INDEPENDENT REVIEW COMMITTEE REPORT (IRC)

November 7th – 22nd 2013

Report for GAVI Board

JANUARY 13, 2013

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Acknowledgements

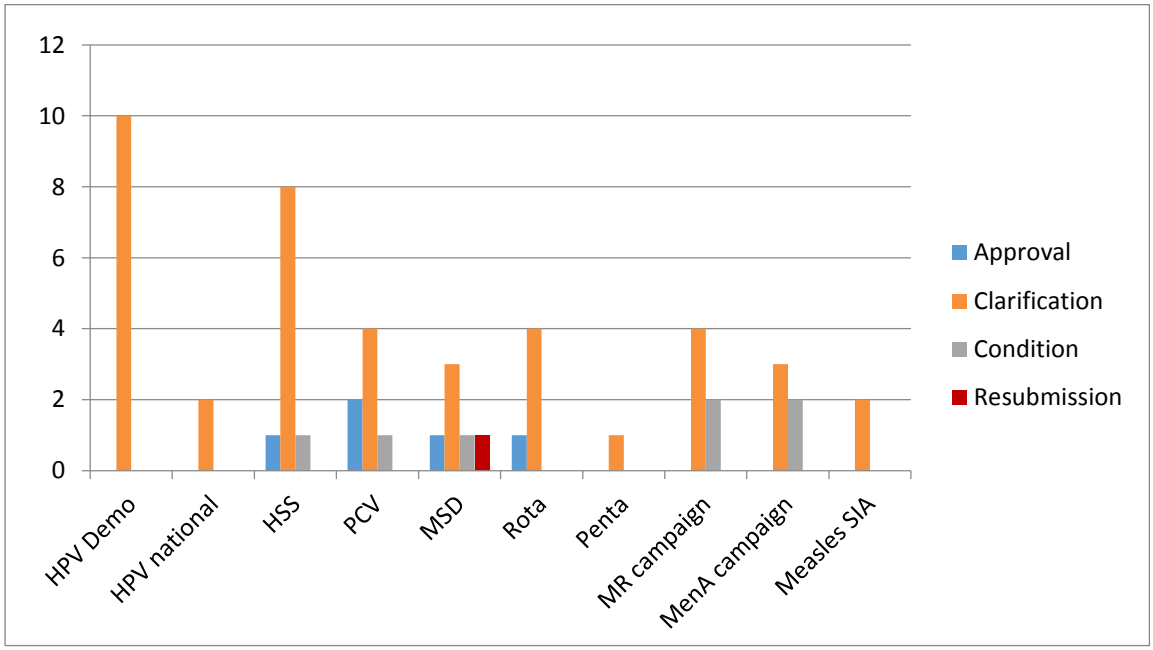
The IRC team would like to acknowledge the support of the GAVI Secretariat including the monitoring and evaluation team, new vaccine and health system technical advisers, country responsible officers, management team and administrators for their support during the IRC process Nov 7 – 22. The technical advice and support of observers and guest speakers from the WHO and UNICEF was also greatly appreciated.

Executive Summary

Background and Process

The purpose of the IRC meeting (November 7th to 22nd 2013) was to make recommendations for approval to the GAVI Board for new grant applications for new vaccines (31), vaccination campaigns (13) and for health system strengthening initiatives (10). Overall there were 36 countries (34 new applications and 2 APRs) who submitted applications for various windows of support in this round. The IRC, with 23 independent reviewers from a range of technical disciplines, undertook this peer review of country proposals and also conducted a thematic analysis of issues relating to the achievement of the GAVI mission. The criteria for assessment of proposals was undertaken on the basis of the extent to which country proposals met the application requirements as specified in the relevant GAVI guidelines for HSS, NVS (incl. immunization campaigns), Measles SIA and HPV demonstration projects. Figure 1 below summarizes the main findings from the proposals review.

Figure 1 Summary of Decisions IRC November 2013



There were a high number of clarifications requested in this review. All HPV proposals required clarifications, with the majority of these clarifications relating to issues of delivery strategy and links to broader public health strategy. All HSS proposals (except for approval in South Sudan and insufficient information for the Ethiopia APR) required either level 1 or 2 clarifications, with problem areas being management arrangements, monitoring and evaluation, capacity to absorb funds, and reported verticalization of immunization. There were also a large number of NVS clarifications, mostly relating to issues of sub-national cold chain capacity and management of surge capacity for campaign vaccines and target populations.

Thematic Analysis

There were particular themes emerging from this review that are summarized below, and detailed elsewhere throughout this report.

(1) ***Increasing Emphasis on Immunization Campaigns****:* There is new emphasis in this proposal round on the role of immunization campaigns in disease control, particularly for attainment of

measles elimination and rubella control objectives, and for prevention of outbreaks of meningococcal meningitis in Africa *(see section 11).*

(2) ***Lack of Certainty on Readiness of Logistics and Cold Chain Systems:*** The campaigns in addition to new vaccine introductions demonstrate new challenges for cold chain management and capacity. Vaccine storage capacity gaps are frequently ill defined and linkages between gaps, and requests for HSS cash support to address needs to eliminate gaps are arbitrary and vague. The EVM Assessment tool provides strong indicators of management readiness, but the Improvement Plans (IP's) do not address strategic measures to improve readiness and indicators to monitor progress. Transport management and availability continues as an important bottleneck to CCL readiness *(see section 3).*

(3) ***Health System Strategies Increasingly Targeted to Immunization Programs and Outcomes:*** The reviewers have observed a generally high quality of applications, with HSS increasingly targeted to immunization programming and outcomes. The quality of applications is improving, particularly in relation to monitoring and evaluation (although as demonstrated in the M & E Section, there are a substantial number of weaknesses that persist). Overall, the IRC considers the HSS investment as being critical to the achievement of the GAVI mission, particularly in regard to improving equity. Despite these advances, reviewers have highlighted the importance of managing the risk of "re-verticalization" of immunization, in contrast to the importance of developing a systems focus for achieving these immunization outcomes *(see section 12).*

(4) ***New Opportunities for Cervical Cancer Prevention:*** The review noted that there were 12 proposals for HPV (incl. 10 for demonstration projects and 2 national introduction) in various regions of the world, which demonstrate significant opportunities for expanding access to cancer preventing vaccines. The proposals were generally of high quality and reflected a mix of strategy (school, routine and campaign strategies) as well as articulating early links to broader cancer prevention and adolescent health strategies *(see section 10).*

(5) ***Increasing Significance of AEFI and Surveillance:*** The rapidly expanding vaccine schedule and increased emphasis on campaigns has heightened awareness of the need for adequate safety and surveillance mechanisms to be in place to respond to adverse events. Equally, the introduction of PCV, Hib, Hepatitis B, HPV and Rotavirus and meningococcal vaccines through the GAVI program is increasing the pressure to develop minimum standards for surveillance performance for monitoring and measurement of vaccine program impacts. Notwithstanding the technical challenges associated with surveillance development, investment in country capacity to monitor and measure vaccine impacts and safety will in the long run build the strongest case for investment in immunization in a post GAVI development context *(see section 7).*

(6) ***Increased Attention to Operational Challenges for Gender, Equity and Fragility:*** The emerging emphasis on campaigns, plus continued roll out of new vaccines, increases the importance of strengthening routine immunization particularly in relation to reaching remote, urban poor and migrant populations (equity in immunization), as well as strengthening roles of CSO partners in reaching these groups. It also calls for a deeper understanding of what are the barriers to caregivers, particularly young mothers, in taking their children to be immunized. In terms of fragility, although recent developments have been undertaken by GAVI in relation to policy development in this area, reviewers noted that work remains to be done in integrating fragility analysis and focus into proposal guidelines and management arrangements *(see sections 8 & 9).*

(7) ***A Changing Governance Context for Immunization:*** The expansion of new vaccines and of immunization services to other age groups, the emergence of local production opportunities, and growing awareness of the significance of evidence in decision making and evaluation of safety, all point to a changing governance context for immunization. Over the last decade, GAVI has

primarily focussed on the ICC model and cMYP planning/costing in order to coordinate and guide investments. In this new "Decade of Vaccines", there are questions as to whether sole emphasis on this model is now "fit for purpose" in all contexts, and suggest the need for governance review and investments in institutional strengthening by GAVI Alliance. This is particularly the case in relation to development of policy, scientific, regulatory functions through NITAGs and NRAs *(see section 5).*

(8) ***Concerns about levels of Financial and Technical support for Monitoring and Evaluation:*** Although reviewers have made observations that the current M & E guidelines, tools and templates in HSS and NVS proposals are of high standard and are fit for purpose, many countries had difficulties with articulation of these M & E frameworks, suggesting the need for more investment and technical support for M&E at country level. The transition to the Grant Application, Monitoring and Review process (GAMR) model also holds important implications for the manner in which country investments are monitored both at the global and country level *(see section 13)*.

Based on the above findings and analyses, the IRC prioritized 10 general recommendations which are outlined in Table 1 below.

Table 1 Overview of Recommendations

1. **Data Quality:** Coverage surveys should be mandatory for NVS application if >5% discrepancy against official estimates. GAVI should commit to support coverage surveys through country agreements.
2. **Cold Chain Logistics**: Support the integration of tools, monitoring strategy, and inclusion of innovative technologies and financing mechanisms to ensure that countries can accurately project gaps in their supply chain and any need for equipment or transport and maintenance infrastructure when introducing new vaccines and undertaking campaigns.
3. **Health System Strengthening**: In terms of sustainability, it is vital to retain the system focus in HSS guidelines, and to target HSS investments to inequity reductions as well as immunization outcomes.
4. **Governance:** Strengthen GAVI Alliance investments in institutional sustainability through NITAGs and NRAs, and review role of ICC to ensure they are fit for purpose. Promote community engagement through dual track financing mechanisms for CSOs.
5. **Immunization Safety & Surveillance**: Increase GAVI Alliance investment and establish norms and standards for safety and NVS surveillance (including WHO pre-assessment of NVS surveillance).
6. **Gender and Equity:** GAVI to ask for more focussed detail about inequities in relation to immunization and how countries intend to meet equity-related gaps in coverage to guide the IRC's assessment of proposed strategies.
7. **Fragile states:** The designation of GAVI fragile states be reviewed annually and their HSS and NVS Guidelines should better reflect the directions of the Alliance's fragile states policy as soon as completed. Management arrangements for fragile states need to be strengthened, with additional CRO and HSS technical assistance targeted to these countries.
8. **HPV** Demonstration projects: Ensure more emphasis in strategy development and monitoring of mapping, delivery strategies, male involvement, and consent and ethical safeguards where applicable.
9. **Campaigns:** GAVI to develop guidelines to ensure minimum standards for campaign support including: (a) updated cold chain inventory/assessment, (b) waste management investments, (c) safety surveillance measures, (d) post campaign coverage surveys.
10. **Monitoring & Evaluation:** The roles of the Secretariat and roles of in-country partners need to be clarified in order to strengthen the GAMR process at global as well as country level.

1. Introduction

Process of Review

A meeting of the Independent Review Committee was conducted from November 7 – 22 in Geneva, Switzerland. The purpose of the meeting was to make recommendations for approval to the GAVI Board for new grant applications for new vaccine proposals and for health system strengthening initiatives.

