GAVI INDEPENDENT REVIEW COMMITTEE REPORT NEW PROPOSALS MARCH 2015

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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
cIP	Country improvement plan (cold chain)
cMYP	Comprehensive multi-year plan for immunisation
CSO	Civil society organization
cVDPV	Circulating Vaccine-Derived PolioVirus
DHS	Demographic and Health Survey
DTP3	Diphtheria-Tetanus-Pertussis, 3rd dose
DQSA	Data Quality Self-Assessment
EPI	Expanded Programme on Immunisation
EVM	Effective Vaccine Management, an assessment tool
FMA	Financial Management Assessment
GPEI	Global Polio Eradication Initiative
HCW	Health Care Worker
Hep B	Hepatitis B vaccine
HPV	Human Papilloma Virus
HR	Human Resources
HSCC	Health Sector Coordination Committee
HSSP	Health Sector Strategic Plan
HSS	Health Systems Strengthening
ICC	Inter-Agency Co-ordination Committee (for immunization)
IDQA	Independent Data Quality Assessment
IDP	Internally Displaced Person
IDSR	Integrated Disease Surveillance and Response
IHP+	International Health Partnership +
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
MNCH	Maternal Neonatal and Child Health
MenA	Meningococcal A vaccine
MoH	Ministry of Health
MR	Measles-Rubella vaccine

MSD	Measles Second Dose
NCD	Non Communicable Diseases
NITAG	National Immunization Technical Advisory Group
NRA	National Regulatory Authority
NVS	New and underused Vaccine Support
OPV	Oral Polio Vaccine
PCV	Pneumococcal Conjugate Vaccine
PIE	Post Introduction Evaluation
PMU	Project Management Unit
PQS	Performance, Quality and Safety (of immunization equipment)
RBF	Result Based Financing
REC	Reaching Every Community
RED	Reaching Every District
RI	Routine Immunisation
RV	Rotavirus Vaccine
SAGE	Strategic Advisory Group of Experts (WHO)
SC	Sub Cutaneous (injection)
SCM	Senior Country Manager
SDD	Solar Direct Drive (vaccine refrigerators)
SIA	Supplementary Immunisation Activities
SWAp	Sector Wide Approach
TA	Technical Assistance
TT	Tetanus Toxoid
TWG	Technical Working Group
VDPV	Vaccine-Derived PolioVirus
VIG	Vaccine Introduction Grant
VPD	Vaccine Preventable Disease
VVM	Vaccine Vial Monitors
WUENIC	WHO and UNICEF Estimates of National Immunization Coverage
YF	Yellow Fever

Acknowledgements

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1. Summary Report

Introduction

A meeting of the Independent Review Committee took place between March 16th and March 27th, 2015 in Geneva. The IRC reviewed 28 applications submitted by 24 Gavi eligible countries. Country applications included 7 IPV vaccine introductions, 10 HSS proposals and support for each of the following vaccines: MR campaign (2), Measles SIA (1), HPV Demo (1), Rotavirus (2), MenA (1), MenA campaign (2), Yellow Fever campaign (1) and JE (1). Nineteen 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 Secretarial (M& E, Policy & Performance and Senior Country Managers).

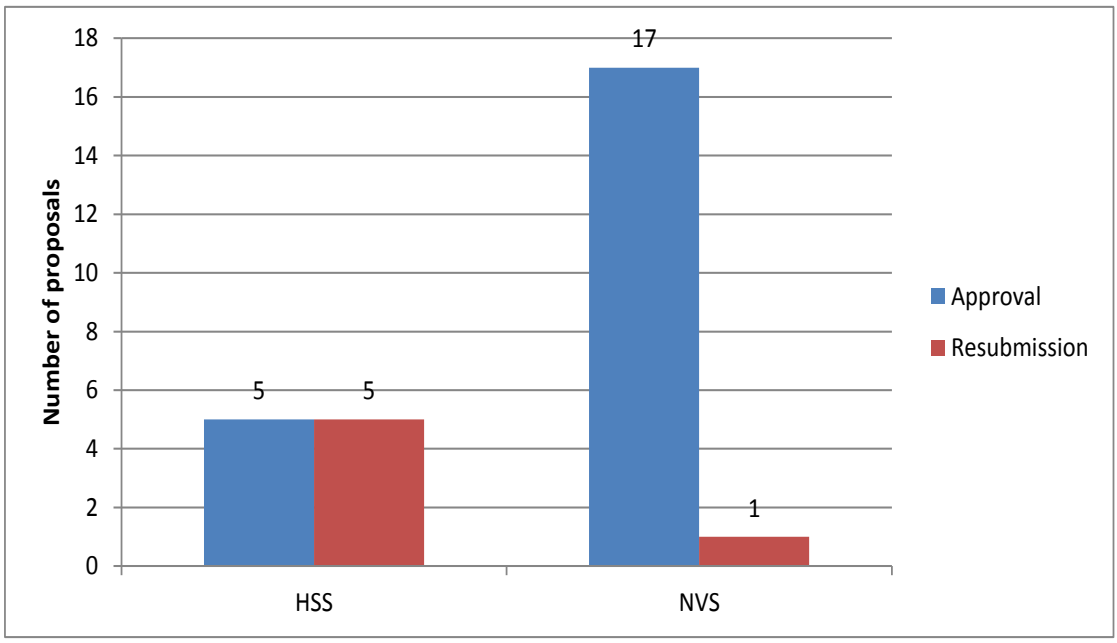
Methods

Two reviewers were assigned to each country, and a country report was generated for each submitted proposal. Selected IRC members focussed on the cross cutting issues of supply chain and logistics, financial management, M&E 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 met the overall Gavi mission and strategic goals.[1] In addition to the individual country reports and recommendations this global report was also developed focusing on the main themes arising from the review.

Main Findings

The main findings are summarised in Figure 1 below. In addition to the information provided, all 7 IPV proposals are recommended for approval. The overall approval rate for proposals submitted (n = 28) is 78%. Five out of ten HSS proposals require resubmission. One new vaccine application for the introduction of RV requires resubmission.

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) 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)*. Coverage performance varies significantly for graduating or near graduating countries. Data quality concerns remain in some countries. While applications are increasingly including plans to improve data quality, the IRC feels that further guidance should be provided to countries on the use of effective international standards for data quality assessment. The Annual Joint Appraisals appears as a promising process to further strengthen coverage data validity and reliability.

IPV proposals*:* To date, inclusive of the 7 IPV proposals submitted for the March 2015 IRC, and in line with the polio end game strategy, all of the 71 Gavi countries expected to apply have now been approved for IPV support. All 7 IPV proposals in this last round were approved. These consisted of mainly graduating countries, which submitted overall good quality proposals. However, two countries (Haiti and PNG) faced challenges in terms of supply chain capacity and proposed timelines, and specific recommendations were provided for the country and the Gavi Alliance to follow-up. The communication issues related to multiple injectionsin one visit remains a concern for countries planning to introduce IPV. The IRC reiterated its recommendation to implement tailored messaging and risk communication planning on multiple vaccinations in one visit. The IRC suggests that Gavi conduct an evaluation of the accelerated introduction of IPV (at global and country level) to inform future fast track introduction of other vaccines.

NVS vaccines and campaigns: There were 11 NVS proposals in this round, 10 were approved and one was asked to resubmit (RV in Lesotho).General issues are persistent supply chain weakness and lack of clear alignment with HSS grants as well as missed opportunities in terms of integrating the new vaccine within a wider public health strategy (Rotaviruseg rotavirus strategy and for diarrheal control and HPV with adolescent health). Gavi and partners are recommended to deploy TA support with an approach focusing on the Gavi portfolio as well as involving other connected MoH programmes (*also see section 2.6*). Issues relating to specific vaccines also included the introduction of MSD vs. MR as second dose, and the lack of presentation of local evidence for decision making (RV).

Specific recommendations are provided to Gavi to assess applications for campaign support, notably an epidemiological risk assessment (which was lacking in many applications), the need to provide adequate time lead for campaign planning and for partners to actively provide evidence based strategies that do no harm to routine EPI and can contribute to reinforcing routine services.

Health System Strengthening*:* The review of health system strengthening proposals was challenging, principally due to the complexity of the proposals and the fact that the vast majority of HSS proposals were not aligned with the broader national health sector strategic plans (8 out of 10). This was one major reason why the approval rate was 50% in this round. The IRC also noted the growing number of applications that contributed to funding sector wide programme, but the IRC felt that the application process was not always very well suited to developing and assessing these type of proposals.

The IRC noted the improving quality of HSS proposals, as assessed by sound bottle neck analysis, clearer objective setting, a better focus on under-served populations, and stronger monitoring and evaluation frameworks. Nevertheless, reviewers continued to note the lack of active involvement of the wider health systems stakeholders outside the immunisation programme, with the increased risk of further fragmentation and verticalisation of HSS activities. The IRC reiterated the need for Gavi to be an active contributor to HSS at country level and to fully support aid effectiveness principles. As a result, the IRC recommends that HSS applications be developed (as far as possible) within the broader health sector strategic plans and that bridging funds, if needed, be provided as a continuation of a previous HSS

grant. Better alignment with national strategy and wider involvement of stakeholders would also bring the additional benefits of fostering a more integrated approach to immunisation activities as a component of the primary care platform (rather than a vertical intervention); funding activities that encourage systemic rather than programme support; increasing country ownership and responsibility on immunization; and promoting better sustainability of investment.

***Supply Chain**:* Gavi investments in supply chain are addressing constraints in vaccine storage capacity in many countries, but investments are not yielding systemic improvements in quality, efficiency, supply chain data management and M&E. Gavi support to manage the implementation of supply chain improvement plans; improve guidance and orientation for systemic improvement; offer innovations which enable countries to adopt "ready-made solutions" (i.e supply chain data management systems, system design strategies and tools) and carrot and stick mechanisms to encourage systemic supply chain improvements; will yield a better return on supply chain investments and improved vaccine management with reduced losses and risks. Waste management remains an area that needs more guidance from Gavi and more attention from countries. The IRC is recommending that Gavi assist countries to develop longer term system design strategies and tools, continue supporting EVM assessments every three years and ensuing improvement plans, and assist the countries with updated transfer of new technologies and management systems.

Governance and Technical Assistance. 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 neither identified nor technically supported to inform or perform decision making and coordination of investments for either HSS or new vaccine introductions. Gavi is recommended to strengthen governance mechanisms, notably in the preparation of HSS grants, through the Annual Joint Appraisal mechanism and through supportive and long term technical assistance. Gavi should also consider playing a more participatory role at country level when sector wide arrangements are being developed and implemented, with a view to encourage ownership, synergies and sustainability.

***Gender and Equity**:* Equity is now more clearly identified as a priority, with all of the HSS addressing the issue in their bottleneck analysis and proposals intending to focus their investments on under-served populations. All M&E frameworks now include mandatory equity indicators, although in some cases missing baselines and targets mean that progress will not be easily measured over time. Despite progress, the IRC continues to note that proposals often do not clearly link the gender and equity analyses and the programmatic activities. The IRC recommends continued support to countries to conduct equity analysis, peer review meetings to strengthen country planning capacity; evaluation of lessons learned of RED/REC strategy; and piloting of innovative outreach strategies in populations such as the urban poor, displaced persons and refugees.

Sustainability: The IRC paid particular attention to sustainability in this review, notably because more than half of the applications were submitted by graduating or intermediate countries. We noted wide variation in the likelihood of financial and programmatic sustainability of these countries. This raised challenges in terms of the sustainability of some of the Gavi support windows, such as IPV, vaccination campaigns and HSS, which at the moment do not provide for a gradual transition of Gavi supported costs towards domestic funding. In line with previous IRCs, reviewers recommended early engagement with countries as well as the monitoring of sustainability performance indicators.

Conclusion and Recommendations

In conclusion, the IRC noted the improved quality of proposal development, resulting in high approval rates for new vaccines. All IPV applications have been recommended for approval, leading 71 countries to introduce the vaccine, in line with the Global Polio end game plan. The comparatively low approval rate for HSS is partly explained by the high number of HSS

proposals submitted outside the currently developed national health strategy framework. Re-submission will ensure better alignment within the health sector of the immunisation strategy as a component of the national health strategy framework, and is likely to deliver a more integrated approach for immunisation as part of the broader primary care platform, hence strengthening sustainability prospects.

With stagnant coverage remaining a concern, continued focus on countries where coverage has remained low or presents wide variations at sub-national level is crucial. More importantly it is critical that persisting wide inequalities drive programme design and that investments are developed with a clear link to the national health strategy activities and within Gavi's portfolio approach in order to address systemic gaps. This alignment is particularly important for graduating and soon to be graduating countries that will need to gradually take over vaccine costs, as well as programmatic and campaign costs while maintaining investment in immunization.

