



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

**Geneva, Switzerland
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List of Acronyms

AEFI	Adverse Event Following Immunization
BCC	Behaviour Change Communication
CC	Cold Chain
CCE	Cold Chain Equipment
CCEOP	Cold Chain Equipment Optimization Platform
DTR	Digital Temperature Recorder
EPI	Expanded Programme on Immunization
EVM	Effective Vaccine Management, an assessment tool
HPV	Human Papilloma Virus
HR	Human Resources
HSIS	Health Systems and Immunization Strengthening
HSS	Health Systems Strengthening
IRC	Independent Review Committee
ISF	Initial Self Financing
MCV	Measles Containing Vaccine
MenA	Meningococcal A vaccine
MNCH	Maternal Neonatal and Child Health
MoH	Ministry of Health
MR	Measles-Rubella vaccine
NITAG	National Immunization Technical Advisory Group
NVS	New and underused Vaccine Support
PIRI	Periodic Intensification of Routine Immunization
PQS	Performance, Quality and Safety (of immunization equipment)
PT/AT	Preparatory Transition / Accelerated transition
RI	Routine Immunization
SCM	Senior Country Manager
SDD	Solar Direct Drive (vaccine refrigerators)
SIA	Supplementary Immunization Activity
SMS	Short Message Service
TA	Technical Assistance
TMD	Temperature Monitoring Device
UNICEF	United Nations Children's Fund
VIG	Vaccine Introduction Grant
WHO	World Health Organization

1.0 BACKGROUND

The third and final Independent Review Committee (IRC) meeting for 2017 was held in Geneva, Switzerland from 3rd to 17th November, 2017. The IRC session was comprised of 20 reviewers with expertise in immunization, cold chain and logistics, MNCH, adolescent health, health systems strengthening, reproductive health program management, epidemiology, monitoring and evaluation, financial analysis, BCC and gender. **(See Annex 1 for list of members).**

The IRC members focussed on the following specific tasks:

- Review funding requests and supporting documentation, including health sector plans, comprehensive Multi Year Plans and supporting documents as applicable to each country.
- Review funding requests and supporting documentation for applications for the CCE optimization platform to support countries with improving their supply chains while contributing to efforts to strengthen the coverage and equity of immunization.
- Provide the Gavi Secretariat with evaluation reports and recommendations for each country.
- Provide the Gavi Secretariat with a consolidated report of the review, including recommendations for improving funding requests, including planning, budgeting, M&E, financial management, gender and equity considerations.
- Provide the Board and the Alliance partners with recommendations improving the processes relating to Gavi policies, governance, and structure.

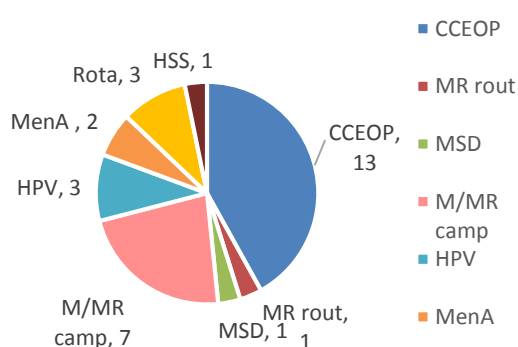
In addition, two members focused on in-depth financial reviews of the budgets submitted by applicant countries; and an external consultant reviewed ICC functionality. During this review window, the IRC also made inputs on to help finalise the previously reviewed PSR application by Zimbabwe.

2.0 REVIEW METHODS AND PROCESSES

2.1 Review process and key outcomes

The review process comprised of an initial stand-alone CCEOP application review by a sub-set of the IRC comprised mainly of CCEOP experts. This was immediately followed by a mixed NVS/CCEOP/HSS/PSR review by the larger IRC.

Figure 1: Nov 2017 IRC - Overview of applications



Review Process: An independent review of each country proposal was conducted by assigned reviewers.

Initial findings were then presented and thoroughly discussed at daily plenaries. Daily plenaries with two parallel sessions were also utilised during the larger IRC review.

Key outcomes and decisions were then consolidated into draft country reports, which then underwent quality review and internal consistency checks.

The IRC was also able to clarify issues with key country officials where necessary through the use of phone calls/emails dialogue. Eight countries were reached through these phone calls and emails.

Decisions: Two decision categories: Approval with issues to be addressed and resubmission with explanations.

Criteria for review: The extent to which proposals (a) meet application requirements and (b) principles of Gavi support and (c) contribution to achieving Gavi mission and strategy.

Key review outcomes: The main outcomes per country application are summarized in Table 1 below:

Table 1		REVIEW OUTCOMES BY COUNTRY AND WINDOW					
Country	CCEOP	MR routine + catch up campaign	MR follow up campaign	Measles follow up campaign	HPV national	Other supports	
1	Afghanistan	Resubmission			Approval		
2	Benin	Approval					
3	Burkina Faso	Approval		Resubmission			
4	Burundi					MenA camp - Approval	
5	Cameroun			Resubmission			
6	CAR	Approval			Approval		
7	Chad				Resubmission	M2: Resubmission	
8	Côte d'Ivoire	Approval					
9	Eritrea					MenA camp: Approval	
10	Gambia	Approval					
11	Ghana	Resubmission					
12	Guinea Bissau				Approval		
13	Kyrgyzstan					Rota: Approval	
14	Lao PDR					Approval Rota: Approval	
15	Mauritania	Approval					
16	Nepal	Approval					
17	Pakistan				Approval		
18	PNG	Approval					
19	Rwanda	Approval					
20	Solomon Islands	Approval				Approval HSS: Approval; Rota: Approval	
21	Sudan	Resubmission					
22	Uganda		Resubmission				
23	Zambia					Approval	

The quality of proposals submitted by countries continues to improve, with 23 out of the total 31 (74%) proposals (77% for CCEOP) recommended for approval. The IRC commends the efforts of the Secretariat and Alliance partners for their technical support to countries and continued efforts to improve the process. The implementation of phone calls/email dialogue with countries provides a further opportunity to demonstrate these improvements.

2.2. Good practices

The IRC further notes that the resubmission process resulted in improved quality and strategic focus of revised proposals. Examples include Pakistan, Solomon Islands, Benin and Nepal.

Country specific good practices are listed below:

CCEOP

Mauritania: plans on using its resources to pay for some of its equipment and for its co-payment in the true sense of building sustainable structures;

Papua New Guinea: plans to use its revitalized CCEOP to systematically monitor CCE status through the use of 30DTR alarms;

Most CMYPs reflect supply chain management reflecting increasing holistic considerations for system strengthening.

High quality HPV National Introduction applications

These applications reflect the excellent support by vaccine implementation focal points, SCM and technical partners to the countries.

HSS

Good transition towards financial sustainability by planning a progressive phasing out of external support for operational costs (Solomon Islands).

Budgets and templates

The IRC notes improved compliance with Gavi budgeting tools and process and better presentation of the NVS budgets, reconciled with proposal figures.

2.3 Feedback on work processes

2.3.1 The IRC commends the Secretariat for its responsiveness to enhance better work processes.

The IRC notes the better-spaced review window period, the re-introduction of country dialogue processes and the ever-increasing efficiency of the support process before, during and after the review process by the A&R and vaccine implementation teams and country managers.

