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

September 2022

Table of Contents

List of Acronyms

2YL	Second year of life
ACSM	Advocacy, Communication and Social Mobilization
AEFI	Adverse event(s) following immunisation
bOPV	Bivalent oral polio vaccine
CCE	Cold-chain equipment
CCEOP	Cold-chain equipment optimization platform
CEO	Chief executive officer
CHW	Community health-worker
cMYP	comprehensive Multi-Year Plan (for immunization)
COVID-19	Coronavirus Disease 2019
cVDPV	circulating Vaccine-Derived Poliovirus
DHS	Demographic and Health Survey
DSA	Daily Subsistence Allowance
EPI	Expanded Programme on Immunization
EVM	Effective Vaccine Management
FED	Fragility, Emergencies and Displaced Populations Policy
GII	Gender Inequality Index
HBR	Home Based Records
HCWM	Health Care Waste Management
HSCC	Health Sector Coordinating Committee (or Council)
HPV	Human papillomavirus
HR	Human resources
HSS	Health Systems Strengthening
ICC	Inter-Agency Coordinating Committee
IMCI	Integrated Management of Child Interventions
IPV2	Inactivated Polio Vaccine 2nd dose
IRC	Independent Review Committee
IRMMA	Identify – Reach – Monitor – Measure – Advocate
MAC	Multi-age cohort
MCV	Measles-containing vaccine
MICS	Multi-Indicator Cluster Survey
MR	Measles-Rubella
NNHS	National Nutrition and Health Survey
NITAG	National Immunization Technical Advisory Group
NVS	New and underused Vaccine Support
ODP	Operational Deployment Plan(s)
Ops	Operational Support
PCV	Pneumococcal conjugate vaccine
PCCS	Post-Campaign Coverage Survey
Penta	Pentavalent vaccine (DTP, Hib, HepB)
PFM	Portfolio Financial Management
PHC	Primary Health Care
PoA	Plan of Action
PSC	Programme Support Costs
RCM	Rapid Convenience Monitoring
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
SFP	Strategy, Funding and Performance
TA	Technical assistance
TCA	Targeted Country Assistance
ToR	Terms of Reference
VPD	Vaccine preventable disease
WUENIC	WHO and UNICEF estimates of national immunization coverage

Executive Summary

The Gavi Independent Review Committee (IRC) met in Geneva, Switzerland from 26 to 30 September 2022 and reviewed applications from three countries. Eight IRC members participated throughout this round (six in person and two by Zoom), with a wide range of expertise that included measles and rubella (MR) disease epidemiology and vaccinology, human papillomavirus (HPV) epidemiology and vaccinology, supplementary immunization activities, health services delivery and strengthening, disease surveillance, field operations and emergency settings, vaccine supply chain and management, cold chain logistics, health economics, financial and budget analysis and programme monitoring and evaluation. Two IRC members conducted in-depth financial and budget reviews of the applications and two others focussed on the supply chain, logistics, vaccine management and waste management. The IRC focussed on the following; (a) Review of countries' funding requests and supporting documentation for vaccine introductions and campaigns to support national efforts to improve immunization coverage and equity; (b) Production of country-specific review reports and recommendations; (c) Development of a consolidated report of the review round, including recommendations for improving funding requests and strengthening routine immunization; and (d) Provision of recommendations to the Gavi Board and Alliance partners on improving processes relating to Gavi policies, governance, and structure. Review modalities included an independent desk review of each application by two designated members and discussion in plenary with the participation of the full committee.

Results

The IRC recommended approval for the application from Yemen (MR follow-up campaign), but to support the target age group 6 months to 5 years only. The application from Nigeria (HPV introduction with a multi-age cohort) was recommended for re-review primarily because there was limited use of sub-national data to justify allocation of resources and demonstrate efforts to ensure equity in HPV vaccine access. The application from Sierra Leone (MR follow-up campaign) was also recommended for re-review because it did not demonstrate how this campaign would reach zero-dose or partially vaccinated children to materially improve coverage. The IRC noted that all three countries made some effort to present equity and gender analyses but these remained minimal and largely descriptive. Epidemiological analysis of available surveillance data on measles and rubella was weak or not done and therefore not used to inform the prioritization of target groups and strategies. The IRC is of the view that countries often lack capacity to undertake appropriate and relevant analysis of available data and therefore fail to develop data driven approaches to vaccinate zero-dose and reach missed communities. Finally, the IRC noted that the thorough Gavi pre-screening process and interaction with countries has resulted in significant improvements in the quality of budgets. In this round of review, the major weakness remained the alignment of the budgets with the proposed strategies.

Methods and Processes

The meeting agenda, allocation of countries for review, country applications, supporting documents and briefing materials were shared with the IRC on 16 September 2022, 10 days before the start of the meeting. IRC members reviewed the applications and prepared individual draft reports of their assigned countries. The Secretariat provided clarifications and additional documents or information requested by the IRC members. Two members of the IRC served in additional roles: Benjamin Nkowane, interim chair and, Beatriz Ayala-Öström, vice-chair. The meeting was opened by Mr Johannes Ahrendts, Director, SFP who welcomed the IRC members and outlined the expectations for

the review. Mr Ahrendts also updated the IRC on the Gavi 5.1 priorities and the shift in work of the HLRP to multi-year approvals and regular performance monitoring of Gavi supported countries. This was followed by updates by Secretariat and WHO on Measles and Rubella, and the HPV vaccine programme. The technical briefings outlined key issues and areas the IRC should consider in relation to the requested support. An additional briefing was provided on the updated Fragility, Emergencies and Displaced Populations Policy (FED) which came into effect in July 2022.

