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

March 2022

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List of Acronyms

ACSM	Advocacy, Communication and Social Mobilization
ADIW	Appropriate Disposal of Immunisation Waste
AEFI	Adverse event(s) following immunisation
bOPV	Bivalent oral polio vaccine
CAR	Central African Republic
CCE	Cold-chain equipment
CCEOP	Cold-chain equipment optimization platform
CEO	Chief executive officer
cMYP	comprehensive Multi-Year Plan (for immunization)
COVID-19	Coronavirus Disease 2019
cVDPV	circulating Vaccine-Derived Poliovirus
DHS	Demographic and Health Survey
DSA	Daily Service Allowance
EPI	Expanded Programme on Immunization
EVM	Effective Vaccine Management
EYE	Eliminate Yellow Fever Epidemics
FPM	Financial and Public Management
GII	Gender Inequality Index
HCWM	Health Care Waste Management
HSCC	Health Sector Coordinating Committee (or Council)
HPV	Human papillomavirus
HR	Human resources
HSS	Health System Strengthening
ICC	Inter-Agency Coordinating Committee
IMCI	Integrated Management of Child Interventions
IPV2	Inactivated Polio Vaccine 2nd dose
IRC	Independent Review Committee
MCV	Measles-containing vaccine
MICS	Multi-Indicator Cluster Survey
MR	Measles-Rubella Vaccine
NNHS	National Nutrition and Health Survey
NITAG	National Immunization Technical Advisory Group
NVS	New Vaccine Support
ODPs	Operational Deployment Plans
Ops	Operational Support
PCV	Pneumococcal conjugate vaccine
PCCS	Post Campaign Coverage Survey
Penta	Pentavalent vaccine (DTP, Hib, HepB)
PFM	Public financial management
PHC	Primary Health Care
PoA	Plan of Action
PSC	Programme Support Costs
RI	Routine Immunization
SAGE	Strategic Advisory Group of Experts on Immunization
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
SCM	Senior Country Manager
SIA	Supplementary immunization activity
TA	Technical assistance
TCA	Targeted Country Assistance
ToR	Terms of Reference
VPD	Vaccine preventable disease
WUENIC	WHO and UNICEF estimates of national immunization coverage
YF	Yellow Fever

Executive Summary

The Gavi Independent Review Committee (IRC) met from 15 to 22 March 2022 and reviewed applications from 5 countries. This was the eighth IRC meeting held virtually because of the COVID-19 pandemic. Nine IRC members participated throughout this round with a wide range of expertise. Areas of expertise of the IRC members included immunisation services; surveillance of vaccine preventable diseases (VPD); immunization safety; health development and health systems strengthening (HSS); outbreaks, epidemics and emergency response; management and evaluation of health services; health policy and planning; primary health care (PHC); epidemiology; reproductive health; cold chain and supply chain management; health care waste management; health economics, health financing, grant management and auditing. Two members conducted in-depth financial reviews and one focused on supply chain and waste management.

The IRC members focused on the following tasks during the review (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. In particular, the IRC paid attention to the guiding principles of the Gavi 5.0 policy in the applications. Review modalities included an independent desk review of by designated members and virtual discussion in plenary with the participation of the full committee. One member of the committee reviewed a request for IPV2 support remotely in advance of the meeting. Applications were for measles/rubella campaign support (Eritrea, Syria-North West Region (NWS), rubella containing vaccine introduction (Sudan), Human Papillomavirus Vaccine (HPV) introduction (Mali), and IPV2 introduction (Moldova).

Results

The IRC recommended approval for two of the three applications for measles-rubella campaigns/ introduction support, and the HPV vaccine introduction. The overall total funding approved was US$16.74 million for a target population of 22,573,343. The IPV2 introduction request was for vaccine support only. The IRC noted that applications that were re-reviews (Sudan and Syria NW) showed improvements in equity analyses, zero-dose focus and differentiated strategies, while the new applications were weak in all aspects of equity analyses. Gender analyses, including examination of barriers to access, remained weak in all applications. Persistent weaknesses included under-utilization of available data from surveillance in developing contextualized strategies, cold chain gap analysis remained poor and waste management activities were rarely budgeted for. Budget presentations were improved in this round but adherence to the recommended thresholds for human resources and transport, the two key drivers of the operational support budget, was poor. This weakness also related to the lack of links between delivery strategies, including low ratios of vaccination teams and targeted children in each context that do not follow WHO recommended standards, leading to inflated budgets. Finally, the IRC noted best practices in the applications. These included from Sudan, attention to social norms by selecting local female vaccination team members, establishing a pool of temporary staff/vaccinators that can be quickly mobilized, and conducting quarterly monitoring and annual mapping of hard to reach and special populations with ad hoc updates during emergencies. Syria (NWS) lifted the upper age limit for measles vaccination and plans to use equity analysis data for addressing hesitancy among parents.

Methods and Processes

The Gavi Independent Review Committee met from 15 – 22 March 2022 by Zoom. This was the eighth virtual meeting because of the COVID-19 pandemic. IRC members communicated by email or met individually by Zoom outside the plenary sessions.

Nine IRC members participated in this round with areas of expertise including immunization services; VPD surveillance; immunization safety and adverse event(s) following immunization (AEFI); health systems strengthening (HSS); outbreaks, epidemic and emergency response; management and evaluation of health services; health policy and planning; primary health care (PHC); epidemiology and burden of disease; reproductive health, cold chain and supply chain management; health care waste management; biomedical equipment maintenance, health economics, health financing, grant management and auditing. Two members conducted in-depth financial reviews and one focused on supply chain and waste management (see Annex 1 for the list of participating IRC members). Two members of the IRC served in additional roles: interim chair, Benjamin Nkowane and vice-chair, Sandra Mounier-Jack.

