

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

Geneva, Switzerland

November, 2018

List of Contents

List of Contents 2

List of Acronyms..... 3

1.0 EXECUTIVE SUMMARY 4

2.0 REVIEW METHODS AND PROCESSES 4

 2.1 Review process and key outcomes4

 2.2. Good practices and promising innovations6

 2.3 Feedback on work processes6

3.0 KEY FINDINGS 7

 3.1. New Vaccines Support and Campaigns7

 3.2 Data Quality, AEFI Surveillance..... 10

 3.3 Immunization Supply Chain Logistics (CCEOP and CCL cross cutting) 12

 3.4 Budget review of NVS Applications..... 15

 3.5 Equity Issues 16

 3.6 PSR Review and Outcomes..... 16

 3.7 Technical Assistance 18

 3.8 Governance 18

4.0 CONCLUSIONS..... 19

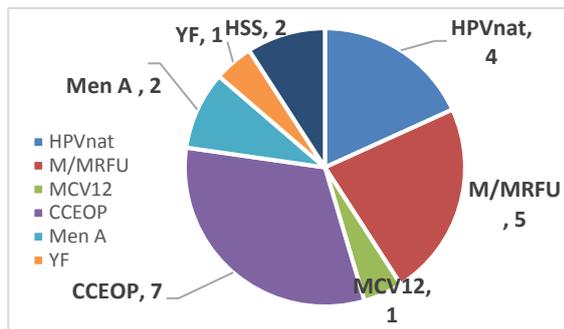
Annex 1: List of IRC Reviewers; November 2018..... 22

List of Acronyms

AEFI	Adverse Event Following Immunization
BCC	Behaviour Change Communication
CC	Cold Chain
CCE	Cold Chain Equipment
CCEI	Cold Chain Equipment Inventory
CCEOP	Cold Chain Equipment Optimization Platform
CCL	Cold Chain Logistics
CMYP	Comprehensive Multi Year Plan
DQA	Data Quality Assessment
EPI	Expanded Programme on Immunization
EVM	Effective Vaccine Management
HPV	Human papillomavirus
HR	Human Resources
HSIS	Health Systems and Immunization Strengthening
HSS	Health Systems Strengthening
ICC	Inter-Agency Coordination Committee
IRC	Independent Review Committee
MCV	Measles Containing Vaccine
M&E	Monitoring and Evaluation
MNCH	Maternal Neonatal and Child Health
MR	Measles-Rubella
NITAG	National Immunization Technical Advisory Group
NRA	National Regulatory Authority
NVS	New and underused Vaccine Support
PEF	Performance Evaluation Framework
PoA	Plan of Action
PBRER	Periodic benefit-risk evaluation report
PSR	Program Support Rationale
PSUR	Periodic safety update report
PQVAR	Prequalified Vaccines Annual Report
PV	Pharmacovigilance
RED/REC	Reaching Every District/Reach Every Child
RI	Routine Immunization
SCM	Senior Country Manager
SIA	Supplementary Immunization Activity
SMS	Short Message Service
TA	Technical Assistance
Td	Tetanus-diphtheria toxoid
TOR	Terms of Reference
UNICEF	United Nations Children's Fund
VIG	Vaccine Introduction Grant
WHO	World Health Organization

1.0 EXECUTIVE SUMMARY

The IRC met between 5TH and 16TH November 2018 in Geneva, Switzerland and reviewed 22 country



applications submitted by 16 Gavi eligible countries. 15 were recommended for approval; 4 were for re-reviews and 3 were recommended for support as part of the PSR.

The IRC session was comprised of 19 reviewers with expertise in immunization, cold chain and logistics, maternal, neonatal and child health (MNCH), adolescent health, health systems strengthening,

reproductive health programme management, epidemiology, monitoring and evaluation, financial analysis, behaviour change communication (BCC) and gender. Six (6) new members joined this IRC meeting bringing in additional expertise in immunization, epidemiology, health systems strengthening, finance, budget and program management. Three members focused on in-depth financial reviews of the budgets submitted by applicant countries (*see Annex 1 – List of IRC reviewers*).

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

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

Finally, the IRC commend Gavi and technical partners on progress made by the Gavi executive and staff for its recommendations from PPC to the Gavi board on the M/MR SIA and the continuing high quality HPV national introduction applications. It further recommends key action points in terms of unpacking the guidance to operationalize the M/MR SIA recommendations; calls for a review of the PSR process based on lessons learned to improve its structure; and an urgency for countries to actively plan for waste management as essential part of health and immunization system strengthening by demanding strict plan and budget.

2.0 REVIEW METHODS AND PROCESSES

2.1 Review process and key outcomes

Review Process: IRC reviewed 22 funding requests from 16 countries. 2 countries submitted 8 NVS/HSS/CCEOP requests as part two PSR packages. 15 were recommended for approval; 4 were for re-reviews and 3 were recommended for support as part of the PSR.

Each country application and supporting documents were independently reviewed by assigned members. This was followed by presentation of initial findings with extensive discussions during daily plenaries. Key outcomes and decisions were then consolidated into draft country reports, which then underwent quality review and internal consistency checks. In certain instances, the IRC members adjourned decision making to avail themselves of additional information/clarifications from SCM/Technical partners and countries. During this review window, this was supported by direct phone dialogue by IRC members with Afghanistan and Ghana. Other countries (e.g. Burkina Faso) provided clarifications through e-mails/additional documentation moderated by the SCM/TA partners.

Decisions: Two decision categories: Approval with issues to be addressed and re-review with outstanding issues/action points to be addressed by country in next iteration.

Criteria for review: This did not change from recent windows and consists of the extent to which proposals (a) meet application requirements; (b) principles of Gavi support and (c) contribution to achieving Gavi mission and strategy. The IRC was also able to engage additionally with a fragile country as part of the key developmental approach to support country applications and provide needed guidance and clarifications to further strengthen the application process.

