REPORT OF THE NEW PROPOSAL INDEPENDENT REVIEW COMMITTEE TO THE GAVI ALLIANCE SECRETARIAT ON THE REVIEW OF APPLICATIONS

Geneva, Switzerland March, 2019

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List of Acronyms

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ADD	Additional Funding (Request)
AEFI	Adverse Event(s) Following Immunization
A&R	Applications and Review (of the Gavi Secretariat)
BCC	Behaviour Change Communication
CC	Cold Chain
CCE	Cold Chain Equipment
CCEI	Cold Chain Equipment Inventory
CCEOP	Cold Chain Equipment Optimization Platform
CCL	Cold Chain Logistics
CMYP	Comprehensive Multi Year Plan
EPI	Expanded Programme on Immunization
EVM	Effective Vaccine Management [assessment and Improvement Plan (IP)]
FER	Fragility, Emergency and Refugee Policy
HLRP	High Level Review Panel
HPV	Human papillomavirus
HR	Human Resources
HSIS	Health Systems and Immunization Strengthening
HSS	Health Systems Strengthening
ICC	Inter-Agency Coordination Committee
IRC	Independent Review Committee
MCV	Measles Containing Vaccine
MenA	Meningococcal serogroup A vaccine
M&E	Monitoring and Evaluation
MNCH	Maternal Neonatal and Child Health
MR	Measles-Rubella
NITAG	National Immunization Technical Advisory Group
NVS	New and underused Vaccine Support
PEF	Performance Evaluation Framework
PoA	Plan of Action
PSR	Program Support Rationale
RED/REC	Reaching Every District/Reaching Every Community
RI	Routine Immunization
SCM	Senior Country Manager
SIA	Supplementary Immunization Activity
SMS	Short Message Service
ТА	Technical Assistance
TCV	Typhoid Conjugate Vaccine
TOR	Terms of Reference
TWGA	Technical Working Group for Health
UNICEF	United Nations Children's Fund
VIG	Vaccine Introduction Grant
WHO	World Health Organization

1. Executive Summary

The IRC met in Geneva, Switzerland 11th – 22nd March 2019, and reviewed 19 applications from 15 Gavieligible countries; 14 were recommended for approval and 5 for re-review.

The IRC was comprised of 17 reviewers with expertise in immunization; cold chain and logistics; maternal, neonatal and child health (MNCH); adolescent health; health systems strengthening; reproductive health program management; epidemiology; monitoring and evaluation; and financial analysis. Six (6) new members joined this IRC meeting bringing in additional expertise in immunization; epidemiology; health systems strengthening; fragilities, emergencies and refugees; cold chain and logistics; finance, budget and program management. Two members focused on in-depth financial reviews of the budgets submitted by applicant countries, and two members (one remotely) focused on cold chain and logistics (see Annex).

The IRC members focused on the following specific tasks during the review period:

- Review of country specific funding requests and supporting documentation for applications (including comprehensive Multi Year Plans (cMYPs), vaccine introduction plans, and plans of action) for vaccine introductions and campaigns to support countries through efforts to strengthen the coverage and equity of immunization.
- Production of evaluation reports and recommendations for each country.
- Development of a consolidated report of the review, including recommendations for improving funding requests, including planning, budgeting, M&E, financial management, gender and equity considerations.
- Recommendations to the Board and the Alliance partners on improving processes relating to Gavi policies, governance, and structure.

The IRC commends Gavi for Board Approval (June 2018) of the Fragility, Emergencies and Refugees (FER) policy, with its focus on transparency, prioritization, flexibility, complementarity and gender. The IRC considers it timely since many Gavi eligible countries are, or risk becoming, eligible for FER support. Six FER countries (CAR; Chad; Somalia; Sudan; Yemen; Zimbabwe) were reviewed during this round.

The IRC commends Gavi for continuing efforts to integrate elements of the portfolio planning process into the Geneva-based IRC review. The lessons learned from the pre reviews, remote reviews, and PSR process must be used to facilitate a more robust review process and improve the PSR structure. One key issue for Gavi is whether to leverage support for community-based targeting, using the specific needs and markers of typhoid risk.

Waste management continues to be persistently neglected by countries, despite its vital importance and repeated comments and recommendations from the IRC. Countries should be urgently encouraged to actively plan for waste management as an essential component of health and immunization system strengthening; plans and budgets should be demanded.



Figure 1: Overview of Applications

Table 1: Summary of Review Recommendations

	COUNTRIES	TYPES OF SUPPORT REQUESTED		JESTED	RECOMMENDATIONS	
		HSS/ CCEOP	MEASLES/ RUBELLA	OTHER		
1	Cambodia			HPV	APPROVAL	
2	CAR			Additional funds for MFU OPS	APPROVAL	
3	Chad		MCV2	MenA catch-up campaign (3 provs)	APPROVAL - MCV2 APPROVAL - MEN A	
4	Ethiopia		MFU		APPROVAL	
5	Ghana	CCEOP			APPROVAL	
6	Guinea		MCV2		RE REVIEW - M 1+2	
	Guillea		MFU		RE REVIEW – MFU	
7	Guinea Bissau	CCEOP			APPROVAL	
8	Lesotho	PSR HSS2			RE REVIEW HSS2	
Ŭ		PSR CCEOP			APPROVAL - CCEOP	
9	Liberia			TCV R+TCV CU	APPROVAL	
10	Mauritania		MCV2		APPROVAL	
11	Rwanda	PSR/ HSS			RE REVIEW	
12	Somalia		MCV2		RE REVIEW	
13	Sudan	CCEOP			APPROVAL	
14	Yemen	PSR HSS			APPROVAL – HSS	
14		PSR CCEOP			APPROVAL – CCEOP	
15	Zimbabwe			TCV R+TCV CU	APPROVAL	

2. Review Methods and Processes

Criteria for review

All applications were assessed by the extent to which they meet application requirements, and whether they align with the principles of Gavi support. Other considerations included the likelihood that the country plan will achieve the proposed results and contribute to Gavi achieving its mission and strategy, taking into account the justification of the introduction decision, soundness of approach, country readiness, feasibility of plans, system strengthening and sustainability, economic and financial considerations and public health benefit of the investment in line with Gavi mission. These criteria were stringently adhered to, in an effort to ensure that the IRC meets its core mandate to contribute towards guaranteeing the integrity and consistency of an open and transparent funding process.

