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

FEBRUARY 2023

GAVI ALLIANCE

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LIST OF ACRONYMS

ACSM	Advocacy, Communication and Social Mobilization
AEFI	Adverse event(s) following immunisation
bOPV	Bivalent oral polio vaccine
CCE	Cold-chain equipment
CCEOP	Cold-chain equipment optimization platform
CEO	Chief executive officer
COVID-19	Coronavirus Disease 2019
cIP	comprehensive Improvement Plan(s)
EAF	Equity Accelerated Funding
EPI	Expanded Programme on Immunisation
EVM	Effective Vaccine Management
FED	Fragility, Emergencies and Displaced Populations Policy
FPP	Full Portfolio Planning
HPV	Human papillomavirus
HR	Human resources
HRH	Human resources for health
HSS	Health Systems Strengthening
ITU	Innovation Top Up
IRC	Independent Review Committee
IRMMA	Identify – Reach – Monitor – Measure – Advocate
MCV	Measles-containing vaccine
MR	Measles-Rubella
NVS	New and underused Vaccine Support
Ops	Operational Support
PCCS	Post-Campaign Coverage Survey
Penta	Pentavalent vaccine (DTP, Hib, HepB)
PoA	Plan of Action
RCM	Rapid Convenience Monitoring
RI	Routine Immunisation
SAGE	Strategic Advisory Group of Experts on Immunisation
SIA	Supplementary immunisation activity
TA	Technical assistance
TCV	Typhoid conjugated vaccine
TOC	Theory of change
TCA	Targeted Country Assistance
WUENIC	WHO and UNICEF estimates of national immunisation coverage

EXECUTIVE SUMMARY

The Gavi Independent Review Committee (IRC) met in Geneva, Switzerland from 30 January to 9 February 2023 and reviewed 14 applications from 9 countries. Applications from two countries were part of Full Portfolio Planning. Support was requested for a measles and measles-rubella (MR) follow-up and catch-up campaigns with introduction of rubella vaccine in routine, Typhoid Conjugated Vaccine (TCV), Cold-chain optimization platform (CCEOP) Equity Accelerator Funding (EAF), Fragility Emergency and Displaced populations (FED), Targeted Country Assistance (TCA), Innovation Top Up funding (ITU) and Health Systems Strengthening (HSS). Nineteen IRC members with a wide range of expertise participated in the review meeting. Two IRC members conducted in-depth financial and budget reviews of the applications and two others on the supply chain, logistics, vaccine management and waste management. The IRC focussed on the following; (a) Review of countries' funding requests and supporting documentation for vaccine introductions and campaigns to support national efforts to improve immunisation coverage and equity; (b) Production of country-specific review reports and recommendations; (c) Development of a consolidated report of the review round, including recommendations for improving funding requests and strengthening routine immunisation; and (d) Provision of recommendations to the Gavi Board and Alliance partners on improving processes relating to Gavi policies, governance, and structure. Review modalities included an independent desk review of each application by two designated members and discussion in plenary with the participation of the full committee.

Results

The IRC recommended approval for the applications for measles and measles-rubella (Mali, Nigeria), EAF (Guinea, Kyrgyzstan), FED (Bangladesh), TCV (Kenya) and the FPP for Madagascar (CCEOP, EAF, TCA, HSS, ITU). The FPP application from Zambia (EAF, HSS) was recommended for re-review because of insufficient justification of the selection of priority districts and lack of rationale for a large share of the budget being directed to salaries. The IRC noted that for ACSM activities supporting campaigns, all countries plan on leveraging support from local religious and non-religious influencers and engaging the community health workers cognizant of local culture. However, the activities are left to be further developed or refined in the microplanning phase and is just sporadically mentioned leaving it unclear if it would happen more than just on ad hoc basis. As regards focus on zero dose children, all applications have an objective to reach and identify zero-dose and under-vaccinated children and most use administrative coverage data for estimating the numbers to tailor interventions. The IRC noted that these estimates of numbers and location of ZD children could be biased as administrative estimates could be inflated and modelling approaches introduced discrepancies in in Zero dose estimates at sub-national level, thus impacting EAF target district selection. Thus The IRC calls for technical partners to strengthen guidance on triangulation of available data for better estimations and support countries in their efforts to estimate ZD and under-immunised children. For applications for EAF and FED, the IRC noted that the applications did not provide information on coordination and governance and as such, there

will be no accountability for implementation of the proposed interventions. The IRC acknowledges the change in policy for the HR threshold per diems/allowances for travel-related activities in the indicative maximum threshold of 40 percent. The IRC recommends that Gavi and partners continue to highlight the need for value for money and ensure that going forward HR costs are soundly justified.

Finally, the IRC noted that the FPP process in-country review process for high impact countries showed the approach provided unique opportunities for context, face to face dialogue with key stakeholders and site visits that enriched the IRC's understanding of the entire portfolio whilst allowing for immediate clarification provided by country-based teams. The IRC highlighted some areas for progress such as more focus on lessons learned from previous HSS be used to develop applications; more guidance for countries for identification and strategic planning for zero dose children; and a better justification of ITU request and linkage to FPP application.

METHODS AND PROCESSES

The meeting agenda, allocation of countries for review, country applications, supporting documents and briefing materials were shared with the IRC on 19 January 2023, 10 days before the start of the meeting. IRC members reviewed the applications and prepared individual draft reports of their assigned countries. Additional documentation or clarifications were provided by the secretariat prior to the meeting. Professor Rose Leke, Chair of the IRC was supported by the two Vice Chairs, Professor Sandra Mounier-Jack, and Dr Benjamin Nkowane. Additional support was provided by Dr Bolanle Oyeledun. The meeting was opened by Mr Johannes Ahrendts, Director, SFP who welcomed the IRC members and outlined the expectations for the review. This was followed by updates by Secretariat and WHO on Malaria vaccine, EAF, Measles and Rubella and Human Resources guidelines. For the applications for measles and rubella vaccines support (Chad, Nigeria), the country programme managers made presentations to the IRC outlining the key issues in the requests for support.