Review process

Each country proposal with the accompanying documentation was reviewed independently by a primary and a secondary reviewer, each preparing individual report. Cross-cutting issues (budgets, financial sustainability, supply chain and waste management) were reviewed in each application by one financial crosscutter and one IRC member specialized in supply chain management. The individual draft reports and recommendations were presented and 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. The first reviewers then consolidated the reports from the secondary and cross-cutting reviewers in line with the outcomes of the plenary discussion, including decisions and recommendations. The IRC then developed recommendations of either approval or re-review (based on consensus) for each application. In each application, action points, or issues to be addressed, were agreed upon during the plenary. The reports were then finalized after editing, fact and consistency checking and quality review.

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, 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.

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; this will entail detailed revision of the application and a submission to the IRC.

Table 1: Summary of requests from countries and review outcomes

Countries	Application/ Support requested	Target population	Requested amount Operational Costs (US$)	Review Outcome
Nigeria	HPV Introduction + Multi-Age Cohort	18,282,848	13,630,832	Re-review
Sierra Leone	MR follow-up campaign	1,373,240	892,606	Re-review
Yemen	MR follow-up campaign	11,477,965 (6 mo - 9 yrs)	6,166,386	Approval (6-59 mo)

Thematic areas sub-committees

During the review, IRC members were organized into five sub-committees (New vaccine support; Equity, zero-dose focus, gender analyses, and strengthening routine immunizations; Data use and quality and review process; Supply chain and waste management; Budget, financial management and sustainability). Each sub-committee identified 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.

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

The de-briefing of the Gavi Secretariat and partners was held on 30 September 2022. A summary presentation of the meeting's outcomes and key issues and recommendations from the IRC was presented. This was followed by a brief discussion, questions, comments, and responses. During the closing session, Dr Seth Berkley, Gavi CEO, expressed his appreciation to the IRC members for participating in the review and providing recommendations on the country applications. He also thanked the interim chair and vice-chair of the meeting, Benjamin Nkowane and Beatriz Ayala-Öström for the agreeing to facilitate and manage the meeting.

Key Findings and Recommendations

NVS (Routine and Campaign support)

Measles and Measles-Rubella applications

During this IRC review, two countries, Sierra Leone and Yemen applied for measles-rubella (MR) support for follow-up campaigns. Both countries requested support for wider target group age-range: Sierra Leone from 6 to 59 months, and Yemen from 6 months to 9 years of age. Funds requested for operational costs amounted to US$7.06 million. Sierra Leone application was recommended for re-review. Sierra Leone last conducted an SIA in 2019 and did not demonstrate how this campaign would reach zero-dose or partially vaccinated children to materially improve coverage. Yemen's application was approved for target age range 6 to 59 months. Yemen's routine coverage is low and is relying on SIAs to control measles.

Justification for proposed interventions and shift in campaign objectives

Following previous IRC recommendations, countries presented routine coverage data and epidemiological analyses to justify their applications. The quality and completeness of these analyses varied, especially in terms of describing age-specific and subnational immunity profiles validated by case data. There was limited information provided from outbreak investigations and responses, with majority of cases having 'unknown' vaccination status. The countries provided measles immunity profiles, but did not compare these calculated profiles with the age distribution of cases. Sierra Leone's application targeted children aged 6-59 months without backing the request for extended lower age with adequate analysis. Yemen's application targeted 6 months to 9 years of age when the standard upper age for follow-up campaign (i.e. 59 months) would have been more appropriate based on the epidemiologic data presented. Given the Yemeni current context, target age range lowered to 6 months is justified.

Countries did not reflect on their stagnant MR1/MR2 coverage and high (>20%) MR1/MR2 drop-out rates which confirm programme challenges to vaccinate in the second year of life. IRC also noted that

the countries plan for nationwide non-selective follow-up campaigns in 3-5 year cycles as the primary means to achieve the high level of population immunity in the attempt to control measles. This is in contrast with findings from post-campaign coverage survey for example from 2019 MR follow-up campaign in Sierra Leone. The post-campaign coverage survey showed that 2019 SIA achieved 93% coverage and identified that of those vaccinated 3% of children had no prior vaccination against measles in the routine programme and only 0.2% had no prior vaccination during routine or previous SIA. Bottlenecks in reaching zero-dose children from previous SIAs were not referenced and there was no focus on increasing MR2 coverage. No data were presented to support another national campaign in the context where it is clear that specific strategies to identify and reach zero-dose children are needed, potentially at the sub-national level. IRC notes with concern that although countries make effort to present differentiation in proposed strategies, they do not factor information available in country such as from equity assessments, DHS, MICS or EPI surveys into their planning. IRC reiterates that SIAs will have the greatest impact if they reach those not reached in the routine or in previous campaigns.