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

Countries		Types of support			
		HSS / CCEOP requests	M/R support requests	Other vaccine requests	Recommendation outcomes
1	Afghanistan	CCEOP			Re-review
2	Burkina Faso		MR follow up		Approval
3	Comoros		MR 1+2 dose + catch up		Re-review
4	DR Congo		Measles follow up		Approval
5	Ghana*	HSS			Approval
		CCEOP			Re-review
				Yellow fever	Approval
6	Guinea Bissau*	HSS			Approval
		CCEOP			Re-Review
				HPV, MCV2, MenA	Recommended for support**
7	Lao PDR	CCEOP			Approval
8	Mozambique			HPV	Approval
9	Myanmar			HPV	Approval
10	Solomon Islands		Measles Rubella follow up		Approval
11	Somalia		Measles follow up		Approval
12	Tajikistan	CCEOP			Approval
13	Togo			HPV & MenA	Approval

14	Vietnam		Measles Rubella follow up		Approval
15	Zambia	CCEOP			Approval
16	Zimbabwe	CCEOP			Approval
<i>* PSR – Programme Support Rational review</i> <i>** Full vaccine application expected at a later stage</i>					

The quality of proposals submitted by countries continues to improve, with 18 out of the total 22 (82%) applications 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 improvements and provide technical clarifications to countries to reduce the turnaround time for country considerations of IRC recommendations on issues to be addressed.

2.2. Good practices and promising innovations

The IRC notes that some country applications presented excellent analyses. These include Mozambique with its EVM IP status progress presentation; Burkina Faso with a good quality crisis communication plan for AEFI and Myanmar/Guinea Bissau with good equity analyses.

Country specific promising activities include the potential for impact as demonstrated by Myanmar's HPV vaccine application. The application places emphasis on microplanning, utilization of immunization delivery structures already in place such as school immunization with Td and monthly outreach sessions, and strong application of lessons learned from recent campaigns and other country HPV experiences giving Myanmar a high chance for success.

2.3 Feedback on work processes

The IRC commends the Gavi executive and staff for its recommendations from PPC to the Gavi board on the M/MR SIA. However, it is important that the portfolio of measles efforts need to be integrated to maximize population immunity with a clear vision for the control of measles and outbreak responses must not be implemented in silos.

Recommendation: Countries should be guided with contextual advice on using outbreak response with country SIA plans.

3.0 KEY FINDINGS

3.1. New Vaccines Support and Campaigns

Measles and Rubella vaccines

In this review window, six countries applied for measles or measles-rubella (M/MR) support: three for MR follow-up campaign (Burkina Faso, Solomon Islands and Vietnam), two for measles follow-up campaign (DR Congo and Somalia), and one for MR catch-up campaign and subsequent MR introduction into routine (Comoros). Of these, only Comoros was not recommended for approval. Somalia proposal was recommended for approval for the standard follow-up campaign given the epidemiologic data presented (i.e. up to 59 months instead of requested up to 10 years), and the proposals for the remaining four countries were fully recommended for approval. Funds requested amounted to US\$ 21,329,821 for operational costs alone, and the total approved, without taking into account reduction of the target population as per IRC recommendation for Somalia, amounts to US\$ 21,105,821.

The six countries IRC reviewed for measles activities had a wide range of routine measles coverage. Highest estimated coverage was seen in Vietnam (97%) and lowest in Somalia (46%). Similarly, there was a wide spectrum of levels of measles control. Measles remains endemic in Somalia and DR Congo with frequent large outbreaks. Comoros have not had sustained transmission for many years but may have been fortunate not to have had importations of measles virus. Solomon Islands, Burkina Faso and Vietnam have demonstrated overall good measles control, but have experienced large outbreaks in past 5 years (Solomon Islands in 2014 with over 4,600 suspected cases reported, Vietnam in 2014 with 16,000 cases and Burkina Faso in 2018 with over 1,600 cases reported to date) proving that significant coverage gaps exist.

Issue 01: Low routine coverage and high birth rate shorten the duration of SIA impact

Figure 1 below illustrates the relationship between routine vaccination coverage and the time to accumulate one birth cohort of susceptible children < 5 years of age.

It summarizes the WHO critical measles indicator of reaching one birth cohort of susceptible children according to routine measles coverage, including a second routine dose of MCV in Vietnam and Burkina Faso. Assuming an overall 85% measles field vaccine effectiveness, in Vietnam, with coverage for both doses approximating 95%, it would take about 6.5 years to accumulate one birth cohort of measles

Figure 1: Relationship between routine vaccination coverage and the time needed to accumulate one birth cohort of susceptible children <5 years of age.

susceptible children < 5 years of age. Indeed, given its record of achieving and sustaining high routine measles coverage, Vietnam

should be supported in its efforts to reach the chronically underserved with targeted vaccination strategies. This strategy will obviate the necessity for the country to conduct regular SIAs. In Somalia with a single dose measles schedule and consistently low routine coverage, one birth cohort of susceptibles is reached in only 1.6 years. In DR Congo with an estimated routine coverage of 77%, one birth cohort of susceptibles accumulates in about 2.9 years. This has important implications: even if an SIA reaches 100% coverage, in countries with chronically low routine coverage, the duration of impact of the campaign will be short. The recently launched *Mashako Emergency Plan for Strengthening Routine Immunization* in 8 DR Congo provinces, if fully implemented, should help to

reduce the accumulation of susceptible children and improve measles control. Another challenge is the high birth rates being seen in many countries with large measles burdens. This puts additional stress on many chronically weak immunization programmes and accelerates the rapid accumulation of susceptible children increasing the risk of measles outbreaks.