2.3.2 Use of the country dialogue process:

Although the IRC had attempted to use this dialogue process in the past, the benefits were unclear. During this window, Gavi re-introduced a more formal process to dialogue with countries as a means of further reducing the turn-around time for clarifications (especially around grey areas) through dialogue by teleconferences and/or emails with countries. A total of 8 countries were contacted through this process. Table 2 illustrates the outcomes of the process:

COUNTRY	REASON	CALLS OR MAILS	OUTCOME	NEXT STEPS
Ghana CCEOP	The IRC could not determine how the country prioritized its Health Centres with no clear CCE gap analysis, the costs for the equipment maintenance, the rationale behind its choice of temperature loggers, and the lack of	Teleconference	The call worked out relatively well but quality of call was not optimal . A team of Ghana EPI and UNICEF were present. Questions were answered and commitment to respond to key issues highlighted was obtained.	Despite country's assurances and commitment to respond to issues identified, the IRC was still unable to clarify key issues around the sources of funds including the PBF reward; the maintenance issues and correct inventory.

	stabilizers for existing equipment.			
Rwanda CCEOP	Lack of clarity on number of equipment requested , no clear source of maintenance costs and gaps in gap analysis	Clarification E-Mail sent, response received by deadline.	Good turn-around time on the dialogue process.	Email communication received. Provided some information whilst other areas were left unanswered.
PNG Previous Resubmission	IRC requested critical information from country manager.	Mail sent, response not received on time despite several reminders.	E-Mail response finally provided and satisfactory.	Response provided much needed information by IRC.
Gambia CCEOP	Application not fully aligned with the HSS. Lack of technical justification for some critical decisions e.g. regional stores, 2 nd and 3 rd choices of equipment. Very vague and non-environmentally compliant disposal plan.		Phone call with country provided limited information. No clear indication of strategic thinking approach underpinning key decisions. Not clear if right persons were in the room for the call. Quality of call was very poor and frustrating.	Call did not provide any meaningful inputs to guide IRC decisions. However, provided a platform to share the IRC concerns especially around the proposed disposal plan of functional equipment.
Uganda MR cu	E-mail	Not useful	Email documentation provided at the instance of the country voluntarily.	Information provided was not really useful to the IRC.
Afghanistan CCEOP		Phone call for both CCEOP and MRFU	Quality of Call was just ok.	All clarifications were fully understood and country comfortable with providing the information within specified period.
Chad	The application did not provide relevant information on the epidemiologic analysis of the measles situation nor the post-campaign coverage survey to inform the strategies for the planned campaign.	Additional documents requested by email	Country provided, with delays, some of the documents requested	Documents provided partial responses to IRC's concerns. Not enough to change IRC recommendation.
Cameroon	Very weak proposal with no clear justifications of the strategies and no clear linkages with other supports and activities	Additional documents requested by email	Partial information provided.	No change in the IRC general recommendation but info provided was useful for the action points.

The IRC found this process useful and commends the SCM for their immense support to make this happen. However, lessons learned can further improve the process, including: i) the need to have the right person(s) around the table providing the responses; ii) critical to share the information required ahead of the call; iii) deep understanding that arranging these calls take time and affect the overall

IRC review process schedule; iv) the results may not be meaningful to the review process especially when they are fundamental issues; and v) calls can only be contextual and only if needed. It is therefore not helpful to assign a target for number of calls/contacts to be made per review.

Recommendation: The IRC supports the use of country level dialogue for immediate clarifications of key issues. However, it is important to consider the lessons learned to further improve on the process and create efficiencies. The calls and time spent waiting for additional documentation mounted additional pressure on the IRC time for finalizing reports. The time requirements and other lessons must be factored in future reviews.

3.0 Key Findings

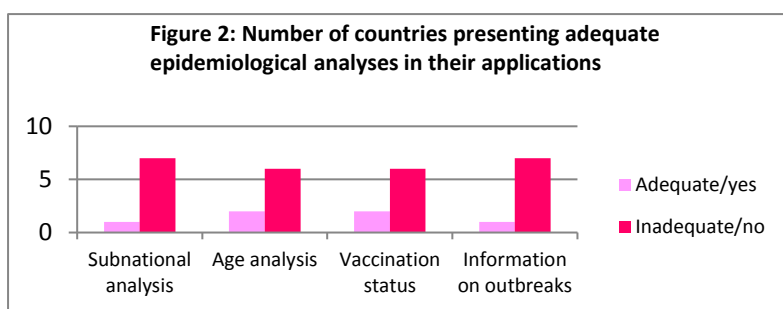
3.1 New Vaccines Support and Campaigns

Measles and Rubella vaccines

During this review, eight countries applied for measles or measles-rubella (M/MR) support. Seven countries applied for measles-containing vaccine (MCV) follow-up campaigns, two of which (Afghanistan and Cameroon) were for wider target age-range (from 9 months up to 10 years) and five (Burkina Faso, CAR, Chad, Guinea-Bissau, Pakistan) for standard follow-up campaign age-range (9 to 59 months). Of these only Burkina Faso and Cameroon were not recommended for approval. One country (Uganda) applied for MCV catch up campaign and subsequent MCV introduction into routine programme. Funds requested amounted to US\$ 44.14 million for operational costs alone, and the total approved amount for four countries is US\$ 28.04 million.

Issue 01: Reliance on nation-wide rather than tailored strategies to reach previously missed children

In spite of recommendations from at least three previous IRC reports, countries are still presenting insufficiently robust epidemiological analyses of surveillance and immunization data that do not adequately inform planned activities. This includes no or inadequately presented vaccination status of measles cases, no or incomplete subnational data, and no analysis of post-SIA measles transmission and comparison with reported and/or survey coverage. In fact, countries often claim previous SIAs as successful despite the lack of evidence for this in terms of interrupting transmission. Further, countries provide limited or no information on outbreaks and outbreak responses. Countries that have introduced MCV2 do not adequately consider its role in measles control, including its implication for current and future SIAs. The IRC notes that little or no strengthening activities for MCV2 are identified for countries that have introduced it, and usually no plans are indicated for integrating other interventions with MCV2 delivery; nor that children who received MCV2 will get minimal benefit from a third dose in the planned SIA; while other children continue to miss out on any dose.. Social mobilization is not sufficiently specific and/or targeted, and it is not often informed by equity analyses and/or surveys. It is disappointing that the lessons learned from previous SIAs remain rather generic and unrelated to the local context. This may be due to post-campaign surveys that are either not completed or delayed to the point that they cannot be considered in subsequent SIA planning. As a result, countries propose to repeat their traditional approach of reaching >95% of the nationwide target population through high-quality SIA and, in the belief that they can obtain high-quality implementation with improvements proposed in the WHO global guideline. Although countries do not always fully adhere to this guideline, the attempt often leads to slightly better plans of action but without taking the local context into full consideration and without clear operational strategies to reach non- and under- vaccinated children. In addition, traditional nation-wide SIAs are continuously supported by technical partners who, in absence of at least better data and funding flexibility, do not offer any alternative solutions and/or approaches. It is also to the countries' benefit to obtain a maximum amount of funding by using a nation-wide target population. Nevertheless, it is not likely that non-selective, non-data driven nation-wide follow-up campaigns, detached from the local



context, will achieve a desirable result (i.e. interrupt measles transmission) and/or facilitate programmatic improvements. Although such SIAs will undoubtedly reduce measles incidence, they cannot be considered cost-effective and a good use of local resources.