Summary Recommendations IRC March 2015

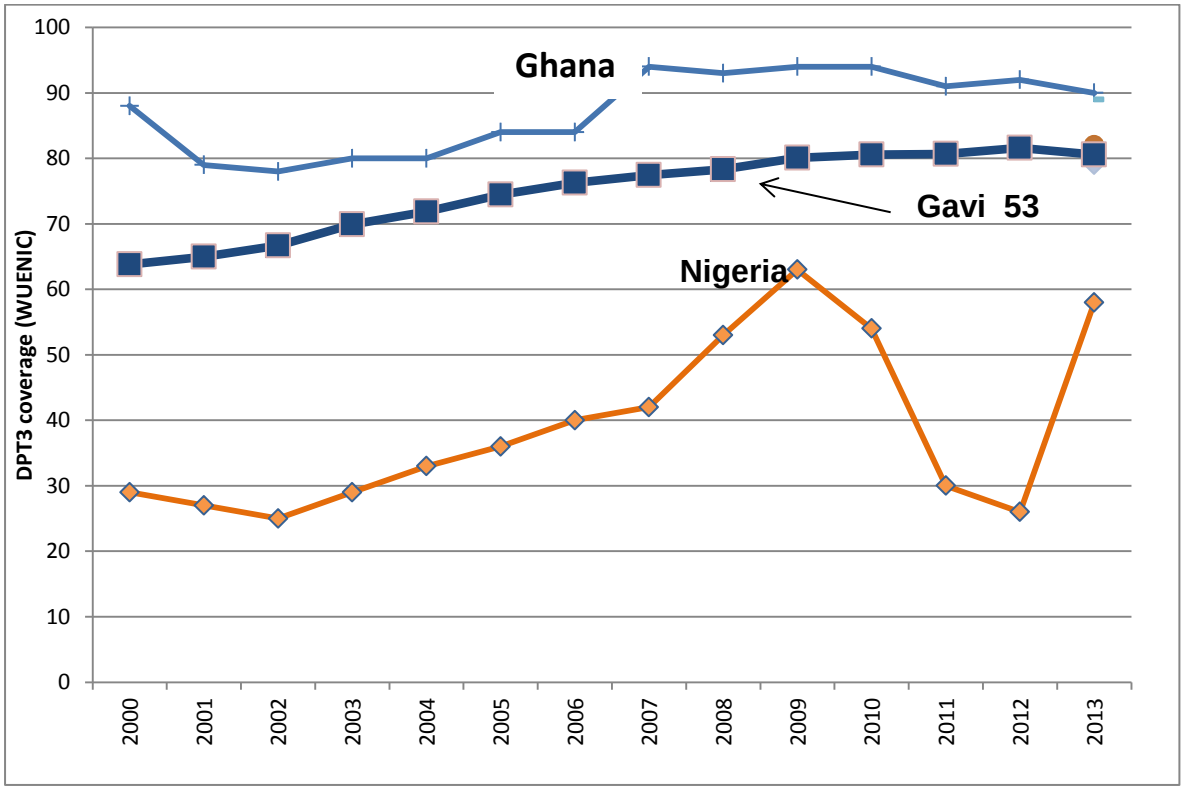
1. ***Coverage:*** (a) Increasing use of high quality EPI Review and Joint Appraisals should be applied in order to analyse and respond to coverage gaps and challenges of data quality; (b) Gavi Alliance should evaluate data quality measures and support countries to better use them
2. ***Polio Eradication:*** Technical support for IPV introductions should be considered as ongoing and focus on:
    a. Countries with weaker supply chain readiness
    b. Additional training, guidance and technical support on multiple injections and MDVP
    c. capitalize on the experience of accelerated IPV introduction both at global and country level (including if/how strengthening of routine occurred) by undertaking a review and accumulating lessons learned.
3. ***NVS and campaign***: introduction of new vaccines and supportive TA should systematically take a sector wider and integrated approach (eg HPV and adolescent health, RV and diarrheal control, measles and the older child visit). Justification for campaigns should be evidenced by epidemiology and risk assessment. Application for campaign support should present evidence of no harm to routine and invest purposely in strengthening routine.
4. ***Supply Chain:*** Gavi to support the development of "Supply Chain System design" tools to assist countries to improve quality and efficiency of supply chain and to continue using 3 year-EVM and cIP to improve performance.
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. Promote alignment with national health sector strategic plan
    b. Discourage verticalisation (PMU, incentives, supervision) and promote approaches that address sustainability from the onset, and create opportunities for collaboration and integration
    c. HSS budget ceiling to be re-considered to foster absorptive capacity and sustainability
    d. Support investment in demand side strategy and/or CSO partnerships to expand the reach of services and ensure that needs of underserved are represented and addressed
    e. Promote strategic long term TA across the Gavi portfolio and over grant life with goal of improving local capacity hence improving sustainability
6. ***Gender and Equity:*** Support evidence based gender and equity analysis to inform demand and supply side strategies.
7. ***Monitoring and Evaluation:*** Gavi should encourage countries to include (a) at least one indicator to assess strengthening of the health systems and (b) equity indicators' baselines and targets.
8. ***Governance:*** Gavi Alliance should use the annual joint appraisal to promote more effective governance at country level. Gavi should play its full active role in sector wide platforms (SWAPs, RBF)
9. ***Communication:*** Provide countries with communication development and implementation guidance, with a view of adapting it to suit each context and issues
10. ***Sustainability***: Include other funding support beside NVS (co-financing) in Gavi financial sustainability policy. Gavi to structure investments in graduating and intermediate countries to foster systemic changes and strengthen country capacities and systems.

2. Findings

2.1 Data Quality, Coverage

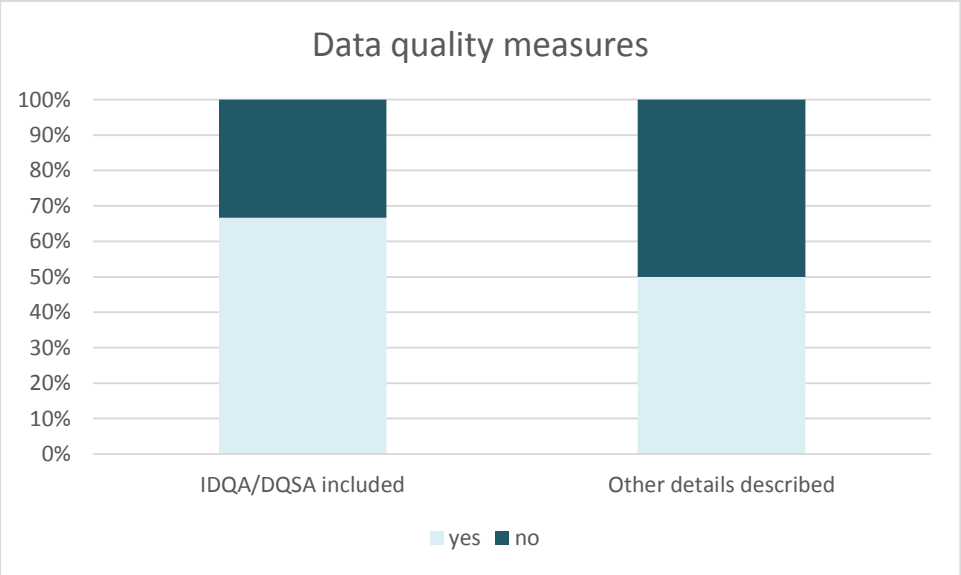
As noted in the final report from the November 2014 IRC, coverage in Gavi countries has stagnated at around 80% (not weighted by population) for the past 4 years. As countries approach and reach Gavi graduation they present differing challenges in terms of coverage. Ghana provides an example of a graduating country still struggling to reach the last 10 – 15%. Nigeria, on the other hand, presents an entirely different challenge, with coverage still far below the Gavi average and gross regional inequities (See Figure 2). Both countries are approaching graduation. These two very distinct challenges both point to a critical need for the Gavi Alliance to explore mechanisms for tailored, ongoing support to graduating countries, either through the secretariat or through coordination among the Alliance partners.

Figure 2: 2013 DTP3 WUENIC coverage



Also as noted in the November report, data quality continues to be problematic. The IRC noted an increase in discussion of data quality measures throughout this round's proposals. However, countries' plans to improve data quality in general relied on IDQA or DQSA as the main approaches (67%) and lacked additional detail about other aspects of data quality improvement activities (50%). (See Figure 3.) Evidence of the effectiveness of these tools remains inconclusive, especially as some countries who have applied them have demonstrated improved data quality scores and yet simultaneously continued to find significant gaps between administrative estimates and survey coverage, e.g. Nigeria. In particular, data quality measures included in this round's proposals focused on national-level training workshops and desk reviews, while not addressing data validation and use at sub-national levels (also see Annex 8).

Figure 3. Data quality measures in proposals (n=24)



Recommendations for Coverage and Data Quality

1. Concerning coverage trends: In line with the IRC's recommendation from its November 2014 report to base Gavi's country tailored approach on recommendations of recent, high quality EPI Reviews and high quality, annual Joint Appraisals. Gavi should create an approach to support graduating countries tailored to their particular coverage patterns, as demonstrated in high quality EPI reviews.
2. Concerning data quality: While countries do appear to be recognizing that data quality is an issue they must address, the available approaches to improve quality are of unproven effectiveness. While the IRC appreciates the value of an annual desk review of data quality, Gavi guidelines should indicate the methodology (i.e. that now promoted by WHO) or at least provide standards for such a review.

2.2 IPV proposals

Issue 1: Completion of the accelerated IPV introduction in Gavi eligible countries in Global Health Context for IPV Introduction

As of March 2015, Gavi had successfully approved 71 countries out of 73 eligible countries for introduction of 1 dose of IPV (the remaining two countries are not expected to apply for support). This is a major achievement, considering that the first approval only happened one year ago. Seven applications were approved by the IRC in this review.

This is in line with the declaration by the 2012 World Health Assembly for completion of the poliovirus eradication, in which WHO announced the Global Polio Eradication and Endgame Strategic Plan 2013-2018 that aims to deliver a polio-free world by 2018. It addresses the eradication of all polio, whether caused by wild poliovirus or circulating vaccine-derived poliovirus, while planning for the backbone of the polio effort to be used for delivering other health services to the world's most vulnerable children. The Strategic Objective 2 of this plan calls for systems strengthening, IPV introduction by the end of 2015 and OPV2 withdrawal in all OPV-only using countries by April 2016.

The IRC strongly urges that Gavi and partners conduct analyses and accumulate lessons learned over the introduction of a new vaccine in a record time. These lessons learned could inform preparedness for another emergency vaccine introduction (eg. Ebola vaccine).

Recommendation 1a: Conduct an analysis of lessons learned from these rapid IPV rollouts, both at country level and with partners (including how strengthening of routine immunisation has occurred). Consider how these lessons can inform the next emergency (fast track) vaccine introduction strategy.

Recommendation 1b: Countries should be encouraged to develop their new cMYP to also include their strategy for eradication of polio detailing introduction of IPV in RI, the strengthening of routine and AFP and polio environmental surveillance.

Issue 2: Ensuring effective introduction of IPV in the approved countries

This last round of applications involved the last seven countries expected to apply for IPV. These consisted of a combination of strong and weaker applications for which we have provided the Secretariat with specific actions points that need to be addressed for these countries.

Considering the programmatic urgency to introduce IPV by end of 2015, Gavi had waived some of the standard requirements for approval of new vaccine introductions. These included vaccine co-financing requirements, the requirement to update the cMYP, the 70% DTP3 coverage filter and the acceptance of applications from graduating countries.

The Gavi waivers have helped graduating countries (Guyana, Armenia, Bolivia and Papua New Guinea) and those having DTP3 coverage below 70% (Haiti and Papua New Guinea) becoming eligible for this round of applications (See Table 1). cMYP for all the applicant countries were ending in 2015, except Guyana, which provided an updated cMYP. Seeing ***how these countries do with IPV and supply chain, after Gavi waived all of the usual requirements*** (updated cMYP, DTP3 coverage >70%, graduation status) would be an important component of the evaluation of this rapid roll out that the IRC is recommending.

Table 1: IPV proposals: Country profiles

COUNTRY	cMYP status	DTP3 coverage (WUENIC 2013)	Cold chain issues	GNI (per capita US$, 2013)	Co-Finance status
Honduras	2011-2015	87%	No	2180	Graduating
Haiti	2011-2015	68%	Yes	810	Low income
Bolivia	2011-2015	94%	No	2550	Graduating
Djibouti	2011-2015	82%	Yes	1030*	Intermediate
Papua New Guinea	2011-2015	68%	Yes	2010	Graduating
Armenia	2011-2015	95%	No	3800	Graduating
Guyana	2013-2017	98%	No	3750	Graduating

**2005 data*

The IRC observed that some countries in this round had major weaknesses in one or more areas of supply chain management, distribution, temperature monitoring and cold chain equipment.

Several countries continued to express concerns on how to communicate with both health care workers and parents on multiple injections at one visit *(see section 2.12).*

Recommendation 2: Gavi Secretariat and Partners need to assist countries to achieve successful IPV introduction (See Table 2)

Issue 3: Supply, Licensing and Implementation timelines

UNICEF Supply Division briefed the IRC that requirement of current 50 million doses of IPV is expected to almost double by 2016 with proposed introduction of at least 1 dose of IPV into the routine immunisation Programme of all countries by end of 2015. UNICEF offered to provide the preferred product presentation to the countries applying in this round and procuring IPV through it. To address the supply gap for the 5-dose presentation, around 10 countries may be asked to delay introduction to October 2015. For the 10-dose presentation, if the request for SIA is approved, then tier 3 & 4 countries will need to delay introduction by around 3 months.