The meeting agenda, country review assignments, country applications with supporting documents, and briefing presentations by Country EPI programme managers requesting measles/rubella support were shared with IRC members on 3 March 2022, 12 days before the start of the meeting. IRC members reviewed and analyzed these applications and prepared draft reports on their assigned countries. The Secretariat provided clarifications and any additional documentation the IRC members requested.

The meeting was opened by Ms Anuradha Gupta, Deputy CEO of Gavi. She welcomed the IRC members and reflected on Gavi 5.0 overarching ambition of reaching zero-dose and missed children. She emphasized the Gavi target of reducing by 25% the number of these children by 2025, while recognizing the difficulties brought about by the COVID-19 outbreak which has severely compromised access to immunization services. Ms Gupta updated IRC on the Gavi Board's approval of the new Equity Accelerator Funding (EAF) envelope of US$1 billion available to help countries accelerate efforts to reach zero-dose children and missed communities with tailored strategies. Ms Gupta also updated the IRC on the Gavi segmentation of countries which has now been re-structured into (a) five high impact countries that comprise 60% of zero-dose children world-wide; (b) fragile and conflict-affected countries; and, (c) remaining Gavi-eligible countries. This segmentation attempts to bring in more tailored and targeted approaches. For the March 2022 IRC meeting, she noted that the number of applications was small due to the slowdown of new vaccine introductions over the last two years, reduced programme space as a result of the COVID-19 pandemic and a rigorous pre-screening process. In addition, the overall impact of COVID-19 on routine EPI has resulted in a 5% drop in DTP3 coverage, with 4/5 million children not vaccinated. She also emphasized the importance of countries requesting support to ensure that all children vaccines on time and give priority to introduction of the second dose of measles. To prevent outbreaks, areas with stagnation or drop in coverage (sub-national gaps) should be quickly identified.

Additional briefings by secretariat and technical partners included an update on actions regarding previous IRC recommendations, background on the EPI Manager presentation for M/MR applications, updates on the measles, rubella and Human papillomavirus vaccine, the COVAX facility and COVID-19 status globally and specifically in applicant countries. An update was provided by the Financial and Public Management (FPM) team on its work and the IRC and the financial review.

Review process

Each country proposal was reviewed by a primary and a secondary reviewer, except for the Moldova IPV2 application which was reviewed by one IRC member. Each IRC member reviewed the application and supporting documents independently and prepared separate, individual reports. Cross-cutting issues related to budgets and financial sustainability and supply chain and waste management were reviewed in each application by one financial crosscutter and one IRC member specialized in supply chain management. These reports were presented during the daily virtual plenaries and the initial findings were extensively discussed. The IRC then came up with the final, consensus outcome recommendation of either approval or re-review for each application. Specific action points for the country and Gavi to follow-up were agreed upon during the plenary. The Gavi Secretariat and Alliance partners supported the plenaries by providing information and clarifications when needed, on country-specific background and context. The first reviewers then consolidated the reports from the different reviewers and the outcome of the plenary discussion, including decisions and recommendations. These drafts were then finalized after editing, fact checking, consistency checking, and quality review. The five applications from five countries reviewed are presented in Table 1.

Table 1: Country applications by type and review modality

Countries	Application/ Support requested	Gavi requested amount Operational Costs and Switch grants (US$)	Number of applications
Eritrea	MR follow-up campaign	302,250	1
Mali	HPV Introduction	780,050	1
Sudan	MR Introduction with Catch-up campaign	14,947,774	1
Syria (NWS)	MR follow-up campaign	1,014,263	1
Moldova*	IPV2 Introduction	Not applicable**	1

** IPV2 introduction application was reviewed remotely by one member of the IRC in advance of the meeting.*
*** Moldova requested only IPV vaccine and did not request the "Switch Grant".*

Criteria for review

Review of the applications was guided by the IRC Terms of Reference and key criteria in line with Gavi's mission. These include justification for the proposed activities, soundness of approach, country readiness, feasibility of plans, contribution to system strengthening, programmatic and financial sustainability, and public health benefits of the investment. The IRC adhered strictly to these guidelines to ensure the integrity, consistency, and transparency of the funding decision.

Decisions

There were two decision categories:

1) **Recommendation for Approval** when no issues were identified that would require re-review by the independent experts. In this case, the minor issues raised by the IRC will be addressed by the country in consultation with the Secretariat and Partners.
2) **Recommendation for Re-review** when there were critical issues that require a new review by the independent experts; this will entail detailed revision of the application and a revised submission to the IRC.

Table 2 presents the review outcomes for this round. Four of the five applications were recommended for approval and one was recommended for re-review.

Table 2: Requests from Countries and Review Outcomes

Countries	Application/ Support requested	Target population	Recommendation
Eritrea	MR follow-up campaign	465,012	**Re-review**
Mali	HPV Introduction	325,019	**Approval**
Sudan	MR Introduction with Catch-up campaign	22,573,343	**Approval**
Syria (NWS)	MR follow-up campaign	758,057	**Approval**
Moldova	IPV2 Introduction	32,000	**Approval**

Thematic areas sub-committees

During the review, IRC members, organized in six sub-committees (New vaccine support; Equity, zero-dose focus, gender analyses, and differentiated strategies; Data use and quality; Best practices and country innovations; Supply chain and waste management; Budget, financial management and sustainability. Each sub-committee identified specific issues in the applications that would be of general interest for Gavi and partners and could be presented in the debriefing session with Gavi Senior Management, Secretariat staff and partners as well as in this report. The suggested issues were reviewed and agreed upon in a plenary session on 21 March 2022.