Twenty three reviewers took part in the review. Reviewers were from a range of disciplines including epidemiology, public health, logistics, health system, gender and equity and health economics. Following an initial orientation of 3 days including briefings and a simulation exercise, there were two plenaries with one focussing on vaccine applications and the other on a mix of health system strengthening and other applications. Every 1- 2 days, joint plenaries were conducted to ensure consistency in decision making and thematic analysis. In support of the overall direction towards integration of windows of GAVI support, a single report template was developed by the Secretariat for all proposals for each country. Two to three reviewers presented their findings on each country to the plenary, after which the IRC then reached consensus on main findings and recommendations. In addition to the country reviews, IRC members chose theme areas that they would contribute to in order to describe and analyse main trends and issues from the applications that in one way or another impact on the GAVI mission. Two page reports were prepared by groups of reviewers and presented to the wider IRC for discussion and for reaching consensus on main recommendations for GAVI Alliance management action. These theme areas make up the main topic headings that are described throughout this report. Additional time to undertake this thematic analysis was provided by the GAVI Secretariat which enabled more thorough analysis of these themes.

Framework for Analysis of Country Applications

At all times, the IRC based its decisions on the GAVI guidelines for applications. These guidelines included guidelines on Health System Strengthening (HSS), New Vaccine Support (NVS), Measles Rubella (MR) campaigns and HPV Demonstration projects. The main question asked was: Are the proposals consistent with GAVI application requirements?

Types of Recommendations for Country Approvals

GAVI application guidelines describe a different category of recommendation according to application window. For example, health system strengthening includes the recommendations of categories of approval, level 1 clarifications, level 2 clarifications and resubmission. Level 2 clarifications require an IRC re-review. The NVS applications have the approval categories of approval, approval with clarifications, approval with conditions and resubmission. The approval with conditions category requires IRC re-review. In contrast, the HPV demonstration project proposal format includes only 3 decision levels of approval, approval with clarifications and resubmission. The main criteria for distinction between a clarification and condition (or level 2 clarification in the case of HSS) is that in the case of a clarification, there are specific actionable points that can be undertaken by countries and the GAVI Secretariat and Alliance to fulfil application requirements. In the case of a condition, the IRC considered that if some basic application requirements were not fulfilled, then this would require re-review by an IRC. While understanding the rationale for the Level 2 clarifications category under the HSS window, it is important for the secretariat to re-evaluate the usefulness of this in order to have a more streamlined approach and consistency in decision making across the funding windows.

Figure 2 below summarizes the applications according to funding window. Figure 3 describes the percentage of decisions according to each classification (% approvals, % clarifications, etc). It should be noted that HPV demo projects do not have a "conditional approval" category. Level 1 clarifications for HSS have been allocated to the area of clarifications, and Level 2 to "conditional approval", as these clarifications will require re-review by an IRC.

Figure 2 Applications According to Funding Window

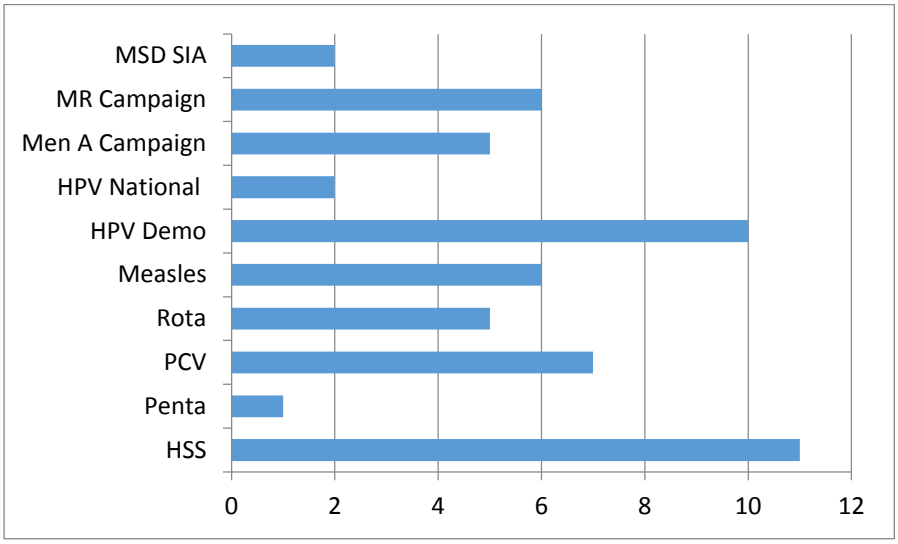
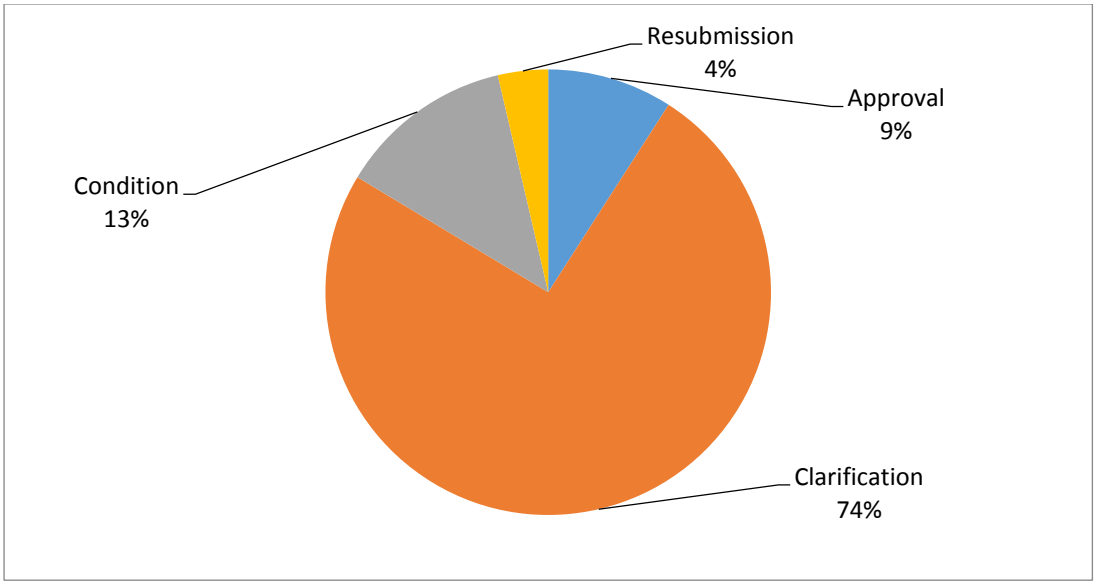


Figure 3 Percentage of Decisions According to Classification (Approval, Clarification, Condition, and Resubmission across all windows).



Resubmissions = Ethiopia for HSS APR (insufficient Information for APR and Sierra Leone for MSD Application)

There are a high number of clarifications requested in this review. All HPV proposals required clarifications, with the majority of these clarifications relating to issues of delivery strategy and links to broader public health strategy All HSS proposals (except for South Sudan) required either level 1 or 2 clarifications, with problem areas being management arrangements, monitoring and evaluation, capacity to absorb funds, and reported verticalization of immunization. There was also a large number of NVS clarifications, mostly relating to issues of sub-national cold chain capacity and management of surge capacity for campaigns vaccines and target populations. Please refer to specific sections for more detail.

2. Immunization Coverage and Data Quality

Issues

The IRC places considerable emphasis on the quality of data used in country applications, and indeed the whole process of reviewing, judging and making recommendations to the GAVI Board depends critically on having reliable information upon which to base decisions. Clearly, this is equally vital for GAVI management, and is an issue that the Alliance has struggled with since its inception. The 2013 NVS IRC review has been no exception in this regard, and numerous examples of questionable target population figures and suspect vaccine coverage data were encountered in the applications reviewed.

Many countries continue to report birth cohorts and populations that differ widely from UN Population Division estimates. In one proposal reviewed this year, the birth cohort stated was 76% higher than the UN figure; in another, population data and all statistics were withheld as 'state secrets'. Eight (23%) of 35 countries had official estimates of the number of surviving infants that were more than 10% greater than UN estimates, and 4 (11%) had estimates that were more than 10% less (see Figure 4).

A number of proposals for campaigns targeting wide age ranges were especially challenging because estimates for the population in the age range 9 months to 14 years, or from 1 year to 29 years for example, are hard for countries to obtain and impossible for the IRC to verify. Any discrepancies in such large age groups will clearly have serious implications for the quantities of vaccines and commodities to be supplied, and for cash grants funded through GAVI.

Reported vaccine coverage data are inconsistent; many countries continue to claim performance well in excess of WHO/UNICEF estimated levels, and well above levels shown by independent surveys. Six (17%) of 36 countries with proposals reviewed this round that had 2012 official estimates of DPT3 coverage that differed from WHO/UNICEF estimates by 10 or more percentage points (see Figure 5).
The Data Quality Audit (DQA) process, which requires data reviewed to attain a minimum 'pass level' to signify that data quality is acceptable and consistent so that it may be used with confidence in estimating needs and planning activities, will not address this issue. In a DQA, all EPI records at each administrative level are checked for quality and consistency. The IRC notes, however, that the DQA process is designed to assess only the quality and consistency of data, and does not (and cannot) provide any analysis or information on the accuracy of the data. As a result, if records are incorrect at the periphery, and the same data is copied into district, provincial and central records, it is possible to have a 'pass level' DQA result despite the data being inaccurate. Therefore, the DQA provides no information about the accuracy of data, and should not be used to determine the validity of

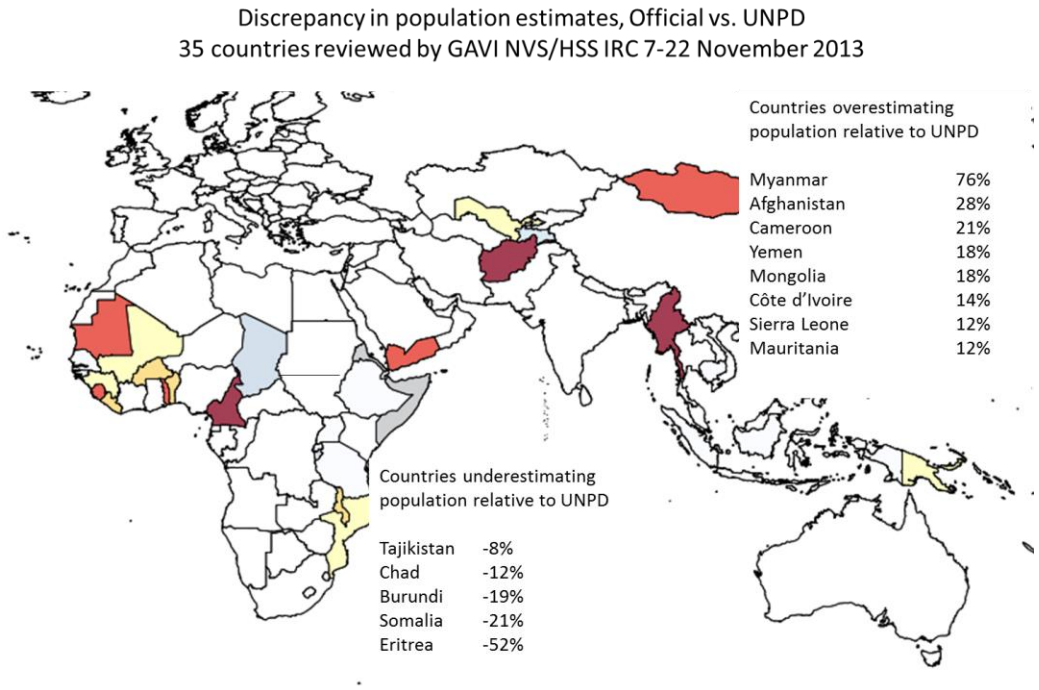
administrative data and reports. This is not to say that DQA results are not important – they are very valuable for checking consistency, which is what the process was designed for. But accuracy is needed before consistency has any value. Therefore, the process should be to survey first to validate accuracy, and then follow with the DQA to ensure consistence.

