GAVI INDEPENDENT REVIEW COMMITTEE (IRC) REPORT, NEW PROPOSALS - NOVEMBER 2014

JANUARY 4, 2015

Table of Contents

List of Figures	3
List of Tables	3
List of Acronyms	4
Acknowledgements	6
1Summary Report	7
2. Findings	11
2.1 Data Quality, Coverage	11
2.2 IPV proposals	12
2.3 Other NVS proposals – Measles, MR, HPV and JE	16
2.4 Health System Strengthening	19
2.5 Supply Chain and Waste Management	22
2.6 Vaccine Markets and Product Selection	28
2.7 Financial Management	29
2.8 Gender and Equity	32
2.9 Monitoring and Evaluation (AEFI, Surveillance, M & E) and data utilisation	35
2.10 Governance (HSSC, ICC, NITAGs, NRA, CSO, other)	37
2.11 Communication	40
2.12 Human Resources	42
2.13 Sustainability	46
2.14 Other Issues – Ebola	49
Annex 1 List of IRC Review Members	50
Annex 2 Supply Chain Issues Listed from IPV Review	52
Annex 3 JRF Reports on District Coverage	55
Annex 4 Previous Gender and equity Recommendations	57
Annex 5 - Previous Recommendations on Governance	57
Annex 6 Summary of IRC Results	57

List of Figures

Figure 1 Summary of Findings

Figure 2 Trends in DPT3 Coverage (WUENIC Estimates)

Figure 3 Number of GAVI Supported Countries Achieving variable Levels of DPT3 Coverage

Figure 4 Comparison of Administrative and DPT3 Coverage Estimates

Figure 5 History of Survey Coverage in GAVI Countries in the last 5 years

Figure 6 Allocations of HSS Budget by Constituency

Figure 7 Number of Recommendations on ISCL

Figure 8 Supply Chain Issues by Type in IRC Comments and Recommendations

Figure 9 Status of EVM proposals in GAVI Countries

Figure 10 Disparity in Coverage by Gender

Figure 11 Gender Inequality Index

Figure 12 Disparities in Coverage by Household Wealth

Figure 13 Communication Issues Identified in proposals

Figure 14 Analysis of HSS Human Resource Budgets

Figure 15 Human Resource Budgets in New vaccine proposals

List of Tables

Table 1 Illustrative Example of Synergies between IPV and Routine Immunisation

Table 2 Countries with IPV Route/Site/Co-administration Discordant with WHO Recommendations

Table 3 Example Kyrgyzstan Immunization Schedule

Table 4 Analysis of HSS Budget allocations

Table 5 Highlights from proposals

Table 6 Summary of HSS proposals

Table 7 Graduating and Intermediate Applications reviewed in IRC Nov 2014

List of Acronyms

AEFI	Adverse Effects Following Immunization					
AFP	Acute Flaccide Paralyses (Polio Surveillance)					
AHI	Adolescent Health Intervention					
BCG	Bacillus Calmette–Guérin (vaccine against tuberculosis)					
CC	Cold Chain					
CCL	Cold Chain Logistics					
сМҮР	Comprehensive multi-year plan for immunisation					
CSO	Civil society organization					
cVDPV	Circulating Vaccine-Derived PolioVirus					
DHS	Demographic and Health Survey					
DTP3	Diphtheria-Tetanus-Pertussis, 3 rd dose					
EPI	Expanded Programme on Immunisation					
EVM	Effective Vaccine Management, an assessment tool					
GAMR	Grant application, Monitoring and Review					
GPEI	Global Polio Eradication Initiative					
HCW	Health Care Worker					
Нер В	Hepatitis B vaccine					
HPV	Human Papilloma Virus					
HR	Human Resources					
HSCC	Health Sector Coordination Committee					
HSS	Health Systems Strengthening					
ICC	Inter-Agency Co-ordination Committee (for immunization)					
IDP	Internally Displaced Person					
IDSR	Integrated Disease Surveillance and Response					
IM	Intra Muscular					
IPV	Inactivated Polio Vaccine					
IRC	Independent Review Committee					
ISCL	Immunisation Supply Chain and Logistics					
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					
МоН	Ministry of Health					
MR	Measles-Rubella vaccine					
MSD	Measles Second Dose					
NITAG	National Immunization Technical Advisory Group					
-						

NRA	National Regulatory Authority				
NVS	New and underused Vaccine Support				
OPV	Oral Polio Vaccine				
PCV	Pneumococcal Conjugate Vaccine				
PIE	Post Introduction Evaluation				
PMU	Project Management Unit				
PQS	Performance, Quality and Safety (of immunization equipment)				
REC	Reaching Every Community				
RED	Reaching Every District				
RV	Rotavirus Vaccine				
SAGE	Strategic Advisory Group of Experts (WHO)				
SC	Sub Cutaneous (injection)				
SCM	Senior Country Manager				
ТА	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 Estimates of National Immunization Coverage				

Acknowledgements

The IRC acknowledges the support of the Gavi Secretariat Monitoring and Evaluation, Policy and Performance, and the Senior Country Managers and Vaccine Specialists for their assistance in preparation of documentation, country briefings and for training / orientation support and administrative and logistics support. Thanks is also expressed to GAVI Alliance partners WHO and UNICEF for briefings on polio eradication, health system strengthening, measles elimination, and vaccine procurement and supply issues.

Summary Report

Introduction

A meeting of the Independent Review Committee was undertaken between November 10th and November 24th, 2014 in Geneva. The purpose of the meeting was to assess proposals for introduction of Inactivated Polio Vaccine (IPV), new and underutilised vaccines such as JE, HPV, rotavirus and measles and rubella vaccines and health system strengthening. IRC reviewed 54 applications submitted by 44 GAVI eligible countries during the meeting. Country applications included 37 IPV vaccine introductions, 5 HSS proposals and introduction for each of the following vaccines: MSD (2), MR campaign (3), HPV Demo (4), Rotavirus (2) and JE (1). Twenty four reviewers from a range of disciplines took part in the review (see Annex 1 for list of members). Background briefings were provided by WHO, UNICEF, GAVI (M&E and other teams) and Senior Country Managers of the GAVI Secretariat.

Methods

Two reviewers were assigned to each country, and a country report was generated for each submitted proposal. Nine IRC members focussed on the cross cutting issues of cold chain and logistics, financial management and gender and equity. Proposals were assessed against application requirements as outlined in GAVI application guidelines, as well as taking into account the degree to which proposals meet the overall GAVI mission and strategic goals.¹ In addition to the individual country reports and recommendations, a global report was also developed focussing on main themes arising from the review (this report).

Main Findings

Main findings are summarised in figure 1 below. In addition to the information below, all 37 IPV proposals were approved with recommendations. The overall approval rate for all proposals submitted (n = 54) was 89%. Three out of five HSS proposals required resubmission (of six submitted one proposal was ineligible).



Figure 1 Summary of Findings

¹ a) The GAVI Alliance's **mission**: 'To save children's lives and protect people's health by increasing access to immunisation in poor countries' and

b) The GAVI **strategic goals**: (a) accelerate the uptake and use of underused and new vaccines; (b) contribute to strengthening the capacity of integrated health systems to deliver immunisation;

Highlights from this Report

Immunisation Coverage and Data Quality: For the last 4 to 5 years, the average coverage has flat lined in Gavi eligible countries at roughly 80% according to WHO / UNICEF estimates *(see section 2.1).* Half of countries had an administrative estimate that differed from the survey estimate by more than 10 percentage points the year of the most recent survey. It is pleasing to note however that a significant number of these countries have undertaken coverage surveys in the last 3 years, which points to increased efforts by countries to measure and take action on data quality issues. On the basis of the above findings, the IRC in this round is recommending more emphasis on higher quality EPI reviews and joint appraisals, and development of international standards for data quality assessment.

IPV and NVS proposals: There were 37 IPV proposals with an approval rate of 100% (see section 2.2). The approval rate is attributed by the IRC to the Global Health timeline for this initiative, as well as the generally high quality of proposal submissions and related introduction plans. Nevertheless, the IRC did note some general issues that are pertinent to high quality implementation of this initiative. Given that routine immunisation strengthening is the main platform on which the Endgame strategy is built, reviewers commented on the need to build synergies between vaccine introduction efforts and routine immunisation strengthening. Analysis of communication issues (see section 2.11) in the proposals demonstrates that over 64% of proposals with a communication strategy indicated that either health workers or communities were concerned about multiple injections at one visit. Both of these issues highlighted in this report have resulted in the IRC recommending situating IPV and NVS introduction efforts in the context of routine immunisation strengthening (see also section 2.3 on NVS) and longer term endgame strategy, as well as recommending more clear and tailored messaging and risk communication planning on multiple vaccinations at one visit (including use of two polio vaccines).

Health System Strengthening: The review of health system strengthening proposals was challenging, principally due to the complexity of the proposals as well as the requirement for reviewers to allocate proposals into one of only two categories - approval or resubmission. Overall, the IRC continues to report on the higher quality of these proposals, as assessed by clearer objective setting, a better focus on immunisation outcomes (particularly for harder to reach populations), stronger monitoring and evaluation frameworks and sound proposal development processes. Nevertheless, reviewers did take note of some emerging trends in proposal developments that present an increased risk of fragmentation and verticalisation of development assistance unless carefully managed. The tendency to establish project management units, to introduce EPI Gavi specific incentive schemes not linked to broader human resources policy or plans, limited development of sector coordination mechanisms and in some cases, weak investments in demand side strategy or CSO involvement, were considered by IRC reviewers to represent high sustainability and fragmentation risk. It is the view of this IRC that a focus on immunisation outcomes need not come at a cost of over verticalisation and fragmentation, and that this risk can be effectively managed through linking of EPI HSS investments to broader sector system developments and coordination mechanisms.

Supply Chain: Health System issues were also raised in relation to other themes in this IRC review. Supply Chain specialists and reviewers indicated that programs are constrained by poor infrastructure and weak management systems. In response to the pressures for ongoing vaccine introductions, countries often generate a "shopping list" of equipment and training needs that is not often linked to longer term supply chain strategic planning. Based on this

finding, the IRC is recommending that Gavi assist countries to develop longer term system design strategies and tools, as well as assist them with updated transfer of new technologies and management systems.

Human Resources and Governance: The IRC has noted the number of proposals identifying human resources placement, retention and motivation as a major constraint to systems and immunisation performance (*see section 2.12*). This has resulted in a number of countries specifying immunisation workforce incentives and salary top-ups, as well as short term training, as a primary area for investment. This being the case, the IRC is recommending much more emphasis on the linking of these investments to national human resources policies and plans including pre-service training systems and continuing education systems. Similarly, with respect to country-level governance, although in many countries there are existing ICC mechanisms, it is apparent that broader health sector coordination mechanisms and NITAGS are either not identified or technically supported to inform or perform decision making and coordination of investments for either HSS or new vaccine introductions.

Gender and Equity: The issue of equity is now a higher level country concern, with all of the HSS proposals intending to focus their investments on vulnerable groups. But despite this vision, it still remains the case that there are not always strong links between equity analyses and programmatic actions. Most proposals focus on geographic inequities rather than socially related variables (economic quintiles, gender, ethnic disparities, urban poor, conflict affected populations etc.). Mandatory equity indicators are not always used to evaluate HSS proposal readiness or measure actions. Importantly, sub-national data and analyses are not frequently applied either to track progress or justify strategy. Gender and equity analyses are also not often linked to programmatic actions, leading the IRC to recommend a much closer RED/Reaching Every Community focus on mothers' empowerment and decision making.

Sustainability: The issues of human resources and governance, in addition to expanding financial sustainability gaps associated with the pace of new vaccine introductions, have raised many questions in this IRC regarding the broader sustainability of this global health investment. Institutional sustainability is threatened by at times weak governance arrangements at country level and poor links to sector governance and political leadership and commitment. Programmatic sustainability is threatened by the depletion of human resources, and short term gap filling supply chain strategies. Financial sustainability is threatened by rapidly expanding immunisation budgets that are internationally financed, development partner financing of traditional vaccines (24 countries), and ongoing pressures on the financing of basic health services (leading to reduced outreach services). Finally, community sustainability is under threat due to under investments in demand side initiatives and CSO partnerships, which is particularly concerning given the rapid rates of urban and cross border migration, persisting socio-economic inequities, and the substantial movement of populations that are fleeing from conflict (IDPs and refugees). These observations have resulted in the IRC recommending a wider sustainability framework for Gavi, and development of indicators to track sustainability progress (see section 2.13). This approach is considered entirely feasible, given that Gavi has already commenced investments in many of these areas, and will increasingly focus on inequity reductions and sustainability dimensions in the upcoming strategic plan cycle (2016-2020). Defining sustainability parameters more clearly will enable Gavi to structure guidance, technical support and investment around these parameters, and provide more accurate measures for assessing progress towards attaining sustainability objectives.