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

The debriefing was held on 22 March 2022. A summary of the IRC meeting's review outcomes and key issues and recommendations from the IRC to Gavi and Alliance partners was presented. This was followed by a brief discussion, questions/comments, and responses from the IRC. At the end of the debriefing session, Ms Anuradha Gupta, Deputy CEO, Gavi expressed her appreciation for the work of the IRC and the recommendations from the review. She emphasized the challenges in countries still not demonstrating they were using and triangulating available data, the gap that exists in approaches to reaching missed children, and the concern that countries with high routine EPI coverage and recent follow-up campaigns that reached over 90% coverage verified by post campaign surveys are likely to vaccinate the same children previously reached by routine and campaigns. She also noted the weaknesses in gender analyses and lack of budgeting for critical activities such as waste management. She noted the positive trend by countries to develop differentiated strategies for reaching zero-dose children and missed populations and the need to provide technical assistance for contextualizing strategies and budgets.

Key Findings and Recommendations

NVS (Routine and Campaign support)

The IRC reviewed four applications from five countries for Measles/Measles-Rubella support (Eritrea, Syria (NWS), Sudan), HPV introduction (Mali) and IPV2 introduction (Moldova).

Measles and Measles-Rubella applications

Applications were reviewed from three countries for NVS support: two for MR follow-up campaigns [Syria (NWS), Eritrea], one for rubella vaccine introduction with MR catch-up campaign (Sudan). Of the requests, Syria (NWS) and Sudan applications were first reviewed in March 2021 and June 2021 respectively and were recommended for re-review at that time. The two countries improved their proposals based on the IRC feedback and were approved this round, while Eritrea was recommended for re-review. Funds requested amounted to US$17.05 million and the total amount recommended for approval was US$16.75 million, of which US$2.260 million was for vaccine introduction and US$14.49 million for MR campaign operational costs.

Rapid Convenience Monitoring during measles-rubella campaigns

All countries applying for measles-rubella campaign support mentioned rapid convenience monitoring while the campaign is still ongoing (intra-SIA RCM) in their plans of action, and only Syria (NWS) also planned to conduct post-SIA RCM using third party at the end of the follow-up campaign (Table 3).

Table 3: Summary of findings on RCM in applicant countries' plans of action and budgets

Country	Rapid Convenience Monitoring (RCM)			
	Type and/or Methodology	To be conducted by whom (implementer)	Mop-up triggers adequately explained	Inclusion in the budget
Eritrea	• intra-SIA RCM/ LQAS	Supervisors	No	No
Syria (NWS)	• intra-SIA RCM • post-SIA RCM	third party monitors third party monitors	No No	Yes, for RCM and mop-up
Sudan	• intra-SIA RCM	Supervisors	No	Yes, for RCM No, for mop-up

While the designation of RCM implementers usually follows the global guidance (i.e. supervisors for intra-SIA RCM and independent monitors for post-SIA RCM), methodology of RCM does not appear clear to countries and triggers for mop-ups remain inadequately described or not explained. Further, inclusion in the budget is difficult to discern as the role of supervisors and monitors in the budget is not always explicit, and budget for mop-ups is generally lacking. This leaves IRC with doubt that RCM which should be planned early and adapted to the needs of the country will be implemented and followed by mop-up activities as needed.

The IRC reiterates the importance of intra-SIA and post-SIA RCM for finding children missed during the campaign to vaccinate them and identify reasons for non-vaccination, while defining areas for mop-up. As a simple pass/fail assessment, RCM does not use random sampling and does not produce

coverage estimates. Rather, it provides information on general SIA performance and suggests how strategies can be refined to reach hardest-to-reach in rapid corrective action, being it while the SIA is still ongoing or quickly afterwards. Along with quantitative information, RCM can contain useful qualitative information which can help improve the routine programme. Therefore, it is important that intra- and post-SIA RCM are planned and budgeted for during the macro- and micro-planning. In addition, it should be ensured that the tools/forms used for RCM are adapted to the needs of the country, triggers for mop-up defined, mop-up budgeted for and adequate training conducted to assure its proper implementation.

Issue 01: Rapid convenience monitoring (RCM) is generally included in campaign applications but the types, methodology and implementers are not well described and appear to be unclear.

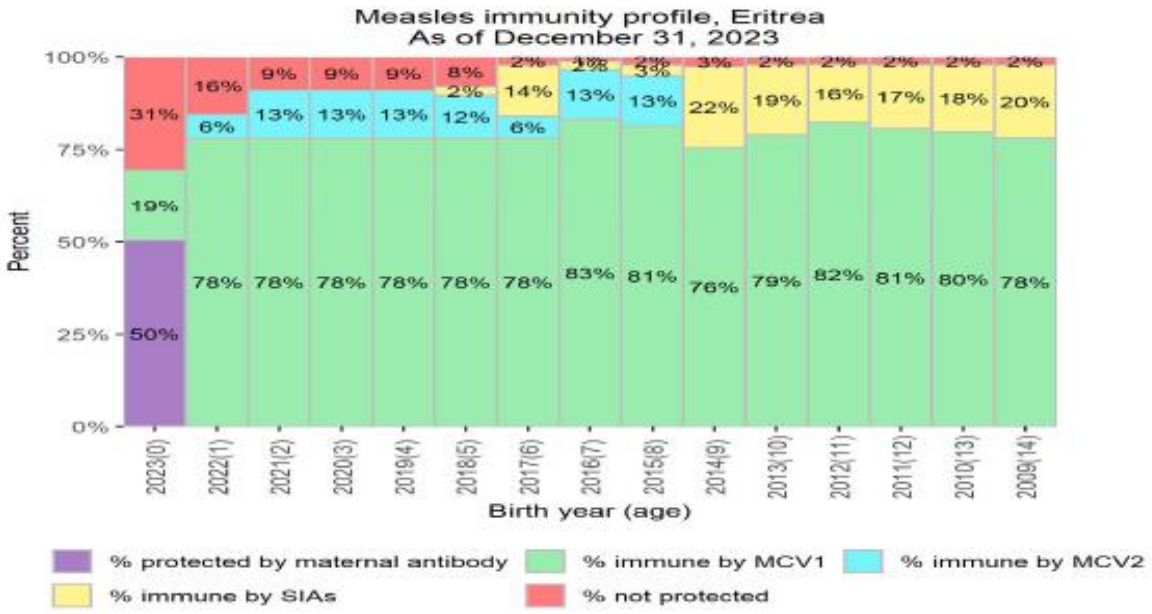
Recommendations:

- Countries should be encouraged to follow the global guidance and to use RCM while the campaign is still ongoing (intra-SIA RCM) and at the end of it (post-SIA RCM), to ensure that the children missed in the campaign are found and vaccinated in mop-up.
- Gavi and technical partners should support countries in better understanding, planning of, and budgeting for RCM, to include adequate tools and triggers for corrective action.

Nationwide non-selective measles follow-up campaigns

The IRC repeatedly expressed satisfaction with Gavi flexibility for the funding of M/MR SIAs as it allows countries to innovate and use the effort to reach consistently missed children. This would be particularly true for high-performing countries such as Eritrea with MCV1 coverage of 93% and MCV2 coverage of 85% since 2017, very high card retention (>90%), and last follow-up SIA coverage of 98% by survey. While Eritrea has practically eliminated measles, it is not using surveillance data to show it. To support its justification for the follow-up campaign, Eritrea presented the measles immunity profile (Figure 1) and its concern about measles importation because of porous borders.

Figure 1: Eritrea measles immunity profile



In reviewing the measles immunity profile for Eritrea, the IRC noted that most campaigns reached the same children that were reached before through the routine programme. Further, the trend analysis of measles-confirmed cases by age shows that prevalence of cases is higher in the age group above 5 years.

With non-selective nationwide campaign planning, irrespective of heterogeneity of vaccination coverage and population dynamics, it is unlikely that the new communities will be reached and the SIA have a desired impact. Residual susceptibility is likely in older cohorts which would not be reached by the follow-up SIA anyway. It should be noted however, that while Eritrea tracks defaulters in the routine programme, this is only up to 23 months of age and that its updated immunization policy draft, foreseeing school entry requirement and checks, and no upper age limit for measles vaccination, has not yet been enacted. Enacting the policy with no upper age limit for measles vaccination would be important, so that routine strategies could be adapted according to the local situation.

Issue 02: Persistent reliance in well-performing countries on nation-wide non-selective SIAs that do not reach previously missed older cohorts, which is where this residual susceptibility likely is, would not be included in the target and thus SIA would not add to the population immunity.

Recommendations:

- Gavi should continue encouraging countries and partners to shift the focus from non-selective nationwide SIAs and emphasize funding flexibility, especially in high-performing countries with low measles susceptibility in children <5 years of age.
- Countries should adapt national policies to allow for vaccination in older age groups, in particular school age, with no upper age limit for measles vaccination, and enact these policies fully; and introducing school entry checks as a screening and catch up mechanism.
- Gavi and partners should encourage countries to foster local innovations to address concerns of measles importations and missed children in selected districts.

Rubella containing vaccine (RCV) introduction into routine programmes

In this review, Sudan applied for a wide-age-range MR campaign in which three phases, planned for February, April and March 2023, would follow a nation-wide introduction planned for January 2023. The catch-up campaign would target all children aged 9 months to 14 years, with an added cohort of 6-9 month old infants at high risk of severe malnutrition in specific identified areas.

While in its previous submission in March 2021, which was recommended for re-review by the IRC, Sudan proposed that RCV introduction followed the staggered campaign, no clear justification for reversing the order of campaign and introduction and diverging from global guidance was provided in this submission.

When introducing rubella vaccine into the routine vaccination programme, the preferred approach is to conduct a wide age-range MR catch-up campaign in the initial phase, to include all children from 9 months to <15 years of age. Introduction into routine should rapidly follow, ideally a month after the catch-up campaign, or within 6 months from the campaign at the latest. The aim of this approach is to protect as many children as possible to ensure that a shift in the age distribution of incident cases to older age groups, and in particular to child-bearing age, does not happen. Achieving high-campaign coverage and sustaining it through the routine immunisation would interrupt the

transmission of rubella virus and avoid risk of congenital rubella syndrome (CRS).

In the case of Sudan, following the global recommendation would mean conducting the staggered catch-up campaign before the RCV introduction in the planned timeframe, and introducing MR vaccine into routine programme ideally in May 2023 for all at 9 and 18 months of age. Reversing the order of interventions as Sudan proposes would require a change in the lower age of the catch-up campaign target with accordingly decreased budget, and would likely lead to missing some infants who would be <9 months old at the time of introduction and not included in the campaign. This would also make the inclusion of 6 to 9 month old infants in the campaign more programmatically difficult. Therefore, reversing the order of interventions should not be a viable option.

