REPORT OF THE INDEPENDENT REVIEW COMMITTEE TO THE GAVI SECRETARIAT

Geneva,
Switzerland
8th – 9th July 2019

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List of Acronyms

AEFI	Adverse Event(s) Following Immunization
BCG	Bacillus Calmette–Guérin
CAR	Central African Republic
CCE	Cold Chain Equipment
CCEOP	Cold Chain Equipment Optimization Platform
CCL	Cold Chain Logistics
cMYP	Comprehensive Multi-Year Plan
DQA	Data Quality Assessment
EPI	Expanded Programme of Immunization
EVM	Effective Vaccine Management
HSCC	Health Sector Coordinating Committee
ICC	Interagency Coordinating Committee
IRC	Independent Review Committee
iSC	Immunization Supply Chain
M&E	Monitoring and Evaluation
MCV	Measles Containing Vaccine
Men A	Meningococcal Sero-group A Vaccine
MNCH	Maternal, Neonatal and Child Health
MR	Measles-Rubella
NITAG	National Immunization Technical Advisory Group
OPV	Oral Polio Vaccine
Penta	Pentavalent Vaccine (Protection from Diphtheria, Pertussis, Tetanus, Hib, HepB)
PIRI	Periodic Intensification of Routine Immunization
POA	Plan of Action
RED/REC	Reach Every District/Reach Every Child
SCM	Senior Country Manager
SIA	Supplementary Immunization Activity
VIG	Vaccine Introduction Grant
WHO	World Health Organization
WUENIC	WHO/UNICEF Estimates of National Immunization Coverage
YF	Yellow Fever

1. Executive Summary

The IRC met in Geneva, Switzerland on 8th – 9th July 2019, and reviewed 3 applications from 3 Gavi-eligible countries; all 3 were recommended for approval.

The IRC was comprised of 5 reviewers with expertise in immunization; cold chain and logistics; maternal, neonatal and child health (MNCH); adolescent health; health systems strengthening; reproductive health, program management; epidemiology; and monitoring and evaluation. These were all experienced reviewers who are active IRC members and had participated in numerous reviews. One member participated remotely, and focused on cold chain and logistics (see Annex).

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

- Review of country specific funding requests and supporting documentation for applications (including comprehensive multi-year plans (cMYPs), vaccine introduction plans, and plans of action) for vaccine introductions and campaigns to support countries through efforts to strengthen the coverage and equity of immunization.
- Production of evaluation reports and recommendations for each country.
- Development of a consolidated report of the review, including recommendations for improving funding requests, as well as HSS and the implementation of the approved campaigns and vaccine introductions.
- Recommendations to the Board and the Alliance partners on improving processes relating to Gavi policies, governance, and structure.

Eritrea submitted an application for support to introduce MenA in 19 high risk sub-zobas (districts) located in 4 zobas (regions); the country has 58 sub-zobas in 6 zobas. In view of the increased risk of countrywide spread due to population movements and potentially through climate change, the IRC recommended approval of the introduction of MenA nationally, and not sub nationally as requested.

Comoros submitted an application for a catch-up Measles-Rubella campaign, followed by the nationwide introduction of Measles-Rubella vaccine first (9-12 months) and second (18 months) dose; this application was submitted for the third time, following the IRC recommendations for re-review. The application was of good quality, and the issues raised by the previous IRC reviews were satisfactorily addressed. The IRC recommended approval of this application.

Sudan submitted an application for support to introduce Yellow Fever vaccine into routine programme. The country is located in the Yellow Fever belt, is a high-risk country surrounded by other countries with high Yellow Fever risks. The country situation is still evolving after marked socio-political disturbances; the GNI has dropped by 35%, and this will entail a re-assessment of the country's classification under the Gavi Eligibility and Transition Policy. If the country is reclassified to "Preparatory Transition Phase", this will necessitate a recalculation of the amount eligible for the VIG. The IRC recommended approval, with the Gavi Secretariat to follow up on the re-calculation of the eligible amount and revision of the budget as appropriate.