It is therefore proposed that first, to address accuracy, more use should be made of independent coverage surveys to verify reported performance. Where official coverage data differs by more than a pre-specified margin (e.g., 5%) from WHO/UNICEF estimates, a recent survey of acceptable quality should be mandatory for any NVS application. It is also proposed that GAVI should provide funds for conducting such surveys if necessary, and that this should be built into the NVS application process in the same manner as, or even as part of, the current vaccine introduction grants. Second, to address consistency, the IRC proposes that the DQA be used to ensure that data generated at the lower levels is regularly and completely transmitted to the central level.

Recommendations

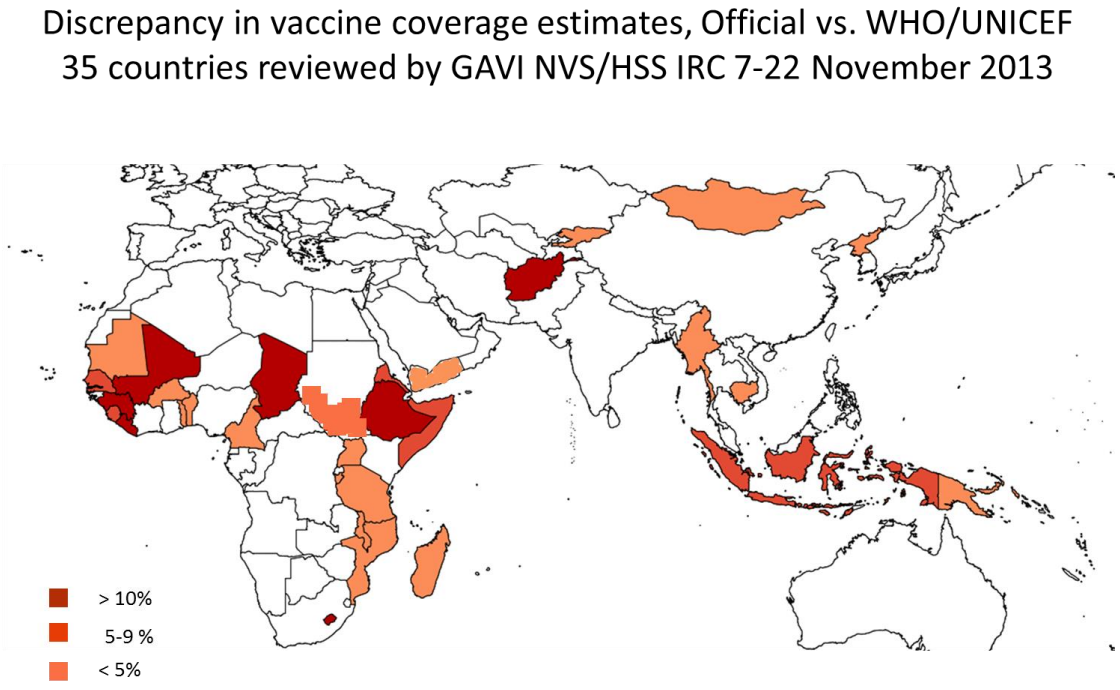
1. Make further efforts to improve the accuracy of target population figures used in GAVI proposals through cross checking against UNPD data: wherever country target population figures differ by more than 10% from the appropriate UNPD figures, the UNPD figures should be taken as more reliable for determining GAVI support, unless a recent and independently validated census indicates otherwise.
2. Make further efforts to improve accuracy of reporting of immunization coverage: if official government-reported DPT3 coverage differs by >5% from WHO/UNICEF-estimated DPT3 coverage, evidence from an independent coverage survey conducted within the past three years should be provided with any application to GAVI for coverage-linked financial or material support.
3. Methodologies, standards, time frames and guidelines for conducting coverage surveys for this purpose should be determined by a working group appointed to advise GAVI on the most appropriate approach to improve accuracy of coverage reporting.
4. Give consideration to providing technical and/or financial support to countries for the conduct of such coverage surveys where these become necessary to enable them to qualify for GAVI assistance, e.g., NVS, HSS.
5. Obtaining a ‘pass level’ in DQA results should not be used alone as a criterion for countries to qualify for any type of coverage-linked GAVI financial or material support. To ensure both accuracy and consistency in reported immunization coverage data, both surveys and DQA should be used together for this purpose.

Figure 4. Discrepancies in Population Estimates Official versus UNPD



Note that borders of South Sudan not correctly shown on map)

Figure 5. Discrepancies in Coverage Estimates Official versus WHO/UNICEF



(Note that borders of South Sudan not correctly shown on map)

3. Cold Chain and Vaccine Management

Issue 1:

There is little evidence of cold chain condition, in most applications. Equipment inventory management has historically been sporadic, time intensive, costly and confronted with barriers of obsolescence if not regularly maintained. Several new inventory management tools are available or under development. These include SMS/GPRS phone apps, a cold chain inventory tool (CCEI) developed by PATH and integrated management information systems such as DHIS2 etc. Applications tend not to reflect and summarise progress and results of inventories.

Recommendation

1. GAVI should be proactive in supporting the integration of tools and inclusion of innovative technologies to ensure that countries can accurately project gaps in the supply chain and the need for equipment when introducing new vaccines or strengthening systems.

Issue 2:

Supply chain equipment is frequently not positioned at strategic locations in the service delivery network, so that the match with need, distribution and service delivery arrangements is sub-optimal. Additionally the multi-tiered cascade delivery mechanisms, were developed decades ago when costs and fragility of vaccines were vastly different than that observed today and integrated supply chains were not to be considered.

Recommendation

2. GAVI should incentivise countries to address the shortcomings of sub-optimal systems by strategies similar to those in place to increase the numbers of children vaccinated. Guidelines are desirable to present model scenarios and potential cost benefits.

Issue 3:

The financial value of vaccine in a cold chain may increase more than 10 fold when several new vaccines are introduced. Precautions to ensure safe storage and distribution of vaccines are not increasing by a similar order of magnitude.

Recommendation

3. GAVI is encouraged to introduce measures through cash based programs to encourage countries to ensure that adequate precautions are set in place to safeguard stored and distributed vaccines. Cash based funding of equipment alone is not sufficient unless coupled with advanced temperature monitoring and stock management solutions and use of WHO/PQS prequalified products with a demonstrated reliability. These precautions will benefit both routine and SIA activities.

Issue 4:

There is little evidence in most GAVI supported countries that the management of health system waste inclusive of immunization waste is improving and progress is being made in the sector to achieve MDG goal #7 (to ensure environmental sustainability) .

Recommendation

4. GAVI should engage with the vaccine and syringe supply industry to explore bundling waste management solutions with vaccine and syringe supplies. In addition GAVI supported PBF

programs could include incentive drivers for waste collection and processing through innovative approaches such as mobile telecom service collaborations with the banking sector.

Issue 5:

The four preceding recommendations imply technology shortcomings. An increasing selection of improved vaccine storage technologies, temperature monitoring and data analysis and communication technologies is emerging. The issue is not the absence of technological solutions, but more an issue of mainstreaming and bringing hard and soft technology solutions into the arena to effectively address the four issues above more succinctly.

Recommendations

GAVI is encouraged to:

5. Further orient its efforts to support the WHO/UNICEF strategy to use Solar Direct Drive (SDD) refrigerators in non-electrified or poorly electrified locations.
6. Support countries improving data management through the adoption of appropriate technologies such as SMS/GPRS mobile phone apps, and remote temperature monitoring of vaccine storage locations.
7. Provide support for advanced data management solutions and full integration of immunization statistics into health and logistics management information systems such as DHIS2.

Issue 6:

We continue to see proposals that are vehicle procurement heavy without clear plans of replacement and recurrent expenditure management and plans especially in the context of MoH's that are not well situated to manage such fleets. We also see continuing conflicts related to inter departmental use of vehicles and non-availability of vehicles for vaccine distribution, maintenance etc. This often results in outreach and vaccine distribution activities being compromised from transport operational constraints.

Recommendation

8. HSS cash support to assist countries, already include provision to migrate from capital-intensive MoH managed transport systems to more cost effective and sustainable options such as outsourced professional networks for transport leasing. This support could be extended by performance based incentives to encourage countries to adopt sustainable transport management policies and solutions that include fuel, maintenance and driver management with inbuilt provision for supply chain equipment maintenance. When effectively implemented by countries, it will be well aligned with the five-year strategic plan of GAVI for 2011-15 to refocus HSS on immunization to "contribute to strengthening the capacity of integrated health systems to deliver immunization by resolving health systems constraints.

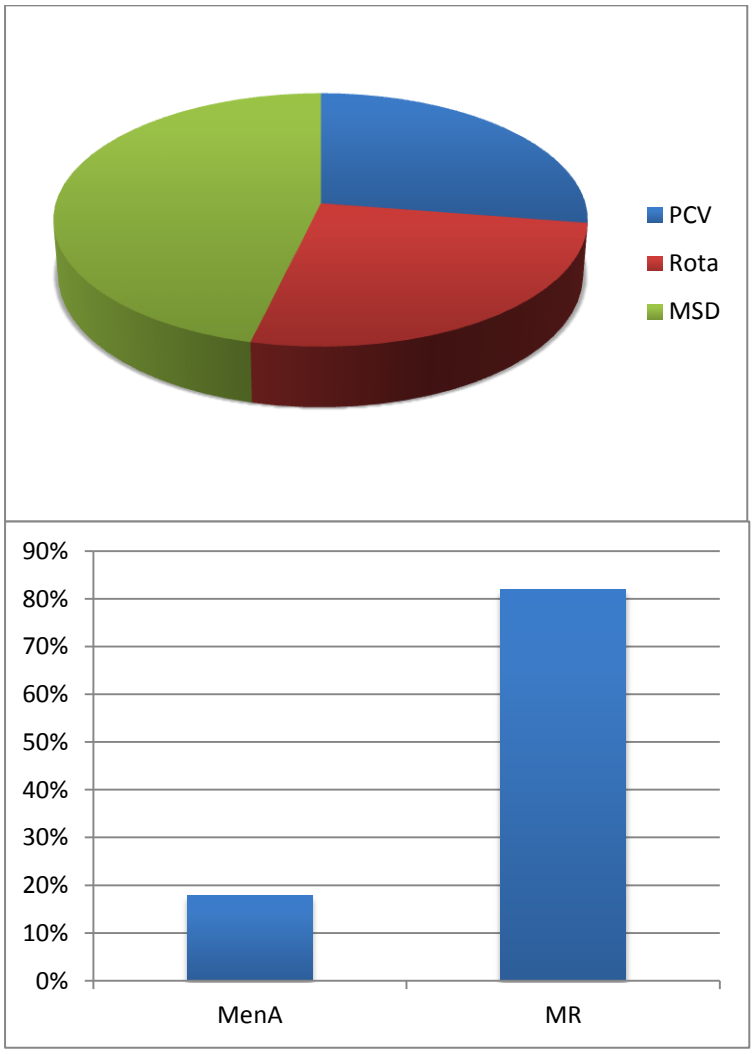
4. Financial Management and Sustainability

Issue 1 NVS cash requests (both routine and campaigns)

MSD vaccine introductions (46%) comprise the majority part of cash requests for NVS routine support. PCV and Rota accounted for only 27% of the requests, respectively. The Mozambique and Myanmar applications alone accounted for 50% of NVS routine cash requests. A considerable increase was seen in applications for preventive campaigns (particularly in Sub-Saharan Africa, including Mauritania, Cote d'Ivoire, Guinea, Burkina Faso, Togo, etc.). MR campaigns represented

82% of the cash support for operational costs of these campaigns vs. 18% for MenA. Operational support grants requested (US$43 million) were 7 times higher than the VIG requests for the routine immunization program (only US$6 million). Due to the large target population's size of the MR campaigns in Myanmar and Tanzania, they account for 63% of the total preventive campaigns allocations: Myanmar (US$15 million), Tanzania (US$13 million), Burkina Faso (US$5 million) just for operational costs.

