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

SEPTEMBER 2021

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List of Acronyms

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

Executive Summary

The Gavi Independent Review Committee (IRC) met 14-21 September 2021 in an extraordinary session called due to the challenges and urgency created by the COVID-19 pandemic. The IRC reviewed 6 applications from 6 countries. This was the sixth IRC meeting held virtually because of the COVID-19 pandemic.

Eleven IRC members participated in this round with areas of expertise including immunization services; vaccine preventable diseases (VPDs); adverse event(s) following immunization (AEFI); health development and health systems strengthening (HSS); outbreaks, epidemic and emergency response; management and evaluation of health services; health policy and planning; primary health care (PHC); epidemiology and burden of disease; reproductive health, cold chain and supply chain management; health economics, health financing and auditing. Two members conducted in-depth financial reviews, and two focused on cold chain and supply issues.

During the review, the IRC members focused on the following specific tasks:

- Review of countries' funding requests and supporting documentation for vaccine introductions and campaigns to support national efforts to improve immunization coverage and equity;
- Production of country-specific review reports and recommendations;
- Development of a consolidated report of the review round, including recommendations for improving funding requests and strengthening routine immunization;
- 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 applications by designated members and virtual discussion in plenary with the participation of the full committee.

Results:

The IRC recommended approval of 5 of the 6 reviewed applications, with an overall approval rate of 83%. The total funding amount recommended for approval is US$ 23.8 million in support of the immunization of a target population of more than 37 million children.

During the reviews, the IRC identified a number of relevant common issues, notably in relation to MCV and MR proposals that, if adequately addressed through technical support, could result in more robust applications and improved implementation. These involve insufficient use of lessons learned from previous campaign technical reports, the cross-use/standardisation of supply chain and waste management tools across GAVI applications, and non-alignment of proposed tailored strategies with composition, norms and budgets for vaccination teams. The IRC also found insufficient documentation of the basis for tailored strategies and reiterated the need to place emphasis on improving budget rationale and budgetary assumptions to ensure key interventions are funded and deliver value for money.

Other issues that the IRC identified for further consideration by partners would be the evaluation of the impact of plans to reinforce RI through SIAs in previous campaigns, as well as other innovations planned by countries, funding of community based organizations/teams/volunteers between SIAs, the scope of activities to achieve the aims of the gender strategy that are feasible during campaigns, the standardisation of coverage evaluation surveys to assure their quality and use and the development of tools for use of survey data at sub-national levels.

Finally, the IRC recognises that in the challenging context of the COVID-19 pandemic, countries should be further supported to maintain routine coverage, deliver high-coverage campaigns, and where relevant introduce new vaccines.

Methods and Processes

Methods

The Gavi Independent Review Committee met from 14 to 21 September 2021. This was the sixth meeting held virtually because of the COVID-19 pandemic. The virtual meeting went smoothly. The IRC met via Zoom as a large group or via small group communication outside the plenary sessions.

Eleven IRC members participated in this review round. Areas of expertise included: immunization services; VPDs (measles, rubella, Human Papillomavirus, and Pneumococcal disease); AEFI; health development and HSS; outbreaks, epidemic and emergency response; management and evaluation of health services; health policy andplanning; PHC; epidemiology and burden of disease; reproductive health, cold chain and supply chainmanagement; health economics, health financing and auditing. Two IRC members focused on in- depth financial reviews, and two members focused on cold chain and logistics issues. (See Annex 1 for the list of participating IRC members). Three members of the IRC served in additional roles: interim chair Karen Wilkins, vice-chair, Dafrossa Lyimo and interim vice-chair, Stefano Lazzari.

Country applications and supporting documents were shared with IRC members on 3 September, ten days before the start of the meeting. IRC members reviewed and analysed these applications and prepared draft reports on their assigned countries. The Secretariat provided clarifications and any additional documentation as needed.

The meeting started off with an address by the Gavi Deputy CEO, Ms. Anuradha Gupta. She welcomed participants, emphasized the importance of addressing the growing number of zero-dose children in the wake of COVID-19 and the link between missing vaccination and missing all services. Ms Gupta noted that Gavi had received fewer applications since the start of the epidemic but stressed that this does not signal a lessening of rigor in the review processes. The Gavi Board has stressed that they do not want sub-optimal plans leading to sub-optimal implementation. Changes in funding guidance include guidance that MR applications address strategies for zero-dose children and bundling of services, with COVID-19 vaccination as feasible response to the COVID- 19 pandemic, and reminded the IRC about Gavi's priority of ensuring that specific activities to identify and immunize zero-dose children are included in all applications and that budgets are aligned with these activities. Applications should also highlight strategies to overcome gender-related barriers such as timing of sessions and distance even if these do not affect the budget.

Additional briefings were provided including on the new application kit which has been shared with countries, though some aspects such as the budget templates and requirement for a gender analysis are not yet in place, Gavi's revised gender policy and PFM guidance.

The briefings also included updates from the Secretariat and Alliance partners on updates on measles, rubella and COVAX.

Each country proposal was reviewed by a primary and a secondary reviewer. Each IRC member reviewed the applications and supporting documents independently andprepared separate, individual reports. Cross-cutting issues related to budgets and financial sustainability and supply chain and waste management were reviewed in each application by one financial crosscutter and one IRC member specialized in supply chains. These reports were presentedin daily virtual plenaries, during which the initial findings were extensively discussed, with a final, consensual, outcome recommendation of either approval or re-review.

The Gavi Secretariat and Alliance partners supported the plenaries by providing information and clarifications when needed, especially on country-specific background and context. Most IRC decisions were agreed upon immediately at the end of the plenaries, though one required postponing the decision due to connectivity problems for the first reviewer. That decision was reached first thing the following day.

The first reviewers then consolidated the reports from the different reviewers and the outcome of the plenary discussion, including decisions and recommendations, in draft country reports. These drafts were then finalized after editing, thorough fact and consistency checking, and quality review.

A total of 6 applications were reviewed from 6 countries as presented below.