2. Review Methods and Processes

2.1. Criteria for review

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

2.2. Methods

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

During the meeting in Geneva, the first and second reviewers presented their initial findings; this was followed by extensive discussions during plenaries. In some instances, the IRC adjourned decision-making to obtain additional information and clarifications from the SCM and other colleagues in the Secretariat, as well as from technical partners. Key outcomes, decisions, and recommendations were then consolidated into draft country reports by the first reviewer; these drafts then subsequently underwent a rigorous process of quality review, fact checking and internal consistency checks as part of the finalization process.

The CCEOP/CCL sections of the applications were reviewed remotely by one cross-cutting reviewer.

2.3. Decisions

The IRC was guided by the two decision categories: approval with issues to be addressed in consultation with the Gavi Secretariat and partners; and re-review with resubmission to the IRC.

The IRC recommended the approval of all three applications, with issues to be addressed in consultation with the Gavi Secretariat and partners.

3. Good Practices and Promising Innovations

3.1. Eritrea

The IRC noted strong country and community ownership of EPI. This contributed to a robust immunization programme that achieves and maintains high coverage; which was verified by a recent EPI coverage survey. A vivid example is that MCV2 was introduced in 2012 and by 2013 had already achieved 40%, increasing gradually to 91% by 2016.

3.2. Comoros

Although the country is in the initial self-financing phase, it is already funding MCV1, and is committed to co-financing MCV2.

The country is also commended for the full engagement of community health workers in routine immunization activities, as well as in the planning for SIAs. The IRC commends the Secretariat and Alliance partners for their technical support to the country.

3.3. Sudan

The national budget introduced a line item for vaccines, and the country has made projections for co-financing post-YF introduction. These are key steps that should contribute towards achieving sustainability of the immunization programme.

The country is also commended for ensuring the full involvement of midwives in demand generation and raising community awareness about the importance and need for vaccinations.

4. Key Findings and Recommendations

The IRC reviewed applications from 3 countries, and the results are depicted in the table below.

Table 1: Country Requests and Recommendations

COUNTRY	REQUEST	RECOMMENDATION	COMMENTS
ERITREA	Men A introduction into routine	APPROVAL	IRC recommended nationwide instead of the requested subnational introduction
COMOROS	Catch-up MR campaign followed by introduction of MR (1 and 2) into routine	APPROVAL	Third submission
SUDAN	Yellow Fever introduction into routine	APPROVAL	

4.1. Cross Cutting Issues

The following paragraphs outline major issues identified across all three country applications, listing recommendations related to these issues.

4.1.1. NVS and Technical Support

Issue 01: Critical importance of surveillance for new vaccine introduction

The three countries reviewed each highlighted the importance of surveillance in introducing new vaccines into countries immunization programs.

- Prior to introducing Meningitis A vaccine, Eritrea used the WHO District Prioritization Tool (DPT) to attempt to rank districts by risk of future meningitis outbreaks. However, given that meningitis surveillance was admittedly incomplete and highly variable among districts there was clearly high uncertainty for the results of this exercise. Given the lack of precision of the DPT and the relatively small size of the country, the IRC recommended nationwide introduction of this new vaccine. Following introduction of the vaccine, careful surveillance will allow Eritrea to closely monitor the changing epidemiology of meningitis in the country.
- Comoros is planning to introduce Rubella vaccine by conducting a catch-up MR campaign and a routine second two dose schedule of MR vaccine. However, the country recently experienced importation of measles virus with ongoing transmission of measles on Grand Comoro. Country is being supported by partners to conduct a careful outbreak investigation as well as an emergency vaccination campaign to interrupt measles virus circulation. Lessons learned from the outbreak investigation can be used to identify areas and populations with large numbers of previously unvaccinated infants and children and strengthen plans and implementation of the upcoming

catch-up campaign. Following the introduction of MR vaccine, surveillance will play a critical role in the timely detection of measles and rubella virus circulation and the occurrence of the Congenital Rubella Syndrome.