Review process

Each country proposal was reviewed independently by a primary and a secondary reviewer, each preparing an individual report. Cross-cutting issues (budgets, financial sustainability, supply chain and waste management) were reviewed in each application by one financial crosscutter and one IRC member specialized in supply chain management. FPP applications reviews were presented to the IRC, and review process depended on country categorization (Core, High Impact. Fragile and Conflict). 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. Where a country submitted more than one request for support, a single report was provided with relevant recommendations for each request.

CRITERIA FOR REVIEW

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

Decisions

There were two decision categories:

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

The outcomes of the IRC review are presented in Table 1.

Table 1. Recommendation outcomes of IRC reviews

Countries		Types of support			
		NVS requests	EAF/TCA/ CCEOP	Other requests	Outcomes
1	Bangladesh*			FED	Approval
2	Chad	Measles follow-up campaign			Approval
3	Guinea		EAF		Approval
4	Kenya*	Introduction of TCV vaccine in routine with TCV catch up campaign			Approval
5	Kyrgyzstan		EAF		Approval
6	Madagascar		EAF, TCA, CCEOP	HSS, Innovation Top-Up	Approval
7	Mali	Introduction of Rubella (MR) in routine with MR catch up campaign			Approval
8	Nigeria	Measles follow-up campaign			Approval
9	Zambia		EAF	HSS	Re-review

*Bangladesh and Kenya were re-reviews from the November 2022 IRC

THEMATIC AREAS SUB-COMMITTEES

During the review, IRC members were organized into six sub-committees (New vaccine support; Equity, zero-dose focus, gender analyses, and strengthening routine immunisations; Health information systems and monitoring and learning; Supply chain and waste management; Equity Acceleration Funds; Budget, financial management and sustainability; Full Portfolio Planning reviews. Each sub-committee identified issues in the applications that would be of general interest for Gavi and alliance partners.

GAVI SENIOR MANAGEMENT, SECRETARIAT AND ALLIANCE PARTNERS DEBRIEFING AND CLOSING SESSION

The de-briefing of the Gavi Secretariat and partners was held on 9 January 2023. A summary of the IRC meeting's outcomes and key issues and recommendations was presented by the Chair of the IRC. This was followed by a brief discussion, questions, comments, and responses. During the closing session, Mr Johannes Ahrendts, Director, SFP, thanked the IRC members for participating in the review and providing recommendations on the country applications.

KEY FINDINGS AND RECOMMENDATIONS

NEW AND UNDER USED VACCINE SUPPORT (ROUTINE AND CAMPAIGN SUPPORT)

During this window, IRC reviewed applications from four countries requesting NVS and campaign support: Chad and Nigeria requested support for measles follow-up campaigns targeting children 9 to 59 months of age, and Kenya and Mali requested support for new vaccine introduction with preceding catch-up campaigns for wide age-range target 9 months to 14 years. Kenya requested support for the introduction of typhoid conjugate vaccine (TCV), and Mali for introduction of rubella vaccine as a combination measles-rubella (MR) vaccine; both Kenya and Mali applications were re-reviews. Funds requested for campaign operational costs amounted to US$23.33 million, and requests for vaccine introduction grants were US$1.63 million. Generally, applications showed more attention to providing the epidemiological information and contextualized operational detail and keep improving alignment of plans and budgets. All four applications were approved.

ADVOCACY COMMUNICATIONS AND SOCIAL MOBILIZATION (ACSM) IN SUPPORT OF CAMPAIGNS

ACSM activities bear significant importance for creating and sustaining demand for immunisation services, including during supplementary immunisation activities. IRC notes with pleasure the increased attention to these activities in countries, reflected in descriptions of social mobilization and communication strategies in campaigns' plans of action, often linked to a wider health promotion and community health strategy. All applicant countries follow the WHO guidance on convening a sub-committee as an entity responsible for planning for the design and implementation of ACSM activities. While the design of ACSM activities may somewhat vary among the countries, all four applicant countries plan on leveraging support from local religious and non-religious influencers and engaging the community health workers cognizant of local culture, recognized as especially effective in rural and hard-to-reach areas, and where house-to-house social mobilization activities are implemented (Nigeria, Mali, Kenya). While not resigning from traditional methods (e.g. messaging via megaphones, banners), all applicants explore the opportunities that mass and social media offer and focus to expand their reach in order to disseminate the logistical information along with positive messages to promote vaccination. However, the activities are left to be further developed or refined in the microplanning phase, and monitoring of social and community mobilization activities is just sporadically mentioned leaving it unclear if it would happen more than just on ad hoc basis or even before the rapid convenience monitoring (RCM) takes place. It is also unclear from the budgets if the designated funds will be adequate to support effective social mobilization. Leveraging social mobilization networks established for other community health activities to improve the campaign reach was not at all considered in the submitted applications.

Examining the findings from the post-campaign coverage surveys, IRC notes with concern that the main reason for non-vaccination for all countries is not knowing that the campaign is taking place (Table 1). Reasons for the simple lack of information are not further explained and it cannot be discerned whether issues lie with the design or implementation of activities. It is also noted that the main sources of information about SIA taking place remain traditional channels of information.

Table 2: Findings from previous campaigns from post-campaign coverage surveys of applicant countries

Country	Main reason for non-vaccination (from PCCS)	Main source of information about SIA (from PCCS)
Chad	unaware of campaign (31.3%)	community mobilizer (77.8 %)
Kenya	unaware of campaign (26.3%)	radio (31.6%)
Mali	unaware of campaign (69.4%)	neighbour (25.3%)
Nigeria	unaware of campaign (7.5%)	town criers (39.2 %)

Effectiveness of social mobilization and communication activities should be monitored, particularly among populations at highest risk of not being vaccinated. Differentiated strategies provide better visibility of these population groups and countries should engage in rapid assessments to determine awareness of campaign among these communities during SIA preparation. At this stage, revision of methods and materials can still happen and gaps in communication can be addressed. During the implementation, analysis of data obtained through RCM should help address the bottlenecks, however, it remains essential to prepare a monitoring framework prior to the SIA implementation. WHO SIA Field Guide provides clear instruction and a monitoring survey form sample that can be adapted for use in countries. While refinements can happen during microplanning, the ACSM activities in campaigns should be guided by a data-driven, evidence-based strategy that is fully integrated within broader immunisation and health systems.