Recommendations: Technical partners need to support countries to design a tailored approach to measles control based on epidemiological and programme evidence, and not rely just on regular nation-wide SIAs. Gavi should consider allowing flexibility to implement such specific interventions and tailored strategies within an allowed maximum amount of funding (i.e. using nation-wide target population) paired with a strict accountability framework. Administrative cost per vaccination team would remain the same but the cost per vaccinated child will likely be higher as these tailored strategies are not the same as the ones that have the ability to increase coverage to 80 or 90%.

These interventions and strategies may include subnational SIAs, outbreak investigation and response, surveillance strengthening-case findings, MCV2 routine strengthening, PIRIs, and other, including innovative approaches that reward reaching 0- and 1-dose children (i.e. conditional cash transfer, SMS interventions etc.). The design of such tailored approach may be supported through quality TA, mentorship and secondment from successful countries.

HPV national introductions

The IRC reviewed three applications for national rollout of HPV vaccine (Zambia, Lao PDR, and Solomon Islands). All three opted to vaccinate a multiyear cohort the initial year, taking full advantage of this Gavi support window, which is in line with WHO recommendations to accelerate impact of the vaccine.

The IRC noted several “best practices” in the HPV applications. The technical support offered to countries via the vaccine focal point, Senior Country Managers, and technical partners was seen in the attention to detail and the revisions that occurred in the writing and pre-submission screening process resulting in complete, thoughtful proposals. The structure of the Gavi HPV application form also assisted with improving proposal quality and could serve as a model for other vaccine window applications since the fine-tuned questions posed in the form prompted countries to develop thoughtful and sustainable delivery plans. Additionally, countries developed approaches that leveraged their local context. For example, Zambia chose a delivery strategy that utilizes the option for a 12-month period between the two recommended doses so that vaccination can be embedded in the well-established annual child health days. Finally, applications from this round demonstrated increased attention to the microplanning and mapping that will be required to achieve high coverage in out of school girls.

3.2 Coverage and Equity

Addressing equity gaps (based on gender, geography, poverty, etc.) requires an **integrated, service-delivery driven strategy** where supply chain, social mobilization, epidemiological investigation, and delivery strategies **focus on reducing inequities**.

Issue 02: Country proposals do provide analyses of inequities in coverage but do not link these analyses clearly to planned activities. While proposals reported on any differences in immunization

coverage between boys and girls, most did not discuss gender-related barriers to caregivers' ability to seek vaccination for children. Examples include campaign plans that do not provide sufficient detail about mechanisms to reach pockets of previously unreached populations and marginalized groups such as HIV+ children or slum dwellers. Of seven MCV campaign applications, 3 were resubmissions, at least in part because of inadequate targeting of activities. On a positive note, MCV campaign applications did include effective measures to reach nomadic and conflict-affected population (i.e., Chad and Afghanistan) and HPV introductions addressed equity gaps around geography, gender, out-of-school status and HIV status (i.e., Zambia).

Recommendations

- Gavi Secretariat should further clarify guidance to countries and communicate that **gender**-related barriers refer primarily to barriers to women caregivers' ability to seek vaccination for her children, rather than to coverage gaps between male and female children.
- Application guidance and technical assistance by partners should support countries to identify and address barriers to women caregivers' ability to access vaccination services for their children, such as mobility, autonomy in household decision making and health worker attitudes. Guidance could specify that difference between vaccination rates of girls and boys need be addressed *only if* significant gaps do exist.
- Gavi should consider working with partners to revise guidance on collection of sex-disaggregated coverage data to de-emphasize sex-disaggregation *through routine HMIS*, as the additional actionable information gained from dis-aggregating routine immunization data rarely justifies the additional effort required. Guidance should clearly communicate that sex-disaggregation of survey data is a required and critical component to identify any **sex**-related gaps in vaccination rates.
- Gavi to support the development of targeted technical support for transitioning successful strategies for reaching the underserved from campaigns for polio and other antigens into measles and other mass campaigns. As an illustrative example, Gavi might coordinate among Alliance Partners and CSOs to develop an annex to the measles campaign field guide specifically describing how to apply concrete measures developed in polio to reach underserved populations (such as conducting rapid campaign monitoring, re-purposing influencers, community maps and community lists or identifying pockets of low coverage for targeted house-to-house coverage) to measles and other campaigns.
- Gavi should also continue to support countries in developing detailed planning and mapping of cold chain resources that allow them to ensure cold chain is available where underserved children are, such as increasing cold chain sites in urban slums.

3.3 Cold Chain Equipment Optimization Platform

During this review, thirteen countries submitted a CCEOP application, of which four were resubmissions (Afghanistan, Benin, Ghana, Solomon Islands). Out of thirteen applications, ten (77%) were recommended for approval, including 75% of the resubmitted applications (Afghanistan which was recommended for resubmission for a second time).

Good practices observed in the application included fully funding the country's joint investment by Nepal and Mauritania, and partial funding by Sudan; accelerating system re-design (Benin); and saving transport costs by increasing supply intervals (Rwanda). However, the CCEOP application is still not sufficiently geared towards catalysing overall supply chain improvements.

Only one country (PNG) mentioned a plan to use 30DTR alarms to monitor refrigerator status; but did not explain how this would work. The IRC has previously noted the potential for temperature

monitoring to not only monitor refrigerator function, but also the effectiveness of maintenance and promptness of repairs.

Solomon Islands plans to collect removed CCE being during the visit to equip that facility, using the same transport for the return trip. The management of non-functional and retired CCE was an issue that the IRC noted the lack of progress and suggests that partners at the global and local levels can facilitate the identification and implementation of effective practices.

The IRC also noted lack of progress on other key issues (in addition to system optimization, use of 30DTR alarms, and disposal of retired CCE): immunization waste management, and potential use of long-term passive storage devices. Documentation and sharing of good practices in these areas could help progress.

Most proposals contained data inconsistencies, highlighting the poor use of data by programmes. The IRC made a generic recommendation (either as a consideration or a required action) to establish or improve data systems to monitor CCEOP implementation and performance.

The strategic vision for immunization supply chain aims at creating the operational foundation upon which the immunization program builds to achieve its objectives defined in the cMYP and/or the national health development plan. The CCEOP applications do not always showcase this vision and most applications tend to be a shopping list of cold chain equipment, without strategic considerations. The EVM addresses operational issues rather than strategic ones. Nevertheless, the EVM remains a useful assessment tool and the only one available one for vaccine and cold chain management processes. Gavi Secretariat and partners should then use EVM numbers while taking into consideration other inputs, including programme priorities, to help countries develop a strategic supply chain plan.