- Having conducted "phased" nationwide Yellow Fever campaigns 2014-15 & 2019 due to shortage of global vaccine availability, Sudan is planning to introduce Yellow Fever vaccine into its routine immunization schedule at 9 months of age throughout the country in 2020. In recent years, Sudan has experience several large YF outbreaks but acknowledges that surveillance capacity is weak and clearly incomplete. Moreover, laboratory capacity for case confirmation is limited to the National Public Health Laboratory in Khartoum. Following introduction of the vaccine into routine immunization services, YF surveillance will be critical for the timely detection and response to YF virus transmission in the country.

Issue 02: Opportunity to develop and strengthen the Second Year of Life (Y2L) platform

Eritrea is planning to introduce routine MenA vaccination at 18 months and Comoros is introducing a routine two dose MR schedule at 9-12 & 18 months of age. The inclusion of routine immunization doses after the first birthday provides an important opportunity for these countries to develop and strengthen the Second Year of Life (Y2L) platform for children.

Potential opportunities for the Y2L platform include:

- Providing new vaccines including MenA and MR vaccines;
- Screening children for previously missed doses of vaccines and providing them; and
- Inclusion of other priority health interventions including Vitamin A, deworming and growth monitoring.

Recommendation

Gavi and technical partners to support countries in the ongoing strengthening of their vaccine-preventable disease surveillance systems, including laboratory capacity and development of solid Y2L platforms for providing children with immunizations and other priority health interventions.

4.1.2. CCEOP, CCL

Issue 03: Supply Chain Performance

- EVM Performance is high (Sudan) or significantly improved (Comoros, Eritrea). Maintenance, information system and supportive functions remain the criteria with the lowest scores.
- Link between high EVM scores and iSC performance measured by the availability of quality vaccines at points of use; wastage control and cold chain functioning is not clear.
- The framework for implementing improvement plans in the 3 countries is poorly developed.

Recommendation

Gavi to support countries in the establishment or strengthening of leadership and management capacities of immunization supply chain managers; they should be able to develop informed plans of action based on effective information systems that provide data on vaccine availability, wastage and CCE status. Support should also be provided for implementation at the lowest level.

Issue 04: Supply Chain – Vaccine Storage Requirements

Except for Comoros (although limited to central and region level), countries do not submit calculations to assess vaccine storage needs. Countries benefit from support for the extension of their cold chain (CCEOP,

other sources) however, the deployment of these equipment is not documented making it difficult to assess the availability of adequate storage capacity.

Recommendation

Countries should provide details on the estimation of vaccine storage requirement at all levels and justify adequate storage or additional needs on the basis of the CCE rehabilitation and deployment plans.

4.1.3. Data Quality and Use

Issue 05 - Use of available data for improving plans of action

During this round of the IRC, all three countries provided data that identify barriers to improving coverage during SIAs and for routine EPI. These data were from recent EPI surveys and special surveys (such as equity assessments). However, the plans of action do not provide adequate information on targeted strategies to address the identified barriers.

Recommendation

All plans of action for SIAs and new vaccine introductions should include a section with tables indicating the list of barriers, a summary analysis of the barriers, where they occur and proposed specific strategies. This information would then be used to guide the supervisors at subnational level to operationalize the tailored strategies. The budget estimates for the activities should be included with the application and should be based on previous experience on SIAs and routine EPI.

Issue 06 - Effective redesign of home-based records to achieve better data tracking and personal record keeping

In this review window Sudan, Comoros and Eritrea applied for introduction of new vaccines into the routine immunization programmes, yellow fever, MR 1st and 2nd dose, and Meningitis A vaccines respectively. Adding a new vaccine to the routine programme requires updating reporting and recording tools. Of the three applicants, Eritrea and Comoros in their current cMYP have planned the revision of reporting tools, including a traditional child vaccination card. Sudan, which reports more than 95% card retention, and Comoros included the revision, update, and printing of the vaccination cards in their request for vaccine introduction grant. This represents a significant portion of the VIG budget: 25% for Sudan and 15% for Comoros. However, vaccine introduction plans do not include detail of this activity and its product.