Issue 1: While countries articulate and budget for advocacy, communication and social mobilization (ACSM) activities for campaigns, the main reason for non-vaccination identified in the post-campaign coverage surveys (PCCS) remains not knowing that campaign is taking place, and the reasons for this deficiency are poorly elucidated.

Recommendations:

- Gavi and technical partners should support countries to design, apply and document effective communication strategies including with other stakeholders and CSOs, along with metrics to measure the results/outcomes.

- Gavi and technical partners should encourage countries to assess the readiness of critical ACSM activities at national and subnational levels during the preparation phase and support them in remedial actions.
- Gavi and technical partners should support countries in evaluating the effect of ACSM strategies used in campaigns, analyse relevance and shortcomings in their design or implementation, and offer evidence-based recommendations for improvement.

IDENTIFYING AND REACHING ZERO DOSE CHILDREN AND UNDER-VACCINATED CHILDREN

IRC has repeatedly called for attention to include reaching zero-dose and under-vaccinated children in country planning of supplementary immunisation activities, to avoid that children missed by the routine remain consistently missed also in campaigns. Although the analyses of unvaccinated children from household surveys and recommendations that the programmes and immunisation stakeholders specifically monitor the proportion of these children have been available for well over a decade, the numbers of zero dose children have for the most part remained static. With firm positioning of zero-dose focus within the IA2030 and Gavi 5.0/5.1 strategy, countries are requested to include in their campaign plans identifying and reaching zero-dose and unvaccinated children. IRC notes difficulties that countries face in establishing these targets regarding limitations around inaccurate denominators and decentralized systems (elaborated in the Data section of this report) and further notes that in this review window all countries show clear ambition to reduce children receiving no vaccines. For example, Kenya and Mali plan to refer all the identified zero-dose children to the nearest health facility or routine immunisation service, Nigeria plans to do the same using the double-card system in which one card stays with the caregiver and the other serves to enrol the children into the RI system, Chad plans to catch up with missed doses at location during the SIA contact, while Mali plans to provide missing vaccines to children identified in remote and conflict zones. Countries do not provide much detail on how programmatically balanced and operationally feasible these strategies are, and how they will be implemented and funded.

In addition, while it is planned that the SIA contact is a starting point, there is little clarity on what the subsequent actions would be, particularly in the context of restrictive immunisation policies which in countries limit the eligibility for vaccinations to the first or second birthday, depending on a specific vaccine. IRC reiterates that the emphasis should be on planning and ensuring a course of contacts following the important first SIA contact, as it is critical that zero-dose or under-vaccinated child progresses through the immunisation schedule towards full vaccination with all appropriate vaccines. At the same time, countries need to establish a realistic level of ambition and define what constitutes a zero-dose or under-vaccinated child reached, as having just one vaccine contact is clearly not enough.

Issue 2: Plans of action for campaigns include an objective to **reach and identify zero-dose and under-vaccinated children** but provide vague description of subsequent actions, leaving

it unclear if proposed strategies are feasible and implementable, and if an appropriate follow up will be ensured.

Recommendations:

- Gavi should request countries to include in their plans of action more operational details of proposed strategies to reach and vaccinate zero-dose and under-vaccinated children and identify risks that need to be considered and mitigated and explain how they will measure the achievements.
- Gavi should request countries to document and evaluate efficiency of proposed strategies including during PCCS, for learning and accountability.
- Gavi and technical partners will continue to encourage and support the countries to review restrictive immunisation policies to allow for late vaccinations as appropriate.

INTEGRATION OF PRIORITY PUBLIC HEALTH INTERVENTIONS DURING CAMPAIGNS

Countries are encouraged by Gavi and partners to integrate the delivery of services to improve the efficiency and increase access to essential public health interventions during large vaccination campaigns. All countries, as described in Table 2, included a range of traditional public health interventions, such as the administration of Vitamin A and deworming tablets, as well as more targeted interventions associated with specific vaccines such as WASH programme activities planned inclusion in the TCV catch- up campaign in Kenya. Two countries, Chad and Mali, planned additional basic health care activities, notably in remote regions with poor access to routine health care services (e.g., delivery and outpatient care in Northern Mali). Two countries considered providing other vaccines during the campaign such as bOPV (Mali) and COVID-19 (Nigeria), while Chad planned to catch up all missing vaccines during the campaign.

While integration of other interventions should be encouraged to improve efficiency of large and expensive national campaigns, while also providing improved access to essential interventions for population rarely in contact with routine health services, it is important to ensure that integration is feasible, and acceptable to health care workers and local service recipients, and quality of service provision is maintained.

All countries mention in their campaign plans of action integration of vaccination delivery with other services, but do not integrate those in planning, health-workers' workload or budget. Countries do not for instance detail how workload will be managed in delivering the integrated package of activities, and who will be doing what, with the exception of Mali which provides limited explanation of how HCWs and volunteers will share the provisions of specific intervention activities. With many interventions included, countries do not discuss feasibility aspects, notably in the case of outreach and mobile teams which tend to have limited staff. Similarly, transportation of health-related products is not addressed in the plans. Budget for costs of procurement and distribution are not included, while arrangement for collaboration

with other programme such as Polio are not discussed. Added interventions may raise logistical and operational challenges: the lower age limit for various interventions can be similar but not the same, for example for vitamin A supplementation it is 6 months, for MCV vaccination 9 months, while deworming with mebendazole is not recommended under 12 months of age; moreover, mass treatment with mebendazole in children below the age of 1 year is explicitly listed as a contraindication (WHO-PQ summary of product characteristics). Other injectable vaccines and particularly if targeting different age group altogether such as in COVID-19 vaccination, should be integrated only after careful consideration, as this requires logistical, training, and financial resources both at the periphery and at the central level.

While some past PCCS provide coverage of some interventions such as Vitamin A and deworming, this is not systematic, and other integrated interventions are generally not evaluated, limiting opportunity to learn lessons for future campaign. Efficiency, one objective of integrating interventions, is not routinely measured.

Table 3: Overview of services proposed for integration in country application.

