics, Health Financing Strategies, Program M&E
22	Beena Varghese	India	Independent consultant	Female	EN	Evaluation of health interventions including cost and cost-effectiveness analysis; Health financing
23	Erika Wichro	Austria	Independent consultant	Female	EN, FR	Emergency settings, outbreak response, HSS, polio, Ebola, measles, COVID-19, surveillance, epidemiology