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

Geneva, Switzerland

June 12-21, 2017

List of Contents

List of Acronyms

AEFI	Adverse Events Following Immunisation
AFRO/IVD	WHO Regional Office for Africa/The Immunisation and Vaccine-preventable Diseases programme
CC	Cold Chain
CCEOP	Cold Chain Equipment Optimization Platform
DQ	Data Quality
DTP3	Diphtheria-Tetanus-Pertussis, 3rd dose
DTR	Digital Temperature Recorder
EPI	Expanded Programme on Immunisation
EVM	Effective Vaccine Management, an assessment tool
HIV	Human Immunodeficiency Virus
HPV	Human Papilloma Virus
HR	Human Resources
HSCC	Health Sector Coordination Committee
HSIS	Health Systems and Immunisation Strengthening
HSS	Health Systems Strengthening
ICC	Inter-Agency Co-ordination Committee (for immunisation)
IM	Intra Muscular
IRC	Independent Review Committee
ISCL	Immunisation Supply Chain and Logistics
JA	Joint Appraisal
JRF	Joint Reporting Form (on Vaccine Preventable Diseases, WHO / UNICEF)
MCV	Measles Containing Vaccine
MenA	Meningococcal A vaccine
MNCH	Maternal Neonatal and Child Health
MoH	Ministry of Health
MR	Measles-Rubella vaccine
NITAG	National Immunisation Technical Advisory Group
NVS	New and underused Vaccine Support
OPV	Oral Polio Vaccine
PIE	Post Introduction Evaluation

PQS	Performance, Quality and Safety (of immunisation equipment)
REC	Reaching Every Community
RED	Reaching Every District
RI	Routine Immunisation
RV	Rotavirus Vaccine
SAGE	Strategic Advisory Group of Experts on Immunisation (WHO)
SCM	Senior Country Manager
SDD	Solar Direct Drive (vaccine refrigerators)
SIA	Supplementary Immunisation Activities
TA	Technical Assistance
TT	Tetanus Toxoid
UNICEF	United Nations Children Fund
VIG	Vaccine Introduction Grant
WHO	World Health Organization

1.0 BACKGROUND

A 15-member team of the IRC met in Geneva, Switzerland between June 12 and 21, 2017 to review 23 applications from 18 countries as distributed in Figure 1 below. The review team was made of reviewers with expertise in Immunisation, cold chain and logistics, MNCH, Adolescent Health, Health systems strengthening, RH program management, Epidemiology, Monitoring and evaluation, Financial analysis, BCC and Gender. (See Annex 1 for list of members).

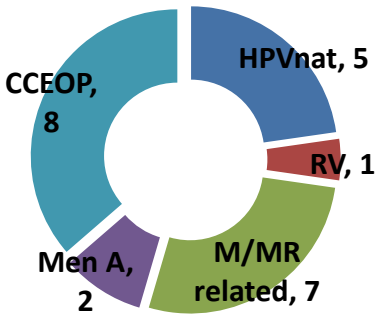
The Independent review committee members focussed on the following specific tasks:

- 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 immunisation.
- 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.

2.0 REVIEW METHODS AND PROCESSES

2.1 Review process and key outcomes

Figure 1: Country Applications



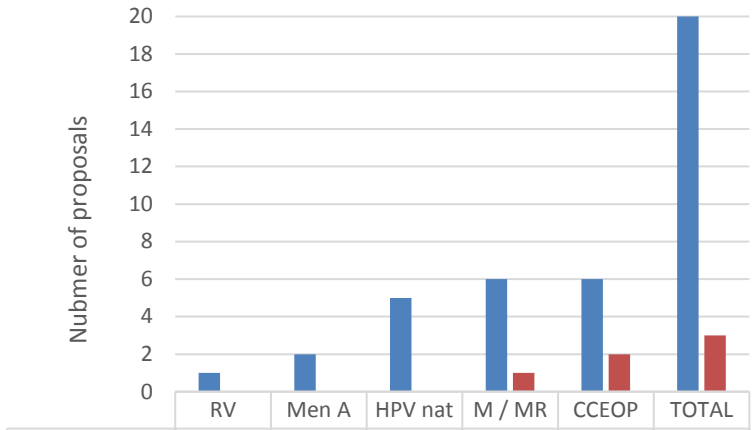
Review Process: An independent peer review of each country proposal was conducted by assigned reviewers. Initial findings were then presented and thoroughly discussed at daily plenaries. Key outcomes and decisions were then consolidated into draft country reports, which then underwent quality review and internal consistency checks.

Decisions: Two decision categories: approval (with issues to be addressed) and resubmission (with explanations).

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

Key review outcomes: The main findings are summarized in Figure 2 below.

Figure 2: Main review outcomes



The quality of proposals submitted by countries continues to improve, with 20 out of the total 23 (87%) proposals recommended for approval. 75% of CCEOP proposals were also recommended for approval. The IRC commends the efforts of the Secretariat and Alliance partners for their technical support to countries. However, it is critical that Secretariat and technical partners support and encourage countries to actively use the epidemiological and programmatic context to guide immunisation strategies for optimum performance and coverage.

2.2. Good practices

The IRC commends the re-introduction of dedicated financial reviews for country budgets submitted as part of application package. This ensures increased and consistent scrutiny necessary to enhance value for money and strengthen country level systems. However, allocating only one person to review of all the application budgets is not realistic given the level of detail needed to be reviewed both programmatically and financially from a value for money perspective. The IRC further notes better linkages between proposed CCEOP interventions and supply chain components of HSS.

Country specific good practices are listed below:

- **Tanzania: CCEOP and HPV Applications:** Scaling up nationally based on lessons learned from HPV demos. Budget and assumptions for HPV application, commitment for DQ reviews, strong linkages between gaps and proposed CCEOP interventions. Fit with HSS.

- **Gambia HPV Application:** Use of routine systems (trainings using integrated HSS, transport systems, etc.) to roll out HPV vaccination.

- **Cameroon HPV Application:** Plans to target vulnerable girls (HIV positive, reduced mobility, hearing or sight impaired) and willingness of government to purchase additional doses for HIV positive girls.