The IRC noted that the Gavi Performance Framework includes the single summary score from the country's EVM assessment as a measure of its supply chain performance. This was not the intention of the summary score. The purpose of the numbers is to provide a measure for continuous quality improvement, and to help prioritise attention. The IRC noted the efforts made by countries to link CC equipment needs with vaccine coverage and equity. Some (Ghana) have tried to space the frequency of vaccine deliveries by increasing the capacity of refrigerators; others (Solomon Islands) plan to extend the cold chain in un-equipped health facilities. Countries are planning the expansion or expansion of CC equipment mainly to solve problems related to geographical access, in remote areas and hard to reach areas. However, a large and increasing number of unvaccinated children live in urban areas (slums).

The CCEOP platform can facilitate innovative delivery strategies in urban areas, particularly through the wider use of passive containers, the provision of icepacks (or chilled water packs), and supporting private facilities to store and deliver vaccines.

3.3.1 Key Issues with CCEOP Applications

Issue 03: CCEOP applications process.

As noted in the previous report, the CCEOP application process continues to evolve to meet earlier IRC recommendations. The IRC appreciated hearing about the response to previous IRC recommendations; more work remains to maximize the potential impact of the CCEOP. The IRC outlines issues to help the Secretariat guide countries to improve their applications.

The amount of documentation required by countries for an application could be reduced, by requiring a strategic view of supply chain improvement in the 'Single Document'. The strategic view must be

evidence-based, building on key elements (inventory report, deployment process, data systems and maintenance plan) in the “Single Document” required for the proposal. Some specific guidance is needed for:

- Countries to better explain current strategies for service delivery and how CCEOP can support, enhance, or innovate these as part of their strategic vision and the entire CCE needs, and to situate the CCEOP support in relation to other supports for meeting overall needs. In other words, outline a strategic view of how CCEOP support will aid coverage and equity.
- Countries to describe the information systems to monitor CCEOP implementation and performance.
- Partner support for innovation in information systems, and use of SDD technology (Eg, use of excess power from SDD systems to charge digital tools or phones) that can be encouraged in the application.
- Secretariat to update budget template to include all newly eligible CCE.
- Secretariat to consider incentives for countries to choose other manufacturers than the two dominant ones (Biomedical and Vestfrost) – as alternative (or complement) to requiring countries to make second and third choices of manufacturer for their CCE.
- Secretariat to provide further guidance to countries on inclusion of spare parts for CCE supplied through the platform (See also service bundle issue, below).
- Gavi Alliance partners to develop guidelines and share best practices for supporting country in the definition of strategies for increasing vaccine equity and coverage, especially in urban areas.

Recommendations: The Secretariat to review the application process (and application form) in consideration of the above issues while reducing the burden on countries, wherever possible.

Issue 04: Consistency check of numbers.

The foundation for CCEOP application is the country’s CCE inventory. The inventory enables a gap analysis by storage site, based on assumptions on storage needs per fully immunized child and population projections for the next 5 to 10 years. The plan to address the CCE gap from all sources is needed to put the CCEOP request into context of meeting calculated needs. The quality of the data submitted and assumptions used in calculations has varied, as has the extent of the review undertaken by individual reviewers. Some reviewers look deep into it while others (permitting time) do spot checks. There is no standardised process to check the numbers submitted, and the quality of the data submitted in the inventory. For this and the previous IRC in June 2017, there has been a financial cross cutter for other applications to provide consistency; a similar approach would improve CCEOP reviews.

Recommendations: Secretariat to consider appointing cold chain rehabilitation plan cross cutter to systematically and consistently review the foundational data (inventory, gap analysis and its assumptions, rehabilitation plan) of all CCEOP applications to bring consistency across applications and related decisions.

Issue 05: Lack of guidance and clarity on freezers for frozen icepacks: The need for stand-alone freezers in CCEOP is questionable, given that frozen ice packs are not needed for most transport, and even if needed, domestic CCE would be more cost-effective, even if they do not perform as well or last as long. The broader question of use of frozen ice packs for programme needs remains an issue of technical controversy that WHO has tried, and needs to find new approaches, to address.

Recommendations: Gavi should require countries to justify requests for freezers from a strategic perspective if only being used for ice packs. (Or provide reasons for not using chilled water packs or domestic freezers if ice is warranted.) WHO needs to find an evidence-based approach to define the programmatic need for ice.

Issue 06: The CCEOP ‘service bundle’ package not consistently understood: The IRC held a discussion with UNICEF SD to clarify the ‘service bundle’. The guidance is clear that the bundle includes temperature monitoring devices (TMDs) and voltage regulators, but is silent on the issue of spare parts and warranties. It was agreed during the call between IRC and UNICEF Supply division that CCEOP bundle should include spare parts kits for CCE requested equipment, in the ratio specified in the PQS. Countries would still be encouraged to consider whether this ratio would be appropriate for their context, and have the opportunity to request less or more. The justification and needs for spare parts for new and existing CCE needs to be specifically considered and explained in the proposal, including if there is a warranty on the CCE that will cover the spare parts. Additionally, the need for voltage regulators and TMDs for existing CCE needs to be clearly specified, and explained in proposal– whether requested or not – to assure the integrity of the overall system. Countries need to be reminded to include procurement fee, maintenance and freight costs to the country.

Recommendation: Gavi should clarify what is included in service bundle, and what countries need to budget as not included (e.g. freight). Specific clarifications on warranty duration, requirements, and implications if voided are also needed.

Issue 07: Replacing CCE at 10 years, rather than on temperature performance.

The practice of replacing CCE simply because it is 10 years old now has an alternative with the continuous temperature monitoring devices. Monitoring 30DTR alarms provides an alternative to age-based that can save costs without risking vaccines. Planning for replacement is ideally based on country data; in the absence of such data, planning for 10 years remains an appropriate method, but actual replacement need not be dictated by age.

Recommendation: Countries planning replacement of equipment with 10 years age benchmark should provide analysis of equipment performance by age in the country as justification.

Issue 08: Supply chain optimization: As recommended in previous IRC reports, the CCEOP should trigger a re-think of the supply chain. A strategic view of immunization delivery is the starting point for developing a supply chain vision. This vision should provide the overview of the proposal and the ‘Single Document’. A supply chain re-design changes CCE needs, so re-design should be a pre-requisite for CCEOP. But countries do have urgent needs to be met (equipping more health facilities and replacing gas with SDD refrigerators) which is why the CCEOP does not require re-design. However, it is time to request countries to develop plans for strategic vision articulation and system re-design and to include them as necessary components in their cMYP and seek their funding through their HSS applications or available sources from other donors.

As an interim measure, by requiring countries to refer to these plans as part of their applications, CCEOP may help to trigger this move. This may link to the recommendations made to the countries in this round to develop a data system to monitor CCE performance, which can provide metrics to compare different supply chain designs. A data system is necessary to monitor CCEOP implementation and should also be a necessary component of the cMYP. Countries need to establish or improve their data systems so that they can monitor the implementation and performance of the CCE supplied. The system re-design may be more effective once data are flowing and new approaches have been tested at small scale.

Recommendation: Review the pre-requisites for CCEOP application/approval to require that due reference is made to existing ‘Strategic Vision’ for supply chain improvement and data system for monitoring the CCEOP implementation and guiding its direction. If such vision and data system are not yet in existence, then due reference must be made to plans to develop them. The data system can be used to prioritise individual sites that need urgent replacement (or repair).

