



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

**Geneva**

**March 7-18, 2016**

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## List of Acronyms

|       |   |
|-------|---|
| AEFI  | Adverse Effects Following Immunization                  |
| AFP   | Acute Flaccid Paralysis (Polio Surveillance)            |
| AHI   | Adolescent Health Intervention                          |
| BCG   | Bacillus Calmette–Guérin (vaccine against tuberculosis) |
| CC    | Cold Chain  |
| CCEOP | Cold Chain Equipment Optimization Platform              |
| CCL   | Cold Chain Logistics                                    |
| cIP   | Country improvement plan (cold chain)                   |
| cMYP  | Comprehensive multi-year plan for immunization          |
| CSO   | Civil society organization                              |
| cVDPV | Circulating Vaccine-Derived Polio Virus                 |
| DHS   | Demographic and Health Survey                           |
| DTP3  | Diphtheria-Tetanus-Pertussis, 3rd dose                  |
| DQSA  | Data Quality Self-Assessment                            |
| EPI   | Expanded Programme on Immunization                      |
| EVM   | Effective Vaccine Management, an assessment tool        |
| FCE   | Full Country Evaluation                                 |
| FMA   | Financial Management Assessment                         |
| GPEI  | Global Polio Eradication Initiative                     |
| HCW   | Health Care Worker                                      |
| Hep B | Hepatitis B vaccine                                     |
| HLRP  | High Level Review Panel                                 |
| HPV   | Human Papilloma Virus                                   |
| HR    | Human Resources   |
| HSCC  | Health Sector Coordination Committee                    |
| HSSP  | Health Sector Strategic Plan                            |
| HSS   | Health Systems Strengthening                            |
| ICC   | Inter-Agency Co-ordination Committee (for immunization) |
| IDQA  | Independent Data Quality Assessment                     |
| IDP   | Internally Displaced Person                             |

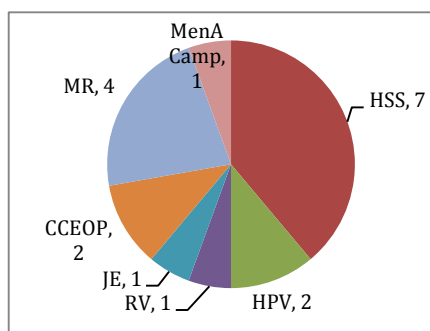
|       |  |
|-------|--|
| IDSR  | Integrated Disease Surveillance and Response                         |
| IHP+  | International Health Partnership +                                   |
| IHR   | International Health Regulations                                     |
| IM    | Intra Muscular   |
| IPV   | Inactivated Polio Vaccine  |
| IRC   | Independent Review Committee   |
| ISCL  | Immunization Supply Chain and Logistics                              |
| JA    | Joint Appraisal  |
| JE    | Japanese Encephalitis  |
| JRF   | Joint Reporting Form (on Vaccine Preventable Diseases, WHO / UNICEF) |
| MCV   | Measles Containing Vaccine   |
| MDG   | Millennium Development Goals   |
| MDVP  | Multi-Dose Vial Policy   |
| MICS  | Multiple Indicators Cluster Survey                                   |
| MMR   | Measles, Mumps and Rubella vaccine                                   |
| MNCH  | Maternal Neonatal and Child Health                                   |
| MenA  | Meningococcal A vaccine  |
| MoH   | Ministry of Health   |
| MR    | Measles-Rubella vaccine  |
| MSD   | Measles Second Dose  |
| NCD   | Non Communicable Diseases  |
| NITAG | National Immunization Technical Advisory Group                       |
| NRA   | National Regulatory Authority  |
| NVS   | New and underused Vaccine Support                                    |
| OPV   | Oral Polio Vaccine   |
| PCA   | Programmatic Capacity Assessment                                     |
| PCV   | Pneumococcal Conjugate Vaccine                                       |
| PEF   | Partners Engagement Framework  |
| PFSA  | Pharmaceutical Fund and Supply Agency                                |
| PIE   | Post Introduction Evaluation   |
| PMU   | Project Management Unit  |
| PPC   | Programme and Policy Committee                                       |

|        |   |
|--------|---|
| PQS    | Performance, Quality and Safety (of immunization equipment) |
| RBF    | Result Based Financing                                      |
| REC    | Reaching Every Community                                    |
| RED    | Reaching Every District                                     |
| RI     | Routine Immunisation  |
| RV     | Rotavirus Vaccine   |
| SAGE   | Strategic Advisory Group of Experts (WHO)                   |
| SC     | Sub Cutaneous (injection)                                   |
| SCM    | Senior Country Manager                                      |
| SDD    | Solar Direct Drive (vaccine refrigerators)                  |
| SDG    | Sustainable Development Goals                               |
| SIA    | Supplementary Immunisation Activities                       |
| SWAp   | Sector Wide Approach  |
| TA     | Technical Assistance  |
| TT     | Tetanus Toxoid  |
| TWG    | Technical Working Group                                     |
| VDPV   | Vaccine-Derived PolioVirus                                  |
| VIG    | Vaccine Introduction Grant                                  |
| VPD    | Vaccine Preventable Disease                                 |
| VVM    | Vaccine Vial Monitors                                       |
| WUENIC | WHO and UNICEF  |

## Summary Report

### 1 Purpose

The IRC met between March 7<sup>th</sup> and 18<sup>th</sup> 2016 to review a total of 18 applications from 15 countries. Applications reviewed included 7 HSS proposals and requests for support for each of the following vaccines: MR campaign (4), HPV Demo (2), Rotavirus (1), Men A (1), HPV National rollout (2) and JE (1). The new Cold Chain Equipment Optimization Platform (CCEOP) was also reviewed during this window and the IRC commends the countries of Ethiopia and Haiti for being early adopter countries through their applications (Figure 1).