2.3 Feedback on work processes

The IRC commends the Secretariat for its responsiveness to challenges especially in obtaining missing and/or additional documents; and their support for an enabling work environment. However, the following observations need to be addressed by the Secretariat to enhance better work processes. The observations include:

Significantly increased work load during a shorter review window period. The Secretariat significantly shortened the review period with the goal to “increase efficiencies”. However,

real time experience showed that this shortened window period did not lead to increased efficiencies but rather to unrealistic workloads and time allocations and a backlog of reports beyond the duration of review. It is important the Secretariat considers realistic time allocation for the preparation of each country review. Efficiencies are better created when there is due consideration for the quality of outputs and the health of the reviewers. The reduced time window and additional pressure also meant that the IRC could not use some of the innovations introduced in this round such as the possibility to ask clarification questions to countries.

3.0 Key Findings

3.1. New and underused Vaccine Support (NVS) and Campaigns

Measles and Rubella vaccines

Six countries applied for measles or measles-rubella (M/MR) support during this review window. Four countries applied for M/MR follow-up campaigns, one for MCV2 introduction, and one for MR catch-up campaign and subsequent MR vaccine introduction into routine. From the countries applying for the follow-up campaigns, two (Yemen, Sudan) requested support for wider target age-range (up to 15 and 10 years respectively) without providing sufficient epidemiologic data to justify their requests. Pakistan presented inadequate epidemiologic analysis of the measles situation in the country, without clear explanation of the ongoing mass vaccination activities. Funds requested from the six countries in this round of review amount to US$37.3m for operational costs alone. As such, while proposals for three countries were recommended for approval, the Yemen and Sudan proposals were only recommended for approval for the standard follow-up campaigns and the Pakistan proposal was not recommended for approval.

From 2016, Gavi's new comprehensive approach for measles and rubella puts routine immunisation in focus while encouraging better planned and more data-driven campaigns where needed. Supplementary immunisation activities (SIAs) can be a highly effective strategy for providing a second dose to individuals missed by routine services and a second opportunity to those who failed to seroconvert after the first MCV dose. Because the risk of measles outbreaks is determined by the rate of accumulation of susceptible individuals in the population, epidemiologic and surveillance data should be used to monitor and analyse the accumulation of susceptibles, and to provide the rationale and inform the decision on conducting the follow-up campaign. This should be a critical element in M/MR campaign proposals. However, there is no clarity in the applications that traditional SIAs are an adequate strategy to reach those missed in previous SIAs, as there is little value delivering a third dose to children.

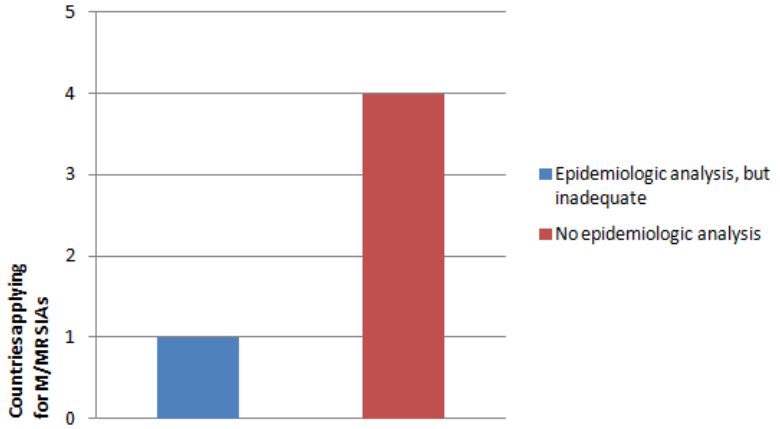
SIAs (mass campaigns) and routine vaccinations remain a necessary alliance for achieving the national measles control goals, until routine coverage can achieve 95% coverage with two doses. Important inputs from the routine programme are necessary for the planning of a campaign, and planning and preparation for the campaign may help address issues within the routine. Further, information generated though the campaign implementation as 'lessons learned' should feed back to the routine and serve for programmatic improvements.

Issue 01: Current screening of applications for M/MR campaigns focuses on completeness of application, not on quality and completeness of epidemiologic analysis

As noted in two previous IRC reports, countries are still not undertaking adequate epidemiological analyses to inform the timing, type, target age group, and geographic scope of campaigns. Current screening of applications focuses on completeness of application rather than on the content of the technical documents and completeness of epidemiologic analysis. Additionally, current Gavi guidelines do not provide details on what is required for sound epidemiological analysis, and the countries - which often have the data – omit to provide national and subnational analysis of reported cases by age and vaccination status, of possible chains of transmission, age specific rates, trends in disease incidence, and population immunity.

Only one out of five countries applying for M/MR campaigns provided epidemiologic analysis, although insufficiently adequate in terms of justifying nation-wide campaign targeting children older than 5 years of age.

Figure 2: Epidemiological justification of request by countries



Recommendations:

Technical partners and WHO pre-screening should ensure that the contents of technical documents are screened for epidemiologic analysis and completeness. To ensure applications of adequate quality, standardized procedures for the application development should be designed and instituted. This may include establishing or strengthening country based technical teams with clear ToR and membership which reflects expertise in all aspects required for the application development, stronger technical assistance from partners, and amending existing Gavi requirements.

Issue 02: RI strengthening objectives using M/MR campaign platform are not reflected in the annual EPI plans

Campaigns provide opportunities to strengthen routine and other health programmes, but RI strengthening objectives are often among the weakest parts of applications. The links between campaign and routine immunisation programme are poorly described, not based on situation analysis, and in cases when post-campaign coverage surveys are conducted, their findings are not linked with routine immunisation strengthening objectives. Further, best practices and/or lessons learned from previous campaigns that can strengthen RI are not detailed enough and are often detached from the local context. This is a real missed opportunity as the campaigns can and should build national capacity as they utilize RI

platform (e.g. human resources, cold chain and waste management facilities, surveillance, social mobilization network, AEFI surveillance, etc.).