Conclusion and Recommendations

In conclusion, this IRC noted the improved quality of proposal development, resulting in high approval rates. Although stagnant coverage is a concern, the IRC also observed that public health and immunisation systems across the globe are under constant pressures from external factors including human resources depletion, conflict and disease outbreaks, social inequalities, fragmented governance arrangements and variable levels of political commitment. But despite these challenges, coverage has been maintained, and through Alliance efforts, 64 out of 73 Gavi eligible countries have mobilized national commitment and international support for introduction of IPV in support of the Global Endgame strategy for polio eradication. This example provides a track record for the Gavi in mobilising global health effort towards a common objective, and demonstrates the potential for taking action on longer-term and more sustainable immunisation and health system strengthening challenges.

Summary Recommendations IRC November 2014

- 1. **Coverage:** (a) Increasing use of high quality EPI Review and Joint Appraisals should be applied in order to detect and respond to coverage gaps and challenges of data quality (b) GAVI Alliance should develop and monitor standards for data quality assessment exercises.
- 2. **Polio Eradication:** Technical support for IPV introductions should be considered as ongoing and focus on:
 - a. IPV in context of longer term routine immunisation strengthening
 - b. Additional training, guidance and technical support on multiple injections and MDVP
 - c. Clear and tailored messaging and risk communication strategy on multiple injections
- 3. **Supply Chain:** GAVI to support development of "Supply Chain System design" tools to assist countries to improve quality, efficiency and cost effectiveness of supply chains
- 4. *Human resources:* Finalize GAVI policy and operating principles for human resource compensation that are harmonized to international best practices and to national HR policies and plans. Consider longer term capacity building and opportunities to strengthen HR system in the country
- 5. *Health System Strengthening:* While maintaining a focus on immunisation outcomes, Gavi should reinforce the principles of aid effectiveness in HSS approaches through the following measures:
 - a. Clarifying conditions for use of PMUs as management instruments,
 - b. Clarifying linkages of HR incentives to wider sector strategy,
 - c. Support development of sector governance mechanisms as the primary instrument for HSS coordination (particularly with HSS programs funded through other sources)
 - d. Support Investment in demand side strategy and/or CSO partnerships to ensure needs of vulnerable groups are represented and addressed
- 6. *Gender and Equity:* Maintain a focus in Reaching Every District/Reaching Every Community Guidelines on mothers' empowerment and decision making
- 7. *Monitoring and Evaluation:* Gavi should encourage countries to include in all relevant planning documents the regular collection and increased use of subnational data for monitoring and planning purposes
- 8. **Governance:** GAVI Alliance should technically support the development of guidance and tools for country level governance of global health initiatives according to IHP+ principles
- 9. *Financial management:* There should be increased structuring of budget categories in HSS and VIG grant proposals to support improved assessment and oversight of cash based support
- 10. **Sustainability:** The GAVI Alliance should develop a longer term sustainability framework (incorporating institutional, programmatic, and financial and community domains) in order to structure investments and track progress towards attainment of sustainability objectives.
- 11. *Emerging Disease Outbreaks (Ebola):* In response to the outbreak of Ebola fever in West Africa (and possibly in other African countries subsequently), IRC requests that the Gavi Secretariat urgently prepare contingency plans for fast-tracking country applications for funding for recovery of health and immunization services.

2. Findings

2.1 Data Quality, Coverage

For the last 4 years, average coverage (not weighted for population) has flat-lined. Coverage among the 5 countries with the lowest coverage has risen little since 2000 and has not risen at all over the last 4 years.



Figure 2 Trends in DPT3 Coverage (WUENIC estimates July 2014)

Over the last 4 years the number of countries with coverage greater than 90% has risen some. However, this transition has slowed down in comparison to the first 10 years of Gavi. More worrisome, the number of countries with coverage below 50% has not changed for the last 8 years.

Figure 3 Number of Gavi-supported countries achieving various levels of DPT3 coverage WUENIC estimates, 2000 to 2013



Nigena, Chau, South Sudan, Somalia, C.A.N.

As figure 4 demonstrates, the administrative coverage estimates of half of Gavi-supported countries differ from survey estimates by 10% or more.

Figure 4 Comparison of Administrative Estimates to Survey estimates of DPT3

Comparison of administrative estimates to survey estimates of DPT3 coverage



Source: Administrative estimates and survey estimates for the year of most recent high quality coverage survey

For 62% of Gavi-supported countries, coverage estimates are available from a high quality coverage survey conducted in the last 3 years. On the other hand, for 17% of Gavi supported countries, no high quality coverage survey has taken place for more than 5 years.

Figure 5 History of Survey Coverage in Gavi eligible countries in the last 8 Years

Years elapsed since the last, high quality immunisation coverage survey



Source: WHO / UNICEF estimates of national immunization coverage

Recommendations Coverage and Data Quality

- 1. <u>Concerning coverage trends</u>, Gavi's country-tailored approach for countries with the lowest immunisation coverage must be based upon recommendations of recent, high quality EPI Reviews and high quality, annual Joint Appraisals.
- <u>Concerning data quality</u>, it appears that some of the current in-country approaches to data quality assessment and data quality improvement need to be considerably strengthened. These approaches should themselves be evaluated and more effective global guidance and support for data quality improvement should be provided.
- 3. With countries for which there is the greatest uncertainty about administrative estimates, high quality coverage surveys need to be organized more frequently than once each 5 years. The majority of Gavi supported countries now conduct high quality surveys once each 3 years.
- 4. Each year many WHO / UNICEF estimates of national immunisation coverage are significantly revised. This reflects the considerable uncertainty surrounding even the most rigorous attempts to estimate coverage based upon inadequate administrative and survey data. Gavi and the Gavi IRC should keep in mind the limitations of WUENIC estimates when using them as the basis for review and decision making, including decisions about performance based financing.

2.2 IPV proposals

Issue 1: Global Health Context for IPV Introduction

The Global Polio Eradication and Endgame Strategic Plan (2013-2018) was developed following a May 2012 World Health Assembly declaring the completion of poliovirus eradication a programmatic emergency for global public health. The Endgame Plan outlines a comprehensive approach for completing eradication including Strategic Objective 2 that calls for the introduction of IPV in all OPV-only using countries by the end of 2015. The primary role of IPV will be to maintain immunity against type 2 poliovirus while simultaneously withdrawing type 2 containing OPV globally at the current target date of April 2016. An additional key component of Objective 2 is strengthening routine immunization, as high immunization coverage is essential to achieving long-term polio eradication goals.

In view of the short timelines to introduce IPV (end of 2015), Gavi has waived some of the standard requirements for approval of new vaccine introductions. These include vaccine cofinancing requirements, the requirement to update the cMYP, the 70% DTP3 coverage filter and the acceptance of applications from graduating countries. The combination of the timesensitive programmatic emergency nature of polio eradication, the Gavi waivers introduced for IPV applications, and the significant additional resources and technical support that has been mobilized by WHO and partners to assist countries to meet the tight timelines for IPV introduction contributed to the high rate of approval for IPV applications (100%). However, for each country a list of actionable recommendations was generated to ensure that the introductions were feasible, safe and well-communicated.

Recommendation: Ensure that Tier 1 and countries with overburdened immunization systems (i.e. CAR, Guinea Bissau, Sierra Leone, etc.) receive the additional technical assistance and support that has been mobilized for IPV introduction and concurrent routine immunization strengthening.

Recommendation: Countries should be encouraged to look at IPV introduction in the context of the larger polio eradication endgame strategy including the development of detailed protocols for the global coordinated switch from tOPV to bOPV, cVDPV risk mitigation strategies at the time of OPV2 withdrawal, and strengthening of AFP and polio environmental surveillance.

Issue 2: Strengthening routine immunization and leveraging synergies with other vaccine introductions

In view of the fact that routine immunization strengthening is the foundation of the Endgame strategy and timeline (as well as of the Gavi Mission), reviewers observed that proposals were quite variable according to the extent to which they addressed routine immunization strengthening actions. Most countries with recent PIEs from previous vaccine introductions utilized the findings in planning the proposed introduction and some countries included synergistic approaches in their IPV introduction (Table 1). However, many proposals did not fully use the opportunity of IPV introduction to strengthen routine systems.

ILLUSTRATI	VE EXAMPLES OF SYNEF	(GIES		
Country	IPV Introduction date/ Other new vaccines, if any	Combined activities/synergies		
Eritrea	July 2015 PCV	Joint launch, training and social mobilization for both vaccines		
India	August 2015	Utilization of social mobilization network for (polio campaigns and routine) in introduction		
Kyrgyzstan	June 2015 PCV	Joint launch, training and social mobilization for both vaccines		
Solomon Islands	September 2015 PCV	Joint launch, training and social mobilization for both vaccines		
Mongolia	October 2015	Formative research survey to identify and address reasons for resistance		
Uzbekistan	July 2015	Joint planning and VIG budgets to better prioritize and address system-wide issues		

Table 1 Illustrative Example of Synergies between IPV and Routine Immunisation

Recommendation: Gavi should facilitate technical assistance to use new vaccine introduction efforts to 1) develop/strengthen systems to track children's immunization status using community-based health volunteer and worker cadre, and 2) develop detailed plans for community engagement that utilize targeted IPC and mid-media communication strategies to support full routine immunization.

Issue 3: Multiple Injections at One Visit

The IRC noted continued confusion in country applications regarding the WHO recommended IPV injection site (thigh as opposed to deltoid) and route (IM as opposed to SC) and co-administration guidelines (i.e. separation of injection sites by 2.5cm if given in the same limb, giving pentavalent in one limb and IPV/PCV in the other limb due to slightly increased local reactions to pentavalent). Table 2 illustrates some of these examples from the country proposals.

Table 2 Countries with IPV Route/Site/Co-administration Discordant with WHO Recommendations

Country	IPV Route, Site &, Co-administration
Sierra Leone	IM Thigh with Penta
CAR	IM Deltoid
Congo	Option for IM Deltoid
Guinea Bissau	IM Deltoid
Mauritania	IM Thigh 3cm apart from Penta OR IM Deltoid
Mali	IM Deltoid
Burkina Faso	IM Thigh 2cm apart from Penta,
Sao Tome	IM Deltoid
Ghana	SC Upper Arm
Rwanda ²	IM Thigh 2 cm from PCV

² Clarification already received from Rwanda on how this would be corrected prior to implementation

Recommendation: Despite the availability of WHO resources, countries require further training and support on the best practices for the administration of multiple vaccinations as this continues to be an issue in the IPV applications submitted for IRC review.

Country concerns around the acceptability of multiple injections occurring during one visit were flagged in many of the submitted proposals, with a varying degree of attention focussed on the need for strong communication plans that clearly communicate with all stakeholders (i.e. general public, HCW, etc.) the safety of multiple injections at one visit.

In countries with a heightened climate of vaccine hesitancy, national programs often modified or considered modification of immunization schedules to avoid providing more than two injections at one visit (Kyrgyzstan, Uzbekistan, Azerbaijan, Eritrea). Modifications such as these often result in increasing the number of required immunization visits which in turn increase the burden on HCWs, parents/caregivers, and health systems and may also negatively impact immunization coverage levels. In addition, national decisions to create or modify schedules to avoid multiple injections at one visit result in conflicting messaging on the safety of multiple injections.

Time	Vaccine	Comments
0-24 hours	HepB-1	1 injection
In maternity hospital	BCG	1 injection
2 months	Penta-1; PCV-1; OPV-1	2 injections
3.5 months	Penta 2; IPV	2 injections
5 months	Penta 3; PCV-2; OPV-2	2 injections
6 months	PCV-3; OPV-3	1 injection
12 months	MMR	1 injection
24 months	DPT	1 injection
6 years	diphtheria tetanus vaccine, MMR	2 injections

Table 3 Kyrgyzstan Immunization Schedule

Recommendation: Countries should reinforce to HCWs and the public the safety of multiple injections at one visit using WHO messaging and should not be encouraged to make unnecessary and burdensome changes to their immunization schedules to avoid multiple injections at one visit.

Recommendation: Countries require field-tested communication messages, using local acceptability data, on the safety and benefits of multiple immunizations at the same visit (i.e. earlier protection, fewer vaccination visits, etc.). These messages should be appropriately tailored to different target audiences.

Recommendation: There is a critical need for countries to develop strong vaccine risk communication plans. Technical assistance and support should be provided to countries to develop risk communication plans, prioritizing countries with significant vaccine hesitancy issues.

Issue 4: Use of Two Polio Vaccines

The IRC noted improvement in IPV introduction plans addressing the importance of communicating the rationale for the administration of both IPV and OPV to various stakeholders.

Recommendation: Countries should continue to ensure that there is clear and tailored messaging on the rationale for the use of IPV along with OPV. Neglecting to prepare appropriate communication messages may inadvertently undermine the use of OPV.

Issue 5 Updated Multi-Dose Vial Policy for IPV

The WHO Multi-Dose Vial Policy (MDVP) for IPV (November 2014) has been updated to indicate that multi-dose IPV vials are now approved for use for up to 28 days after opening provided that the product is appropriately handled and stored. Presently, the multi-dose vials of IPV are manufactured with the VVM on the flip-off cap, signaling that the vial must be discarded at the end of the immunization session, or within 6 hours, whichever comes first. With the new approval of use for up to 28 days after opening, the VVM placement will now be changed to the label of the vaccine vial. WHO strongly recommends that countries start using the IPV multi-dose vials for up to 28 days only after the VVM placement appears on the vaccine labels, expected from May 2015.