Recommendations: Routine immunization services remain the foundation of efforts to control or eliminate measles. With sustained high routine measles vaccine coverage, the interval between “follow-up” SIAs can be increased and, if high routine coverage is maintained over time, SIAs can eventually be discontinued. In this regard, the IRC echoes the SAGE recommendation that all countries should provide two-doses of measles-containing vaccine through routine immunization services. To prevent measles outbreaks, technical partners need to support countries to assure that > 90% coverage is achieved in all districts for both routine doses of measles-containing vaccine. Indeed, the IRC is fully aligned with the recent recommendation of the Programme and Policy Committee (PPC) that countries should be strongly encouraged to develop innovative and tailored approaches for SIAs to assure that previously unimmunized children are reached that can result in the ongoing strengthening of routine immunization services. Secretariat should also ensure that Gavi operational guidelines reflect the flexible options/strategies recently approved by the Gavi Board.

Issue 02: Late and poor implementation of measles outbreak response activities and disconnect between measles outbreak response activities and planning for follow-up SIAs.

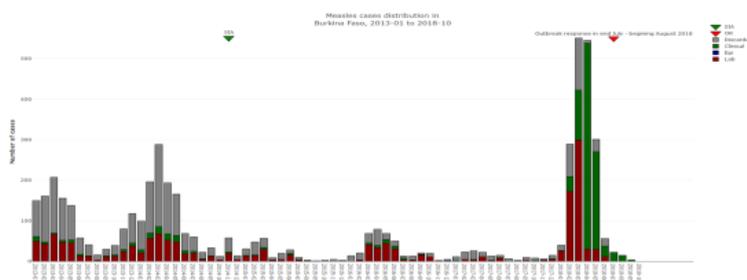
The IRC continues to see measles outbreaks in countries with high estimated measles coverages, including DRC and Burkina Faso. Potential factors for these outbreaks include:

- overestimation of national vaccination coverage;
- provinces and districts with large pockets of under-immunized children;
- sub-optimal vaccine effectiveness due to improper vaccine handling; (i.e. quick loss of potency if exposed to light after reconstitution);
- combination of above factors.

In some countries, the IRC increasingly note a “vicious cycle” of poor quality SIAs, low routine measles coverage, frequent measles outbreaks and late, poorly implemented outbreak response activities resulting in limited impact. Indeed, we are seeing an overlap and conflation between outbreak response and outbreak prevention activities.

**Figure 2: Burkina Faso:
Follow-up SIA planning vs Outbreak Response?**

• 30 districts August 2018 Target population: 1,492,531, 9-59 months



The measles situation in Burkina Faso is a case in point (Figure 2). The country is planning to conduct a national “follow-up” campaign in 2019 targeting all children 9-59 months of age. In early 2018, however, the country observed a major increase of confirmed measles cases

throughout the country. Between January and July, over 1,500 cases were reported.

To respond to this outbreak, the country requested emergency outbreak response support from the Measles-Rubella Initiative in March 2018. The response targeted all children 9-59 months of age (about 1.5 million children) living in 30 of 70 districts with relatively high measles incidence. However, outbreak response immunization did not begin until late July 2018 when the epidemic was clearly ending. Although estimated achieved vaccine coverage was high, the outbreak response occurred too late to have had a significant impact in stopping the outbreak.

The IRC understands that there is epidemiologic evidence demonstrating that rapid implementation of measles outbreak response immunization activities can result in decreased measles morbidity and mortality. However, most large measles outbreaks occur in countries with relatively weak immunization systems that lack the capacity to mount a rapid, high-quality measles outbreak response. Given the above, it seems pragmatic that measles outbreak response activities be implemented as soon as possible after measles transmission is detected and target those children at highest risk from dying from measles (i.e. previously unvaccinated children < 5 years of age). The term “emergency follow-up campaign” seems inappropriate.

The goal of follow-up campaigns is for the prevention of measles outbreaks. To be successful with very high measles coverage, careful and timely planning and preparation are required. Conducting a rushed follow-up campaign without adequate macro and micro-plans and training will likely result in sub-optimal SIAs returning poor value for money. In this regard, we have seen several countries that have requested emergency support from the Measles Rubella Initiative to respond to measles outbreaks that occur before planned follow-up campaigns. IRC is concerned about the blurring between outbreak prevention and outbreak response activities in Gavi countries. A major objective of national immunization programs is to achieve and maintain high population immunity to measles in children <5 to prevent measles outbreaks. Measles outbreaks are due to major gaps of population immunity.

Finally, countries need clear criteria for whether districts included in outbreak response activities should be included or excluded from “follow-up” campaigns that are planned to take place within the next 12 months.

Recommendations: To reduce measles mortality during outbreaks, increased efforts are needed to assure that outbreak response activities are implemented as soon as measles virus is detected and is

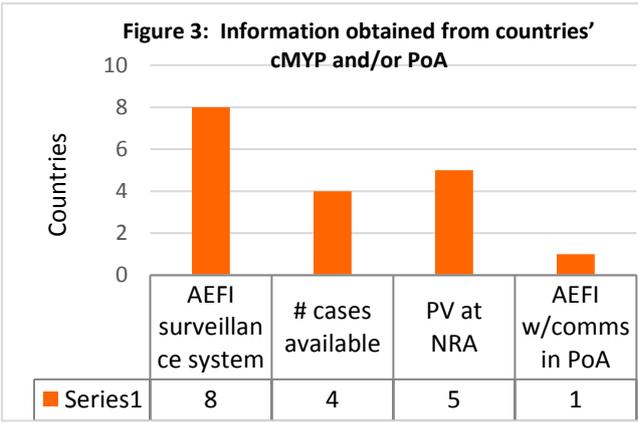
focused on reaching previously unvaccinated children < 5 years of age. Technical partners should provide clear guidance to countries for the inclusion or exclusion of districts that have been recently covered during outbreak response activities in upcoming SIAs.

Finally, countries need clear criteria for whether districts included in outbreak response activities should be included or excluded from “follow-up” campaigns that are planned to take place within the next 12 months.