None of 5 applications for M/MR campaigns provided specifics on how RI will be strengthened, objectives listed do not often feed into the annual EPI plans, nor are reflected in the budget. None of these 5 applications fully integrates RI strengthening objectives into the campaign planning process nor realizes the benefit of having and fully integrating the RI 'focal point' in SIA process. It should be noted that RI system issues can be successfully addressed during different phases of the SIA, and that for many activities carried out before and during the campaign, no additional resources will be needed, and/or resources from the RI programme and from the campaign can be pooled together. However, this remains insufficiently recognized in all applications.

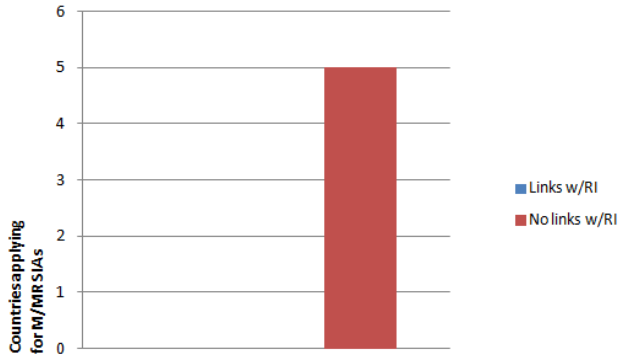


Figure 3: Linkages with Routine Immunisation

Recommendations:

Countries should base their RI strengthening objectives on the carefully conducted situational analysis and include the specific RI strengthening activities in the campaign's planning process and consequently in the plan of action and implementation. In order to show clear links with strengthening the national immunisation programme within the country context, these activities should be incorporated into the annual EPI plans and budget, with the realistic timeline and designated responsible persons. Making the annual EPI plan a required document accompanying applications for review should be considered by Gavi.

HPV National Introductions

This is the second round of applications that applied the new Gavi guidelines enabling countries to introduce nationally without the requirement for prior HPV implementation experience and facilitated immunisation of multiple cohorts of girls aged 9-14 years during the first year of vaccination as per WHO SAGE recommendations. The IRC received five applications for national rollout of HPV vaccination (Cameroon, Gambia, Kenya, Mauritania and Tanzania). It is positive to note that countries submitted good quality proposals that applied lessons learned from HPV demonstration projects to develop their strategy for the HPV national roll-out. Countries have striven to select strategies that fit their local context and minimize delivery costs. In particular, they have chosen delivery models that take into account level of school enrolment and a wide range of strategies to reach in-school and out-of-school girls. They have introduced innovative practices such as vaccination of HIV+ girls in Cameroon, and using other programmes to advocate and mobilize girls to get vaccinated at health care facilities (See Table 1). Previous recommendations provided by the IRC in March 2017, such as the need to adequately estimate routine and multi-year cohort population numbers (i.e. through use of UNDP estimates) were still applicable for this round of applications.

Table 1: Features of HPV Applications by country

Country	Strategy	Target population*	Challenges	Best practices
Cameroon	School-based strategy + community outreach X2 a year	1,490,022 322,757	55% secondary school enrolment EPI to fund additional outreach costs	Vaccination of HIV positive girls Plans to combine HPV delivery with Td booster dose
Gambia	School-based strategy + community outreach X1 a year	108,132 30,442		Scaling up a successful demo strategy Crisis communication plan
Kenya	Health facility strategy + outreach to schools and community X2 a year	2,467,913 766,207 (10 y.o)	Need careful microplanning and mapping for all health facilities Bring the girls to HF	Increase HF attendance (e.g. social mob in schools) to reduce costs Leverage other child health programmes
Mauritania	Phased introduction of HPV Health centre strategy with school outreach + communities X2 a year	202,264 38,948	Vaccinating vulnerable girls (OOS, married girls <14 (18%), marginalized population) Underestimated target?	Planning to learn from first phase (no demo) and adjust strategy
Tanzania	Health facility strategy + Outreach to schools and community X2 a year	3,422,859 680,799	Need careful microplanning and mapping for all health facilities Bring the girls to HF Keep up teachers' motivation	Ensure sustainable programme

*MC= multi-age cohort target
R= Routine cohort target

Issue 03: Maximizing preparedness/momentum and ensuring programme viability

Because the programmatic and financial sustainability of routine HPV vaccine delivery will hinge on each district planning for the most cost-effective way to deliver vaccines to girls, careful microplanning along with micro-mapping will be critical for the programme to achieve its results.

Recommendation: In the context of HPV vaccine supply shortages, Gavi should disburse sufficient VIG funds at least one year before introduction to allow initiation of detailed microplanning activities. This will assist the country with determining the most suitable and sustainable delivery strategy by district. Gavi should also facilitate access to high quality TA for all countries to support this process, possibly using GIS mapping.

Issue 04: Evaluating the programmatic and financial sustainability for the routine cohort

It will be critical for countries and Gavi to evaluate the programmatic and financial sustainability of the selected mechanisms for routine HPV vaccine delivery, to optimize delivery models and ensure that the programme can be sustained over time.

Recommendation: Countries should carry out a Post Introduction Evaluation (PIE) at least 24 months after launch, with a view to assessing routine cohort delivery, once the multi-year cohort vaccination has been completed, in order to evaluate the long-term programmatic and financial sustainability. Global HPV partners may want to commission case studies of current vaccination micro-planning processes.

Issue 05: Recording vaccine doses

Lessons from demonstration projects have often shown poor card retention rates, coupled with a significant share of the budget spent on printing costs for these cards.

Recommendation: Gavi should consider testing innovative ways to record vaccine doses such as tracking doses with phones or non-card electronic support. These mechanisms can also be used to support girls that missed a vaccine dose to get vaccinated at health centres.

Issue 06: Lack of vaccination policy for countries with high HIV sero-prevalence

HIV positive girls are more likely to develop cervical cancer, a leading cause of death. Some Gavi countries have high levels of HIV infection and need to ensure that HIV+ girls are equitably protected from infection by HPV vaccination.