Recommendation: Gavi Secretariat and Partners should ensure timely communication with countries regarding the new MDVP and the anticipated timelines for changes in the product VVM placement for each individual country.

Recommendation: Gavi Secretariat and Partners should ensure that countries receive adequate support for the implementation of the MDVP including the training/retraining of HCWs.

2.3 Other NVS proposals – Measles, MR, HPV and JE

The IRC considered four applications for HPV Demonstration Projects (HPV Demo), three measles rubella (MR) campaigns, two Measles Second Dose (MSD), two Rotavirus applications (RV) and one Japanese Encephalitis (JE) application. This was the second Gavi IRC session during which a JE proposal was evaluated. This session also represented the second opportunity for HPV applications to implement the latest WHO SAGE recommendations on the use of a 2-dose HPV vaccine schedule.

Issue 1: Lack of integration of NVS proposals with current HSS grants that country may be receiving

For many countries, the funding for NVS (such as cold chain) appeared inadequate given documented country cold chain weaknesses. However, for countries that have ongoing HSS funding, often a major component of HSS is cold chain. The IRC did not know from reading the NVS proposal that this other funding stream was present in the country and may compensate for areas of seemingly inadequate budgeting.

Recommendation: NVS proposal should have an opportunity to state how ongoing HSS funding integrates/synergizes with the current proposal being evaluated by the IRC

Measles Second Dose

Issue 1: Leveraging the 15-18 month visit

WHO recommends administration of MCV2 at 15-18 months of age. This establishes a contact with the health system beyond the traditional target age group for immunisation of infants under 1 year, providing an opportunity to link with other child health programming and interventions such as Vitamin A supplementation, deworming, growth monitoring, etc. It also provides an opportunity to review the child's immunisation record and catch-up any missed doses of other antigens according to the national schedule.

Recommendation: Countries should consider using the MCV2 visit to link to other child health programming and interventions. This visit should also be used as an opportunity to review the child's immunisation record and catch-up missed doses in accordance with the national immunisation schedule.

HPV Demonstration Programme

Overall, the strength and clarity in these applications are improving; three of four proposals were approved. The target group, timelines, and integration of the Adolescent Health Intervention, and Cervical Cancer strategy have markedly improved in this round of proposals, and the Secretariat is to be congratulated for the technical assistance supplied to applying countries. Two excellent examples of integration were the Bangladesh proposal which proposed synergy with an already existing school health program, and Ethiopia which will use results from a prior HPV vaccine sensitization study to create sensitization and communication. Areas that remain problematic are described as issues below.

Issue 1: Inclusion of boys in the adolescent health intervention and IEC materials Countries are not consistently capitalizing on the opportunity to include males in this vaccine program that is otherwise gender-specific. The adolescent health intervention (AHI) is an opportunity to include boys when appropriate for that particular intervention. The core message is that boys and older males should be included at least in communication strategies as secondary beneficiaries. The exclusion that often prevails is neither technically based nor historically justified and carries the risk of negative consequences. Additionally, devising educational materials and messaging that includes both genders is another entry point for males in this vaccine program. Only one proposal discussed inclusion of males in the AHI.

Recommendation: Countries should be encouraged in the guidelines and description of the AHI to include males. Countries should be asked in the application about how the sensitization and communication strategies will be made appropriate for males.

Recommendation: Countries should state explicitly whether an informed consent/assent for HPV is required or not in the current country cultural or legal context.

Issue 2: Accessing out of school girls in the Target Group

All proposals used school as their primary target, and one application specifically addressed private school girls also. These out of school girls are some of the most vulnerable with the least access to care. Specific strategies to find them and deliver the HPV vaccine are an important equity component of a demonstration project. Gavi is to be congratulated that the guidelines now ask for a plan in reaching out-of-school girls. However, it remains a challenging area for countries. One country (Bangladesh) had a mapping exercise to find and describe all these out-of-school girls. If this mapping is not feasible as part of the demonstration project, it may be useful to suggest a formative research project or focus group discussion to help countries understand who and where these out of school girls are and devise appropriate strategies to reach them.

Recommendation: Countries are encouraged to conduct a mapping exercise or focus groups discussion to locate out-of-school girls. Once these out-of-school girls are mapped, the country should be encouraged to design appropriate delivery strategy (ies) for reaching them.

Issue 3: Providing a more detailed, carefully planned budget evaluation including planning for monitoring

Currently, the budget template in the proposal asks for line items, but countries seem to be inconsistent and lack clarity in amounts to include in the line items, and all applications had deficits in providing a realistic budget. One of the weakest budget planning components was for evaluation. Gavi is to be congratulated for making this a necessary requirement in the HPV Demo Proposals, and including technical assistance in the business plan. However, countries remain confused as to when evaluation is needed (ie after both year one and year two), and how to budget for it.

Recommendation: The application should be more explicit about the methodology, budgeting needs and timeline considerations for evaluation after year one and year two. Sub-unit costs and multipliers for the line items in the budget may help countries plan more realistically for the steps and financial needs of the HPV Demo projects.

Japanese Encephalitis

The one JE proposal from Cambodia did not have any new issues. This IRC supports the recommendations made in the July IRC report concerning JE proposals.

Issue 4: Other New Vaccine Issues

Rotavirus: One of the new vaccine applications for rotavirus (Nigeria) was a request for resubmission on a number of grounds. These include lack of clear information on how inequity reductions would be reduced through routine immunization strengthening, concerns regarding temperature monitoring arrangements for rotavirus vaccine as well as serious concerns regarding financial sustainability of new vaccine introductions.

Measles Rubella: Measles Rubella Campaigns: The IRC took some time to consider the applications for measles and rubella. The principal problem in two of the cases was the difficulty in the Cameroun case in determining accurate assessment of coverage, particularly given the very high numbers of internally displaced populations in the country, as well as recent coverage rates close to 80%. In the Zimbabwe context, there were serious concerns regarding the financing of routine immunization services, leading to expressions of concern from this IRC as to whether the program of rubella vaccine introduction can be sustained. The Sierra Leone MR Campaign case was assessed to be a resubmission based on the current collapse in routine immunization services resulting from the Ebola outbreak. The resubmission was not based on technical weaknesses of the proposal, but rather on the current epidemiological context. The IRC therefore considered that Gavi should technically and financially support contingency planning for revitalization of immunization services in that country post-outbreak (see final section of this report).

2.4 Health System Strengthening

General Overview: Overall, 5 countries were reviewed in this round. A sixth country (Bolivia) was ruled to be ineligible, as this was a graduating country with WUENIC estimates above 90%. Table 4 analyses HSS budgets according to Government, development partner and CSO allocations.

Countries	HSS Budget Allocation (in millions of USD)			
Countries	Total	Government	CSO	Partners
Cambodia	18	18	0	0
Gambia	6.2	4.6	0.3	1.3
Mali	20.1	20.1	0	0
Senegal	13.4	11.9	1.5	
Tajikistan	9.5	6.9	0	2.6
Totals	67.2	61.5	1.8	3.9
Percentage	100%	92%	3%	6%

Table 4 Analysis of HSS Budget Allocations

*Note: Bolivia HSS proposal is not included in this list.



Figure 6 Allocations of HSS Budget by Constituency

HSS Issues

The overall strengths of the HSS proposals were as follows:

- Inclusive and participatory for proposal development process: reinforced in-country dialogue (MoH, Alliance Partners, etc.)
- Improved quality of the proposals from round to round
- Completeness of the application (deeper understanding of the guidelines and the budget templates led to more complete sections of the proposals, including budget summaries provided) – 4 out of 5 summary tables match correctly for the HSS
- M&E framework and results chain well-articulated in proposals (including Gavi immunization-related indicators (mandatory);

The overall weaknesses of the HSS proposals were as follows:

- Lack of alignment of NVS/HSS applications with in-country planning cycles and policies
- Insufficient description in proposals of the sector coordination mechanisms required to oversee and coordinate the HSS investments
- Insufficient focus of HSS investments on equity or gender-related barriers, particularly in relation to the strategy to be applied to reach these disadvantaged groups
- Lack of clear links between HSS and NVS to boost routine immunization there's no holistic view of Gavi efforts at country level
- Linkages and/or learning from previous or on-going HSS grants (delays, turnover of personnel, financial management, innovative strategies, etc.) not strongly considered for new HSS applications
- No clear integration with Primary Health Care Services and other health interventions in some cases
- Participation of CSO and allocation of budgets for this purpose were not explicitly seen in some of the proposals, and nor was demand side strategy adequately articulated
- Lack of budget allocation for HSS evaluation, and in some cases, lack of alignment of HSS budget with HSS strategy
- Underestimation of organizational and institutional risks

Table 5 Highlights from proposals

4 out 5 proposals demonstrate very strong focus of HSS strategy on specific areas/themes (e.g. bottlenecks): Cambodia (high-risk communities), Mali (low performing districts in the North), Tajikistan (mobile groups), Bolivia (underserved municipalities) (although Bolivia was assessed to be ineligible due to coverage status), Senegal (20 low performing districts) HSS proposals in three countries promote verticality and duplication within the health system (e.g. of PMUs). PMUs in the Tajikistan, The Gambia and Bolivia (although Bolivia was assessed to be ineligible due to coverage status)

There are no evidence that HR policy/arrangements proposed in the HSS proposals are integrated in overall health sector (e.g. of incentives, top-ups). Serious problem in Cambodia.

Lack of multi-sectorial participation of relevant constituencies (community sector, private sector, academia) in implementation of the HSS activities. Problem in Cambodia and Bolivia, Tajikistan.

Dissonance on budget allocations within the HSS investments. Demand generation objectives/activities underestimated in overall HSS investments requested by the country (Cambodia)

Table 6 summarizes the main HSS proposals according to budget, main content areas of each proposal and IRC recommendations.

Table 6 Summary of HSS proposals

Country	Type of application	Cash support requested (US \$)	Gavi budget ceiling (US \$)	Potential to strengthen the health system	HSS approach	Outcome	Comment
Cambodia	HSS new application	\$18 million	\$21.5 million	+	High risk approach, strengthen HR and supervision, Incentive schemes, improved data management	Resubmission	Strong focus on high risk communities, significant HR incentive investment without strong links to HR policy, weak demand side investment
Gambia	HSS new application	\$4,619,977	\$5.5 million	+	Strengthen HR, planning, surveillance & financial management with support for logistics, service delivery & demand generation.	Resubmission	No link between proposed activities and actual vaccination coverage in country. 5% for activities delivered by CSOs.
Mali	HSS new application	\$20,160,000	\$ 20.16 million	+	Strategic focus on low performing regions, resilience strategies are in place for the insecure regions of the country, Performance-based schemes to be introduced with CSOs ; Cold chain and data quality improvement	Approval with recommendations	Budget inconsistencies, gender and supply chain issues, product presentation for rotavirus to be reviewed, PBF scheme implementation to be clarified. Strategy for waste management to be defined. Institutional risk: underestimated
Senegal	HSS new application	\$13,439,440	\$14.6 million	+	Strengthen cold chain; improve data systems & financial management, increase service delivery & demand generation in 20 districts with low coverage.	Approval with recommendations	44% of total budget dedicated to cold chain equipment and logistics. Strong focus on unreached areas. 11% for activities delivered by CSOs.
Tajikistan	HSS new application	\$9,660,000	\$11.50 million	+	Strategies for hard to reach populations by increasing number of mobile teams. Improvement of village health centers and PHC facilities. Improve health information system	Resubmission	Program management not oriented towards sustainability. Strategies for outreach require better description including health information system at basic level. Cold chain 13.4% of the HSS grant that is required for NVI for 2015.

Recommendations HSS:

Gavi, while maintaining a focus on immunisation outcomes, should reinforce the principles of aid effectiveness in HSS approaches through the following measures:

- 1. Clarifying conditions for use of PMUs as management instruments,
- 2. Clarifying linkages of HR incentives to wider sector strategy,
- 3. Support development of sector governance mechanisms as the primary instrument for HSS coordination
- 4. Investment in demand side strategy and/or CSO partnerships to ensure needs of vulnerable groups are represented and addressed

2.5 Supply Chain and Waste Management

General Overview: A total of 401 recommendations /comments were made in the 54 funding applications reviewed by the IRC. 284 of these recommendations/comments were made to countries and the balance of 117 made to the Gavi Secretariat. 24% (68) of the recommendations/comments to countries were related to supply chain issues.



Figure 7 Number of Recommendations on ISCL

The 68 ISCL related comments/recommendations cover 16 different aspects of the supply chain. This is a clear indication that the supply of equipment to address deficits in storage capacity is only part of a more global solution to improving supply chain standards, quality and efficiency.

Figure 8 Supply Chain Issues by Type in IRC Comments and Recommendations



Whilst 19 ISCL related recommendations relate to vaccine storage capacity, for the most part these statements indicate lack of clarity rather than inadequacy of storage space. The same applies to the 10 recommendations relating to equipment (14.7%).

The NVS proposals reviewed do not indicate any specific measures, other than "Find and Replace or Increase equipment" to improve ISCL quality, efficiency and cost effectiveness.