Issue 09: Rehabilitation plan not comprehensive and poor linkages with inventory: The linkage between the CCE inventory and the rehabilitation is not always clear, including the mapping of CCE currently procured and CCE to be provided from other sources. Also, the numbers across key documents (Gap analysis, rehabilitation plan and application itself is not always consistent.)

Recommendation: The application and review process needs to ensure that CCEOP support takes account of all recent and planned investments. These should be required in the rehabilitation plan.

3.3.2 Specific Issues with NVS applications (cold chain cross cutting)

Applications for campaign or new vaccine introduction for 14 countries were reviewed. Cold chain was not identified as a major constraint for approving these.

Issue 10: Demonstrating adequacy of storage for additional needs from NVS

In general, countries do not provide detailed calculations or methods/assumptions used to check for adequacy of storage. Data that are provided tend to be limited to national storage and average by level, rather than to ensure adequacy at each site. The need for such calculations depends on spare storage capacity at each site.

Recommendation: Gavi should consider requesting countries to provide an updated inventory with sizing calculations to demonstrate adequacy for NVS; or alternatively provide basis to show adequacy.

3.3.3 Waste management plans and budgets

Information provided by applicant countries are generally limited, especially for campaigns where 'burn and bury' remains common. Some good practices noted in this round include the following:

- Use of private sector for incineration of waste generated by measles and MenA conjugate Vaccines campaigns (Burkina Faso, Burundi, Chad)
- Ongoing procurement or plan for procurement of incinerators to eliminate waste generated by current and new vaccines (Lao PDR, Chad).
- Government funding of waste management at all levels (Zambia).

Issue 11: Waste management. In some countries, where incinerators have been installed (e.g. Eritrea) but evaluation mentions burning waste in pits. This suggests incinerators are not being appropriately utilized for waste disposal. Many countries developed health care waste management policies and plans a little more than a decade ago as part of a WHO global initiative. Waste management, supervisory and monitoring roles and responsibilities were also assigned. Policies were adopted in many countries; sometimes but plans were generally not implemented.

Recommendations:

- Gavi alliance partners to provide TA to countries for review and implementation of waste management policies and guidelines, and ensure appropriate funding to plan and implement.
- WHO and partners to review recommendations and provide comprehensive updated guideline for effective, sustainable and environmental friendly immunization waste management. Partners are demanded to mobilize adequate resources (globally) and to support country for domestic funding of HCWM policies, guidelines, plan implementation, monitoring and evaluation.

Issue 12: Disposal of vials (empty or full) of live attenuated vaccines

Method for elimination of live attenuated vaccine is sometimes unclear: There is a slight contradiction for disposal of empty plastic tube, once vaccine administered (with remaining vaccine in it) and for disposal of filled containers (expiry date or heat exposure). If this were an important risk, disposal methods should be similar. For example, for Rotavirus Vaccine in Kyrgyzstan, both incinerating and autoclaving or trash in regular health care bin are planned for full and empty vials, respectively.

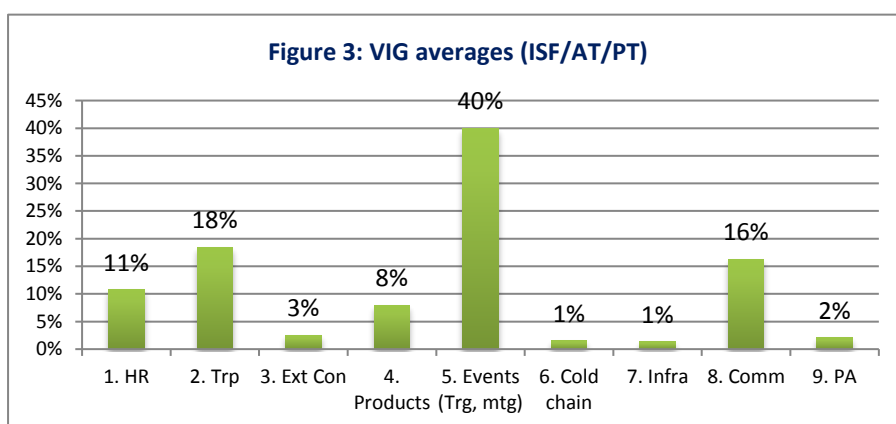
Recommendations: Request WHO to guide countries on safe disposal for both used, and expired/damaged full, vials of live attenuated vaccines (Rota, MR, OPV, BCG) to mitigate any risks, if present, from any residual live viruses.

3.4 Budget review of NVS Applications

During this review, financial cross-cutters have applied some guidance and norms provided by Gavi to scrutinize certain critical areas of the budgets such as HR, transport, training and other operational costs. These review protocols served as benchmarks/guidance for the budget analysis including checks on any material and substantial deviation between the budgets submitted by countries and from the historical trends for budget allocation towards Gavi cost categories.

Budget Review tasks included budget appraisals from 14 NVS applications submitted by 8 initial self-financing countries (ISF) and 6 countries in preparatory or accelerated transition (PT/AT). 13 countries submitted budgets for operational costs of campaigns and 6 for VIG requests; 1 HSS resubmission was also tabled for review. Size of the budgets reviewed varies from \$16 million in Pakistan to \$156 thousand in Guinea Bissau. Although, all countries reviewed have been compliant with the new Gavi budget template, there are still issues around correct generation of summary tables and graphs and tracking of other funding sources to complement Gavi cash investments on EPI activities. Reviewers also faced challenges to find detailed costing assumptions and budget notes explaining certain cost drivers in the country budget. In many cases (Burkina Faso, Burundi, Chad, etc.), countries send multiple budget sheets which contain different numbers and financial data or other separate excel sheets which have no links to the overall Operations or VIG budget in the Gavi template to be reviewed by the IRC. Some of the countries did not provide either the overall budget for their campaign activities or the allocations by country or other partners to the overall budget. Almost all countries seem to be requesting full Gavi ceiling (except Uganda, 72% of ceiling; Afghanistan 11% over ceiling).

In terms of distribution of budgets across Gavi cost categories, for VIGs, almost all countries in this