Country	Services listed for integration	Integration included in planning and workload
Chad	package of activities: vitamin A, deworming, bednets, zero dose children identification and catching up with missed vaccines	**NO**
Kenya	integration of TCV with WASH programme activities	**NO**
Mali	vitamin A, deworming, bOPV, larger package for remote and conflict areas to include ANC and child delivery	**PARTIALLY**
Nigeria	vitamin A supplementation, deworming, birth registration, COVID-19 vaccination	**NO**

Issue 3: All countries' plans of action integrated vaccine campaign with other public health interventions, but plans remained at high level, with poor consideration for the feasibility and acceptability of the integrated campaign.

Recommendations:

- Gavi and partners should continue to encourage countries to provide a more integrated approach to campaigns especially in areas of poor population access to routine health services.
- Gavi and partners should support countries in evaluating feasibility and acceptability of integrating other services with campaigns, particularly with regard to differentiated strategies, vaccinators' workload and client safety.
- Partners should support the countries in planning the team composition and workload for integrated interventions.
- Countries should evaluate the efficiency of an integrated approach in campaign as part of PCCS.

FRAGILITY EMERGENCIES AND DISPLACED POPULATIONS (FED) AND EMERGENCY ACCELERATOR FUNDING (EAF) REQUESTS

Humanitarian emergencies often attract multitude of new actors to the health arena which requires strong governance and coordination capacities. In this round of the IRC, one country, Bangladesh applied for support under the FED policy to cover immunisation activities in the Cox Bazaar region and both Guinea and Zambia requested EAF support. The Bangladesh/Cox Bazaar application did not provide a description of the health services in the humanitarian setting/refugee camps and how health activities were coordinated. In the absence of a governance and coordination structure, the IRC found it difficult to understand the lines of responsibility as well as accountability of the various actors involved in providing immunisation services. The application however states but there were no set indicators for monitoring of performance. In addition, key information about zero dose children, their possible locations, effect of migratory patterns was not provided.

Issue 4: Information about leadership, governance, coordination, and organisational structures in fragile and humanitarian settings was not provided (Bangladesh/Cox´s Bazaar and Guinea).

Recommendations:

- Countries applying for support for immunisation activities in both emergency and humanitarian settings should include information on governance, the management and coordination structures of all players working on health in order to ensure accountability.
- Gavi to work with technical partners to come up with clearly defined key performance indicators and measure them as part of routine supervision.
- Countries should also provide as much information as possible on zero dose children, including their likely location and migratory patterns in the areas facing humanitarian crises.

EQUITY, ZERO DOSE FOCUS, GENDER ANALYSES AND STRENGTHENING ROUTINE EPI

All countries in this round of review identified gender related barriers to health care and immunisations. The interventions proposed are however vague and non-specific. Guinea proposed raising awareness and communication strategies but there was no clarity of what was going to be done. As regards equity, access to immunisation services related to socio-demographic and economic factors (e.g. urban/slums/settlement vs. rural, wealth level) were insufficiently addressed in Guinea and Kyrgyzstan. In addition, the limited demand from higher wealth quintiles in Kyrgyzstan compared with poorer groups due to their greater exposure to social media which leads to hesitancy were not addressed in the application. None of the proposals mention the meaningful role women can play in identifying zero dose children.

Issue 5: Gender related barriers, equity issues are identified and outlined, but proposed solutions remain weak.

Recommendation:

- IRC re-iterates its previous recommendation on ensuring technical support is provided to propose relevant and evidence-based intervention to address identified gender and equity issues.
- Gavi and technical partners should document successful gender and equity interventions and best practices and share these with countries seeking support to improve their immunisation programmes.
- IRC recommends countries to ensure meaningful engagement of women at community level to reach out ZDC and promoting them at the forefront in the process of developing appropriate gender-specific responses in strategic objectives of applications.

HEALTH INFORMATION SYSTEMS AND MONITORING AND LEARNING

Multiple applications this round demonstrated that countries are committed to reaching zero-dose children but struggling to reliably identify them and monitor whether they are reaching them. Large investments are being made for geographically targeted EAF activities that include activities such as microplanning and identification of zero-dose (ZD) children. However, these activities will successfully identify zero-dose children only with more reliable data or estimates on who lives where and how many of them have been vaccinated. Countries often do not describe clearly how they quantify numbers and location of ZD and under vaccinated children, though they note that they triangulate different sources of information. These include administrative data, survey data, surveillance information, modelled estimates and data from other programmes such as antenatal care (ANC1 used in Zambia). For targeting of their EAF funding, those preparing Guinea's proposal adopted an interesting method of adjusting administrative estimates using findings from a population-based survey.

USE OF SURVEY STATISTICS FOR ESTIMATING NUMBERS OOF ZERO DOSE CHILDREN

The use of geospatial re-analysis of survey data to estimate the coverage of individual districts is a common approach used in this round by countries such as Zambia and Guinea (using data from IHME and other organisations). Such analyses in some cases are outdated when the last high quality coverage survey was many years previously. Of the 8 country proposals reviewed during this IRC round, for 6 of them the most recent high quality coverage survey was conducted 5 or 6 years ago. Applicants may thus consider such estimates to be out-ot-date, thus preferring to use their administrative data.

Issue 6: Use of out-of-date survey data may limit the accuracy of ZD children estimates developed with modelling approaches that rely on survey data as a key input.

Recommendations:

- While efforts continue to improve on the reliability of both routine numerators and official denominators, countries, Gavi and partners to pay critical attention to numerator/denominator challenges. This could involve sharing practical guidance to caution applicants about the pitfalls of overly simplistic zero-dose analyses such as identifying and reviewing all possible data sources and assess their reliability before interpreting them. It would also be useful to give examples of best practices with use of diverse data and approaches to estimating the number, location and other characteristics of unreached populations. This guidance should also build on knowledge from successful field operations (e.g. polio, COVAX, PIRI, etc.) as well as recent innovations with use of data from aerial imagery and geospatial analysis to support micro-planning[1].
- Gavi and partners should continue to encourage countries to conduct regular survey to support the estimation for the quantification and location of ZD children.