Recommendation

While practices, effectiveness and costs of electronic immunization records/registries are explored, paper home-based vaccination records will continue to play an important role in tracking and documenting vaccination services both for personal record keeping as well as for cross-checking during surveys and monitoring. The changes required by the addition of the new vaccine in the national routine programme provide an opportunity to review and improve how information is gathered and used. A traditional format of vaccination card may not always be easy for the health workers to complete accurately and legibly, and the users may not understand the data that are recorded or the value of such a document. Therefore, countries should use this opportunity for change and funding to invest in redesign of vaccination cards and produce clear, durable and difficult to counterfeit vaccination certificates, combined with education on the importance of these documents. As in some countries redesign approaches have proved successful in meeting the needs of health-care workers, parents, and the health system, technical partners should

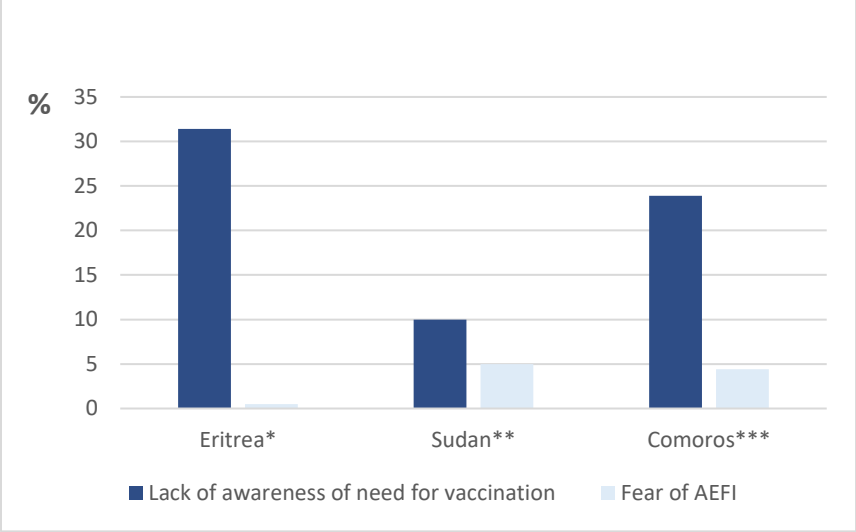
assist the countries in this undertaking and provide reference on the process, stakeholders involved, points to consider, and positive examples.

4.1.4. AEFI Surveillance

Issue 07: Lack of awareness of need for vaccination remains unrecognized as hesitancy and still unaddressed

Reasons for non-vaccination are assessed in immunization programme reviews and programme and population surveys. Among this IRC review's applicants, the predominant reasons for non-vaccination are 'the lack of awareness of need for vaccination' and 'fear from AEFI'. National EPI coverage survey in Eritrea (2017) reveals that 31.4% of reasons cited by mothers for children not to receive vaccinations related to 'unawareness of the need for immunization' while 'fear from AEFI' although in the questionnaire, was not reported. The 2016 measles post-campaign coverage survey in Comoros cited that 23.9% of reasons for non-vaccination in the routine programme related to 'unawareness of the need for immunization', and 4.4% to 'fear from AEFI'. Similar is in yellow fever post-campaign coverage surveys for groups of states of Sudan, while the country cMYP (2017-2020) reports 'unawareness of the need for immunization' to make 10% and 'fear from AEFI' 5.1% of reasons for non-vaccination. While fear from AEFI is regularly included in training and communication plans for both campaign and vaccine introductions into routine, lack of awareness of need for vaccination which is a larger proportion of the reasons for non-vaccination remains unaddressed as it is not recognized as vaccine hesitancy.

Figure 1: Comparison of reasons for non-vaccination



Sources: *National EPI coverage survey 2017; ** cMYP (2017-2020): yellow fever post-campaign coverage survey in 4 states;

*** Measles post-campaign coverage survey 2016

Recommendation

Delay of acceptance of vaccination services in spite of their availability due to lack of awareness of need for vaccination, is in fact vaccine hesitancy, not just the lack of information. It is complex and context specific, and can vary across time and vaccines. Countries should be made aware of vaccine hesitancy definition. Gavi and partners should assist countries to incorporate into their routine programmes adequate plans to monitor it, and help identify strategies that should be carefully tailored according to

the target population, keeping in mind that health-care workers remain the most trusted advisors and influencers of vaccination decisions.