Recommendation: Gavi needs a policy for HIV positive girls that should be developed in collaboration with WHO, including:

a. Funding for the additional required doses,
b. Age range (consider expanded beyond 9-14),
c. Confidentiality issues (i.e. needing more doses and not adhering to the regular schedule two-dose schedule),
d. Maximizing synergies with HIV+ clinics,
e. How to calculate number of doses.

Issue 07: Tailor communication strategies to the wider target age group of the multi-age cohort to optimize uptake and increase delivery model effectiveness

With exception on Kenya and Tanzania, communication and social mobilisation strategies often replicate traditional approaches without taking sufficiently into account the fact that different target groups may need different approaches.

Recommendation: Technical partners should encourage and support countries to test innovative communication and social mobilisation approaches, tailored to reaching out to multi-cohort girls (e.g. social media and SMS) and evaluate results to share with countries applying for HPV national programme.

3.2. Data Quality, Immunisation Coverage

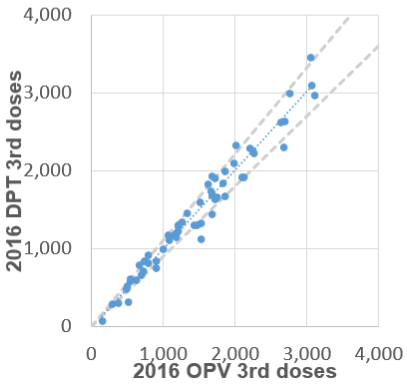
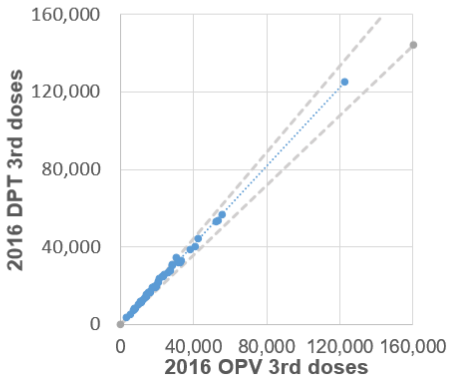
Gavi's first data quality requirement for countries is an "annual desk review" of their immunisation data. The concept of a "data desk review" is a new one that program managers are only beginning to understand and practice.

Data desk reviews featured prominently at the WHO Immunisation Data Quality Workshop, Rwanda, 9 to 19 May, 2017. With funding from Gavi, WHO/AFRO/IVD convened a pair of 4-day workshops in Kigali, Rwanda to support staff of National Immunisation Programs and Health Management Information System (HMIS) units to review the quality of their routine immunisation data and draft data quality improvement plans. An anglophone workshop (Eritrea, Gambia, Kenya, Lesotho, Zambia, Malawi, Mozambique, Rwanda and South Sudan) was followed by a francophone workshop (Angola, Burkina Faso, Chad, Comoros, Congo, Guinea Conakry, Guinea-Bissau, Madagascar, Mauritania, Niger, Sao Tome & Principe, and Togo).

Participants from all countries, with one exception, were able to carry out a desk review of the internal consistency of their immunisation data quality. The following figure illustrates, for a pair of countries at the workshop, two metrics which are assessed by desk review:

1. % of districts which, over a full year, report a higher number of third doses of Penta than first doses of Penta (negative drop-out);
2. % of districts which, over a full year, report a number of third doses of Penta which differs by more than 10% from the number of third doses of OPV vaccine.

Table 2: Comparison of Immunisation quality between two countries using selected indicators

	Country A	Country B
1. Districts with negative DPT1 to DPT3 dropout	31/58 districts (53%)	0/47 districts
2. Districts with DPT3 doses > 10% different from OPV3		

The 2016 routine data of country A show poor consistency: over half of districts had negative dropout and one third of districts had annual DPT3 totals which differed by more than 10% (shown by the dotted lines in each graph) from their OPV3 totals. In contrast, data for country B were highly consistent: for all districts, DPT1 was greater than DPT3 and DPT3 was roughly equal to OPV3. This consistency of data suggests that the routine data of country B are more reliable.

As a result of the Rwanda workshops and the sharing of files from previous desk reviews, an archive has been compiled of 28 desk reviews from 23 countries. Going forward, there is a pressing need to develop norms/benchmarks and thresholds with which to interpret the findings related to each data quality metric ("If the DPT1 to DPT3 drop-out rate is negative for 5% of districts, is this an excellent result, an average result, or a below average result?"). From the results shown in the following figure, it appears that an excellent result, achieved by 3 countries, would be for there to be no districts with a negative DPT1 to DPT3 dropout rate. On the other hand, if 15% or more of districts have a negative dropout rate, this is a below average result. Negative drop-out is usually evidence of inaccurate reporting – either deliberate or accidental. When DTP3-based reward systems are in place, there is a higher risk of deliberate misreporting, with inflation of DTP3 but not DTP1 leading to negative dropout.

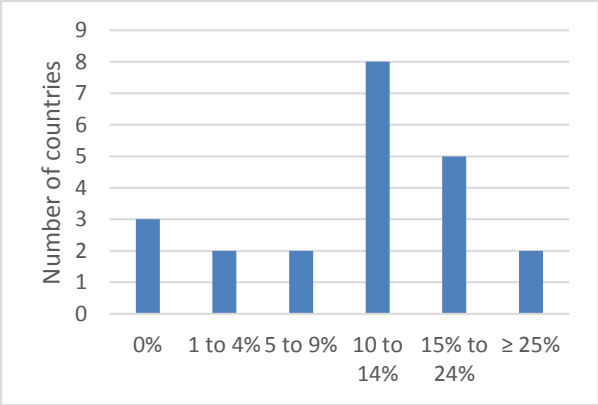


Figure 4: Classification of 22 countries according to the % of districts with a negative DPT1 to DPT3 dropout rate