PAHO has clarified that 10-dose presentation would not be available for countries procuring vaccine through its Revolving Fund.

Table 2: IPV proposals: country target population and preferred presentation

COUNTRY	Birth Cohort (2015)	IPV Presentation (in order of preference)	Proposed Month of Introduction	Additional support needed
Honduras	211,027	5, 10, 1	October, 2015	
Haiti	263,968	5, 1, 10	September, 2015	Yes
Bolivia	278,011	1, 5, 10	October, 2015	
Djibouti	24,026	5, 10, 1	September, 2015	
Papua New Guinea	214,827	5, 10, 1	November, 2015	Yes
Armenia	39,455	1, 2, 5	October, 2015	
Guyana	15,819	1,5,10	September, 2015	

Four countries had the 5-dose presentation as their first preference, while Armenia, Guyana and Bolivia requested the 1-dose presentation.

No licensing issue was identified in any of the applicant countries as IPV was either already registered (Guyana, Papua New Guinea) or they did not require registration of the vaccines if acquiring from PAHO RF/ WHO PQ mechanism (Djibouti). On a number of occasions, concerns were expressed by the IRC regarding the feasibility of implementation timelines (eg. Guyana, Haiti), and recommendations were made for postponement to ensure effective introduction.

Recommendation 3: Gavi Secretariat to work closely with UNICEF and PAHO to identify actual availability dates of the vaccines for the respective countries and provide guidance to the countries so that they may submit revised timelines for IPV introduction.

Issue 4: 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. Accordingly, the wastage rates for the multi-dose vial products have been reduced to 15% for 5-dose presentation and 20% for 10-dose presentation. Most of the countries requesting 5-dose presentations in their original proposal submitted before the communication of the MDVP of WHO. The higher wastage rates was later clarified and reduced by the Gavi Secretariat. However there appears to be a need for training of health workers so that they adhere to these wastage limits to avoid stock outs later.

Recommendation 4 Gavi Secretariat and Partners at country level should ensure that health workers receive training on issues related to vaccine handling, storage, monitoring and administration.

2.3 Other NVS proposals

This IRC reviewed 11 NVS proposals: one MenA routine introduction, two rotavirus applications, one HPV Demo application, two MenA campaigns, two MR campaigns, one measles SIA, and one yellow fever campaign.

Issue 1: Integrating other health interventions with Rotavirus and HPV Demonstration Program Proposals

Gavi strongly encourages countries to adopt comprehensive and integrated approaches to disease control that place vaccines alongside with other health high impact interventions that contribute to improved outcomes. Please note that integration with other health interventions is encouraged, it is not a requirement of Gavi's RV programme.

Both rotavirus (for diarrheal disease control) and HPV Demonstration projects (for Adolescent Health Intervention) would strongly benefit from an inter-sectoral approach to be developed in the new vaccine application. This requires a broader perspective and partnering beyond areas of expertise outside the traditional EPI program. For both Lesotho (Rotavirus) and Sao Tome and Principe (HPV Demo), this inter-sectoral planning was difficult, and country capacity may be minimal.

Recommendation 1:

- When offering support to countries to develop these proposals, Gavi should consider technical assistance that helps the country build capacity for these inter-sectoral approaches, beyond the technical assistance of simply writing the proposal. This may require consultants not traditionally involved in EPI as their primary role, and may require longer term TA.
- Experts from other programmes should be associated early in application development and be part of the ICC discussions (Water & Sanitation and Nutritionists; adolescent health) If possible, integrated activities should be aligned, planned and budgeted along with the vaccine introduction proposal.

Issue 2: E*ncouraging countries to introduce MR second dose into routine immunization*

The WHO position paper recommends the strategy of conducting a wide age-range catch-up campaign followed by the introduction of one dose of MR vaccine in the routine vaccine programme. Gavi does not pay for Rubella vaccine in the routine programme. Countries are required to pay the full cost of the rubella component of the MR vaccine. As Gavi pays for measles second dose (MSD), some countries will be opting for first dose MR and second dose MSD, leading to more complex schedule, challenges in stock management and increased wastage.

Recommendation 2: The Gavi Alliance should provide evidence for countries to make the decision to introduce the 2nd dose MR vaccine in their routine schedule.

Issue 3 (Rotavirus vaccine): Disease burden inadequately documented by countries to justify vaccine introduction decision-making process
Essentials of burden of disease relates to infants and children under 5 years old. It is therefore important that countries applications report specifically on disease morbidity and mortality specifically among infants and children under 5 years old.

Recommendation 3: Relevant disease burden data should be appropriately gathered and presented to the ICC to inform the decision-making process. Countries are encouraged to establish or strengthen multiple and functional rotavirus surveillance sentinel sites to enhance accurate data capture.

Vaccination campaigns

We reviewed seven proposals for Gavi support for mass vaccination campaigns against meningococcal group A meningitis (DRC, Guinea Bissau, Ghana), yellow fever (Ghana), measles and rubella (Kenya), measles (Nigeria), and Japanese encephalitis (Nepal).

To be considered for support for campaigns, country applications should describe in their plan of action how campaign activities will achieve high coverage including strategies to reach non- and under-vaccinated populations. Country applications should also describe how planning campaign and/or follow-up will strengthen routine immunization.

Issue 4: Lack of attention given to routine immunization strengthening compared to the campaign itself.
For some countries (Kenya, Gambia), during the measles/MR campaign proposal development, the focus is on how to achieve very high coverage (>95%) with measles vaccine or MR vaccine during the campaign. There is good micro planning with mapping for unreached populations, supervision, daily monitoring meetings with supervisors, etc. However, nothing specific is planned to strengthen routine immunization system (or to mitigate possible harm to routine during campaign). In contrast, the Ghana proposal for MenA and yellow fever campaigns could be used as a good example of best practices for doing this.

Recommendation 4: Countries should take the opportunities offered by the measles/MR campaign, before the campaign (micro planning, revision of training and management material, coordination meeting, etc.), during the campaign (communication / social mobilization, supervision, daily monitoring meetings) and after the campaign (update RI micro plans, coordination for monitoring and supervision) to reinforce routine immunization system. Best practices should be promoted by supporting partners.

Issue 5: Relatively short lead time from campaign to vaccine introduction
Ghana proposed its YF campaign in July 2015; however, the lead time for approval, cold chain upgrade and delivery of vaccines which is usually between 6-8 weeks at the earliest would be a serious challenge to overcome.

Recommendation 5*:* Gavi and partners at the country are encouraged to discuss and suggest a delay of at least six months, to achieve an effective coverage through adequate planning and support logistics in place.

Issue 6: Lack of epidemiological evidence

The epidemiological evidence presented was often not adequate or not specific enough (distribution of age in cases, geographical distribution, birth cohort calculation, probability of outbreaks).

An epidemiological risk assessment was done for men A in the DRC and yellow fever (Ghana). However, a risk assessment was not done for men A in Guinea Bissau, measles and rubella in The Gambia and Kenya, men A in Ghana, measles in Nigeria, and Japanese encephalitis in Nepal. According to current guidance documents, risk assessment is required for Men A and yellow fever but not for meningitis mini catch up vaccination campaigns, measles, rubella, and Japanese encephalitis. The justification for these other campaigns was often based on international recommendations and data collected through routine data collection systems (such as health management information systems and case-based surveillance) within countries. For Guinea Bissau, for example, according to data from the National Public Health Institute, the country has not reported a single case of meningitis in the last three years. However, since the country is located in the African Meningitis Belt, it is following the recommendation to conduct a preventive MenA vaccination campaign. The information sources for epidemiology and disease burden come from the weekly notification database of the National Institute of Public Health and JRF 2013. There was no risk assessment available describing the epidemiological situation attached to the proposal, but there was an accompanying note from WHO recognising that the country shares borders with at-risk areas in two countries within the meningitis belt and recommends conducting a mass preventive campaign to help establish population immunity.

There was often pressure on planning and timelines (for fear of potential outbreaks). The period between the Gavi grant approval process (IRC review of proposals, Executive Committee or Board approval, and release of funds) and the planned start of the campaigns was often very short. Examples include the men A vaccination campaign in the DRC, which is planned for September 2015, and the measles campaign in Nigeria which is planned for September-October 2015.

Recommendation 6

- Gavi should evaluate its ongoing strategic role in supporting measles control/elimination
- WHO should provide objective epidemiologic risk assessment for all mass vaccination campaigns (including measles) as is now done for men A and yellow fever.
- The risk assessment should include whether the proposal should cover whole or only parts of the country

Issue 7: Limited use of lessons learned

The proposals and introduction plans were generally well written, although campaign strategies were not always based on lessons learned from prior campaigns and evidence-based practices. For example, the planned measles vaccination campaign in Nigeria will be based on a fixed-post approach, but the application cites alternative campaign approaches that have proven to be effective in the country such as health camps and influencers in high-risk/high refusal rate communities; supply-side innovations used in the security compromised states; and outreach tactics. The measles vaccination campaign will be coordinated with a polio vaccination campaign and are to utilize all existing structures, resources and strategies from the polio programme. The Gavi pre-screening states that “some donors in Nigeria have expressed concern about the quality of the 2013 campaign, and have asked Gavi to ensure due attention is given to proper planning and implementation of the 2015 campaign.”

Recommendation 7: Partners should support planning and implementation of proven tactics that also support routine immunisation systems

Issue 8: Lack of clear guidance for application of MenA mini catch-up campaigns
For MenA vaccine introduction, the support for use of terms such as campaign, mini-catch-up campaign and routine introduction of the vaccines was not differentiated and created confusion. In Guinea Bissau, activities related to routine introduction and mini catch-up campaign were incorporated in the application for a Men A campaign. It should be made clearer that a country cannot apply for all 3 strategies of MenA delivery at one time. For example, Guinea Bissau should apply separately for conducting a MenA campaign. Routine introduction should only have a mini catch-up campaign if years has passed since the main campaign. The sequence should be clearly defined. In the Ghana application, it seemed as if the Gavi application form did not cater appropriately for the catch-up campaign along with routine introduction.

Recommendation 8: Clearer guidelines are needed regarding the scope and sequence of activities for MenA campaigns, catch-up campaigns and routine vaccine introduction programmes to guide compliance with the application process.

2.4 Health System Strengthening

General Overview: Overall, 10 country applications for HSS support were reviewed in this round. One country (Cambodia) was resubmitting its application from the November 2014 IRC.

The IRC noticed the good quality of most proposals, based on sound situation and bottleneck analysis and clearer links with the proposed approaches. Most proposals expressed a clear focus on the “missing %”, the hard to reach population, through a number of different strategies, from strengthening logistics to HRH support, to integration of immunization activities with primary health care, to increasing investments on the demand side at community level using CSO capacities. The focus on immunization outcomes, consistent across most proposals and supported by good M&E frameworks, was relatively less vertical than in previous rounds. One country proposed to maintain and expand a PMU (Burundi) while the other nine proposed management and implementation arrangements within the already existing institutions, procedures and coordination mechanisms.

Several HSS proposals showed a usual pattern of bulky procurement of equipment and transports, not always fully justified (outdated EVMA in four cases). But the harmonized approach proposed by some countries, as the contribution to sectoral pooled funds and to RBF schemes, is a sign of alignment to evolving aid effectiveness approaches. While Gavi was already engaged in SWAps and sectoral schemes in the same countries, this represents an innovative approach from countries, likely becoming a positive increasing trend toward country ownership and aid effectiveness, with related challenges to be addressed.

For five HSS proposals out of ten, the IRC recommended resubmission after a thorough and challenging review. These five countries were advised to better exploit the potential benefits of planning their HSS grants over 5 years consistently with their broader ***Health Sector Strategic Plans (HSSP)***. HSS grants should be viewed as critical opportunities to address the underlying causes of “flattening coverage”, to reach missing children through every health worker, community worker and facility in the country’s health sector

Table 3 summarizes the outcomes of the IRC review and some key features of the ten HSS proposals, providing a background for the issues described below.

HSS issues

1. ***HSS proposals are often prepared with insufficient active involvement of Health Systems actors in country (MoH and Partners).***

Proposal development was coordinated by the MoH in each country, mostly initiated and guided by the ICC or the immunization programme and related departments, with limited involvement of other MoH expertise. Engagement of other health sector stakeholders was mainly through consultations, including Civil Society, with varied degrees of active participation and contribution. Four applications were supported and endorsed by a sector wide coordination committee. In the other countries, this was not consulted, even where other HSS initiatives were ongoing (eight out of the ten countries have pooled funds and / or RBF schemes currently ongoing with multiple donors).

2. ***Inadequate alignment with country Health Sector Strategic Plans (HSSP)***

Only one (Nepal) out of 10 HSS applications was aligned with the country's national health sector strategic plan for its full period. The Congo three-year proposal was aligned with the last 2 years of the HSSP. The other countries have their planning cycle finishing in 2015 and no new strategic plan in place. This is a matter of concern for 5-year HSS proposals in terms of alignment and insertion of Gavi's potential contribution within the wider context of domestic and external support to the health sector. As a result, Gavi's contribution to the country may become indiscernible and underestimated.