Methods

Two reviewers were assigned to each country (three for the reviews of Guinea and Liberia); each reviewed the application independently and prepared individual assessment reports. Prior to arrival in Geneva, IRC members reviewed the applications and supporting documents, and prepared the analyses of as many of their assigned countries as possible. This afforded the opportunity to clarify any points and provide additional documents and/ or country information prior to the review in Geneva.

Gavi's intention is to integrate elements of the portfolio planning process into a Geneva-based IRC review; in line with this, an innovative approach to reviewing the country documents was done during this round, with the pre-review of two countries (Ethiopia; Chad), and remote review of three countries (Yemen, Rwanda, Lesotho) prior to the IRC desk review in Geneva. This involved the early start of country engagement and iteration/dialogue between IRC and countries. Two reviewers provided comments on the original application, and these were sent to the country for responses prior to the Geneva IRC. Unfortunately, a teleconference with one of the countries, Ethiopia, during the review in Geneva was unsuccessful due to technical reasons, and communications had to be continued by email. The findings and recommendations for the PSR/Pre-Review/Remote Review processes are outlined in the relevant section of this report.

Each country application and supporting documents were independently reviewed by assigned 1st and 2nd reviewers. This was followed by presentation of initial findings with extensive discussions during daily plenaries. In some instances, the IRC adjourned decision-making to obtain additional information and clarifications from the country, the SCM and other colleagues in the Secretariat, as well as from Technical Partners. Key outcomes, decisions, and recommendations were then consolidated into draft country reports by the 1st reviewer; these drafts then subsequently underwent a rigorous process of quality review, fact checking and internal consistency checks as part of the finalization process.

Two financial cross-cutters provided support to the reviewers on all matters related to finance, including budgets and financial management and sustainability. The CCEOP/CCL reviews were supported by four cross-cutters, one remotely.

During this round, four IRC members had to be recused during the review of four countries (Mauritania, Rwanda, Somalia, and Zimbabwe) because of conflicts of interest.

Decisions

The IRC recommendations were in two decision categories: approval with issues to be addressed in consultation with the Gavi Secretariat and partners; and re-review with resubmission of the revised application to the IRC.

Good Practices and Promising Innovations

Country specific promising activities included a pilot of direct electronic payments (for field staff) in Chad. The IRC considers this a promising idea that needs to be evaluated (with Gavi support) prior to recommendation for introduction into other countries.

Mauritania is the first country to document the establishment of a Steering Committee on Measles that is functioning effectively in support of the country's efforts to eliminate measles. Although this is recommended by WHO, the country's implementation is considered laudable and must be shared with other countries to inspire them to ensure that every child has had two MCV doses by the age of school entry.

Yemen is a country in crisis, and the work done by the Secretariat, partners and consultants to succeed in bringing together, for the first time since the beginning of hostilities, the two opposing sides in Yemen to agree on the PSR objectives and strategy for the country, is truly commendable.

3. Key Findings and Recommendations

NVS and Campaigns

The IRC examined 7 applications for new vaccine introductions of which 4 were MCV2 introductions, 2 TCV introductions with preceding catch-up campaigns (Liberia, Zimbabwe), and 1 HPV introduction (Cambodia). The IRC also examined 2 applications for measles follow-up SIA, and two requests: one for supplemental doses for previously approved MenA catch-up campaign (Chad), and a request for additional funding for previously approved measles follow-up campaign (CAR). Total amount requested was US\$ 19.86 million, and the total amount recommended for approval was US\$ 16.93 million.

The quality of the proposals was variable, with several providing rather generic and not sufficiently tailored approaches needed to ensure high coverage and reaching un- or under-vaccinated populations. There seems little exploration of options offered by technological developments and the rapid take-up of smartphones. On the other hand, vaccination cards continue to be printed despite retention rates being so low as not to be useful for measuring coverage.

Measles and rubella vaccines

During this review window, five countries applied for measles or measles-rubella (M/MR) support. One country (Ethiopia) applied and was recommended for approval for MCV follow-up campaign while three countries (Somalia, Mauritania and Chad) applied for measles second dose (MCV2) introduction into routine and of these, Chad and Mauritania were recommended for approval. One country (Guinea) requested support for MCV2 introduction and a preceding follow-up campaign, and neither was recommended for approval. Further, under Fragility, Emergency and Refugees Policy, CAR requested additional support for already approved follow-up campaign (November 2017) as Government development partners (WHO, UNICEF, MSF) during the planning phase were unable to mobilize the committed funds. This additional funding request was recommended for approval. Funds requested amounted to US\$ 13.65 million for operational costs and introduction grants, and the total amount recommended for approval for 5 countries and additional FER-policy request is US\$ 10.72 million.

Issue 01: Countries did not recognize MCV2 introduction as an opportunity to develop tailored and impactful introduction plans

In the effort to control measles and end the reliance on resource-intensive SIAs, countries apply for the MCV2 introduction. While some attempts are made to identify operational strategies to offer vaccinations to children >1 year of age, the introduction plans often remain generic, not specifically tailored to country needs. In many countries, even when the policies and guidelines are put in place, the change in practice appears slow to happen (Figure 2 shows little or no impact of MCV2 introduction on MCV1 coverage). This may be also magnified by the fact that countries might fail to record and report MCV1 vaccination >12 months.



Figure 2: MCV1 and MCV2 coverage in countries having recently introduced MCV2

Countries seldom reflect that their administrative coverage data are inflated in their applications. So, they set unrealistically high targets for MCV2. The countries recognize the importance to shift the perception of vaccinations as a health intervention only for infants (i.e. up to 12 months) but miss to use the wealth of local data/information to thoughtfully develop introduction plans which would have an impact on both measles control and on routine immunization strengthening.

In their applications countries seldom reflect on their inflated administrative MCV1 coverage and current practices, and set rather high and unrealistic targets for MCV2. The countries recognize the importance to shift the perception of vaccinations as a health intervention only for infants (i.e. up to 12 months) but miss to use the wealth of local data/information to thoughtfully develop introduction plans which would have an impact on both measles control and on routine immunization strengthening.