### 2 Introduction

Sixteen (16) reviewers from a range of disciplines took part in the review (see Annex 1 for list of members). The review team was made of reviewers with expertise in Health Systems strengthening, EPI, MNCH, RH program management, epidemiology, monitoring and evaluation, financial analysis, BCC and Gender. Two (2) reviewers are current/past cross-cutting members of the Technical Review Panel of the Global Fund.

#### 2.1 Methods

**Review methods** included independent peer review with daily plenaries and subsequent consolidation of findings. **Decisions** were made according to two decision categories - Approval with issues to be addressed and resubmission with explanations.

**Criteria for review** include the extent to which proposals (a) meet mandatory requirements and (b) principles of support as specified in Gavi guidelines and (c) contribution to achieving Gavi mission and strategy.

#### 2.2 Focus of IRC Review

The 16-person independent review committee focussed on the following specific tasks:

- Review funding requests and all other documentation attached to the requests which include Health Sector Plans, comprehensive Multi Year Plans and supporting documents as applicable to each country.
- Review funding requests and supporting documentation attached to applications for funding through the CCE optimization platform to support countries with improving their supply chains and contribute to efforts to strengthen the coverage and equity of immunization.
- Provide the Gavi Secretariat with final evaluation reports and recommendations of support for each country.
- Provide the Gavi Secretariat with a consolidated report of the review, including recommendations for improving funding requests, including planning, budgeting, M&E , financial management , gender and equity

- considerations;
- Provide the Board and the Alliance partners with recommendations improving the processes relating to Gavi policies, governance, and structure.

### 2.3 Secretariat response to previous IRC recommendations

The IRC commends the Secretariat for more structured briefings and reiterates the need to streamline on-going work processes for better outcomes for Gavi (steering committees, PCA, simplification team, guidelines consultants, PEF etc.). There is also a need for Gavi Secretariat and partners to ensure that PEF, PCA, JA etc. have very clear linkages/alignment to enhance overall grant performance and progress made and monitored through the HLRP. Finally, the IRC reiterates the need for the Secretariat to further review November report recommendations alongside emerging ones from this review window.

### 2.4 Evaluation grids on Key performance indicators

During this review, the IRC was requested to evaluate each country in terms of quality of its application. The IRC supported the Gavi Secretariat in developing and testing out two (2) evaluation grids to measure the Alliance KPI 1.4- addressing the “% of reviewed HSS proposals rated good quality by IRC”. The IRC was requested to evaluate each country in terms of quality of its application using the two evaluation grids. Grids were pilot tested but were not particularly useful to determine the quality of proposals

The IRC was unable to draw any meaningful conclusion from the two grids. The IRC recommends strongly that quality of the proposals can be assessed indirectly from comments of IRC and approvals/resubmissions.

### Main Findings

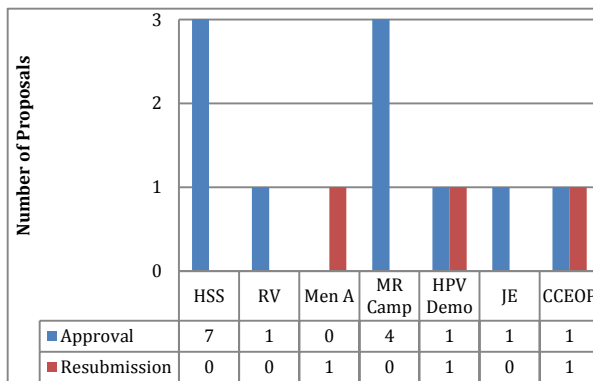


Figure 1: Main review findings

**Main Findings:** The main findings are summarized in Figure 2 below. 15 out of the 18 proposals were approved by the IRC (83% approval rate for all proposals). HSS proposals reviewed had an approval rate of 100%. However, the HSS applications included both the resubmission of the Data Quality Application by Afghanistan, and a reprogramming request (PNG).

Country applicants approved were requested to strongly consider additional comments and recommendations by the IRC to strengthen their interventions whilst at the same time requested to address/clarify critical concerns within thirty days of receipt of their decision letters. This round reviewed two country applications from Ethiopia and Haiti on the new CCEOP introduced. During this round, the IRC gave an exceptional recommendation to split a catch-up campaign from Men A routine introduction in Niger due to epidemiological considerations. It is imperative that countries must be supported by the Secretariat and technical partners to ensure that

applications meet minimum standards to ensure optimal use of resources for meaningful impact.

The IRC recognizes the continued improvement in the quality of proposals submitted by countries and commends the efforts of the Secretariat and Alliance partners for their technical support. During this window, Burundi demonstrated an example of resilience by managing to keep its health system functioning despite the security challenges. The IRC recommends that Gavi considers documenting the Burundi experience as a case example/learning opportunity for resilience. Other good practices include better M and E frameworks from country applications and improved gender and equity analyses and attempts to link into proposed interventions (e.g. Cameroon).

The IRC reiterates that resubmissions help to further strengthen the quality and feasibility, and enhance value for money of submitted proposals and commends Afghanistan for addressing key gaps previously highlighted by the IRC. The IRC also commends the responsiveness of Gavi and partners, especially the BMGF, to enhance high quality technical support at country level (Lesotho).

The IRC noted that there was an effort by countries to consider CSOs in the majority of the proposals; however, where this happened, it is still unclear how this translated into corresponding allocation of funds. The IRC reiterates that as the Gavi strategy 4.0 evolves, it is imperative that there are clear guidelines on how CSO participation and involvement will be more inclusive and robust.