In addition, Gavi funding guidelines limit the target population age range for the catch-up campaign to 9 months and under 15 years of age, requiring that any expansion of the age group is funded by the country. While this approach is entirely reasonable given the overall goal of such intervention, given that this is also a measles campaign, a fragile country would certainly benefit from the opportunity to expand the lower age-range to 6 months to offer additional protection to special populations identified as in high risk of severe malnutrition.

Issue 03: Reversed order of campaign and introduction in preferred approach to introduce rubella vaccine into the routine immunization programme

Recommendations:

- Countries should be strongly encouraged not to diverge from the global guidance and recommendations for rubella introduction, to avoid missing children and potentially shifting the incidence of the age distribution to older age groups.
- Gavi should consider funding the expansion of the age group to 6 to 9 months of age in MR catch-up campaigns on a case-by-case basis, to take advantage of the intervention and to align with global recommendation to offer a supplementary dose of MCV to 6 to 9 months old infants for internally-displaced, refugee, and conflict-affected populations, especially if at high risk of severe malnutrition.

Second dose of IPV (IPV2) introduction

Moldova applied for support to introduce the second dose of IPV in routine immunization programme. The country chose to maintain the IPV1 schedule at 6 months and introduce IPV2 at 22-24 months. The choice for 22-24 months is primarily for operational reasons and acceptance (no more than two injections at any vaccination visit). This schedule is in line with the SAGE recommendation of no less than 4 months between IPV1 and IPV2. The country requested support for vaccine only. The IRC requested the country to consider contingency for additional vaccine as a result of current influx of refugees from neighbouring Ukraine.

Equity, zero-dose focus, gender analyses and differentiated strategies

Equity and gender review is pivotal to developing tailored strategies to address specific barriers. The IRC review of equity and gender found that more applications included primarily examinations of

geographical barriers and consideration of special groups such as refugees, internally displaced and nomadic populations. In particular, the 2 countries that were submitting applications after the IRC recommended re-review previously (Sudan and Syria (NWS)) had adequate analyses; the other 2 countries were more superficial in their analyses.

All four countries largely limited analyses of coverage and gender equity to differences in coverage by sex. Sudan included a statement that there was a certain degree of gender disparities in some areas, albeit without documented evidence to conclude on its effect on immunization services. In these areas, vaccination teams are selected from the local community and female volunteers are engaged to ensure the provision of vaccination in routine immunizations and campaigns. Other applications, including for HPV introduction , included no strategies to address gender barriers.

The development of differentiated strategies to address special populations was closely related to the identification step. Sudan and Syria (NWS) which did an improved analysis were also able to identify specific demand and supply side barriers, though not all identified barriers were explicitly included in the differentiated strategies. Estimations of the percentage of the population affected by a given challenge remained theoretical, perhaps an inherent limitation of the available data. Eritrea and Mali, which provided inadequate analyses also provided unspecified differentiated strategies.

Issue 04: Whereas applications that were re-reviews showed improvements in equity analyses, zero-dose focus and differentiated strategies, gender analyses remain weak in all applications. New applications were particularly weak on all aspects of equity analysis, including examination of barriers to access related to gender.

Recommendation:

- As the analysis of barriers, in particular those faced by marginalised population groups, remains limited in first time applications, Gavi and partners should provide additional TA to develop contextualised strategies to address equity, zero-dose children and gender.

Data Quality and Use

Data driven root cause analyses

All countries prepared root cause analysis and identified different intra-country contexts with varying level of difficulty, and target populations were determined from a range of sources of data. Syria (NWS) used data from routine EPI and SIAs, MCH home visits and Third Party Monitoring reports. Sudan updated the 2019 EPI micro-plans and annual vulnerable population estimates and Eritrea used population estimates from the National Statistics Office and local administration. The countries listed the barriers and differentiated strategies to reach the target population in most intra - country context groups. However, how the target populations in each intra-country context was calculated was not clear or explained. The IRC however noted that proposed solutions are generic, high level and standard practices (advocacy, social mobilization, health education), which are not detailed.

Issue 05: The POAs in all countries do not show the data analysis or triangulation methods used to determine the target populations in each intra-country context and the proposed solutions remain generic.

Recommendations:

- Countries should provide the data analysis and describe triangulation methods used to determine target populations for each intra-country context.
- Gavi and technical partners should support countries in conducting the in-depth root cause analysis and develop detailed and tailored differentiated strategies.

Epidemiological analysis of surveillance data

All countries have presented national level measles or rubella surveillance performance indicators for the last five years. However, subnational level surveillance performance was only provided by Syria (NWS). Epidemiological analysis of surveillance or outbreak data of measles and rubella by age, vaccination status, geographic location and other relevant characteristics (e.g. nomadic, displaced) of cases was inadequate. Although both Sudan and Eritrea have integrated measles and rubella case-based surveillance, Sudan provided age distribution for rubella cases only while Eritrea provided age distribution for measles cases only. The vaccination status of measles cases, which is critical for developing strategies, was only provided by Sudan but this was not disaggregated for suspected and laboratory confirmed cases.

Issue 06: Available data from case-based surveillance for measles and rubella remain underutilized by countries for developing appropriate differentiated strategies.

Recommendations:

- At a minimum, applications for measles/MR vaccine support should include trends in vaccination status of the cases from surveillance and outbreak investigations by age group.
- All applications should provide subnational surveillance performance indicators.

Best Practices and Country Innovations

The IRC noted some best practices and innovative approaches described by countries in areas of planning and implementation to improve their campaign and immunization performance. Best practices noted from Sudan included careful attention to social norms by selecting female vaccination team members from local communities to ensure provision of service, establishing a pool of temporary staff/vaccinators that can be quickly mobilized, and conducting quarterly monitoring and annual mapping of hard-to-reach and special populations with ad hoc updates during emergencies. Syria (NWS) lifted the upper age limit for measles vaccination and plans to further study hesitancy among parents to be able to adequately address it.

