



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

GENEVA, MARCH 2017

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List of Acronyms

AEFI	Adverse Event Following Immunisation
CC	Cold Chain
CCEOP	Cold Chain Equipment Optimization Platform
CCL	Cold Chain and Logistics
cIP	Country improvement plan (cold chain)
cMYP	Comprehensive multi-year plan for immunisation
EPI	Expanded Programme on Immunisation
EVM	Effective Vaccine Management
FMA	Financial Management Assessment
HPV	Human Papilloma Virus
HR	Human Resources
HSS	Health Systems Strengthening
ICC	Inter-Agency Co-ordination Committee (for immunisation)
IFPRI	<i>The International Food Policy Research Institute (IFPRI)</i>
IRC	Independent Review Committee
JA	Joint Appraisal
MCV	Measles Containing Vaccine
MNCH	Maternal Neonatal and Child Health
MoH	Ministry of Health
MR	Measles-Rubella vaccine
MSD	Measles Second Dose
NHSDP	National Health Sector Development Plan
NITAG	National Immunisation Technical Advisory Group
NRA	National Regulatory Authority
NVS	New and underused Vaccine Support
PCA	Programme Capacity Assessment
PEF	Partners Engagement Framework
RCM	Rapid Convenience Monitoring
RI	Routine Immunisation
RTM	Routine Temperature Monitoring
RV	Rotavirus Vaccine

SAGE	Strategic Advisory Group of Experts on Immunisation
SCM	Senior Country Manager
SIA	Supplementary Immunisation Activities
TA	Technical Assistance
UNDP	United Nations Development Programme
WHO	World Health Organisation

INTRODUCTION

This final report of the March 2017 IRC review meeting contains an analysis and summary of the main findings of the key thematic areas. It also highlights key issues and specific recommendations. The IRC met in Geneva between March 13th and 24th 2017 and reviewed a total of 13 applications from 11 countries. This report reflects the detailed outcomes of this meeting with broad recommendations to Gavi and its Alliance partners to help improve the application and implementation processes. The 16-member IRC was chaired by Bolanle Oyeledun (Nigeria).

BACKGROUND

Table 1		Outcome of country request by type of support					
Country	CCEOP	MR routine + catch up campaign	MR follow up campaign	Measles follow up campaign	HPV national	Rota	
1	Afghanistan	Resubmission				Approval	
2	Benin		Approval			Approval	
3	Djibouti	Approval					
4	Ethiopia				Approval		
5	Kyrgyzstan	Approval					
6	Mauritania		Approval				
7	Nepal	Resubmission					
8	Rwanda		Approval				
9	Sudan			Resubmission			
10	Vietnam	Approval					
11	Zimbabwe				Approval		

Methods: The independent review process consisted of independent peer reviews followed by daily plenaries and consolidation of findings. Reviews were based on the extent to which proposals (a) meet mandatory requirements, (b) principles of support as specified in Gavi guidelines and (c) contribute to achieving Gavi mission and strategy. Internal consistency and quality checks were applied through rich plenary discussions and post plenary reviews by the chair, vice-chair/editors. Two countries namely Tanzania and Ghana were not reviewed as mandatory signatures were missing.

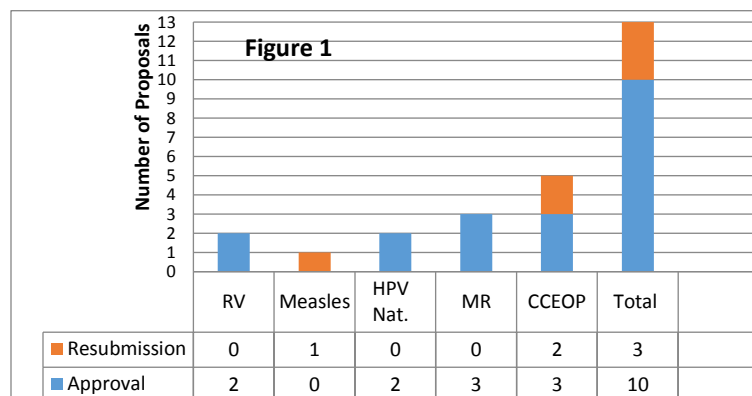
Decisions remain based on two main decision categories: Approval (with issues to be addressed) and resubmission (with explanations) as stipulated by current Gavi guidelines. The review criteria remained mainly as for previous windows, with some additional criteria on ICC functionality and CCEOP document requirements. For measles/MR campaigns, epidemiological justification remains the key consideration.

IRC Work Process: Briefings and new member orientation were held during this review. The secretariat is commended for taking into consideration previous IRC feedback on the orientation and briefing structure.

However, it is important that new member briefing orientation should be peer-inclusive and also include other “not so new “reviewers to provide peer support and insights.

Recommendation for Gavi Secretariat:

- Ensure that orientation process actively involve peers for a more robust support mechanism.



Overall approval rate for all proposals reviewed was 77% (10 of 13). The CCEOP window has a 60% approval rate (3 of 5).

Both countries who applied for HPV national rollout took advantage of multi-year cohort; both were approved.