## 3 Key Findings and Recommendations

### 3.1 Data Quality, Immunization Coverage

**Issue 01: Quality of results chain/performance frameworks** - Past IRCs have cited the weakness of results chains/performance frameworks repeatedly in previous sessions, especially noting the tendency of applications to rely heavily on process indicators, primarily counts of outputs. The IRC notes some improvement in the quality of this aspect of proposals in this round. Fewer applications relied solely on count indicators and at least one (Kenya HSS) was an example that might serve as a model for other countries. Intermediate results indicators should assess quality and reach of activities and changes in attitudes, behaviours and policy that are logically related to improved immunization outcomes.

**Recommendation:** Specifically, the IRC recommends providing guidance both in the application guidelines and in technical support to proposal developments to encourage countries to 1) emphasize indicators that assess quality of implementation and behaviour and policy change (changes in practices, knowledge, policy etc.), and 2) to limit the number of indicators selected for each objective in order to focus measurement effort on the highest value data.

**Issue 02: Unrealistically high targets:**

Several performance frameworks cited unrealistically high targets. While the IRC encourages countries to be ambitious in setting targets, it is important that consideration be given to key drivers that will enable country achieve proposed targets realistically.

**Recommendation:** The IRC urges the Secretariat and Alliance partners to support countries in selecting targets that are ambitious but achievable, and relative to the baseline data.

**Issue 03: Duplication between results chains and performance frameworks** - The results chains and performance frameworks contain nearly identical information.

**Recommendation:** The IRC recommends eliminating the results chain, and focusing on developing high-quality performance frameworks that integrate the results framework and link activities to intermediate results to immunization outcomes. (Once a performance framework is developed, the portal could include an option to generate a graphic that would fill a similar function to the current results chain.)

**Issue 04: Performance frameworks via the portal** - Accessing the performance frameworks through the portal presents both challenges and opportunities. While the interactive functions of the portal were useful to some reviewers, the interface lacked easy to use graphical and table based outputs.

**Recommendation:** To encourage utilization of the portal by all end users, the IRC recommends exploring options for including more graphical and table-based formats.

**Issue 05: Quality of official data** - As in previous IRC sessions many countries continue to report administrative data that are dramatically different from survey results. The IRC reiterates its concern over this situation and its support for

continued efforts by the Alliance partners to support countries in strengthening their routine health information systems.

**Recommendation:** Overall, while room for improvement remains, there was gradual improvement in the quality of performance frameworks/results chains as well as the positive outcome of the resubmission of Afghanistan's application for supplemental funding for data quality improvement activities; significant improvement in Lesotho's EPI program capacity along with clear actions taken as a result of IRC recommendations, point to some movement on this issue. The IRC encourages continued efforts in this direction.

### 3.2 HPV Proposals

**Issue 06: Adolescent Health Intervention (AHI) Assessment:** Possible misinterpretation of guidelines on need to conduct an AHI assessment as an optional rather than a mandatory requirement. One HPV application did not demonstrate any plans to conduct an AHI assessment, contrary to normative guidance as the HPV demonstration programme **should** be used to explore synergies for promoting and strengthening health interventions for adolescents.

**Recommendation:** Specifically, make question 22b in the application mandatory, to ensure appropriate consideration regarding the integration of HPV immunization with other AH services.

Gavi to modify guidelines to ensure clarity on mandatory requirement to conduct an AHI assessment to determine feasibility of integrated delivery with HPV vaccine.

**Issue 07: Leveraging Lessons Learned:** Country applications show little indication of the use of lessons learned from the *accumulated wealth of country experiences* implementing HPV vaccination.

**Recommendation:** Need to include a section in the application form asking countries to indicate how lessons learned from other countries were taken into account during the development of the application.

For future demonstration proposals, when selecting the target zones, the decision should be based on how this demonstration project can be replicated in the national routine immunization, taking into consideration regions/zones that also represent the marginalized, out of school, rural, married before 13 years, nomads etc.

### 3.3 Campaigns and Measles SIA

**Issue 08: Countries under Fragile Conditions**

There is a need to understand the minimum insecurity parameters to allow for exceptions (e.g. lift cMYP requirement for an application by Burundi).

**Recommendation:** For longer term fragile situations, encourage the use of innovative alternative strategies to maintain coverage (e.g.; Niger could carry out periodic campaigns instead of fixed site immunization while rehabilitating cold chain).

Use experience as a learning opportunity for resilience where the country has managed to keep the health system functioning despite the security challenges. (e.g., Burundi).

Consider exceptions for funding to bypass the lengthy process to release funds in a timely manner in view of outbreak and disease control (e.g., fund MenA campaign in Niger).

**Issue 09: Poor linkages** of campaigns to broader behavioural change interventions.

**Recommendation:** When planning and carrying out campaigns, countries should consider linking to systems strengthening. Campaigns should not be seen as one off activities but as entry points to comprehensive programming (e. harmonization of service delivery, supply and demand creation). When developing the proposals' communications plans, they were limited to basic IEC or at most strengthening interpersonal communication as strategies for demand creation. Programs would benefit from broader behaviour change interventions that aim at individual and institutional behaviour change (e.g. social marketing, positive deviance).

### 3.4 Health System Strengthening

**Issue 10: Decentralization and Devolution**

A number of countries are moving to decentralize their governments. HSS applications sometimes do not sufficiently take into consideration the implications that the possibly new forms of organization, with different lines of authority and accountability and with new decision-making arrangements, will inevitably have for the types of requests still being made for HSS under new proposals. More often than not, it is anticipated that more training will bring about the organizational changes desired.

**Recommendation:** It is recommended that HSS grants be used for creative and innovative strategies and activities using participatory, collaborative and bottom-up approaches. These should be able to strengthen communication and system networks that can help advance and strengthen the centralization process.

**Issue 11: Results frameworks and Monitoring and Evaluation:** These continue to remain weak and linkages between activities, and an M&E framework that shows meaningful linkages between inputs, processes, intermediate results and outputs, and final outcome are often insufficiently and inadequately developed. There are also too many tables requiring completion.