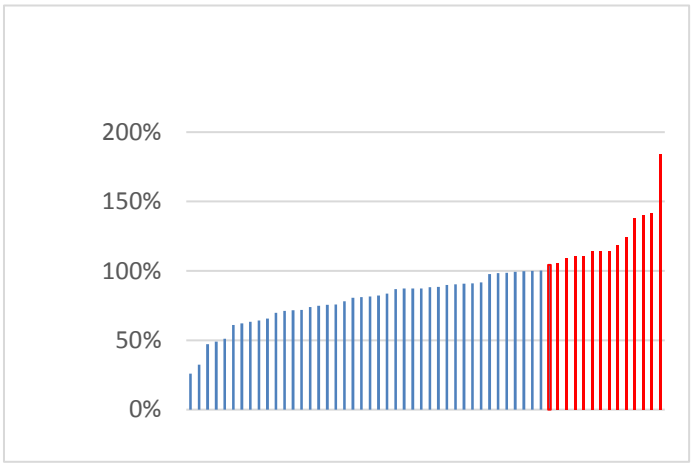
Other data quality metrics that are measured by a desk review include:

- The number of extreme outliers (monthly values that are more than 3 standard deviations above or below the average monthly value of the indicator);
- Consistency from year-to-year of district values;
- Consistency of routine estimates of immunisation coverage with survey estimates;
- Percent of districts with routine coverage estimates in excess of 100%.

WHO/AFRO/IVD has a database of several years of monthly immunisation data, by district, for most countries of the region. With such a database, it should be possible to conduct a meta-analysis and arrive at robust evidence-based recommendations for norms/benchmarks and thresholds for each of the data quality metrics.

Immunisation Coverage

Figure 5 2016 DPT3 coverage, Country C by district



Issue 08:

Gavi have adopted, as a core indicator of geographic equity, % of districts with coverage > 80%. Yet review of sub-national data from 8 of the 18 countries submitting proposals during this round shows that 39% of districts had DPT3 coverage estimates in excess of 100%. This is due to unreliable district estimates of the target population as well as to data quality problems. Presently, the JRF does **not** ask countries to report on the number (%) of districts with coverage >100%.

Assuming that Gavi had access to "% of districts with coverage >100%", how should the data then be analyzed to assess geographic equity? One option would be to exclude from the analysis all districts with coverage >100%. A second option would be to somehow adjust downwards all coverage estimates so that the adjusted district coverage for the great majority of districts was <100%.

In most Gavi-supported countries, due to significant problems with the denominator and/or numerator, use of district coverage estimates to identify disadvantaged districts and to assess progress with geographic equity is problematic.

Recommendation: Equity analyses should acknowledge limitations of routine coverage estimates and compile evidence from multiple sources (qualitative, surveys, etc.) to identify disadvantaged populations. This should inform strategic programming to reach the underserved.

3.3. Supply Chains and Cold Chain Equipment Optimization Platform

During this review, eight countries submitted a CCEOP application. Six (6) or 75% were recommended for approval and two recommended for resubmission.

Good practices and positive development

Countries are developing more comprehensive and accurate CCE inventories and benefitting from the advanced features of the WHO cold chain equipment and gap analysis tool to identify needs, and segregate equipment.

All countries provided the 'single document' that provides the key data on CCE status, gaps and strategies proposed by the countries to address these; as well as the required documentation. Most of the EVM IP progress reports were up-to-date and showing progress.

Other Observations: The CCEOP application process continues to evolve to meet earlier IRC recommendations. The IRC appreciated hearing about the response to previous IRC recommendations. However, more work remains to maximize the potential impact of the CCEOP. In particular, recommendations on engaging in system design and optimization, and incentives for countries to use HSS funds liberated by CCEOP for operations; and disposal of used CCE need to be addressed. The recommendation on time between application and timing of 'start', was partly addressed with data showing that it took about a year to start procurement, but much more time is needed for implementation. It is not clear what 'start date' means in relation to procurement: arrival in country or initiation of the procurement; this needs to be clarified in the guideline (as do other issues mentioned below).

The IRC noted the slow implementation of CCEOP, with no equipment yet installed from previous applications. As in the previous reviews, no country is planning to use the CCE investment as part of network redesign, and limited impacts on efficiency apart from replacing inefficient and inappropriate CCE. Benin has embarked on system re-design; but this was not reflected in its application.

3.3.1 CCEOP

Issue 09: Readiness of country systems to successfully implement CCE

Capacity to provide oversight of the distribution, installation and training adequacy and commissioning of the new CCE and to then monitor the performance of the CCE was a concern for all countries. Two countries were asked to resubmit their proposal primarily for this reason. (As noted in previous IRC reports, Gavi needs to ensure that data on CCE supplied through the platform is systematically collected and analysed, to ensure that countries are making good use of the CCE; and to ensure that the new CCE performs at "grade A" level in the field, as expected from their laboratory testing for PQS listing.)

Recommendations: Gavi and technical partners need to set minimum standards for 'country readiness', especially in relation to monitoring implementation of CCE, its ongoing performance, and ability to maintain CCE. Gavi should also consider evaluating first CCEOP execution carefully and share lessons learned to stakeholders.

Issue 10: Impact of new CCE on coverage and equity

Linkages between CCE and improvements in coverage and equity are not easy to demonstrate. However, the submitted proposals show variable attempts to prioritize CCE to address equity. Providing CCE is not sufficient to improve equity without adequate human resources and vaccine supply; it is also possible to extend the supply chain without using CCE. Nevertheless, CCE remains an important component to extend provision of immunisation services. Several applications justified CCE in that it enables more frequent than monthly immunisation. However, monthly immunisation can achieve a fully immunised community, when that community is linked to the health worker, who can provide immunisation sessions at an appropriate time for the community and turns up, as planned. Some of the countries had already embarked on extending CCE, but no data were presented on the impact of doing so on coverage or equity.

Recommendation: Gavi should seek to collect data, or undertake studies, to assess if extending CCE has been part of strategies that have improved coverage and equity.

Issue 11: CCEOP application guidance

Whilst the secretariat has been working assiduously to make the guidance more user friendly, countries still are not providing the necessary details.