KEY IMPROVEMENTS NOTED DURING THIS REVIEW PERIOD

During this review process, the IRC noted key improvements across EPI programming and Cold Chain optimization from these countries:

- **Zimbabwe:** Commendable efforts to establish a functional NITAG with inputs from the PEF/TCA resources;
- **Afghanistan:** Documentation suggestive of a functional ICC (clear ToR, regular meetings, advisory roles clearly demonstrated etc.) and strong linkages with other Gavi support streams;
- **Kyrgyzstan :** Forward planning for Cold Chain capacity by 8 years ahead;
- **Djibouti:** Innovative way of using old CC equipment
- **Rwanda:** Good equity analysis to support application for Measles campaign; consistent and timely post campaign monitoring

New and underused Vaccine Support (NVS) and Campaigns

Measles and Rubella Vaccines

During this review, five countries applied for measles or measles-rubella (M/MR) support. Ghana’s submission was not presented to the IRC due to lack of documentation, so only four proposals were reviewed. All countries except one applied for MR. Sudan applied for a measles follow-up campaign when an application for MR campaign and introduction would have been more appropriate, given their

plan to move to MR in 2020, and the target age of 9 months to 14 years in a third of districts. Funds requested from 4 countries and presented for the IRC March 2017 review amount to US\$15.26m for operational costs alone. The IRC notes a missed opportunity by Sudan to introduce rubella vaccine in 2018.

By the end of 2015, Gavi funded measles-rubella catch-up supplementary immunisation activities (SIAs) had reached 164 million children (aged 9 months to 14 years). SIAs increase population immunity and are a key strategy for elimination of both measles and rubella. As supplementary to routine immunisation, SIAs are designed to reach and protect children missed by routine services and those who failed to develop immunity after the first dose of measles vaccine.

However, health benefits are achieved only if the SIAs reach close to 100% of the target population. Along with strong epidemiological analysis to ensure the right targets, good project management is needed to ensure the targets are reached.

Issue 01: Detailed epidemiologic analysis of measles and rubella status for countries requesting support for MR follow-up or catch-up campaign support.

As noted in the Nov 2016 IRC report, countries are still not undertaking epidemiological analyses to inform the timing, duration, type, target age group, and geographic scope of campaigns.

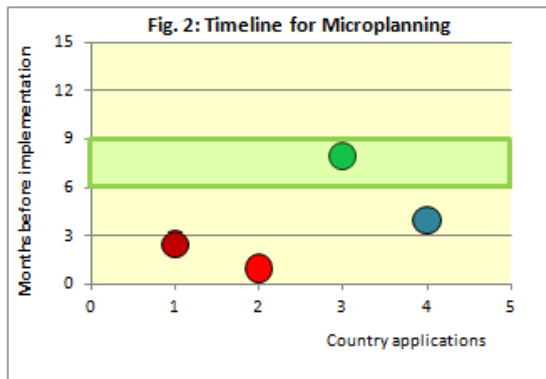
One country (Rwanda) did present an epidemiological analysis of measles cases. However, this was not used to plan an appropriate response, given that half of the recent confirmed measles cases were aged over five years. But the country still plans a catch-up for those aged 9 months to five years, thus not addressing the immunity gap in school-aged children.

Recommendations: As previously recommended, Gavi Secretariat should ensure that Alliance partners provide support to countries to provide a detailed epidemiologic analysis of cases and modeling to justify the campaign type, timing, duration, target age range, and geographical scope. There should also be scope for Gavi support for tailored SIAs that focus on identifying those without documented receipt of two MCV doses. The tailored focus on these children instead of a traditional follow-up campaign is more rational when most of the target population would have already received two routine doses.

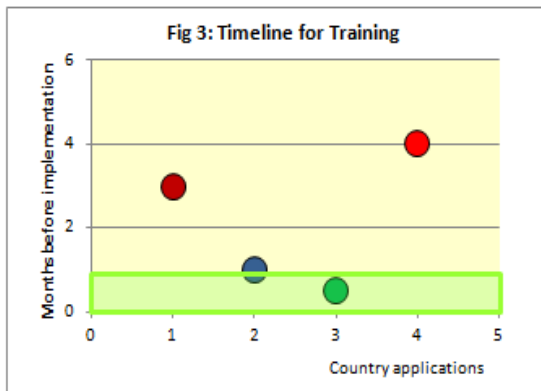
Issue 02: Programme planning and WHO guidelines

Early and comprehensive planning and budgeting are needed to ensure that critical but often overlooked activities are undertaken effectively. Yet, only one of the four countries mentioned an SIA

readiness assessment and none planned or budgeted for intra-SIA rapid convenience monitoring (RCM) and mop-up activities.



Critical activities, such as microplanning and training, must be well and timely planned and implemented. Again, only one country (Fig. 2) scheduled microplanning early enough (8 months prior to the SIA start) to allow for in-depth planning and consolidation of plans. Similarly for training (Fig. 3) only one country places training in recommended number of cascades (two) and in time late enough (2 to max 4 weeks before the SIA) to prevent the messages to be diluted, misinterpreted or forgotten.



The use of SIA Readiness Assessment Tool, a requirement for application for funds, is massively neglected. Even the single country mentioning it did not schedule periodic assessment at national and subnational levels to allow for timely implementation of critical activities and follow up of corrective actions and feedback necessary for decisions.

Further, SIAs are not and should not be isolated interventions. Important inputs from the RI programme are necessary for the successful SIA planning (target population, maps of the catchment areas, etc.) and thorough planning and preparation for the SIAs may help address some issues within the RI programme. This was not reflected in the proposals reviewed.

All of the above points are covered in existing WHO guidelines that are not being adequately followed. In order to achieve better progress toward measles elimination goals, the business as usual is not enough. For the settings where there is a clear disease control objective and where the resources and programme capacity can be mobilized, the bar should be raised to achieve high-quality SIAs which would supplement and strengthen routine immunisation programmes.