Three of the HSS proposals target improved data management systems. This contributes to ISCL quality improvement, but falls short of the goal of "ISCL system design" improvements which lead to improved ISCL quality, efficiency and cost effectiveness. Furthermore, more and more countries are adopting web based computerised logistics information management systems (LMIS) and a number of countries are attempting to integrate EPI ISCL parameters as a real time program management tool rather than data periodic reporting tool. This is turning out to be a real challenge.

EVM assessments and improvement plans remain problematic. A review of the 46 countries which submitted applications to Gavi shows that 19 countries were due to conduct EVM assessments in 2014 having last conducted assessments in 2011. Assessments were conducted or are in progress in only 13 of these countries in 2014. Only 3 of these 13 countries did an assessment within 36 months of the preceding assessment. The average interval between assessments is 40.6 months. Additionally Chad and Congo, which conducted EVM assessments in 2010, have still not conducted follow up assessments 4 years later.

Waste management using incineration or barrel burning is practiced to some extent in 30% of the 46 countries submitting applications. Only 1 country (Lesotho) claims that all waste is processed in district level incinerators. 3 countries are practicing or introducing non-incineration disposal techniques. Policies in some form are in place in most countries. Much remains to be done to guide and encourage countries to adopt improved waste disposal practices.

Issue 1 Network Design

Supply chains improvements focus on adding equipment to increase vaccine storage capacity, rather than reviewing "**supply chain system (network) design**" and introducing measures to improve supply chain quality and efficiency.

Programmes are increasingly constrained by poor infrastructure and inefficient immunisation supply chains. Increasing performance beyond existing levels to support the ambitions for raising coverage; improved quality of immunisation service delivery and introducing new vaccines is going to be difficult without rethinking the network design for the future. The need for meaningful, systematic improvements in immunisation supply chain infrastructure and systems is essential. Long term fragility may also require a country tailored approach.

Recommendations:

- The Gavi Alliance with expertise from industry, support "Supply Chain System (Network) Design" improvements in countries to maintain product quality and patient safety through supply chain integrity rather than the present focus of equipment supply to address shortcomings in supply chains. Support change of mind from common practise to best practise.
- 2. The Gavi Alliance support countries to fully understand, consider and adopt the "6 Rights" of immunisation supply chain logistics

Right Product

Right Quantities

🗹 Right Place

- 🗹 Right Time
- Right Quality
- Right Costs

- 3. Gavi draw upon technological and systemic advancements and innovations (tracking and tracing), and vast experience of industry (pharmaceutical in particular) to improve ISCL guidelines and provide guidance to national programs and alliance partners to achieve the above recommendations.
- 4. Gavi support science based relevant tools and metrics that will allow the organisation to assess risk across the supply chain (Risk Management for Temperature Controlled Distribution).

Issue 2: EVM Assessment

EVM assessments and improvement plan status provides valuable but not sufficient indicators of supply chain readiness, either to manage vaccines in the current immunisation schedule or for new vaccines planned for introduction.; also standards of EVM assessments vary and reporting of improvement plan implementation progress is generally poor. Furthermore countries are not complying with the Gavi guidelines for EVM assessments at 36 month intervals or less.

Recommendations:

The approach of the 2014 WHO/UNICEF Joint statement of "Achieving Immunisation Goals with Effective Vaccine Management" is adopted which ensures inclusion of supply chain upgrade plans, supply chain logistics managers are positioned to provide improvement plan implementation oversight and ensures close linkages with HSS investments.

Issue 3 Monitoring vaccine Stocks

Continuous monitoring of vaccine stocks and movements, vaccine storage temperatures and equipment condition is essential as is prompt and accurate communication of information to senior management for management action. Efforts to establish real time monitoring of supply chains, whether as standalone ISCL data management systems or linked or integrated into health system logistics management information systems (LMIS/DHIS2) have not facilitated continuous real time monitoring of supply chain status. There is insufficient information flow and experiential exchange between countries and insufficient guidance provided

Recommendations:

- 1 Gavi support information flow of web-based EPI and health systems data management experiences between countries through regional eHealth workshops
- 2 Gavi initiate a mechanism for technical guidance as a component of its "innovations" activities to countries seeking support introduce real time ISCL monitoring (Senegal for example) through HSS cash support.

Issue 4: Waste management

Immunisation waste management practices are less than adequate in most Gavi-supported countries. The volumes of infectious immunisation waste continue to increase however. Some countries introduce incineration technology, but often without appropriate guidance and program planning. UNICEF shipped 2.79 billion doses of vaccine in 2013 which means that approximately 2.5 billion syringes were issued amounting to 12,500 tons of plastic waste in 2013 alone.

Recommendations:

- 1 The Gavi Secretariat creates in-house expertise in waste management or outsources the responsibility. Preliminary tasks to be assumed are:
 - a. Explore measures to make pharma suppliers responsible for immunisation waste management. Safety boxes are bundled with syringe supplies, can this approach be extended to include final disposal solutions.
 - b. Guidelines to countries for the safe and cost effective disposal of immunisation waste.
 - c. A review of Gavi waste management guidelines to encourage and orient countries towards improved waste management practices

Issue 5: The vaccine supply chain evaluation in the IPV proposals (37)

The immunization supply chain is evaluated for each country with the objective to define how well the country is prepared and capable to store, transport and manage the vaccine stocks, and ensure delivery (repetition) of potent vaccine in the right condition, right quantities, at the right place, at the right time. For this the key documents studied are the latest EVM report, the status of improvement plan, any cold chain related inventory or assessment report, the activities in the cMYP, besides the new vaccine application, the pre-screening report and joint / internal appraisal.

The key strengths and weaknesses in the supply chain and the progress made with regard to the recommendations provided in the improvement plans have been assessed.

The IRC reviewed 37 IPV introduction applications. Most countries provided the status of implementation of the improvement plan, albeit for an out dated EVM assessment. A few countries provided a good analysis of cc capacity, and most have a good alignment with cMYP.

On the other hand, in many cases, the EVM report is too old (more than 36 months), and an updated information on the supply chain management, or recent progress made in the area is missing. This made it difficult to define precisely the actual status of the supply chain. While several countries have introduced a new vaccine in the last 12 months, only a few have submitted a summary of the PIE, and the PIE reports have not always been available.

The key issues encountered in many countries concern:

- Temperature recording and handling of vaccine in freezing environment
- Cold chain capacity
- Condition and maintenance of cold chain equipment
- Vaccine stock recording and management, including information on stock-outs
- Timely distribution of required vaccines
- Waste disposal

Unless these aspects are well planned and implemented there remains a serious threat to the quality of the vaccine in the supply chain. Such situations may end up with the vaccines having lost their potency before being provided.

In particular, in some of the fragile / post-conflict countries, the supply chain is fractured or totally inexistent beyond the central level. This raises questions of the programme capacity to ensure delivery of quality vaccines to the children. Additionally, none of the countries have provided any information how they plan to do the switch from tOPV to bOPV which was not requested in the application.

Based on the present exercise, and in order to get a more complete and clear picture of the supply chain, in future, it is recommended to include more detailed information in the application forms. Two tables (with sample data) are presented as examples in annex 3.

Recommendation: Follow up with technical partners on Improvements Plans in Fragile States

Ensure timely follow-up by the technical partners to support the implementation of the HSS / Improvement plan, particularly in the fragile states.

Issue 6: Multi dose vial policy (MDVP) and vaccine presentation in IPV proposals

8 countries have requested a single dose presentation. In most cases (with one exception) this decision is based on the lack of awareness and information regarding the possibility of implementing MDVP on a 10 dose presentation. The remaining countries have opted for 10 dose presentation. In a significant number of countries for which IRC recommended to consider postponing IPV introduction, a recommendation was based on immunization supply chain issues currently faced by the country.

Most countries base their choice for vaccine presentation on balancing the vaccine wastage and cold chain capacity. The WHO and UNICEF (Nov. 2014) newly defined IPV Multi-dose vial policy states that multi-dose vials of currently available IPV are approved for use for up to 28 days after opening, for vials having the VVM on their labels. Therefore, countries are likely to change their initial choice of single dose presentation to 10 dose presentation, which besides reducing the wastages, offers the advantage of reduced storage volume requirements.

Choice on IPV presentation may have significant impact on vaccine storage requirement at central and intermediate level, highlighting the impact on MDVP implementation in the countries. Depending on IPV presentations, incremental vaccine storage volume at central level may vary from 3,8% with IPV 10 dose vial, to 24,5% for IPV 1 dose vial for a full immunized child³, while vaccine cost increases by 7.9% or 14.7% respectively (without wastage consideration). Though the impact at the service delivery point is high, in general the total storage space required at service delivery is far below (less than 10 litres for an annual target population of 1200 infants) what available (more than 25 litres) is. The issue in this case is the availability of a properly functioning cold chain.

Switching from one vaccine presentation to another may expose countries to programmatic issues (i.e., over estimation of cold chain capacity requirement, high vaccine wastage, increased cold chain and vaccine costs); and unnecessary actions (retraining of HC workers,

³ Estimates for a country using the following vaccine schedule and presentation: 1 dose of BCG and 4 doses of OPV, both in 20 dose presentation, 3 doses of Pentavalent, 1 dose of measles, 1 dose of yellow Fever and 3 doses of TT for pregnant women, all in 10 dose presentation, and finally 3 doses of PCV in a single dose presentation.

dissemination of new training material and guideline, increasing supervision). The latter may require an additional financial contribution through a second VIG.

Recommendations: MDVP and vaccine presentation

Ensure proper mechanisms for providing timely and comprehensive information to countries for a better informed decision making process. Countries should be informed of the different options and their consequences. This applies specially to those countries that have had their application approved before this new policy was known.

Issue 7: Documents for Evaluation

Based on the current experience, for enabling the IRC to conduct a comprehensive evaluation of the supply chain, the following recommendations are provided:

Recommendation: documents for evaluation

The documents listed below may be requested from the countries or collected and provided to the IRC members in a single folder for each respective country. (Some of these are already requirements as per Gavi Guidelines)

- Last 2 EVM reports (for those countries which have completed two EVMs)
- Latest status on implementation of the Improvement Plan
- cMYP
- Cold chain inventory or any report on the CC inventory status Evaluation of capacity (e.g. from Logistic forecasting tool)
- SCM trip report
- Pre-screening with some inclusions
- PIE report of the last vaccine introduction
- Organograms of the vaccine supply chain with number of vaccine stores
- Mention if push or pull system for vaccine request
- Status of cold chain rehabilitation plan with budget.

Recommendation: Application form

In addition to the two tables mentioned in Annex 2 to be included in the application forms, the country should be requested to provide a summary on experience of introduction of new vaccine in the last 12 months – Challenges and lessons learnt. This should be available from the PIE document, but if not, separate information should be obtained. This will give a more accurate picture of how the country has managed the vaccine flow in the country, in case the supply chain strengthening process was incomplete, as has been seen in a few countries.

Recommendation: Pre-screening form

The pre-screening form is very helpful to get a summary status of the application. The same may be further strengthened with the following points:

- 1. Is EVM report submitted? Its date
- 2. Is status of IP submitted? Its date
- 3. Vaccine introduced in the last 12 months with details of antigen and date
- 4. Inputs / feedback from the cold chain team

2.6 Vaccine Markets and Product Selection

Issue 1 Multi Dose Vial Policy (also see ISCL recommendations)

In the present round of IRC applications, a number of countries have opted for single-dose or 5-dose IPV vials. This choice has largely been made to minimize wastage. Countries made this choice without knowledge of the very recent WHO guidelines relating to the option to use of IPV for up to 28 days after first opening (assuming certain conditions are met). Thus a 10-dose vial would mean a lower cost per dose and result in lower wastage rates than 5-dose vials in most circumstances.

From the specific to the general, introducing and sustaining vaccines in national immunization programmes is becoming more and more complex because of the number of parameters and factors to take into account. Assessment of these factors is needed to make the best choices possible both from programmatic suitability and financing sustainability perspectives. Among the factors to consider are: the efficacy, safety, cold chain, storage and distribution requirements, operational costs, environmental impacts, presentation and packaging, number of doses per course, vaccine prices, supply constraints, and what vaccines and technologies are in the pipeline.

All these factors and others can dramatically impact the success of new vaccine introduction, particularly in low-resource settings.

Despite recent efforts of WHO and UNICEF Supply Division, the IRC is uncertain whether countries are fully aware and continuously informed by partners about this complexity and its impact. National ICCs and NITAGs are not being sufficiently assisted to properly assess these elements when preparing proposals to Gavi. Nor do they always fully understand the short and long term consequences of their product choices on immunization programme and on health system financing.

Recommendation

IRC recommends to Gavi and partners that they should provide to national programmes regular, rigorous and unbiased information and data on product features and presentations, vaccine market dynamics and methods so as to select better those products meeting the programmatic suitability and financial sustainability requirements.

2.7 Financial Management

Issue 1: Lack of linkage between activities and budget

Budgets presented by countries across the different funding windows are seldom sound and coherent. This indicates lack of capacity rather than lack of attention. A budget should clearly reflect the relative relevance of critical activities. It is a management tool that requires careful consideration. Budget design is a determinant of the success of any activity or project. In the IRC proposal review process, appropriate attention ought to be paid to the assessment of the budgets presented.