Issue 01: Limited use and interpretation of the available data and recommendations to determine the target group for MR SIA and campaign objectives

Recommendation:

- Technical partners should support countries in how to justify the target group age range. Specifically, countries should justify any changes from the standard follow-up SIA target age recommendation, i.e. 9-59 months.
- Gavi and technical partners should encourage countries to use the available data when determining the geographical scope, target age range, special and underserved populations, and appropriate SIA strategies. Countries should justify a choice for national non-selective SIA where a national or sub-national but selective SIA may achieve the objectives.
- Along with national and subnational coverage, the proportion of and distribution of zero-dose children reached during SIAs should be used as an indicator for quality of campaigns.

Routine immunization strengthening objectives

Both applicant countries introduced MCV2 in their national vaccination schedules (Yemen in 2005 as MCV and as MR in 2015) and Sierra Leone as MR in 2019. Both countries however still strongly rely on nation-wide campaigns to reach the previously unreached in the routine programme. While campaigns provide such an opportunity if adequately planned, prepared and implemented, they should not serve as a replacement for efficient routine programme or a deterrent to immunizations throughout the life course. In fact, there should be a strong focus on increasing MR2 coverage to ensure that all children receive two doses of MR vaccine. This process requires different strategies, often accompanied with the need to change immunization policy and legislation. IRC notes with pleasure that Yemeni immunization policy has no upper age eligibility for MR vaccination. Sierra Leone immunization programme, while offering various catch-up opportunities, still limits the MR vaccine eligibility to 23 months, restricting the opportunities to catch up for missed MR vaccinations through other encounters with the health system. This does not align with objectives with IA 2030 strategic priority 4 (Life-course and integration). Neither of the applicant countries mentions the 2YL platform as an opportunity, through the delivery of other interventions that have high community

demand, to reach the children in and beyond the second year of life to close the coverage gap between MR1 and MR2.

Issue 02: In spite of repeated IRC recommendations, countries are reluctant to change their immunization policies and limit eligibility for MR1 and MR2 in the routine programme, leading to reduced opportunities for catch up of late vaccinations and an over-reliance on SIAs.

Recommendation:

- Gavi and partners to further encourage and assist countries in updating their immunization policy and support its enactment, to be aligned with WHO guidance and recommendations, and adhere to IA 2030 strategic priorities.

Integration of vaccine campaign cards with existing health records

There were large repeated budgets requested for specific campaign vaccination cards (Table 2), as they continue to play an important role in documenting vaccinations during the campaign both for personal record keeping as well as for cross-checking during surveys and monitoring.

Table 2. The amount budgeted for campaign vaccination cards in each application

Country	Amount budgeted for cards	% of the total budget
Sierra Leone	US$ 243,478	27%
Nigeria	US$ 1,350,351	10%
Yemen	Not included	-

However, there is a low retention of these one-time cards and they lose their value for PCCS as these usually happen several months after the campaign, and not 1 to 2 weeks after the campaigns as recommended in WHO guidelines. While this may appear aspirational, if planned 9 to 6 months before the campaign as recommended, this goal can be achieved. Unlike the one-time vaccination cards, home-based records (HBR) are much better safe-guarded, though IRC seldom has an insight into their design or quality. As with all the recording tools, the HBR get occasionally reviewed by the programme, which offers an opportunity to improve its design and which, as a result, may improve how information is gathered and used. While electronic immunization registries continue to be explored and are generally not-supported by donors, an option to include section on supplementary vaccinations into HBR should be considered/tested.

Issues 03: Vaccination cards included in budgets of most requests: high volume, low retention

Recommendations:

- Countries to consider including the section on supplementary immunizations in their Home-Based-Records (HBR).
- Gavi and partners to support and assist countries in redesign of HBR, and document the process, points to consider and positive examples.

Human Papillomavirus Vaccine national introduction

During this review window, the IRC reviewed one application for HPV vaccine introduction support in Nigeria. This application targeted a routine cohort of 9-year-old girls with an initial multi-age cohort (MAC) campaign for 10-14 year-old girls. Operational support requested was US $13.6 million. This application was recommended for re-review.

Nigeria supplied state-level data that were used to select states in each phase of implementation but did not use these data in their application to justify targeting the resources required for delivery of the vaccine. Although specific strategies to reach specific groups were mentioned, the approach across the country was not differentiated. The size and distribution of target populations across states was not used to allocate resources. Instead, every ward was allocated the same resources, a strategy which does not adequately consider areas with a greater proportion of out-of-school and hard-to-reach populations. Information provided by state and Local Government Administrations (LGAs) could have also been used to highlight areas in which a more resource intensive delivery strategy might be required.

Issue 04: Limited use of sub-national data to justify allocation of resources and demonstrate efforts to ensure equity in HPV vaccine access

Recommendation:

- Partners to provide guidance on the justification required to demonstrate differentiated strategies across different geographical areas. Allocation of resources at a sub-national level should be based on target population together with an estimate of the proportion of girls that are hard-to-reach to ensure equitable HPV vaccine delivery.