Recommendations:

- Gavi secretariat needs to ensure that countries receive adequate project management support.

- Alliance partners should ensure that countries are assisted to understand and use the WHO guidelines to inform critical program planning and decisions
- The pre-screening by the secretariat must ensure that WHO guidelines have been met before proposals are submitted for IRC review.

Issue 03: MVC2 coverage and options for countries with high MCV2

Most countries are struggling to achieve MCV2 coverage close to MCV1. One country (Rwanda) is progressively closing the coverage gap between MCV1 and MCV2. Rwanda should be commended for this achievement and to document the reasons for this success. This success in reaching children in the second year of life provides an opportunity for strengthening delivery of other interventions. Equally, it may be possible to schedule other interventions that have high community demand (e.g. deworming, bed-nets) with MCV2 to increase coverage.

Recommendations:

- Gavi Alliance partners should document successes and failures in MCV2 coverage, and their causes, to help other countries achieve high MCV2 coverage and strengthen delivery of other interventions at the same time. Countries achieving high and sustained 2-dose coverage that meet WHO SAGE recommended thresholds should be considering strategies other than the standard catch-up campaign. In these situations, the focus should be on identifying those who have missed out on routine and/or previous campaigns. This information can be used for programmatic improvements and strengthen the routine.
- School-entry immunisation checks are one strategy that could be more effective in countries with high enrolment and reasonable 2-dose coverage. Gavi should consider supporting this as an option to follow-up campaigns.

HPV National Introductions

This is the first round of applications that applied the new Gavi guidelines enabling countries to introduce nationally without the requirement for prior HPV implementation experience and facilitated immunisation of multiple cohorts of girls aged 9-14 years during the first year of vaccination as per WHO SAGE recommendations. The IRC received two applications for national rollout of HPV vaccination (Ethiopia and Zimbabwe). It is encouraging to note that both countries applied lessons learnt from HPV demonstration projects and from previous new vaccine introductions and campaigns in planning for the

HPV national roll out. As a result, both countries realized the importance of careful training and planning, chose not to request signed consent and used grade based strategy for the target population, having learned age-based strategy was more time consuming. Moreover, Zimbabwe implemented an annual vaccine delivery schedule (vs. twice yearly) to reduce costs by only delivering vaccine in schools once a year.

Issue 04: Estimation of routine and multi-year cohort population

Estimation of the routine target population and the larger multi-year cohort population is a challenge. Significant differences were observed between country estimates and UNDP estimates for girls 10-14 years (in Zimbabwe a difference of 189,000), which has considerable implications for the calculation of vaccine doses required. In addition, accurate estimation of the target population (i.e. denominator) will be particularly important to determine HPV vaccine coverage estimates given a national coverage survey is not mandated in the new Gavi guidelines.

Recommendation: Gavi should work with Alliance Partners to assist countries with ascertaining and reconciling target population estimates to obtain robust estimates.

Issue 05: Effect of 'Campaign style' delivery on routine health system

Countries are planning to leverage the routine health system for transport and delivery of vaccine. With the targeting of a multi-year cohort in year one, the burden on the routine health system may be considerable and it does not appear that countries are adequately accounting for this possible burden.

Recommendation: Appropriate technical assistance at the micro-planning level will be crucial to anticipate and plan for increased demand on routine services, including budgetary and personnel implications.

Issue 06: Large number of out of school girls in the target population

Even when primary school attendance is high, older girls of the multi-year cohort are often no longer in school. In Zimbabwe, school enrollment drops from over 95% in primary school to closer to 50% in secondary school. In Ethiopia, some geographic regions only have 30% primary school attendance. Hence, delivery strategies beyond primary school will often be crucial for reaching the target population. However, planning and financing for reaching these secondary school or out of school girls was not appropriately elaborated.

Recommendation: There is a need to augment school based delivery strategies. This may be a challenge primarily for the first year (to deliver vaccine to the older girls of the initial multi-year cohort), or may be an on-going issue in countries with lower primary school enrolment. Gavi should ensure countries are aware of the importance of having more than one delivery strategy, especially for the initial multi-year cohort. Countries should ensure that strong strategic planning documents are developed that elaborate on the required strategies for multi-year cohorts and out of school girls and are linked to specific budgetary requirements.

Issue 07: Insufficiently detailed vaccine introduction plan

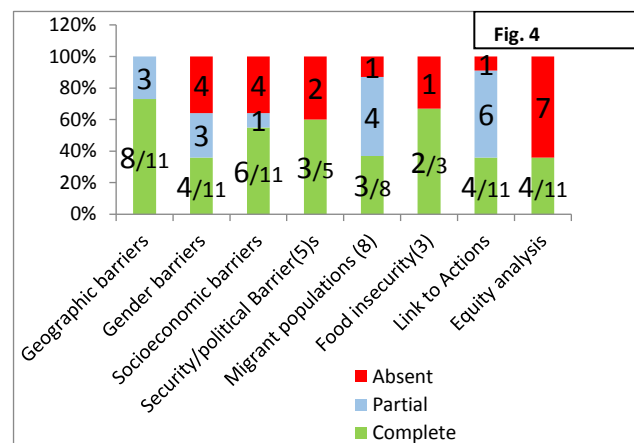
The Gavi application contained more details than the country vaccine introduction plans. However, since country documents are used for implementation and needed for ongoing sustainability of the program, country documents should have adequate detail to stand-alone since the Gavi application is not a formal country strategic or operational document.

Recommendation: For sustainability, it is essential that country vaccine introduction plans are complete and detailed.