HPV National introductions

The HPV applications continue to demonstrate growing high quality with clear incorporation of lessons learned from recent campaigns and other country HPV experiences. The comparatively higher quality of HPV applications most likely speak to the positive impact of TA provided by partners in the development of the applications. The IRC recommends lessons learned from this model be extended to other vaccines application development processes as well.

3.2 Data Quality, AEFI Surveillance



3.2.1. AEFI Surveillance related issues

Issue 03: Slow improvement of AEFI surveillance systems, lack of collaboration between stakeholders at country and international levels.

Functional AEFI surveillance system remains an important factor to maintain confidence in immunization programmes. Strengthening technical capacity of AEFI surveillance systems in countries has been a recurring IRC recommendation. However, in the most recent 3-year period (2015-2017) countries have shown slow improvement in reporting AEFIs and stagnant establishment of AEFI committees. Out of 10 countries (Burkina Faso, Comoros, DRC, Mozambique, Myanmar, Solomon Islands, Somalia, Togo, Vietnam, Ghana) applying for support in this review cycle (SIA operational costs and/or new vaccine introduction support), 8 countries report that they have basic AEFI surveillance in place but only 4 countries had some information from AEFI surveillance either in their Plans of action (PoA) or cMYPs. This information was limited to the number of AEFIs categorized according to seriousness (serious/non-serious). There was no information or analysis as to the types, frequencies, and age, therefore the utility of this information is limited. Only one country paired the AEFI monitoring plan for the SIA with the crisis communication plan in the PoA. Further, countries do not describe links of their national immunization programmes with national regulatory authorities (NRAs). Out of 10 countries, 9 reported to have NRAs established, and 5 countries out of these 9 reported vaccine pharmacovigilance (vaccine PV) as one of their functions.

WHO requires that prequalified vaccines are first registered in the country of their manufacture by that country’s NRA which is responsible for regulatory oversight of the product, and that they are

licensed in the country of use. In many resource-limited countries national regulatory systems are evolving and may have various performance maturity levels according to the WHO global benchmarking tool. As a minimum, countries sourcing vaccines through UN agencies must have licensing and surveillance of vaccine field performance (i.e. vaccine safety) in place as basic regulatory functions.

Safety surveillance is a fundamental pharmacovigilance tool used to assess the safety of licensed vaccines and to promptly identify and address any unexpected safety concerns arising from their use. Passive surveillance with spontaneous AEFI reporting remains the cornerstone of vaccine PV. Accurate, complete, and timely reports should be sent from the service-providing level upward, and finally shared with the NRA. Therefore, vaccine safety surveillance within a country requires involvement of both national immunization programme (often with smaller amount of data, but valuable because it is local data) and NRA (which should have much larger information from procuring UN agencies, manufacturers and/or marketing authorization holders). However, almost all applicants lack a robust passive vaccine surveillance system and a stable, well-functioning and integrated regulatory system, which makes determining the benefit-risk profile of vaccines and using that information meaningfully challenging at best. Supporting both AEFI surveillance systems through building the culture of AEFI detection, reporting, and analysis, and enhancement of NRA capacity in resource-limited countries, is becoming increasingly important as the landscape is changing: traditionally vaccines were introduced after years of use in other countries, but recently new vaccine products have been directly introduced into such countries, which puts greater responsibilities on their systems.

Recommendations:

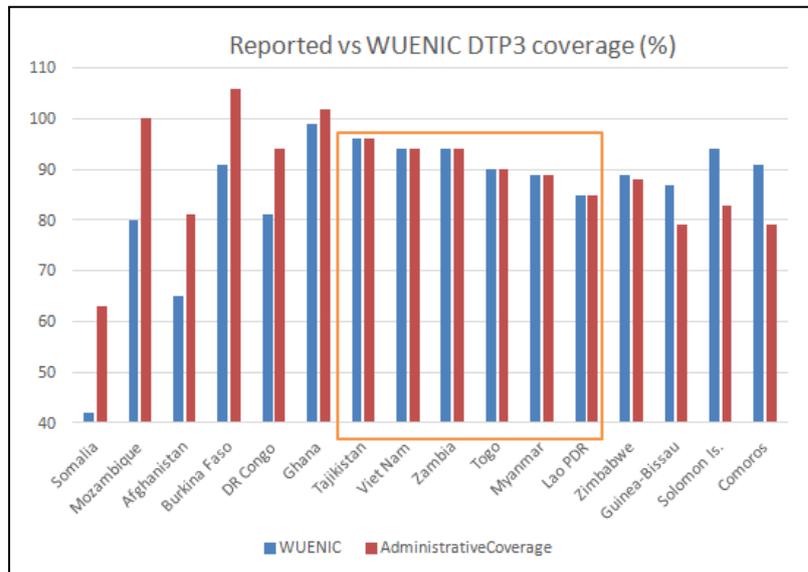
- Within a country, Gavi should encourage establishment and strengthening of dialogue among stakeholders – national immunization programme, NIP technical groups, NRA – should be encouraged as it may identify information necessary to evaluate and manage AEFI risks, issues and/or gaps in vaccine safety surveillance, and mechanisms to address them. WHO may have access to information that would help supplement, refine and address any of the issues and/or information gaps identified within countries as it has established the procedure of yearly safety review of prequalified vaccines which results with the prequalified vaccines annual report (PQVAR). PQVAR includes the assessment of cumulative global safety information obtained through periodic safety update reports (PSURs) or periodic benefit-risk evaluation reports (PBRER) provided to WHO by manufacturers in the effort to ensure continuing quality and safety of prequalified vaccines. Therefore, dialogue between countries and WHO should be encouraged so that necessary safety information is shared. This collaboration at the regional/global/international level is important as AEFI reported in one country may have implications for other countries/regions that use the same product or batch of a particular vaccine.
- As news or rumours about vaccines can quickly spread locally and globally, countries need to be aware of issues that may influence local public opinion in order to generate meaningful communication plans and maintain trust in immunization programmes, WHO/technical partners should provide clear guidance and assistance to countries along with obtaining WHO/technical partners' encouragement and assistance.