Examples of these include the following:

- **Country duty exemption for supplies:** For CCEOP, the supplies are procured through UNICEF. However, the consignee is the government. Some countries provided details on the UNICEF exemption, which is not appropriate.
- **Mandatory indicators:** Two of 6 countries did not include key indicators on CCE maintenance, which are mandatory (Somalia and Burkina Faso) and 3 did not include key indicators on temperature monitoring (Burkina Faso, Senegal and Somalia). However, these areas are reported as the weakest in situational analysis in most countries. In several cases the baselines, denominators and/or numerators did not appear meaningful. Countries also referred to annual inventory updates for monitoring indicators, but did not explain how this would be undertaken or funded.
- **Lack of comprehensive replacement plans:** Country plans for CCE replacement should be comprehensive and include all CCE needs; not just those applied for in CCEOP. Current or planned procurements need to be specified as part of the overall needs. In addition, the needs for non-CCEOP eligible CCE should be detailed in the application, to understand how the country intend to strengthen the end to end cold chain.
- **Guidelines for provision of CCE for countries in fragile condition or experiencing emergency situation are not available:** This is crucial to prevent potential loss or damage of expensive CCE.

- Disposal of CCE needs to be undertaken without damaging the environment from release of greenhouse gases. Some countries referred to following guidelines, but did not specify exactly how this would be achieved. The potential to repair CCE for sale, or to sell unsuitable CCE (e.g. domestic fridges) was not specified by any of the countries applying in this round.

Recommendations: These issues are critical issues that need to be further explained/clarified to countries in both written guidance and additional support by technical partners and Gavi including the WHO pre-review. The opportunity to plan to achieve greater results should be maximised and encouraged.

Issue 12: Maintenance

Preventive and curative maintenance has been a persistent problem across all countries, with and inadequate focus on addressing these issues in proposals. Only 1 of 8 CCEOP applications included temperature monitoring for tracking maintenance issues. Though this round of application includes one mandatory indicator on maintenance, most applications did not use it appropriately.

Recommendation: WHO pre-screening should focus on maintenance indicators specifically and scan applications if maintenance plan addresses the issue adequately.

Issue13: CCE performance and vaccine quality

To maintain quality, vaccines must be protected from temperature extremes. Vaccine quality is maintained using a cold chain that meets specific temperature requirements. Effective temperature alarm monitoring provides a tool that can be used to assess CCE performance, as well as to monitor the effectiveness of preventive maintenance, and the timeliness of repairs. Establishing systems to collect monthly 30DTR alarm or RTM data is one aspect of the infrastructure that countries need to consider to enable monitoring of new equipment.

Countries are now using 30DTRs for continuous monitoring of temperature performance, at some or all levels of the cold chain. However, no proposal included alarm data analysis as part of their situation analysis.

Recommendation: Gavi to support countries in systematic collection and analysis of temperature alarm data for prompt curative and preventive maintenance of CCE to ensure quality of vaccines and prevent waste of vaccines. Support needs include costs for communication of data, training, incentives, and evaluation studies.

Issue 14: Alignment between budget spreadsheet and narrative proposal

Some proposals showed discrepancies between the budget spreadsheet and the part-D of the narrative proposal in terms of numbers of particular CCE, cost of CCE etc. e.g. the price of voltage regulator is sometimes overestimated (up to $400 against the fridge price of $500/600). The quantities of spare parts are not aligned with the WHO recommendations

Recommendations: Countries should align the equipment quantities and budget in the spreadsheet and narrative proposals. Quantities of spare parts requested should be aligned with recommended WHO/PQS norms.

3.3.2 Immunisation Supply Chain and Logistics (iSCL)

Issue 15: iSCL performance and efficiency

None of the applications for the 13 countries reviewed for NVS support indicated measures for systemic improvement linked to improved performance and efficiency other than within the context of CCEOP applications, allowing replacement, expansion and extension. The CCEOP process only addresses efficiency in terms of better adapted CCE and not from a systemic design approach.

Recommendations:

- Gavi should provide appropriate guidance to Alliance partners and host government to encourage countries to invest in holistic and systemic supply chain improvements.
- CCEOP applications should clearly indicate how CCE supplied through CCEOP will contribute to systemic design improvements when under consideration (e.g. Benin and Senegal).
- Gavi Alliance technical partners to consider the need and type of incentives to support countries to rethink the processes and their structure to optimize their supply chain; adapting principles used in commercial distribution to the public health sector. Countries need, at minimum, holistically evaluate current processes and structures of supply chain systems to consider options for the iSCL in the context of pharmaceutical, nutritional, and commercial supply chains.

Issue 16: Inaccurate supply chain inventories

Countries are progressively being urged to establish accurate supply chain inventories, and the WHO "Cold Chain Equipment and Gap analysis tool", particularly with recent features incorporated, provides an excellent inventory enabling mechanism with inbuilt features for equipment segmentation. The tool also provides scope to identify poorly performing communities, but in its present form does not include features for segmentation of CCE or other measures to ensure vaccine storage to prioritize poor performing communities. The value of such features whilst facilitating CCE placement, also has the potential to provide guidance for programmatic benefits.

Recommendation:

Gavi should make CCE inventories a mandatory requirement for NVS and HSS applications, and that tools are further refined to better inform "supply chain readiness" in hard to reach and poor performing communities.

3.3.3. Immunisation Waste Management

Issue 17: Adequacy/availability of waste management equipment

Applications do not generally indicate waste management equipment (e.g. incinerator) available and the status of equipment although the WHO and PATH inventory tools include

these. Applications do not indicate the volume of waste generated in immunisation programs and the additional burden when new vaccines are introduced. Many countries developed health care waste management policies and plans a little more than a decade ago as part of a WHO global initiative. Waste management, supervisory and monitoring roles and responsibilities were also assigned. Policies were adopted in many countries; sometimes with plans to implement policies; but generally do not get implemented.

Recommendations: Guidelines should require that countries draw from national equipment inventories (which are already mandatory for CCEOP applications) to quantify waste management equipment and its status in applications for support other than CCEOP applications.

The WHO Cold Chain Equipment and Gap Analysis Tool (2017 Version), which is used by many countries to develop a CCE inventory, should be more specific in defining waste management equipment and its status. The tool currently only requires the quantities of equipment.

The WHO Supply Chain Sizing Tool (2017), which estimates the amount of vaccination waste, generated during RI and SIAs should define waste volumes to be disposed rather than just the numbers of pieces.