Figure 6 Distribution of cash grants among vaccine types for NVS and campaigns



Issue 2 cMYP Costing Tool and Countries' Vaccine Requests

Almost all the countries submit an updated version of their cMYP when requesting NVS support. However, except for a few countries (Cambodia, Togo, and Senegal), the cMYP costing tools were not updated to reflect the new GAVI vaccine support requested. In more than 50% of the NVS proposals, countries have not even indicated total vaccine needs for the particular vaccine they were applying for because the cMYP was not updated accordingly. The cMYP costing tool was completed at a certain point in time and efforts were made at that time to fill it out in detail. However, for the large majority of countries it has since then not been updated. Programs do not have the capacity to

update the tool. The tool is too vertical and not helpful for day-to-day management of EPI managers. It is noted that the planning and costing tools are currently being updated by WHO.

The review notes also that most of the countries have their cMYP ending in 2015/2016. We therefore believe that now would be a very good point in time to review the usefulness of the cMYP Tool and decide whether this or any similar type of information should be requested in the future. It should be taken into account that any EPI planning and costing system should first of all fit the needs of in-country EPI decision-makers and managers. If this is not the case, the system will not be regularly updated and therefore not useful for GAVI and partners either.

Issue 3 Funding gaps

NVS: Routine vaccine introduction plans show a funding gap of 48% to be mobilized by Government and other in-country partners. However, no specific resource mobilization strategy/approach is described to make sure that financing will be secured by the time of vaccine introduction. Some countries (PNG, Eritrea, Mozambique, Senegal and Malawi) have more than 40% of their vaccine introduction budget to be mobilized outside of GAVI support before they can launch their new vaccine introduction.

Preventive campaigns have generally a much smaller funding gaps (8% on average) compared to NVS routine. But in some countries there is still a significant funding gap for operational costs that need to be secured - for instance 60% in Solomon Islands and 30% in PNG.

*Campaigns***:** Operational grants for campaigns are US$ 0.65 per person. For large countries with campaigns targeting wider age groups, this is a relatively large budget request. The IRC found that these campaign budgets were rarely linked to proposed strategies and activities. Importantly, most countries stated that they would conduct a coverage survey, but this activity was rarely budgeted for. Moreover, it is concerning that many budget items were not tied to some of the GAVI emerging issues, such as waste Management and AEFI.
To summarize, main findings are as follows:

- Substantial surge in campaign requests: MSD vaccine introductions (46%) of the NVS routine requests and MR campaigns (82% of the requests for a grant value of US$36 million).
- Vaccine needs (in doses and dollar amounts) are not updated in the cMYP costing tool that most of the countries submit with their application. This raises many issues, including whether it should continue to be used as an EPI planning and costing system at country level. Is the tool adapted to the needs of the EPI? Is there another way to track EPI expense records at country level? Do EPI units have in-house capacity and resources to collect, analyze and complete adequately the tool?
- Funding gaps are reported by almost all countries without adequate strategies or mechanisms being described to leverage additional funding. This may put at risk the EPI activities in the longer term.

Recommendations

- In spite of the fact that all GAVI countries have extensive experience in conducting vaccination campaigns, financial planning and management of these campaigns remain surprisingly weak. If

GAVI decides to continue funding these expensive campaigns, it is recommended that costs are closely monitored and documented and used for best practices in subsequent campaigns.

- GAVI should use the opportunity of the 2015/2016 ending period for most cMYPs to revisit the method of requiring financial information for NVS applications.

5. Health System Strengthening

In 2006, GAVI opened the HSS cash support window in recognition that strengthening country health systems is critical to achieving GAVI's core mission of increasing access to immunization. With the new five-year strategic plan for 2011-15, the Board made a decision to refocus HSS on immunization to "contribute to strengthening the capacity of integrated health systems to deliver immunization by resolving health systems constraints, increasing the level of equity in access to services and strengthening civil society engagement in the health sector." GAVI's approach to HSS has continued to evolve in the last two years, in response to a number of challenges faced in the planning and implementation of the HSS cash support window, and an increasing emphasis on demonstrating results in terms of improved immunization outcomes. The proposals for HSS under review by the IRC November 2013 are the result of recent discussions in the GAVI Board and other work by the GAVI Secretariat and represent the 4th generation of GAVI HSS support.[1]

The IRC reviewed 7 new applications for HSS cash support, 3 reprogramming requests and one APR. The table in the Attachment provides an overview of key features of these requests for support and the IRC's recommendations. All were recommended for support, most with level 1 and level 2 clarifications. One APR (Ethiopia) was found to have "insufficient information." The total financial implications for new HSS applications amount to US$106,011,680.

Some applications propose innovative approaches to health system strengthening and promote alignment of the immunization program with national health plans and harmonization with partners (e.g., Bénin's proposal for supporting RBF in two health districts). South Sudan demonstrates an active participation of its civil society organizations in its ICC and a potential for this to extend to strengthening of the health system. Its report is probably a testament to the strong role of its civil society and the contributions of GAVI Alliance partners. Yemen's application demonstrates how a fragile state through innovative and integrated outreach activities that builds on previous lessons learned from the first HSS grant shows clear linkages between well identified bottlenecks, lessons learned, and proposed M&E plans and clear immunization outcomes.

Issue 1: (Overarching) Are we talking about ISS or HSS?

A key finding and conclusion concurred by a number of the IRC members on the review, is that GAVI is inadvertently encouraging a greater emphasis on ISS (Immunization Services Support) rather than HSS through the use of often unclear or imprecise wording in the guidelines.

Why do we say 'inadvertently'?

- The wording in the first grant category 'Health services' in the table 1 of the GAVI HSS

[1] The "first generation" of HSS grants, those approved until 2010, were specifically targeted at bottlenecks/barriers in health systems that make it difficult to improve the provision of, and demand for immunisation and other child and maternal health services. However, there was no specific requirement for country applications to show a direct link between proposed activities and improved immunisation coverage, nor to demonstrate a clear results chain or theory of change. For this reason and due to other delays in cash disbursements and implementation, seventeen of the old grants were "reprogrammed" over 2010-2012 to be "second generation" HSS grants. The "third generation" is comprised of the HSFP grants starting with one pilot in 2011.

guidelines (31st May 2013) places such emphasis on immunization hardware that countries, especially fragile states, inevitably see this support window as the (prime) opportunity to build/renovate infrastructure and buy equipment especially as few other donors will support such expenditure. Some of the wording in other categories could be edited to better identify wider health systems investments that would contribute to improved immunization outcomes.

- Some of the language used in the guidelines and related documentation is ambiguous. It can be, and has been, interpreted very differently by different countries.

The IRC is concerned about this trend as there is little evidence that narrowly targeted investments in immunization systems alone will suffice to enable countries to reach their immunization goals, especially in countries with weak or overburdened health systems. Annex 6 indicates that, with few exceptions, the proposals reviewed in this round primarily concern ISS, and have limited potential to build synergies with other efforts to strengthen health systems. Furthermore, many IRC members were uncomfortable about approving such proposals, when it was clear that significant health system constraints remained unaddressed. It did so because countries could not be faulted. They were following the GAVI guidelines on a subject that is complex, not well understood, and in the case of GAVI applications needs strategic thinking or a leap of faith between what could or should be done in the wider health system context to improve immunization outcomes. The sections below elaborate on some key issues that are central to GAVI's strategic focus.

Sub-issue 1: Equity

Few of the applications for HSS grants currently reflect an awareness of the range of equity issues. Most proposals only referred to gender issues and geographical access to immunization. This was backed by a dearth of equity related indicators in the M&E frameworks. In the context of strengthening health systems in GAVI-eligible countries, the achievement of equitable access to services is crucial. In many countries, the access barriers for immunization and broader MCH services have not properly been explored. Consequently, many of the activities proposed in the current round of HSS proposals have been designed based on perceptions, e.g. IEC strategies.

Immunization can serve as a vehicle to reduce access barriers and increase utilisation of health services. This is one possible lever for the future design of programs under GAVI's HSS Cash Support. Unless equity oriented measures are built into an HSS program's early stages, it will be challenging to achieve the goals.

Sub-issue 2: CSO Participation

GAVI guidelines advocate for the strengthening of civil society engagement in health sector planning and development. Civil Society Organisations (CSOs) have a unique role to play in improving utilisation of health services broadly and specifically in improving and sustaining immunization coverage and response to adverse events. CSOs also have a role to play in ensuring that health systems are accountable to people and responsive to their needs. CSOs range from the national organizations without community footprints such as professional associations to community based organizations such as village youth associations without a national focus. All of these have potential contributions to make but the engagement of community-based organizations is desirable for GAVI's purposes (in particular, to address equity issues). More guidance is needed.

The applications reviewed in this round, as in previous IRC meetings, mention the engagement of CSOs but provide limited evidence that CSOs are able to avail HSS funding. This opacity is even greater when HSS funds go into a general basket of funds, e.g. Ethiopia's MDG Performance Fund.

Furthermore, an important weakness of the current approach to engagement of CSOs is the lack of performance measures for CSO engagement. If CSO engagement is to be promoted and funded by GAVI then there must be guidance on the measures of CSO engagement that countries must report on.

Sub-issue 3: Sustainability

Sustainability is another area that is unconvincingly presented in current HSS proposals. It is introduced with a couple of paragraphs in GAVI's Guidelines for Applications but not clearly defined. The applications pick particular aspects of sustainability to demonstrate awareness. None of the proposals reviewed has presented a holistic strategy towards sustainability that would have included maintenance of equipment and infrastructure, the institutionalisation of capacity building and health communication, ideas on financing, etc. This becomes more alarming especially in the case of graduating countries that will soon become ineligible for GAVI cash support.