The potential alignment and synergy with other HSS support – e.g., from the Global Fund, which is ongoing in at least 5 of the 10 countries – is an opportunity for optimizing the investment. (In Cambodia, there is a health sector pooled fund – HSSP2, second Health Sector Support Project, and funds from Gavi and the Global Fund are parallel, not pooled, but contribute to the national plan, with financial and implementation management led by the same body, the HSSP secretariat within the MoH.)

3. ***Verticalisation (PMU, incentives, supervision) and missed opportunities for a more sustainable integrated platform.***

The proposal of parallel structures and systems seems to be decreasing – only Burundi proposed a PMU while the governance structure of STP was not entirely clear– in favour of management and implementation arrangements within the already existing authorities, institutions and coordination mechanisms. In terms of service delivery, integration of EPI with PHC is pursued by some countries. However, support for assets, supervision, incentives, on-the-job training for selected service tended to be delivered in a vertical way and thus would still require more contextualization and a more sustainable approach.

4. ***HSS ceiling often not linked to absorptive capacity and failing to promote sustainability***

First some budgets seem to be constructed to reach the ceiling, but lack meaningful allocation of funds and activities in geographical areas and over time. This raised IRC concerns about absorption capacity notably in weak contexts; and about sustainability when a Gavi grant may delay – or even replace – domestic funding.

Second, countries with country tailored approach can (according to Gavi guidelines) apply for the full HSS ceiling for a 3-year project instead of for 5 years. The IRC noted that these countries are often those with particular limited absorptive capacity for implementing systemic reforms and it can therefore be questioned if this should be a recommended policy. In particular, the IRC thought that the Chad proposal presented a large risk to the investment because a large amount of funds were going to be spend in a short time spent. Many of these countries, including Chad, have not been able to spend their first HSS grants due to lack of absorptive capacity.

5. CSOs and community engagement

There is limited CSOs engagement in proposal development, with ad hoc consultations rather than consistent involvement. Involvement of CSOs and communities in implementation is mentioned in all proposals (except Lao PDR), mainly in relation to demand creation and service expansion. The Gavi grant was proposed to be partially channelled through CSOs in Cameroon (16%) and Zambia (28%); three countries (Bangladesh, Cameroon and Congo) had a budget line earmarked for CSO work in the grant implementation.

6. HSS previous experience.

Although required by the guidelines, lessons learned and linkages with previous or on-going HSS grants are insufficiently considered in new HSS applications, or their use is limited to the situation analysis rather than applying lessons learnt to substantiate the proposed priorities and activities. Also, the role of the HSS grant in strengthening systems for the introduction of new vaccines should be better explored and developed. For example, more than merely funding equipment, the HSS grant may provide critical support to the fifth "fundamental" of supply chain capacity, the System design, and link this with the country's national health strategy.

Table 3 Summary of HSS budget allocations

Country	Type of application	Cash support requested (US $)	GAVI budget ceiling (US $)	Outcome
Bangladesh	New application	83,498,375	84,000,000	Resubmission
Burundi	New application	29,898,611	48,300,000	Approval
Cambodia	Resubmission	18,058,048	18,060,000	Approval
Cameroon	New application	23,520,000	23,520,000	Resubmission
Chad	New application	15,378,848	15,960,000	Resubmission
Congo	New application	4,419,990	4,420,000	Approval
Lao PDR	New application	7,560,000	7,560,000	Resubmission
Nepal	New application	36,540,000	36,540,000	Approval
Sao Tome and Principe	New application	3,043,173	3,500,000	Approval
Zambia	New application	14,670,561	14,700,000	Resubmission

Gavi as a full participant to HSS at country level

As an IHP+ signatory, Gavi aims to assure that its HSS support is aligned with national health strategic plans, M&E frameworks and processes (eg annual, sector-wide health sector reviews and planning meetings). To truly strengthen health systems and assure national ownership, HSS support should be guided by these sector-wide documents and processes. Without strong governance mechanisms and procedural safeguards, there is a risk that the design of HSS support reflects only a programme support approach for immunization (HSS support then becomes ISS).

It is for this reason that Gavi guidelines stipulate that "Gavi encourages the timing of HSS applications to align with the timeframe of National Health Plans." This requires that the process for developing HSS proposals engages key stakeholders and decision makers (eg

national health planners and policy makers, those responsible for sector wide M&E, etc). Such engagement is much more challenging when the timeframe for the development of an HSS proposal is not synchronized with the timeframe for developing/updating the National Health Strategic Plan.

In order to foster greater programmatic sustainability, it is critical for Gavi to review HSS proposals in terms of overall health system, routine immunisation and Gavi portfolio context (i.e. no "silo" reviewing where possible), including for graduating countries. Gavi's contribution to the country's HSS effort and national health sector programme should allow Gavi to positively influence country programmes towards full integration and ownership of the immunisation programme.

Need for bridging grant

Apart from support for IHP+ principles, Gavi has a core mission: to improve access to vaccines. For this purpose Gavi is strategically allied with national immunization programs (NIPs). These programs have their own requirements for finance, technical capacity and equipment (especially cold chain and logistics equipment). Many of the Gavi 53 countries have become dependent on Gavi support (and Gavi HSS/cash support in particular) to meet these NIP requirements. Immunization coverage in a number of countries would be at risk if Gavi HSS support to the NIP were to be interrupted.

Under these circumstances, Gavi needs to find a way to respond to the fundamental needs of NIPs until the national strategic planning processes can appropriately guide the development of HSS proposals. Gavi should have a mechanism for providing bridging grants to NIPs during this interim period with the understanding that any long term (5 year) HSS proposal that is subsequently submitted to Gavi will be fully in alignment with the National Health Strategic Plan and fully owned by those responsible for establishing those NHSP's.

Recommendations on HSS:

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

Reinforce principles of aid effectiveness*:*

1. Support sector and multi sectoral governance mechanisms. Promote Gavi engagement at country level, through SCM or Alliance partners.
2. Encourage countries to support a more integrated primary care platform, to promote programmatic sustainability and increase value for money.

Other:

3. The process for submitting proposal to Gavi should be reviewed and updated. For instance, the Expression of Interest (EOI) made by countries should make sure to highlight national cycles, and clarify whether bridging funding will be needed
4. Consider bridge funding as an extension of the previous grant (rather than as a new grant)
5. Clarify conditions for the use of PMUs as management instruments and if considered relevant, consider synergies and possible merger with other donors PMUs.
6. Consider reviewing the budget ceiling policy for countries with very large birth cohorts
7. Make optimal use of the Joint Appraisal process at country level as it provides more constant guidance and monitoring while looking at the whole national Gavi portfolio.

8. Re-consider the policy of granting countries with country-tailored approaches the full ceiling in only three years instead of five years.
9. Consider systemic strengthening versus programme support, especially on
    - Wide health sector governance and coordination
    - Training – Preference for integrating content in pre-service curricula for competency-based training of the health workforce rather than specific and ad hoc on-the-job training. It should qualify professionals at all levels on immunization issues and, preferably, be linked to career progression.
    - Supply chain system building (including skills building, maintenance, stable procurement channels, management) instead of only procurement.

Table 4 summarizes the main HSS proposals according to budget, main content areas of each proposal and IRC recommendations.

Table 4 Summary of HSS proposals

GAVI - HSS - Mar 2015			HSS budget - All figures in million US$									
Country	**Type of Application**	**IRC outcome**	**Gavi budget ceiling**	**Budget requested ($)**	**Budget granted**	**Budget Recipients**			**Gavi in Pooled fund**	**Sectoral multi-donor programme / pooled fund**	**IHP+**	**GFATM HSS Grant**
						Gov	CSO	Partners				
Bangladesh	HSS new application	Resubmission	84.00	84.00	0.00	na	na	na	Yes	MDTF of HPNSDP (WB)	no	no info
Burundi	HSS new application	Approval, 3 years	48.30	29.90	28.92	100%	0%	0%	no	RBF with MDTF (WB)	Yes	Yes
Cambodia	HSS re-submission	Approval, 5 years	18.60	18.06	18.06	100%	0%	0%	no	HSSP2 (2nd Health Sector Support Project): WB + 6 DPs	Yes	HSS grant $24.5 million
Cameroon	HSS new application	Resubmission	23.52	23.52	0.00	52%	16%	32%	no	RBF with MDTF (WB)	Yes	Yes, in Malaria grant
Chad	HSS new application	Resubmission	15.96	15.38	0.00	na	na	na	no	RBF with MDTF (WB)	Yes	no info
Congo	HSS new application	Approval, 3 years	4.42	5.20	5.20	0%	0%	100%	no	RBF with MDTF (WB)	no	No
Lao PDR	HSS new application	Resubmission	7.56	7.56	0.00	na	na	na	no	no	no	HSS grant from Global Fund will run simultaneously
Nepal	HSS new application (+JE)	Approval, 5 years	36.54	36.54	36.54	100%	0%	0%	Yes	Sectoral pooled fund	Yes	no info
Sao Tome & Principe	HSS new application (+HPV, Rota)	Approval, 5 years	3.50	3.04	3.04	na	na	na	no	no	no	Yes
Zambia	HSS new application	Resubmission	14.70	14.67	0.00	57%	28%	16%	no	RBF piloted (WB)	YES	no info
TOTAL		5/10	257.1	236.97	91.84							

2.5 Pooled Funding

In this IRC round, approximately half of the HSS proposals showed increasing interest in participation in pooled arrangements, SWAps and RBF programme (4 in this round, see Table 5). Zambia also referred to participation in an RBF programme in its proposal, but with no details.

Table 5: HSS countries in pooled arrangements

SWAP	**Result based financing programme (RBF)**
Bangladesh (1997) Nepal (2004)	Burundi (2011) Cameroon (2013)

In brackets the year when the common pooled funding arrangement was established

There have been documented benefits of pooled funding arrangements. The principal ones have been in the areas of country ownership, donor coordination, financial and programme management, the establishment of a country results frameworks, support for CSO involvement, improvements in the countries' budgetary allocation to health, and the predictability of funding for health. RBF schemes are more recent and evaluation of the results is only starting to emerge.

Gavi was one of 19 development partners who initially signed the IHP+ Global Compact in 2007, making commitments to improve aid effectiveness and development cooperation. Now that the opportunities to join common financing and programme arrangements are increasingly materializing, the implications of these commitments for Gavi engagement need to be specifically laid out and more carefully reflected in the proposal guidelines to the countries.
These must subsequently be taken into consideration by IRC members. The current guidelines - which are the existing ones for the standard proposals with some minor modifications for proposals for pooled funding - do not easily allow proper and adequate assessment of the quality and feasibility the proposals presented. This led to challenges in assessing the feasibility of budgetary requests and allocations and therefore the value added by the proposed programme of work.

Although the IRC does not encourage Gavi to be too prescriptive as this is contradictory to the pooled funding principles, there needs to be clearer and more explicit guidance to countries and the IRC of how and in what (if any) ways the following issues are to be addressed:

a. Where there is to be participation in wider pooled arrangements, there needs to be clarity as how to assess the contribution of pooled arrangements to Gavi's goals and objectives; how it deals with investments in the Cold chain for immunisation, for instance; how it addresses immunisation system bottlenecks and equity concerns and in turn, how to assess the value added by Gavi's contribution.
b. What are Gavi's formal expectations in terms of reporting of results, outcomes and data quality?
c. Performance monitoring: what should be the appropriate M& E framework? How to ensure that the national M&E framework allows the implementation of the Gavi PBF reward scheme.

d. In the case that funds are entirely pooled, what assessment should be made of the functioning and performance of the pooled funding; how, and in what ways, should the financial management be audited and monitored?
e. What are the relationships between Gavi and other partners? How to ensure operationalization of peer and/or mutual accountability? It is not clear how Gavi currently makes sure that it plays an active role at country level?
f. What are the arrangements for a remedial strategy if there is no or unsatisfactory progress in the pooled arrangement?

Recommendations

- Ensure Gavi's participation in annual planning and review of the pooled fund arrangements
- Review the evaluation of the results of the overall pooled arrangement, including sustainability aspects, in the Joint annual appraisal
- Guidelines should better reflect Gavi's policy on participation in pooled arrangements with a view to enhancing proposal preparation and assessment processes.
- Background documents such as those governing the goals, objectives and functioning of a pooled arrangement or a SWAp should be made available to the IRC for the review process.

2.6 Technical assistance

Gavi expects HSS applications to provide a plan for TA as well as a procurement plan.
Countries described the following approaches for technical assistance (TA):

- Hiring of international and national consultants (all of the proposals)
- Public tender and out-sourcing TA in specific areas
- Using existing national scientific institutions and groups to provide ongoing TA
- Involving CBOs for planning, implementing and evaluating activities at local levels
- Long-term and short-term staff placement for TA:
  - Increasing staff of EPI (international and national advisors)
  - Enabling (newly hired) EPI staff to provide TA
- WHO and UNICEF as constant technical partners providing short-term and ongoing TA (all of the proposals)

The IRC noted some signs of improvement from previous proposals:

- Some proposals have started looking at TA beyond consultants
- Only limited mention of CSOs as TA providers
- Efforts to strengthen EPI staff within the health system as TA providers
- Efforts in some countries to think short-term and long-term solutions
- Some mention of looking for additional support from a pool of partners
- New HSS format permitted equity and gender issues to come through in countries that have previous experience in these areas; but exposed even more those countries that had not considered it as part of the process. Not a key issue in TA.