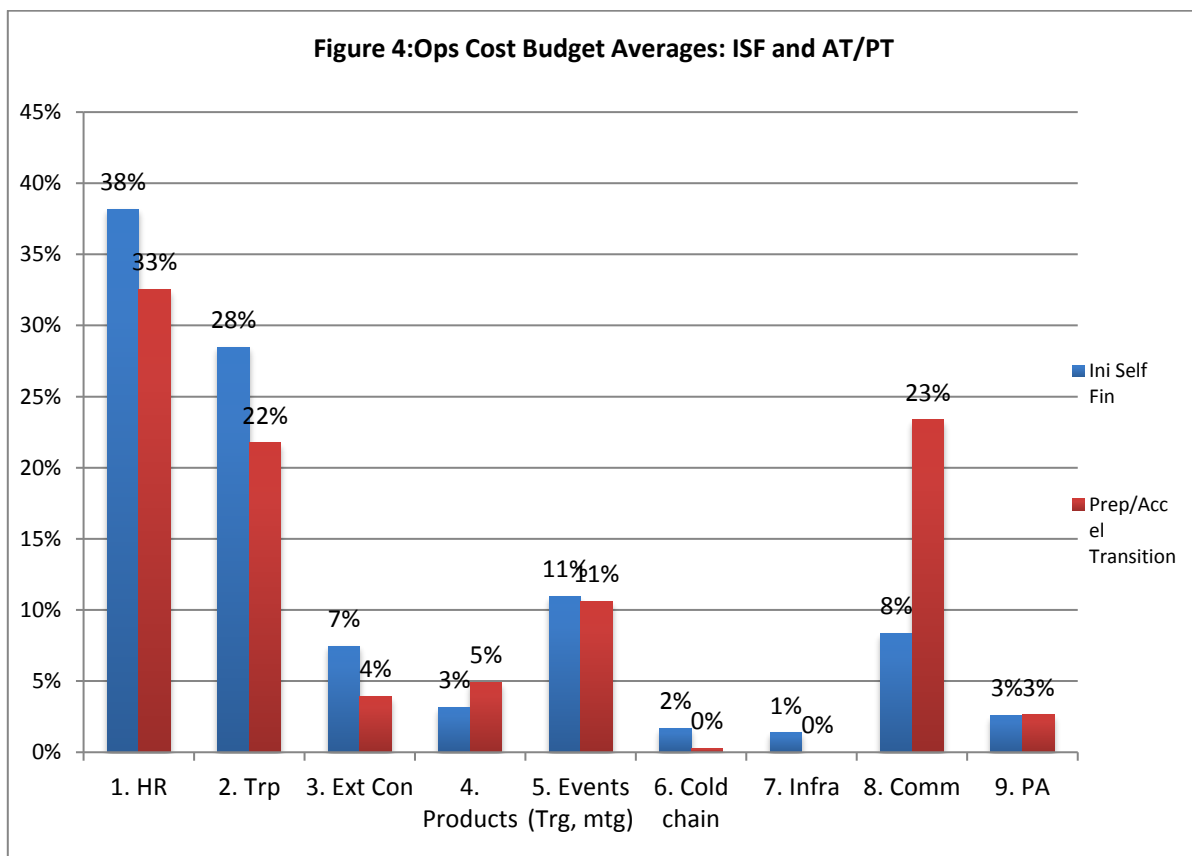


round were in line with past GAVI averages overall. The largest component of VIG budget (Figure 3) is allocations for trainings and meetings at 40%, followed by transport (18%) and communication (16%). HR remains a small component of VIG costs.

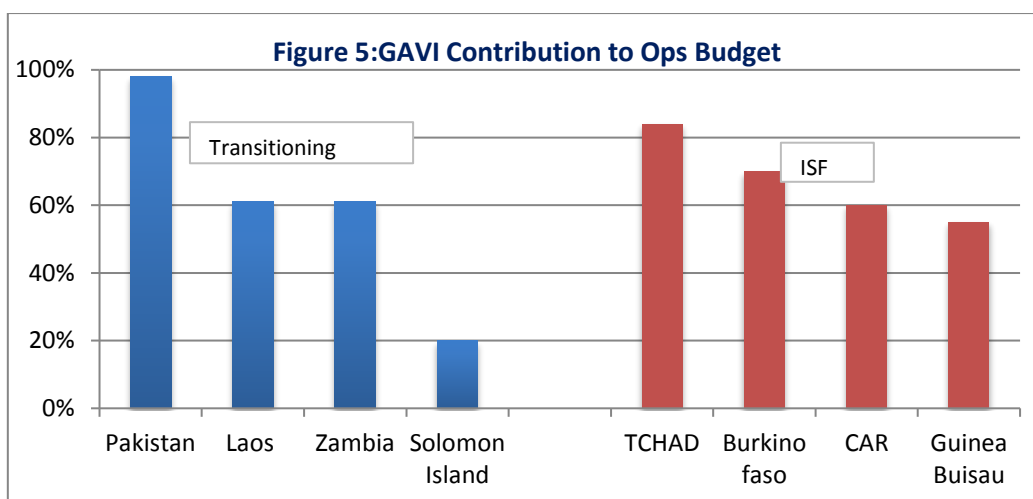
However for Ops costs, countries continue to allocate around 1/3 of their Gavi budget to incentives and allowances for the health work force for vaccine introduction activities, irrespective of their

transition status. For example, HR budget allocations represent on average 33% of the total cumulative OPs budget for PT/AT countries and 38% for ISF countries. Given that these are campaign costs, most countries would require HR support, however for transitioning countries, the level of Gavi contribution to HR should perhaps decrease and country contribution should increase. Zambia submitted a model budget demonstrating real efforts to sustainable domestic financing of EPI activities. Another area for great attention is the transportation line item in the budget: more and more countries are budgeting for unusual rental of vehicles and trucks particularly during the campaigns. It is not clear from the information provided in the application that systematic rental of cars and trucks is needed without comprehensive inventory and checks on availability of functional vehicles within the MOH, partners and other stakeholders. Transportation costs (rental, fuel, etc.) represented 22% to 28% of the cumulative budget. Examples include Pakistan (7,000 vehicles to rent, one for each Union Council), Afghanistan (5,782 vehicles, one for each supervisor), Chad (160 vehicles), Burundi (32 vehicles), Burkina Faso (22 vehicles) Guinea Bissau (15 vehicles), etc.

As Figure 4 below illustrates, it is important to note that the % allocation remains similar for both—poorer countries and those in transition, suggesting that countries in transition need to use Gavi support more strategically for improving coverage rather than on HR and transport which should be provided through country budget.



It is encouraging to note that countries in PT or AT stage are contributing to the total vaccine introduction costs (Laos and Zambia being good examples). However, Solomon Islands in accelerated transition phase is using Gavi funds to support 57% to 67% of its total vaccine introduction costs for HPV and Rota. For Operational budgets for campaigns, it is good to note that both groups of countries—those in transition and those in ISF, contribute to Operational budgets. However, as illustrated by Figure 5 below, the level of contribution among the countries in transition is much lower than expected and needs attention.



Issue 12: Campaigns an important part of immunization—and HR investment is required for many countries. Strictly following the HR OG means many campaigns would not be recommended for approval. Gavi needs to re-visit the OG to provide a more pragmatic approach.

Recommendations: Consider new /revised policies regarding level of contribution from countries, especially for transitioning countries towards operational budgets, and especially towards HR and transport component of budget.

Gavi to provide:

- a. Better guidance to the countries on benchmarks with regard to some critical cost elements of the NVS applications (HR, Transport, Trainings, etc.). Budget to Gavi to reflect total budget required for vaccine introduction or for operational costs and require countries to clearly show the funding components including Government and EPI Partners' contributions along with Gavi contribution for each category.
- b. Improve the guidance to countries on:
 - Categorization of activities and line items in Gavi cost and activity categories: for some of the activities like outreach, consultant for M&E, surveillance, it is difficult to identify the appropriate Gavi category. There seems to be also some confusion also between program management and program support costs.
 - Unit costs calculations- **should be based on technical elements/ parameters of country application (birth cohort, sites, vaccinators, etc.)**. Eritrea was a good example of budget with clear unit costs, assumptions etc.