Equity, gender analyses, zero-dose focus, and strengthening routine EPI

Equity and gender

All countries recognise they need to consider gender and other forms of equity in applications and programming. Each made efforts to include at least some elements of equity and gender analyses in applications, but these remain minimal and largely descriptive. For example, Sierra Leone had considerable data from recent assessments such as the DHS survey, and an assessment conducted in some poor performing districts, and studies published in peer-reviewed journals. Data from these sources were not included in the gender analyses or design of strategies.

Issue 5: Countries are not using available equity data or analyses in the design of strategies.

Recommendations:

- Gavi and partners to provide additional TA on using Gavi's new gender guidance and how equity and gender analyses findings can be incorporated effectively in differentiated strategies with focus on zero-dose and under-immunized children.

Identifying and reaching zero-dose children and missed communities

All countries in this round of reviews indicated the importance of identifying and vaccinating zero-dose children and missed communities in campaign objectives and action plans. However, most

continue to propose what they have always done, and efforts do not appear innovative. Similarly, countries are aware that community engagement efforts are essential but continue to rely on information and advocacy approaches once decisions have been made, rather than including target communities in co-design processes. The traditional approach of leaving strategy development to the microplanning stage does not lead to innovative data-driven strategies, especially in hard-to-reach areas and frequently missed communities where zero-dose children are likely to be found.

Issue 6: Strategies proposed in applications remain generic and are unlikely to effectively identify and vaccinate zero-dose children and missed communities.

Recommendations:

- Gavi to consider requesting earlier and clearer technical oversight and support for priority areas/locations instead of the traditional approach of leaving this to the microplanning phase.
- Gavi and partners to encourage and disseminate innovative/successful approaches to identifying and reaching more challenging target groups.

Strengthening routine EPI

All countries identify and list the key challenges for routine EPI. These include the important roles of community engagement and lay personnel such as community health-workers (CHWs). However, none of the countries this round mentioned the importance of the second year of life (2YL) platform as a strategy for improving MR2 coverage and catch-up of defaulters or unvaccinated children in the second year of life and beyond. Furthermore, campaign budgets did not include support to CHWs who were assigned to participate in immediate pre-campaign and post-campaign activities that included registration and tracking of zero-dose and under-vaccinated children. The methods for estimation of at-risk populations did not appear to include levels of malnutrition among children less than 5 years old, especially as available data (e.g. Sierra Leone) indicated that in some districts the prevalence of stunting was as high as 45%. Among best practices in this round included the expansion of the upper age limit to 5 years for MR catch-up vaccination of children in both Sierra Leone and Yemen, primarily because of disruption to routine EPI services during the COVID-19 outbreak. However, it is not clear in Sierra Leone if a specific policy for removing the 23-month eligible age limit for MR vaccination is planned.

Issue 7: Countries do not provide specific analysis or clear estimation of at-risk populations or include factors such as malnutrition. Integrated approaches, 2YL platform strengthening, and catching-up schoolchildren are not prioritised outside of the non-selective campaign approach.

Recommendations:

- Gavi to consider requiring that countries increase integrated approaches and interventions, especially in hard-to-reach areas.
- Gavi and technical partners to support countries to explore and evaluate implementation of 2YL strategies and document adaptations to increase coverage in the second year of life and beyond.

Data Quality and Use

All three countries described the lessons learnt from recent SIAs as well as other EPI interventions. Priority was given to data from intra-campaign rapid convenience monitoring (RCM) and post-campaign coverage surveys (PCCS). Sierra Leone and Yemen listed priority areas based on difficult access, sub-optimal performance in recent SIAs and poor routine EPI performance and hence likely to have zero-dose and under-vaccinated children. However, strategies proposed in PoAs were not geographically aligned and key findings from recent RCM or PCCS not reflected in strategy designs. For example, in Sierra Leone, vaccinator workload was uniform across strategies and geographic areas. Despite the main reason for non-vaccination in the 2019 measles SIA being "vaccinator did not come", the application does not address this. Countries also note challenges in measles and rubella case-based surveillance, including outbreak investigations, but application data are either not updated or insufficiently analysed (e.g. Sierra Leone) so data-driven approaches are lacking. In both countries, available data was not used in adequate justification for the proposed expanded age group target populations.

Issue 8: Countries often lack capacity to undertake appropriate and relevant analysis of available epidemiological information including outbreak investigations, PCCS and equity assessments and fail to incorporate data in development and implementation of tailored strategies.

Recommendation:

- The IRC re-iterates its previous recommendation for Gavi and Alliance partners to work with countries to conduct appropriate and relevant analyses of available data so as to use the information for strategy development and impact evaluation.

Supply chain and waste management

Effective Vaccine Management Assessment (EVMA)

The IRC notes that only Nigeria submitted an EVMA report within the recommended 5-year timeframe and achieved a national level score above the 80% threshold. In contrast, Sierra Leone and Yemen submitted outdated EVM reports from 2016 and 2013 respectively. The 2016 Sierra Leone EVMA showed a decrease with an overall composite score of 68% due to the inadequate supply chain and low implementation of the comprehensive improvement plan (cIP). The 2013 Yemen EVMA is likely not reflective of the current supply chain as significant cold chain investments have occurred and ,Yemen intends to conduct an EVMA before 2023.