Issue 1: TA is often not accompanying the life-cycle of the grants within a systems approach and is mostly grant-specific, not across the country's whole Gavi portfolio (HSS, NVS, HPV demo, campaigns)

For the most part, TA comes across as an appendix of the proposal, not as an intrinsic and crucial element for the success of the implementation of the grant. TA does not seem to affect the proposal's design that, with few exceptions, seem to have activities delivered in a "business as usual" mode. Most of the proposed TA is output driven (e.g., preparation of the

proposal, developing guidelines) rather than outcome driven (e.g., sustainable institutionalized knowledge transfer, competency-based training). Not enough effort is placed on the rationale behind the proposed activities, budget allocation and linkages/synergies with existing in-country TA efforts that are being developed by other technical areas (e.g., HIV/AIDS, MNCH, family planning). Most proposals describe TA starting with the first disbursement; thus, the period between proposal approval and disbursement, which can take 6 months to over a year, seems to be a lost opportunity to increase country preparedness for implementation.

Issue 2: Generally proposals lack innovative HSS program design and TA rarely addresses sustainability or preparation for graduation

The proposal design tends to be too much focused on a "project" approach and with attention given to equipment and short-term support. The descriptions of TA in the HSS proposals fail to take into consideration the multiple grants that make up the country's Gavi portfolio. TA does not seem to take into consideration sustainability and/or country preparedness for graduation even in countries that will be graduating sooner than expected. It seems that the TA provided to several countries is mainly oriented at compensating weaknesses, replacing the national institutional capacities when they are not in place. There is very little social innovation and, for the most part, technological innovation seems to be restricted to bits and pieces of activities instead of anchoring it to national systems (e.g., national eHealth plans) and inclusion of key stakeholders (e.g., Ministry of Technology or equivalent, operators, regulators). South-South collaborative networks are not developed as TA options and there is no mention of using PMUs as potential catalyzers of TA.

Recommendations

- Comprehensive TA planning is required to address full life-cycle (from pre-proposal stage to closure of grants) with medium/long term and consistent TA oriented at building capacities of the national officers.
- Assess TA needs as a core component of joint country reviews and pre-screening process should include gender and equity in the analysis and TA planning
- Technical partners (especially at country level) to engage in developing joint TA plans and coordinating the TA delivery as well as monitoring the quality of the TA to avoid pulverizing TA into a myriad of activities
- TA planning should differentiate TA needs related to grant implementation from those that are systemic in nature
- Sustainability and graduation to be part of TA design from inception
- TA should be system-oriented and ensure broader and long-term vision, and include the full Gavi portfolio instead of just the HSS grants

2.7 Supply Chain and Waste Management

Immunization supply chains should demonstrate a state of "Readiness" for the introductions of new routine and campaign vaccines and that measures are in place through HSS support or otherwise to improve "quality, accountability and efficiency" of the supply chain over the period of an HSS investment.

HSS proposals tend to be focused and based on improvement of isolated bottlenecks. Increasing performance beyond existing levels to support the ambitions for raising coverage and introducing new vaccines is going to be difficult without rethinking the supply chain network design for the future. Programmes are increasingly constrained by poor infrastructure and inefficient immunisation supply chains. To ensure regulatory "Good Distribution Practices," thinking globally and acting locally becomes a challenge.

The only structured mechanism in place until mid-2014 to provide a measure of supply chain logistics was the Effective Vaccine Management (EVM) assessment and list of commodities and actions to address specific weaknesses identified in the EVM assessment, often accompanied by a completion timeline and budget. On occasion this was supported by an equipment inventory in some countries and occasionally rehabilitation plans. From mid-2014, there have been a handful of attempts to develop comprehensive EVM improvement plans (cIP's), rather than the earlier shopping list of remedial actions and equipment (IP). Only three countries of the 24 submitting applications (10 of which submitted HSS applications), have conducted such cIP's. The cIP for Lao PDR was not submitted since it would appear not to have been finalised; Bangladesh and DRC cIP's were available for IRC review.

A detailed review of 35 supply chain comments for consideration, 27 issues to be addressed and associated action points are presented in Annex 4.

Conclusions

1. Major improvements are observed in SC storage capacity, but maintenance, distribution and stock management practices remain bottlenecks (See Figure 4).

2. 4 countries are considered "not ready" for vaccine introductions and a 5th country requires close monitoring.

3. The selection of appropriate and WHO/PQS prequalified equipment is frequently not evident.

4. Supply chain improvements respond to weaknesses identified in EVM assessments, rather than addressing measures for systemic improvement. The comprehensive improvement plan (cIP) strategy adopted mid 2014 appear to address this shortcoming.

5. Adoption of DHIS2 in about 40 countries does not provide EPI logisticians with a tool to adequately manage and monitor vaccine stocks, or vaccine quality.

6. Improvement Plan management and procurement guidance is weak.

7. Risk of supply chain readiness will be compromised further if Gavi relaxes guidelines for EVMA's and Improvement Planning from the 36-month mandatory minimum frequency of EVM assessments to 5 years. This will further encourage countries not to focus on ISCL improvements.

    - EVM/IPs are the only basis for defining SC needs in HSS proposals. Inventories and rehabilitation plans only address equipment status and equipment needs. A 5-year-old EVM assessment does not address the current maintenance, distribution and stock management weaknesses and provides no indication of the adequacy of data or temperature management systems.

    - Recent EVMA's provide a measure of supply chain readiness. Five of 10 HSS applications received exceed the 36-month mandatory timeframe by up to 24 months. A 5 year old EVMA even with an updated status report of improvements is no measure of readiness for the introduction of new or campaign vaccines.

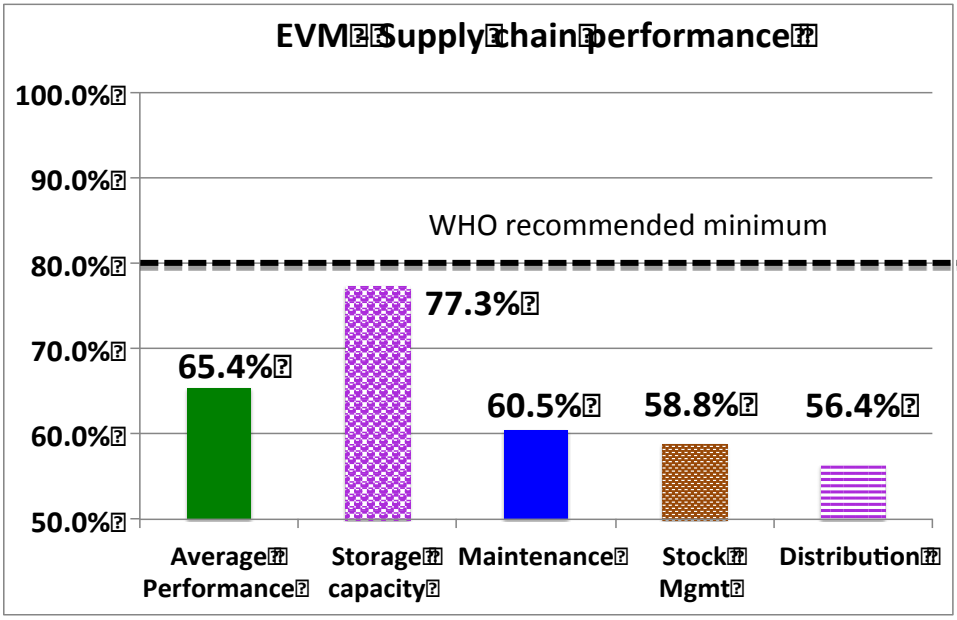
    - Countries are likely to default to 5-year cycle if the opportunity exists: there is already a tendency since Gavi has been less rigorous in the application of the 36 month guideline. (Chad, Burundi, Congo and Cambodia). A 5 year cycle will

provide a loophole for countries and partners to be less proactive and vigilant in the improvement process.

- cIP implementation is already weak; IP management support (Nepal, Bangladesh, DRC, and Lao PDR) is key to timely IP improvement and reporting. A 5 year EVM cycle is too long for support and transition of responsibilities into EPI management.
- Chad and Congo are two examples of HSS applications with objectives based upon a 5-year-old EVM assessment which are insufficient to adequately define ISCL activities for HSS support.

8. Little or no progress is being made to encourage safe and environmentally sound waste management practices.
9. Supply chain equipment issues are related to the absence of appropriate technical knowledge in appropriate equipment selection by country partners and host country governments, rather than WHO/PQS standards.
10. The 2016- 2020 strategy highlights strengthening of EPI management systems. Establishment of an EVM process framework (cIP Implementation secretariat or similar), in line with its 2020 strategy, will support countries to implement ISCL improvement plans in a timely manner.

Figure 4: EVM performance by indicator (20 countries)



Recommendations

1. **Improvements to ISCL related topics in Guidelines and Application templates** should include:
   - The WHO/PQS catalogue does not yet include waste disposal devices. The Gavi requirement for WHO/PQS compliance of equipment should note that this does not apply to waste disposal equipment.
   - Supply chain quality and availability of vaccines is not explicitly stated in applications. Guidelines should require that temperature-monitoring arrangements are clearly

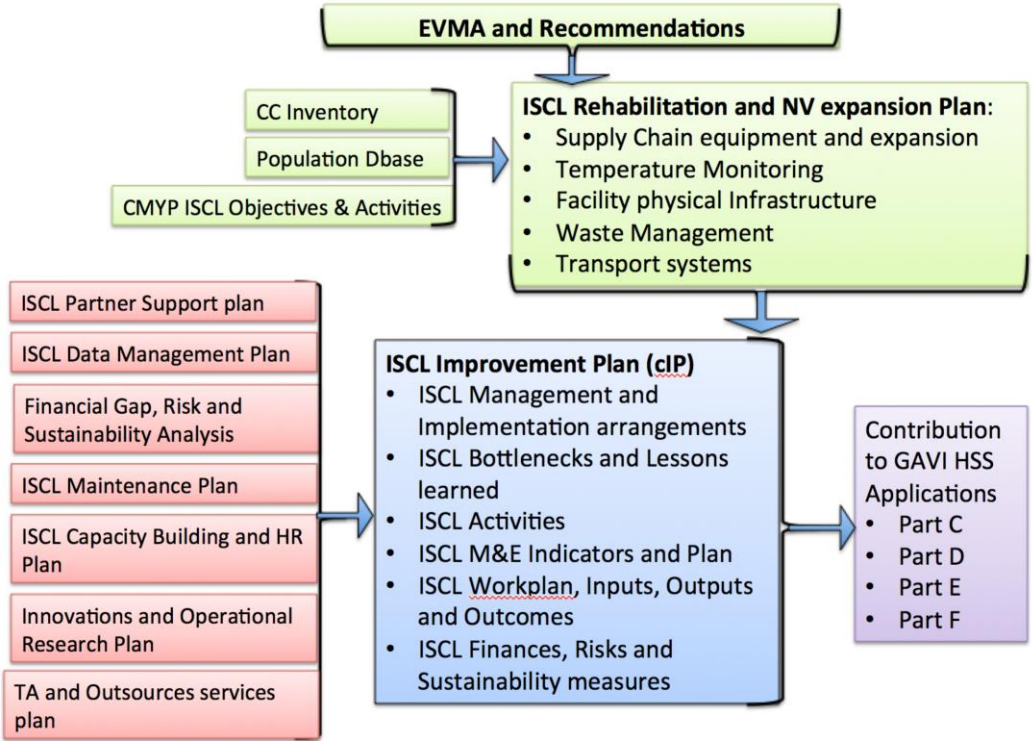
stated and vaccine stock-out data in the preceding 12-month period is provided for antigens at each level of the supply chain.

- Measures are included in guidelines to require that countries define maintenance, distribution and stock management bottlenecks and arrangements to address these in applications.
- Countries are required to provide recent supply chain equipment inventory or preferably supply chain rehabilitation plan.
- Countries are required to define the supply chain data management system in use for monitoring vaccine stock levels, supply chain equipment status, and supply chain quality (storage temperatures).
- The guidelines encourage countries to set in place management mechanisms for the implementation of EVM improvement plans. The Gavi 2016-2020 strategy highlights management as being a critical driver to supply chain improvement.

2. **Support countries to enact EVM improvement plan implementation**- and mandate periodic reporting of progress through the placement of EVM implementation plan managers within EPI programs.

3. **Gavi should seek synergies between EVMA's/ country Improvement Plans (cIP)'s and submission of HSS applications rather than synergies with cMYP- NSSP cycles.** The EVM process indicates supply chain readiness for the introduction of new vaccines, and defines improvements to ensure supply chain quantities, vaccine quality and program efficacy only when coupled with other measures (*indicated in RED*) necessary to adequately respond to the needs of an HSS application such as those indicated in Figure 5.

Figure 5: Supply chain assurance quality pathway



4. **Gavi should reconsider its decision to revise the requirements for EVM assessments.** Rather than relaxing the Guidelines for EVM assessments and improvement planning by removing the 36-month mandatory clause, Gavi should require that countries strengthen management capacity to implement EVMA recommended improvements in a timely manner. This should be complemented by a call for periodic (minimum annual) progress report on cIP implementation. This approach will encourage ISCL improvement rather than providing a loophole for countries and partners to be less proactive and vigilant in the improvement process.