3.2.2. Data Quality

Issue 04: Failure to use available data for planning and decision making

Figure 4: Reported vs. WUENIC DTP3 coverage

There appears to be an easy readiness to accept “inflated” administrative coverage data as the basis for planning. Review of WUENIC coverage estimates from the applications suggests that for 6/16 countries their administrative data overestimate their true coverage by up to 20 percentage points, while for 4/16 countries the administrative coverage is estimated lower than WUENIC (Figure 4).



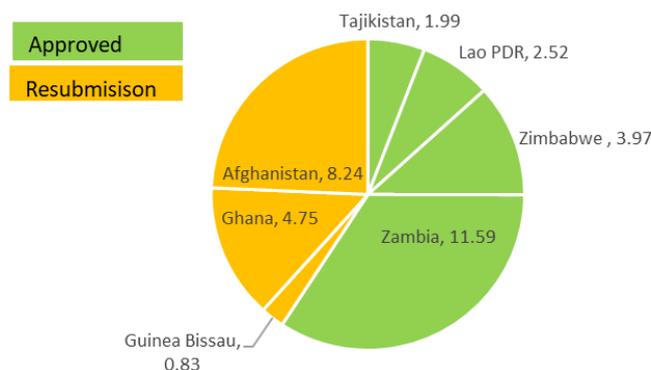
For instance, Burkina Faso did not acknowledge its estimated lower routine immunisation coverage from a high quality 2016 post-campaign survey in its Gavi MR Follow up SIA application. Similarly, Comoros Islands did not use the most updated demographic figures to determine targets for campaigns. Vietnam does not have a DQA: and has measles despite very high reported coverage for both MCV doses. These uncertainties about coverage as a result of problems with data quality may undermine efforts to increase coverage and equity.

Recommendation: Gavi is encouraged to implement the new data quality strategy with strong support to countries. The IRC recognizes the strong political undertones and highly recommends country level dialogue. There is a need to incentivize the use of good quality data at all levels for strategic planning and decision making. Gavi and WHO should support on-going efforts to increase data quality in countries and strengthen the capacity for data analysis and use.

3.3 Immunization Supply Chain Logistics (CCEOP and CCL cross cutting)

The November 2018 IRC received seven CCEOP applications, of which two were part of remote PSRs (Ghana and Guinea Bissau) and five were independent applications (Figure 5). The IRC recommended for approval four applications and three were recommended for re-reviews. This IRC round received

Figure 5: CCEOP applications budgets in million \$



CCEOP applications with a total value of \$33.89 million of which \$20.07 million has been recommended for approval. Reviewers identified some key good practices and issues to be addressed.

3.3.1 Good practices

- 1. Good quality of inventory:** The applications from Ghana, Lao PDR, Tajikistan and Zimbabwe were received with good quality inventories. Countries either use web based cold chain inventory tools or good adaptations of the WHO CCEI tool for country deployment requirements and systematic rehabilitation plan formation.
- 2. Comprehensive rehabilitation plans:** The majority of countries submitted comprehensive CCL plans and budgets. However, not all of these provided specific plans and budgets for the funding that would actually be available once Gavi ceilings were applied. In practice, both are necessary for an objective review of applications (see Issues to be addressed #1 below).
- 3. Guidance and engagement with country:** IRC as part of the solution: On November 14th 2018, a teleconference was organised with Afghanistan and partners (WHO and UNICEF). IRC explained the issues, concerns and considerations based on their review of CCEOP proposal. Country and partners were sent one day prior to the call an e-mail explaining issues, and concerns raised by the IRC. During the teleconference, the country and partners confirmed understanding of issues and concerns and will consider the IRC suggestions to revise the country approach and reply by January 21st, 2019. This is considered positive within the specific context of Afghanistan after 3 previous resubmissions.
- 4. Improved data management and maintenance tracking practices:** Lao PDR application presented the scale up of Cold Chain Information System, a SMS and android based reporting and recording of cold chain equipment performance using 30 DTR and DHIS-2.

3.3.2 Emerging issues to be addressed are as follows:

Issue 05: Rehabilitation plan not complete and tailored to Ceiling: Countries like (Afghanistan and Ghana) tailor their rehabilitation plan for cold chain to match the budget ceiling. Countries need to develop comprehensive rehabilitation plan irrespective of the ceiling to have a clear overview of needs, including replacement of absorption technology.

Recommendation: Technical partners and Gavi guidelines must provide clear understanding within country that the IRC needs a comprehensive rehabilitation plan and budget, with current and potential future funding commitments clearly shown, irrespective of the ceiling to have a clear overview. This comprehensive plan should be supplemented with a specific plan and budget for the CCEOP application which makes clear what the request will fund when approved; and how this fits into the overall plan and budget.

Issue 06: Use of HSS funds for joint investment: Countries are using non-budgeted/ earmarked HSS funds for Joint Investment CCEOP. Effectivity of CCEOP depends on Cold Chain infrastructure and supply chain.

Recommendation: An impact analysis on the original scope of HSS should be performed and reviewed by Gavi Secretariat and IRC in instances where CCEOP co-funding is not budgeted within HSS but plans to finance CCEOP using HSS funding.

Issue 07: Generated data not used: It is positive that countries are generating CCL data to measure the quality of cold chain functionality. Nevertheless, data generated through these logs must be reviewed and analysed to be useful for continuous improvement of CC management.

Recommendation: Technical partners should encourage and stimulate countries to review, assess and use data to improve maintenance and to plan for cold chain rehabilitation.

Issue 08: Supply chain optimization: CCEOP should not be used to fund large scale deployment of refrigerators in situations that could be more cost-effectively addressed by providing walk-in cold rooms from other funding sources.