Sub-issue 4: The 'how' of implementation

The HSS proposals covered (some of) the 'what' that needs to be implemented. However, the GAVI guidelines and application form do not ask for detail on the 'how' of implementation. The 'what' is relatively easy to describe, the 'how' is more complex and requires a strategic, management, participatory approach which is often lacking or weak in health institutions. Such information is crucial to help ensure that HSS funds will be used efficiently, effectively and in line with the 2005 Paris principles.

Sub-issue 5: Evaluation

The IRC reflected that countries seem to be struggling with the requirement to develop an M&E framework that accommodates immunization-specific indicators as well as key national health system indicators and the interrelationships among them. The specification of 6 mandatory immunization indicators ensures that key measures of vaccine coverage and equity are in place. However, this focuses all attention on immunization as no health systems performance indicators are discussed in the guidelines.

The IRC noted that all HSS proposals described plans for an external end-of-grant evaluation. It also noted that an effort is ongoing to support evaluations of a few soon-to-be completed HSS grants. However, it felt that these evaluation efforts were insufficient given significant investments made by GAVI in HSS cash support. In addition, the current design of ongoing and planned evaluations pose methodological challenges (there is no counterfactual approach, and measurement of both intermediate and outcome indicators is limited to immunization services). It will therefore not be possible to determine the extent to which HSS grants helped to increase access to immunization through systems improvements.

Recommendations

1. GAVI needs to soon convene a small group of IRC members and Secretariat to: a) edit the HSS guidelines and application form to improve clarity; b) change the guidelines and application form to ask the 'how' of implementation which is crucial for HSS; and c) address issues related to equity, community system strengthening, sustainability and evaluation.

2. GAVI should encourage and fund operational research on the predisposing and enabling factors of access to immunization as well as research on social determinants. In this context GAVI should review available evidence to assist countries with ideas and tools.
3. GAVI should provide better guidance, illustrate the multiple dimensions of sustainability and refer to practical examples and measurements.
4. GAVI should work with partners to develop guidance on the engagement of CSOs under the HSS grant.
5. The M&E plans of approved proposals should be strengthened, by ensuring that the necessary data on key indicators, including measurements of improvements in health systems performance, are in place to maximise the potential of future evaluation efforts across GAVI's HSS portfolio.

Sub-Issue 6 Financial Management and HSS

Most of the 11 HSS reviews considered by the IRC have been applications for new support. All of these applicants exhaust the budget ceiling set by GAVI. The HSS multi-year programs are mainly used to fund gaps (identified as "bottlenecks") and sometimes allocate a considerable amount to equipment and infrastructure, e.g. cold chain equipment and vehicles. Consequently, the broader objective of strengthening the health system is generally weak. Yet a few applications reflect an HSS focus; examples are Benin that allocates more than two thirds of the proposed budget to the implementation of RBF and Yemen with a very strong capacity building component and a share for materials and equipment (including medical supplies, IT and printed matter) of less than 25% of the total budget.

The spreadsheet tool "HSS Budget Gap Analysis and Workplan" provided by GAVI supported transparent program budgeting. Not only has this tool benefited applicants to compile a structured budget, it also offers an excellent approach to budget analysis. The tool allows the important quick assessment of proper budgeting for each activity, it provides an insight as to whether the budget is well balanced between the objectives, it gives an overview of the budget allocation according to GAVI grant categories and it reflects the relative role of different implementers in the proposed program of work.

Specific HSS observations were as follows:

- All the 7 new HSS applications requested a budget similar to GAVI's specified maximum amount.
- The allocation of funds to program management varies significantly between applications. Even though there are differences in country context and different management models required, this component should be addressed more explicitly in country applications, as often roles and allocated tasks are not clearly presented. A well-designed and properly funded management structure is a key determinant of program success.
- The GAVI grant categories play an important role in supporting GAVI's mission. Currently, the budget according to grant categories is not interpreted and does not play a major role in the design of HSS applications.
- The budget gap analysis in the context of new HSS applications does not produce meaningful benchmark figures, given the five-year time horizon.

Recommendation: As GAVI considers a further review of the HSS guidelines and application form, it is important to consider how best to capture meaningful budget inputs and gap analysis within a realistic time frame.

6. Governance Issues (ICC, NITAG, HSCC)

Issue 1: Regulation, Science and Safety
Many of the issues being raised in this IRC review point to increased complexity of immunization services, with respect to:

1. Volume of vaccines
2. Types of vaccines
3. Expanded aged groups
4. Routine, campaign and school based strategies
5. The challenge of generation of scientific evidence to inform vaccine introduction, vaccine impact and monitoring of safety
6. Health system governance

Up until this time, the GAVI Alliance has relied on ICCs and multi-year planning and costing approaches to guide and coordinate immunization investments. Many of the issues mentioned above are often beyond the scope of an ICC, which is a governance mechanism principally concerned with resource coordination.

But given the increasing complexity and scope of immunization programming that is evident in this round of NVS proposals, the GAVI Alliance may need to place more emphasis on institutional development in order to guide and sustain this expanded scope of immunization programming. This points to a changing governance context for immunization, with increasing importance of scientific bodies (NITAG), regulatory mechanisms (NRAs) and safety committees (national pharmocovigilance committees). Given this increasing emphasis on regulation, science and safety, there may also need to be a gradual shift from sole emphasis on the ICC and cMYP (planning) as a guidance mechanism, to additional emphasis on regulation, policy and law in global vaccine strategy.

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

Issue 2: Coordination and meeting aid effectiveness obligations
Along with the increasing complexity of immunization services is the increasing complexity of coordination arrangements in countries that may have limited technical and managerial resources and weak administrative systems in the health sector. The ICC, NITAG, HPV TAG, Health Sector Coordination Committee share many common agendas, often involve many of the same personnel and collectively may incur significant transaction cost for governments.

GAVI HSS funding is an important contribution to developing and/or strengthening systems to deliver improved immunization outcomes. However, the IRC had concerns that the ICC model fails to realise potential gains from coordination with wider health sector programming.

The IRC is concerned over immunization programming and coordination in isolation from wider developments in the health sector. There is evidence in HSS funding applications of re-emergence of vertical project management units in the MOH to oversee and manage GAVI grants, the failure to consider linkages with other agencies and programs, potential duplication of funding and inefficiencies across GAVI, GFATM and World Bank funding for primary health care and systems strengthening. Particular areas include infrastructure and logistics systems, training staff, strengthening supervision and introducing modern IT based information management.

There are examples where a targeted coordination body, the GFATM-supported Country Coordination Mechanism (CCM), has expanded its remit at the request of government and development partners to assume a wider health sector coordination function as in Myanmar. The ICC may no longer be the most effective arrangement to coordinate support to improve immunization outcomes in poor countries with limited capacity. It may be that the NITAG could assume much of the current ICC function and that the coordination function could be assumed by a wider coordination body. There is no single model to fit all settings. This suggests the need for review of the ICC arrangement. Is the ICC still fit for purpose? Does it recognise in-county limitations and the transaction costs that it may incur? Does it ensure that resources, particularly for HSS, are used with the greatest effectiveness and efficiency? Does it maximise coordination with others and use and strengthen government systems?

Recommendation

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

7. CSO and Demand-Side Issues

Issues

Strengthening civil society engagement in the health sector is an objective under Strategic goal 2 of GAVI's 2011-2015 Strategy, and GAVI works continually to strengthen its engagement with civil society at all levels: governance, advocacy, resource mobilization and service delivery[2] . Over the years GAVI has increasingly recognized civil society's strength and value in service delivery and advocacy for immunization and broader child health. CSOs have a particularly important role to play in overcoming inequitable access within countries for marginalized and hard to reach communities, but their contributions overall are not well described in proposals (both for HSS and NVS Proposals).

Application guidelines for proposals reviewed by the November IRC focused on CSO representation and involvement in ICCs/HSCCs - and for HPV Demo Projects, TAGs - for all proposal categories

[2] GAVI defines civil society as community and faith-based organisations, non-governmental organisations (NGOs), professional associations, academic and research institutions and organisations representing key affected population groups which, collectively, are committed to working with governments and Alliance partners to achieve GAVI Alliance strategic goals.

and under HSS, on the engagement of Civil Society in Action Planning and implementation and on the presence of indicators to measure CSO contribution to HSS and immunization activities. Evidence of CSO representation and involvement in ICCs/HSCCs was not sufficient to ascertain CSO meaningful contribution to EPI agenda at country level.

Some countries evidenced CSO representation on governance bodies (e.g., Somalia), while others were missing relevant CSOs such as women's and youth organizations (e.g., Cameroon, Burundi, Gambia, Mali). Some countries provided strong narrative descriptions of CSO involvement as well as indicators to measure this involvement (e.g., Benin), while others provided strong narratives for the role of CSOs in proposed activities but no indicators to measure the effectiveness of this involvement (example, Indonesia where CSO involvement was especially strong at sub national level but without indicators to measure this involvement). For some countries, CSO involvement was mentioned but not well defined and lacking specific indicators (e.g. Uganda). One country (Ethiopia) submitted an HSS reprograming proposal that described a greatly diminished role for CSOs without explanation (and with no acknowledgment in the budget that CSOs would directly receive any of the funding). Still other countries described no CSO involvement whatsoever, and this was especially true for the NVS proposals (e.g., Côte d'Ivoire, Tajikistan, Kyrgyzstan). It must be noted, however, that these applicants were not asked to describe a role for CSO partners in their NVS strategies. Overall (with exceptions), CSOs action plans and budgets within HSS support were not well described and exhibited a lack of consistent performance frameworks.

Roles for CSOs varied greatly according to country context and included:

- engagement in identifying the poorest performing districts for immunization, including through definition of the criteria and methodology by which to make this assessment (Uganda)
- Engagement in follow up assessment activity to understand the impact of a new Village Health Team model to promote immunization (Uganda)
- Direct involvement in door to door outreach and vaccination (South Sudan)
- Scale up of immunization services by FBOs/NGOs directly providing PHC services (South Sudan)
- Collaboration with County Health Management Teams in performance reviews
- Strong involvement in community mobilization and monitoring of these activities (South Sudan)
- Strong engagement in HSS proposal development process (Somalia)
- Recruitment of additional staff for health centres directly supported by CSOs (Somalia)
- Capacity building for smaller NGOs in BCC (Somalia)
- Partnerships with MOH to promote child health (Somalia)
- Develop and disseminate key messages to promote immunization campaigns (Somalia)
- Special assistance to immunize children in rebel controlled areas (Somalia) or conflict areas (Yemen)
- Involvement in baseline data collection and completion surveys (Somalia)
- Data collection to inform HMIS (Somalia)
- Operational research (Somalia)

Although the NVS guidelines were silent on CSO involvement, IEC/social mobilization events budgeted in almost all proposals reviewed during this IRC do not indicate that countries intend to leverage community resources to conduct these vaccine introduction preparatory activities. Countries are missing an opportunity to make routine and preventive campaigns work better at peripheral levels.

CSO Type B support remains very marginal in applications submitted by the countries. CSOs' action plans and budgets within overall HSS support are not well described and exhibit a lack of consistent performance frameworks, which make it very difficult for GAVI to evaluate their added value to EPI activities. NVS routine and preventive campaigns described in the proposals do not provide evidence that countries leverage the community sector for sensitization and social mobilization events prior to introduction of new vaccines or launch of vaccination campaigns.