5. **Gavi should provide guidance to countries seeking support for vaccine storage equipment.** Subsequent to the IPAC recommendation and SAGE endorsement in 2013 supply chain equipment procurement is oriented towards the use of solar direct drive vaccine refrigerators (SDD) in locations where a reliable power supply is not assured. Whilst SDD is clearly the solution for non or very poorly electrified vaccine storage locations, SDD is not the least cost solution for sites where an intermittent power supply is available for a few hours some days of the week. In addition, Gavi should through its CCE initiative encourage the development of hybrid (solar/mains) electricity powered vaccine storage devices.

6. **Gavi should provide guidance to countries for EPI data management systems and support the development of EPI tools for program management as well as program data reporting.** About 40 countries receiving support from Gavi are adopting or considering the Health System Management Information Package DHIS2. This package in its present form does not provide EPI logisticians with a tool to manage vaccine stocks or vaccine quality.

7. **Gavi should address the need to ensure supply chain quality and availability for vaccine storage rather than supply chain equipment.** Proposals for Gavi support provide clear evidence that management is the key to supply chain quality rather than equipment. EPI program managers are trained to manage immunisation service delivery but not maintenance and transport infrastructures. This requires a different skills base. Pooling strategies for outsourced maintenance and transport services with the equipment assets owned by the service providers and ***leased to EPI programs***, will relieve EPI managers of non-core business responsibilities and ensure maintenance and distribution norms are respected and managed by professionals in the sector. Furthermore, scientific based technical solutions for Good Distribution Practices could be retrieved from well-known organizations like PDA (Parenteral Drug Association) and ensure compliance with regulatory quality standards.

8. Gavi should reconsider the **recommendation on waste management** made in the Global report of the IRC of November 2014. (Page 11 Recommendation #4)

9. **Joint Appraisals add considerable value to the IRC review process.** The inclusion of ISCL expertise on Joint Appraisal teams would further advance the value of Joint reviews.

2.8 Financial Management

The IRC noted some progress in how financial management is addressed in proposals, more particularly in HSS applications.

- Budgeting/costing of HSS grant is improved due to better HSS proposal technical contents: it is easier to link key proposal activities to some major budget items (Burundi, Cameroon, Congo and Lao PDR). Detailed assumption and costing sheets completed by the countries is a now a key source of budget information for the IRC review. Unit costs provided within this assumption sheet generate the overall budget using the Gavi template.

  Although budgeting quality has generally improved, unit costs related to human resources require still more 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 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).

- Computerized accounting systems: some EPI (DRC, Burundi) are upgrading their accounting systems and using accounting software (TEMPRO, SAGE). This should lead to better expense tracking and financial reporting for these EPI;

- External audit arrangements are described/planned: even in the case where the MoH is grant recipient (so subject to Government Auditor General requirements), countries plan for additional fiduciary scrutiny by independent/external auditors (Cameroon, Nepal, etc.)

The committee also observed some issues that were detrimental to the sound management of the grants.

- Upfront HSS ceilings: Gavi pre-filled ceilings communicated to countries per year do not allow for efficient cost allocation during the grant lifetime. Countries tend to align activity planning and budgeting to the annual ceiling provided by Gavi without considering the feasibility and the logical coherence of their work plans.
- Summary budgets: variations continue to be observed in all HSS budgets between budget inputs sheets and budget summary sheets.
- Gender and equity budget information: the gender/equity budget figures are not coming out clearly in the proposals. Countries still report all their activities as gender/equity sensitive. It is not possible to figure out what is the proportion of the budget allocated to a topic which is important for Gavi.
- FMA findings: For most of the countries applying for HSS, FMA was conducted 4-5 years ago. There is a need for an overall FMA refresher for all Gavi HSS applicant countries to make sure that financial management systems are upgraded for better budget absorption rate.
- Capital expenditure: Whether it is vehicles (Burundi) or cold chain equipment (Congo, Cameroon and Chad). The IRC is concerned about potential duplications with purchase of key assets being budgeted every 4 years (2011 – 2015 and then the current HSS grant lifetime);
- Implementation arrangements: These depend on country context. All countries outline that CSOs played some part during the HSS proposal development process, but this was only translated into direct budget allocations for the CSO platform in Cameroon ($3,8M), Bangladesh ($1,2M), Congo ($0,66M) and Zambia ($3.6M).

Recommendations:

1. Re-consider ceiling policy (also *see section 2.5*)
2. Provide clearer guidelines to allocate gender/equity activities costs
3. Whenever proposals contain Human Resources payments (incentives, per diem, top-ups), Gavi should request documentation certifying the appropriateness of amounts paid, e.g. government guidelines and standards, Memoranda of Understanding between development partner organizations. Gavi should also request a demonstration of the intervention's sustainability (See Annex 3, recommendations of Nov 2014 IRC).
4. Ensure that capital expenditure is monitored and inventory conducted before new HSS application is submitted.
5. As a follow up of FMA and audits, encourage countries to establish an effective risk-based monitoring and review function with related accountability mechanisms.

2.9 Gender and Equity

Gavi Alliance Strategy 2016-2020 Goal 1: Accelerate equitable uptake and coverage of vaccines

There is now more solid evidence of the link between gender inequality and child mortality[2]. Figure 6 shows the acute level of disparity in the Gender Inequality Index across Gavi eligible countries. The Gavi 2015 HSS proposal templates have been changed so that countries should be able to better demonstrate how equity analysis informs the HSS proposals. While some countries' proposals are targeting specific underserved populations, others are vague in the identification of target groups and related actions (see Annex 5 for details by country).

Some countries addressed equity issues in the HSS bottleneck analysis. However, a bottleneck analysis should not be used as a substitute for an equity analysis, which needs to be based on a deeper analysis at the sub-national level (JRF data, DHS, MICS, other surveys). Countries that received support through Gavi or others to produce equity plans had stronger, more equity-tailored proposals. However, even when an equity statement refers to a gap, the programmatic actions proposed in the HSS do not necessarily address the gap.

For example, a number of country proposals referred to low immunization coverage in urban or peri-urban slums but did not describe concrete activities to address these populations. In some proposals, there is insufficient JRF reporting on sub-national equity indicators and this could mean that the RED/REC strategies or micro-planning are inappropriate. The IRC welcomes the number of countries that are building on health interventions beyond EPI in order to strengthen services for the mother and for a minimum package in support of MNCH.

The IRC notes that a number of countries described issues related to fragility and cross border refugees or displaced populations.

[2] **"Association between the gender inequality index and child mortality rates: a cross-national study of 138 countries** http://www.biomedcentral.com/1471-2458/15/97/abstractas

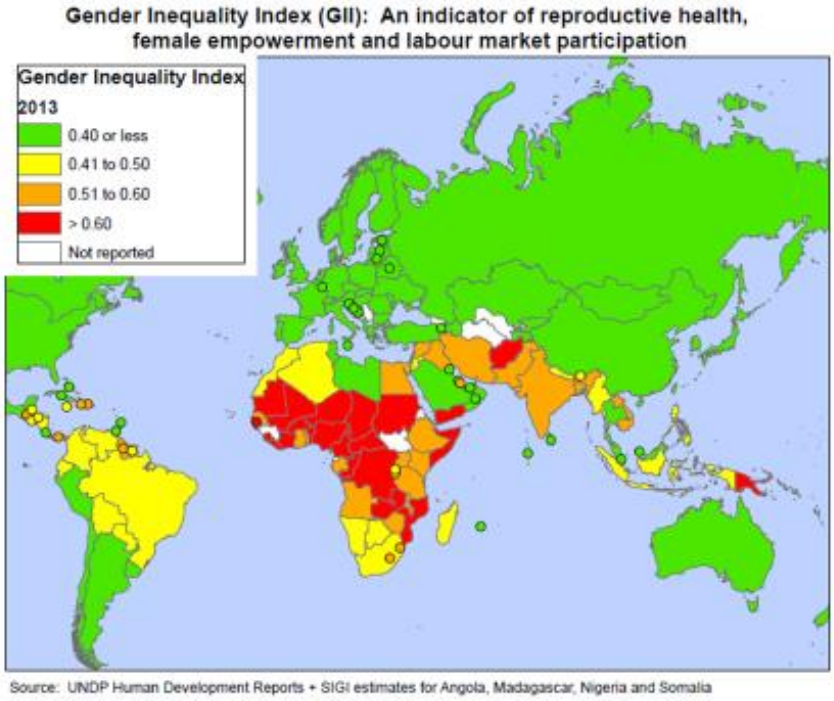
There are still gaps with some countries not completing the M&E frameworks with the mandatory indicators, including adequate baselines. However, programmatic activities to serve these populations were often poorly defined.

The pre-screening of proposals does not address equity issues or the presence of the mandatory indicators on the M&E framework.

Recommendations

- Through the Business Plan, Gavi should continue to provide funding to support gender and equity analysis, including at the sub-national level in large states where there are stark inequalities among the states/districts. As part of this support to analysis, Gavi may consider developing case studies on gender and equity and health issues to guide countries drawing on lessons learned by Gavi and Alliance partners.
- Gavi and Partners should consider using regional meetings of country level EPI managers to strengthen capacity with a focus 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.
- Both the 2016 Gavi proposal guidelines for HSS (and NVS) and subsequent application review process (pre-screening by WHO/SCM) should ask for data on coverage gaps by equity drivers (geography, fragility, gender, socio-economic quintile, etc.) as well as baselines and objectives for the mandatory equity indicators.
- Gavi should encourage countries to deliver outreach activities including RED/REC and Intensified Immunization Days that focus on demand creation, mothers' empowerment and decision-making to improve coverage. Demand side strategies should be based on gender and equity analysis.
- New approaches to reach urban populations should be piloted to inform Gavi, partners and countries' strategies.
- This requires targeted and appropriate communication strategies. In countries where the situation is changing rapidly (such as conflict and influx of refugees, etc.), thinking out of the box and coming up with country specific innovative approaches based on the equity analysis will enhance implementation.

Figure 6 Gender Inequality Index (GII)



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

The IRC reviewed 24 countries proposals for compliance with the M&E requirements, out of which 10 HSS M&E frameworks where comprehensively assessed (see Annex 2 for details)

HSS

The IRC noted the improved quality of monitoring and evaluation frameworks in HSS applications, compared to prior rounds of IRC review.

Two key issues could contribute to further strengthening of the monitoring and evaluation frameworks: measurement of explicit health system indicators, and target setting for equity indicators. In the review, only 40% (4/10 of HSS country proposals) included indicators for other elements of the health system (example: "% sub-districts where supervision visits carried out as planned," "% pregnant women receiving 4 ANC visits" (Bangladesh)).

Only 70% (7/10 of HSS country proposals) had targets for equity outcomes; this means that the ability to measure progress over time and capacity to take corrective actions might be challenged.

Recommendations

- Guidance to countries should emphasise the need to include at least one additional indicator that represents other sectors of the health system and which will illustrate integration more broadly. Recommendation: In addition to identifying the indicators for improved immunisation coverage, at least one indicator should assess the extent of actual health system strengthening HSS) and its impact on improvements in immunisation. It can also show their ability to deliver immunisation as an integrated intervention.

- Guidance to countries should indicate the importance of including targets and baseline data for inequity related indicators. Gavi should ensure that they are included in all proposals. Recommendation: Equity indicators should include targets and baseline data for outcomes and intermediate results to help determine the extent to which reduction of inequities is being met.

Vaccine Preventable Disease and AEFI Surveillance

Issue 1: Campaigns are increasingly being conducted in countries with limited capacity for surveillance of adverse events following immunization (AEFI). These campaigns usually involve a large number of doses given over a short period of time leading to more vaccine reactions and coincidental events requiring crisis response. Countries should be required to demonstrate the presence of an AEFI committee with crisis management capacity before these large vaccine campaigns are conducted. See Table 6.

Issue 2: 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. This is particularly critical for soon-to-be graduating countries that will have to justify the soundness of investment to their governments.

Table 6: vaccine preventable disease and AEFI surveillance in proposals (16 countries applying for vaccine introduction including campaign)

Questions	Response in proposals	
	Yes N (%)	No N (%)
Pharmacovigilance Capacity	12 (75)	4 (15)
National Expert Committee Injection Safety Policy (main components): • Vaccine administration Policy • Waste management	11 (69) 16 (100) 15 (94)	5 (31) 0(0) 1(6)
AEFI integrated into VPD surveillance	11(69)	5(31)

Recommendations

1. Countries should be requested to demonstrate in their proposals the presence of a strong and integrated AEFI system with strong committee and crisis management capacity. The proposal must also describe preparedness plans to address any vaccine safety issues that may emerge prior to introduction of vaccine and launch of campaigns
2. Gavi should consider supporting local sentinel surveillance building capacity, in intermediate and graduating countries

2.11 Governance

The main issues related to governance are similar to those highlighted by the IRC in November 2014.