Table 1: Country Applications by Type and Review Modality

Countries	Application/ Support requested	No. of applications
Nigeria	Rotavirus introduction/ additional doses after initial recommendation	1
Central African Republic	MCV follow-up campaign	1
Ethiopia	MCV follow-up campaign	1
Mozambique	MR follow-up campaign	1
Uganda	MR follow-up campaign	1
Zimbabwe	MR follow-up campaign	1

Criteria for review

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

Decisions

There were two decision categories:

I. **Recommendation for Approval** when no issues were identified that would require re-reviewby the independent experts. In this case, the minor issues raised by the IRC will be addressed by the country in consultation with the Secretariat and Partners.

II. **Recommendation for Re-review** when there were critical issues that required a new review by the independent experts; this will entail detailed revision of the application and a revised submission to the IRC.

Table 2 presents the review outcomes for this round. Five of the 6 applications were recommended for approval and one was recommended for re-review, with an overall proportion of recommendations for approval of 83%.

Table 2: Requests from Countries and Review Outcomes

Countries	Application/ Support requested	Recommendation
Nigeria	Rotavirus introduction/ additional doses after initial recommendation	Approval
Central African Republic	MCV follow-up campaign	Re-review
Ethiopia	MCV follow-up campaign	Approval
Mozambique	MR follow-up campaign	Approval
Uganda	MR follow-up campaign	Approval
Zimbabwe	MR follow-up campaign	Approval

Thematic areas sub-committees

During the review, IRC members, organized in 6 sub-committees, identified specific findings and issues in the applications submitted that would be of general interest for Gavi and partners and could be addressed in the Secretariat's debrief session as well as in this report. The suggested issues were initially reviewed and agreed upon in a special plenary session held on the 20th September to be presented by the interim Chair to Gavi Secretariat Senior Management, staff and partners on the final day of the meeting.

Secretariat debrief and closing session

The debrief of the Gavi Secretariat was held on the 21st of September and included a summary presentation of the meeting's outcomes and key issues and recommendations from the IRC to Gavi and Alliance partners. This was followed by a brief discussion, questions/comments, and response.

During the closing session, Ms Anuradha Gupta, Gavi Deputy CEO, expressed her appreciation to the IRC members for the excellent work. She also expressed her gratitude to the interim chair and vice-chairs of the meeting for agreeing to take on the responsibility of facilitating and managing the meeting, especially in the context of COVID-19.

Key Findings and Recommendations

NVS (Routine and Campaign support)

The IRC reviewed six applications from six countries for New Vaccines and Campaign support: one for additional vaccine doses for Rotavirus vaccine introduction after an initial recommendation for approval in 2016 (Nigeria), three for measles-rubella (MR) follow-up campaigns (Mozambique, Uganda, Zimbabwe), and two for measles vaccine follow-up campaigns (CAR, Ethiopia).

Rotavirus introduction (additional doses)

Nigeria's application for rotavirus vaccine (Rotarix) introduction in routine EPI was recommended for approval by the IRC in 2016 but its implementation was put on hold by Gavi because of unresolved audit issues. In 2019, due to a supply disruption of the requested Rotarix vaccine, Nigeria requested to change vaccine preference to Rotavac (liquid) and submitted this revised proposal. Changes other than the choice of vaccine include a revised target population number for vaccine introduction, updated Gavi contribution of US$0.60 for the first year birth cohort, and additional emphasis on intensification of routine immunization and reaching zero-dose children.

In its plan of action, Nigeria mentions intussusception surveillance before and after Rotavac introduction and strengthening of AEFI surveillance, but no budget was allocated for these activities. IRC has repeatedly emphasized the importance of monitoring risk for intussusception when new rotavirus vaccines are introduced into new populations, although lack of such surveillance should not impede the vaccine introduction. Rotavac has overall demonstrated a good safety profile, however, post-licensure safety data are still limited. Therefore, IRC reiterates the importance to establish and strengthen sentinel surveillance for intussusception in hospitals to determine background rates prior to introduction as well as to monitor vaccine safety profile post-introduction, with particular focus on documenting any intussusception cases. These cases are expected to occur by chance alone and establishing their baseline incidence and using epidemiological studies appropriate for resource-limited settings such as the self-controlled case series method, can provide important data on intussusception risk and on safety of the rotavirus vaccine. These activities should be adequately planned and funded, they are recommended by WHO, and countries should be supported and encouraged in their strengthening. WHO and partners should also encourage countries to join the global surveillance network.

Measles and Measles-Rubella (M/MR) applications

IRC notes with pleasure continued improvement in quality of applications for measles-containing vaccine (MCV) campaigns. Overall, countries provided good epidemiological analysis and identification of high-risk areas at subnational level and triangulation of available data to identify poor performing districts or localities. However, strategies to reach these hard-to-reach and chronically missed children remain mostly non-specific, without a clear equity focus or consideration of gender-based barriers. In addition, several other persisting issues are identified.

The post-campaign technical report, prepared at the national level, represents a compilation of findings from review meetings held at all levels after the completion of the campaign. It is prepared within 1 month of the end of the campaign. This report summarizes the results of the campaign, along with administrative coverage by district and age group and results of mop-up activities. It makes quickly available the results and evaluation of activities for routine immunization strengthening and summary of lessons learnt with recommendations by programme component (e.g. planning, coordination, financing, logistics, etc.). These recommendations, along with those from post-campaign coverage surveys usually available months later, should be used to improve upon subsequent campaign.

All applications included a list of lessons learnt from previous SIAs. However, Mozambique, Uganda and Zimbabwe provided no clear link as to how these lessons feed into operational planning for the campaigns and routine EPI strengthening. Similarly, the lessons learned listed in the CAR application were not reflected in planning or strategies and were based only on the findings from 2020 post-campaign coverage survey conducted only in Bangui district due to accessibility, limiting their use. Lessons learned from other less accessibility areas may have been discussed in the technical report. In contrast, pending post-campaign coverage survey findings, Ethiopia incorporated information from the most recent SIA technical report into the campaign plan in a systematic way and proposed diverse approaches to reach hard-to-reach and special underserved groups.

Issue 1: The value of post-campaign technical reports is not fully recognized. When done well, they can help identify challenges to reach missed children.

Recommendation

- The findings of the post-campaign technical reports should be used in operational planning, along with those from post-campaign coverage survey whenever available.