3.5 Technical Assistance

The IRC continues to see better quality of proposals especially from strategic directions. Examples include the good quality of the support and TA provided to the Solomon Islands, Guinea Bissau and Zambia. The IRC has continuously flagged the need for high quality technical assistance. It is important that these issues are taken seriously and also reflect on the many observations and recommendations made in previous IRC reports. Over the years, many issues raised and recommendations suggested by the IRC relate to the following:

- Transparency of TA selection and PEF development process
- Sustainability of support provided and Capacity building
- Efficacy and quality of the TA and integration of the PEF

Some have been taken into account by Gavi management for example in the guidance documents for 2017-18 and 2018-2019. These steps and advances should be commended. However, it is imperative

that the implementation be well planned and conducted rapid especially for the countries that need the most technical assistance. Particular attention should be paid to the integration, transparency, innovation and sustainability dimensions.

Issue 13: During this review, some proposals were not approved due to obvious deficiencies in their design and relevance to achieve the objectives. This is particularly the case for some CCEOP and campaign proposals. One of the weaknesses is certainly the quality of the technical assistance received and how it was integrated or not at the country level. For example, many applications for catch-up campaigns do not include robust epidemiological analyzes, detailed contextualization, and strong linkage with planned activities and expected results. Some proposals use the same conventional approaches that have yielded little results when the country has already conducted campaigns in the past. Innovation is often absent and the definition of specific strategies for groups is vague and unconvincing as well as integration with other activities of the national immunization program. All these weaknesses and many others are indicative of weak country capacities but also of the likely poor quality of technical assistance provided to some countries. This has been noted in countries like Cameroon, Chad and Afghanistan.

Recommendation:

Gavi to work with TA providers and PEF beneficiaries to insure quality support to countries and more **accountable** and efficient processes for the TA and PEF.

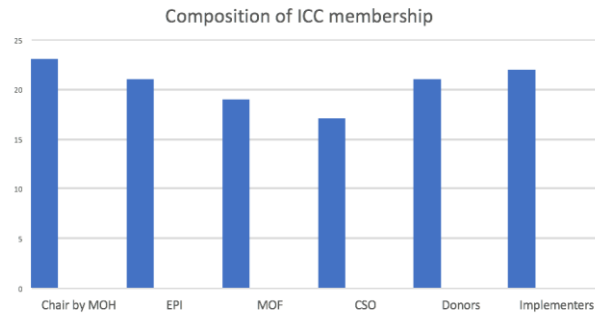
3.6 Governance

3.6.1 Functionality of ICC

The IRC note that significant progress has been made in developing the ICC in most countries. Of the 23 countries reviewed by the IRC, every country had a Coordination Forum (either an ICC or HSCC or equivalent). The review and approval of the various Gavi proposals by the Coordination Forums was generally well documented by countries. However, there are still missed opportunities to use the ICC effectively in advocating for immunization in practically all countries reviewed by the IRC. In some instances, it was not clear how the proposal was assembled prior to presentation at the Forum. It was also frequently unclear from the minutes what was the process used in the meetings. Few countries documented the meeting process, and even when a quorum was minuted as having been reached, the definition of a quorum was usually missing in the TORs. The writing up of the minutes of Forum meetings was very mixed. Several countries did not record clearly the recommendations and action points for each agenda item, thereby weakening the impact of the meeting. Many times, countries focused on signing off on the Gavi proposal, with less emphasis on a general oversight of the immunization programme.

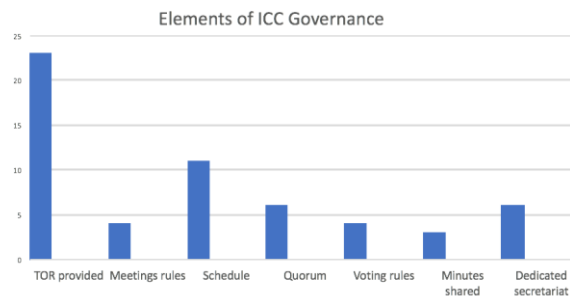
The IRC further reviewed the three main categories of ICC functionality defined by the Gavi guidelines with the following outcomes:

Membership. Membership was generally broad. Six countries did not appear to include CSOs in their Coordination Forum. In four countries, the TORs omitted the Minister of Finance as a voting member. Even when senior officers were named in the TORs, frequently officers of lower rank would substitute for them, thereby weakening the recommendations.



Mandate. All countries described the mandate of their Forum, but varied greatly in the detail, specificity and relevance to the Gavi guidelines. Afghanistan and Kyrgyzstan provided exceptional high quality descriptions of their mandate.

Governance. All 23 countries provided TORs for their Forum. But most failed to provide details of meeting procedures. Only one country described the Forum activities in the context of the Paris Accord.



Issue 14: Immunization programmes generally fail to take advantage of the presence of the Minister of Health or an equally highly positioned officer at the meetings to showcase the successes. For instance, only one country used a dashboard to update the meeting on progress in achieving coverage targets. Such a simple device presented at the start of each meeting and recorded in the minutes could transform the process of programme monitoring. It also identifies poorly performing districts or provinces that may need special support.

Issue 15: Application review process by ICC: The review and support of the various Gavi proposals was generally well documented by countries in the minutes of meetings submitted along with the application package. In some instances though, it was not clear how the proposal was assembled prior to presentation at the ICC. In addition, few countries documented the meeting process, and even when a quorum was reached, the definition of a quorum was usually missing in the TORs. Membership in the TORs frequently omitted the Minister of Finance as a voting member. Even when senior officers were named in the TORs, frequently officers of lower rank would substitute for them, thereby weakening the recommendations.

Issue 16: Quality of ICC Meeting notes: The writing up of the minutes of ICC meetings was very mixed. Several countries did not record clearly the recommendations and action points for each agenda item, thereby weakening the impact of the meeting.

Recommendations

1. The Gavi Secretariat and SCMs should use the missing elements of the Coordination Forum of the country applications to engage countries in discourse to strengthen their respective

Forums. Where appropriate, countries should be encouraged to widen discussion at the Forum beyond just reviewing Gavi proposals to include overall monitoring of their immunization programme. Bilateral discussions should include exploring the need for Gavi to provide technical assistance to strengthen basic functionality.

2. The Ministry of Finance (or its equivalent) should be better represented in the formal TORs, and encouraged to be more involved in the meetings.
3. Whenever possible, the ICC member nominated in the TORs should attend in person, and not be represented by a substitute lower ranking officer (especially non decision making officers).

3.6.2 Functionality of NITAG

The number countries with a functional NITAG that provided a technical review in their vaccine application reached 5 out of 6 countries (Kyrgyzstan, Lao PDR, Pakistan, Uganda, and Zambia). Burkina Faso has a functional NITAG but did not submit a review to support the MR SIA application.

Issue 17: There are other countries currently without a NITAG including a combination of countries under the Gavi fragility policy and small countries for which establishing a national NITAG might not be feasible (Afghanistan, Burundi, CAR, Chad, Eritrea, Guinea Bissau, and Solomon Islands). Cameroon was reported to be re-operationalizing its NITAG, although it was not fully functional yet. Quality of NITAG reviews varied, notably for MR campaigns with insufficient epidemiological analysis to support the recommendation.