Gender and Equity

Issue 08: Are countries undertaking a “robust analysis of barriers related to equity in access and utilisation of immunisation services”?

In the review of the proposals from 11 countries, seven of the applicant countries (Fig. 4) provided good information on equity barriers although only 4 based their proposals on a sound equity analysis that included a gender perspective. The reviewers were pleased to note more linkages between the equity analysis and the strategies chosen for implementation.



It would have been helpful if equity-related documents were mandated for inclusion in applications, particularly CCEOP applications which demonstrate weak linkages with equity analysis.

There are certain high risk populations - refugees not in camps; migrants to peri-urban areas; seasonal migrants; and those internally displaced due to food insecurity – who risk being overlooked in

immunisation. Several applications were not transparent about either the size or existence of such at-risk groups.

Recommendations:

- Gavi and Technical Partners to ensure countries focus on populations at risk of being overlooked: out of school girls for HPV; refugees not in camps; migrants to peri-urban; seasonal migrants; and those internally displaced due to food/political insecurity
- Evolving CCE OP application guidelines 'should ask countries for clearer linkages between the deployment plan and equity in practical terms, not general principles.

Technical Assistance/Partnership Engagement Framework

The Partnership Engagement Framework (PEF) is designed to provide to Gavi eligible countries the adequate technical support in EPI planning and implementation. In the last two years, IRC has been briefed on many steps and action points taken by the Gavi Secretariat and Alliance partners to operationalize the PEF arrangements and make the technical assistance resources available to countries. Since the rollout of this technical support scheme, IRC reviewers look in the applications for evidence, which document the effectiveness and the relevance of the PEF arrangements for the countries. During this March review, IRC has noticed concrete and clear move from the Alliance partners to address technical assistance needs of applicant countries. This is materialized by TA needs discussions and planning steps during in-country forums (JA, EPI reviews, etc.). All eleven (11) countries which have submitted applications (whether CCEOP or NVS) during this IRC review have in place TCA plans with a total budget effort of 8 million USD. Countries like Ethiopia, Afghanistan, Djibouti, Mauritania, etc. have substantial TA resource allocations channeled to Alliance partners (WHO, UNICEF) and other key stakeholders (such as the World Bank) in order to deliver on countries' technical support needs. This is a bold step forward in ensuring that Gavi eligible countries get an effective and high quality TA to implement the approved applications and achieve EPI performance objectives. The technical assistance agenda on the Gavi portfolio is critical at this stage where the countries are expected to be transitioning and moving to more sustainable EPI programs. However, the PEF mechanism has to be flexible enough to adapt to countries' needs and capacity levels. It is also important that access, utilization and monitoring of PEF resources be embedded into transparent and accountable rules of engagement which are shared with recipient countries.

During this March review, IRC identified the following positive findings and made recommendations to Gavi and its partners around the PEF arrangements:

- a. PEF/TA arrangements are now translated into operational work plans and budgets, with clear outcomes and timelines;
- b. NITAG in Zimbabwe was effectively supported with PEF resources with demonstrable progress and results.

Further Recommendations:

Gavi and its technical partners should:

- a. Strongly encourage countries to utilize PEF resources for critical TA needs during application development and implementation phases;
- b. Make PEF arrangements flexible enough to allow countries to address TA needs brought up after IRC review (in this round: Examples of Mauritania, Ethiopia, or Sudan);
- c. Make available and share with Gavi recipient countries transparency and accountability rules around PEF resources utilization to increase uptake of TA services.

Cold Chain Equipment Optimization Platform

During this review, five countries submitted a CCEOP application. Three (60%) were recommended for approval and two recommended for resubmission. The IRC appreciates the efforts to address earlier CCEOP recommendations.

Positive developments:

All CCEOP proposals included the required documentation. However, some were inappropriate (e.g. minutes of a different group than the ICC) or inadequate (e.g. tariff exemption). [See also the November 2016 IRC recommendation that the “adequacy and accuracy of the CCE inventory and rehabilitation plan should be undertaken as part of pre-review, and only applications including fully updated inventories and rehabilitation plans submitted to the IRC for review.” This remains valid, and is not a technically challenging task.]

The Kyrgyzstan proposal, in addition to making explicit assumptions about storage need, used the projected 2025 population to ensure that storage would be adequate for future population size, planned new vaccine introductions, as well as unplanned needs. The use of a 10-year horizon for planning CCE needs is to be commended for equipment that is expected to last at least 10 years.

The November 2016 IRC recommendation led to an addendum to application guidelines requesting a single document that covered inventory, rehabilitation and expansion, segmentation and selection, and strategic deployment. Kyrgyzstan used this approach to provide these as well as monitoring indicators. This improved the review process.

All the CCEOP proposals were generally aligned with their HSS and cMYP. Mandatory indicators for monitoring and evaluation were appropriately proposed by 3 out of the 5 countries (Djibouti, Kyrgyzstan, and Vietnam).

In Djibouti, there was a plan to use obsolete/ non-functioning CCE for training at technical high schools. This result in a good connection between Health and Education, as well as providing income from CCE that has been repaired.

However, the IRC identified key issues and made recommendations to further improve the process as follows:

Issue 09: Need to further improve the CCEOP application process and content to better meet the Alliance's aim to sustainably add new vaccines and increase coverage equitably.