Recommendations:

- Countries should identify sites where the required cold storage capacity can be more cost-effectively met by walk-in cold rooms;
- Gavi and partners should encourage the development of Grade A cold rooms. This can become Gavi eligible only by special considerations and exceptions as determined.

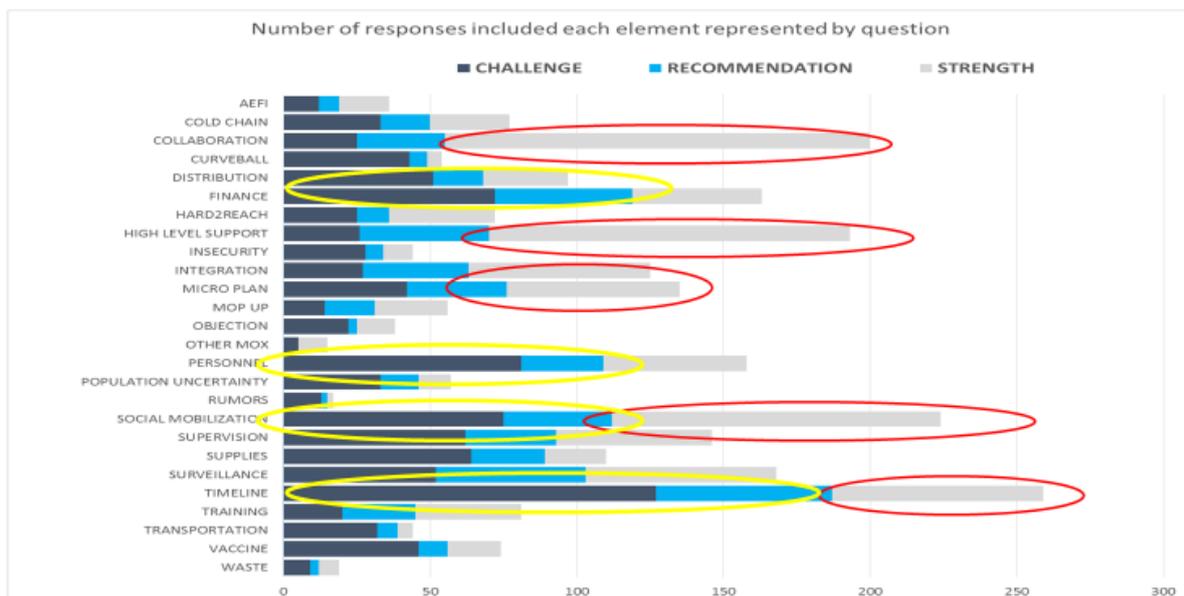
3.3.3 Waste Management

Issue 09: Majority of campaign applications lack attention to waste management. CCEOP applications refer to waste management policies and planned equipment inputs, but with little operational detail. Furthermore, the waste management component for HPV vaccination do not put into consideration that the campaign activities take place outside of the health facilities (e.g. schools) and therefore do not give priority to the management of the waste following the campaigns. Waste management is more about changing human behaviour than it is about the availability of safety boxes and incinerators, but this aspect was not addressed in the applications.

Figure 6

SIA Technical Reports, 2010 – 2015

Analysis of 170 technical reports from 315 SIAs conducted 2010-2015



Recommendation: The IRC further reiterates its previous recommendation on the urgent need for Gavi and technical partners to strongly encourage countries to consider waste management as essential part of health and immunization system strengthening by demanding strict plan and proper/increased budgets (see Figure 6).

3.4 Budget review of NVS Applications

3.4.1. Budget review

GAVI has made real efforts in developing and rolling out a new budget template to be used by countries applying for funding. Compared to previous rounds, this IRC acknowledges that countries made more efforts to use the recommended budget template and to provide costing assumptions, explain unit costs and quantities used to arrive at budgeted figures. As per Gavi applicable requirement, most of the countries also provided the per diem policies upon which they based cost elements for training and meeting activities.

Issue 10: Incorrect cost classification by countries: It is observed that the budget guidelines are not being fully adhered to, particularly when it comes to the cost classification. Many applicant countries completed their budgets using the wrong cost categorization. Given the lack of clarity around definition and interpretation of HR-related costs in the budgets, countries tend to avoid or to hide any per diem costs or to split it into other sub-categories such as food, drink and refreshments to be provided to training and meeting participants (e.g. Ghana, Burkina Faso).

A classic example of incorrect data input into the budgets reviewed this round is the prominent wrong classification of per diem, allowances and other cash payments: any inappropriate filling or cost categorization results into misleading interpretation and subsequent decisions being based on wrong information.

Recommendations:

- Gavi Secretariat should better identify the causes of budget deficiencies and deviations from budget guidelines. A work of simplification of the current guidelines and harmonization with countries' costing/budgeting practices and other key donors (e.g. GFATM) should be considered by Gavi.
- Practical trainings, in various forms, using also the e-modules already developed by Gavi Secretariat, should be provided to assist countries in preparing and monitoring their budgets. Focal points on budgeting and financial management in the big countries and at the sub-regional level will be greatly helpful and appreciated. Such capacity building activities will not only alleviate scrutiny burden on Secretariat teams but will also provide to financial cross-cutting reviewers with quality budgets that will facilitate swift and effective review;
- Gavi Secretariat should ensure that guidance around HR-related costs in VIG and OPs budgets be more specific by listing out unallowable HR-cost items and clearly defining the notion of "the exceptional circumstances" under which these costs can be funded. Cash payments during events such as trainings and meetings should be explicit enough to allow countries to be transparent about their cost approach on per diems, allowances, incentives, etc.

3.4.2 Financial Sustainability

This review was concerned about the lack of effective consideration devoted to programmatic and financial sustainability across many of the applications.