Supply chain and waste management

Effective Vaccine Management Assessment (EVMA)

The IRC noted that, in all four countries, Effective Vaccine Management Assessment (EVMA) were conducted within the recommended timeframe of 5 years with two of them (Sudan and Syria NWS)

using the new EVM 2.0 tool. Only one country (Eritrea) scored above the threshold EVM score of 80%. All countries developed their comprehensive supply chain improvement plan and are monitoring level of implementation. Eritrea should be commended for its high performance with a jump of 30 points while efforts should be put in place in Sudan which experienced a drop of 20 points between two assessments.

Countries did not provide an updated CCE inventory gap analysis, and passive devices were not accounted for. Considering that over the past year a considerable amount of CCE has been delivered to countries, this should be reflected in the gap analysis provided by countries and inventory should be a routine activity for supply chain staff and not done in a rush because of an upcoming Gavi NV or SIA application. Gavi should consider asking countries to add to their analysis the recently procured CCE listed in various Operational Deployment Plans (ODPs). To allow meaningful analysis, the "WHO supply chain sizing tool" should accompany the CCE inventory gap analysis (most countries are familiar with the tool as it was used in the 2021 COVAX/CCE applications).

Dry storage is equally important as cold storage to safeguard ancillaries from weather conditions and theft, but countries generally remained silent around this matter except Sudan.

Issue 07: Persistent weaknesses in cold chain gap analysis: Tools with outdated CC inventories; passive containers not considered; and dry storage not evaluated.

Recommendations:

- The IRC reiterates its previous recommendation and urges that standardized "CCE Inventory and Gaps Analysis Tool" including passive contains and "WHO Sizing Tool", both based on inventory not older than 6 months should be mandatory for all applications.
- Dry spaces availability and adequacy should be systematically analyzed and included in the supply chain preparedness section.

Waste management

Some progress was noted in this round with well-described waste management procedures and activities (Mali, Syria NWS, and Sudan). However, most countries failed to have their planned activities reflected in the budgets.

Issue 08: Countries rarely budget for planned waste disposal activities and do not have comprehensive waste management plans.

Recommendation:

- Planned waste management activities should be appropriately budgeted, and countries strongly encouraged to develop/update their comprehensive nationwide multiyear waste management plans.

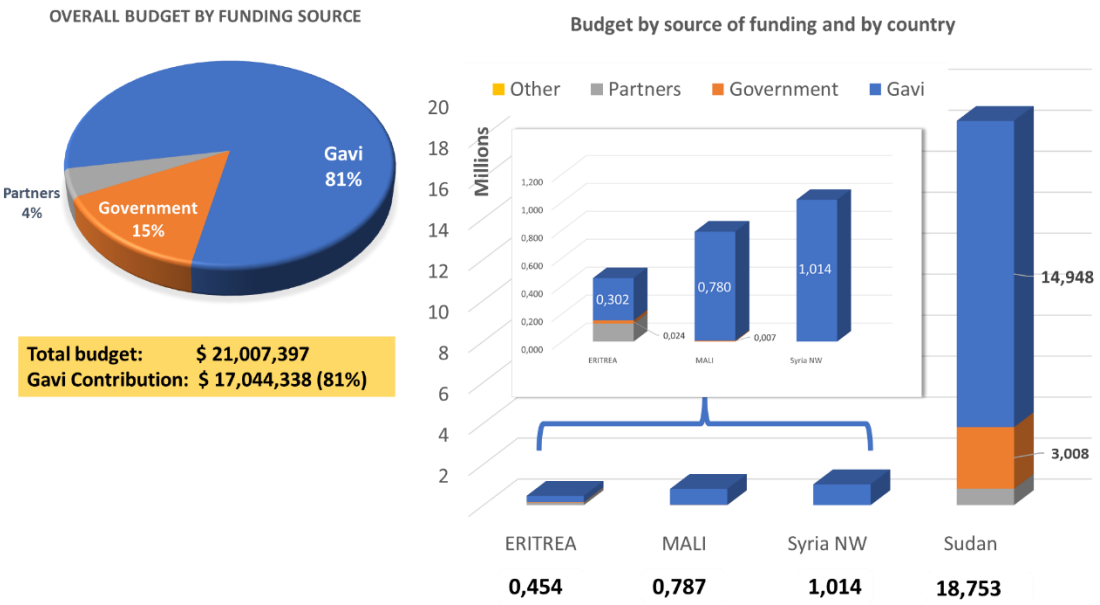
Budgets, Financial Management and Sustainability

Budget overview

The four applications this round had five budgets totalling US$21,007,397. The requested Gavi contribution was US$17,004,338 (81% of total), while government contributions were 15%. This relatively high proportion of non-Gavi contribution due to Sudan's government contributing

US$3,008,354 (20% of total budget). Partner contributions amounted to US$924,684 (4% of total budgets). Syria (NWS) requested 100% Gavi funding. Figure 2 shows Sudan, Eritrea and Mali government contributions and Sudan and Eritrea with Partner contributions.

Figure 2. Non-Gavi contributions



Eritrea presented a total budget of US$453,784 to be funded at 67% by Gavi and the rest by Government and other donors. Syria presented a 100% request to Gavi and the Mali request was at 99%. The share of the Gavi contribution by antigen was 95% (US$ 16,300,000) for Measles-Rubella, and 5% (US$ 780,050) for HPV. OPC budgets accounted for 86.78% (US$ 14,800,000) and VIG accounted for 13% (US $2,300,000) of the total requests to Gavi.