Recommendations: As noted in the November 2016 IRC report, Gavi needs to evaluate if (1) the bundling process is getting functioning CCE in place; (2) monitoring systems have been established to provide data on field performance meeting the expected quality and duration of CCEOP equipment; and (3) CCE is being appropriately maintained. It is easy for the proposal to state that monitoring and maintenance will be undertaken, but it is imperative for the Alliance to systematically collect data on the performance and impacts of its CCE investments.

Issue 10: The application guideline refers to optimization of supply systems, but this is not being addressed.

Optimization should have been initiated since the onset of HSS support. However, to date only a handful of countries have engaged in that direction (e.g., Benin). At present, the CCEOP investment is a missed opportunity to catalyze optimization of the supply chain, especially given the opportunities offered by HSS, Alliance partners' support, and public-private partnerships.

The IRC recognizes that political and other constraints may impede redesigning the supply chain, despite its potential financial gains.

Recommendations: A potentially easier aspect to implement is increasing the supply interval for peripheral stores and health facilities to reduce transport costs and increase availability. Reducing frequency of supply to district level also facilitates removing the level above to optimize network design.

The justification for limiting supplies in peripheral sites is to limit impact of temperature damage. The risks of damage are reduced in CCE with documented performance using continuous temperature monitoring and electronic updating of stock levels from peripheral stores. WHO advice remains for one month's supply, but it could be reviewed in light of these new technologies, and the high quality of CCEOP supported equipment. Providing several months of supply reduces logistics costs, and enables supply during seasons when access is more challenging.

Issue 11: Lack of clarity around country plans on replacing ageing equipment.

As in previous rounds, countries use HSS funds, when available, for their joint investment share. Only Vietnam, in accelerated transition phase and without HSS funds, used national resources. No country had a plan for the post-CCEOP needs to replace ageing equipment.

Recommendations: Countries need to plan, for budgeting reasons, to replace equipment after 10-years. However, age alone is not a reason to replace equipment, unless it needs repair or performing sub-optimally. While the risk of failure may increase over time, the data submitted in this round showed that CCE aged >10 years had the same or better proportion that were functioning compared to 5 to 10-year-old CCE; and failures remain common even for CCE <5-years old.

Continuous temperature monitoring data, from the 30-day temperature recorder (30DTR) or remote temperature monitoring (RTM), can be used as a performance-based measure to replace CCE, instead of age alone.

Issue 12: Missed Opportunity for Innovation-Limited use of 30DTR/RTM Data

The potential to use 30DTR/RTM data to monitor the speed of repairs and adequacy of preventive maintenance is not being explored in country plans. Systematically recording temperature alarms, as part of monthly reporting, provides positive evidence of adequacy of CCE performance as well as management response to failures.

Recommendations: Gavi and technical partners should encourage countries to key into the use of RTM/30DTR alarm reporting. This has the potential to monitor the quality of user-level maintenance and to trigger timely demand for repair, and provide monitoring for outsourced maintenance contracts.

Gavi to consider incentives to motivate countries to innovate, test new approaches and to use the CCE investment as a catalyst for a new way of operating. Use of RTM technology to monitor and improve performance of equipment and maintenance.

Issue 13: Need for adequate provision of operational funds by applicant countries.

Now that CCEOP can increase CCE support from HSS funds, there is potential for HSS funds to fund key aspects of operation, such as continuous improvement, capacity development, maintenance, transport, and monitoring.

Recommendation: Ideally, operational costs should come from national budgets. But the reality is that operational funds are inadequate and/or delayed, interfering with supply. Gavi could recommend this reallocation, perhaps with documentation of its impact to make a case for adequate operational budgets.

Issue 14: Countries need more guidance on the minimum time from application to start of implementation.

Countries proposed a start date as soon as 6 months from date of IRC review which is clearly inadequate.

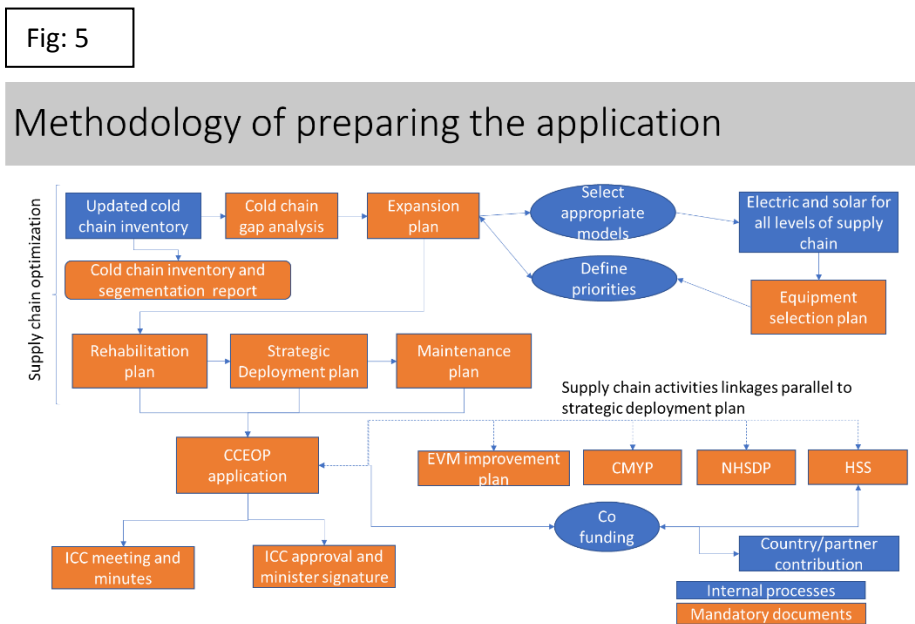
Recommendation: Gavi Secretariat can provide examples of the data on actual times from the decision letter to the start of procurement, and the time from then to receipt in countries, based on data to date from approved CCEOP applications from UNICEF supply division. This can illustratively guide countries in realistically timing their start dates.