USE OF ADMINISTRATIVE COVERAGE DATA FOR ESTIMATING NUMBER OF ZERO DOSE CHILDREN

Some countries prefer to use their own administrative data to identify zero-dose children. However, this presents special problems, not only where administrative data appear to be inflated, as in many countries in comparison with WUENIC estimates, but also where WUENIC agrees that nationwide coverage is high, but sub-national denominator estimates are imperfect and there are thus large numbers of districts with administrative estimates of coverage exceeding 100%. The result, as shown with the chart below showing estimates of zero-dose children in 10 regions of Zambia, is that 6 of the regions of this country were found to have a *negative* number of zero-dose children for most of the last 5 years. In such cases, regions said to have coverage of 100% or more are rendered ineligible for prioritization (which raises question of equity) and the estimated number of zero-dose children is inflated in the other 4 regions. Due to the way that the zero-dose analysis was performed (i.e., by assuming that there were zero zero-dose children in regions with administrative coverage > 100%), the

[1] Additional information: WHO/UNICEF concept note and related research article.

"negative zero-dose children" estimated in these 6 regions show up as positive zero-dose children in the other 4 regions – thus inflating the numbers in these regions as well as the nationwide estimate of zero-dose children.

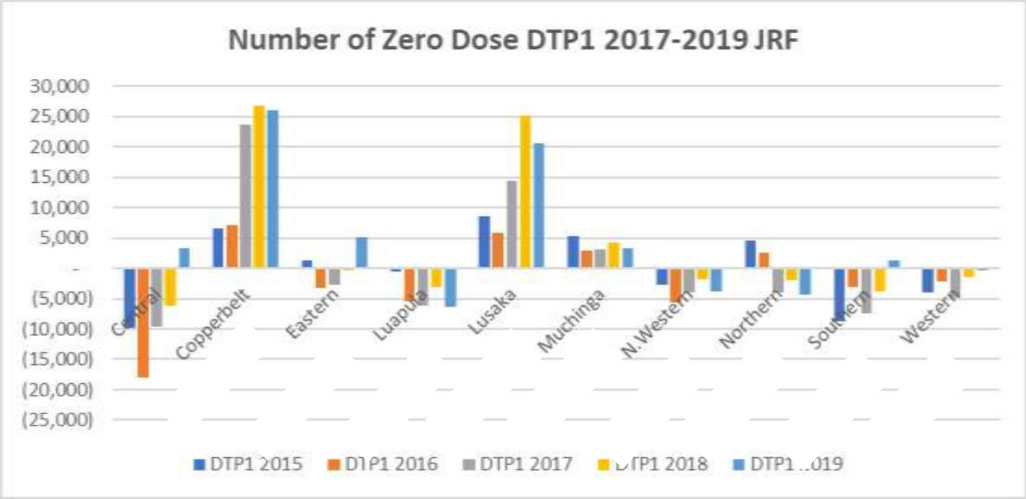


Figure 1

Zero-dose analyses conducted by external partners do not acknowledge such fundamental shortcomings of their analyses – failing to report on fundamental shortcomings with both the numerator (e.g., districts with negative dropout rates; districts with administrative data which differ substantially from vaccine supply data) and the denominator (a leading reason for coverage >100% and a key parameter for calculating zero-dose children).

Issue 7: Estimation of the number of ZD children using administrative data may overestimate ZD children in some districts while underestimating numbers in others, thus biasing strategies, and allocation of EAF funds to target ZD children.

Recommendations

- Gavi and partners to provide countries with guidance on how to triangulate administrate coverage estimates with alternative, more robust data sources including those for more reliably estimating numerators (e.g. vaccine consumption data), those for more reliably estimating denominators (e.g. data from vaccination campaigns) and those for identifying unreached populations (poverty assessments, nutrition surveys, and other information about inequities).
- Gavi and partners to explore alternative approaches to estimate and locate ZD children in countries where a significant number of districts report administrative coverage >100%. Where this appears to be due to unreliable estimation of denominators one example of such an approach, for a country with high coverage of antenatal care and high-quality data, is to estimate the number of ZD children based upon the dropout between the number of first ANC visits (ANC1) and the number of Penta 1 doses. For these countries with high ANC1 uptake, ANC1 may be used as the denominator instead of an estimate of the number of surviving infants.

BUDGET, FINANCIAL MANAGEMENT AND SUSTAINABILITY

Budget overview

Nine countries presented 11 budgets with a total proposed amount of US$78,005,714. Of this amount, proposed contributions comprised US$76,657,536 (or 98 percent) from Gavi, US$961,973 (or 1.2 percent) from governments and US$386,205 (or 0.5 percent) as other contributions.[2] Seven out of nine countries proposed 100 percent Gavi funding, while two (Nigeria and Mali) included contributions from partner governments and other contributions.

Figure 2. Overall budget by funding source

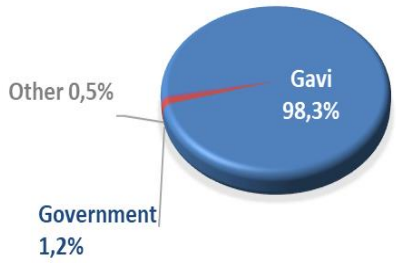
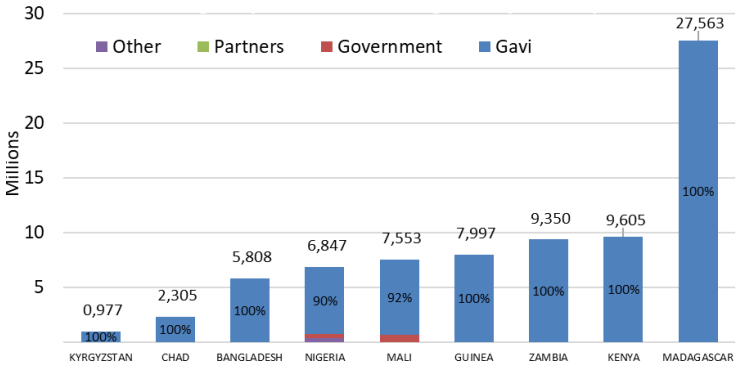


Figure 3. Budget by source of funding and by country



Applications for Gavi support for New and Underused Vaccine Support (NVS) comprised US$24,961,514 (or 32.5 percent) of the total budget. NVS budget by antigen included US$9,605,342, for Typhoid Conjugated Vaccine (TCV), US$8,436,325 for Measles Conjugated Vaccine (MCV) and US$6,919,847 for Measles-Rubella. Of the total the total Gavi contribution of US$76,657,536, 31 percent related to Health system Strengthening (HSS) (including Innovation Top-Up), 29 percent for Equity Accelerator Funding (EAF), 30 percent for Campaign Operational Support (Ops), 8 percent for Fragility, Emergencies and Displaced Populations (FED) and 2 percent for Vaccine Introduction Grants (VIGs).