Most proposal budgets that included a CSO component indicated that they would be funded by ministries of health. Such granting arrangements through a ministry of health or other public bodies do not guarantee involvement of CSOs in EPI early planning activities nor access to relevant funding envelopes that can make a difference at community level. Current granting mechanisms through MoH are not adequate to ensure CSOs full access to GAVI available in-country resources**.**

Recommendations

1. CSOs (especially groups that reflect target populations) need to be included as *active* participants in TAGs established for HPV demonstration programs as well as ICCs/HSCCs. Governance bodies need to provide evidence that CSO engagement is genuine and not a token gesture.
2. The action plans and budgets of CSOs within countries' applications should describe added value and link to well-defined performance frameworks; GAVI inequity and access strategies and policies should outline and reinforce the role of CSOs in EPI activities at country level.
3. GAVI in-country governance and granting mechanisms should make sure that CSOs have access to increased level of resources in order to address immunization gaps at community level (end-beneficiaries perspectives). Funding arrangements for CSOs within the GAVI model may need to be reviewed to explore alternative granting arrangements for the civil society sector. A scheme like the dual track financing mechanism of the Global Fund (a Principal Recipient for public sector and a Principal Recipient for community sector) would help scale up CSOs engagement on GAVI supported programs at national level. These arrangements could be implemented and overseen through current GAVI governance mechanisms (ICC, HSCC and NITAGS).

8. AEFI and Surveillance

Issues

There has been great progress in GAVI eligible countries in the surveillance of adverse events following immunization (AEFI) and integrated disease surveillance and response. The findings of the current IRC are identical to those of the July 2013 Monitoring IRC (Tables 2 and 3).

Table 2: Status of AEFI surveillance in GAVI eligible countries in 2012

Questions	Response	
	Yes N (%)	No N (%)
Pharmacovigilance Capacity	43 (63.2)	25 (36.8)
National Expert Committee	41 (60.3)	27 (39.7)
Injection Safety Plan	43 (63.2)	25 (36.8)
Sharing of Vaccine Safety Data	27 (39.7)	41 (60.3)
Risk Communication Strategy	29 (42.6)	39 (57.4)

Source: IRC Monitoring Global Report, July 2013 (permission, Monitoring IRC Chair)

Table 3 Status of VPD surveillance in GAVI eligible countries in 2012

Questions	Response	
	Yes: N (%)	No: N (%)
Existence of sentinel surveillance rotavirus	46 (67.6)	22 (33.4)
Existence of sentinel surveillance for bacterial meningitis/ pneumococcal or meningococcal disease	49 (72.1)	19 (27.9)
Conduct special studies on rotavirus	41 (60.3)	27 (39.7)
Conduct special studies on bacterial meningitis/ pneumococcal or meningococcal disease	34 (50.0)	34 (50.0)
Use of sentinel, study data to monitor and evaluate impact vaccine introduction and use	53 (77.9)	15 (22.1)

Source: IRC Monitoring Global Report, July 2013 (permission, Monitoring IRC Chair)

Although there has been improvement, countries are still at varying stages of development of AEFI systems. For example, Senegal has an excellent AEFI surveillance system and supplied a chart on number of AEFIs reported; Gambia stated it has an "effective routine data and surveillance reporting system in place" and this will be used to provide AEFI for its proposed HPV Demo. Mongolia stated that AEFI will be strengthened by training AEFI members. PNG acknowledges the need to strengthen surveillance and response to AEFI. On the other hand, Burundi admitted that the absence of a good AEFI monitoring system was one of the weaknesses of the EPI program and they plan to conduct AEFI capacity building activities for health workers, parents and teachers. Similarly, Mali plans to invigorate its surveillance and AEFI systems.

Men A campaigns and MR catch-up campaigns in which eligible recipients range from 5-29 years or 1 to 14 years pose some risks that warrant the establishment of active surveillance systems and the AEFI committees. For example, in some countries these mass campaigns cover women in childbearing years. There is inadequate experience globally with the administration of these vaccines in pregnant women. Moreover, some of the "new and underutilized" vaccines (e.g. Men A) have not been used in countries with strong surveillance capacity. It is important therefore that good data is collected for the early detection and prompt response to any unforeseen consequences of administering these vaccines.

Recommendations

1. GAVI should consider developing guiding principles to assist countries to develop functional AEFI and VPD surveillance systems
2. GAVI could make more use of the HSS window to steer countries towards WHO-recommended investments in AEFI and IDSR monitoring systems.
3. WHO should ensure systematic pre-assessment of surveillance systems and capacity for all NVS proposals.
4. NVS grants should be contingent upon detailed costed plans to develop AEFI surveillance systems, and their function should be technically monitored and supported.
5. GAVI Alliance partners to develop (or use) available standard and benchmarks for VPD surveillance systems to assess readiness for new vaccine introduction.

9. Gender and Equity

Most countries, whether or not they routinely collect sex-disaggregated data, reported parity in coverage of routine infant vaccinations. The exception was Côte d'Ivoire which reported that preliminary data from 2011-2012 DHS demonstrated a 5% point (66.3% vs. 61.5%) discrepancy between the coverage rates for males and females but did not identify the vaccine(s).

Very little information is presented on the target groups for MR, MenA, and yellow fever campaigns past infancy. For example, the IRC found no information on the number of people in the extended cohorts, sex-disaggregated data, or equity analysis in the reach of these campaigns (see section 12 for information on gender and equity in relation to HPV).

The majority of proposals, whether HSS (70%) or NVS (64%), were gender blind[3], in particular, they did not consider any gender related barriers that might prevent caretakers (mainly female) from taking their child or themselves for immunization. Where identified, there was no analysis of subjects in a way to drive meaningful programming and measurement. In the November 2013 round, two proposals described caregivers in gender blind terms as "too busy" (Papua New Guinea) or "negligent" (Togo) without identifying the caregivers as a mother or father or guardian and there was no consideration of how the mobilization or IEC strategies could affect their decisions to take their children for vaccination.

Only 30% of the HPV-demo proposals (Benin, Core d'Ivoire, Togo) mentioned activities to engage men/boys as secondary beneficiaries and most were generic description of community mobilization with poorly defined strategies and scanty information. However, a comparison with previous IRC

[3] Gender blindness is the failure to recognize that gender is an essential determinant of social outcomes impacting on projects and policies. A gender blind approach assumes that a policy or programme does not have unequal (even if unintended) outcome on women and men.

reports reveals improvement. Almost all HSS proposals (90%) in this round identified equity related barriers, (e.g., South Sudan stated a 24-percentage point difference between the poorest and richest wealth quintiles). This is an improvement from IRC NVS 2012 when almost 88% of countries did not identify gender/equity issues in their proposals. On the other hand, many applications still do not analyze the barriers identified in any detail or make plans to address them. In this round, only 55% of the NVS proposals considered equity barriers and even fewer (41%) planned to address such barriers in their strategies. However, this represents an improvement from IRC NVS 2012 when only 8% planned to address the barriers.

Given the limitations of the application forms and guidance, the IRC would like to commend Yemen, Mozambique, Sierra Leone, and South Sudan for identifying gender/equity related barriers and some efforts to address them.

The guidelines for application for New Vaccine Introduction (NUVI) support do not include any guidance on gender and equity analysis. The next iteration of the NUVI guidelines could draw on the section "Health system bottlenecks to achieving immunization outcomes" in the guidelines for applications for HSS to provide clearer guidance to countries.

Many of the partner countries[4] with proposals in this round have high rates of child marriage, defined as a formal marriage or informal union before age 18 which generally indicates that girls are being married to significantly older men. Usually these girls are taken out of school which raises questions around inequality within these relationships, and the ability of such young women to make decisions about their own and their children's well-being. Revised gender and equity guidelines could specifically mention this consideration and note that mobilization and IEC strategies may need to be reviewed to reflect this reality.

On the whole, disadvantaged groups are either not described or the descriptions are so general as to be inadequate to guide development of, or fine-tuning of, appropriate strategies. Examples of issues identified include early marriage (care-givers/adolescents), refugees/IDPs, out-of-school girls, isolated communities, undocumented urban slum dwellers, street-dwellers, migrants, ethnic/religious minorities, nomadic pastoralists. Without a description (who are they, where are they, how many?), it is very difficult to assess whether the strategies proposed to reach them are appropriate.

Recommendations

1. GAVI to consider revising its proposal templates to ask countries to provide, where available, vaccine coverage information comparing:

    - Urban/rural
    - The richest/poorest quintiles
    - The provinces/districts with highest and lowest coverage
    - Caretakers' (Mothers') education from lowest and highest levels
    - Gender Inequality Index

2. GAVI to ask how the proposed activity will address the gaps identified in coverage and how this will be reflected in the M&E framework. (Note: the guidelines must match the forms). GAVI may consider developing a model case study on gender and equity and health issues to

[4] Greater than 20% : Afghanistan, Burkina Faso, Côte d'Ivoire, Eritrea, Ethiopia, Guinea, Liberia, Malawi, Mauritania, Mozambique, Papua New Guinea, Senegal, Sierra Leone, Solomon Islands, Togo, Yemen

guide countries. This case study could demonstrate what equitable access to health services means in different contexts and draw on lessons learned by GAVI and Alliance partners.

3. GAVI to consider the approval of the revised gender policy and the roll out of GAMR as opportunities to provide training for CROs on gender and equity in health programming so that they can engage in dialogue and assist countries to reflect these considerations in their programming and proposals.
4. GAVI to consider adding extra time at regional meetings to address the capacity strengthening of country level EPI managers on gender and equity in health programming. Such meetings should be focused on practical measures to reach equity in immunization, that is, how to analyse and plan to help ensure that gender and equity barriers do not prevent the fullest possible immunization coverage.

10. Fragile States

In the IRC of November 2013, proposals were considered from 6 of the 11 countries identified as fragile states and selected for support by a tailored approach in accordance with the GAVI Alliance Fragility and Immunization Policy, December 2012. Review of the proposals and their supporting documents confirm the characterization of weak health systems with sub-optimal immunization coverage, limited CSO involvement, data quality issues, challenged governance and low government expenditures for health underpinning these states.

Table 4 GAVI fragile states with tailored approach reviewed in 2013 IRC

Country (% expenditure on health)	Humanitarian emergency	Failed state index	Low vaccine coverage	Resubmission/ no submission of proposals	Large numbers of unimmunized children
Afghanistan (9.6%)	+	+	+	-	+
Chad (4.3%)	-	+	+	-	+
Cote d'Ivoire (6.8%)	-	+	+	-	+
Guinea (6%)	-	+	+	-	+
Somalia (2.3%)	+	+	+	-	+
South Sudan (2.5%)	+	+	+	-	+

Issue 1 Designation Review

With conflict and population dislocations continuing in many regions of the developing world, the requirement for an ongoing revision of the list of countries needing tailored approaches is evident. The absence of Yemen and Mali from the list of those countries currently designated by GAVI as fragile is noteworthy.