The IRC noted that all plans of action attempted to describe tailored or differentiated strategies to address barriers to immunization. However, none of the applications fully explained team size based on identified barriers whether geography, difficulty to reach, opportunity for integration etc. or reached the granularity of planning to be expected after repeated campaigns. Hence, the workload of the teams is not considered in the budgets for activities with tailored strategies. The uniform pattern of delivery strategies, for example 60% for fixed/permanent, 30% for outreach/temporary posts and 10% for mobile, is retained throughout the applications regardless of subnational specificities and despite proposed tailoring of strategies. While this pattern may serve as a tool for budgeting, it does not apply for planning of tailored and differentiated strategies in the specific country context.

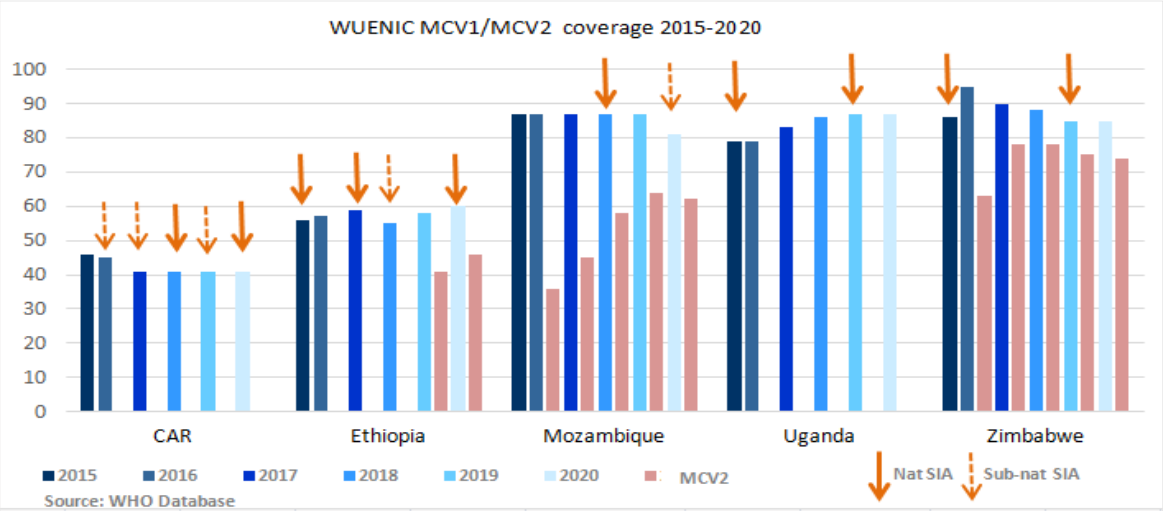
Issue 2: The composition of vaccination teams and vaccination norms/daily workload remain inadequately justified, and budgets are often not aligned with proposed strategies.

Recommendation

- Countries should align plans of action, vaccination team/personnel requirements and vaccination team norms/workload with proposed strategies. Team composition and workloads should be reflected in both the plan and budget, with assumptions underlying calculations for team composition and distribution clearly explained and aligned with country context.

Programmatic information generated during campaign planning, preparation and implementation should be used for programmatic improvements and may help address issues within the routine programme. Between 2015 and 2020, all five of the countries applying for M/MR campaign support had conducted at least two non-selective national MCV follow-up campaigns which included plans or activities to strengthen routine EPI (Figure 1). However, the impact of these disease-specific interventions to broader systems is not evident and is not reflected in changes in coverage at district and national levels or in decrease in number of zero dose children. The countries either had a drop or stagnation in survey or administrative coverage for Penta3 measles coverage (MCV1, MCV2) which predated the COVID-19 pandemic.

Figure 1: MCV1/MCV2 coverage (WUENIC) and national/subnational SIAs in applicant countries in the 2015-2020 period



Issue 3: Despite all five of the countries applying for follow-up campaigns conducting two to three campaigns in the recent past with plans to strengthen routine immunization, the impact on RI activities is not evident.

Recommendation

- Gavi and technical partners should work with countries to collect process and outcome indicators (e.g. updated maps, microplanning as well as changes in coverage) and systematically evaluate impact of the proposed strategies and interventions during campaigns on routine immunization at district and national level.
- Best practices on activities that strengthen routine immunization during campaigns should be documented and shared.

Coverage, Equity and Gender

While countries have been asked consistently to describe gender-related barriers and any specific issues related to access by women to the health system within their coverage and equity situation analyses, Gavi 5.0 strategy brings renewed and greater attention to gender equity in immunization. The IRC has noted that applications have tended to concentrate on sex differentials between boys and girls in vaccination coverage, seldom on how broader aspects of gender inequality (e.g. mother's education, socio-economic status) affect access for both boys and girls, and never on identification of how the system and society mechanisms and norms contribute to under- and non-vaccination. Therefore, suitable gender-sensitive or gender-specific approaches were not addressed in the design of campaign strategies, nor were underlying gender issues identified and/or local, contextualized solutions proposed to address them. While gender-responsive approaches that would work around gender-based barriers will need to be articulated and used in design and implementation of campaign vaccination strategies in order to reach chronically missed children, it remains unclear how selective, disease-specific interventions such as campaigns would potentially be gender-transformative interventions.

Issue 4: In the context of immunization, the societal/cultural change desired for a transformative gender strategy is a very ambitious and laudable but might be unrealistic to achieve during a campaign.

Recommendation:

- Regardless of societal barriers, a campaign reaching all children requires addressing gender barriers to demand and access (supply) as identified, i.e. need to reach all children where they and their parents are, with limited opportunity for addressing root causes. HSS or PFP may provide more opportunity to promote the Gavi gender transformative strategy.

The IRC noted that all five MCV campaign applications have made effort to describe identified hard-to-reach and special populations. There currently exists a wealth of information to assist identification of hard-to-reach and special populations at the national level, but what is presented in the POA received does not draw on all the information and what is presented is in a fragmented fashion. Planning of strategies is left to the microplanning phase at local levels where it is unclear how national level data will relate to local expertise. PoAs would benefit from summarizing relevant information from all sources that would serve as a starting point for further refinement of appropriate vaccination strategies at the district microplanning phase. These considerations should be included in the plan of action and would then serve as a starting point for further refinement at the district microplanning phase.