Countries must ensure that their applications are specific in defining the waste management equipment situation, the need in terms of volumes to dispose, transport and HR arrangements for waste management activities directly associated with the waste to be generated through the Gavi support requested, and for immunisation programme waste in general.

Issue 18: CCE disposal

No provision is made to ensure that CCE replaced through the supply of new CCE with Gavi support is responsibly and safely disposed. Some countries did not have a final decommissioning and disposal policy and/or disposal plan for the old cold chain equipment in the applications.

Recommendations:

- Any country application for Gavi support which includes the supply of equipment, (cold chain, temperature monitoring or waste management) should clearly specify how replaced equipment will be decommissioned and then subsequently disposed, recycled, or reused. This should go beyond policy to highlight current practice and include full details of methods (e.g. how refrigerant gas is disposed).
- Gavi should earmark an amount in CCEOP to support the cost of recovery and disposal of obsolete or replaced CCE, payable against evidence of disposal according to appropriate norms.

3.4. Financial Review and Budgets

Positive development:

During this June IRC, 13 countries have applied for NVS support whether for VIG or for Operational costs (OPC). Budget review was completed by the IRC in line with these newly developed guidelines and tools. IRC welcomes the introduction of the new planning and budgeting tool and has noticed adherence to the new template by many applicant countries. There is a genuine attempt by countries to adhere to the Gavi new budgeting guidelines and tools (10 countries out 13 have submitted their budget in the new template, 8 countries out of 13 have also provided budget assumptions and documented DSA policies). Only Ethiopia, Yemen and Tanzania did not use the new planning and budgeting tool.

Gavi has recently provided to eligible countries new guidance on criteria and requirements for use of cash support for human resources (HR) capacity in the EPI, i.e. funding of salaries, top-ups or incentives. These new guidelines also cover the use of cost recovery mechanisms such as per diems and allowances paid to staff, community workers and other volunteers on duty. All new requests for NVS support as per the 3 May 2017 application cut-off date should adhere and comply with this new guidance, particularly countries in preparatory transition phases. A new budget template has been developed by Gavi Secretariat to support the planning and costing process by the applicant countries, including requirement to provide detailed budget notes/assumptions and documented HR/DSA policies to back up cost elements in vaccine introduction grants (VIGs) and operational costs of campaigns (OPCs).

Issue 19: Compliance with new budget tools

It appears that most of the countries need more support and capacity strengthening to make good use of the new tool. This becomes more critical in the areas of completeness and accuracy of excel summary sheets/graphs in the budget template and with regard to the submission of meaningful and acceptable budget assumptions. Narrative and budget notes provided in the last column of the new template are not comprehensive and substantive enough to enable IRC to get the full rationale/justification of some high cost elements, such as per diems and allowances for health workers, for trainings, for vehicle rental or fuel costs, etc. Even printing costs of vaccination cards have not systematically been articulated to the actual target population indicated in the application for new vaccine introductions or campaigns (Ghana, Yemen, Sudan, Pakistan, etc.). The fundamental limitation in the budget assumptions provided is the lack of reference/links between unit costs and quantities in the budget with numbers outlined in the technical component of the application, such as target population, intervention sites, people to be trained, etc.

The lack of any sort of justification/rationale for countries in transition phase budgeting for high HR-related costs is another weakness that came out clearly during the budget review. The countries did not follow and comply with the new Gavi guidelines on HR costs nor with the submission of transparent and well-documented national standards and policies on per diems and incentives. Only 7 out 13 applicants included short letter outlining general practices at country level, including alignment to UN agencies per diems rates.

IRC has also noticed that there is a trend of countries close to transitioning that do not demonstrate adherence to generally accepted financial management standards and practices, leading Gavi to channel the funds through partner agencies (WHO, UNICEF, etc.).

Issue 20: Budget drivers

A critical analysis of operational costs and VIG grants requested by the countries revealed that HR and transportation related costs represent the biggest budget items of the cash requests (76% of the total Sudan cash request, 75% for Yemen, 70% of Pakistan, 56% for Ghana and 48% for Mauritania). It appears that countries have more challenges to fund the deployment of health workforce and community workers/volunteers during vaccine introductions and campaigns, leading to huge budget lines on per diems/incentives and vehicle rental costs being charged to Gavi only. It is important to institute increased scrutiny of all cash-sensitive costs in countries' requests (per diems, incentives, vehicle rental costs, etc.). In general, other partners often cover less risky budget items such as surveillance, evaluation, social mobilization, waste management, etc. and leave Gavi to cover with the higher risk items.

Recommendations:

Gavi should:

- as a matter of urgency, reinforce the absolute necessity for countries applying for cash support to provide solid budget notes and narrative linked to delivery of the actual technical proposal;
- look critically and holistically at budget and financing constraints at country level which pushes applicants (including those in transition phase) to systematically charge all cash-sensitive cost items to Gavi support;
- institute layers of scrutiny of all cash-sensitive costs pre-, and post applications using benchmarks and upper limits. It is imperative to ensure that HR costs through cash support are not duplicating health workers' payment scheme at the country level as campaigns should not be used to top up deficient HR payments;
- enable countries to adopt a ***"plan and spend money wisely"*** approach (e.g. ceilings and budgets, HPV and beyond the first year financial support).

3.5. Governance

Good governance is about the processes for making and implementing decisions. Most countries formalize their decision without emphasis on the best possible process for making those decisions. Gavi should be able to follow and understand the decision-making process and clearly see how and why a decision was made – what information, advice and consultation council considered, and which legislative requirements (when relevant) are followed. There is an obligation for countries to report, explain and be accountable for the consequences of decisions it has made on behalf of the community it represents.