QUALITY OF BUDGET INFORMATION

IRC noted improved focus and effort by Gavi Country and Secretariat Teams in pre-screening and screening applications for validity and consistency and to ensure compliance with mandatory requirements. This resulted in improved documents and budgets for applications screened out during previous IRC review rounds. That is, two applications were screened out from IRC review in November 2022 and two applications were re-reviewed. Notwithstanding this, strengthened compliance with processes and procedures, continuous efforts and improvements are required from governments, development partners and Gavi Secretariat Teams to ensure all applications comply with requirements, namely:

a) Countries often do not provide required information in specific columns in Budget templates. For example, no, little or inconsistent information in specific columns on Unit Price, Quantities, and Budgets Assumptions. This is often the case in Work Plan templates

[2] Nigeria presented the Program Support Costs for WHO and UNICEF in the budget as other contributions.

also. Nigeria, Zambia, and Kyrgyzstan did not provide adequate and/or consistent information to meet requirements, while Bangladesh did.

b) Further, countries often provide none, incorrect, or inconsistent information in the specific column for Referencing in Budget templates. Without Referencing (or with incorrect or inconsistent Referencing), IRC faces increased challenges in matching and tracking information on activities and sub activities between key documents, including the Theory of Change (ToC), Plan of Action (PoA), Work Plan and Budget. Kyrgyzstan, Nigeria, and Chad did not provide required referencing information, while Kenya did.

c) Several countries used many worksheets / tabs and lines within worksheets / tabs to document and present assumptions and calculations for activities and sub activities, making IRC review unnecessarily complicated and cumbersome. For example, Nigeria structured its budget with 60 worksheet tabs, Kenya worksheets / tabs with more than 187 lines, and Madagascar worksheets / tabs with more than 2,770 lines.

d) Several countries misclassified activity and sub activity costs in terms of Cost Grouping and Cost Inputs. For example, approximately 30 percent of budget costs for Nigeria's application was misclassified under Cost Grouping 3. External Professional Services. For Madagascar, Cost Grouping 2. Transport and Travel-Related Costs (Cost Inputs 2.2 Vehicle Rental and 2.3 Fuel for Vehicles) were misclassified; this meant the proposed 7 percent of costs equated to at least 12 percent of the HSS budget and was above the is indicative maximum of 10 percent.

Issue 8: While the quality of budget information presented to IRC is improving due to support to countries and pre-screening, basic issues remain including noncompliant and/or inappropriate use of Budget templates, inadequate presentation of budget information, assumptions and calculations, and misclassification of activities against Cost Groupings and Cost Inputs. Where countries do not present other donor funded activities, a comprehensive overview of the budget is not provided.

Recommendation:

- Gavi to continue to focus effort on pre-screening applications to ensure improved information, assumptions, costs, and budgets before submission for IRC review.

BUDGET TEMPLATES

Budget templates do not include safeguards to identify/alert where information is omitted or requires correction (e.g. where columns are not completed and/or when Cost Inputs are not compatible with Cost Categories). Notwithstanding this, budget templates include protection that restricts countries as well as IRC to make develop and review information (respectively). For example, it is not possible to "click in cells" to see calculations and follow corresponding dependent cells or change the position of worksheet tabs in templates. This makes a thorough review unnecessarily cumbersome and time-consuming.

Issue 9: Despite improvements, budget templates do not include safeguards to identify/alert where information is omitted or requires correction.

Recommendation:

- Gavi to improve budget templates by including safeguards and removing unnecessary protection that hinders budget development and review by countries and IRC respectively.

Lack of and / or inconsistent information on budget assumptions across key documents

Information on strategy, rationale, and assumptions for activity and sub-activity costs are not adequately provided for in and across ToC, PoA and Work Plan documents to support budget analysis. For example, inadequate information was provided for within and across documents for applications from Madagascar, Kyrgyzstan, and Zambia, again meaning IRC faced increased challenges in matching and tracking information on activities and sub activities between key documents. This resulted in the need for increased questions for Gavi Country Teams during review as well as Action Points for the Gavi Country and Secretariat Teams as part as recommended approvals and re-reviews. It is worthwhile noting that key issues relate to FPP or EAF applications, as the ToC template does not include a section that requires an explanation on activity and sub activity assumptions, costs, and calculations to link strategy, delivery, and budget.

Issue 10: Narrative documents (ToC, PoA and Work Plan) lack specific and linked information on strategy, rationale, and assumptions for activity and sub activity costs which does not support budget analysis. Moreover, the ToC template does not include a clear requirement to provide these details.

Recommendation:

- Gavi Secretariat to improve application documents to require specific information to link and present activities assumptions, costs, and budget to strategy (i.e. specific section in application form to present key activity assumptions and costs and budget).

Recommended thresholds for HR related costs

Guidelines no longer include cost inputs for per diems/allowances for travel-related activities in the indicative maximum threshold of 40%. This change reduced perceived budget requirements for countries and led to increased challenges for IRC to review costs and ensure value for money (i.e. the change – coupled with the need for more clear messaging to and change management for countries and Gavi Country Teams – seemed to reduce established leverage for IRC to request countries explain and justify costs). For example, applications from several countries included increased HR relates costs (e.g. 47% for Nigeria, 60% for Mali and

69% for Kenya). While this threshold has been removed, it was provided for guidance only and all HR inputs and costs must be evidence-based and justified in line with a strong business case underpinned by proposed strategies and interventions.

Issue 11: The change in HR guidelines reduces non-compliance with the indicative maximum threshold but while the questions can still be asked, it reduces Gavi and IRC leverage to request countries explain and justify costs.