Issue 5: In spite of available information from recent equity analyses (MICS, DHS, PCCS), most plans of action do not include a summary of this information.

Recommendation:

- Plans of Action should include a consolidated summary of information on equity and gender barriers. The summary should demonstrate how proposed interventions will be incorporated in the district level integrated campaign and routine EPI microplans.

All countries applying for MCV follow-up campaigns describe activation and engagement of village health teams/community volunteers in the preparation and implementation of the campaign. They plan to train and equip community-based actors to do campaign-related tasks including enumeration, screening and social mobilization. All countries face a shortage of health workers and responding to these shortages by utilizing village health teams/community health workers is a reasonable approach. However, it would appear that programmes work with these actors only for campaigns, which represent rare opportunities for these community volunteers to be provided with some allowance, training or possibility for career advancement. It appears that government or local funding for the community-based health activities falls short of actual needs, making their activities reliant on donor/implementing partners' sometimes intermittent funding. The applications do not describe the challenges that stem from such arrangements, and while these findings cannot be generalized, community health workers/village health teams who build community relationships and are trusted with important tasks, could make powerful contributions to the immunization programme outside of campaigns.

Issue 6: Village health structures/community health workers seem not to be active between campaigns where they would be very useful for ongoing public health interventions

Recommendation:

- Sources other than campaign operational costs should be leveraged to fund the activities of village health teams/community volunteers between the campaigns which may enhance their status in the community, their motivation, and potentially increase their longer-term

retention.

Data Quality and Use

Although data quality and use has been the focus of past IRC recommendations, efforts to triangulate more recent and more granular information to improve accuracy and planning of routine delivery or SIAs are still lacking. The prioritization of districts with low coverage and high proportion of zero dose children in most the countries reviewed in this round was based on administrative reporting of routine immunization performance which is often affected by both under- or over-estimated denominators or numerator problem. Countries mainly base their immunization target population calculations on national administrative coverage estimates or WHO and UNICEF Estimates of National Immunization Coverage (WUENIC).

Regular routine immunization coverage surveys are essential to validate the data collected through administrative data reporting and calibrate national and WUENIC coverage estimates. All countries reviewed have conducted national routine immunization coverage surveys, though the frequency, type and validity of the survey differs substantially among countries. In some countries, routine immunization coverage surveys of standard quality were not done regularly in last 10 years, affecting the validity and usefulness of WUENIC estimates. A case in point among the 6 applications is CAR where the WUENIC estimates remain calibrated to a survey conducted in 2011 due to lack of quality surveys since then.

National routine immunization surveys are mostly integrated with surveys conducted for other purposes (e.g. DHS, MICS, NNHS, etc.). Methodologies used to implement these surveys, including sample size and sampling frames, varies between the different surveys, reducing the validity of comparisons, even when implemented in the same country. In the countries reviewed, a quarter of the surveys of the last 10 years were ignored by WUENIC due to design or implementation flaws. However, they are still referred to both at national and international levels.

While available population data, administrative immunization coverage and survey results have been used together by WUENIC since 1980 to validate and calibrate national immunization coverage estimates, a similar approach is not routinely used by country programmes at national and subnational level. In particular, surveys are not always exploited to estimate coverage and number of unimmunized or under-immunized children at sub-national (e.g. State, Province, District) levels, undermining efforts to better target and prioritize both RI and SIAs. When triangulation of data is used, it does not follow any standardized or validated methodology. Only three countries reviewed included sub-national coverage estimates based on survey data in the PoA, but it is unclear if and how these were used in campaign planning.

Between 2009 and 2019, the 6 countries submitting applications this round conducted 28 national surveys of routine immunization coverage - Nigeria had the highest number of surveys (8) while Mozambique had only 2.

Countries use and combine different survey opportunities. DHS were the most common (10 surveys), followed by MICS (7), and EPI NICS (6) to justify and plan campaigns.

Some countries (e.g. Nigeria, CAR, Zimbabwe) implement several different types of surveys, complicating comparison and trend analysis.

Six surveys (27%) were ignored by WUENIC because of issues with their design or implementation.

Table 3. Frequency and types of coverage surveys conducted in the reviewed six countries

		CAR	Ethiopia	Mozambique	Nigeria	Uganda	Zimbabwe	
Coverage Surveys in the last 10 years (DTP3 coverage)	2009	MICS 2010 (32%)			EPI NICS 2010 (68%)		DHS 2010-11 (73%)	**DHS** = Demographic and Health Survey (10 surveys)
	2010		DHS 2011 (36%)	DHS 2011 (76%)	MICS 2011 (45%)	DHS 2011 (72%)		
	2011	EPI NICS 2012 (47%)	EPI NICS 2012 (60%)			EPI NICS 2012 (92%)		**MICS** = Multiple Indicator Cluster Survey (7 surveys)
	2012				Cross-sectional NNHS 2013 (42%)			
	2013		DHS 2016 (45%)				MICS 2014 (87%)	**EPI NICS** = National Immunization Coverage Survey (6 surveys)
	2014		DHS 2016 (53%)	MASIDA 2015 (82%)	National NNHS 2015 (48.8%)	DHS 2016 (77%)	DHS 2015 (83%)	
	2015	EPI NICS 2016 (59%)			MICS 2016-17 (34%)	EPI NICS 2017 (73%)		**NNHS** = National Nutrition and Health Survey (4 surveys)
	2016				National NNHS 2018 (57.2%)		MICS 2019 (90%)	
	2017		mini-DHS 2019 (61%)		DHS 2018 (50%)		MICS 2019 (91%)	**MASIDA** =Survey of indicators on Immunization, Malaria and HIV/AIDS (1 survey)
	2018							
	2019	MICS 2018-19 (35.1%)			National NNHS, 2018 (67%)			= Accepted by WUENIC
Sub-national coverage data presented (Adm)		YES (District)		YES (District)			YES (District)	= Ignored by WUENIC
Sub-national coverage data presented (Survey)			YES (Region)		YES (State)	(YES (Region)		= Not yet assessed by WUENIC

Issue 7: There is substantial difference between countries on both the frequency and type of immunization coverage surveys, and the quality of the surveys is not always assured.