**Recommendation:** It is recommended that the tables on performance measurement and assessment, and those on M&E be merged and simplified, so that an easy and clear line may be drawn from activity input through the evaluation of intermediate results and eventually to the final outcome relating to immunization coverage. In this exercise it is necessary to be able to identify the impact of the HSS activities on the final outcomes.

**Issue 12: Demand creation:** The importance of improving the knowledge levels and demand for immunization services has been increasingly recognized. However, there is now abundant evidence that the simple distribution of knowledge and information has very little impact on actual behaviour change. Different and more

extensive community-based strategies that can bring about sustained behaviour change are required.

**Recommendation:** Partners need to work closely with countries in the development of more robust evidence based and innovative communication strategies that go beyond basic IEC for demand creation to promote sustainable personal and institutional behaviour change (e.g., social marketing, positive deviance)

**Issue 13: Sustainability:** Many countries continue to utilize HSS grants for the payment of staff salaries, equipment and transportation costs. More often than not there is no discussion of how these costs are to be maintained once the grant has come to an end. There is also little indication of how staff are to be used, deployed and retained - especially within a clear human resource utilization and development policy.

**Recommendation:** Countries should be reminded again to provide specific and clear information on how these activities are to be sustained in the short, medium and long term in their applications.

### 3.5 Gender and Equity

Gavi is now providing better guidance to those preparing HSS proposals. Of the 5 HSS proposals reviewed at this Committee, none seriously examined whether there were gender-related barriers to immunization. However, the reviewers noted the following good practices: inclusion of experts from a department of statistics in microplanning; use of a multidimensional poverty index and data on vaccine coverage to identify priority areas; and microplanning with the participation of different ethnic groups. More worrisome was the failure to identify violence against women as a risk in the programming of outreach activities and insufficient attention to strategies for reaching nomads, internal migrants, and/or displaced persons.

**Issue 14:** Gavi is providing better guidance on “National coverage and equity analysis” for HSS Proposals but not all countries are using the guidance, and gaps in analysis are not being picked up in pre-screening. Examples are highlighted below:

- The HSS Guidelines have ANNEX 3: NATIONAL COVERAGE AND EQUITY ANALYSIS GUIDANCE which is quite good. But countries are not picking up on all the guidance although some are better than others (good: Cameroon, Myanmar/ weak: Eritrea, Kenya)
- There is a discrepancy between all the guidelines which have no language on fragility and the application forms where only NVS asks about fragility (NB: HSS does not). If a country is fragile, it is asked to describe how these issues may impact its immunisation programme, planning for introduction of routine immunisation or campaigns and financing of these activities. However, this question is often left unanswered.
- The CCEOP application form does not ask the right questions about how improvements in the supply chain and cold chain equipment will lead to better coverage and equity results.

**Recommendation:** There is need for a revised form and guidelines that could assist countries to reflect on these issues. Technical and Alliance partners also need to flag these issues to applicants at country level.

## 3.6 Supply Chains and the CCE Platform

### 3.6.1 Cold Chain Equipment Optimization Platform

**Issue 15: CCEOP Concept:** The present CCEOP focuses upon a “replace and expand” strategy of cold chain equipment at health service delivery locations to store vaccines for underserved and/or hard to reach populations. Whilst this may contribute to reducing bottlenecks of vaccine availability in the proximity of these populations, it does not address vaccine quality issues at national and intermediate supply chain locations and may detract from improving supply chain operational efficacy. Additionally, it should better use the opportunity to encourage innovation, adoption of emerging cold chain technologies, operational solutions and learning from doing. ISCL is a complex process in which equipment is only one component required for successful operation. Inventory management and temperature monitoring are integral elements of the long-term effective use of installed equipment. Management Information Systems and real time monitoring of systems should also be included in the concept.

#### Recommendations

- i. Adopt a holistic approach to reach underserved and hard to reach populations by 1) minimizing the tiers of active storage locations in the supply chain, 2) ensuring vaccine quality at the point of use of vaccines, 3) simplifying maintenance practices, 4) continuously monitoring cold chain quality from end to end of the supply chain and 5) matching storage device capacity and characteristics to target population numbers and contact practices.
- ii. Five adjustments are suggested to be made to the present CCEOP to enable supply chain improvements that enhance efficiency of supply and ensure quality and availability of vaccines.
  - a. Adopt a “Commodity supply” +”Operating budget” funding modality as a CCEOP model for supply chain improvement. (Similar to NVS Campaign applications).
  - b. Combine “technology innovation” and “operational innovation” as a model for supply chain improvement, rather than cold chain improvement through technology innovation alone. This combined approach ensures that an appropriate vaccine storage device is positioned at an appropriate strategic location to serve a catchment population commensurate with the volume of the storage device and delivery cycle to that location. (Encourage simulations/modelling through Llamasoft or similar network optimization tools)
  - c. Include innovative “end.to end” stock and continuous temperature data management solutions to monitor availability and quality at all active and passive storage locations. (Encourage real time stock management and continuous monitoring of temperature alerts and GPRS communication from fixed storage locations.)