The requirement to provide a narrative on the budget is generally not taken very seriously in proposals. There is little guidance from Gavi to the countries as to the expectations related to budgeting and the presentation of budgets. Particularly with regard to budgeting for HSS and presenting comprehensive information linking activities and budgets coherently and articulately, more guidance and support are required.

Recommendation

Gavi should provide clear guidance on the presentation of budgets across the different types of Gavi support based on the principles of activity-based budgeting. This guidance will not constitute an attempt to micromanage countries' EPI activities, but rather to support countries in achieving accountability and transparency.

Issue 2: Lack of detail compromises budget assessment

Most budgets presented in country applications are lacking critical detail that is essential for an assessment of the appropriateness. The templates provided to countries in Excel format are well designed in principle but require supporting documentation by the country. Transparency may require that activity-related line items be broken down further. Assumptions on unit costs and quantities need to be presented and made plausible.

Neither countries nor reviewers can fall back upon guidance relating to limitations to budgeting or the allowance of expenses, e.g. number of vehicles for supervision (Gambia), lump sum for office set-up (Tajikistan). Without guidance for budget allocation, countries have an open door for the budget.

Unit costs related to human resources require particularly precise justification. Human resource expenditures - for salaries, salary top-ups, incentive payments, etc. - need to be in line with valid government guidelines (where they apply), with market conventions and with other existing schemes that the government or partners may have implemented. The country must further demonstrate that these payments do not cause distortions within the health system and that they are sustainable (beyond the end of Gavi funding).

Regarding HSS proposals, there is also an apparent lack of transparency regarding allocations for CSOs/NGOs, in so far as there was limited evidence of CSO planning involvement and financing for HSS. Out of the five HSS proposals reviewed, only two (Senegal and the Gambia) feature an explicit respective budget for CSOs.

Recommendation s:

 Gavi Secretariat should routinely undertake financial analyses of proposal budgets (HSS, NVS) to assess the overall budget structures as well as budget allocation according to types and categories of activities. The grant should be adjusted based on findings of financial analysis and the main objectives of the grant.

- 2. Gavi should communicate the need for clear explanation of budget line items and outline a format for presentation of unit costs, budgeted quantities and respective explanatory information. The current templates do not provide the required degree of detail.
- 3. Whenever proposals contain HR payments, Gavi should request documentation certifying the appropriateness of amounts paid, e.g. government guidelines and standards, MoUs between development partner organizations. Gavi should also request a demonstration of the intervention's sustainability (refer also to section on Human Resources).

Issue 3: Budgeting for PBF

None of the HSS proposals presented to the November 2014 IRC reflects a proper understanding of performance-based funding at sub-national levels, which is the idea put forward by Gavi apart from Gavi's PBF approach that is applied to HSS grants at the national level. Further guidance may be required if this aspect should constitute an objective in Gavi supported countries.

Recommendation

As Gavi has expressed its support to PBF approaches at the sub-national level, strong evidence-based guidance needs to be provided to countries preparing HSS grant proposals. The current documentation is clearly not sufficient and does not contain information as to what works, what does not work and why.

Issue 4: Multiple funding windows - capitalizing on synergies

Most countries manage several windows of Gavi funding. The current suggested presentation of separate budgets per window makes it difficult to assess the reasonableness and coherence of single budgets. Not only should the presentation of the budget make clear how the new activity fits within the overall activity framework of the countries EPI, also would the integrated budget potentially facilitate the identification of synergies and thus increase efficiency. The presentation of similarly high amounts for training and document production in separate budgets for the parallel or subsequent introduction of new vaccines by a country seems questionable (e.g. Sierra Leone IPV VIG [74.5% 'Training and meetings'] and MR VIG [76.7% 'Training and meetings']). However, the attempt in one of the reviewed proposals to squeeze two introductions and a campaign budget into one was also inappropriate (Zimbabwe), partly because the current NVS budget template is too simple for this purpose.

Recommendation

Gavi should provide guidance on the appropriate presentation of linkages and synergies between budgets for separate funding windows. A template allowing the analysis of overlaps and synergies would identify potential efficiency gains. ICCs should look at budgets for separate funding windows and promote transparency and consistency and seek for linkages and synergies between these windows.

Financial sustainability (to complement section "sustainability")

Issue 1: Insufficiency of toolkit provided to guide activities towards financial sustainability

Financial sustainability forms one core area of concern within the discussion of ensuring sustainability of EPI during and beyond the end of Gavi support. One activity towards improving financial sustainability would be to ensure financial management capacity building within the EPI structures.

A tool that Gavi provides to countries is the Excel template 'Gavi HSS Detailed Budget, Gap Analysis and Workplan'. The instrument allows the country to present the EPI funding gap over the envisaged timeframe of HSS support. The gap analysis in the template and the brief reflection in the proposal form remain without consequences. There is no common understanding as to what percentage of the overall EPI budget may constitute a serious funding gap that requires immediate attention and (joint) development of a plan of action. Foresight becomes particularly critical in the light of graduation.

The cMYP (and the associated costing tool) is not suited to a very fluid context with many new vaccines being introduced quickly. (Most cMYPs presented with the new proposals do not include the envisaged new vaccine introductions and unfortunately also do not cover enough years ahead to allow for a proper assessment of financial sustainability.)

Recommendation

Gavi should provide further support in addressing the need to provide a clear forecast of financial commitment aligned on graduation period. There is need for a flexible financial modelling tool that also captures the dynamics around co-financing. Financing of operational costs, traditional vaccines, and HR investments require more attention.

2.8 Gender and Equity How gender and other inequities affect the core business of Gavi







There are gender dynamics (map of Gender Inequality Index in Gavi countries) that impact access to and demand for immunization services, and the implementation of RED/REC strategies need to empower primary care givers, usually the mothers. The map of disparity in DPT3 coverage by sex indicates that gender disparity still exists at the national level; however, gender gaps may be may be more pronounced across disaggregated socioeconomic groups at sub-national levels. There is a need to unmask these disparities.

IPV Proposals

The most common equity barrier identified was geographic (24), followed by economic (14), conflict and security (6), nomadic populations (5), and ethnic disparities (6). However many of the proposals did not provide clear or specific plans to deal with the inequities. Many countries say that a RED strategy was adopted to address inequity issues but there is no relevant information on outcome/evaluation of the strategy. Because of low coverage, some countries should conduct equity analyses, especially in the under-covered/uncovered areas to highlight and better address related barriers. The Pre-screening sheet for IPV applications did not comment on gender and equity; however several SCM appraisal reports highlighted equity issues and in some instances, the SCM requested clarification and proposed that the country considers carrying out equity analysis.

HSS and NVI Proposals

In general countries gave priority to inequities related to geographic barriers and fragility but paid little or no attention to gaps in coverage related to wealth quintile, ethnicity, gender (including mother's education), or other sources of vulnerability (nomads, forced labour). In HSS proposals, countries are asked to include two mandatory equity indicators in the M&E framework. The mandatory indicator of geographic equity that Gavi requires is "% of districts with DPT3 coverage greater than or equal to 80%". This is an indicator which WHO and UNICEF ask countries to report on annually on the Joint Reporting Form. See Annex 3 for the JRF data on this from 2013 where one can see that 2 of 73 countries do not report.

Another indicator is vaccination coverage by wealth quintile that is mapped below for Gavi countries, showing disparities persisting in many countries. Many countries DO NOT include this in their M&E Framework.

Figure 12 Disparities in Coverage by Household Wealth



Source: most recent DHS or MICS reporting DPT3 coverage by wealth quintile

Issues

- Gavi is not well-equipped to provide technical advice and guidance to its country
 managers and technical teams on gender and equity. Application forms do not provide
 clear guidance on what is expected nor do Alliance partners and SCMs screen
 systematically for quality equity analysis of available data (DHS, MICS, other sources) on
 coverage gaps by factor (wealth quintile, geography, ethnicity/caste, gender barriers).
- Most proposals do not demonstrate a clear link between equity analysis and programmatic actions contained in the proposal. Many countries do not respond to the barriers defined in their analysis in a way that tackles inequity, including gender inequity, and do not include appropriate indicators in their results framework. Some proposals fail to include both mandatory equity indicators.

Recommendations

- The IRC reiterates its recommendations from the meetings since November 2013 (Annex 4).
- The IRC recommends that Gavi consider creating a position for a gender equality and equity specialist (P5) with experience in programming for equity in the health sector in Gavi to provide technical advice and guidance to SCMs and technical teams.
- Given the new binary nature of the IRC decision-making process, countries should be advised that proposals which fail to include both mandatory equity indicators will be returned for resubmission.
- Gavi should encourage countries to deliver outreach activities including RED/REC and Intensified Immunization Days that focus on mother's empowerment and decision-making to improve coverage. This requires targeted and appropriate communication
strategies. Countries could benefit from cross learning from equity-related evaluations in other Gavi countries to undertake equity-based micro planning at the country level.

- Gavi should reinforce JRF reporting on the geographic equity indicator by asking countries to report, on each proposal (NVS or HSS) and once each year, the % of districts with DPT3 coverage falling into various bands of DPT3 coverage :<50%; 50% 79%; 80% 89%; and 90% and above.
- Countries should analyse and act on sub national data where coverage is <50% (preferably at district level) by developing tools and indicators, preferably at the district level, related to gender specific interventions. Research on sub-national equity issues and planning should be encouraged as part of proposals.

2.9 Monitoring and Evaluation (AEFI, Surveillance, M & E) and data utilisation

The IRC reviewed 42 countries proposals for compliance with the M&E requirements (1 country without a report). To summarize, for existing functioning AEFI surveillance systems out of 41 countries reported, 46% report having a functioning AEFI surveillance system. Out of 41 countries reported, 56% reported planning for a PIE. (Note, the Gavi proposal guidelines did not specify if the country had to include a PIE.)

M&E data issues (all windows)

Progress in improving the quality of routine data related to immunization was weak.

The review found that an *increased use and analysis of data* to improve program management and indicate where to find unimmunized children is needed. Few proposals provided any data at the sub-national levels, although this type of administrative reporting is found through the indicators already reported in the annual JRF (i.e., % districts at different coverage range levels and % dropout rate). In addition, few countries mentioned conducting regular EPI reviews.

Recommendation 1 Data Collection, Analysis and Use

The IRC recommends Gavi encourage countries to;

- Include in all relevant planning documents the regular collection and increased use of subnational data
- Conduct and include the results of high quality country EPI coverage surveys and reviews at least every 3-5 years, to encourage the in-country use and analysis of results to improve program management as well as update the cMYP as needed
- Add to systematic district level monitoring the addition of a set of equity indicators with a focus on country specific indicators such as women's literacy rates by district.

HPV demonstration issues

The purpose of HPV demonstration window is to capture and disseminate countries' early experience reaching a new target group with HPV vaccination. This being the case, it is important to ensure that the evaluation, documentation and dissemination are an essential requirement of HPV demonstration funding.

Recommendation 2 for HPV Demonstration; Include a budget for evaluation

 Gavi's guidance for the HPV demonstration window should require a budget allowance included for follow up evaluation (including evaluation framework and timeline) and documentation/dissemination of results and recommendations to carry out the next steps after demonstration outlining the 1) lessons learned, 2) steps to expand nationally, and 3) If there is a need to change the strategy, to specify the steps to move forward.

AEFI and Surveillance Issues

Almost half of the countries reported having functional AEFI system, and few addressed a risk communication plan to respond to adverse events. It is important to recall that a single report of an adverse event following immunization (AEFI), real or imagined, can derail an entire national immunization campaign. This was recently confirmed in Vietnam when a media report of an alleged adverse event was reported, resulting in the Minister of Health closing down the entire programme. Similar examples exist from other countries e.g. Jordan, as well as from polio eradication activities.

In addition, while 46% of the countries mentioned having an AEFI system in place, few discussed the integration of surveillance of adverse events, AFP and other vaccine preventable diseases. Integrating surveillance activities would not only improve surveillance but would capitalize on the significant experience gained by strengthening AFP surveillance for GPEI and strengthen VPD and adverse events surveillance. IRC reviewers also indicated the need to report on the in-country evidence (if available) to assist decision making on vaccine introductions as well as to assess vaccine impacts.

Recommendation 3 AEFI Surveillance Crisis Response and Integrated surveillance

- The Gavi secretariat should consider working with partners to support national workshops for senior staff on how to anticipate a crisis of confidence following an AEFI and how to handle communication with the media⁴.
- Gavi should support improvement of effective, sustainable integrated surveillance of VDP and AEFI such as IDSR, and potentially use Gavi resources to support evaluation of effectiveness of integrated surveillance.

⁴ The WHO/EURO publication: "Vaccine safety events: managing the communications response" that can be downloaded at: <u>http://www.who.int/vaccine_safety/publications/aevi_manual.pdf?ua=1</u>. Details of the training course using this manual can be found at:<u>http://www.euro.who.int/en/media-centre/events/events/2014/02/inter-country-training-workshop-on-vaccine-safety-management-and-communications</u>. The Communications Initiative GPEI website also provides resources for combatting rumors and misinformation related to immunization. (http://www.comminit.com/polio/category/sites/global/polio/).