Recommendations

- Promote with country and partners the use of standardized surveys to provide data of acceptable quality to justify and plan the campaign at national and subnational levels.
- Gavi and partners to provide technical support to countries to ensure both the frequency (per WHO recommendations) and high quality of all surveys.

Issue 8: National and subnational coverage survey data is rarely used when planning campaigns or prioritizing interventions in areas of low coverage and high number of zero-dose children.

Recommendations

- Subnational RI and post campaign coverage survey results, where available, to be used for prioritization and campaign planning.
- Gavi and partners to consider developing, in collaboration with WUENIC, specific guidance and simplified tools for use at sub-national level to assist in validating and calibrating the local immunization administrative data with available survey data along the lines used for national estimates ("mini-WUENIC").

Best Practices and Country Innovations

The IRC noted some best practices and innovative approaches described by countries in their applications in key areas of planning and implementation to improve their immunization performance. These could be shared with other countries to encourage them to focus/adopt on improving in the key identified areas.

Best practices noted from countries include:

- The joint investment of Global Fund and Gavi to expand national storage capacity (Uganda).

- The use of a simplified inventory management tool (ODK-X) at district level for regular inventory updating (Uganda).
- Collaboration with village chiefs for identification of zero-dose children. (Uganda)
- The use of geospatial mapping of communities in conflict-affected and hard to reach areas (Mozambique, Ethiopia).
- Using SELV (iLMIS) to provide up to date coverage information at national and provincial level (Mozambique).
- Collection of behavioral and social data from the behavioral survey and it's use to inform social mobilization and communication strategies needed to reach prioritized populations (Ethiopia)
- Programming of about 50% of each campaign budget item from non-Gavi sources for co-funding (CAR)

Innovations seen in the applications include:
- Expansion of the use of geospatial tools to identify and reach zero dose children (Mozambique)
- The application of behavioural insights from survey in social mobilization and communication strategies to reach prioritized populations (Ethiopia)

Issue 9: There is insufficient documentation of the outcome or impact of innovations and best practices to allow other programmes to benefit for planning and implementation of their SIAs.

Recommendations

- Innovations proposed by countries should be evidence-based and monitoring of results including in the monitoring plan.
- Gavi and partners to evaluate and share experiences, positive and negative, with other countries to inspire them to focus on improving their planning and implementation areas.

Supply chain and waste management

The IRC noted that only one of the six countries reviewed in this round (CAR) had an outdated Effective Vaccine Management Assessment (EVMA), which was conducted in 2015. Two countries (Uganda and Zimbabwe) scored above the threshold EVM score of 80%. No countries used the new EVM 2.0 tool, even for assessments conducted in 2019 and 2020 after its release. Most countries developed comprehensive supply chain improvement plans and levels of implementation are being monitored. Uganda, in particular, should be commended for putting in place a well-functioning maintenance system with recruitment of 170 district cold chain technicians. This will certainly contribute to safeguarding the large cold chain equipment (CCE) investments made in recent years.

Countries still failed to provide a comprehensive CCE gap analysis, especially for passive devices. This lack of analysis is difficult to justify given it is a requirement for concurrent funding streams (e.g. Gavi CCEOP, HSS, COVAX CCE, World Bank) for supply chain procurement and countries provided this data effectively. For example, all used the WHO supply chain sizing tool for COVAX CCE requests yet did not include this or similar analysis for new vaccine support or campaign requests.

Issue 10: There is no cross-use or standardisation of tools (e.g. CCI, WHO Sizing Tool, HCWM) used for other Gavi applications (e.g. CCEOP, COVAX CCE).

Recommendations

- Ensure sufficient cold chain TA to support countries to conduct timely CCE gap analyses for inclusion in NVS or campaign applications.
- Work with WHO to provide a consolidated tool, for example based on the WHO sizing tool used for COVAX CCE applications, to support CCE gap analysis for multiple/simultaneous applications (e.g. routine, campaigns, pandemic).

No country included consideration of dry storage capacity. This should be provided at least to district level to ensure procured ancillaries (e.g. safety boxes, syringes) are not exposed to weather or theft. Countries often have temporary storage gaps during campaigns but usually try to procure additional permanent storage capacity to address this. Countries could instead rent storage as needed during campaigns to fill temporary storage gaps, but most do not consider doing this.

Issue 11: Dry storage capacity not considered in applications despite its importance for safeguarding syringes and safety boxes.

Recommendations

- Ensure countries provide dry storage capacity analysis for campaigns, at least to district level, and if necessary, describe contingency plans such as rental when there are gaps.
- Allow flexibility and increasing awareness across countries, of their capacity to rent storage as needed during campaigns to fill temporary storage gaps.

Waste management remains poorly described. It is difficult for the IRC to assess policies, plans, adherence to recommended methods and funding given the lack of information provided. Countries' waste management policies, if they exist, are outdated and countries are not using new opportunities offered by NVS and HSS to develop/revise their policies, support microplanning and make the necessary investments. Activities, if they are described, are generally inadequately budgeted. Additionally, some countries (e.g. Mozambique) still rely on open-pit burning for waste management and this should be strongly discouraged.

Issue 12: Countries do not routinely use funding opportunities (e.g. SIAs) to develop comprehensive waste management plans that could also benefit routine immunization, the entire health system, and national environmental targets.

Recommendations

- Support dissemination and implementation of available global goods, e.g. UNICEF Appropriate Disposal of Immunization Waste (ADIW) platform and Gavi HCWM-Maturity-Model.
- Require campaign waste management activities be clearly articulated and budgeted.