Issue 1: Governance at country level

An effort from the countries to meet Gavi requirements can be seen in the provision of information and documents of the coordinating bodies, the reporting of wider consultations in proposal development, and the intention, in many proposals, to involve CSOs in the implementation. The ICC is active in all countries submitting applications for NVS and HSS (although in some cases seems to be activated ad hoc). A NITAG was found to be fully functional in five countries and being established or formalized in other countries.
A matter of concern for IRC remains the engagement of the wider health sector coordination and governance mechanisms in Gavi grants, especially HSS, from proposal preparation to its alignment and contribution to the health sector programme, potential synergies, oversight, M&E and finally increased country ownership, toward sustainability. In Bangladesh, Burundi and Cameroon (HSS applicants) the health sector coordination committee was fully involved and responsible for the proposal preparation, in Nepal the HSS proposal was aligned to the national plan (for Gavi contribution to the sectoral pooled fund), in other countries the ICC and the NIP had the major role, leaving some concerns about the systems view of HSS proposals.

Issue 2: Health governance at global and national levels.

Developments in global health bring new challenges for donors and the need for new engagement for aid effectiveness and coordination. The ongoing changes include the post-MDG agenda, the rise of non-communicable diseases (NCD) and the Universal Health Coverage goal 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.
Country-led governance mechanisms become increasingly important so national agencies have the institutional capacity to make evidence-based decisions, coordinate, regulate and guide investments, and monitor their impact.
At the same time, the engagement of donors in national governance, in compliance with international commitments on aid effectiveness (such as IHP+) and on specific health goals, becomes increasingly demanding.

The IRC reiterates some of the recommendations on Governance provided in previous reports:

Recommendations
IRC recommends to Gavi and partners to consider the re-definition of governance requirements at country level and – where deemed appropriate – the opportunity to adapt Gavi strategies to the evolving context in health governance at global and country level. Recommendations on Governance from previous IRC meetings should be taken into consideration. The new phase should consider:

1. The Joint Appraisal should include key governance issues and be an opportunity to strengthen and contribute to the governance mechanism in country
2. 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 also play the role of health sector partners in country on behalf of Gavi, to support and monitor health sector coordination mechanisms
3. Where contributing to HSS and sectoral schemes and tools (SWAp, RBF, pooled funds), Gavi should play an active role in positively influencing the national

programme toward ownership and responsibility for the immunization programme, toward sustainability.

4. Considering the increasing Gavi contribution to RBF in several countries, Gavi should consider engaging in a dialogue with the World Bank, as a key partners, for greater attention to immunization and other potential synergies.
5. Expectations on CSOs involvement has to remain flexible and realistic in consideration of national contexts.

2.12 Communication

With the introduction of new vaccines, such as inactivated polio vaccine (IPV) and rotavirus in most countries, children will be receiving 3 or more vaccines on the same day during regular immunization sessions and more than 9 as part of the routine immunization schedule. The acceptability and concerns of both mothers and health workers is not fully appreciated. Sociocultural barriers and extent of adverse events following immunization remain unknown; caregivers, health workers' knowledge, attitudes and practices are potential barriers to the uptake and sustained demand for vaccination; thus, having an effective and evidenced based communication plan and strategy is very important.

Issue: Communication strategies tended to be generic and not rooted in the bottleneck analysis

The proportion of total budget allocation to communication and social mobilisation activities varied from 6 per cent to 47 per cent overall. Guyana, Cameroon and Zambia submissions demonstrated good communication plan approaches that start by looking at what works and the need to generate evidence before designing and updating the existing IEC materials. However, in other applications, the proposed intervention strategies and activities were rather generic with, for example, no specific response to address health workers perception and attitudes as part of the interpersonal communication (IPC) approaches nor addressing adverse events following immunization (AEFI) for caregivers. Secondly, no targeted interventions were described (such as peer education, mobilising and engaging teachers, religious leaders and parents) or were seldom considered.

Strategically, the mention of advocacy was minimal or absent in most of the submissions. Countries continued with the traditional practices of investing in social mobilization and reproduction of IEC materials not directly related to new evidence or identified need. The key activities and funding investment also varied across countries with no clear basis, consistency and had no post introduction communication strategy or plan impact evaluation.

Recommendation: Provide communication guidance that can be adapted to suit each country's context and issues (see example on Figure 7). This can be further elaborated with a generic example in both the guidance note of the HSS and NVS applications.

Figure 7: Communication for Development (C4D) framework

Source: Communication for Development (C4D) December, 2012. New York: UNICEF Programme Division.

2.13 Graduation and financial sustainability

Different sustainability issues than in most other IRC reviews have been prominent in the present review. Gavi's financial sustainability policy is largely concerned with sustaining new vaccine introductions, in the form to gradually increasing co-financing. In this round, the IRC reviewed only two applications for new vaccines for graduating and intermediate countries: rotavirus in Lesotho and in Sao Tome and Principe. As seen in Table 7 below, applications from these countries were mainly received for IPV, campaigns and HSS. None of these support windows are subject to Gavi's co-financing policy.

Table 7: Graduating and Intermediate Applications reviewed in IRC March 2015

Graduating				**Intermediate**			
IPV	**HSS**	**Measles campaign**	**MenA routine and YF campaign**	**IPV**	**HSS**	**HSS, rota, HPV demo**	**Rotavirus**
Armenia	Congo	Nigeria	Ghana	Djibouti	Lao PDR**	STP*	Lesotho*
Bolivia					Cameroon		
Guyana					Zambia**		
Honduras							
PNG							

*Expected to enter in graduation in 2016
** Expected to enter in graduation in 2017

Issue 1: Sustainability in the graduating countries

The IRC reviewed proposals from seven graduating countries. Five of these countries applied for IPV. Nigeria applied for a measles vaccine campaign costing US$ 61 million.

Ghana applied for a MenA vaccine catch-up campaign, routine MenA in Northern districts and a yellow fever campaign in high-risk districts for a total application budget of US$ 8 million. Congo applied for a HSS grant of US$ 4.4 million.

The sustainability issue for IPV is different than for other new vaccines being supported by Gavi. Co-financing is not required and graduating countries as well as countries in default with Gavi's co-financing requirements can apply. The duration of Gavi IPV support is however uncertain in the longer term. In the IPV application guidelines, it is stated that Gavi's IPV support will last until at least 2018 and subject to additional polio specific funding, support would continue until 2024 or until an appropriate exit strategy for GAVI has been identified prior to 2024. It is hoped that polio will be eradicated by 2024 and it is hypothesised that polio vaccination could cease completely after eradication. There are thus several uncertain issues with regard to sustainable financing of IPV. It is by no means certain that polio will be eradicated by 2024 and even if it is, there is no guarantee that cessation of polio vaccination will be recommended by global technical advisory committees. For instance, there is overall agreement among experts that it is unlikely high-income countries will stop vaccinating against polio. For these reasons, the IRC recommends that sustainability of IPV vaccine is included in future transition and graduation plans. IPV was not included in any of the transition plans of the graduating countries included in this review.

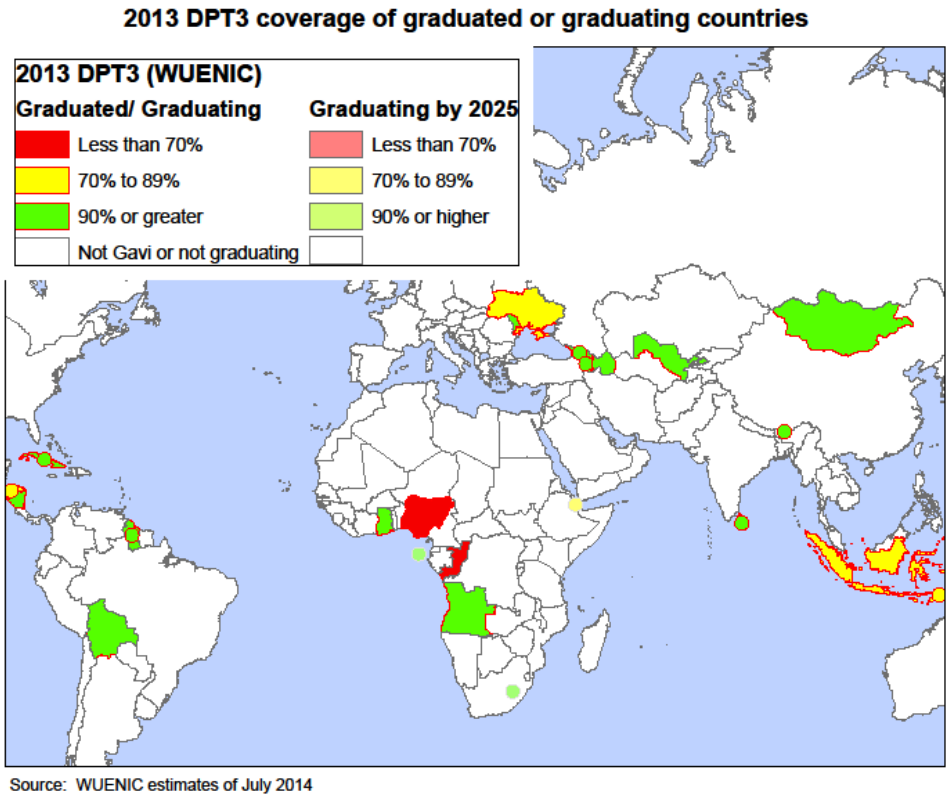
The economic, social and governance environments vary considerably among Gavi graduating countries. The GNI per capita thresholds can easily disguise a wide variation between this group of countries. The figure below shows wide variation in vaccination coverage rates of graduating countries, implying that the robustness of the immunization systems varies considerably. Nigeria and Congo Republic have coverage rates below 70% (See Figure 8).

Of the seven graduating countries reviewed, sustainability appears to be strongest in the three South American countries, especially due to their vaccine laws, which ensure vaccines are included in the government budget. However, funding gaps for vaccines have still been seen in several countries in the PAHO region.

Financial sustainability is of particular concern in Nigeria, Congo Republic and Ghana. Ghana and Congo Republic and have not fully met their co-financing obligations during the past two and three years, respectively.

The support for campaigns approved for the three African countries have different sustainability implications compared to new vaccine introductions. They are normally considered as one-off initiatives and have traditionally been funded by donors. However, in several countries, vaccination campaigns have become a frequent occurrence and it can be argued that campaigns in some places have replaced routine vaccination services. The sustainability of these campaigns is therefore an important issue. The last measles campaign conducted in Nigeria was in 2013, which was also funded by Gavi.

Figure 8: 2013 DTP3 coverage of graduated and graduating countries (by 2015)



Issue 2: Sustainability of HSS support

The IRC reviewed HSS applications from four graduating and intermediate countries; Sao Tome and Principe, Zambia, Lao PDR and Cameroon. None of these countries addressed the graduation issue in their HSS applications. This is concerning in light of the fact that Gavi aims for countries to view their support from different windows as linked and coherent.

Several of the HSS applications reviewed promoted a disincentive for financial sustainability because a relatively large proportion of the budget was for operational costs, such as health worker salaries, printing of child health cards and fuel for outreach sessions. This was in particular the case for the Bangladesh and Zambia applications. The IRC believes that an important reason for the tendency to include operational, routine costs in the HSS is a desire to ensure that the budget reaches the Gavi ceiling. It may be challenging for countries to design innovative health systems strengthening initiatives for the full amount of the country ceiling, unless the support is more broadly targeted to the primary health care platform rather than more narrowly on immunisation. The IRC noted that some HSS proposals only marginally addressed systemic issues and proposed projects, which would enhance financial sustainability in the longer term.

Recommendations

1. Include other funding support beside NVS in Gavi financial sustainability policy
2. Early engagement with soon-to-graduate countries through HSS grants needs to be achieved

3. In graduating and intermediate countries, HSS should respond to capacity building and long term systemic needs, to maximize transition to programmatic, institutional and financial sustainability
4. Use indicators of sustainability for countries, to monitor domestic versus external funding of both vaccines and the vaccination programme operational costs.