Countries acknowledge the need to change their policies and guidelines to allow for extended upper age limit as in many countries vaccinations are not offered to children over 1 year of age even if they were never vaccinated. Countries, however, do not elaborate how 0-dose children >1year of age will be reached and vaccinated with 2 doses of MCV, if and how school entry checks will be organized, and if these school-entry checks will be coupled with provisions for catch-up vaccinations. Along with changes to legislation, policies and guidelines, substantial resources are needed and IRC noted that this is not reflected or prioritized in the introduction and implementation plans.

The plans for MCV2 introduction assume that establishing the second-year of life (2YL) platform, often just mentioned in passing, will be straightforward, without recognizing its complexity and potential for impact on routine programme. Indeed, MCV2 introduction is an opportunity to establish an additional routine contact, which would serve as a platform for catching up with missed vaccinations, and receiving booster doses (i.e. 1st DTP booster). Importantly, it also creates opportunities to integrate with other health services/interventions to children and mothers such as traditional growth monitoring and vitamin A supplementation, health education, family planning, etc. Feasibility of integration with other interventions and creating 'a healthy child visit' should be assessed and planned so that it is tailored to the country context and prioritised based on local disease burden.

Recommendations:

- Gavi and partners to encourage and assist countries to use local data, intelligence and wisdom to develop context-specific MCV2 introduction plans. WHO recommendations and guidelines provide the generic guidance that needs to be adopted to the context of each health facility and leverage HSS funding so that MCV2 introduction increases MCV1 and other national/local schedule vaccines.
- Alliance partners to support countries in collecting, and reporting routine vaccination in children >12 months, notably MCV1; to identify and share best practices on using MCV2 introduction to increase MCV1.

Issue 02: Printing of vaccination cards in countries with low card retention rates

The IRC continues to see requests for high quantities of vaccination cards for measles SIAs in some countries where card retention rate is low. Assumptions for quantity and unit price calculation were not always clearly provided. The only justification for SIA-specific cards is for coverage monitoring that is more effectively done through finger-marking.

Out of 10 NVS applications, all the MFU SIA requested vaccination cards with Ethiopia applying for the highest support amounting to \$2,483,743 (21% of total budget) and Guinea \$154,858 (11% of budget). Other applications were VIG related to new vaccine introduction and share to overall budget ranged from zero to 12%. Ethiopia retention card post SIA is reported to be 51%.



Figure 3: Resources allocated to vaccination cards and card retention rate

Source: IRC applications/ in country surveys

Recommendations

• Vaccination campaigns: Countries and partners to use finger-marking for intra- and post campaign survey monitoring.

Routine vaccination: Gavi and partners should encourage sustainable and cost-effective approaches to health records, including home-based vaccination record (HBR). In its core content these records can have space for vaccines received outside of the routine schedule (i.e. SIA). Programs should be encouraged to develop plans for motivating parents to retain and complete HBRs. In countries where vaccinations are an integral part of child-health programs, comprehensive health services HBRs can be considered. Innovative approaches (e.g. digital home-based records) need to be developed, tested and evaluated.

Issue 03: Introduction of Typhoid Conjugate Vaccine (TCV) and SIAs are nationally focused by default and not being used as a pro-equity tool and to target communities most at risk

Two countries, Zimbabwe and Liberia, submitted applications to introduce TCV. Both countries opted to have a nation-wide program with a catch-up SIA based largely on modelling, supplemented in Liberia by an analysis of intestinal perforations – as suggested in the WHO guidelines. Both countries also had data on clinical cases that suggested risk was nation-wide to support this decision. However, the risk is not based on districts/administrative area but the specific community and its access to safe water.

The Gavi guidelines allow this option and do not provide any incentives for more targeted use and to use the vaccine as a pro-equity tool. Consideration should be given to either provide funding for sub-national strategies OR allow countries to use the funding (calculated on national need) for other ways to achieve the same/better outcome in terms of disease transmission. Extreme poverty, lack of paved roads, and lack of clean water and sewage systems provide potential ways to target specific communities within districts, rather than using the more traditional district-based targeting which programs tend to use. So, this would cause programming challenges, but would require bottom-up planning (and community codesign) that could be broadly beneficial for reaching consistently missed communities.

Overall no equity approach or efforts were used to target communities most at risk, and at the same time addressing issues related to low coverage. Steps could have included identification of these communities; collaboration with the targeted communities to co-design service delivery; and evaluation and adjustment. These populations are also likely to have low routine immunization coverage, and TCV implementation could be used to reach them with other vaccines, in both SIA and routine.

Recommendation

- Gavi policy should incentivise a TCV introduction based on targeting high risk local communities that have one or more known risk factors (as detailed in the current guidelines) such as:
 - No paved roads
 - Poor WaSH situation (clean water, sewage)
 - Extreme poverty
 - Low coverage.
- TCV use as a pro-equity tool to increase overall vaccine coverage in the above communities.
- Country to use typhoid risk analysis as a pro-equity tool to increase overall vaccine coverage amongst the poorest.

AEFI

Issue 04: AEFI surveillance systems are still not functional despite investments at national levels

Vaccine safety monitoring requires reporting of adverse events following immunization (AEFI) so that they can be rapidly investigated and effectively responded to. Strengthening of vaccine safety surveillance is a standing strategic objective in countries' cMYPs, with the defined target to improve reporting. However, despite previous IRC recommendations, not much progress is observed in reaching this target.

We analyzed AEFI surveillance in 12 countries reviewed in this round (Cambodia, Chad, Ethiopia, Ghana, Guinea Bissau, Guinea, Liberia, Mauritania, Rwanda, Somalia, Sudan, and Zimbabwe). Most countries have made important investments at the national levels to establish AEFI committees, produce the national guideline, and have high-level causality assessment trainings.



Figure 4: Number of countries with AEFI committees, AEFI monitoring only in campaigns, and routine AEFI monitoring

Almost all countries now (11/12) have national advisory committees for AEFI in place ('AEFI committees'). However, 7/12 countries report on adverse events **only** during campaigns, and even then the reports are scarce and mostly limited to immunization errors (previously called 'programmatic errors'). Five countries report carrying out AEFI surveillance in their routine immunization programs, but with insufficient involvement of subnational and service delivery staff as the number of AEFI reports remains very low (underreporting). Immunization program reviews often note no zero-reporting and often describe the collected reports inadequate in terms of timeliness and completeness; this limits the possibility of rapid and meaningful assessment and analysis, and leaves very little to do for national AEFI committees.