Issue 15: Proposal development process: The two proposals that were not recommended for approval did not follow the guidelines. The CCE storage requirements were estimated on arbitrary rationale in one case and blanket replacement in another. Despite guidance, the estimation of CCE storage needs for each site, optimization of supply chain networks, selection of appropriate equipment, and other required aspects of the application process were bypassed. In addition, the IRC notes the huge amount of work required to develop a proposal and its accompanying documents. When this work is done just for the proposal, it does not strengthen country capacity, and leads to consultant dependency.

The key mandatory documents should flow easily from following updating and analyzing the CCE inventory. However, this requires using one of the recommended inventory tools. A single tool can provide analysis of current status, cold chain gaps, segmentation analysis, and rehabilitation and

deployment plan. This was seen in the Kyrgyzstan report. Other countries focus on producing documents instead of the suggested process itself.

Recommendation: Countries that are applying for CCEOP need a detailed briefing, and support, from Gavi, to encourage systematic proposal development based on an up-to-date inventory and gap analysis for future needs (5 to 10 year horizon, including planned introduction of vaccines). See Figure 5 for suggested methodology to prepare the CCEOP application.



Issue 16: Disposal of non-PQS, obsolete, and non-functioning CCE: The five countries requested a total of 4921 fridges and freezers, mostly to replace non-PQS, obsolete, and non-functioning CCE. Disposal of decommissioned CCE is generally planned to follow national environmental regulations. Some countries proposed innovative solutions: sale of decommissioned equipment through public tender/auction (Vietnam, Nepal); use in technical high schools to provide material for practical training of students (Djibouti); and harvesting spare parts to maintain the existing old but functional equipment (Djibouti, Kyrgyzstan). These practices should be commended and promoted.

However, final disposal remains critical. Most countries do not describe appropriate methods, referring only refer to ‘dump or bury’, without considering the hazard to the environment from coolant agents.

Recommendation: Gavi to provide guidance as part of CCEOP to help countries to engage with ministries in charge of environment to organize the safe and environmental friendly policies and plan for disposal. In addition, the disposal of replaced cold chain equipment could be included in service bundle such that the cost of responsible disposal and practice is funded and channelized. (Nov 2016 IRC recommended incentives for return and appropriate disposal of decommissioned CCE).

Issue 17: System optimization: Most CCEOP funded equipment are planned to replace equipment, rather than rehabilitation and expansion of the cold chain, and rarely supply chain redesign. Strengthening CCEOP will gain in effectiveness and efficiency if the supply chain system is optimized (e.g., removal of redundancies, integration of other health products, etc.).

Recommendation: Gavi to consider creating incentives to use HSS funds, Alliance partner support, and public-private partnership/third parties to engage in the process of optimizing the supply chain and use Comprehensive Effective Vaccine Management Improvement plan build around the system optimization.

Cold chain and logistics assessment for NVS

Eight applications for vaccine introduction (HPV, Rota, and MR) or campaigns (measles/MR), from 7 countries were reviewed. Cold chain and logistics (CCL) was not a reason for asking any countries to resubmit; but countries were asked to provide data to show CCL adequacy.

Introduction of a new vaccine (except replacing measles with MR) or measles/MR campaigns adds large volume storage and transport needs for the supply chain.

Countries need to carefully and comprehensively assess their storage and vaccine management capacities at all levels of the supply chain to determine adequacy well ahead of the application. Should there be any gap, alternatives and back-up plan including their source of funding must be clearly articulated in the application.

Issue 18: Data on CCL adequacy: At present, there is no requirement to provide data to compare current capacity with NVS needs. Applications have provided no, or minimal, evidence to show adequacy.

Recommendation: Gavi should guide countries to provide data on cold storage capacity down to at least the lowest distribution level (district level), and plan for addressing the gaps or mitigation strategies

Issue 19: Waste management: Countries provided either no information on injection waste disposal, or plans that show problematic disposal (only ‘burn and bury’).

Recommendation: Alliance partners must support countries to use NVS as an opportunity to improve waste management; the application guidelines can emphasize this opportunity and require countries to provide better plans, including how they will address the gaps or mitigate issues around waste management.

Data Quality

Issue 20: Data quality and immunisation – Progress being made, effectiveness should be monitored

Generally, the IRC found that application during this review process reflected meaningful efforts to improve accuracy and completeness of immunisation data. Afghanistan reported progress in implementing its data quality improvement plans. In addition, the IRC found that countries are taking data quality issues seriously; Rwanda met Gavi-specific data quality requirements fully; and, rather than focusing on basing decisions on data that may have serious issues, Benin and Mauritania were both transparent about gaps in their data quality. What remains unclear at this point is the impact of increased effort and transparency. In Afghanistan, while it is encouraging that the country is moving forward with data improvement activities, no evidence is yet available that data are improving. Zimbabwe, struggling with potential data quality issues for the first time in recent years, put in place plans for improved data quality which were delayed; a full data quality review is scheduled for later this year. Ethiopia is in the process of transitioning to an improved data management system run on the DHIS2 platform, but it is not yet possible to determine whether this will improve the quality of their administrative data.

Recommendation:

As a part of its ongoing support for countries in these efforts, the Gavi secretariat should collaborate with Alliance partners to assess the effectiveness of the range of data quality activities currently underway. This assessment could incorporate a case study methodology focusing on countries with dramatic improvements or deteriorations in data quality coincident with progress (or lack thereof, respectively) in implementing data quality, for example.