Operational costs for MR applications

When analysed per child, Sudan and Eritrea were within the grant limit of US$0.65 per child for campaigns and the average for all budgets presented was US$0.67. Syria (NWS) budgeted US$1.34 per child under Gavi's Fragility, Emergencies Refugees policy. The breakdown of Gavi contribution for all applications (MR and HPV) by activity shows that an average 64% of budgets will be used for service delivery (with a wide range of 16% in Mali to 85% in Eritrea), 14% will be used for capacity-building (varying from 3.04% in Syria (NWS) to 39% in Mali), 11% for procurement and supply chain management (mainly due to Sudan budgeting US$1,871,530) while Syria (NWS) budgeted only 1%. The breakdown of Gavi contributions by input costs shows that on average 37% will be used for human resources (range 20% in Mali to 41% in Sudan), 31% for transport (range 10% in Mali to 44% in Eritrea), and 17% for events-related costs (range 3% in Syria (NWS) to 65% in Mali).

Introduction of 5.0 budget templates

Mali and Syria (NWS) used the new Gavi 5.0 template, but did not complete all required tables, e.g. the new 'Theory of Change' tab and costs of differentiated delivery strategies to reach zero-dose and missed populations. Overall, although issues remain, there is general improvement in budget presentations with reduced classification errors and unit cost inflation.

Issue 09: Countries still using old budget templates or not using the new 5.0 templates properly and not reflecting costs for differentiated strategies in the budgets

Recommendation:

- Gavi and partners to provide TA support to countries on completing the new 5.0 budget template

Staffing requirement and HR-related costs

The Gavi 5.0 HR guidelines have improved the analysis of HR costs, but issues with compliance remain. The new guidelines introduced an indicative limit of 40% of HR related costs to the total budget (HR & HR-related costs, with inclusion of HR events and travel related costs). In this IRC review, three out of the four countries, Mali, Eritrea, and Sudan submitted budgets with HR related costs of 46%, 44%, and 41% respectively which are above the limit, while for Syria (NWS), the HR budget was at 38%. The main driver of these high costs is the inaccurate estimation of staffing requirements, which appears to be a recurring issue.

The delivery strategies are better presented in the new POA template but the link with target populations is lacking: Countries do not present the target population to be reached by each strategy in line with WHO standards, and/or this breakdown is not reflected in the budget calculations. This often leads to a low ratio of target population to vaccination teams and subsequent over-estimation of staffing costs. For example, Mali's budget used a standard vaccinators number depending on the number of health facilities and not linked to the target population (1 day per month for 8 months) which leads to a ratio of 20 vaccinations/day/team and Eritrea presented the WHO standard vaccination ratio in the POA, but actual number of vaccinations teams for the target population was much lower (49 vaccinations/day/team).

Issue 10: Countries are still not budgeting within the recommended HR thresholds and although differentiated delivery strategies are better presented in the POA, the link between vaccination team numbers and targets is lacking.

Recommendations:

- Gavi Secretariat to continue current efforts in pre-screening budgets with focus on the appropriate use of the budget template, and alignment of the budget with the POA *(staffing requirement vs target population*).
- Gavi and partners to sustain ongoing efforts to fully implement past IRC recommendations, including:
  a) Ensure that technical staff and finance staff work together on budget preparation
  b) Requesting countries to demonstrate that budgets are aligned with POAs
  c) Ensuring inclusion in the budget of the costs associated with operationalizing differentiated delivery strategies.
  d) Ensuring that campaign staffing requirements are calculated based on WHO standards
  e) Adhere to the budget thresholds for HR costs.

High transport costs

Gavi 5.0 places a threshold of 10% on transport costs (vehicles rental and fuel) and this new threshold seems to be creating challenges for countries. In this review, Mali was at 10 % and the three others

were not within the threshold; Syria (NWS) was at 19%, Sudan at 33%, and Eritrea at 44%. Staffing numbers, calculation errors, non-justification of quantities, number of vehicles and days for vehicle hire are main drivers of the high transport costs. For example, Eritrea did not present any explanation for the number of vehicles to be rented and the budget contained calculation formula errors in fuel consumption and rented camels. Mali's budget did not present details on the fuel assumptions for supervision and used a high fuel ratio of 20 litres/km.

Issue 11: Non-compliance with Gavi 5.0 transport cost thresholds.

Recommendation

- Gavi and Alliance partners to work with countries so that they adhere to the recommended 10 % transport threshold costs when they prepare the budgets.

Non-budgeted activities

The IRC continues to express concern that key priority activities are not budgeted in the application as a recurring issue. In this review, Eritrea and Mali did not budget for waste management expenses despite the descriptions in the POAs. Mali and Syria (NWS) did not include budgets for microplanning activities and due to lack of detailed explanations in the budget items of Eritrea, some training activities indicated in the POA appeared excluded from the budget, for example, training of health workers and community volunteers in interpersonal communication and counselling (IPCC), community engagement around key measles rubella vaccine messages, and the training related to safety were not reflected in the budget.

Issue 12: Key priority activities such as waste management, microplanning and training reflected in the POA are often under-funded or unfunded

Recommendations:

- Gavi and Alliance partners to request countries to:
  a) Ensure that technical staff and finance staff work together on budget preparation and ensure all priority activities are reflected in the budgets or explicitly indicated if funded by non-Gavi sources.
  b) Country applications should demonstrate that budgets are aligned with POA activities by cross-referencing budget lines to relevant sections of the POA.