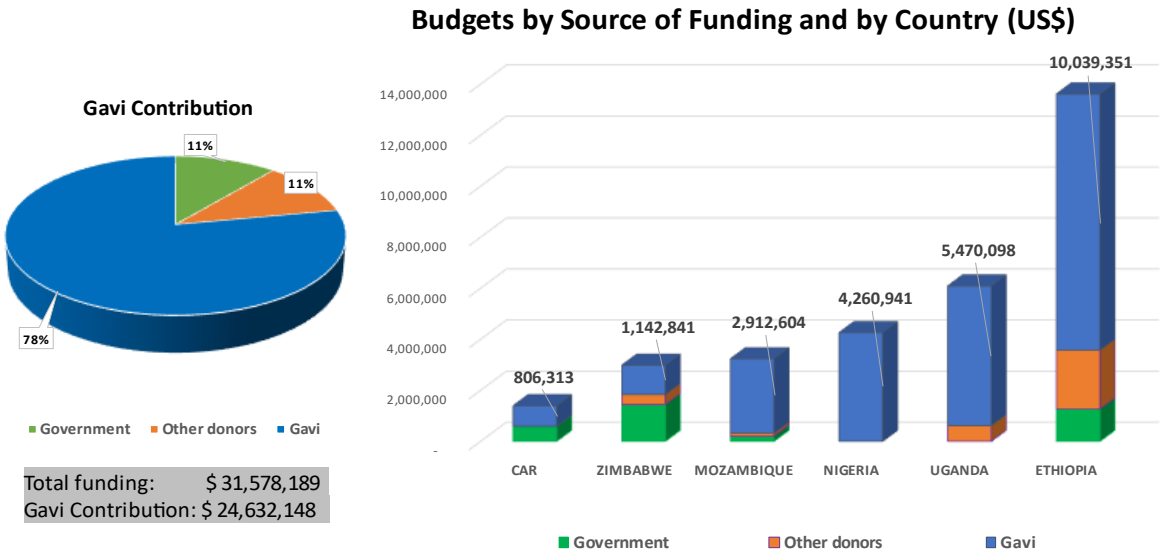
Budgets, Financial Management and Sustainability

1. Budget overview

In this round, six applications for support totalling US$31,578,189 were reviewed. The requested Gavi contribution of US$24,632,148 constituted 78% of the total planned budget, with governments and partners contributing 11% each. As shown in Figure 2, the relatively high share of non-Gavi funding in this round is explained by the high government contribution in Zimbabwe, Ethiopia, and CAR, and by the high contributions of other donors in Ethiopia and to some extent in Uganda. It should also be mentioned that only Nigeria did not disclose other funding sources.

In addition, the IRC noted a new commendable practice in this round: the CAR would be co-funding with Gavi all planned activities, except program support, in the same fixed proportions of 43% from the government and 57% from Gavi.

Figure 2: Overall budget requested by country and by source of funding.



Of the total requested Gavi contribution, 63% accrued to Ethiopia and Uganda; 29% to Nigeria and Mozambique; and 8% to Zimbabwe and CAR.

The proportion of Gavi contribution requested by antigen was 44% (US$10.85 million) for Measles, 39% (US$9.53 million) for Measles-Rubella, and 17% (US$4.26 million) for Rota, driven by the number of countries requesting and the target population of those countries.

It is clear from the above graph that the size of Gavi contribution by country is driven by the size of the target population in each country. However, all countries face not only variable costs which are driven by the size of the target population (e.g. number of vaccination teams, number of vaccination cards) as well as fixed costs which are less dependent on the size of the target population (planning and coordination, design of training materials and guides, launches, some ACSM activities, etc..). Countries with larger target populations are in a better position to absorb these "fixed costs" than those with smaller target populations, unless the latter can mobilise additional funding as was the case for CAR and Zimbabwe in this round.

Issue 13: Given the importance of fixed costs in Gavi-supported activities, the formula for calculating budget ceilings which is largely driven by variable costs put countries with smaller target populations at disadvantage.

Recommendation

Gavi should consider including in the calculation of budget ceilings for countries with smaller target populations some measure to alleviate the impact of fixed costs on smaller budgets. One way to do this is to breakdown the budget ceiling into two components: a semi-fixed component that varies only marginally with the size of the target population and a variable component that varies entirely with the size of the target population.

2. Campaign staffing requirements as the main cost driver of the budget and other costs

Human resource (HR) costs are the major cost drivers in all SIA applications. This is partly because HR requirements are generally higher for campaigns than for routine immunization but also because

countries tend to systematically over-estimate those requirements, resulting in artificially inflated budgets.

While the IRC recognizes that the delivery of mass vaccination activities relies heavily on vaccinators at the front line during the campaign days, most applications failed to articulate the human resources requirements with the overall campaign approach.

CAR was the only country which provided a detailed and differentiated costing and budgeting of the 3 campaign delivery strategies (fixed, outreach, mobile). No other country made genuine efforts to articulate the number of the vaccination teams with the overall campaign approach.

As a result, the large number of staff involved in the various campaigns is often lacking programmatic rationale in both the POAs and in the budgets. For example, Uganda based most budget calculations on data which is artificially inflating the number of vaccination teams compared to the POA (11,221 vaccination teams used in budget calculations compared with 9,618 vaccination teams stated as the requirement in the POA).

Ethiopia used a 6-member vaccination team composition in all budget calculations without supporting justification. This alone resulted in an inflation of the number of staff and associated costs by approximately 50% compared to other countries (Uganda) which used a 4-member team composition.

CAR included 2 vaccinators in all vaccination teams, including for outreach and mobile delivery strategies where the expected workload per team may not justify deploying 2 vaccinators.

It should be mentioned that the large numbers of staff involved in the campaigns have a multiplying effect on other costs, including training, transport, supervision, etc.

For example, transport cost in the Ethiopia application account for 27% of the total Gavi contribution. This cost is largely driven by vehicle rental (US$1.4 million) and fuel cost (US$791K).

In addition, there is a large number of Woreda level coordinators (2,256) whose role in the campaign is not clearly defined in the POA or in the budget, and who will be deployed at a cost of $1.33 million (including US$427K for training, US$256K for DSA and US$649K for transport).

In the Mozambique application, there is a large number of social mobilisers (16,704 individuals) engaged in ASCM-related activities of the MR follow-up campaign which has inflated this budget line item (US$638K, almost 22% of the total OPs costs requested from Gavi).