2.10 Governance (HSSC, ICC, NITAGs, NRA, CSO, other)

Issue 1: The governance structure and mechanisms at country level, expected to support the immunization programme, in many cases present challenges:

Coordinating bodies do not function as expected.

The structure and functions of coordinating bodies is often not clear, with confusion between technical / policy / coordinating bodies, their functions and their position within the health sector. Their composition is often limited to MoH, WHO and UNICEF; the presence of other actors seems to be on individual or organization basis, rather than representing a constituency. (e.g.: Chad, The Gambia, Eritrea, and Myanmar)

These bodies fail to meet some of the key needs (not requirements) for support of the immunization programme, such as:

- To be part of the coordinating functions of the Ministry of Health, as a forum for immunization stakeholders that need to be involved and that can contribute to the programme (including professional associations, private sector, community organizations, other national sectors, international donors, ...)
- To link the immunization programme with the overall health sector and its crosscutting components (systems) – health financing, human resources, health information, service delivery.
- To provide evidence based advice about the introduction of new vaccines and related implications. E.g. MR campaign and the need for subsequent introduction of rubella vaccine in the routine EPI; introduction of Rotavirus vaccines and the implications on cold chain and logistics. (examples: MR in Cameroun; Rotateq in Mali and Rwanda)

Coordinating bodies do not comply with Gavi requirements.

The requirements described in Annex C of the guidelines are NOT met in many proposals. Not all required documents are submitted, the ICC / HSCC do not meet the minimum requirements in terms of composition and operating procedures, the development of the application documents is not consultative and inclusive as recommended; their endorsement is not properly documented.

Many countries have created an ICC for Gavi support only and not linked with the health sector. This does not facilitate the coordination of the immunization programme (or Gavi contribution to it) with the overall health sector. This was noticed already in previous IRC meetings, and the related IRC reports did provide recommendations (see previous recommendations attached below Annex 1)

Issue 2: Gavi requirements on the governance mechanisms at country level are not clear.

In the Guidelines, Annex C: "*Requirements for ICC or HSCC endorsement of applications*", ICC / HSCC are defined as "*country-led fora with a role in supporting the coordination and sustainability of immunization programmes*". ICC and HSCC are treated as equivalent and the country is advised to use what already existing rather that establishing new bodies. However, confusion is created by the sentence "*Gavi requests that the HSCC should have a formal reporting link to the ICC and can draw on ICC advice*", which seems to imply two different bodies.

Issue 3: The focus on polio eradication has an impact on all Gavi operations, up to end 2015.

In the context of the Polio Eradication and Endgame Strategic Plan, for the period 2013 – 2015 Gavi is focusing on the introduction of IPV as the first priority. The Gavi Board opened a funding window for this purpose and Gavi is strongly supporting eligible countries in applying and in the implementation of this measure. The requirements related to the IPV windows are less stringent than the general requirements.

Gavi is exercising an increased flexibility on governance requirements, an approach consistent with the current priority and somehow extended to all applications. The IPV introduction period will last until end 2015, by which time the IPV should have been phased in in all eligible countries. Gavi guidelines for 2015 applications are published with procedures and approach consistent with 2014. A new phase will open in 2016, for support to immunization programme in a context that is rapidly changing and will require adjusted strategies.

Issue 4: The context of health sector governance at country and global level is changing and Gavi will follow these changes.

There are now substantial developments in global health which are providing major challenges for aid effectiveness and coordination. These include the post MDG agenda and Universal Health Coverage at global level, as well as decentralisation, emerging private and civil society sectors, rapid urbanisation and persisting conflicts and other humanitarian emergencies including disease outbreaks. There are also pressures relating to depletion of health human resources and health sector financing. Taking all of these factors into account, the importance of country led governance mechanisms (including HSCCs, ICCs and NITAGs) will become increasingly important in order that national agencies have the institutional capacity to make evidence based decisions, coordinate, regulate and guide investments, and monitor their impacts.

Recommendation: IRC recommends to Gavi and partners to consider, in the next months, the re-definition of governance requirements at country level and – where deemed appropriate – the opportunity to change Gavi strategies to adjust to a changed context in health governance at global and country level. Recommendations on Governance from previous IRC meetings (Annex 5) should be taken into consideration. The new phase should consider:

- Gavi should invest in governance and coordination in-country, as institutional strengthening. The opportunity should be pursued to support coordination mechanisms through meaningful participation of all health sector actors including professional associations, private sector (profit and non-profit), community organizations, and all stakeholders that contribute to health services.
- Gavi can pursue the realization of the International Health Partnership (IHP+) compact at country level, where not already enforced and operational. This implies actual efforts to implement its principles: harmonization and alignment, country ownership, mutual accountability, focus on results. Government donors / their Cooperation Agencies who are partners in the Gavi Alliance could play the role of health sector partners in country also on behalf of Gavi, to support and monitor health sector coordination mechanisms
- Gavi requirements can be re-defined in terms of functions, rather than bodies. This would include technical, coordination, policy, regulatory and scientific advisory functions, that the country can perform in different existing or reformed bodies.

Recommendation: Strategy developments and new tools should be operational from 2016 (when the intensive IPV introduction phase is concluded).

No changes are feasible, or desirable, for 2015 application rounds, while IPV introduction remains a priority and this clearly affects other Gavi operations. However, this provides

appropriate time to work on a "next phase" of support to immunization programmes, able to cope with challenges and to exploit opportunities of the changing context. The new phase should take into account the appropriateness of ICC as a coordinating body, the value of scientific, technical and regulatory bodies (NITAG, EPI TWG, NRA) and the need to link and integrate with the overall health sector coordination (HSCC).

2.11 Communication

Social mobilization is one of the key strategies to achieve high immunization coverage and ensure reaching the difficult to reach population. The main communication strategies that usually affect the immunization and vaccines introduction include advocacy, programme communication and social mobilization.

In view of the fact that routine immunization strengthening is the foundation of the Endgame strategy, reviewers observed that proposals were quite variable in relation to the extent to which they addressed the communication plans.

Issue 1: Communication planning

Most of the communication plans provided with the vaccine introduction applications were not comprehensive. Lists of activities were given that will be implemented for the introduction and most probably will stop after that vaccines have been introduced.

More than 80% of the countries applied for vaccines introduction, have communication plans developed, or planning to develop it, without identifying what are the main communication barriers, including equity barriers, or problems for immunization, and the majority of them did not develop a specific crisis management communication plan. Communication plans are not grounded by behavior change theories or evidence from studies and experiences that, even if conducted by other areas such as HIV, family planning, etc, could be relevant in designing appropriate messages and strategies.

The five countries applied for HSS addressed communication in the plans and had allocated a budget for communication varied from 2% to 14% of the country HSS grant.

Recommendations:

- Planning for communication should be an ongoing strategy as part of routine immunization at all levels, it is a critical requirement for new vaccines introduction and improving immunization coverage. Gavi with partners may consider providing the required support to ensure that countries will analyze their communication barriers and have comprehensive communication strategies considering the Potential added value of partners, expert groups, and CSOs in advocacy and communication.
- Ensure that Gavi proposals forms and monitoring arrangements indicate clearly the communication issues by revising the communication section on the application form to include:
 - Clear problem identification/ analysis,
 - How the country will address the identified problems
 - Has the country have crisis communication plans
 - Has the country have the capacity to plan and implement communication strategies (need for technical assistance)

Issue 2: Vaccine Co-administration and multiple injections

Most of the countries (64%) expressed concerns of the community and health workers regarding multiple vaccines administered simultaneously, and fear from multiples injections.

There were also concerns from some of the health workers providing 2 polio vaccines at the same time. Insufficient information on the rationale for IPV introduction may undermine the use of OPV.





Recommendation s:

- Gavi with partners to ensure availability of technical assistance (as required) and training materials for the health workers on IPV introduction and its rationale.
- Communication plan should address concerns of the community regarding vaccine safety and fear of multiple injections, with more emphasis on interpersonal communication training. Crises management communication plan should be integral part of the communication strategy.

2.12 Human Resources

Rationale for a HR section in the Global Report

The IRC acknowledge Human Resources as one of the key resources for effective immunization programmes, along with vaccines, funds, supply chain etc. Human resources could be the most durable resource for the country that remains when Gavi support is finished. In addition to this point, the following should be considered:

- A considerable share of Gavi funds are spent on HR: training, compensation of health workers, supervision, technical assistance.
- Where HR limitations (in number, capacity, and distribution) are mentioned in the proposals, they are major constraints for the performance of the immunization activities.
- In graduating countries HR should be a key asset for technical and programmatic sustainability, to be built before the end of the graduation period.
- Effective investments in HR are feasible within the current funding mechanism, with an effort toward system building and sustainability. This opportunity should not be missed.

Issue 1: Salaries / top ups / incentives / per diem

The request for this support is present in all applications, with a wide range of justifications and scope. Within budget lines of incentives, training / meetings and supervision, this takes a significant share of the budget of VIGs, campaigns and HSS grants.

The request for compensation of health workers is not always justified and levels requested are not documented to be in line with national rules and standards (e.g. wide disparities between *per diem* allocated to national level staff and supervisors and the one allocated to vaccinators who actually deliver the service). The IRC finds it difficult to judge 1- the eligibility of this cost and 2- how much it is appropriate with respect to profiles, tasks, country context, national wages, civil service rules, etc. Gavi needs a clear policy and operating modalities on this issue.

The outline proposed in the presentation "Draft Operational Guidelines" seems to go in the right direction to provide guidance. The guidelines should include and explicitly mention the *per diem* and apply the same principles (aligned to country documents / harmonizing with other partners) to this form of compensation.

- The guidelines should clarify in the principles that compensation is provided for job tasks rather than for positions, i.e. for activities/tasks performed as included in the profile / job description, and not for the title the person holds.
- The policy cannot define actual amounts but should reflect on recognizing need to retain those who deliver immunizations, and promote integration with other PHC services.

The guidance seems sufficiently clear for the countries and will help IRC review, provided that the background documents of HR management in the country are attached to the proposal (HR strategy and operational plans, profiles, wages levels, approval by the ICC/HSCC).

If there is a specific gap in HR the country can ask Gavi to support this, in a transparent system and as a transitional measure within a longer term plan. Performance based incentives can be used, for services (not for individuals). Some kind of non-financial incentives can be promoted (housing, free electricity, digital training, etc...) to support retention measures.

Issue 2: Training

Training takes a significant share of the budget in most proposals. It is always in-service training, short term, focused on specific tasks related to the activities. Training is often held in rented facilities completely separated from health sector facilities. Some proposals requesting support for multiple introductions of vaccines and campaigns miss the opportunity to synergize trainings in terms of common modules, budget, logistics and management.

These trainings can be effective in providing instructions for specific tasks, in updating on new methodologies and techniques. However, their effectiveness in really building competences seems to be limited and the limitation of capacities in the health sector / immunization activities is not adequately addressed. As figure 14 illustrates, training is the greater part of budget allocated for HR and this varies from country to country.



Figure 14 Analyses of HSS HR Budgets

* Note: Bolivia (graduating Country) ineligible for HSS.



Figure 15 HR Budgets in Vaccine Proposals (20 countries analyzed)

Issue: Effective investments in Human Resources

Within the current funding mechanism it seems possible to make a more effective investment of the money spent on HR with a focus on system building and sustainability. The IRC consider this as an opportunity that should not be missed.

The IRC consider that among the permanent assets needed by the immunization programme and the wide health sector, two important elements are:

- Competences. In all sections of the immunization programme, from logistics to service delivery. These competencies can be clearly defined and standardized (where not already so) and included in training modules. Besides the in-service training currently used, adequate training modules can be developed and included in pre-service training within health training institutions. This is a long term activity to be aligned with the cMYP and the health sector / HR plan, aimed at building a more permanent pool of competent workers. Capacities of health training institutions can also be supported, from simply making use of their resources to support the definition of curricula towards more complex mentoring / twinning plans with other institutions.
- *HR management tools.* Profiles, job descriptions, attendance monitoring, payroll system, HR needs and distribution plans, projections, etc. These tools definitely facilitate the work and the request for support from donors but, where they are not functional, support could be given to strengthen the system.

A third important element cutting across the two above is the involvement of relevant actors who can contribute to effective immunization programmes and to system building. These include professional associations, academia, and private sector (health service providers and training facilities).

Gavi support in these fields, if requested by the countries, is feasible and could contribute to building the systems in a durable way. Technical assistance can be used for this purpose, in a structured manner, maybe through a special window dedicated to HR capacity building. There is a window in Gavi, but neither countries nor TA providers seem to be using it to plan for sustainable capacity development.