EPI reviews and post-campaign coverage surveys note gaps in knowledge about AEFI reporting at subnational/service delivery levels, absence of standard operating procedure/protocols, and unclear reporting pathways. Such findings raise concern with regard to the capacity of programs to detect, report and investigate suspected adverse events. They also suggest a possible lack of clear articulation of the important objectives of the system at the time of establishing it, which resulted with deficient support of health workers in AEFI reporting. Clearly, the existence of committees and guidelines is important, but

without timely and complete reporting, it cannot lead to quality evaluation of vaccine safety. 'House should not be built from the roof down.'

Recommendation:

An effective safety surveillance system requires the involvement of healthcare workers at all levels of the program. Countries should re-examine the objectives for establishing their AEFI surveillance systems. Gavi and partners should encourage countries in focusing their efforts to early detect and report the AEFI, so that they could be appropriately investigated, analyzed, and quickly responded to. An important and often forgotten element is feedback to service delivery levels. Feedback should further ensure and encourage reporting, and subsequent actions should have a positive impact on national immunization programs.

Issue 05: Reasons for non-vaccination are not addressed in service delivery strategies

As more children get vaccinated, vaccine-preventable diseases are often no longer perceived as a threat. Instead, attention is drawn to AEFI. Public awareness of vaccine safety has grown also through increased access to information and rumours.

In seven countries for which we had information available from EPI reviews, post-campaign coverage surveys, or KAPB research (Cambodia, Chad, Ethiopia, Guinea, Mauritania, Somalia, Zimbabwe), fear from AEFI, together with rumours and lack of trust, was stated as a reason for non-vaccination. It accounted for 8-38% of non-vaccinated children. In 6 out of these 7 countries AEFI monitoring is conducted only during campaigns. Because of increased number of administered vaccines during campaign, there will be AEFI, readily apparent to both health-care workers and public. If not properly addressed, this may contribute to further fear and hesitancy which may result in a challenge for the immunization program to reach the coverage targets and pose risk for outbreaks.

In their plans of action countries very often include standard communication messages in hope that they will suffice in keeping or increasing public confidence in vaccines. These commonly used messages focus on the vaccine product promotion and/or are used as a reaction to the public opinion to a certain vaccine product. However, these standard communication messages may not always work as intended. Their effectiveness may vary, depending on existing parental attitudes toward vaccines. Although information on these is available from various reviewers, assessments and research, this information is not applied in service delivery strategies, to effectively reach chronically missed children.

Recommendation:

EPI reviews, post-campaign coverage surveys, and formative research may help identify and understand the characteristics of population groups with real and false concerns about vaccines and immunization. Countries should use the findings from these reviews and surveys to tailor strategies, which will address concerns, and build and sustain vaccination uptake.

Data Use and Quality

Issue 06: Use of data for strategic planning and targeting interventions

During this round of the IRC, there was an overall improvement of the data provided with the applications in support of interventions. However, even when the data was of good quality, it was often not linked to the strategies proposed. Measles outbreak investigations were either not done or of poor quality and the interventions proposed/implemented were inappropriate.

Country	Available Data	Data quality	Use of available data
Ethiopia (Measles follow-up)	 Equity analysis Outbreak investigation 	 Good Poor 	 No reference of findings in POA for tailoring interventions Response strategy inconsistent with findings of outbreak investigation
Somalia (MCV2 introduction)	 Accessible areas Equity Formative research on key behavioral and communication barriers 	 Good Good Good 	 No evidence that this information was used to develop the plan of action submitted in the current application for introduction of MCV 2 into the routine immunization in Somalia.
Mauritania (MCV2 introduction)	 Recent measles Post campaign survey (2018) Outbreak investigation 	 Report not available Poor 	 Data not used for developing interventions because of delays in preparing report. Response strategy inconsistent with data from outbreak investigation
Guinea (Measles follow-up and MCV2 introduction)	 Equity Analysis Survey of factors related to the persistence of measles disease Measles outbreaks 	 Good Good Good 	 Data not used in strategies for either activities Data not used despite recommendation from ICC
Chad (MCV2, MenA subnational CU campaign)	 Equity Analysis Data on poor performing regions 	1. Good 2. Good	 No prioritization of districts/regions No link between activities with the HSS plan for 10 low-performing regions

Table 2: Data availability, quality and use in selected countries

Recommendation: Technical support should be provided to countries to ensure available data is used for tailoring interventions. For all support related to measles vaccine, updated national outbreak preparedness and response guidelines should be mandatory and be part of the Plan of Action; including any data collected on recent outbreaks to identify who is infecting whom and the role of vaccine failure vs. failure to vaccinate.

CCEOP and Supply Chain Logistics

CCEOP applications

The IRC reviewed five CCEOP applications, of which four were part of PSRs (Ghana, Guinea-Bissau, Lesotho and Yemen). Three were resubmissions (Ghana, Guinea-Bissau, and Sudan). All applications were recommended for approval.

Applications included the required documentation, but with some issues that ranged from minor to moderate. The foundation for a CCEOP application is a CCE inventory (CCEI) to assess CCE needs. In this round, all applications included a recent inventory in a recommended format. But various errors and issues were noted; for example, not identifying the CCE manufacturer and model at some sites (Sudan). No critical issues were identified.

Important issues were found in calculating CCE capacity storage gaps. For example, Sudan did not seem to project for future population growth and used estimated 2018 infant population data, instead of projecting for 5 to 10 years, as recommended. It is also easy to make errors, such as not including planned new vaccine introductions, even when included in the tool.

One surprising aspect, given the partner support for the application, is the definition of the key indicators to monitor CCEOP. This may reflect the way that the guidelines are written, as well as the lack of a data culture in both government and partner agencies. Two key issues (Ghana, Sudan) are that equipment indicators tend to focus on the CCEOP-supplied CCE rather than the entire cold chain; and that indicators are given for each year rather than being cumulative.

A reflection of this issue, is that when countries who have been approved for CCEOP apply for NVS they do not provide the status of these indicators.

Countries could provide the status of the CCE rehabilitation plan and the maintenance plan and update on supply chain indicators monitored by the country (dashboard), as planned in the CCEOP application. This will provide IRC a much better view on the country readiness for vaccine introduction and supplementary activities, in addition to the IP implementation status.