Sustainability and financial management

In this IRC, Syria (NWS) and Mali are requesting 100% and 99% funding support respectively for the New Vaccine (NVS). This poses severe sustainability challenges. In particular, Mali did not present clear future funding plans for the HPV program, which is important for long-term strategic planning once HPV vaccine is introduced in the country. For Syria (NWS) and Mali, the funds will be managed by WHO and UNICEF and Eritrea will rely on their Governmental PMU for the management of the grant. Sudan is facing a difficult economic situation manifested by devaluation of local currency, high inflation rate and decrease in purchasing power of the local currency as well as rapid unpredictable increase in prices of commodities and fuel. Given the political situation in Sudan, Gavi is in the process of evaluating the risks and designing the fund flow mechanism for all grants to ensure safeguarding of Gavi funds/investments and effective implementation of the grants.

Issue 13: Countries do not provide enough details on the financial sustainability of their programs and on financial management capacity within the PMU's for the Operational budget, in some cases, accounting capacity needs reassessment.

Recommendations:

- Gavi and partners to provide more long-term TA to countries to improve financial management of grants.
- Gavi to request from countries more efforts to demonstrate their plans to improve programs sustainability.

Review process

Pre-screening

The IRC noted that 4 applications for this round were returned to countries after pre-screening. This suggests that extensive assistance is urgently needed for improving the application process. Progress on strengthening applications appears better for technical aspects and the POAs are more complete and accurate than in previous rounds. However, the IRC noted that a deeper inspection can often reveal that the POAs are generic, minimally contextualised, or with sections that are copied directly from preparation guidelines. This suggests a checklist approach to application preparation rather than an improved use of data or methods.

Issue 12: The large proportion of applications that are returned to countries and the insufficient contextualization of POAs and budgets remain a challenge for countries.

Recommendations

- Gavi to work with partners to strengthen TA for Gavi budget template and ensure POAs sufficiently consider country contextual realities.

EPI manager presentations

Presentations were useful and provided the opportunity for questions and answers (Q&A). Presentation slides did not appear to add much to application documents and may have been an added burden for the EPI managers. A better approach might be a short 5-minute highlights presentation of proposal rational, strategy, and challenges followed by a Q&A session.

Recommendation:

- Gavi to continue piloting EPI manager presentations, but reduce presentation length (e.g. to approximately 5 minutes and 3 slides covering justification, application process challenges, intended outcomes) with approximately 20 minutes for Q&A.

Gavi 5.0 guidelines issues and adherence

Countries that used 5.0 budget template and 5.0 POA templates made noticeable efforts to adhere to the guidelines though they still had difficulties, particularly with Gavi's Theory of Change template sheet. Equity and gender analyses, despite their importance for Gavi 5.0, did not appear to have

improved significantly among new applications since previous rounds. However, the IRC did note improvements in these areas in re-review applications.

Recommendation:

- Gavi and partners to provide more training to countries in using Gavi 5.0 templates.

Conclusion

The IRC appreciates the efforts of the Gavi Secretariat and technical partners in ensuring that previous IRC recommendations are implemented. This is reflected in improvements in use of the new Gavi 5.0 POA template and attempts to contextualize proposed interventions. Countries do not however fully use available epidemiological data such as vaccination status of measles cases from both surveillance and outbreaks and subnational surveillance data in the design of interventions. The IRC noted improvements in budget presentations due to pre-screening with focus on the appropriate use of the budget template and alignment of the budget with the POAs. The IRC however noted that the primary drivers of the operations budget in applications are transport and human resources and these are overestimated. Often, this is because staffing requirements, such as vaccination team composition and numbers are not linked to target populations for the differentiated strategies and do not follow WHO recommended standards. Gavi and technical partners should ensure the recommended budget thresholds are adhered to and applications should demonstrate the links between the POAs activities and the budget by cross referencing.

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Finally, we wish to recognize the essential contribution of the Alliance partners who supported countries in preparing the applications, attended the contributions and clarifications on global policies and strategic issues.

Annex 1: IRC Members for the 15 - 22 March 2022 Meeting

	Name	Nationality	Profession/Specialization	Gender	French	Expertise
1	Aleksandra Caric	Croatia	Independent consultant	Female	FR	Measles, AEFI Surveillance and vaccine safety, programme management, primary health care.
2	Teklay Desta	Ethiopia	Measles elimination advisor to Ethiopia Ministry of Health	Male		Managing immunization programs, Vaccine Preventable Disease surveillance and outbreak investigations, NVS introduction and data management.
3	Natasha Howard	Canada	Associate Professor, NUS School of Public Health and LSHTM, Singapore	Female		HPV, immunisation service delivery, FER settings.
4	Sandra Mounier-Jack, Vice-Chair	France/UK	Associate Professor in Health Policy, LSHTM Faculty of Public Health and Policy	Female	FR	HPV, measles, immunisation programmes, HSS, health policy and health financing.
5	Wassim Khrouf	Tunisia	Auditing and Consulting Worldwide, Partner	Male	FR	Financial & budget analysis, audits, project assessment.
6	Alex Nartey	Ghana	Independent consultant	Male	FR	Health financing, public financial management, project management, funds and grant management.
7	Benjamin Nkowane, Interim Chair	Zambia	Independent consultant	Male		Measles, epidemiology, mass vaccination campaigns, technical support for field operations in risk areas.
8	Ousmane Tamba Dia	USA, Senegal	Independent consultant	Male	FR	Routine immunization, Project/Program management, Supply chain management, Biomedical equipment maintenance, Health care waste management.
9	Karen Wilkins	USA	Independent consultant	Female	FR	Routine immunisation, measles, polio, surveillance, planning & evaluation.