- d. Make it a mandatory requirement in CCEOP applications that countries define strategies for supply chain sustainability in the longer term. This strategy should include the five subjects mentioned in recommendation
  - e. Make post equipment introduction evaluations (PEIE) a mandatory activity upon completion of the first phase (Year 1) of supply and installation, and a trigger for phase II supply.
- iii. CCEOP requires rehabilitation plans which defines:
- a. Replacement or additional cold chain and temperature monitoring equipment required from the national store(s) to the points of use of vaccines in the EPI supply chain.
  - b. The deployment, installation and maintenance plans for rehabilitation.
  - c. The M&E arrangement existing or to be put in place which ensures timely monitoring of “roll-out”, maintenance effectiveness, vaccine quality assurance.
  - d. Segregates the elements of rehabilitation to be supported by the CCEOP.
  - e. Informs of rehabilitation activities supported by other Gavi cash grants or requests for cash grants.
  - f. Informs of rehabilitation support from Government or other partners.
- iv. CCEOP applications define material (equipment) and operating (deployment, maintenance, M&E) needs and budget for **the first year of support ONLY** as indicated in rehabilitation plans. CCEOP financial support for the 2<sup>nd</sup> and subsequent years is determined by Gavi based upon annual active and passive storage capacity addition (Litres) as defined in the rehabilitation plan; deployment, maintenance and M&E activity scaled proportionally to year one unit costs plus inflation.

#### Issue 16: Application/Guidelines:

The application process requires attachments for deployment, maintenance, rehabilitation, EVM improvement plan progress, inventory, in addition to signatures, program plans (cMYP), strategies (NHP), endorsements etc. Preparation is time consuming for countries, tends to create inconsistencies across documents and, approaches the CCEOP investment as a fragmented component rather than an integrated business plan.

#### Recommendations

Simplify and streamline the application and review process by:

- Minimizing and merging mandatory attachments. Refer to revisions proposed in Table 1 below
- Providing templates for summary tables, tabular overviews.
- Controlling narrative volume in the online portal.

- Embedding cross linkages to HSS, cMYP, coverage and equity, bottlenecks and M&E source and reference data in the online portal application.
- Improving compatibility and guideline synergies with HSS-PQS and CCEOP eligible equipment.
- Address weaknesses in M&E frameworks and linkages to coverage and equity.

| Attachment Ref | Present Attachments   | Proposed Attachments  | Comments/Location of Information   |
|----------------|---|---|--|
| 1              | Signature Sheet for the Minister of Health and Minister of Finance, or their delegates  | Signature Sheet for the Minister of Health and Minister of Finance, or their delegates  | Attachment: No change  |
| 2              | Signature Sheet for HSCC (or equivalent) endorsement  | Signature Sheet for HSCC (or equivalent) endorsement  | Attachment: No change  |
| 3              | Effective Vaccine Management (EVM) Assessment report (conducted within the preceding 5 years)   | Effective Vaccine Management (EVM) Assessment report (conducted within the preceding 5 years)   | Attachment: No change  |
| 4              | Status of most recent EVM Improvement Plan (or provide justification and identify a plan for developing an improvement plan)  | EVMA Improvement plan if separate from EVM report   | Attachment or inclusive in #3. Provided as separate document only if not included in EVMA report   |
| 5              | Most recent Progress Report on the EVM Improvement Plan Implementation (should not be older than 6 months prior to application submission or provide justification as to why this is not available) | Most recent Progress Report on the EVM Improvement Plan Implementation (should not be older than 6 months prior to application submission or provide justification as to why this is not available) | Attachment (excel). Summary (% completion status) in narrative of application. No change in requirement except that progress report should be Excel sheet cross referenced to EVM improvement plan.  |
| 6              | CCE inventory and facility segmentation ( <i>detailed in Application Instructions</i> )   | Facility list and facility segmentation + CCE inventory/facility + TARGET(catchment) POPS/facility  | Attachment (Excel). Summary directly in application Narrative. Excel workbook with filters/pivot tables for supply tiers (segmentation)  |
| 7              | CCE rehabilitation and expansion plan ( <i>detailed in Application Instructions</i> )   | CCE rehabilitation and expansion plan (worksheet for each tier of supply chain)   | Attachment (Excel). Summary directly in application Narrative. Excel Sheet cross linked to Facility/Equip list (#6) or attachment #6 workbook extended to indicate: 1) Year on Year capacity Need; 2) Year on Year gap analysis; 3) Yr on year capacity addition inclusive of removal of obsolete or Non PQS equipment |
| 8              | Equipment selection ( <i>detailed in Application Instructions</i> )   | Attachment Not required: Table of equipment derived from excel sheet (#7) directly in Application   | Application. Year by year/tier by tier/make and model (or size)  |
| 9              | Strategic deployment plan ( <i>detailed in Application Instructions</i> )   | Installation Deployment and Maintenance Plan (Preventive and Unscheduled.) Timeline of the 3 components (Gantt Chart or Excel) inclusive of Transport, materials and HR inputs + yr on yr budget)   | Attachment (Gantt chart or excel file). Summary table of 3 components and sub-components directly in application. Yr by Yr. New requirement which provides resource requirements (human, material, transport and financial and costs for implementation  |
| 10             | Maintenance plan with financing ( <i>detailed in Application Instructions</i> )   | Included in #9  | Included in #9   |
| 11             | Proof of status for CCE tariff exemptions waiver  | Proof of status for CCE tariff exemptions waiver  | Attachment. No change  |
| 12             | National M&E Plan   | Supply chain related M&E components of National M&E plan included as links or imbedded object in Application  | Link or imbedded object in Application   |
| If Applicable  |   | Supply chain and/or Bottleneck information in cMYP included as links or imbedded object in Application  | Link or imbedded object in Application   |
| If Applicable  |   | Supply chain information in HSS and/or NVS applications included as links or imbedded object in Application   | Link or imbedded object in Application   |
| If Applicable  |   | Bottleneck information in HSS and/or NVS applications included as links or imbedded object in Application   | Link or imbedded object in Application   |

**Table 1**

**Issue 17: Management Issues**

The management capacity, human resources, transport systems and financial resources required to successfully implement the deployment, maintenance and monitoring of equipment supplied through the period of support from the CCEOP is not defined. Additionally, the strategies and measures to ensure continuity after the end of CCEOP support are also not defined.