One of the requirements for the CCEOP and NVS is a recent update on the status of the EVM improvement plan (IP). Countries report progress on the implementation of EVM IP activities. This is reported as a percentage of activities that have been implemented. A more strategic view would give lessons learned about successful implementation and constraints that have prevented starting or completing implementation. However, the key issue is the impact of activities on system performance, which could be provided by CCEOP indicators as an interim measure of success/failure until the next EVM assessment is conducted.

Of note, some countries that have a low rate of completion of EVM IP activities, yet still improve their score at the next EVM assessment. Others that have a higher completion rate still do not improve at the next EVM. This could reflect issues with the IP itself, the quality of implementation, or that a small number of critical activities were not completed, whilst less critical ones were completed.

Reviewers identified some key good practices and issues to be addressed.

For example, more countries are integrating CCE requirements for the entire supply chain into their rehabilitation plans, and no longer only for the equipment requested from CCEOP (Ghana, Guinea Bissau),

which allows them to consider long-term improvement from end to end supply chain. Also, some countries are using the opportunity provided by the PSR to consider the establishment of CCE management, including a robust maintenance system (Yemen).

Issue 07: Icepacks for vaccine transport and outreach delivery.

Most countries use the conditioned ice pack policy for transport thus request freezer capacity and do not request freeze-free vaccine carriers. Use of cooling material for out-reach or immunization session at fixed post is not well documented (ice pack, conditioned ice pack, chilled water pack).

Recommendation: Gavi and Partners to support countries to develop national policy for keeping vaccines cold during transport and during vaccination sessions (fixed post, outreach), that will support CCE selection. Partners (WHO) should provide guidance to countries to decide on a country specific policy based on its context and local evidence. Gavi should consider requiring a national cold chain policy as part of CCEOP to help provide an appropriate standard for the requested CCE.

Issue 08: CCEOP ceiling too low to meet country needs.

Countries have responded to their ceiling in different ways. Ideally, the ceiling would not be an issue. For Sudan, the ceiling amounts to less than \$4 per child in the birth cohort. This is much less than Gavi vaccine support, and suggests that the ceiling needs to increase to ensure that Gavi's investment in vaccines is safeguarded.

Countries have taken two approaches to the ceiling being lower than need. Some, like Sudan have applied to the ceiling; others (Ghana) have applied for their full need but prioritize the initial support to the ceiling, and others have just applied for their need but not prioritized support until after approval.

Recommendation: Gavi guidance to state that the country should apply for its entire need, but then prioritize so that urgent needs can fit within the Gavi ceiling (first two years of support).

Cold chain and logistics (CCL)

The CCL aspects of new vaccine introductions and SIAs were also reviewed for all other applications. As noted in previous IRC reports, countries generally provide limited or no data on the adequacy of cold chain storage and transport capacity, but state that it is adequate, making assessment of adequacy difficult.

Issue 09: Assessing adequacy of CCL for NVS introductions and SIAs.

The IRC has previously recommended that these data, especially at subnational levels, should be provided. However, the IRC has not placed much emphasis on this given that there have not been any issues. Rather than restate the recommendation, the IRC proposes this:

Recommendations: Gavi to evaluate if there have been any CCL capacity issues for introductions and SIAs by systematically reviewing PIEs and PCCS reports to identify issues that arose compared to the IRC assessment. (This review is also for immunization waste, as described below.)

Gavi to require countries to provide annual status of the CC rehabilitation plan and update on supply chain indicators monitored by the country (dashboard). This will provide IRC a much better view on the country readiness for vaccine introduction and supplementary activities, in addition to the IP implementation status.

Issue 10: Safe disposal of immunization waste.

The IRC noted no progress in the management of immunization waste, despite repeated recommendations from the IRC. The IRC recognizes that this is a challenging issue as it is a broader health issue than just for immunization; and that there are no environmentally acceptable solutions are implemented yet. However, most countries use the second worst option of 'burn and bury', even when incinerators (the least bad option) is available but costly. (The worst option is disposal in landfills).

Recommendations: Gavi to document county practices and any issues that may have arisen, as documented in PIEs and PCCSs, (This review is also for cold chain adequacy, as described above.)

Gavi Alliance to develop innovative solution for immunization waste management (as part of a broader strategy for health waste management), and provide guidance to countries on minimum standards for waste disposal, based on the review of country experience.

Issue 11: Vaccine wastage.

Countries set wastage rate target that may impact immunization coverage (Guinea). Increasing the number of immunization sessions may not increase coverage but probably wastage (Somalia). (The HLRP has recommended daily immunization to improve coverage but having planned sessions that meet community needs and are delivered as planned may be more effective as well as reducing wastage).

Recommendation: Gavi to encourage countries to focus on closed vial wastage; and allow site specific wastage rate for open vial (that depends on session size) to ensure that coverage remain the main objective. Gavi to support countries in decision for increasing number of sessions vs increasing session attendance, considering coverage and wastage issues.

Equity

All of the country applications submitted to the March 2019 IRC included at least a short a description of equity issues and eight (Cambodia, Chad, Ethiopia, Guinea, Rwanda, Somalia, Yemen, Zimbabwe) included a more comprehensive equity analysis as part of their application. All applications included some consideration of how inequities affect coverage, e.g. descriptive statistics and/or qualitative analyses by caregiver education, household wealth, geography (urban/rural, subnational regions), sex differences in coverage, and migration/displacement in some countries. However, among those countries that presented a more comprehensive equity analysis, only four applications (Cambodia, Mauritania, Sudan, Zimbabwe) clearly used the equity analysis provided to inform the implementation plan, e.g. social mobilisation approaches, outreach.

For example, Rwanda and Ethiopia provided good equity analyses, but these did not align with proposed social mobilisation activities and did not appear to be used to prioritise interventions. This lack of alignment was particularly notable in TCV applications, which require an equity lens to identify needs, target those at greatest risk, and address vaccination barriers. In contrast, Mauritania used its analysis to inform outreach for nomadic populations.

Issue 12: Limited evidence that equity analysis is informing plan of action and budget

Countries are increasingly funded to produce detailed equity analyses. Some, generally descriptive, analysis of equity issues is being included in applications. However, this is often relatively superficial

and/or identified equity issues are often not used to prioritise, refine, and budget action plans. There is only limited evidence that equity analyses are used to plan strategies to increase coverage.

Recommendation: Countries and partners are strongly encouraged to ensure that equity analyses explicitly inform application action plans and budgets, particularly in terms of prioritising outreach and social mobilisation activities, resources, and timelines.