Issue 2 More Intense Engagement and Annual Review of Programs

The portfolio of support for fragile states would seem to need more intense engagement by GAVI. For example, the current arrangement of one CRO handling up to 4 of these countries needs review. It is recommended that no more than 2 fragile states be allocated to a single CRO to strengthen proposal development and fund utilization and monitoring. Consideration should be given by GAVI to the long-term in-country placement of technical/management assistance as an integral part of HSS funding in fragile states to facilitate planning and implementation. It is proposed that the tailored approach be extended to a tailored M&E framework for fragile states. Such frameworks would have annual targets evaluated by annual in-country reviews, the results of which would help the portfolio performance and guide future investments.

Issue 3 Adapted Application Guidelines for Fragile States

The GAVI Alliance Fragility and Immunization Policy should be extended to a simple-to-follow guidelines adapted for fragile states by incorporating elements from the IRC recommendations. The guidelines would emphasize how to best address and manage the (even more) complex effectiveness and efficiency issues of grant implementation in fragile states. This should be based on lessons learned and innovative approaches honed by GAVI and other development partners in their work in fragile states with an emphasis on systems and institutional stability. Countries for example, could benefit from raised awareness about the benefits of assured continuity of program leadership and support for independent surveys of immunization coverage. Six of the 11 countries budgeted less than 5% of government expenditures for health and GAVI support may be linked to achieving allocations above that level within 3 to 4 years of the grant, to encourage financial sustainability.

Issue 4 New Strategies

With its 'lessons learned' approach, the guidelines should offer suggestions for introducing new strategies for enhancing vaccination demand and supply and improving data quality. Meaningful engagement of the program with CSOs should be mandated and advice offered on working with non-state actors that are influential in fragile states. Attention should be paid to gender and equity issues, and to issues of insecurity that are preventing access to vaccines for minority or hard to reach groups. Female health worker schemes may be encouraged where these are not in operation. As an example, community health workers could be "rewarded" for bringing mother and child for the child's DPT3 vaccination and health professionals be given a subsidy for going out to hard-to-reach areas. The objective of improved health worker performance in fragile states would be facilitated by incentives or top-up salaries coordinated with other development partners and through the establishment of a for-the-purpose multi-donor-trust-fund-like arrangement.

Issue 5 Management of Greater Fiduciary Risk and Inventory System

Financial management of grants assumes particular import in fragile states in the context of greater fiduciary risk and the states should be guided to be in compliance of GAVI TAP policies. Direct budget support is preferred by many countries and if use of the country system is to be made, additional financial safeguards such as an accounting firm verifying government expenditures as disbursement are made, should be instituted for fragile states. Inventory systems for capital expenditures (including spares) made out of GAVI funds need to be established in the countries with tracking of all equipment, vehicles etc. This would allow any new request for support to avoid duplication of procurements and rationalization of equipment budgets.

Recommendations

1. The designation of fragile states by GAVI needs to be a dynamic process in light of changing realities of conflict and emergencies.
2. CRO to be responsible for no more than 2 fragile states and be complemented with in-country HSS TA.
3. Guidelines for fragile states to be developed and new strategies offered from the list.
4. Tailored M&E framework with annual program review including agreed target assessment.
5. Inventory systems of capital expenditures and prioritized management of fiduciary risk.

11. HPV Vaccine Issues

This was the fourth consideration of new proposals for the GAVI supported HPV programs. In contrast to the initial review where all HPV proposals were consolidated into one review, in this round of submissions, HPV was integrated into other proposal reviews. Many countries submitted an HPV application along with other NVS or HSS applications. The IRC considered 10 HPV Demonstration (Demo) proposals, and two country proposals for national introduction. All 12 were approved with clarifications. The applications were much stronger this year, as evidenced by no recommendations to resubmit. The Secretariat is to be commended for the technical assistance offered to countries in the application process. The IRC wishes to bring forward a few issues that may further strengthen planning and success of the HPV proposals.

Issue 1 Vaccine Delivery

Most countries are continuing to choose school based delivery as the primary delivery strategy, either picking an age to vaccinate in school, (such as 10 year olds) or picking a grade, (such as primary year 4). Few proposals discussed private schools in the district, or how they would be involved. "Out of school" strategies typically mention fixed and mobile delivery strategies. A major weakness in proposals is identification and description of the out of school girls, and how these girls would be reached. The IRC recommends that each country undergo a mapping exercise to learn the location of these out of school girls (are they working in homes as maids? in the market? nomads? etc.). Senegal is an example of a country that described a mapping exercise, using female elders in villages to locate all girls, regardless of school enrolment. Accurate knowledge of these girls' locations and their situations is necessary to design situation appropriate vaccination strategies, which will facilitate good coverage. Additionally, it will further 'learning by doing', and draw attention to a particularly vulnerable group of girls who may experience unequal access to vaccination.

Recommendation

To encourage this, the IRC recommends the budget contain a line item for this mapping exercise. Additionally, GAVI may want to include a cut off percentage for out of school girls, above where more extensive details on the situation and immunization plan for the out of school girls will be required.

This year, one country (Solomon Islands) proposed a campaign approach targeting 9-12 year olds all together. This was due to the island geography and dispersal of the population. Transportation was

one of the hardest challenges, so this country proposed vaccinating four age cohorts together. The IRC felt this was an excellent opportunity to "learn by doing".

If the countries picked more than one district for the demonstration project, they were encouraged to pick districts sufficiently unique to broaden the 'lessons learned'. Most countries took advantage of this, though some countries (such as Liberia) picked geographically contiguous districts with similar demographics and some countries (e.g. Gambia) only chose one district. Also, despite picking different districts, the delivery strategies for the two districts frequently were the same.

Recommendations

The IRC recommends continued encouragement to vary districts and vary delivery strategies according to the local district context.

Recommendation

Some countries are still confused about dose spacing. Placing a box in the application form with the appropriate dose spacing, and asking countries to justify variance from the recommended dose spacing would be useful.

No countries commented on consent issues for vaccinating 9-13 year olds. Countries should be encouraged to consider issues of parental permission or/and assent of the preadolescent girls, as appropriate in their cultural context.

The HPV demonstration projects mandate coverage assessments but also encourage some type of assessment of acceptance by girls, parents and communities. Assessment of acceptability was rarely referred to in the applications. No countries mentioned a need for ethics consideration.

Recommendation

The IRC recommends that countries should be reminded that evidence of application for ethics approval is necessary if a country determines that ethics review is required for operational research. Assessment of acceptance by girls, parents and communities should also be included.

Issue 2 Adolescent Health Intervention

The adolescent health intervention (AHI) component continues to create some confusion. The timeline with the first year being a 'desk assessment' of potential health interventions, and the goal for the second year to integrate the chosen AHI into vaccine delivery was commonly misunderstood. Few countries realized that, to be eligible for an additional $25,000 of funding, it is necessary to conduct joint delivery of interventions. These funds were often included in the budget without specific mention of plans to do joint delivery. Because most countries chose a target population of girls around 10 years old, when countries named potential health interventions, primary care interventions or screening (such as vision screening) were common. Some countries intended to take

advantage of already planned activities for this age group (such as tetanus booster or deworming), and this could be further encouraged.

Recommendation

The IRC recommends that research can be conducted on the types and successes of the AHI countries implement (which will be dictated in part by the age of the primary target group) to further 'learn by doing'.

Issue 3 Gender and Equity Issues

More attention could be paid to male engagement in the HPV projects, both in the proposal instructions and application. Most applications lacked specific plans for sensitization and education efforts that target the male gatekeepers in the community, whether they be the fathers, or religious leaders, or elders. Additionally, plans to educate boys to explain that they are secondary beneficiaries of the HPV vaccine were rarely mentioned. Several countries (Senegal being one) mentioned inclusion of the males in the AHI, and this gender inclusive approach to the AHI should be encouraged. Equity issues for out-of-school girls were mentioned above. Guidelines which include links to resources on very young adolescents, and strengthening technical support for proposal development to address gender equality and equity issues in HPV vaccination may be desirable, especially for fragile states.

A summary assessment of gender and equity for each of the countries in presented in Annex 3.

Recommendation

Lastly, this IRC continues to feel strongly that GAVI, Partners, and countries could broadly benefit from accumulating and disseminating the lessons learned from these innovative demonstration projects in peer review literature.

12. Campaign Issues

Issue 1 Impact of campaigns on routine immunization
Vaccine campaigns are particularly resource intensive and may disrupt routine immunization services and other services of the health system. While campaigns have the potential to strengthen health systems, recent studies have shown that this does not happen automatically, and the risk of negative effects is especially high in countries with weak health systems. When substantial resources are allocated to frequent campaigns, the entire health system may be undermined. GAVI funds should support the strengthening of routine immunization programs, which would eventually reduce the need for campaigns.

Issue 2 Waste management
Campaigns, especially those that cover wide age groups, generate an enormous amount of biomedical waste. Applicants to GAVI for funds to conduct campaigns should demonstrate that they have taken

into account the amount of waste they will generate and their plans for dealing with such wastes with minimal adverse effects on the environment, and minimum risks for health personnel.

Issue 3 Cold chain
Storage capacity needs during campaigns are different in type and scope from those during routine operations. Mobilization of increased volume of vaccines and supplies requires good micro planning and management at all levels of the health system. The EVM does not usually assess the cold chain capacity for such a purpose. MenA vaccine is sufficiently heat-tolerant that it can be distributed to the periphery in a controlled temperature environment.

Issue 4 AEFI surveillance & crisis communication
Campaigns require a well-designed IEC strategy. The general population and health workers should have accurate information well in advance of the campaign. Anti-vaccination groups may take advantage of gaps in communication or provision of information to stakeholders.
Large campaigns are increasingly being done in countries with limited capacity for surveillance of adverse events following immunization. There is a risk of perceived adverse events occurring and of rumours being spread; these could undermine the whole immunization program if not managed appropriately. Likewise, there may be actual vaccine-related adverse events which should be monitored to inform appropriate responses. Countries should be required to demonstrate the presence of an AEFI committee with crisis management capacity before these large vaccine campaigns are conducted.

Issue 5 Post-campaign coverage surveys
The idea of a campaign is to reach as many people as possible, and a country should be able to accurately determine within a short time the coverage reached by the campaign. Post-campaign assessment of coverage and AEFI requires detailed planning, including budgeting of needed resources, as well as a methodologically sound design to be able to determine coverage estimates. A post-campaign survey is mandated by GAVI, but it is unclear who is willing to take the responsibility of funding this – the Government, GAVI, or UN agencies? The budget template for support of campaigns should include an explicit line item for "post-campaign survey".

When a country is applying for a vaccination campaign, it would be useful for the IRC to know whether there have been previous comparable campaigns in the country and if so, how the performance of these was in terms of achieved coverage. Report should request info on coverage in past 3 campaigns.

Issue 6 Campaign target population estimates
The MR and the MenA campaigns target wider age groups than the campaigns GAVI countries are used to undertaking, which usually target children less than five years. To reach adolescents and adults, both male and female, strategies other than those used in polio and measles vaccination campaigns are likely to be necessary, such as school-based delivery. In this round of applications, countries did not clearly explain the planned strategies for reaching older age groups and they did not seem to have thought carefully about who the people they aim to reach really are.

It may be challenging to generate reliable estimates of the number of people in the population targeted by the campaign. It would be ideal if a WHO pre-assessment could validate the estimate of the target population. This could be done, for example, by citing data from UNPD (UNPD estimates of

population by 5 year age groups for each country for 2010 are available from the following website: http://esa.un.org/unpd/wpp/unpp/panel_indicators.htm).