Recommendations:

- Gavi to continue support technical capacity building of NITAGs, including economic evaluation - critical in particular in transitioning countries;
- Because of their skill sets, NITAGs should be strongly encouraged to provide evidence based epidemiological review to support measles/rubella SIAs.

3.7 PSR Review Outcome

A PSR desk review of Zimbabwe was conducted by three independent reviewers (Two from IRC and external consultant) earlier in the year. The preliminary outcomes were presented for further discussions by the IRC. The IRC tested a hybrid review model proposed by Gavi. Major lesson learned is that there is no clear advantage compared to CEF/IRC review process. The IRC was able to make inputs only based on the final outcomes as presented by the consulting team. Process would have been more meaningful if IRC members had access to the documents reviewed prior to the presentation.

Recommendation:

IRC contributions will be more useful if members had documentation and if another peer reviewer had been assigned to supplement the CEF review.

4.0 Conclusions

The IRC commends the efforts of the Secretariat especially the focal points/SCM and Alliance partners for their technical support to countries and continued efforts to improve the application process. The effectiveness of the Gavi HPV application form and the technical support provided could serve as a model for other vaccine window applications.

Whilst the IRC has continued to see significant improvements in the quality of applications, it is critical that technical efforts be scaled up to ensure that investments made in immunization and CCEOP give

value for money. To ensure that this happens, the IRC reiterates the need for technical and Alliance partners to ensure that immunization applications are based on adequate and sound epidemiological analyses to inform the timing, type, target age group and other key parameters that facilitate high quality campaigns with meaningful impact on routine immunization.

From a financial review perspective, the level of contribution among the countries in transition is much lower than expected and needs attention. Gavi and Alliance partners should work closely with governments of countries especially in the accelerated transition phase to increase investments in immunization and system strengthening.

Significant volumes of waste are increasingly generated by countries due to new vaccine initiatives. However, most countries still do not have realistic and environmentally complaint waste management systems. It is critical that countries are supported to focus on translating waste management plans where they exist into full function or prepare and implement plans where they are non-existent.

Finally, the IRC reiterates its support for the use of direct dialogue with countries during IRC sessions via phone/email to provide further opportunity to enhance the turnaround time in addressing clarifications and other related issues. However, it is important that the additional time required to make this effective be realistically factored into the review period.

Acknowledgements

The IRC acknowledges the Gavi executive team for their continued responsiveness to key IRC recommendations; the A & R Team especially Adrien de Chaisemartin, Patricia Kuo, Sonia Klabnikova, Verena Oustin, Elodie Sarreau; Friederike Teutsch, Ebun Okunuga, the Country Programme Team especially Hind Khatib-Othman, and all the Senior Country Managers/key members for invaluable insights into the country activities and progress. The IRC further acknowledges the role of the CCEOP/HSIS Team: Alan Brooks, Hamadou Dicko and Gopal Nadadur in ensuring that the lessons learned from the roll out of the CCEOP platform continue to be rapidly integrated and shared through revised guidelines. Finally, the IRC particularly thank the WHO and all the Alliance partners for their invaluable technical inputs and increasing attention to quality technical support to countries.

Annex 1: List of IRC Reviewers

NO.	Name	Nationality	Profession/Specialisation	Gender	French Speaking
1.	Aleksandra Caric	Croatia	Independent Consultant	Female	
2.	Beena Varghese	India	Independent Consultant	Female	
3.	Benjamin Nkowane	Zambia	Independent Consultant	Male	
4.	Bolanle Oyeledun – CHAIR	Nigeria	CEO, Centre for Integrated Health Programs	Female	
5.	Charles Wiysonge	Cameroon	Deputy Director in the Centre for Evidence-based Health Care, South Africa	Male	X
6.	Claude Mangobo	DR Congo	Regional Advisor for Immunization Logistics and Supply Chain	Male	X
7.	Dora Curry	USA	Senior Technical Adviser, CARE	Female	
8.	Emmanuel Addo Yobo	Ghana	Associate Professor of Child Health at the School of Medical Sciences, Ghana	Male	
9.	Linda Eckert	USA	Professor, University of Washington (Gynaecology)	Female	
10.	Miloud Kaddar -VICE-CHAIR	Algeria	Independent Consultant (ex WHO)	Male	X
11.	Modibo Dhicko	Senegal	Project Director, IntraHealth International, Senegal	Male	X
12.	Osman David Mansoor	New Zealand	Public Health Physician, Regional Public Health, New Zealand	Male	X
13.	Ousmane Amadou Sy	Senegal	Independent Consultant	Male	X
14.	Philippe Jaillard	Benin/France	Independent Consultant	Male	X
15.	Ranjit Dhiman	India	Independent Consultant	Male	
16.	Salah Al Awaidy	Oman	Communicable diseases advisor, MOH/Epidemiologist/Public Health	Male	
17.	Sandra Mounier-Jack	France/UK	Lecturer London School Hygiene and Tropical Medicine (Health Policy)	Female	X
18.	Shaikh Humayun Kabir	Bangladesh	Independent Consultant	Male	
19.	Terence Hart	UK	Independent Consultant	Male	X
20.	Zeenat Patel	Canada	Independent Consultant	Female	

Annex 2: Summary of CCEOP applications reviewed

Country	# times Review	Decision	Good points	Issues
Afghanistan	2	Resubmission	Good links with coverage and equity	Did not address previous IRC point adequately. Plan not comprehensive of other support. Calculations missing.
Benin	2	Approval	Accelerating system redesign. Addressed deficiencies of previous submission	The annual maintenance budget is 4.2 million USD; however, presently national budget provides only a total of 708,000 USD per year for central and regional levels: how will the rest be funded?
Burkina Faso	1	Approval	Needed cold rooms for central and regional stores will be procured with government funding	The maintenance plan should be revised to include a section on CCE disposal.
CAR	1	Approval	Good links with coverage and equity	Deployment plan is too ambitious (1 year): consider extending it over 2-year period
Côte d'Ivoire	1	Approval	Equity and security aspects and health facility focus	Maintenance work is assigned to DIEM but it covers only 6 Regions out of 20 and only 4 Districts out of 82.
Gambia	1	Approval	Fair links with coverage and equity	No transport optimization
Ghana	1	Resubmission	Extended storage in remote; with vaccine delivery	
Mauritania	1	Approval	Joint investment (50%) from Government. First year funding in 2018 from national budget.	
Nepal	2	Approval	Joint investment (50%) from Government. Proposal addressed main deficiencies of previous submission	
PNG	1	Approval	Good assessment of needs	No system optimization; comprehensive needs not included; some issues with inventory and population data. Limited links to coverage and equity
Rwanda	1	Approval	Projects to 10-year population growth. Reduces transport cost (monthly to quarterly shipment).	No system optimization or significant parallel supply chain activities (e.g. data for management)
Solomon Islands	2	Approval	Good assessment of needs. Addressed main deficiencies of previous submission	
Sudan	1	Resubmission	Co-financing from government funds	Mismatch in numbers in analysis, deployment plan and CCEOP application