Budget and Financial Sustainability

Waste Management:

In this, as well as in previous reports, the IRC frequently raised the critical importance of correct management of vaccination waste by countries. Waste management has become a particularly sensitive area in the context of growing and frequent vaccination campaigns responding to recurrent outbreaks of measles, and also in the view of new vaccines being introduced into countries' immunization schedules (Typhoid, IPV, HPV, etc.).

During this March review, IRC found that countries are not adequately addressing critical issues related to waste management, including sufficient budget allocation to this line item in the funding requests to Gavi.

HSS/Waste Management: Varying and low budgeting of waste management activities

Three countries submitted PSR applications during this IRC round: Lesotho, Rwanda and Yemen. Within the HSS component, countries should provide a detailed situation analysis on waste management and outline appropriate strategies/interventions to address any gaps identified. However, despite HSS proposals including a specific objective on cold chain and vaccine management, waste management was generally neglected. For example, Rwanda and Yemen had no budget allocation for waste management and Lesotho budgeted less than 2% (only 1,24%) without further details.

It is not clear to the IRC if other partners (under PEF arrangements) are providing support and technical assistance to countries on waste management, or if the countries have their own sources of funding. Such support is not clearly articulated and described in the NVS and PSR applications reviewed during this round.

Findings:

- Only 3 out 8 NVS applications have a budget line item allocated to waste management which is relatively very low (varying from 1% for Liberia to 3% for Ethiopia).
- Overall, the waste management budget represented only 2% of the total NVS requests (approx. USD17M) submitted to Gavi in this round.
- PSR applications (including HSS component) have not planned and budgeted for waste management, which is a missed opportunity from the health system strengthening perspective.

Recommendations:

• Countries should be requested to have detailed description of waste management strategies/activities when conducting campaigns or implementation HSS grant, with e-marked

budget allocations; if not planned or budgeted for, countries should provide an explanation on how waste management should be financed.

• Waste management related support and technical assistance provided by partners should be clearly described/outlined in the NVS or HSS applications.

Issue 13: HR-related Costs need to be better defined and justified

Gavi is in the process of having a more defined and realistic approach to what is called HR-related costs (per diems, incentives, allowances, salaries, etc.) in NVS applications. It is a particularly sensitive budget line item which is recurrent during vaccine introduction and campaign activities. Even though the IRC recognizes that the motivation of health workers, supervisors, volunteers, etc. is critical for day-to-day operations of the EPI, 5 out of 8 applications have HR-related costs that were in average 36% of the total NVS budget requests. Considering that appropriate Gavi cost categorization is not applied consistently by all applicants, it is very challenging to draw meaningful comparison of proportions across different budget line items. HR-related costs vary from 31% in Somalia to 73% in Liberia and around 56% for Cambodia, Guinea and Zimbabwe.

There is an urgent need for Gavi to specify an appropriate and realistic definition of HR-related costs and to support applicant countries to complete the budget template to reflect the true activity description and the real nature of each budget line item. Improvement of budget cost categorization will help IRC reviewers in making sound financial analysis of the requests.

In **PSR applications**, HSS's purpose may be to address human resource deficiencies, including shortage of qualified and motivated work force to advance immunization agenda in the context of fragile and non-resilient health systems. In these cases, budget allocations for HR-related costs to deploy health workers in low coverage areas and groups with inequities, appear justified; the PSR needs to clearly outline this in the situation analysis as well as activity description and corresponding budget.

Findings:

- 5 out 8 NVS applications have HR-related costs above the bar of 30% and 4 countries have HR-related costs between 56% (Cambodia which is in preparatory transition phase) and 73% (Liberia);
- There is a misinterpretation of HR-related costs as not all what is categorized as HR costs in the budgets is actually real HR costs; items eligible under the cost recovery mechanism (DSA paid for frontline vaccinators, DSA paid to staff on travel duty: training, supervision, meetings, etc. outside of their work station, etc.) are still categorized as human resource costs by many countries;
- HR-related costs may well be justified and accepted by IRC given the country context but countries are not providing sufficient explanatory and budget notes to back up their costings.

Recommendations:

- Gavi should provide countries with a clear definition of HR-related costs and have a realistic approach on how these costs can be budgeted based on country specific context. A list of HR costs as example, should be available to countries.
- Applicant countries should provide detailed costing assumptions which justify any HR-related budget above the range and explain how these fit into their strategies to close coverage and equity gaps within the EPI.

PSR and Pre-Review Outcomes

The IRC continued to explore the implementation of Pre-reviews and PSR reviews in conjunction with the secretariat. It acknowledges the strong support of the country teams and A&R teams in helping to plan and move the process forward. Key lessons learned from the evolving processes are as follows:

Pre-review Process (experiences with Ghana and Ethiopia during this window):

- Pre-review offers countries the opportunity to engage in valued dialogue processes with the IRC to clarify issues and address gaps based on already available information at country level.
- Also provides the opportunity for the IRC to seek clarifications on specific issues in the application with good spacing if well-handled ahead of the Geneva-based review. Most of these are key in reaching a decision. The overall common factor in this is that the countries usually have information to provide for the clarifications.
- Although questions are sent to the country in advance, it is better to have a follow-up conference call to discuss the country responses. Essentially it is better to have a dialogue in addition to the answers provided in writing.
- The pre-review will not however solve fundamental issues in the proposal (such as strategy/intervention design). Given the lengthy and multi-actors engagement process which happens during the full country portfolio planning (PSR), if material and strategic changes are requested by IRC in the application during the iterative/pre-review phase, EPI team alone does not have sufficient time and capacity to come up with the IRC desired and expected improvements during the pre-review period.
- It is best to always manage expectations at country and secretariat level that in spite of these dialogue processes, the outcome does not necessarily mean an approval by the IRC.

In-country/Remote PSR Review (experience with Nigeria; Lesotho, Rwanda, Yemen)

The in-country PSR review was useful in that it provided an opportunity for in-depth discussion with the country team. It was much easier to clarify important items/considerations related to the application. Overall, almost all questions for clarification were resolved through the country presentations and open discussions. However, the remote PSR reviews were a little more challenging as the countries were unable to provide adequate clarifications. This is due to the fact that when the strategic approaches/interventions are flawed, this is beyond clarification and countries will need to do the work again and that should turn into another proposal re-writing process if the changes to be made are substantial.