Issue 9: Outdated EVMAs and lack of comprehensive implementation plans do not adequately reflect country supply chains in applications.

Recommendation:

- IRC re-iterates its previous recommendation that Gavi and technical partners to assist countries to complete EVMAs within the recommended 5-year timeframe and support development and follow-up of cIP implementation.

Cold Chain capacity and dry storage

Recent cold-chain inventories were not provided by any of the three countries. Sierra Leone submitted a 2017 update on cIP implementation while Nigeria relied on the 2021 EVMA for the cold-chain capacity to be determined. Yemen on the other hand submitted a 2019 Inventory gaps analysis but to determine current capacity, the IRC relied on proxy documents such as the Gavi Secretariat pre-review notes and country presentations. Yemen specifically noted that dry storage was being built by UNICEF at the central level in Sanaa but there were frequent storage constraints in Aden and at the governorate levels.

Issue 10: The lack of updated cold-chain inventories and information on CCE in the pipeline limits the assessment of the adequacy of the cold-chain capacity for planned SIAs.

Recommendation:

- Gavi and technical partners should work with countries facing challenges in providing updated EVMAs and cold chain inventories to provide useful documents for assessing cold chain capacity for planned NVS or campaigns.

Waste management

Yemen presented an acceptable waste management plan for all waste generated during the MR campaign. The waste disposal will include burial or incineration at all levels of the health system in compliance of existing laws and regulations. Nigeria adopted the WHO/UNICEF policy on injection safety and aims to optimise storage, transport and disposal of immunization waste through incineration at state level. Although state level incinerators are being repaired, waste management remains weak at service delivery level. Sierra Leone budgeted some activities for waste management, but activities are not comprehensive or adequately budgeted.

Issue 11: Vaccination campaign waste management remains weak at all levels of the health system and is particularly challenging at lower levels of the health pyramid and especially at the health facility level.

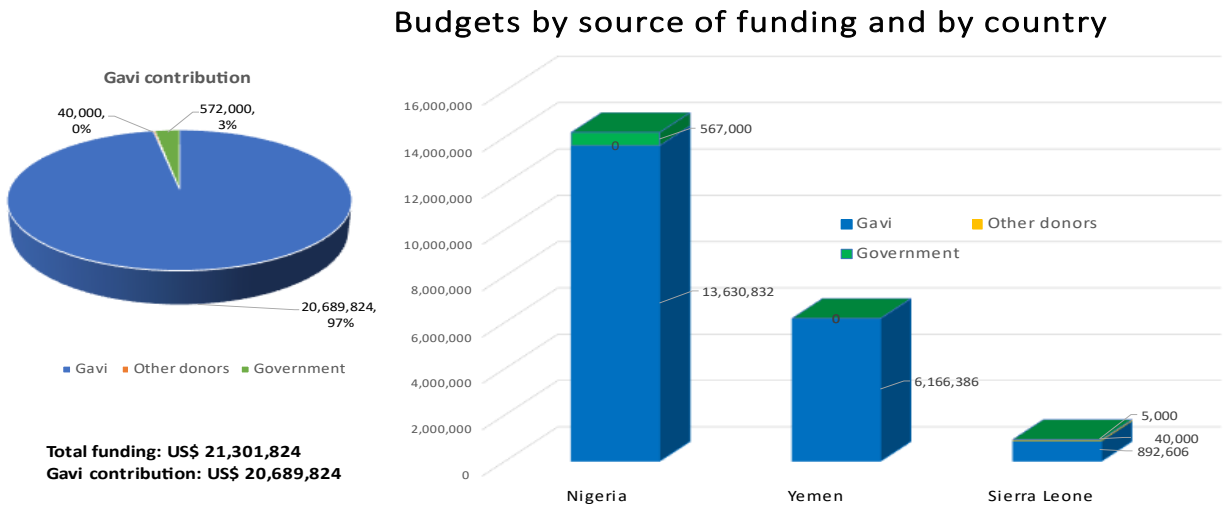
Recommendation:

- The IRC re-iterates its previous recommendation that Gavi and technical partners should work with countries to develop comprehensive and sustainable nationwide immunization waste management plans that include standard operating procedures, capacity building in safety, security and transportation and disposal of waste.

Budgets, Financial Management and Sustainability

Budgets from three countries totalling US$ 21,301,824 were reviewed. The requested Gavi contribution of US$ 20,689,824 accounted for 97% of the total budgets. Government and other partners contribution accounted for 3%, e.g. less than 5% for Nigeria, 0.5% for Sierra Leone, and none for Yemen.

Figure 1. Budgets by source of Funding, Nigeria, Yemen and Sierra Leone



Of the total requested Gavi contribution, 66% accrued to Nigeria, 30% to Yemen and 4% to Sierra Leone. The share of Gavi contribution by vaccine(s) was 66% (US$ 13.63 million) for HPV and 34% (US$ 7.06 million) for Measles-Rubella.