Recommendation:

- Gavi Secretariat to continuously improve budget guidelines (e.g. this could include continuous improvement based on ongoing feedback from each IRC review round).

UNCLEAR ASSUMPTIONS AND JUSTIFICATIONS FOR HR RELATED COSTS

Further improvements are required by countries in explaining and justifying inputs and quantities for HR related cost inputs in line with Gavi's philosophy on supporting HR related costs (i.e. they are eligible for funding provided there is a strong business case aligned to Gavi's strategic objectives, costs are reasonable and perceived risk is managed). For example, further information was required on Quantities, and Budgets Assumptions, based on target populations and / or specific delivery strategies in applications from Nigeria, Madagascar, and Kenya. Emerging issues include lack of information and clarity on the purpose and responsibilities for each team member, especially for vaccinators, which has an impact on the calculations for workload, team composition and the number of vaccination teams (e.g. applications from Kenya and Mali). The application from Zambia included high costs for training without adequate justification or information on training plans, highlighting the need for more cost-effective and innovative training methods that reduce out-of-office time and impact productivity. The application from Madagascar included a high number of meetings, events, and training sessions, which targeted the same population without consideration of the additional burden and disruption to service delivery. The application for Mali included the same proposed vaccination team composition across all three delivery strategies, which required a high number of staff unlikely to be available in country (i.e. 26,665 staff, including 24,261 vaccinators and 2,404 supervisors).

Issue 12: Lack of information and justification for HR related costs, including assumptions on specific target populations and/or delivery strategies, including team composition leads to inadequate staff quantification. Calculations on activities and staff numbers are not considered with reference to workload and available resources, which lead to unrealistic estimates.

Recommendations:

- Gavi Secretariat and partners to ensure clear justification for HR related cost assumptions

including, for example, target groups, delivery strategies, vaccination team composition(s) and numbers and ensure budgets align with the PoA.

- Gavi Secretariat and partners to ensure WHO recommended standards are applied for estimating HR related cost inputs.
- Gavi Secretariat and partners to provide technical support to selected countries in planning and budgeting, including involving fiduciary agents to support budget pre-screening/screening.

SUPPLY CHAIN AND WASTE MANAGEMENT

Countries that submitted applications for NVS (Kenya TCV) or for catch up and follow up campaigns (Mali MR and Nigeria and Chad Measles) presented relatively resilient supply chain systems given CCE investments through CCEOP and COVAX. It was noted that EVMAs (Effective Vaccines Management Assessments) and cIPs (Comprehensive Improvement Plans) were not consistently updated (Chad and Madagascar) due to challenges such as the COVID-19 pandemic impact, other supply chain and CC (cold chain) capacities for vaccine campaigns, particularly dry storage capacity (Chad and Nigeria). Mali and Chad presented weak waste management capacities and strategies including insufficient incinerators. In particular, Nigeria and Kenya's immunisation supply chains have been improved through significant CCE investments. However, CCE inventories and dry storage capacity in Nigeria were not adequately documented which has been a challenge in some of the country applications including Chad which lacked similar information. Dry storage capacity and the lack of a gap analysis for passive containers was shown in Mali. Kenya should be acknowledged as the country who presented a strong immunisation supply chain with adequate storage capacity including dry storage.

Issue 13: Insufficient information provided on dry storage capacity
Recommendation :

- Gavi to request countries to include information on the status of dry storage capacity in all applications for support.

Issue 14 : Despite some countries undertaking an Effective Vaccines Management (EVMA), there is limited implementation of comprehensive Improvement Plans (cIPs).
Recommendation :

- Countries should be strongly encouraged to implement cIPs to track improvements in the immunisation supply chain. Performance measures should be linked to cIP implementation.

FULL PORTFOLIO PLANNING REVIEWS

Review Process

The FPP review process has fully taken off with using different modalities: remote, in-country and hybrid (with some members doing remote review and the rest of the team in country). As Gavi continues to roll out the FPP application process, this review window assessed two Geneva based country applications namely Zambia, and Madagascar (Table 4). Decisions for the FPP applications were approval for Madagascar and re-review for Zambia. Main reasons for re-review was insufficient justification of the selection of priority districts in this high coverage country, and lack of rationale for large share of the budget being directed to salaries. During this window, the outcomes of the in-country review for Pakistan was also presented to the larger IRC for consensus and learning purposes.

Table 4. FPP by type of support and review modality

Country	Support	US$ Amount Requested	Recommendation	Review modality
Pakistan	HSS, EAF, TCA, CCEOP	**214,566,606**	Partial approval[1]	In-country review
Zambia	HSS, EAF	**9,350,000**	Re-review	IRC main review
Madagascar	HSS, EAF, CCEOP, TCA, ITU	**34,056,377**	Approval	IRC remote review
TOTAL		**257,972,983**		

[1] *all support partial approval*

Lessons Learned

a) Consistently with previous in-country review, lessons from the Pakistan in-country review process (High Impact country) showed that this hands-on process provided unique opportunities for context, face to face dialogue with key stakeholders and site visits that enriched the IRC's understanding of the entire portfolio whilst allowing for immediate clarifications provided by country-based teams.

b) Full portfolio reviews (especially when including all components) largely provide a clear understanding of the complementarity of the different windows in an integrated manner. However, some applications remain siloed especially for training activities (e.g. Madagascar).

c) The adequate sequencing of the review process allowed for enough time to review materials. The timely receipt of pre-reading materials, ample opportunities for in-country/in person IRC deliberations, the responsiveness of the country and secretariat teams especially in the feedback communication loop with countries plus very good

country feedback mechanisms fostered the success of these reviews (***Madagascar, Pakistan, Zambia).***

d) The availability of dedicated and technically sound financial reviewers further enriched the review process by providing strong technical inputs for financial reviews of applications from a value for money perspective.

e) Whilst the FPP encourages the inclusion of CSO and private sector engagement, this varies across applications but the IRC considers this promising and evolving with the support of the technical and expanded partners. There is a need for this to be strongly supported and encouraged especially in the context of reaching the zero-dose and under-immunised children. Countries should be strongly encouraged to look inwards, recognise and support these CSO to complement government capacities and capabilities across various areas it is unable to reach effectively.