For the IRC members, it was useful to see the dynamics of the partnerships and their contributions to the proposals. Even though discussions were open, there was no situation where the IRC members felt they did not maintain their independence.

The amount of time that was allocated to the review was optimal. However, this was probably because the secretariat and the country team had done extensive planning prior to the in-country review. This PSR preparatory work between EPI and Gavi Secretariat is a good practice to highlight in this review window.

Issues 14:

• Deployed TA do not always support the countries through the continuum of using available data/research study findings especially coverage and equity to help define strategically appropriate and costed interventions with good indicators.

• The dialogue process is often seen as a panacea for addressing proposals that are not strategically sound.

Recommendations:

- Gavi secretariat, technical partners and countries should ensure that the needed support is strategic and builds on country level inputs to develop high quality and value for money responses that would strategically impact the lives of children.
- In the country portfolio planning process (PSR), Gavi should encourage locally and regionallybased technical expertise with clear quality assurance mechanisms to make sure countries received the support outlined in consultants' TORs.

Technical Assistance

The IRC has previously noted both improvements and challenges with the TA provided to countries for developing the proposal. In this round there was a stark contrast between these two aspects, with some countries clearly benefitting from high quality TA in developing their applications (e.g. Ghana, Liberia, Zimbabwe) and others where TA quality was poor (e.g. Rwanda, Guinea, Lesotho, and Somalia) or likely worse than country would have done by itself (Rwanda).

For one country (Guinea-Bissau), the country failed to respond adequately to some action points, despite TA being provided by the regional office focal point; so the issue can be the quality of partner agency staff as well as consultants. Another country responded to Gavi's pre-screening advice to define the storage volume required per fully immunized child (cm³/FIC) by stating that WHO and UNICEF consider that this measure was 'out-of-date'. Yet, this remains the quantitative basis for defining CCE needs.

Previous reports have noted the failure of the TA to use the available country data to inform planning and hence the application. This continues to be an issue, especially in relation to using existing equity analyses to guide the program (Chad, Ethiopia).

The IRC has previously noted that countries are not presenting data from their measles case-based surveillance. Although this is now generally improving, this remains an area for better TA support. But even when these data were provided, they were not used to guide their planning (e.g. Ethiopia).

Another aspect of quality TA is that it should meet country needs, and that the country feels ownership and can direct the TA to its needs. The TA should also be building country capacity.

The use of TA by countries is also uneven for different aspects. For example, both TCV applications had good, comprehensive introduction plans – but the budget seemed unrelated to the plan. The disconnect appeared to result from different people doing the plan and budget and not working as a team. The issue was also noted in other applications (e.g., Cambodia). One of the roles of the IRC is to ensure that planned activities have appropriate budget assumptions. Activities that are not budgeted for are unlikely to happen! If the activities are funded from other sources, this should be stated.

Issue 15: Monitoring TA quality to improve it.

The IRC does not need to, and should not, know the identity of the individual or agency providing TA to help countries with their application. However, given the IRC's recurrent concern about TA quality, Gavi should explore ways to improve its quality. One aspect may be to simplify application guidelines and

processes so that countries do not need external TA to submit an application. Monitoring TA results may also provide a way forward; with an important caveat that a poor outcome may be how the TA was used by the country rather than the TA itself.

Recommendations

- Gavi can systematically collect data (as part of the application process) on TA provided in terms of country ownership and IRC outcome. As noted above, this needs to be done with care and with a focus on improving the system and not to blame individuals or partners.
- To address the challenge of the disconnect between different parts of the application, Gavi could consider asking countries to define the person who will have overall responsibility for preparing the application (including ensuring that the budget reflects the plan) and to define the role of any additional TA. This information could be submitted as part of the initial expression of interest, and any changes in TA noted with the final application.
- Gavi could explore the greater use of local TA (institutions and individuals) that would be more cost-effective, better in tune with the local context, develop local capacities, and promote local solutions. The proposed monitoring system would enable comparison of the outcomes of local vs. international TA.

Issue 16: Training

One issue that highlights the TA quality is budget allocation. (As noted already in relation to vaccination cards). Another important example is training. The budgets for vaccine introductions and campaigns had large contribution for classroom-based training (Figure 5), despite its known limitations. It is generally ineffective for sustained skills development and takes health staff away from their work, sometimes for several days. Training provides salary supplementation that may be important for program staff, but could be done more explicitly without taking health workers away from their duties.



Figure 5: Classroom training budgets for NVS and/ or VIG as % overall budget and \$m

Vaccinators need practical skills training, on vaccination techniques, vaccine management, and especially for interpersonal communication. Even microplanning, record-keeping, and reporting are practical skill that are best learnt on-the-job for the specific context of the health worker than in classroom-based training. However, most countries do not have staff skilled in teaching through supportive supervision, despite widely using the term. A smartphone/tablet app could be used to not only provide skills and knowledge training, but also to collect data and provide feedback on performance. Service quality is key for coverage and safety.

Recommendations

- Gavi should consider making classroom-based training ineligible for support (unless well justified). The resources should be used instead for supportive supervision, if the country has the capacity to provide on-the-job training.
- Gavi needs to develop alternative methods, such as building the capacity for on-the-job training; developing app-based training; community and data-based feedback to provide guidance to health workers; and explore other innovative approaches using adult-learning techniques to address the critical need to improve service quality.

Governance

ICC and NITAG governance mechanisms

Fourteen countries submitting applications to the March 2019 IRC had an established ICC or equivalent, though one (Sudan), did not provide TORs.

Eleven countries (78%) submitted minutes of ICC meetings that reviewed and approved the Gavi applications (Guinea Bissau was a re-submission, Yemen was waived under the FER policy, Cambodia only had a mention in the MCH sub-TWGH of the intention to apply). Most countries included at least one CSO representative in their membership (often an NGO representative), indicating some diversity of membership, though Sudan and Zimbabwe either did not or it was not clearly indicated.

An example of good quality in ICC reporting was noted in this round (Guinea) with minutes providing a detailed and clear description of the discussion, summary of decisions taken, and list of actions to be taken with the identified responsible persons.