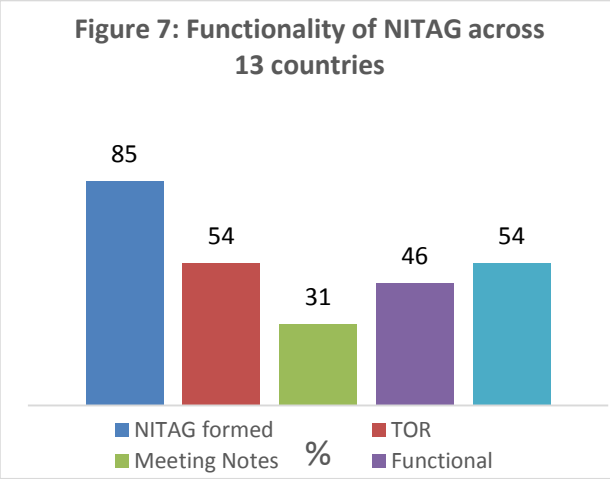
Well-functioning and formalized National Immunisation Technical Advisory Groups (NITAG's) are recommended to be part of this decision-making process.

Issue 21: Functionality of NITAG

Out of 13 (thirteen) countries submitting applications during this round, 11 (eleven) have

committed to forming a NITAG, but only 46% are functional. Only 31% of the countries provided meeting notes.

Recommendation:



Gavi and the WHO should:

- Support the establishment and strengthening of NITAGs and emphasize the importance of functionality;
- Provide direction and identify issues for countries to consider when establishing or improving the functioning of a NITAG, and outline roles and activities in support of the establishment and strengthening of NITAGs;
- Encourage countries to conduct regular review of the value and functions of NITAGs to determine progress.

Issue 22: Poor country responsiveness to operationalise NITAG

Countries should implement decisions and follow processes that make the best use of the available people, resources and time to ensure the best possible results for their community. NITAG should be a technical resource supplying guidance to national policy makers and programme managers to enable them to make evidence-based immunisation related policy and program decisions, independent of politics and influence.

Recommendations:

WHO should support countries to ensure that NITAGs are formal, technical and their decisions and/or recommendations evidenced-based and independent of political and influence. NITAG should be primarily composed of technical experts. NITAG should serve as a technical resource supplying guidance to national policy makers and programme managers that will further strengthen their capacities to make evidence-based immunisation related policy and program decisions.

3.5. Technical Assistance (TA)

Issue 23: Impact of TA for proposal development

The impact of technical assistance during the proposal development is not clearly evident in some of the submitted proposals. Only 3 of 6 countries applying for M/MR campaign and MCV2 introduction asked for and received TA.

Recommendation

Within available Gavi funding, technical partners should ensure **high-quality** TA support is made available to countries.

Issue 24: Need for technical assistance for CCEOP and Supply Chain system strengthening

Situational analysis of the cold chain emphasized weaknesses in supply chain management and particularly in the areas of temperature monitoring and CCE maintenance; two key areas for successful equipment deployment, performance and sustainability. No countries requested for TA for implementation of the CCEOP grant this round. Furthermore, there is need for TA to support the establishment of a performing information system to support the deployment of the CCE; and implementation of activities contributing to the CCE efficiency and sustainability.

Recommendations:

1. Include a section on TA in the CCEOP application, requesting countries to describe the needs of TA for the deployment of CCE, strengthening of maintenance system, monitoring of CCE performances and optimization of the supply chain; and to provide the plan for provision of TA.
2. Follow up the provision of requested TA through the annual joint appraisals

4.0 Conclusion

The IRC recognises the increasing efforts of Gavi and its technical partners to improve the quality of submitted country applications. These efforts have led not only to an increase in IRC approval rates but also demonstrate innovative strategies that can potentiate the investments made in immunisation and the CCEOP. However, it is critical that technical partners support countries to ensure adequate and sound epidemiological analyses to inform the timing, type, target age group and other key parameters that facilitate high quality campaigns with meaningful impact on routine immunisation.

Given the impending HPV vaccine supply shortages, it is critical that Gavi and its technical partners maximise the wait times and momentum created by timely release of funds for optimum planning and preparation for the introductions. It is also imperative that Gavi work closely with WHO to develop a policy to support HPV vaccination amongst HIV- positive young girls.

The IRC highlights the tremendous progress made on the CCEOP applications and commend the Gavi Secretariat team and the technical partners for the work done through very quick turnaround of guideline revisions, up to date EVM reports and more comprehensive CCE inventories. As the CCEOP matures, it is important that countries are supported by technical partners to optimise the system design holistically and address the disposal of obsolete or old equipment more concretely.

Finally, IRC processes and review timing/duration must be realistic to ensure quality review of country applications. The IRC has continued to provide invaluable inputs into the Gavi funding process with significant cost savings over time (e.g. Ethiopia in this window). It is therefore important for Gavi to safeguard its investments from the outset through well-funded quality review processes and schedules.

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Annex 1: List of IRC Reviewers

No.	Name	Nationality	Profession/Specialisation	Gender	French Speaking
1.	Salah Al Awaidy	Oman	Communicable diseases advisor, MOH/Epidemiologist/Public Health	Male	
2.	Aleksandra Caric	Croatia	Independent Consultant	Female	
3.	Ranjit Dhiman	India	Independent Consultant	Male	
4.	Linda Eckert	USA	Professor, University of Washington (Gynaecology)	Female	
5.	Terence Hart	UK	Independent Consultant	Male	x
6.	Philippe Jaillard	Benin/France	Independent Consultant	Male	x
7.	Shaikh Humayun Kabir	Bangladesh	Independent Consultant	Male	
8.	Osman David Mansoor	New Zealand	Public Health Physician, Regional Public Health, New Zealand	Male	x
9.	Benjamin Nkowane	Zambia	Independent Consultant	Male	
10.	Sandra Mounier-Jack	France/UK	Lecturer London School Hygiene and Tropical Medicine (Health Policy)	Female	x
11.	Bolanle Oyeledun - **CHAIR**	Nigeria	CEO, Center for Integrated Health Programs	Female	
12.	Zeenat Patel	Canada	JSI - Independent Consultant (for the duration of the IRC)	Female	
13.	Robert Pond	USA	Independent Consultant	Male	
14.	Mario Stassen	Netherlands	Independent Consultant	Male	
15.	Ousmane Amadou Sy	Senegal	Independent Consultant	Male	x