Issue 11: One of the most striking observations is that the vast majority of countries fulfil, sometimes with delays, their obligations regarding co-financing, but this is not the case for domestically financed traditional vaccines. 6 out of 15 countries reviewed this round have no government funding for MCV1.

Government spending for routine immunization remains low in most countries even in countries in transition phases. These are warning signs that funding for traditional vaccines and transition policy and processes are not fully adhered to by countries.

Recommendation: Gavi should make guidelines and pre-screening processes more stringent and firmer on country financial obligations particularly for traditional vaccines (initial self-financing countries) and level of expenditures on routine immunization (for countries in transition).

3.5 Equity Issues

Overall, most country applications describe and discuss the distribution of coverage by wealth, urban/rural and regions or districts as well as mothers' education, suggesting that considering socio-economic, geographic and gender-based inequalities has become established practice.

At the same time, new considerations are emerging.

Issue 12: Strategies to address low performing regions or districts are typically associated with strengthening RED/REC approaches, suggesting that geographic distance remains a key challenge in reaching these settings. Yet, social distance is receiving increasing attention, as it also affects motivation to seek out immunization services. Social distance denotes rejection (or acceptance) of individuals or groups within a wider community, in relation to their ethnicity, religion, language, or migration status. Pockets of under immunized children – for instance - have been identified among religious communities in Myanmar, Democratic Republic of Congo (DRC), and Togo, and among language and/or ethnic minorities in Vietnam and Lao. These populations are marginalised and characterised by poorer health and living conditions.

Issue 13: The challenges of reaching high coverage in urban settings: Some urban contexts have recorded the lowest coverage in recent campaign efforts and decision makers in countries like Togo have raised the need for a specific urban strategy.

Recommendation: While the capacity to analyse inequalities in coverage seems to have improved, countries need to be more strategic in their interventions to address under-immunised and hard-to-reach groups with specific activities and earmarks. Gavi and technical partners need to continue working with countries to develop specific interventions that will address these identified gaps.

3.6 PSR Review and Outcomes

The PSR aims to:

“make a significant contribution to achieving sustainable improvements in coverage and equity of immunisation”. PSR reviews focus on whether the PSR will:

- Align with national priorities and respond to relevant bottlenecks and identified challenges related to advancing immunisation and related systems-strengthening objectives
- Achieve the results proposed by the country (reflected in the performance framework indicators).

3.6.1 Review Process

Several countries have now had PSR reviews using different modalities: remote, in-country and hybrid (with one member doing remote review and the rest of the team in country – mostly planned, but also caused by visa issues). In addition, some PSR reviews were concluded at the IRC, with the input of the IRC.

Remote + IRC:	Zimbabwe, Guinea-Bissau, and Ghana
In-country:	Guinea -Conakry, Liberia, Sierra Leone, Tanzania, Malawi
Hybrid:	Togo, Haiti (in-country, but one participant not in country)

The aim of the PSR was to engage with the country and to provide an overview of Gavi support, in the context of the overall support for country. The key goal of the PSR process is to better engage with countries and have a more holistic review of a portfolio of support.

The in-country reviewers are generally given adequate time to prepare for the country reviews, but the time in country varied from 3 to 5 days. Generally, the reviews are very time-demanding and with iterations and submitting of updated proposals, reviewers need to take more time than contracted for. WHO and UNICEF are key informants, but the participation of other partners varied across countries. It is useful to get the input of a wide a range of stakeholders.

Issue 14: Need for better standardisation of review process: There are advantages in undertaking a PSR review in-country, especially for the review team to gain better insights and understandings of the programme and its plans and to engage in a dialogue with key stakeholders. However, there remains the possibility of bias from relationships formed and the need to make recommendations at the end of the country visit which maybe challenging if the outcome would not be a recommendation for approval.

Recommendations:

- In-country reviews need to be evaluated in terms of costs and benefits/possible bias. Guidelines should clearly help standardize process and minimise possible bias.
- It is also inappropriate to call the review team the IRC, as the team is not often representative of the IRC, nor all members of the team are always IRC members. Therefore, the review team should be renamed properly as an expert committee and not as “IRC”.
- The lack of a second reviewer for CCEOP or other aspects, or if the team lacks financial expertise to review budgets, can lead to a suboptimal review. Need to ensure that team has two views on all technical aspects, as well as at least one financial expert.

Issue 15: PSR strategy

The PSR represents an ambitious and appropriate aim to provide a holistic review of country planning to increase impact of each Gavi support. However, countries have not met the challenge to develop a holistic vision, integrated strategies, and use the PSR to achieve the aim of sustainable improvements in coverage and equity. Even at the basic level of doing integrated training for different activities, the PSR does not appear to have had the expected impact.

A key question here is whether the basis idea of the PSR is sound and just needs better implementation or if the PSR approach is inadequate. The IRC members have different views, and in fact there may be an element of truth to both ideas. One major issue remains that every type of support still requires a separate application with its own specific needs, thus undermining planning across specific activities.

There also appears to be a lack of visibility of currently implemented HSS efforts in the PSR development process, as well as limited root cause analysis for coverage failures and inequities. This is compounded by the failure to use data, or to accept inflated administrative coverage data as the basis for planning.

Recommendation: Gavi guidance should consider defining a timeline for the different windows with the country articulating how different activities are funded across different applications, with the potential for integration across activities.

3.7 Technical Assistance

There are noticeable efforts to improve quality of TA over the years with the introduction of the PEF and especially with the HPV National Introduction applications which continue to demonstrate clear strategic focus and feasible interventions. With these investments, countries are paying more attention to strategic focus and especially to data generation. However, there is still limited use of data in critical decision making and planning especially in large countries.

Issue 16: Gavi is investing in the PEF with both traditional and non-traditional partners providing TA. Large quantity of data available at country level is not regularly used to target un-immunized population or to develop the most suitable interventions. It is unclear how technical assistance is provided to countries with tons of data especially from analysis and use perspectives.