Recommendations:

- 1. Finalize the Gavi policy / strategy / operating modalities for HR compensation, i.e. salaries, top ups, incentives <u>and *per diem*</u>. Include a consultation of the IRC on the final draft (in the March 2015 meeting).
- 2. Request the country to provide, with the application, a situation analysis of the human resource needed / available for the planned activities, the country background documents on HR (Human Resource plan, wages levels, relevant labour law), the HR compensation plan for the proposal and the approval by the ICC/HSCC).
- 3. For multiple vaccine introductions / campaign, request the country to synergize programmatic and budgetary aspects (and provide guidance for it).
- 4. Consider longer term capacity building.
 - Standardize competences and training modules
 - Training modules for pre-service training in health professional schools
 - Plan workforce production in cMYP
 - Use of local resources of existing training facilities
 - Build capacities of the training institutions including in the use of new technologies

- Consider Innovative and transformational training modalities and stimulate collaborative learning among institutions Consider innovative training modalities and transformational training modalities and stimulate collaborative learning among institutions.
- 5. Consider opportunities to strengthen HR system in the country
 - Support HR management tools (definition and/or use): Profiles, job descriptions, attendance monitoring, payroll system, HR needs and distribution plans, projections, etc
 - Link health sector overall HR strategy with immunization (help immunization to shift to the HSS mode!).
 - Involve CSOs: professional bodies, academia, private sector.
 - Make use of technical assistance for long term system building

2.13 Sustainability

Gavi states in its guidelines to countries: "To maintain and extend the life-saving gains from expanded use of vaccines, countries should ensure the financial sustainability of their national immunisation programme. HSS applicants need to describe the country's policy and approach to sustainability of financing for immunisation services and recurrent cost liabilities incurred during health system strengthening, as well as programmatic sustainability. For NVS, Gavi requires a level of *co-financing of most vaccines*, to increase country ownership of vaccine financing and ensure that countries are on a *trajectory towards financial sustainability* to prepare for eventual phasing out of Gavi support. The co-financing commitments of a country should be reflected in the NVS application and corresponding multi-year plan."

Gavi HSS guidelines state: "Applications must include information on how sustainability of activities and results will be addressed from a financial and programmatic perspective beyond the period of support from Gavi."

Gradua	ating		Intermediate		
NVS	HSS IPV		NVS	HSS	IPV
	Bolivia**	Angola	Cameroon	Senegal	Ghana*
		Azerbaijan Congo	Cote d'Ivoire Nigeria*		Sao Tome Vietnam*
		Cuba			Zambia
		Lesotho			
		Moldova			
		Mongolia			
		Nicaragua Solomon Islands			
		Timor Leste			
		Uzbekistan			

Table 7 Graduating and Intermediate Applications reviewed in IRC Nov 2014

*Intermediate countries entering graduation in 2015

** Bolivia was assessed not eligible

*** Note: India not included

Issue 1: Sustainability Frameworks

There is little or no discussion in country application of what sustainability means and how to address it. There is a need to define and articulate what sustainability means across Gavi and Alliance partners and countries. Potential dimensions of sustainability include:

1. Institutional & system sustainability (Policy, Law, Regulation, Coordination Bodies, HR Policy)

To sustain investments, there will need to be increasing emphasis on law and policy so that EPI issues are presented in parliaments and cabinets. Country ownership can be advanced through ongoing technical support for in country governance mechanisms such as NRAs, NITAGs, ICCs and HSCCs. Finally, human resource support should be linked to wider

human resource systems and policy developments, so that these system developments can be supported beyond the Gavi project timeline.

2. Programmatic Sustainability (capacity of EPI to generate and translate evidence to practice manage and advocate)

The sustainability programs can be advanced through development of longer term systems strategies, particularly for the supply chain and waste management and transport systems. Program efforts can also be financially sustained through generation of higher quality country evidence for vaccine decision making and assessment of vaccine impacts, in order to provide a sound investment case for ongoing country financing of increasingly expensive vaccines. Programmatic sustainability also includes introducing new approaches such as equity-based planning, programming within an HSS mindset and developing more robust strategies for optimising the human resources skill mix and retention.

3. Financial Sustainability (how to address gaps, traditional vaccines , NVS, cofinancing)

Financial sustainability strategy has already been well developed by Gavi. However, the fact that 24 countries (of the Gavi 73) are still not financing traditional vaccines, and also limitations on outreach and operational funding, point to the need to revisit the concept of financial sustainability planning at country level to address major gaps in vaccine and operational financing.

4. Community Sustainability (weak demand in context of mobile marginalised populations)

Many of the proposals document the challenges of reaching hard to reach, mobile and migrant populations, including the urban poor and internally displaced persons. Given the increasing mobility of populations, more efforts made need to be placed on demand side strategy, so that mobile and migrant populations are attracted to immunisation service delivery points or are reached through targeted and appropriately designed outreach strategies. In addition, more attention has to be placed on identifying, strengthening, integrating and/or developing community-based networks. This includes better integration of community health workers and CSOs providing services.

Recommendations:

With many countries coming to graduation, and intermediate countries soon entering graduation, the sustainability strategy should be revised to a broader framework of sustainability including the 4 dimensions above.

- Provide a **framework** to assess sustainability and **tools (HOW TO)** to countries and partners strengthen the path towards it
 - Institutional/governance: Sustain political support
 - Financial: Pay for vaccines and operational costs
 - Programmatic: Maintain coverage at national AND sub-national coverage in an integrated approach
 - Community Promote pro-active behaviour of population to get immunised
- Countries should be encouraged to provide a PLAN for their sustainability strategy and to report on progress and achievements

- Develop **indicators of sustainability** for all countries and analyse change in trends that could include for example
 - Total EPI expenditures as share of MoH budget
 - Share of domestic financing of national immunization programme vaccines
 - Share of domestic financing of operational costs
 - Numbers of countries financing traditional vaccines with domestic resources,
 - Human Resource : numbers and distribution
 - Demand generation (% vaccinations provided at fixed sites)
- Conduct a study for graduating and intermediate countries using these types of indicators to develop a framework for sustainability and measure progress towards successful graduation

2.14 Other Issues - Ebola

Issues

The IRC is very mindful of the dreadful burden the entire health service of certain West African countries is under at this present time, managing the outbreak of Ebola fever. The committee understands that health providers place themselves at extreme risk in many instances and we offer our admiration and respect for such efforts.

The IRC extended latitude to applications from affected countries such as Sierra Leone for this reason. While applications have been accepted overall, the committee felt that there had to be flexibility in timelines for implementation to meet local conditions relating to the Ebola outbreak. In affected countries, the outbreak is distorting all aspects of the health service including EPI – for instance, all immunization activities are apparently at a stop in Sierra Leone.

The IRC anticipates that there will be a need for a measles mass campaign in the near future as the number of measles susceptibles will be accumulating. As a means of catching up, we also anticipate the possibility of multi-antigen campaigns offering a range of EPI antigens once the Ebola crisis subsides.

There are gender equity issues relating to the Ebola outbreak. Women are on the front lines of this disease, with female nurses representing the majority of the medical personnel who have died from the virus. UN sources in Sierra Leone report women represent around 59 per cent of their deceased.

Since Ebola is spread through bodily fluids, women as primary care providers in the community and as medical professionals and hospital launderers are at an increased risk of contracting the virus. Furthermore certain traditional practices and rituals performed on the deceased that women typical perform, can also pose and increased risk. The particular vulnerability of women in this specific context is still overlooked. There is a need to integrate a gender perspective in the international response to the crisis in terms of communications, outreach, and support. Any Ebola response should address the needs of women and harness their leadership roles as caregivers and community leaders.

As of end-November 2014, the International Community has no certainty about the outcome of efforts to contain the outbreak to West African countries. If containment is not successful, many more countries in Africa could be involved. The need for international support could be enormous in this eventuality.

Recommendations:

In response to the outbreak of Ebola fever in West Africa (and possibly in other African countries subsequently), IRC requests that the Gavi Secretariat urgently prepares contingency plans for fast-tracking country applications for funding for recovery of health services. Among other aspects, these applications are likely to be for mass campaigns of single antigen (e.g. measles vaccine) or multiple antigen campaigns. In addition, please urgently consider developing ways of supporting countries to reconstruct their health services that have been decimated by the events surrounding the Ebola outbreak.

While we recognize gender issues related to Ebola, it is difficult to know what to suggest that would be actionable at this time. Considering the increasingly recognized high risk for women and for health workers, if and when a vaccine becomes available, it would be appropriate to give preference to female health workers.

Annex 1 List of IRC Review Members

Name	Current role
Adepeju Olukoya	Independent consultant
Ahmed Darwish	Independent consultant
Amani Mustafa	Public Health Training Initiative Project Manager, The Carter Center, Sudan. National Director of Planning, Monitoring, and Policy Directorate, National Medicines and Poisons Board, Sudan
Arletty Pinel	Independent consultant
Asnakew Tsega	Immunisation senior technical officer at USAID funded Maternal and Child Survival Program (MCSP)
Charles Wiysonge	Full Professor and Deputy Director in the Centre for Evidence-based Health Care, Stellenbosch University, South Africa
Diana Rivington	Senior Fellow in the Faculty of Social Sciences at the University of Ottawa, Canada
Dora Curry	Senior Technical Advisor for Monitoring and Evaluation in CARE-USA's Sexual, Reproductive and Maternal Health team
Gabriel Carrasquilla	Founder and Director of ASIESALUD
Kshem Prasad	Independent consultant
Jean Marie Edengue Ekani	Immunisation specialist MoH, Cameroon
John Clements	Independent consultant and Associate Professor in the School of Population Health, Faculty of Medicine and Dentistry, University of Melbourne
John Grundy	Independent consultant
Linda Eckert	Professor in Obstetrics and Gynecology and Adjunct Professor in the Department of Global Health at the University of Washington in Seattle
Marina Madeo	Independent consultant
Mario Stassen	Lecturer at Faculty of Science, Department of Biopharmacy at University of Utrecht; Board member of the Edufarma Foundation
Maryanne Neil	Independent consultant
Michael Thiede	Managing Director of the Scenarium Group GmbH
Miloud Kaddar	Independent consultant
Ousmane Amadou Sy	Independent consultant
Philippe Jaillard	Program Director: Technologies and Health Logistics. Project coordinator of LOGIVAC
Rafah Aziz	Independent consultant
Robert Pond	Independent consultant
Sandra Mounier-jack	Lecturer in Health Policy at the Faculty of Public Health and Policy of the London School of Hygiene and Tropical Medicine
Shamsa Zafar	Head of Department, Centre of Excellence in MNCH at the Health Services Academy, Pakistan
Stephanie Tache	Independent consultant

Terry Hart	Independent consultant
Zeenat Patel	Independent consultant

Annex 2 Supply Chain Issues Listed from IPV Review Summary of the IRC review of the IPV applications

Ser #.	Country	Date of introductio n	Vaccine presentati on	Key supply chain issues to be followed up and remarks	Consider postponement
1	Angola	April 2015	10 dose	Strengthen cold chain capacity at district and service delivery level.	Yes
2	Azerbaijan	July 2015	1 dose	Strengthen continuous temperature monitoring Developing medical waste policy	
3	Burkina Faso	July 2015	10 dose	Vaccine storage capacity, vaccine safety	
4	Burundi	December 2015	1 dose	Collect information on cold chain at health facilities Consider use of solar direct drive in place of battery backed solar units.	
5	CAR	June 2015	5 dose	Unreliable supply chain outside the capital.	Yes
6	Chad	June 2015	5 dose	EVM assessment with IP required.	
7	Combodia	October 2015	1 dose	Limitation of cold room space as JE is to be introduced in January 2016.	
8	Congo	July 2015	10 dose	Cold chain capacity to be expanded at mid & service level. Poor waste management	
9	Côte d'Ivoire	June 2015	10 doses		
10	Cuba	October 2015	1 dose	EVM and cold chain inventory required	
11	Eritrea	July 2015	10 dose	Consider a wider use of solar operated cold chain equipment	
12	Ghana	August 2015	10 dose	Review strengthening of the supply chain logistics based on the new EVM and its improvement plan.	
13	Guinea Bissau	April 2015	5 dose	Strengthen supply chain capacity and management	Yes
14	India	August 2015	5 dose	Provide status of implementation of improvement plan.	
15	Kenya	July 2015	5 dose	Strengthening cold chain logistics and waste management	
16	Kyrgyzstan	June 2015	1 dose	Ensure sufficient cold chain capacity at service level planned through HSS funds.	Yes
17	Lesotho	July 2015	10 dose	Needs assessing cold chain capacity at service level	
18	Mali	June 2015	10 dose	Plan EVMA, define waste management strategy	