4.1.5. Budgets and Financial Management

Issue 08: Incomplete budget

- VIG budgets do not always include some key activities.
- The budget lines for the various activities are given as lump-sums, without assumptions and detailed explanations.
- Activities and contributions from other sources are not indicated.
- Inconsistencies between narrative and budget.

Recommendation

Guidance should be provided to countries on proper budget preparation and use of the Gavi budget template. Budgets for the introduction of vaccines should be comprehensive, and include:

- key activities;
- assumptions and detailed explanations for the various activities; and
- activities and contributions from other sources.

4.1.6. Governance Mechanisms: ICC, HSCC, NITAG

Issue 09 - Non-functional NITAGs

All three countries submitting applications to the IRC had established NITAGs. However, in two of the countries the NITAGs were non-functional (Comoros and Eritrea), even though in the case of Eritrea, the NITAG members were trained by the WHO Regional Office. Without a functional NITAG, technical guidance is left to the ICC and often there is limited or no technical review of the application. In the proposal submitted by Eritrea, the IRC finds it unlikely that the NITAG would have endorsed the plan for sub-national introduction of MenA vaccine.

Recommendations

Gavi and partners should facilitate making NITAGs operational in all Gavi eligible countries. Strict adherence to the governance mechanism, especially on providing detailed notes in the minutes of the NITAG where technical and strategic decisions are made on the applications submitted to Gavi.

WHO and technical partners should ensure that Regional Immunization Technical Advisory Groups (RITAGS), as well as the WHO Regional Offices, provide support to those countries with limited capacity to maintain functional NITAGs.

5. Conclusions

The IRC noted the marked improvement of the quality of the applications, especially the one from Comoros. This suggests that more effective technical assistance is being provided to countries, creating the possibility to improve the in-country capacity for preparation of applications.

However, there are still areas that need improvement and could benefit from continuing intensified support from the Gavi Secretariat and partners, including TA. Notable among these are:

5.1. **Data quality and use of data:** Weak data management continues to undermine efforts to improve data quality, set targets, and monitor coverage. In addition, the IRC noted that data available in-country (from surveys, assessments and other studies) are not being optimally utilized for decision-making, development of tailored strategies, and planning. Countries should be further supported to improve data quality and the use of data, to include triangulation of available data from various sources.

5.2. **NITAGs:** are not fully functional in two of the three countries reviewed, although they have been established. Countries should be further supported, especially by the WHO Regional Offices, to address this issue. It is recognized that some countries may lack the professional expertise to run functional NITAGs, and partners should take steps to ensure that the countries receive support from Regional Immunization Technical Advisory Groups (RITAGs) and from the WHO Regional Offices.

5.3. **Budgets:** Countries continue to submit incomplete budgets (e.g. with key line items missing, with lump-sums that are not accompanied by needed details and assumptions, and with line items that are not in accordance with the plan narratives). This prevents a complete assessment of the budgets. As a result, all three countries are requested to revise their budgets in order to rectify various deficiencies. Gavi and partners should further support countries to improve budgeting, and ensure proper understanding of the guidelines and the utilization of the relevant budget templates.

5.4. **Vaccine management:** This is still weak, but improving as evidenced by the increased scores of some EVM assessments. However, the implementation of the EVM improvement plan is often considerably delayed. The importance of EVM cannot be over-emphasized, as it impacts the availability of potent vaccines on a timely basis at the service delivery points. Efforts by Gavi and technical partners should continue to support the countries to establish and maintain Logistics Working Groups at national and district levels to oversee the implementation of the EVM improvement plans.

6. Acknowledgements

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Annex 1: List of IRC members

Name	Nationality	Profession/ Specialization	Gender	French Speaking
Aleksandra Caric	Croatia	Independent Consultant	F	X
Benjamin Nkowane	Zambia	Independent Consultant	M	
Bradley Hersh	USA	Independent Consultant	M	X
Clifford Kamara	Sierra Leone	Lecturer, College of Medicine, University of Sierra Leone (Chair)	M	
Philippe Jaillard	France	Independent Consultant (remote participation)	M	X