Issue 21: Evaluation – Utilization of lessons learned from prior vaccine introductions in action planning

In general, the IRC found mixed results in terms of countries applying lessons learned from experiences from prior vaccine introductions in their plans in this round of applications. Among seven applications for new vaccine introduction support, no country included PIE reports from prior introductions as part of their country-submitted application materials, although PIE reports were made available to the IRC upon request through other channels. At least one country (Afghanistan) had failed to conduct a PIE in prior introductions, despite this being a requirement.

The IRC is keenly aware of the heavy burden placed on countries by mounting additional requirements for documentation, evaluations and data collection. Accordingly, the IRC wishes to emphasize that, in line with recent guidance from the Secretariat, conducting an additional household survey solely for the purpose of evaluating a new vaccine introduction is not necessary. Rather, utilizing existing high-quality survey data in combination with monitoring data from the introduction can provide sufficient information to take a critical look at the quality of the new vaccine introduction. Specific action points related to conclusions should be reflected in subsequent introductions.

Recommendations:

- To emphasize the importance of taking into consideration the experience of previous vaccine introductions in preparing an application, the IRC recommends that PIE reports be added as a field in the optional documents section for attachments to an application.
- In addition, the IRC recommends that countries' lessons learned tables in applications not only present issues from prior introductions but also cite clear and specific resulting action steps in any pending introduction application submitted for IRC review.

Governance

Issue 22: Non-existence/poorly functioning NITAG in countries despite increasing vaccine introductions.

Recommendations

- Gavi's renewed focus on strengthening governance mechanisms should actively support NRA and NITAG in becoming *non-negotiable institutions* in the decision making process and evaluation of programme effects, outcomes and impact;
- Gavi to provide IRC with summary tables on NRA and NITAG status per reviewed country (based on WHO criteria and assessment outcomes).

PCA and Financial Management

Financial Management Assessments (FMAs) have been replaced by Programme Capacity Assessments (PCAs) in light of the new Gavi risk mitigation framework which is built on three (3) lines of defence. Gavi cash support is heavily subject to the assurance that implementing entities maintain solid and robust financial management systems to track, account for and report on Gavi funds. Generally, FMAs' results reported in the countries' applications reveal weak and non-reliable financial arrangements and internal controls within the Government entities (MoH, Central Directorates, EPI, etc.). As a safeguard policy, Gavi cash support is channelled through Alliance partners such as WHO and UNICEF (especially for the procurement component of any cash grant). The PCA model was designed to assess countries' programmatic and financial capacity level and reflect the results in the grant arrangements to be put in place after proposal review and approval by IRC.

However, the strengthening actions proposed after the PCA exercises at country level to address identified gaps are not reflected in the applications reviewed by the IRC. Reviewers do not have evidence of clear capacity building and improvement plans proposed by the PCA to assess the risk environment around applications being reviewed and recommended for approval. IRC noticed also that in many countries reviewed this round (Mauritania, Benin, Zimbabwe, Sudan, etc.), channelling of cash resources outside the Government entities has been the standard operating model for many years rather than an interim risk mitigation measure while Gavi and Alliance partners are building in-house capacity and expertise within MoH and its relevant directorates. Transfer of skills and capacity development plans would have permitted some of these countries to be direct recipients of their cash grants, managing, accounting and reporting to Gavi Secretariat. As countries build-up their level of confidence and capacity, they should be made accountable on resources provided to the health sector and get benefit from financial management strengthening training and tools.

During this March 2017 review, IRC identified the following issues and made recommendations to Gavi and its partners around the PCA process and associated financial management issues

Issue 23: Lack of details in the country applications on strengthening actions resulting from PCA exercises conducted and/or on-going since 2016;

Recommendation:

Gavi Secretariat should make available key outcomes and capacity building action points arising from PCA conducted for each country under review.

Issue 24: Lack of skills transfer transition plans for financial management functions

Capacity building and skills transfer plans are not clearly outlined in countries' applications once financial management function is performed through Alliance partners (Examples of Mauritania, Benin, etc.).

Recommendation:

Alliance partners to fast track skills transfer and capacity building plans on financial management to EPI/MoH to ensure accountability, efficiency and long term sustainability