Financial review process

The Gavi Secretariat's thorough pre-screening process and interaction with countries has resulted in significant improvements in the quality of budgets and the impact is reflected in their alignment with the PoAs. For example, the share of HR cost in the Nigeria budget was reduced from 55% to 35% in a revised version of the budget based on the findings and recommendations of the Gavi pre-screening team from an earlier version of the budget. Similarly, several incremental changes to the Sierra Leone and Nigeria budgets, including allocating funds for unfunded or inadequately funded activities, revised unit prices and input quantities, resulted in noticeable improvements. However, some challenges remain and these include the finding that the new Gavi budget template was not appropriately used by countries. For example, both Nigeria and Sierra Leone used the new budget template by budgeting by inputs rather than by activities. This practice leads to the artificial multiplication of budget lines and most importantly in de-linking inputs, activities, outputs and outcomes and the underlying theory of change. Misclassification of activities and input costs remain widespread in all budgets reviewed resulting in misleading patterns of resource allocation between activities and cost groupings. In addition, in the case of Nigeria, budget calculation details were scattered in 112 worksheet tabs making the review highly cumbersome and unnecessarily demanding.

Issue 12: Although there are improvements in the quality of the budgets, remaining challenges include budgeting by inputs instead of activities and misclassification of activities and input costs.

Recommendations:

- Gavi to continue current efforts in-pre-screening budgets and requesting revision from countries before submission to the IRC.
- Gavi to request countries to limit the budget calculation details to less than 20 worksheet tabs for each budget.

Budget ceilings

Countries with larger target populations are allocated larger budget ceilings and generally tend to inflate budgets to fully absorb budget ceiling amounts (Nigeria, Yemen). Due to economies of scale, these countries have a cost advantage over countries with smaller target populations (Sierra Leone) because they are able to spread the fixed costs, which usually take a significant share of the budget, over a larger amount of output (i.e. number of children in the target population). All countries, with smaller or larger budgets, face fixed costs that do not vary significantly with activity scale. These costs include planning related activities, preparation of guides, reports and survey questionnaires, design of TV and radio communication messages, and advocacy. Countries with smaller target populations and therefore a smaller budget ceiling are at a disadvantage and tend to spread thin their budgets over a large number of activities, which in the absence of significant additional contributions from the government or other partners, often results in critical activities being underfunded or unfunded (Sierra Leone). This is further compounded by equity considerations and the need to differentiate delivery strategies to reach zero-dose children and missed communities.

The budget ceiling calculation formula is based on a fixed amount per child in the target population for all countries in the same transition phase regardless of the size of their respective target populations. This formula assumes that the cost of vaccinating a child is constant, when in fact it varies with the activity scale, the size of the target population and the strategy required (selective vs non-selective). We also need to recognise that it is more expensive to identify and reach those who have not been reached before either in campaigns or in routine. When countries develop their PoA they should specify the activities and related costs for reaching these children.

Issue 13: Budget ceilings are a major determinant of how budgets are formulated as the ceilings are based on a fixed amount per child for all countries irrespective of size and nature of the target population.

Recommendation

- Gavi should consider re-visiting the budget ceiling calculation formula for SIAs to take into account economies of scale in countries with larger target population and diseconomies of scale in countries with smaller target populations.

Budget thresholds are useful guards but country context matters

HR related costed are within the allowed threshold of 40% for both Nigeria and Sierra Leone, but significantly higher (61%) for Yemen where such threshold may be less applicable due to its fragility and emergency context. In the case of Sierra Leone, the threshold may not be a good indicator since HR requirements for the campaign are underestimated because of budget constraints (see the paragraph below on HR requirements and delivery strategies). For Yemen, the high share of HR and transport costs in the budget is likely due to non-inclusion in the budget of other key activities funded from other donors. As a result, the share of budget allocated to activities funded from Gavi contribution appears artificially high and not aligned with budget thresholds. It is important for countries to show all the funding received from other partners and domestic funding to give confidence that the vaccination campaign can be delivered successfully. Funding not indicated in the budget template gives rise to disproportionate thresholds.

In addition, the concept of materiality of budgetary items, while useful in focusing the analysis on important aspects of the budget, does not appear to be applicable to smaller budget since the associated threshold of US$ 250,000 would render most or all budget lines immaterial and therefore not worthy of scrutiny.

Issue 14: Budget thresholds are useful guards but country context matters for appropriate budgeting of activities.

Recommendations:

- Gavi pre-screening teams should consider the country contexts and the size of the budget when applying budget thresholds.
- Gavi and partners should encourage country teams to include funding in the budget and an indication of activities funded from other donors.

Human Resources requirements and vaccine delivery strategies

The PoAs of both Nigeria and Yemen do not clearly articulate HR requirements (number of vaccination teams, supervisors, team composition) and their distribution by delivery strategy. In addition, differentiated delivery strategies are increasingly outlined in the POAs but often not reflected in the budgets (Nigeria, Yemen). Furthermore, WHO recommended standards (vaccinator workload by delivery strategy, supervision of vaccination teams) were not used in any of the three applications for estimating HR requirements. Examples are given below.