EMERGING ISSUES

a) Follow on grants/new applications do not sufficiently demonstrate how they build on lessons learned and possible scale up using empirical evidence. The crucial challenge stems from the inadequate timing to allow for completion of proper evaluations before the new grant application commences. This is especially when the country is unable to bridge the funding gap that may emanate from this. This leads to highly resourced grants not being formally evaluated for impact, outcomes and lessons learned to feed into new applications.

b) The methodology to identify, quantify and strategically program for zero-dose children needs to be more strategic as it is still challenging especially in the absence of good quality immunisation data. **(*Madagascar, Pakistan, Zambia).***

c) Budget not always aligned with TOC, and persistent budgetary issues/overlaps ***(Madagascar, Pakistan, Zambia).***

d) Persistent high HR costs with little or no consideration for sustainability. This is more especial in the context of Zambia where almost a quarter of allocated funds are earmarked towards Human Resources for Health support with no clear demonstration of how these positions will strongly impact zero-dose children. ***(Pakistan, Zambia)***

e) Whilst the IRC commends Madagascar for identifying its ITU funding priorities, it is pertinent to note that this lacked detailed rationale and evidence on how current implementation (Drone. E-sigl) is performing nor the sustainability of such investments over time.

Recommendations

The IRC strongly recommends that Gavi, the secretariat and technical partners:

- Consider how earlier timed independent evaluation (including funding) of on-going HSS grants possibly in year 4 of investments can be instituted as part of grant planning. This

will ensure that by the end of the year 4 of any on-going grant, an evaluation is carried out to measure outcomes and impact so far. The learnings can then be taken into new grant design and applications for greater effectiveness and more focus on scale up of interventions that are working plus support of innovations.

- Support the development of simplified guide/methodology for identification and strategic planning for zero-dose children.
- Consider development of simplified microplanning guide (with TA partners) that incorporates strategic, contextual, and tailored approaches to zero-dose and under immunised children
- Provide more support for budget reviews from a value for money perspective rather than size of envelope.
- Support countries to better streamline HR costs and maximise TCA opportunities based on strategy needs and sustainability context.
- ITU requests should be better justified with clear details on interface and/or continuity with other country activities.

GOOD PRACTICES

In this round of reviews, the application from Bangladesh/Cox Bazaar, in an effort: to conduct successful vaccination of children, there is active involvement of affected (refugee) population in vaccination teams in Cox's Bazaar. This practice is likely to improve access to all children during immunisation and increase accountability to the refugee community.

CONCLUDING REMARKS

This has been the IRC contribution during this round of reviews towards enabling GAVI to attain its overarching vision of the Alliance to leave no one behind with immunisation, in strong health and immunisation systems.

ACKNOWLEDGEMENTS

Gavi Secretariat

- Gavi Executive Team for their continued support.
- FDR team (Lindsey, Verena, Sonia, Anjana) for their excellent organisation of the meeting and Noelia who coordinates our travel.
- SCMs, VP, HSIS and PFM team members

Alliance partners

- Alliance partners who attended and provided insight and clarifications during the deliberations of the IRC.

ANNEX 1: IRC MEMBERS PARTICIPATING IN FEBRUARY 2023 MEETING

#	Name	Nationality	Profession/Specialisation	Gender	Review language	Expertise
1	Andrew Azman	USA	Associate Scientist, Department of Epidemiology, Johns Hopkins University	Male	EN, FR	Epidemiology, outbreak response, cholera
2	Alvaro Alonso-Garbayo	Spain, UK	Independent consultant	Male	EN, SP	Health systems development, immunisation, NGOs, fragile countries
3	Beatriz Ayala-Öström	UK,Sweden ,Mexico	Independent consultant	Female	EN, SP	Health system strengthening, supply chain management
4	Blaise Bikandou	Congo / France	Independent consultant	Male	EN, FR	HSS, project/program management, Preparedness and response, vaccine preventable diseases, epidemiology
5	Aleksandra Caric	Croatia	Independent consultant	Female	EN, FR	Measles, AEFI Surveillance and vaccine safety, programme management, primary health care
6	Ousmane Dia	Senegal/ USA	Independent consultant	Male	EN, FR	Program management, supply chain management of health commodities, vaccine and CC management
7	Wassim Khrouf	Tunisia	Auditing and Consulting Worldwide, Partner	Male	EN, FR	Financial & budget analysis, audits, project assessment
8	Rose Leke **- CHAIR**	Cameroon	Emeritus Professor of Immunology and Parasitology, University of Yaoundé, Cameroon	Female	EN, FR	Malaria. Global Health, HSS, training of the next generation of scientists
9	Jean-Pierre Matwanga	Burundi	Independent consultant	Male	EN, FR	Finance expert
10	Sandra Mounier-Jack ***- Vice-chair***	France/UK	Professor in Health Systems and Policy at the Faculty of Public Health and Policy of the LSHTM	Female	EN, FR	HPV, measles, immunisation programmes, HSS, health policy and health financing

#	Name	Nationality	Profession/Specialisation	Gender	Review language	Expertise
11	Pierre-Corneille Namahoro	Rwanda	Director of Public Health, Global Supply Chain & HSS, Fascinans Ltd	Male	EN, FR	HSS, Supply Chain Management and Cold-Chain Logistics
12	Benjamin Nkowane ***- Vice-chair***	Zambia	Independent consultant	Male	EN, FR	Measles, epidemiology, mass vaccination campaigns, technical support for field operations in risk areas
13	Bolanle Oyeledun	Nigeria	Chief Executive Officer at Centre for Integrated Health Programs (CIHP), Nigeria	Female	EN	Health systems strengthening, MNCH, immunisation, adolescent reproductive health & HPV, programme assessments and evaluations
14	Bob Pond	USA	Independent consultant	Male	EN, FR	Health systems strengthening; data quality assessment; epidemiology
15	Susan Rackstraw	Australia, UK	Policy Adviser to Kiribati MoH	Female	EN	HSS, policy and governance, planning, budgeting and financial management
16	Erika Wichro	Austria	Independent consultant	Female	EN, FR	Emergency settings, outbreak response, HSS, polio, Ebola, measles, COVID-19, surveillance, epidemiology