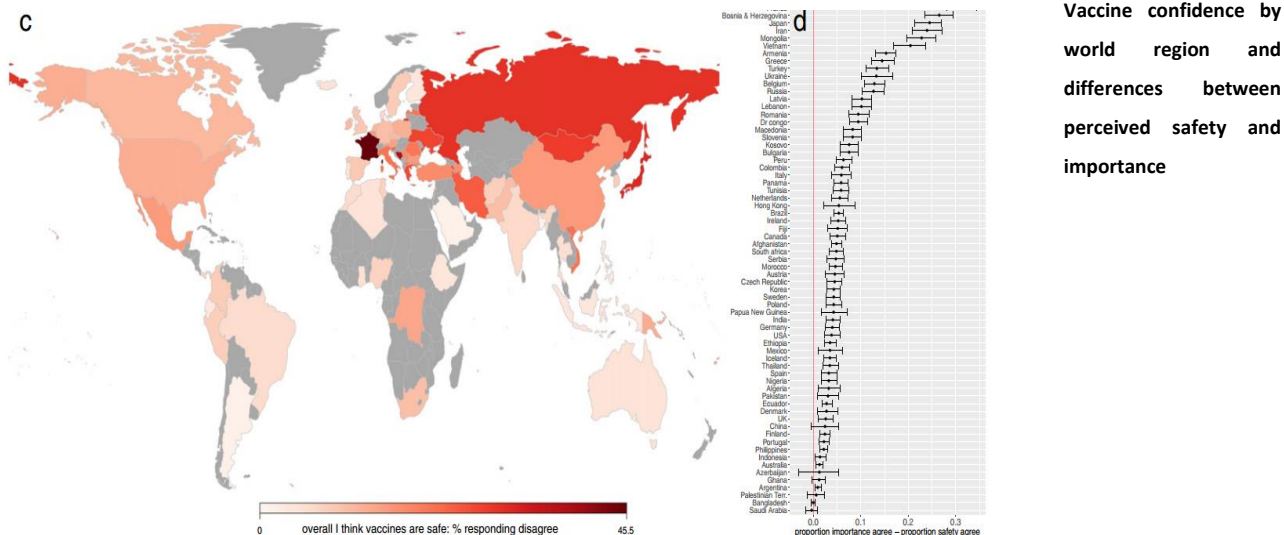
Emerging Issues

Vaccine Confidence and Hesitancy

Issue 25: There are reported cases of vaccine hesitancy and acceptance of vaccines and immunisation in countries e.g. Afghanistan, Benin, Kyrgyzstan in this current review and from Azerbaijan, Vietnam, Armenia, DRC in past recent reviews *for very different reasons*.

Recommendations:

- Gavi Secretariat, Alliance partners and broader immunisation stakeholders need to promote public trust in immunisation as an important global health issue to reduce hesitancy
- Increasing need to reduce disease outbreaks and challenging immunisation goals in Gavi eligible countries;
- Increase support for AEFI surveillance and reporting including strong response plans;
- Gavi and technical partners to support country level efforts to establish and strengthen country level structures e.g. NRA and NITAG; better monitoring of vaccine attitude to identify emerging concerns before they evolve into vaccine confidence crises.



Vaccine confidence by world region and differences between perceived safety and importance

Issue 26: Coming challenges of food insecurity (drought, climate change)

The IRC calls flags the increasing challenges of food insecurity to Gavi and its Alliance partners. During this review process, according to IFPRI, 6 (Afghanistan, Nepal, Ethiopia, Mauritania, Sudan, Zimbabwe) of the countries applying to the March 2017 IRC are experiencing either “alarming” or “serious” hunger in some part of their territory. For some, drought in neighbouring countries means refugees/ clandestine migrants.

Implications for immunisation:

- Locating those internally displaced (e.g. Sudanese hiding on islands in the Nile)
- Cost benefit analysis of introducing new vaccines in a drought-stretched country (e.g. Ethiopia)
- Innovations to promote immunisation under such conditions e.g. “package” vaccination with food or other supplies?

Conclusion

- The IRC continues to see stronger and better aligned country applications across board and commends the efforts of Gavi Secretariat and its technical partners to achieve this.
- The IRC notes that the PEF/TCA is working. It further encourages countries and technical partners to better engage to address critical bottlenecks whilst building in increased flexibility, transparency and accountability of process;
- Gavi and Alliance partners to support countries in greater use of strong epidemiologic analysis including modeling of age-specific immunity profiles where applicable and technically sound/

context based strategies to better inform high-quality campaign planning, guide roll outs and improve routine immunisation;

- Gavi and technical partners should strongly encourage applicant countries to actively and correctly use global guidelines and tools to guide country applications. The IRC re-emphasises the need to properly pre-screen applications to raise the quality of submissions before IRC review;
- Gavi's renewed focus on strengthening governance mechanisms should actively support NRA and NITAG in becoming ***non-negotiable institutions*** in the decision making process and evaluation of program effects, outcomes and impact;
- Gavi to pay closer attention to emerging issues around food security, increasing vaccine confidence and increasing hesitancy.

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ANNEX 1: LIST OF IRC MEMBERS MARCH 2017

NO.	Name	Nationality	Profession/Specialisation	Gender	French Speaking
1.	Aleksandra Caric	Croatia	Independent Consultant	Female	X
2.	Dora Curry	USA	Senior Technical Adviser, CARE	Female	
3.	Ranjit Dhiman	India	Independent Consultant	Male	
4.	Modibo Dhicko	Senegal	IntraHealth	Male	X
5.	Linda Eckert	USA	Professor, University of Washington (Gynaecology)	Female	
6.	Zeenat Patel	Canada	Public Health Physician/Independent Consultant	Female	
7.	Philippe Jaillard	Benin/France	Agence de Medecine Preventive (AMP) Country Representative	Male	X
8.	Shaikh Humayun Kabir	Bangladesh	Independent Consultant	Male	
9.	Miloud Kaddar - VICE-CHAIR	Algeria	Independent Consultant (ex WHO)	Male	X
10.	Osman David Mansoor	New Zealand	Public Health Physician, Regional Public Health, New Zealand	Male	X
11.	Benjamin Nkowane	Zambia	Independent Consultant	Male	
12.	Bolanle Oyeledun - CHAIR	Nigeria	CEO, Center for Integrated Health Programs	Female	
13.	Diana Rivington	Canada	Independent Consultant	Female	X
14.	Mario Stassen	Netherlands	Independent Consultant	Male	
15.	Ousmane Amadou Sy	Senegal	Independent Consultant	Male	X
16.	Shamsa Zafar	Pakistan	Head of Department, Centre of Excellence MNCH	Female	