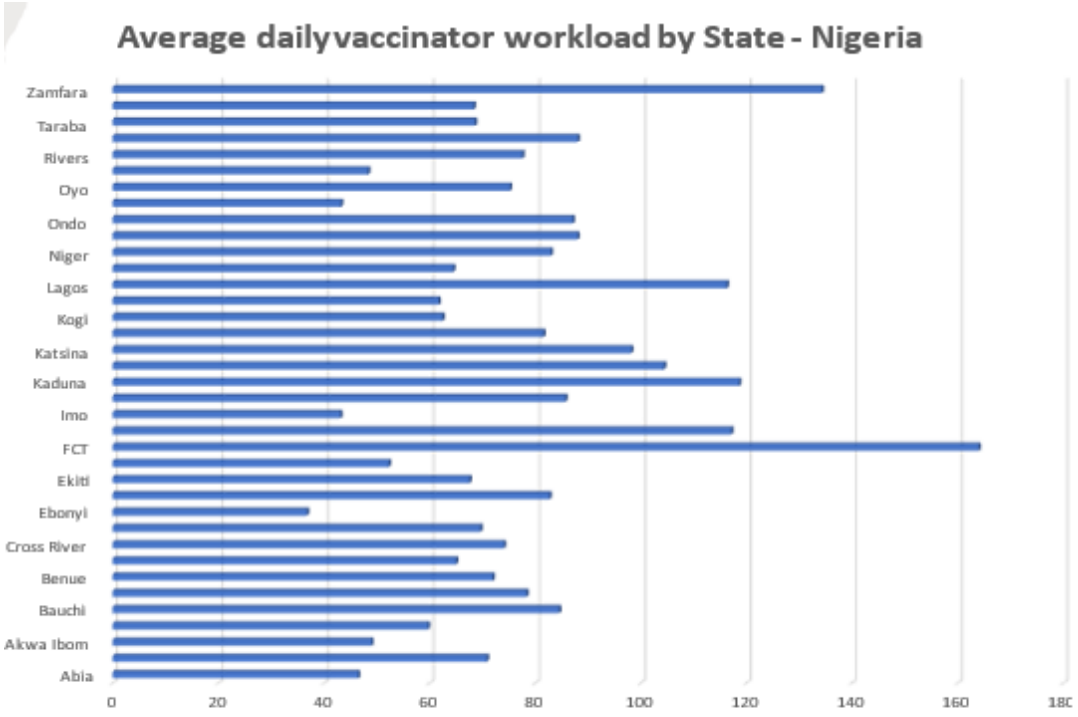
Sierra Leone: Sierra Leone used significantly higher daily vaccinator workload per delivery strategy which resulted in under-estimation of HR requirements by approximately 33%. Based on our calculation of HR requirements using WHO workload standards, Sierra Leone would require approximately 1,800 vaccinations team to reach the expected coverage target. However, the country is planning on using only 1,200 vaccination teams partly because of the budget constraint that the country faces in the absence of additional funding from the government and partners. This is also likely to affect the country capacity to reach high coverage for the planned campaign.

Yemen: Yemen had significantly different daily vaccinator workloads between delivery strategies (a 15-fold difference). There is a need to have a motivation in the POA on reasons for the difference in workload and more work needs to be done to ensure that vaccination targets are reached without simply increasing the number of HR per team. For example, one outreach team in Yemen indicated a need of 1782 teams to vaccinate a total of 53,460 children over a 6-day period resulting in 5 children per day, which is inconsistent with the 30 children per day per vaccinator in the POA. Based on the target of 53,460 and 30 vaccinations per day (which is lower than WHO recommended of 50-75 for door to door and 100 for mobile) the number of teams should be 297. This would result in savings of US$205,884 on vaccination team allowances and additional savings for reduced supervisors assuming a ratio of 1:4 of approximately US$31,164.

Nigeria: Nigeria used an administrative criterion for estimating HR requirements attributing every Ward in every State the same number of vaccination teams regardless of the size and distribution of the target population between and within Wards and between and within States. Such criterion is based on the principle of equality of treatment of States (each State receiving the same number of

resources per Ward) and ignores the fact that the target population is not distributed equally between and within States. It also does not make any provision for hard-to-reach areas and missed communities. As a result, daily vaccinator workload by State shows a significant variation ranging from 37 vaccinations in Ebonyi to 164 vaccinations in the Federal Capital Territory, indicating significant inefficiencies and inequities. This is because States are allocated the same number of vaccinators per Ward regardless of the size and distribution of the target population.

Figure 2. Average vaccinator workload by State based on allocation of resources by Ward, Nigeria



Issue 15: Countries do not clearly articulate HR requirements (number of vaccination teams, supervisors, team composition) and their distribution by delivery strategy, and do not follow WHO recommended standards.

Recommendations:

Gavi and partners to sustain ongoing efforts to fully implement past IRC recommendations, including:

- ensuring a clear articulation of HR requirements per delivery strategy in the PoA;
- using WHO recommended standards when estimating HR requirements and clearly indicating reasons in the PoA if they deviate from the standards;
- budgets to include costs associated with operationalizing differentiated delivery strategies; and
- ensuring that budgets are fully aligned with POAs.