## Recommendation

The CCEOP application is to be revised to permit an assessment of:

- Whether the “rehabilitation implementation scale” is matched with “management capacity, financial and human resources”
- Any CSO and partner involvement.

A (SMART) project plan is provided including clear HR structure with skilled and clearly defined personnel responsible for execution of the implementation plan.

## Issue 18: Use of Appropriate Technology

The IRC acknowledges that the CCEOP strategy targets increased availability of vaccines for high risk/hard to reach populations at peripheral levels of cold chains. Supply of eligible equipment to intermediate and even primary stores is however not excluded. There is a risk that this will encourage the installation of large numbers of refrigerators/freezers at intermediate level rather than small cold rooms (as they are not eligible for support from the CCEOP).

The range of products eligible for CCEOP platform support is continuously changing and hopefully will improve as technologies evolve and field experiences increase. The present CCEOP design bases future equipment requirements and budgetary needs on current day eligible technology offerings.

Accredited suppliers may only validate warranties for equipment supplied if installed and commissioned by company-accredited technicians. This detracts from building national capacity.

## Recommendations

The CCEOP platform application is more specific in defining where support is available, and substantially more flexible in defining and quantifying equipment and operational support needs post year one.

Limit the use of CCEOP resources at primary or intermediate levels of the cold chain to locations where electrification (PV or Hybrid) of intermediary stores does not offer a more sustainable, comprehensive and economic solution.

Include flexibility for revising equipment supply requests prior to procurement in approved CCEOP applications as innovations occur. (e.g.: B Medical).

Mandate that training or installation support from equipment suppliers include a certification component for nationals of the receiving country, making them eligible to install and service equipment in compliance with equipment warranties.

## Issue 19: PQS/CCEOP Synergy

Supply chain equipment procured through Gavi HSS or NVS grants are required to be WHO/PQS<sup>1</sup> prequalified. Supply chain equipment eligible for support through the CCEOP also require WHO/PQS prequalification but are subject to additional restrictions. (i.e. only “Hot Climate” equipment is eligible regardless of the climate in the applicant country; and “User Independent Freeze Protection {Grade

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<sup>1</sup> Performance, Quality and Safety



A}, Ref Annex 2, {Page 14} of the Application Instruction for CCEOP). Two situations arise where this becomes an issue: 1) Funds from an HSS grant can be applied towards a CCEOP investment; 2) Resources from an on-going HSS or NVS grant is used to procure equipment.

### Recommendation

Align equipment procurement eligibility norms across Gavi supported windows.

### Issue 20: Risk Management

The CCEOP is a new funding window in its infancy, with a clear message from the Secretariat that the 2016 program will be a learning experience. Unless the presently committed financial envelope is shared across and number of successful applications, there would appear to be two important risks; 1) insufficient diversity in applications to fully benefit from the 2016 experience, and 2) a significant reputational risk for the Alliance if a single large investment does not yield a positive return.

### Recommendations

Limit the Investment ceiling of any single application so that risks are distributed across several applications in the CCEOP present budgetary envelope (\$50m).

Revise the present CCEOP application prior to the September 2016 submission date to consider recommendations from the present IRC review and the learning's of the WHO pre-assessments.

### Issue 21: Quality Assurance

Prompt and comprehensive feedback from 1<sup>st</sup> year supply, deployment, installation, maintenance and M&E experiences are critical, as this early learning experience will make provision to adjust the roadmap for subsequent years of support. The CCEOP application does not mandate sufficient checks and balances to ensure early learning.

### Recommendations

The IRC recommends the following measures relating to progress monitoring, learning by doing and quality assurance are included in rehabilitation planning and reflected in CCEOP budgets:

- A Year 1 CCEOP Post Equipment Introduction Evaluation (PEIE) is mandatory. (Reference: Recommendation Error! Reference source not found. above)
- A **cluster rollout strategy** is adopted for the **1<sup>st</sup> year program only** rather than the nation-wide prioritized approach. A parallel may be drawn with an HPV demo grant, where 1-2 localized geographic zones are selected prior to nationwide routine program adoption. This strategy simplifies deployment, installation and training for bundled supply and provides a quick response mechanism for learning by doing.
- The Gavi Secretariat sets up a due diligence cell for equipment (QA). This cell would monitor the reliability and vaccine storage quality of equipment supplied through CCEOP, assess the effectiveness of M&E frameworks, provide feedback to equipment suppliers and provide an information resource for new CCEOP applicants.

### 3.6.2 Supply Chain Findings

The ISCL situation in twelve (12) countries were reviewed. Afghanistan was not included and two (2) applications (Ethiopia and Haiti) for CCEOP are reported in a separate section. Six (6) from the twelve (12) were HSS proposals (including PNG for HSS reprogramming).

**Issue 22: Weak Supply Chain across countries:** Programs are increasingly constrained by poor infrastructure and inefficient immunization supply chains, especially at the lower distribution and service delivery levels. Increasing performance in countries beyond existing levels to support the ambitions for raising coverage and introducing new vaccines is going to be difficult. Few countries considered operational improvement as strategic investments for their supply chain. Progress in strengthening supply chains other than measurable increases in vaccine storage capacity is limited. There is limited systematic verification and monitoring of the quality of vaccines administered and the opportunities lost to vaccinate due to none or infrequent availability of vaccine supplies. To ensure vaccines of good quality are supplied efficiently and reliably to target populations, meaningful, systematic improvements in immunization supply chain infrastructure and systems are essential. There is a sense of urgency for countries to validate and analyse their supply chain design to avoid unnecessary investments in, for example, cold storage capacity in current bottlenecks. (For example Cameroon and Angola). The results of this analysis (in the context of the benefits and detriments of changing processes) may support the maintenance of the current process, the adoption of an alternate process, or a fusion of different aspects of each process within the supply chain. In addition; the Gavi CCEOP will contribute to technological innovation in storage capacity at the lower distribution and service delivery points of supply chains.