Only nine countries reported having a NITAG (Cambodia, Ethiopia, Guinea, Ghana, Lesotho, Mauritania, Rwanda, Yemen, Zimbabwe), with TORs included for three (not required for PSR and CCEOP applications). NITAG meeting minutes were only submitted by two countries (Ethiopia, Zimbabwe). Ethiopia and Zimbabwe were the only countries that explicitly included NITAG review of the country proposal, indicating that even those countries with active NITAGs are not making full use of the expertise these national advisory bodies can provide. This raises the question whether the added value of NITAGs and differences in mandates between ICC and NITAG are well understood by countries.

Issue 17: Many NITAGs are still not functional and even when they are, countries are not taking advantage of their input to ensure that Gavi applications are robust and technically sound. Though countries are required to submit NITAG terms of reference and meeting minutes, it is unclear whether NITAGs are required by Gavi to review applications.

Recommendation: Gavi should clarify the role of NITAGs in the development/review of applications. Countries and partners are strongly encouraged to ensure that NITAGs are established and supported to be functional.

Fragility, Emergency and Refugee (FER) Policy

Issue 18: Review of applications from FER countries

The IRC finds that the FER revised policy approved by the Gavi Board in June 2018, is a very positive step in enabling a more tailored approach and additional flexibilities in applying Board-approved policies and processes in countries facing particularly challenging circumstances.

In the March 2019 session, 6 of 15 countries (and 9 out of 21 applications) reviewed (CAR, Chad, Somalia, Sudan, Yemen, Zimbabwe) are identified as FER countries. The applications included 1 PSR (HSS+CCEOP), 1 CCEOP, 2 MCV2 routine, 1 MenA campaign, 1 TCV (campaign and Introduction), and 1 request for additional funds for MFU Operational costs. All applications were approved except one (Somalia, MCV2).

IRC review of applications from FER countries is particularly challenging. Applications are often incomplete and/or poorly developed due to lack of capacities, resources, and time for their development; baseline and coverage data are usually unreliable; and situation assessments are of less value due to uncertainty and volatility. The IRC needs flexibility in applying some of the key review criteria (e.g. country readiness, process for application development, feasibility of plans, value for money, routine immunization and system strengthening, fiduciary risks, financial and operational sustainability). However, the FER policy does not indicate if and how the IRC should apply flexibilities in reviewing applications from FER countries, apart from the administrative requirements (e.g. eligibility; funding ceilings).

PSR/HSS applications pose specific challenges. This is because of the holistic, structural and long-term development nature of the PSR, the need for an extensive preparatory consultative process, the difficulties in planning HSIS strengthening over a period of 5 years in situations of major uncertainty and volatility, and the increased number of partners supporting HSS (including integrated immunization services (e.g. WB, bilateral donors, UN agencies, NGOs).

In situations characterised as fragile or humanitarian emergencies, simpler and potentially shorter timeframe (e.g. 2 years) applications for support and rehabilitation of affected services, ideally aligned with support from other donors, would seem more appropriate. They would reduce the risk of confusion and duplication with partners and avoid the need for repeated reprogramming exercises that require major efforts by the country and Gavi, delay implementation, and might eventually totally distort the objectives and targets approved in the initial application.

Recommendation: Gavi should consider developing appropriate simplified and short-term funding opportunities for FER countries experiencing great uncertainty and volatility.

4. Conclusions

The IRC will like to highlight the following major issues that need focused attention:

- There is a wealth of information at country level, including equity analyses, which is not being used to develop effective strategies that focus on coverage and equity. Encouragement, and if necessary additional technical support, should be provided to countries to ensure available data is used for tailoring interventions and corresponding budget.
- 2. For the FER eligible countries, there should be a review/ evaluation of the current policy with a view to ensuring the provision of appropriate, targeted, and timely support. For example, by providing shorter-term focused funding opportunities or by limiting the period of initial planning for PSR/HSS implementation to two years.
- Gavi should monitor the quality of Technical Assistance (TA). It should also focus on supporting local TA; this is expected to contribute towards strengthening country ownership and decreasing TA dependency. TA needs to address quality of training for front line health workers as key priority.
- 4. Emphasis should continue to be placed on strengthening routine immunization, using every opportunity, including the introduction of MCV2.
- 5. Gavi and partners should encourage countries in focusing their efforts to detect and report the AEFI early, so that they could be appropriately investigated, analyzed, and quickly responded to.
- 6. HR cost guidelines should provide clearer definition of HR, cost recovery support, and clearly indicate maximum limits.

5. Acknowledgements

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Finally, the IRC thanks WHO, UNICEF and all the Alliance partners for their technical inputs during the plenaries, especially pertaining to global policies and strategic issues; as well as for their quality technical support to countries.

Annex: List of IRC Members

No	Name	Nationality	Profession/Specialisation	Gender	French Speaking
1.	Aleksandra Caric	Croatia	Independent Consultant	Female	
2.	Benjamin Nkowane	Zambia	Independent Consultant	Male	
3.	Bolanle Oyeledun	Nigeria	CEO, Centre for Integrated Health Programs	Female	
4.	Clifford Kamara – CHAIR	Sierra Leone	Lecturer, College of Medicine and Allied Health Sciences, University of Sierra Leone.	Male	
5.	Dafrossa Lyimo*	Tanzania	EPI Manager	Female	
6.	Djordje Gikic*	Switzerland	Independent Consultant, Public Health Physician	Male	x
7.	El Hadj Cheikh Hafis Seck*	Senegal	Independent Consultant	Male	x
8.	lan Pett	United Kingdom	Independent Consultant	Male	
9.	Landry Kaucley*	Benin	EPI Logistics Manager	Male	x
10.	Mario Stassen**	The Netherlands	Independent Consultant	Male	
11.	Natasha Howard*	UK	Assistant Professor, London School of Hygiene and Tropical Medicine	Female	
12.	Osman Mansoor	New Zealand	Independent Consultant	Male	x
13.	Ousmane Amadou Sy	Senegal	Independent Consultant	Male	Х
14.	Philippe Jaillard	France	Independent Consultant	Male	Х
15.	Sandra Mounier-Jack – Vice Chair		Associate Professor, London School of Hygiene and Tropical Medicine	Female	x
16.	Stefano Lazzari Italy Independent Consultant		Independent Consultant	Male	Х
17.	Tawanda Marufu*	Zimbabwe	Lecturer, University of Zimbabwe College of Health Sciences, Harare, Zimbabwe.	Male	

*New IRC Members **Remote participation