Transport requirements

Travel and transport were the second biggest expenditure driver after HR costs in the case of Yemen. It is sometimes difficult to understand how the number of vehicles budgeted for is determined. In the case of Yemen, a large portion of the budget is allocated to transport vaccinators to temporary locations however, it is unclear how many staff will be occupying the vehicles and the differentiation

between vehicles for vaccinators, supervisory or monitoring staff. In many instances IRC considers that there could be better efficiency of the use of vehicles (i.e. more staff per vehicle) and instances where supervisory/monitoring staff could share vehicles with vaccinators.

Issue 16: Transport requirements for supporting vaccination team logistics and supervisory activities are often not clearly described and there is a lack of optimization of the use of vehicles.

Recommendation:

- Gavi and partners should work with country to ensure there is a better description of transport requirements in the POA and optimize use of vehicles between HR.

Review process and briefings

EPI Country Programme Manager Briefing

The EPI manager presentations were interesting but not particularly useful, as information in presentations tended to repeat information in applications and background documents already provided to the IRC for review. Additionally, not all questions and requests for clarification were insufficiently addressed in briefings. Finally, because the presentations were long (up to 20 Slides), insufficient time was available for reviewers' questions.

Issue 17: The EPI Manager presentations are too long and tend to repeat what is already included in applications thereby limiting time for questions and discussion.

Recommendation:

- Gavi to request EPI Managers to restrict their presentation to one slide, or five minutes, providing a summary of the context of the application. The remaining time should spent addressing reviewer questions.

Fragility Emergencies and Displaced Populations Policy

The new FED policy is a welcome effort to further articulate and clarify Gavi's approach to supporting fragile and conflict-affected countries. However, requiring completion and review of the standard application while considering these countries' special circumstances clashes with the IRC mandate and requirements for consistency and thus does not appear to be a sufficient change.

Issue 18: The IRC already routinely considers countries' special circumstances in review of applications. However, current application guidelines remain general and not adapted to the new FED policy or particular constraints of FED-eligible countries.

Recommendation:

- Gavi to consider developing an adapted FED country NVS/Ops application to ensure eligible countries can be more effectively reviewed.

Hybrid meetings of the IRC

Hybrid meetings require some adjustments to ensure all members can effectively engage. For

example, reviewers on Zoom reported feeling left out of conversations or unable to follow, particularly as in-person reviewers did not always use microphones. Similarly, participants on Zoom did not always turn on video when speaking, making it difficult for in-person participants to identify who was talking. Overall, these issues were relatively minor but worth noting if hybrid becomes the norm.

Issue 19: If hybrid formats occur more regularly, further adjustments can be made to ensure more effective engagement between in-person and remotely-participating members.

Recommendations:

- Gavi to suggest all meeting participants sign into Zoom and remote participants switch on video when speaking, so everyone's participation is effective.

Concluding remarks

The IRC recognizes the improvements resulting from follow up of previous meeting recommendations in the areas of inclusion of disease epidemiologic data on measles and rubella in applications for campaign support, listing of lessons learnt from previous SIAs and other EPI interventions, and identification of geographic areas with regard to level of difficulty to reach. Although countries are trying to include differentiated strategies for reaching zero-dose children and missed communities, the approaches proposed are not well articulated and activities are not aligned with the budgets. In many instances, available epidemiological data and information from equity and gender assessment is not used in the design of the approaches. Furthermore, in this round of reviews, the second year of life (2YL) platform was not considered or mentioned as a strategy for improving MCV2 coverage as well as improving vaccination coverage for under-vaccinated children. Gavi and Alliance partners should prioritise provision of technical support to countries to develop data driven approaches for applications requesting Gavi support.

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Annex 1: IRC members participating in September 2022 meeting

	Name	Nationality	Profession	Gender	French	Expertise
1	Aleksandra Caric	Croatia	Independent consultant	Female	FR	Measles, AEFI Surveillance and vaccine safety, programme management, primary health care.
2	Beatriz Ayala-Öström Vice-Chair	British, Swedish, Mexican	Independent consultant	Female		Health system strengthening, supply chain management.
3	Katherine Gallagher	UK	Assistant Professor, London School of Hygiene & Tropical Medicine	Female		HPV, immunization service delivery, epidemiology
4	Natasha Howard	Canada, UK	Associate Professor, NUS School of Public Health and LSHTM	Female		HPV, immunisation service delivery, FER settings.
5	Pierre-Corneille Namahoro	Rwanda	Director of Public Health, Global Supply Chain & HSS, Fascinans Ltd	Male	FR	HSS, Supply Chain Management and Cold-Chain Logistics
6	Benjamin Nkowane, Interim Chair	Zambia	Independent consultant	Male		Measles, epidemiology, mass vaccination campaigns, technical support for field operations in risk areas.
7	Gavin Surgey	South Africa	Radbound University Medical Centre	Male		Financial and Budget Analysis, Health Economics, Health Financing Strategies, Program M&E.
8	Abdel Tibouti	Morocco, Canada	Independent consultant	Male	FR	Financial and Budget Analysis, Health Economics, Health Financing Strategies, Program M&E.