Compounding all of the above is the number of staff involved in training activities. For example, Ethiopia plans to train a total of 105,389 participants with the help of 36,982 facilitators in a cascade training covering the national, regional, zonal and woreda levels. While many of the same participants will be involved in several training activities indicating duplication of activities and costs, the average ratio of 3 participants per facilitator is another indication of the low efficiency of the planned training. In addition, no justification is provided in the POA or in the budget for these high numbers of staff.

In the Mozambique application, the number of vaccination teams (5829) and the training participants (1,268 participants @US$95.50 =US$121,094 in total because of the training multiplier) is a significant cost driver.

As a result, it is not surprising that the share of HR costs in the total budget reaches 68% in Ethiopia budget and respectively 54% and 50% in Uganda and CAR budgets. These shares[1] are significantly higher than the Gavi ceiling of 30%.

Issue 14: Over-estimated staffing requirements for campaigns result in inflated budgets and in higher shares of HR costs in the total budgets

[1] These shares include per diems classified under Events, Training & Meetings, and are therefore higher than those shown in the budget template summary table of each country.

Recommendations

- Ensure inclusion in the application of information related the calculation and distribution of the vaccination teams as the main cost driver of other costs (e.g. allowances, transport, supervision)
- Ensure that the number of staff involved in all planned activities are fully justified
- Keep the share of HR in the budget at a reasonable level, in line with Gavi budgeting guidelines.

3. Inflated input quantities and prices

While the number of staff involved in the planned campaigns remains the main cost driver, other input quantities make significant contributions to budget inflation. These quantities are generally inflated with little supporting justification in the budget template or in the POAs. For example, in the Ethiopia application many of the input quantities are calculated based on "previous experience" without specifying the actual basis for such calculations.

In the CAR application, DSA was budgeted for respectively 8, 10 and 12 days for different categories of staff, while the campaign duration is only 5 days. In the Uganda application, the cost of TV and Radio spots which take a large share of the budget (US$683K) is calculated on the basis of 3 months continuous daily airing while the campaign duration is only 5 days.

Inputs prices are generally not a major cost driver in the budgets reviewed in this round, except for unit prices of vehicle rental and DSA rates. Although the per diem rates used in different applications appear generally aligned with government policy (Uganda, Ethiopia), the systematic use of UN rates in some applications (CAR, Zimbabwe) tend to inflate the budgets.

Issue 15: Inflated input quantities and prices with little supporting justification

Recommendations

- Request countries to provide justification and programmatic rationale for planned quantities and prices.
- Encourage transitioning countries to develop and adopt their national DSA policies to ensure sustainability of activities currently funded from Gavi contribution
- Ensure greater focus in pre-screening on planned quantities and unit prices.

4. Misalignment of budgets with POA

The disconnect between budgets and POAs was quite significant in this round. For example, Ethiopia and Uganda which are receiving the larger share (63%) of Gavi contribution both submitted good quality technical proposals but largely mis-aligned budgets.

The pattern of resource allocation reflected in the Ethiopia budget is largely mis-aligned with the strategies and activities outlined in the POA. In addition, while the POA outlines detailed strategies for reaching the hard to reach and zero dose children in different settings, none of these strategies, except for the traditional support given to the developing regions of Afar, Somali, Benishangul and Gambella, are costed and reflected in the budget.

The Uganda budget was also largely misaligned with the POA. For example, the target population, vaccination team's workload and number of vaccination teams stated in the POA were used only for the calculation of the cost of vaccination cards, while other budgeted activities used inflated and unjustified values for these 3 parameters, resulting a significant overestimation of staffing requirements and related costs[2].

[2] See Uganda budget review for more details.

Nigeria provided an excellent PowerPoint presentation outlining a clear chronogram of activities for the additional request for Rota doses. The March 2020 detailed workplan was updated in April 2021 before submission to Gavi. However, the key activity headings: proposal revision, planning, pre-implementation, implementation and post implementation very well described in the final chronogram are not reflected as such in the excel budget sheet. Activity items budgeted are not reflective of the final chronogram submitted by Nigeria.

Zimbabwe plan of action (section 7.1. Timeline of the MR follow-up campaign) included key ASCM-related activities such as *"intensified social mobilization and communication activities"* which are translated into 8 different budget line items in the costing sheet for a total of approximately US$46K. It made it difficult to link activities planned in the plan of action with the budget allocations.

For Mozambique, Table 1: Summary Timeframe for 2022 MR follow up Campaign in the plan of action is provided with high level activities which are detailed in the costing sheet included in the budget but there's no linkages between the two documents.

Issue 16: Mis-alignment of budgets with the POAs

Recommendation

- Request countries to demonstrate that budgets are aligned with PoAs and that programmatic rationale for the range, frequency and scale of planned activities is provided as part of the application, in particular for vaccination teams, training participants and similar cost inputs.

5. Unbalanced budgets

Another key characteristic of the budgets reviewed in this round is that they generally unbalanced, providing a large share of resources to some activities while other key activities are either inadequately funded or unfunded. This was the case of Ethiopia allocating 52% of the budget to service delivery and 36% to training, while other key activities received only a small share of the budget. Uganda allocated 62% of the budget to service delivery and 30% to ACSM, leaving all other activities with only 8% allocation of the budget.

In most applications, unfunded or inadequately funded activities included those targeting hard-to-reach areas and zero dose children, as well as ACSM activities at the community level, waste management (Uganda and CAR), and mop-up activities (Ethiopia, Uganda).

The CAR application was an exception as the pattern of resources allocation to activities such as service delivery, training, ACSM, capacity building, production of documents, HIS, waste management, and AEFI appear generally adequate with no single activity taking a large share of the budget.

Issue 17: Unbalanced budgets result in some activities taking a larger share of the budget and leaving other key activities either inadequately funded or unfunded

Recommendations

- Ensure that all planned activities are adequately funded
- Ensure a greater focus in pre-screening on patterns of resource allocation in budgets

6. Strategies for reaching zero-dose children and hard to reach areas

Although it was not a key requirement in this round, the IRC expected applicant countries to demonstrate efforts and design strategies to reach zero-dose children in their vaccination campaigns.