Recommendations

- There is an urgent need that technical partners support countries to analyse and use available data to target high risk areas to locate and reach consistently missed children;
- Gavi and technical partners need to ensure that countries are supported to provide the relevant information rather than wait for IRC to tease it out of them (e.g. Burkina Faso, Democratic Republic of Congo).
- Countries should also be requested to provide comprehensive epidemiological and strategic analyses especially for Measles SIA.

3.8 Governance

ICC and NITAG Functionality

All of the 16 countries submitting applications in September 2018 had either an HSCC or an ICC. In six countries (Afghanistan, Comoros, DRC, Ghana, Solomon Islands and Zambia) the ICC is either integrated (or integration is planned) with other health programs (HSS, IDs, CCM). Eleven countries (69%) provided ICC TORs.

All applications were approved by the ICC and minutes of approval meeting were provided. With a few exceptions, minutes show good participation and good technical discussion among ICC members of

the proposed applications before approval. In one country, the approval meeting took place after the application deadline. In another country, the ICC meeting could not take place and the approval was received by e-mail. Signatures of participants were missing in one application. 11 countries (81%) provided additional minutes of past ICC meetings. Five applicant ICCs (DRC, Lao, Myanmar, Tajikistan, Vietnam) had no listed CSO/NGO members.

Only 12 countries had established a NITAG and in 3 of them (Comoros, DRC, Ghana) the NITAG was not yet functional. NITAG TORs were provided in only 3 applications. NITAG review was documented in only 4 applications (Burkina Faso, Mozambique, Myanmar and Vietnam).

Finally, it was noted that none of the resubmission of NVS proposals after re-review (Burkina Faso, Comoros and DRC) had been endorsed by NITAGs or ICCs. This means that the IRC issues and concerns are not discussed by the ICC and NITAG and the resubmission is not reviewed to determine whether all the issues have been addressed.

Issue 17: No formal request for reviews of re-submitted applications by country mechanisms: The IRC was concerned to observe that none of the 3 applications coming back from re-review had been endorsed by their national ICCs before submission.

Recommendation:

In case of re-review, Gavi should require ICCs formal approval of the responses by the country to the issues for consideration and the action points listed in the IRC report. The responses should be included in a specific table developed by the Secretariat and submitted with the application materials.

Issue 18: Limited or no involvement of NITAG in the application development or review process.

Recommendation:

Where NITAGs are established and functional, they are strongly encouraged to sign off on re-reviews to ensure IRC concerns especially where technical have been fully addressed.

4.0 CONCLUSIONS

The IRC commends Gavi and its Alliance partners for the significant progress made with the M/MR SIA and request for further work on the operational guidance. It is imperative that the portfolio of measles efforts need to be integrated to maximize population immunity with a clear vision for the control of measles. Countries should be guided with contextual advice on using outbreak response with country SIA plans.

With the significant progress made with the PSR process, Gavi should also consider a revision of the PSR process based on lessons learned to improve its structure, provide clearly defined processes, and recommendation guidance fit for purpose.

Waste management remains continually underscored and underfunded in country applications. Gavi and technical partners should strongly encourage countries to consider waste management as essential part of health and immunization system strengthening by demanding strict plans and budget. With significant investments in improving data quality, countries have now begun to pay critical

attention to data aggregation and analyses. However, it is important that Gavi and technical partners incentivize the use of data at all levels for strategic planning and decision making through its new data quality strategy whilst paying attention to political dialogue and country ownership.

As countries continue to recognise drivers of inequities and low coverage; Gavi and technical partners should further encourage them to use this information more strategically whilst paying more attention to other equity drivers such as urban slum populations and social distance.

Finally, the IRC commends the efforts of the Secretariat staff especially the A&R team, the focal points and SCM managers for their technical support to the review process. During this window, the IRC particular noted; and identified proposed innovations in country applications with a potential to make significant positive differences to service delivery. It enjoins Gavi and its partners to provide technical support to countries to refine these innovations whilst documenting learnings for scale up and experience sharing purposes.

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ANNEXES

Annex 1: List of IRC Reviewers; November 2018

No	Name	Nationality	Profession/Specialisation	Gender	French Speaking
1.	Aleksandra Caric	Croatia	Independent Consultant	Female	X
2.	Benjamin Nkowane	Zambia	Independent Consultant	Male	
3.	Bolanle Oyeledun – CHAIR	Nigeria	CEO, Centre for Integrated Health Programs	Female	
4.	Bradley Hersh	USA	Independent Consultant	Male	X
5.	Clifford Kamara	Sierra Leone	Lecturer, College of Medicine and Allied Health Sciences, University of Sierra Leone.	Male	
6.	Ian Pett	United Kingdom	Independent Consultant	Male	
7.	Linda Eckert	USA	Professor, University of Washington (Gynaecology)	Female	
8.	Mario Stassen	The Netherlands	Independent Consultant	Male	
9.	Marta Felletto	Italy	Independent Consultant	Female	X
10.	Miloud Kaddar	Algeria/France	Independent Consultant (ex WHO)	Male	X
11.	Osman David Mansoor	New Zealand	Public Health Physician, Regional Public Health, New Zealand	Male	X
12.	Ousmane Amadou Sy	Senegal	Independent Consultant	Male	X
13.	Peter Nsubuga	USA	Medical Epidemiologist, Global Public Health Solutions, Atlanta, USA	Male	
14.	Philippe Jaillard	France	Independent Consultant	Male	X
15.	Pierre Bwale	DR Congo	Independent Consultant	Male	X
16.	Ranjit Dhiman	India	Independent Consultant	Male	
17.	Sandra Mounier-Jack	France/UK	Lecturer London School Hygiene and Tropical Medicine	Female	X
18.	Stefano Lazzari	Italy	Independent Consultant	Male	X
19.	Toagoe Karzon	Liberia	Financial Controller, Redemption Hospital, Monrovia, Liberia	Male	