Annex 1: List of IRC Review Members

Name	Current role
Emmanuel Addo-Yobo	Professor of Child Health at the School of Medical Sciences, College of Health Sciences, Kwame Nkrumah University of Science and Technology, Ghana
Sam Agbo	Head of Health & HIV at Save the Children
Roland George Amehou	Health economist in developing countries
Salah Awaidy	Advisor at the Ministry of Health, Oman
Rafah Aziz	Independent consultant
Gabriel Carrasquilla	Founder and Director of ASIESALUD
Dora Curry	Senior Technical Advisor for Monitoring and Evaluation in CARE-USA's Sexual, Reproductive and Maternal Health team
Linda Eckert	Professor in Obstetrics and Gynaecology and Adjunct Professor in the Department of Global Health at the University of Washington in Seattle
Ulla Griffiths	Senior Lecturer in Health Economics, London School of Hygiene and Tropical Medicine
Terry Hart	Independent consultant
Miloud Kaddar	Independent consultant
Elsie Le Franc	Professor Emeritus and Adjunct Professorial Research Fellow, University of the West Indies, Jamaica
Kapil Maithal	General Manager and Head-Research and Development at Indian Immunologicals Limited (IIL), Hyderabad, India
Marina Madeo	Independent consultant

Name	Current role
Sandra Mounier-jack	Senior Lecturer in Health Policy at the Faculty of Public Health and Policy of the London School of Hygiene and Tropical Medicine
Maryanne Neil	Independent consultant
Michel Othepa	Senior Immunisation Technical Officer, Maternal Child Health Integrated Program (MCHIP), Washington, DC
Arletty Pinel	Independent consultant
Kshem Prasad	Independent consultant
Robert Pond	Independent consultant
Diana Rivington	Senior Fellow in the Faculty of Social Sciences at the University of Ottawa, Canada
Mario Stassen	Lecturer at Faculty of Science, Department of Biopharmacy at University of Utrecht; Board member of the Edufarma Foundation
Ousmane Amadou Sy	Independent consultant
Charles Wiysonge	Full Professor and Deputy Director in the Centre for Evidence-based Health Care, Stellenbosch University, South Africa

Annex 2: Data quality and M&E indicators completeness summary

	Data quality			AEFI						M&E for HSS					
Country	DQS/IDS/ DQA included	Add'n. description of data quality approach	Indicator related to data quality included (HSS only)	National Expert Committee	Pharmacovigilance (Surveillance for men/ pneum & rota as a proxy)	Vaccine administration policy	Waste management policy	AEFI surveillance in place	Risk Communication Strategy (NVS only)	Baselines included for all outcomes	Targets for inequity outcomes	Intermediate results related to inequity	M&E framework complete	Strength of IR indicators	Indicators for other elements of health system
	Yes/No	strong/ adequate/ weak/absent	yes/no	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	adequate/ weak/ absent	yes/no
Armenia	no	no	N/A	yes	yes	yes	yes	yes	yes	N/A	N/A	N/A	N/A	N/A	N/A
Bangladesh	yes	no	no	yes	yes (excludes rota)	yes	yes	yes	N/A	yes	yes	no	yes	strong	yes
Bolivia	no	no	N/A	yes	yes	yes	yes	yes	No	N/A	N/A	N/A	N/A	N/A	N/A
Burundi	yes	yes	yes					yes	N/A	yes	yes	no	yes	strong	no
Cambodia	yes	yes	yes	no (IP?)	no	yes	yes	yes	N/A	yes	no	yes	yes	adequate	no
Cameroon	yes	yes	yes	yes	yes	yes	yes	yes	N/A	yes	no	yes	yes	weak	no
Chad	yes	yes	no	yes	no	yes	yes	no	N/A	yes	yes	yes	yes	yes	yes
Congo (Br)	yes	no	yes	no (IP?)	no	yes	yes	no	N/A	yes	yes	yes	yes	weak	no
Djibouti	yes	no	N/A	yes	yes (excludes rota)	yes	yes (in proposal)	no	yes	N/A	N/A	N/A	N/A	N/A	N/A
DR Congo	yes	yes	N/A	yes	yes	yes	yes	yes	no	N/A	N/A	N/A	N/A	N/A	N/A
Gambia	no	no	N/A	yes	yes	yes	no (IP?)	yes	no	N/A	N/A	N/A	N/A	N/A	N/A
Ghana	Yes	Yes	N/A	yes	yes	yes	yes	yes	no	N/A	N/A	N/A	N/A	N/A	N/A
Guinea-Bisseau	no	no	N/A	no (IP?)	yes	yes	yes	yes	Yes	N/A	N/A	N/A	N/A	N/A	N/A
Guyana	no	no	N/A	yes	yes	yes	yes	yes	yes	N/A	N/A	N/A	N/A	N/A	N/A
Haiti	no	no	N/A	yes	yes	yes	yes	yes	no	N/A	N/A	N/A	N/A	N/A	N/A
Honduras	yes	yes	N/A	Y	Y	Y	yes (source: JRF)	Y	Y	N/A	N/A	N/A	N/A	N/A	N/A
Kenya	yes	yes	N/A	yes	yes	yes	yes	yes	yes	N/A	N/A	N/A	N/A	N/A	N/A
Lao	yes	yes	yes	In proposal	yes (excludes menin./	yes	yes	yes	N/A	yes	yes	no	yes	adequate	no
Lesotho	yes	no	N/A	no	yes	yes	yes	No?	no	N/A	N/A	N/A	N/A	N/A	N/A
Nepal	yes	yes	yes	yes	yes	yes	yes	yes	yes	no	Yes	Yes	Yes *Results Frame.	Strong	yes
Nigeria	yes	no	N/A	yes	yes	yes	Yes	yes	Yes	N/A	N/A	N/A	N/A	N/A	N/A
PNG	no	no	N/A	no	yes	UNK	yes	No?	No	N/A	N/A	N/A	N/A	N/A	N/A
STP	no	yes	no	No	yes (excludes menin./	yes	Yes	yes	No	yes	yes	no	Yes	adequate	no
Zambia	yes	yes	no	yes	yes	yes	yes	yes	N/A	no	no	no	No	weak	yes

Annex 3: Previous recommendations IRC November 2014

Recommendations Human Resources

1. Finalize the Gavi policy / strategy / operating modalities for HR compensation, i.e. salaries, top ups, incentives and *per diem*. 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.

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

Annex 4: Summary of supply chain comments, issues to be addressed and action points.

A total of 35 “Comments for Consideration” relating to supply chain issues were made, plus 27 “Issues to be addressed” and “Action Points” relating to supply chain issues were necessary in the IRC reviews of the 24 countries. Supply chains remain a bottleneck in some form in 16 of the countries reviewed or the transparency of the supply chain was not evident (13 countries). Bangladesh (HSS application) was the only country reviewed which provided adequate transparency of its supply chain and a clear improvement plan. Nine out of 10 HSS proposals submitted include supply chain strengthening objectives, demonstrating recognition by countries of a need to strengthen iSCL.

The IRC considered that supply chains are “Not Ready” to introduce new vaccines requested in 4 countries (Cameroon, Lesotho, Ghana and Zambia). There are issues or uncertainty relating to PQS compliance of equipment being procured or proposed for procurement through HSS support in four countries (Sao Tome and Principe, Nepal, Cambodia and Burundi). The selection of appropriate equipment is also questioned in Burundi, Cambodia, Congo, and STP. Gavi should provide clarification to countries and monitor procurement actions to ensure compliance with Guidelines. Senior Country Manager (SCM) personnel may not have an appropriate technical profile to perform these tasks.

Chad and Congo have not conducted EVM assessments since 2010. Bolivia and Honduras are scheduled to conduct their first assessment in 2015. PNG is planning to conduct its next EVMA in 2016, five years after its 2011 assessment. Gavi should collaborate with Partners to ensure EVM assessments are conducted in all 5 countries as per the planned schedules. The Gavi guidelines applicable to these submissions for support (except campaign submissions) have not been adhered to in all except 2 countries (Nepal and DRC).

The results of EVM assessments are insufficient to develop comprehensive supply chain improvement plans unless equipment inventories are maintained up to date. Actions are requested from 3 countries (Nigeria, Lesotho and Lao PDR) to update or provide clarification on equipment inventories. The status of equipment inventories was unclear in a number of countries.

The IRC has flagged waste management issues to be addressed in 3 countries (Nepal, Kenya and Haiti). Issues range from budgetary allocations (Kenya) and planning (Nepal) to disposal (Haiti). Four of the 24 countries reviewed provided no information on waste management plans or status in applications. 8 of the countries acknowledge that open burning is practiced. 6 countries claim to use incineration for disposal of waste. Only 3 countries (Nepal, Chad, and Bangladesh) have any form of pilot project in place. Major weakness in waste management practices in most Gavi supported countries have been flagged in 2013 and 2014 IRC reports, but guidelines have not addressed measures to ensure improvement.

Freeze Risk and the knowledge of freeze damage to vaccines remains an unknown in most Gavi supported countries. The EVM assessment penalises countries for not conducting freeze risk assessments, but countries rarely conduct assessments. Bangladesh is the only country reviewed which is known to be already using chilled water packs for vaccine transportation in part of its supply chain and is planning to adopt this strategy nationwide.

Transport related issues require action in 2 countries (procurement phasing in Cameroon and availability for campaign vaccine distribution in DRC).

Issues of storage space are flagged only in DRC (vaccine storage) and Gambia (dry goods storage) and equipment related issues in Lesotho and Chad.

A review of supply chain and logistics performance across the 9 criteria of EVMA's in the countries reviewed (except Bolivia and Honduras) indicates that "Maintenance", "Stock Management" and "Distribution" are the critical weak links in supply chains and that "Storage Capacity" is generally adequate and one of the better performing criteria assessed. See Figure 4.

The IRC country reports only one comment relating to maintenance issues (Armenia) and one comment relating to data management (Burundi) in all 24 countries reviewed. This suggests that the Gavi guidelines and application templates are not adequately addressing the critically low performing criteria of supply chains.

Annex 5: Gender and Equity Profile of Countries Reviewed (March 2015)

Country GII[1] Highest / Lowest	Gender Inequality Index[3] (GII)	Female Adolescents Married or in union[4] %	Sex disag. data in the proposal		Barriers identified in country proposal						Plan to collect data related to barriers	CSOs
			NIP	Other Source	Conflict/ fragile	Gender	Geographic	Socio-economic	Ethnic	Culture Relig.		
Chad	.707	47.6	N	N	Y	Y	Y	N	Y	N	N	Y
D R Congo	.669	25.0	N		Y	Y	Y	Y	Y	Y	N	y
Cameroon	.662	10.2	N	Y	Y	Y	Y	Y	N	N	Y	Y
Gambia	.624	22..5	N	Y	N	Y	Y	Y	N	N	Y	Y
Papua New Guinea	.617	14.8	N	N	N	N	Y	N	N	N	N	Y
Zambia	.617	17.8	N	Y	N	N	Y	Y	N	N	Y	Y
Congo	.617	19.3	N	Y	N	N	Y	Y	Y	N	N	Y
Haiti	.599	11.9	N	Y	Y	N	Y	Y	N	N	Y	Y
Lesotho	.557	24.7	N	Y	N	N	Y	Y	N	Y	Y	Y
Ghana	.549	7.0	N	Y	N	N	Y	N	N	N	Y	Y
Kenya	.548	12.1	N	Y	N	N	Y	N	N	N	Y	Y
Lao PDR	.534	23.3	N	Y	N	N	Y	Y	Y	N	Y	N
Bangladesh	.529	44.7	N	Y	N	N	Y	Y	Y	N	Y	Y
Guyana	.524	16.2	N	Y	N	N	Y	Y	N	Y	Y by gov	N
Cambodia	.505	10.2	N	Y	N	N	Y	Y	Y	Y	N	Y
Burundi	.501	8.6	N	Y	N	N	Y	Y	Y	Y	Y	Y
Honduras	.482	22.6	N	Y	Y	Y	Y	Y	N	N	Y	Y
Nepal	.479	28.8	Y	Y	N	N	Y	Y	Y	Y	Nat. equity plan	N
Bolivia	.472	13.4	N	Y	N	N	Y	Y	N	N	Y	Y
Armenia	.325	7.9	N	Y	N	N	N	N	N	N	N	N
Djibouti	n.a.	4.2	N	N	Y	N	Y	Y	Y	N	N	Y
Guinea Bissau*	n.a.	18.5	N	N	Y	N	Y	N	Y	Y	N	Y
Nigeria*	n.a	20.2	Y	Y	Y	N	Y	Y	N	N	Y	Business plan
Sao Tome & Princ.	n.a	19.8	N	Y	N	N	Y	Y	N	N	Y	Y

* Ranking based on Social Institution & Gender Index (SIGI) estimates

[3] The Gender Inequality Index (GII) is a composite measure which captures the loss of achievement within a country due to gender inequality. The GII is interpreted as a percentage and indicates the percentage of potential human development lost due to gender inequality. Higher GII values indicate lower achievement. In 2013 Slovenia ranked most favourably on the GII with a loss of 2.1% of human potential lost due to gender inequality. (Source: UNDP)

[4] Generally early marriage indicates that girls are being taken out of school and married to significantly older men. This raises questions around inequality within these relationships and the ability of young women to make decisions about their own and their children's wellbeing.

Annex 6: 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
Lao PDR	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
Togo	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 7 Summary of IRC Results

NEW PROPOSALS IRC – OUTCOMES
16 – 27 MARCH 2015

Country		Type of support						
		IPV	HSS	MR	YF campaign	MenA campaign	MenA routine	Other NVS support
1	Armenia	Approval						
2	Bangladesh		Resubmission					
3	Bolivia	Approval						
4	Burundi		Approval					
5	Cambodia		Approval					
6	Cameroun		Resubmission					
7	Chad		Resubmission					
8	Congo		Approval					
9	Djibouti	Approval						
10	DR Congo					Approval		
11	Gambia			Approval				
12	Ghana				Approval		Approval	
13	Guinea Bissau					Approval		
14	Guyana	Approval						
15	Haiti	Approval						
16	Honduras	Approval						
17	Kenya			Approval				
18	Lao PDR		Resubmission					
19	Lesotho							Rota: Resubmission
20	Nepal		Approval					JE: Approval
21	Nigeria							Measles SIA: Approval
22	Papua New Guinea	Approval						
23	Sao Tome & Principe		Approval					HPV demo: Approval Rota: Approval
24	Zambia		Resubmission					