However, most countries did not make genuine efforts to articulate differentiated delivery strategies and reflect them in the budget. CAR was the exception in this round as all the planned 3 delivery strategies (fixed, outreach and mobile) appear well costed and reflected in the budget. However, the specific strategies for reaching hard to reach and zero dose children outlined in the POA are not costed as their operationalization requires the identification of those targets through micro-planning which will take place during the campaign implementation phase.

Issue 18: Strategies for reaching zero-dose children and the hard-to-reach are increasingly outlined in the POAs, but not reflected in the budget.

Recommendation

- Ensure that differentiated delivery strategies targeting the hard to reach and zero-dose children are adequately costed and reflected in the budgets.

Review Process

In this round, we observed continued improvements in the process, including the use of Zoom though in-person meetings remain more suitable; scheduling the meeting with an intervening weekend which allowed for report writing and presentation preparation; a half day schedule which is preferable for remote IRC; and more systematic and higher quality budget pre-screening than in past. However, there remain some challenges for the appraisal related to the period of transition to Gavi 5.0 and the process of pre-screening and preparation of application packages.

Issue 19: Transition to Gavi 5.0 with new expectations but not new templates complicated the process. Some expectations under Gavi 5.0 require use of additional data and further tailoring of strategies, while new templates to facilitate this at country level had not been issued in a timely manner.

Recommendation

- Maintain flexibility in review using 5.0 standards in next round

Conclusion

While this round was comparatively small in terms of the number of applications submitted, the overall funding amount requested was large. Several applications required lengthy reviews and discussions, as reflected in the issues raised in this consolidated report.

Countries are commended for developing successful applications, notably because several of these countries are fragile, and all are additionally affected by the COVID-19 pandemic. Approval rate for this round was 83%, 80% for the MCV applications. This may reflect more in-depth pre- screening reviews, as well as the Secretariat increasing the quality threshold to submit country applications to the IRC. While the IRC appreciates that it is not asked to review inadequate applications, it is concerned that applications being returned at any level of review delays the ultimate approval of justified activities. The ultimate goal of the process being to assure high-quality activities as described in high-quality plans, efforts to assist countries in the development of acceptable first applications would be optimal.

The analysis did identify a number of recurrent issues and weaknesses with MCV and MR proposals that, if adequately addressed through technical support, could result in more robust applications and improved implementation. These involve insufficient use of lessons learned from previous campaign technical reports, the cross-use/standardisation of supply chain and waste management tools across GAVI applications, and non-alignment of proposed tailored strategies with composition, norms and budgets for vaccination teams. The IRC also found insufficient documentation of the basis for tailored strategies and reiterated the need to place continuous emphasis on improving budget rationale and budgetary assumptions to ensure critical interventions are funded and deliver value for money.

Other issues that the IRC identified for further consideration by partners would be the evaluation of the impact of plans to reinforce RI through SIAs in previous campaigns, as well as other innovations planned by countries, funding of community based organizations/teams/volunteers between SIAs, the scope of activities to achieve the aims of the gender strategy that are feasible during campaigns, the standardisation of coverage evaluation surveys to assure their quality and use and the development of tools for use of survey data at sub-national levels.

Finally, the IRC recognises that COVID-19 presents deep challenges for countries to both respond to the pandemic but also to recover and maintain their routine immunisation programme. This is true for all countries in this round and particularly so for those that are set in a fragile context and thus at increased risk in particular of measles outbreaks. It is therefore important that targeted TA support is provided to these countries to maintain routine coverage, deliver high-coverage campaigns, and also where relevant introduce new vaccines.

Acknowledgements

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Our sincere thanks go to all the Gavi Secretariat, SCMs and country team members, Focal Points, Finance Team Members and the Vaccines Programme Team members in particular. Their timely and informative pre-screenings and the inputs during plenary sessions, often providing country-level perspectives, were particularly useful during plenary discussions and final decision-making. We are also very grateful to the Gavi IT team for ensuring the smooth conduct of this virtual IRC meeting.

Finally, we wish to recognize the essential contribution of our key technical partners, UNICEF and WHO. Their support to countries in preparing the applications, and their valuable contributions to the IRC reviews with timely contributions and clarifications on global policies and strategic issues, are always greatly appreciated.

Annex 1: List of IRC Members

#	Name	Nationality	Profession/Specialisation	Gender	Lang.	Expertise
1	Aleksandra Caric	Croatia	Independent consultant	Female	FR	Measles, AEFI surveillance and vaccine safety, programme management, and primary health care
2	Natasha Howard	Canada, UK	Associate Professor, NUS School of Public Health and LSHTM, Singapore	Female		Health policy, social epidemiology, immunization service delivery, fragile setting, refugees
3	Stefano Lazzari INTERIM VICE-CHAIR	Italy	Independent Consultant	Male	FR	Outbreak, epidemic and emergency response, fragility, emergency, and refugees
4	Dafrossa Lyimo VICE-CHAIR	Tanzania	Independent consultant	Female		Immunisation campaigns, programme and health systems management, disease control, RI, surveillance
5	Benjamin Nkowane	Zambia	Independent consultant	Male	FR	Measles, epidemiology, mass vaccination campaigns, technical support for field operations in risk areas
6	Tcha Landry Kaucley	Benin	National EPI logistics manager	Male	FR	Cold Chain, vaccine logistics, EPI monitoring & evaluation, public health management
7	Abdel Tibouti	Morocco, Canada	Independent Consultant	Male	FR, AR	Financial and Budget Analysis, Health Economics, Health Financing Strategies, Program Planning M&E
8	Karen Wilkins INTERIM CHAIR	USA	Independent consultant	Female	FR	Routine immunization, measles, polio, surveillance, planning & evaluation
9	Teklay Desta	Ethiopia	Measles elimination advisor to Ethiopian Ministry of Health	Male		Managing immunization program, Vaccine Preventable Disease surveillance and outbreak investigation, NVS introduction and data management
10	Ousmane Dia	USA	Independent consultant	Male	FR, RU	Routine Immunization, project/program management, supply chain management, Biomedical equipment maintenance, healthcare waste management.
11	Ousmane Sy	Senegal	Independent consultant	Male	FR	Financial Management, Grant Management, Health and Community System Strengthening, Donor-compliance