Ser #.	Country	Date of introductio n	Vaccine presentati on	Key supply chain issues to be followed up and remarks	Consider postponement
19	Mauritania	March 2015	10 dose	Accelerate the strengthening of supply chain which is already planned for Rota introduction in December 2014.	Yes
20	Moldova	October 2015	1 dose	No supply chain issues.	
21	Mongolia	October 2015	5 dose	Follow up on 4 recommendations of Improvement plan.	
22	Mozambiqu e	July 2015	10 dose	Strengthen vaccine storage capacity at central level.	
23	Myanmar	July 2015	10 dose	Conduct EVM and follow up on cold chain expansion.	
24	Nicaragua	October 2015	1 dose	Reinforce the temperature monitoring particularly service level. Develop and implement waste management plan.	
25	Niger	June 2015	10 dose	Strengthen cold chain capacity, vaccine management and temperature monitoring.	
26	Rwanda	Aug 2015	10 dose		
27	Sao Tome & Principe	Oct 2015	1 dose	Synergies with other NV intro plan	
28	Sierra Leone	May 2015	10 dose	Delays in strengthening due to Ebola crisis	Yes
29	Solomon Islands	September 2015	10 dose	Improve vaccine distribution plans and waste management.	
30	Somalia	October 2015	10 dose	Conduct PIE for Pentavalent.	
31	South Sudan				
32	Timor Leste	September 2015	10 dose	Consider conducting a PIE for Pentavalent	
33	Togo	April 2015	10 dose	Conduct EVM assessment, assess cold chain capacity at health centre level. Ensure procurement of PQS equipment.	
34	Uzbekistan	July 2015	5 dose	Ensure cold chain readiness and waste management	
35	Vietnam	October 2015	10 dose	Complete distribution cold chain at facilities lacking them.	
36	Zambia	November 2015	1 dose	Improve waste management	
37	Zimbabwe	June 2015	1 dose		

Detailed information on country immunization supply chain system and performance, to be integrated in future applications

Level	No. of stores	No. of maintenanc e technicians	Rehabilitati on plan	Status of rehabilitatio n	Budget for strengtheni ng	Waste disposal method
National	1	Out-sourced	2 CR	1 CR installed, 1 procured	40,000\$	Incineration
Sub-national	3	1	6 CRs			
Sub-national-2						
Last distribution level - district	20	Out sourced or 5				20 pits - Burying in pits
Service point	345	0				34 incinerators rest in pits

2. Table for collecting details of the Cold chain status

Table for collecting details of the Vaccine logistics

Level	Distributi on system	Push / pull / mixed /	Logistic manageme nt Informatio n system	Stock out instance s in last 12 months	Wastag es of closed vials	Which vaccine s	Reason
National			SMT				
Sub-national			SMT				
Sub- national-2	*						
Last level – district			DVD-MT				
Service point	V						

Annex 3 JRF Reports on District Coverage

71 out of the Gavi 73 reported on the JRF on the percentage of districts falling into various ranges of DPT3 coverage.

Of these 71, 37% of countries reported that they had some districts with coverage below 50%.

Country	% of districts <50%	% of districts 50-79%	% of districts 80-89%	% of districts >=90%	Districts <50% as well as districts>=90%
Afghanistan	9	24	10	56	1
Angola	5	29	14	52	1
Armenia	0	0	6	94	0
Azerbaijan	0	2	8	91	0
Bangladesh	0	2	11	88	0
Benin	0	16	39	45	0
Bhutan	0	0	15	85	0
Bolivia	17	42	15	26	1
Burkina Faso	0	0	10	90	0
Burundi	0	7	27	67	0
Cambodia	1	21	24	54	0
Cameroon	0	22	24	54	0
Central African Republic	75	21	0	4	1
Chad	16	23	17	43	1
Comoros	0	35	24	41	0
Congo	0	27	43	30	0
Costa Rica	0	5	16	79	0
Côte d'Ivoire	0	1	11	88	0
Cuba	0	4	3	93	0
Djibouti	0	50	33	17	0
Eritrea	14	47	9	31	1
Ethiopia	19	31	17	33	1
Gambia	0	0	17	83	0
Georgia	0	6	23	71	0
Ghana	1	24	21	54	0
Guinea	0	8	13	79	0
Guinea-Bissau	0	9	18	73	0
Guyana	0	0	23	77	0
Haiti	19	24	14	43	1
Honduras	1	35	22	41	0
India					
Indonesia	5	12	20	63	1
Kenya	15	40	20	25	1
Kiribati	0	0	0	100	0
Kyrgyzstan	0	0	0	100	0
Laos	2	23	31	43	1
Lesotho	20	80	0	0	0
Liberia	0	13	33	53	0
Madagascar	0	24	31	45	0
Malawi	0	25	29	46	0
Mali	13	10	18	58	1
Mauritania	8	51	21	21	1

Mozambique	3	11	20	66	1
Myanmar	8	45	33	12	1
Nepal	1	8	29	61	0
Niger	0	10	31	60	0
Nigeria	5	24	16	56	1
Pakistan	10	16	13	61	1
Papua New Guinea	46	20	6	26	1
Moldova	0	7	9	84	0
Rwanda	0	0	33	67	0
Sao Tome and Principe	0	0	0	100	0
Senegal	18	43	11	21	1
Sierra Leone	0	7	36	57	0
Solomon Islands	10	40	30	20	1
Somalia	61	20	1	10	1
South Sudan	44	34	6	16	1
Sri Lanka	0	0	0	100	0
Sudan	1	5	16	77	0
Swaziland	0	75	0	25	0
Tajikistan	0	0	0	100	0
Timor-Leste	0	38	38	23	0
Тодо	0	8	55	38	0
Uganda	3	14	15	68	1
Ukraine					
Tanzania	1	19	19	61	0
Uzbekistan	0	0	0	100	0
Viet Nam	39	46	6	9	1
Yemen	4	18	34	42	1
Zambia	5	42	18	35	1
Zimbabwe	0	11	17	71	0
North Korea	0	0	0	100	0
Congo DRC	1	18	24	56	0

Annex 4 Previous Gender and equity Recommendations

November 2013

- 1. Gavi to consider revising its proposal templates to ask countries to provide, where available, vaccine coverage information comparing:
 - Urban/rural
 - The richest/poorest quintiles
 - o The provinces/districts with highest and lowest coverage
 - o Caretakers' (Mothers') education from lowest and highest levels
 - Gender Inequality Index
- 2. Gavi to ask how the proposed activity will address the gaps identified in coverage and how this will be reflected in the M&E framework. (Note: the guidelines must match the forms). Gavi may consider developing a model case study on gender and equity and health issues to guide countries. This case study could demonstrate what equitable access to health services means in different contexts and draw on lessons learned by Gavi and Alliance partners.
- 3. Gavi to consider the approval of the revised gender policy and the roll out of GAMR as opportunities to provide training for CROs on gender and equity in health programming so that they can engage in dialogue and assist countries to reflect these considerations in their programming and proposals.
- 4. Gavi to consider adding extra time at regional meetings to address the capacity strengthening of country level EPI managers on gender and equity in health programming. Such meetings should be focused on practical measures to reach equity in immunization, that is, how to analyse and plan to help ensure that gender and equity barriers do not prevent the fullest possible immunization coverage.

March 2014

- 1. The approval of Gavi revised gender policy and the roll out of GAMR are opportunities to train Gavi staff, in particular CROs, on gender and equity in health programming to better equip them for dialogue with countries and partners on addressing gender equity gaps in proposals to Gavi. Gavi could develop case studies on gender and equity and health issues to guide countries and to demonstrate what equitable access to health services means in different contexts, drawing on lessons learned by Gavi and Alliance partners. Consider adding an extra day at regional meetings for capacity strengthening of country level EPI managers on gender and equity in health programming with a focus on practical measures to reach equity in immunization. Provide guidelines for gender and equity analysis as part of coverage studies, bottleneck studies, and M&E frameworks.
- 2. Provide funding, as appropriate, to support gender and equity analysis, including at the sub-national level in large states where there are stark inequalities among the states/districts.
- 3. Assist countries to define baselines and annual targets for "mandatory equity indicators" where these have been left blank in M&E frameworks.

July 2014

1. Gavi should use the new joint assessment system (GAMR) to assess how its contribution to strengthening health systems overall is making immunisation more effective and efficient.

- The Gavi Alliance at the country level, building on RI successes and child health days with integrated packages of services, should encourage in conversation on health interventions beyond EPI in order to strengthen services for the mother and for a minimum package in support of MNCH as is observed in the Sudan IPV application or child health days.
- 3. Gavi to add questions related to internally displaced and cross border displaced populations to applications forms and review the related guidelines. CROs should be prepared to engage in conversation with governments that may not recognized conflict as an immunisation related issue.
- 4. Gavi to be prepared to support technical assistance, additional components in the VIG, or other contingency support as part of a country tailored approach affected countries.
- 5. Support Gavi as a learning Alliance by funding case studies in programmatic resilience (Madagascar) and operational strategies in conflict settings (Pakistan).
- Provide input into development of global strategies for enhancing immunisation strategy and access in conflict settings: Health Worker Security; Negotiation strategy e.g. Corridors of Peace; Immunisation Delivery Strategy (campaign, mobile services, routine scheduling); internally Displaced Persons; Early Warning Systems; and Resource Mobilisation in conflict settings.
- 7. The IRC recommends that the DRC be considered as a country for an equity plan.
- 8. The IRC also recommends revision of the CRO checklists to capture attention to gender and equity issues.

REFLECTING THE NEW GAVI ALLIANCE GENDER POLICY ("TOWARDS REDUCED GENDER INEQUALITIES FOR INCREASED IMMUNISATION COVERAGE")

The "*Check list for a complete application*" on all application forms should be revised to ask for the most recent DHS, EPI evaluation, Social Indicator Survey, Equity Analysis and Plan or other similar documents.

Under the "*Situational Analysis*" section, countries should be asked to specifically include, where possible, data on the key statistics including: rates for early marriage, maternal and infant mortality, vaccine coverage by wealth quintile differences, and coverage disaggregated by sex. Data on vaccine coverage by maternal education should also be included.

If relevant, include information on the impact on the health system of refugee, internally displaced populations or unregistered cross border migrants due to conflict, and share strategies to reach and immunize this population.

These items should also be included on the **Screening Templates** used by the IRC Team and the CRO to assess the completeness of applications.

Annex 5 - Previous Recommendations on Governance

July 2014

- 1. The Alliance should seek to support coordinating mechanisms that include all health sector actors.
- 2. Gavi should invest in WHO's effort to strengthen NITAGs and NRAs.
- Gavi could consider if it and its partners have a role in the promotion of comprehensive health protection and promotion and immunisation policy or law, particularly in the context of decentralisation and immunisation across multiple age groups.

November 2013

-The IRC supports recent Gavi initiatives to finance adequate technical support to countries to develop regulatory functions through NRAs and safety surveillance mechanisms, as well as increasing capacity of countries to provide scientific oversight of national immunization programs through NITAGs. These functions could be technically supported in larger population countries. For smaller countries (for example in Western Africa and the Pacific Island States), Gavi should technically support the development of regional mechanisms for regulation, safety, and scientific oversight.

- Gavi to undertake a review of the ICC model in a range of countries. This would identify strengths and weaknesses of the existing arrangement, review the effectiveness in light of other mechanisms and developments in the health sector and look at the opportunities and threats of merging the ICC with other coordination arrangements.

Annex 6 Summary of IRC Results NB: Approval with rec. = Approval with recommendations

	0				Type of support			
	Country	IPV	HSS	HPV Demo	MR campaign	Rota	MSD	JE
1	Angola	Approval with rec.						
2	Azerbaijan	Approval with rec.						
3	Bangladesh			Approval with rec.				
	Bolivia		Not eligible					
4	Burkina Faso	Approval with rec.		Approval with rec.				
5	Burundi	Approval with rec.						
6	Cambodia	Approval with rec.	Resubmission					Approval with rec.
7	Cameroun				Approval with rec.			
8	CAR	Approval with rec.						
9	Chad	Approval with rec.						
10	Côte d'Ivoire	Approval with rec.				Approval with rec.		
11	Congo	Approval with rec.						
12	Cuba	Approval with rec.						
13	Eritrea	Approval with rec.						
14	Ethiopia			Approval with rec.				
15	Gambia		Resubmission					
16	Ghana	Approval with rec.						
17	Guinea Bissau	Approval with rec.						
18	India	Approval with rec.						
19	Kenya	Approval with rec.						
20	Kyrgyzstan	Approval with rec.						

	Country				Type of support			
	Country	IPV	HSS	HPV Demo	MR campaign	Rota	MSD	JE
21	Lesotho	Approval with rec.						
22	Mali	Approval with rec.	Approval with rec.					
23	Mauritania	Approval with rec.						
24	Moldova	Approval with rec.						
25	Mongolia	Approval with rec.						
26	Mozambique	Approval with rec.						
27	Myanmar	Approval with rec.						
28	Nicaragua	Approval with rec.						
29	Niger	Approval with rec.						
30	Nigeria					Resubmission		
31	Rwanda	Approval with rec.					Approval with rec.	
32	Sao Tome	Approval with rec.		Resubmission				
33	Senegal		Approval with rec.					
34	Sierra Leone	Approval with rec.			Resubmission*			
35	Solomon Isl.	Approval with rec.						
36	Somalia	Approval with rec.						
37	South Sudan	Approval with rec.						
38	Tajikistan		Resubmission					
39	Timor Leste	Approval with rec.						
40	Тодо	Approval with rec.						
41	Uzbekistan	Approval with rec.						
42	Vietnam	Approval with rec.						

43	Zambia	Approval with rec.						
44	Zimbabwe	Approval with rec.			Approval with rec.		Approval with rec.	
	TOTAL (54)	37	5	4	3	2	2	1

*Sierra Leone's proposal for MR is requested to be resubmitted due to ebola.