**Recommendation:** Countries should analyse gaps in processes, not equipment, and the gulf between the existing outcome and the desired outcome of immunization to justify proposals. Proposed investments by countries should be clearly linked to addressing these identified gaps to optimize investments made.

#### **Issue 23: Human Resource Limitation**

Human resource availability, turnover and the operational efficiency of programs often compromise program quality (e.g. Cameroon, Angola). These are the root cause for most poor performing ISCL. Proposals for Gavi support must provide clear evidence that management is key to supply chain quality rather than equipment. Countries do not report systematically on the progress in the implementation of EVM improvement plans, mostly due to lack of resources (for example Angola and Kenya). Countries have to ensure HR for key functionalities for the supply chain management: dedicated skilled motivated, able to design, implement and evaluate supply chains.

**Recommendation:** Management teams should be supported to develop and implement with clear roles and responsibilities and should work along a SMART project plan.

## Issue 24: Internal Consistencies in Application

Although proposals were complete and comprehensive, differences between narratives and figures occurred.

EVM assessment reports were provided by 11 countries (except for Mauritania). Ten (10) EVM assessments were dated  $\leq 3$  years. The EVM report of Burundi was dated 2011 and new EVM assessment is planned in 2016. The most recent EVM assessment findings in the countries reviewed and the WHO recommended minimum standards, indicate major shortcomings in certain key criteria (stock management, maintenance, distribution). A similar pattern was observed for countries reviewed in the November and March 2015 IRC.

For three countries (Kenya, Niger, PNG) no clear cold chain inventory and gap analysis was provided to justify all the planned investments and to clearly understand the improvements in the supply chain (for example replacement of old equipment and /or increasing capacity).

**Recommendation:** Updated information of key ISCL criteria requested in more tabular form would make assessments of adequacy and completeness easier to compare. Gavi may need to rethink its new policy, changing the EVM frequency to 5 from 3 years. A reporting template that is substantially more robust is required.

Country must provide a gap analysis based on recent inputs and current request. The analyses should result in a clear investment and rehabilitation plan including allocation of equipment to location and objective replacement/ capacity.

### 3.6.3 Sustainable Environment and Procurement

Disposal of immunization waste by “burn and bury or” in poorly functioning incinerators is still common place, even in countries where a disposal policy may be in place. Only three countries (Cameron, Mauritania, Niger) requested budget for waste management within their proposals. Angola, Burundi and Indonesia indicated no source of funding for proceeding to appropriate elimination of waste generated. The remaining countries reported no specific activities to handle immunization waste in their proposal.

A large number of countries are investing substantial resources in SDD vaccine refrigerators (for example Cameroon, Niger, Myanmar,) and some countries (Kenya) plan to avail of Gavi CCEOP support that will increase the quantities of equipment and maintenance complexities at peripheral levels. 1 country (Papua New Guinea) continues to procure absorption refrigerators, though none are PQS pre-qualified.

## 3.7 Governance Issues

Despite the fact that countries are introducing a number of new vaccines, paying increasing share of co-financing and facing complex immunization system and policy challenges, ICC-HSCC, NRA and NITAG are still, in most low income countries, in their establishment stage.

**Issue 25: Country Level Structures (ICC, HSCC, NITAG):** Significant support should be provided by Gavi partners to country-led government mechanisms so they have the institutional capacity to make evidence based decisions, coordinate, monitor, regulate, guide investments and evaluate their sustainability and impact.

Need to investigate whether :

- the ICC mechanism is still a meaningful and credible coordination vehicle for ensuring meaningful immunization policy analysis and programme monitoring and evaluation.

The IRC made a recommendation to evaluate the functioning, the relevance and lessons learned from ICC/HSCC experience so far. Results and recommendations should be shared with the IRC for feedback and advice.

**Issue 26: Harmonization of aid and the global health agenda:** Developments in global health bring new challenges for donors and the need for new engagement for aid effectiveness and coordination. The on-going changes include the health related SDG agenda, the rise of chronic and non-communicable diseases (NCD), the Universal Health Coverage goal and global health security agenda including humanitarian emergencies and disease outbreaks.

**Recommendation:** Gavi should actively contribute to the global health agenda design and implementation to make sure immunization remains a global priority and indicator to promote health related SDGs. Gavi could develop operational strategies to benefit from the UHC, Data quality and NCD programs and MCH/GFF initiatives.

**Issue 27:** In countries utilising a **SWAp, RBF, pooled funds mechanisms**, specific role of Gavi in the arrangements with and linkages between HSCCs, NITAGS, the ICCs and Technical working groups are not clear enough.

**Recommendation:** For pooled funding and SWAp arrangements, Gavi needs to strengthen its participation on the Joint Consultation and Coordination Committees as well as on the technical working groups so as to ensure sufficient and appropriate attention to the complexities of achieving the desired immunization coverage outcomes.

HSS grants rarely request funds to support governance issues or organisational reform to support the immunisation programme. Given the many challenges in these areas countries are encouraged to explore the opportunities that may be utilised in this area.

### 3.8 Financial Sustainability

**Issue 28: Financial gaps analysis (HSS budget template):**

Information is isolated and fractioned, insufficient information on role of partners for fund and programmatic allocation. Inadequate to view the catalytic nature of Gavi HSS funds.

#### Recommendations

Gavi to encourage countries to provide financing gap analysis in terms of complementarity with programmatic perspective and health interventions across partners.

Guidance to countries in preparatory transition to provide clear information on plans for transition. IRC review to also focus on these evolving transition plans within Gavi grant period.

### Issue 29: Countries in transition

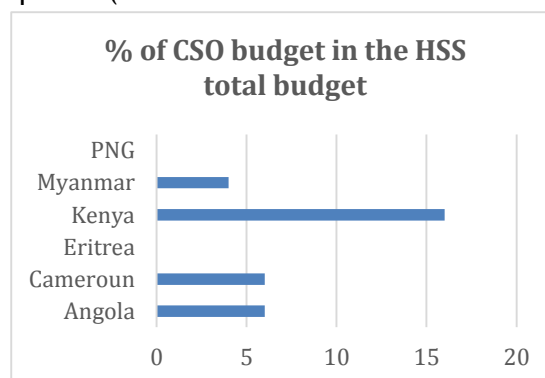
Critical concerns about graduating countries based on relatively “artificial” GNI per capita which does not demonstrate critical social investments and/or protection. Graduating countries often with poor data quality and no real indication of the immunization levels to date.

**Recommendation:** Gavi PPC and Board should commission an in-depth study of graduating countries as to ascertain the key sustainability aspects that need to be considered in developing an exit strategy”.

## 3.9 Civil Society and Private Sector Involvement

Current applications show broader engagement of CSO constituency. There is increasing engagement of a broader range of local actors and players (CSOs, professional associations, public health and management institutes, academia, private sector.) in supporting and strengthening immunization systems and activities.

However, the proportion of the CSO/private sector budget in overall HSS budget remains insignificant in most of the proposals (far less than 10% for 3 countries= Angola, Cameroun, Myanmar). Two countries have no budget for this constituency (Eritrea, PNG). Kenya is the only country which budgeted a substantial allocation for CSO (16%).



**Issue 30: Activities and cost categories dedicated for CSO/private sector in the HSS workplans are not properly**

**documented and easily identifiable.** HSS planning and resource allocation should be directed to clearly defined areas, such as demand generation, CSO capacity building and community and local actors’ empowerment in the delivery of immunization services.

In almost all Gavi support windows (NVS, HSS), countries put efforts in providing documented evidence that CSOs were associated to proposal development process and/or have attended endorsement meetings. However, when it comes to implementation, IRC hardly find activities and budgets earmarked for CSOs. The fact that CSOs are a recognized constituency group in Gavi in-country governance mechanisms has not yet empowered civil society implementers in the delivery of immunization services. Furthermore, IRC could hardly find activities and budgets earmarked for CSO at implementation.

**Recommendation:** Gavi should reiterate governance mechanisms, as well as EPI planning and implementation processes which allow CSOs access to immunization resources and investments against clear objectives and measurable outcomes, especially coverage and equity.

### 3.10 Technical Assistance (TA)

**Issue 31:** It is increasingly evident that there is **growing country dependence on donors to provide TA** in the areas of program and financial management without leading to sustainable capacity development. Most do not provide comprehensive and rational plans. While TA may be needed in the short-term, there needs to be an evolution towards sustainable capacity.

**Recommendation:** Where TA assistance is being used in this way, countries must have comprehensive TA plans that show a clear and timed transition plan towards fully developed internal capacities. TA support should encourage innovations and systems wide thinking at country level to address key challenges

## 4 Conclusions

The IRC commends the on-going efforts at the Gavi Secretariat to review processes with the aim of improving them. However, there is a need to streamline and integrate on-going work processes across Gavi for better outcomes (steering committees, PCA, simplification team, guidelines consultants, PEF etc.).

It is also critical that Gavi's resources should catalyse innovations. The new CCEOP should balance technical and operational innovations.

## 5 Acknowledgement

The IRC acknowledges the Gavi executive team for their responsiveness to key IRC recommendations over time. The A & R Team especially Peter Hansen, Patricia Kuo, Verena Oustin, Sonia Klabnikova, Biljana Nechkova and all the Senior Country Managers/key members for invaluable insights into the country activities and progress. The IRC particularly thank the country managers; WHO and all the Alliance partners for their invaluable technical inputs and increasing attention to quality technical support to countries.

## Annex 1: List of IRC Reviewers

| NO. | Name                     | Nationality  | Profession/Specialisation   | Gender | French Speaking |
|-----|--------------------------|--------------|---|--------|-----------------|
| 1   | Rafah Aziz               | Iraq         | Independent Consultant  | Female |                 |
| 2   | Dora Curry               | USA          | Senior Technical Adviser, CARE  | Female |                 |
| 3   | Terence Hart             | UK           | Independent Consultant  | Male   | X               |
| 4   | Philippe Jaillard        | Benin/France | Agence de Medecine Preventive (AMP) Country Representative                          | Male   | X               |
| 5   | Miloud Kaddar            | Algeria      | Independent Consultant (ex WHO)   | Male   | X               |
| 6   | Elsie Le Franc           | Jamaica      | Independent Consultant  | Female |                 |
| 7   | Marina Madeo             | Italy        | Independent Consultant  | Female |                 |
| 8   | Bolanle Oyeledun – CHAIR | Nigeria      | CEO, Center for Integrated Health Programs  | Female |                 |
| 9   | Zeenat Patel             | Canada       | Independent Consultant  | Female |                 |
| 10  | Diana Rivington          | Canada       | Senior Fellow, University of Ottawa   | Female | x               |
| 11  | Mario Stassen            | Netherlands  | Independent Consultant  | Male   |                 |
| 12  | Ousmane Amadou Sy        | Senegal      | Independent Consultant  | Male   | x               |
| 13  | Beena Varghese           | India        | Senior Health Economist<br>Public Health Foundation of India                        | Female |                 |
| 14  | Shamsa Zafar             | Pakistan     | Head of Department, Centre of Excellence MNCH                                       | Female |                 |
| 15  | MaryAnne O'Neill         | USA          | Health information systems, cold chain logistics, immunization coverage estimation. | Female | x               |
| 16  | Arletty Pinel            | Panama       | Health systems strengthening, maternal health                                       | Female |                 |