It would help the IRC as well as the authors of applications for GAVI support, if there were some brief guidelines for GAVI support of MenA campaigns as well as WHO risk assessments supporting the campaign.

There is pressure to approve campaigns in the context of broader disease control strategies (especially for measles control and elimination). For this reason, more real-time monitoring of campaigns is required. In some cases, a "fast track" IRC mechanism may be required for more rapid re-assessment of conditional approvals.

Recommendations

The IRC recommends the following:

1. A summary of the results of a cold chain inventory or inventory update conducted within 12 months prior to the submission of the application should be provided with the application.
2. An up to date version of the WHO published EPI_Log Forecasting Tool which provides a cold chain gap analysis at sub-national stores should be provided with the application.
3. A vaccine management improvement plan, clearly indicating the status of improvements recommended and endorsed by the ICC is provided.
4. Increase investment in development of appropriate waste management solutions for GAVI countries.
5. Require countries to allocate funds for AEFI surveillance and crisis communication when planning and budgeting for campaigns.
6. Include an explicit line item for "post-campaign survey" in the budget template for support of campaigns that would address gender and other equity determinants.
7. Request that countries applying for campaign provide information on coverage in past 3 campaigns.

13. Monitoring and Evaluation

Issues

The IRC reviewed the M&E requirements within all 3 funding windows and looked at proposals' compliance with these requirements.

For HSS, South Sudan is noted as a good practice example of compliance with new M&E guidelines:

- M&E framework matches objectives, includes intermediate results and required GAVI indicators. All impact and outcome indicators and some intermediate indicators are similar to those in the M&E indicator framework of the HSDP, and HSS activities will use national processes and sources of data to measure (10 key) indicators. Data sources are described in detail and include national HMIS, integrated disease surveillance system, health facility mapping, household surveys and planned EPI program reviews, all of which are intended to be strengthened through the grant.
- As part of tracking the variance between administrative and survey data, an EPI coverage survey will be conducted as part of the mid-term evaluation (2016) and end of project evaluation (2018). This will bridge the gap between planned SSHS surveys to be conducted in 2015 and 2020.

- Activities for strengthening M & E include review of data collection tools; institutionalizing DQA; quarterly supervision by EPI focal points and M&E officers; training and mentoring managers; ensuring quarterly production of reports disaggregated by gender and equity considerations; bi-annual EPI reviews; annual national health sector reviews-linking EPI performance with other services critical for child survival; and midterm and end of grant evaluations.

Strengths noted throughout HSS proposals:

- Inclusion of mandatory GAVI indicators (South Sudan, Somalia, DPR Korea, Uganda, Uzbekistan, Benin, Yemen) and in some cases additional equity indicators (e.g. Uganda proposes to use a socio-economic equity indicator for vaccines coverage from the Uganda DHS 2011 as a baseline and to measure progress based on results of the UDHS 2015).
- Clear linkages from objectives to improved immunization outcomes, (DPR Korea, Yemen).
- Outcome and/or impact indicators are aligned with national indicators and data sources (South Sudan, Uganda, DPR Korea).
- Evaluations and studies are included (Kyrgyzstan proposes a study to follow up baseline for immunization among urban migrants and hard to reach areas, conducted mid-term and end term.)
- Strong focus on strengthening M&E (Lesotho, South Sudan).

Weaknesses noted in HSS proposals:

- M&E framework intermediate indicators not clearly aligned with outcome indicators (DPR Korea, Kyrgyzstan, Uzbekistan - confusing mix of qualitative and quantitative indicators)
- Absence of baseline data in M&E Frameworks (Somalia - mitigated by including collection of baseline data for some indicators in reprogrammed activities)
- Limited data strengthening activities (Uganda)
- Intermediate results included in the results chain but not the M&E framework (Uzbekistan).
- Although country has a national health M&E framework, proposal does not integrate HSS M&E with this framework (Uzbekistan)
- Mandatory gender and equity indicators not included in results chain (Uzbekistan)
- Intermediate indicators included in results chain but not M&E framework (Yemen)
- No evidence of plans to analyze data at sub national level (all)

HSS M & E Recommendations

1. GAVI and partners intensify technical support for weak areas noted above prior to proposal submission.
2. GAVI clarify in HSS guidelines whether it wants countries to demonstrate alignment with national health indicators specifically for the 6 mandatory indicators or more broadly.

HPV M & E Issues

Applicants are instructed to evaluate for coverage achieved, acceptability in the community, feasibility of implementation, and cost of delivery. Countries are required to lead the evaluation, identify researchers or evaluators to carry it out and include WHO, UNICEF, or other international partners as appropriate and also to conduct a feasibility assessment for integrating one or more adolescent health or SRH interventions with delivery of HPV vaccine to the target age group.

Of 12 countries that applied for HPV demonstration program funds, all addressed the requirement to evaluate for achieved coverage. Fewer countries described plans to evaluate feasibility of implementation and acceptability of vaccine in the community. Assessments for integrating adolescent health and SRH interventions were not mentioned in all proposals. Most countries did not clearly identify researchers or evaluators to carry out evaluations. Inclusion and roles of in country partners such as WHO, UNICEF, or other international partners were not always adequately described in proposals. Overall, evaluation strategies were not clearly developed in accordance with guidelines. However, Cameroon stands out with a strongly developed proposal with detailed strategies for campaign implementation and evaluation and inclusion of operational research.

HPV Recommendation

3. Monitoring and evaluation related Annexes B-D are clear and detailed, however IRC recommends that HPV application form also include a budget and work-plan template that reflects unit cost, total level of support to be provided, and delineation of activities by partner to facilitate monitoring.

NVS M & E Issues

Application guidelines require countries to assess coverage and data quality through routine monitoring systems and periodic independent surveys and surveillance or vaccine effectiveness data, report on progress against targets and coverage achieved, as well as monitor vaccine stocks and waste management, use of funds and vaccine procurement. Countries receiving cash must report on doses procured and delivered and cost savings.

Of 19 proposals reviewed for NVS, nearly all proposed surveys to assess the level of coverage achieved. Data monitoring plans were often not clearly described (e.g. "Monitoring of rotavirus vaccine will be incorporated into monitoring system of routine coverage" – Tajikistan). Some proposals did address plans to track progress against targets, management of vaccine stocks and wastage, quarterly reporting on use of funds, and evidence of vaccine procurement in compliance with the co-financing agreement. Kyrgyzstan provided clear and linked work plan, budget and indicators and an in-depth analysis of previous experience and lessons learned.

Routine monitoring under the new GAMR system will be enhanced by new tools, in line with national M&E frameworks, which may include scorecards to track a set of standard indicators across all grants, with possible additional activities based on a country's risk or impact profile, as well as more in-depth risk assessments and actions plans to be undertaken quarterly. Monitoring data will include progress against targets, management of vaccine stocks and wastage, use of funds on a quarterly basis, and evidence of vaccine procurement in compliance with the co-financing agreement. In addition, countries who receive cash in lieu of vaccines and injection safety supplies will submit monitoring reports on number and value of doses procured, any savings made, and number of doses delivered.

NVS M & E Recommendation

4. While tools and templates enhance capacity to develop solid monitoring and evaluation plans, technical support is still required as countries adapt to new guidance. Countries

should be asked to better describe monitoring and supervision systems in place for vaccine introduction.

Broader recommendation

5. The new GAMR process needs to clearly define how all reprogrammed/renewal proposal and annual report technical details previously monitored by the IRC will be taken up by the Secretariat or Alliance partners, as well as in-country technical support monitoring and evaluation activities. The IRC recommends that GAVI consider testing the new approach in at least one country prior to its global roll out in 2014.

14. Summary of Recommended changes to GAVI NVS or HSS Guidelines

The following set of guidelines was provided to HSS and NVS reviewers in the IRC of November 2013.

1. Health System Strengthening Guidelines
2. New Vaccine Introduction Guidelines
3. Measles Rubella Campaign Guidelines
4. HPV Demonstration Guidelines

The NVS guidelines provided varying level of details on specific vaccine introductions including measles second dose, and meningitis A campaign guidelines. In general most of the guidelines were considered fit for the purpose of evaluation of proposals, but various gaps have been identified by reviewers which include the following:

1. *Meningitis A Campaigns:* Absence of detailed guidelines on Meningitis A campaigns. Given the scale of the program in terms of both finance and population coverage (age groups 1-29), reviewers considered that such investments should be guided by specific guidelines. The attached annex provides details on the main issues and recommendations, but the main points are that there is a) lack of specificity on management of surge capacity for vaccine storage and (b) absence of safety surveillance minimum standards.
2. *NVS Guidelines:* Absence of adequate reference in NVS guidelines to cold chain assessments and safety surveillance. In this round of proposals, there has been heightened awareness by reviewers of issues relating to safety surveillance and to cold chain capacity. (a) In the NVS guidelines, there is no reference to safety surveillance minimum standards, which is of some concern to reviewers, given the increasing complexity of vaccine programs and implementation of large population campaigns. (b) Reviewers often found that lack of adequate evidence on existing capacity to manage expanded volume of vaccines, whether for new introductions or of campaigns. The guidelines may need to be more explicit regarding up to date cold chain status (including more recent updates of improvement plans). (c) In relation to campaigns and HPV proposals, at times it was not evident that there was adequate documentary evidence for how the target population was arrived at, which is of concern particularly in relation to the large scale campaigns. (d)At times it was not clear on the post evaluation and coverage survey methodology to be used for assessing the quality and coverage of campaigns. An addendum to the guidelines for support of these and other vaccination campaigns would provide guidance on the sampling methods to be used as well as some guidance on costing of such a survey.

Main Recommendations
It is recommended that GAVI NVS application guidelines be reviewed / revised in the following areas:

1. **NVS**

The NVS guidelines should be updated to ensure the following:

(a) Minimum standards for safety surveillance
(b) Inclusion of a cold chain gap analysis for the period of NVS support (using the WHO EPI_ Log_ Forecasting Tool) , and in cases where substantial funds are requested to bridge the gap, a rehabilitation plan and budget derived from a recent equipment inventory or inventory update and cold chain assessment.
(c) Strategy for management of surge capacity of cold chain systems for campaigns
(d) Specific Meningitis A guidelines (refer to Annex for details)
(e) A specific section in the application template should be included on the post campaign coverage survey, with information in the guidelines on minimum standards for design of such surveys. The guidelines for support of MR campaigns should ask countries to plan and budget for a post-campaign coverage survey.
(f) The guidelines and the application template for support of MR campaigns should adopt a simpler and more effective approach to assuring future financing of routine rubella immunization. This could be achieved by modifying the application template so that it automatically calculates and displays the future additional cost of routine rubella immunization so that the government and ICC can review and approve of this increase in expenditure.
(g) The guidelines and the application template for support of MSD should request countries to provide information on the same surveillance indicators featured in the guidelines and template for support of MR campaigns (i.e. the reporting rate and the lab confirmation rate). As several countries submitted data this year that suggest a weak understanding of these indicators, GAVI should review and consider changes to the explanations of these indicators that are included in the guidelines and the application template.

For Gender and Equity, HSS and HPV please refer to 5, 8, and 13 for recommended guideline changes.

15. Other Issues

Other Issue 1 - Private Sector and Immunization

In various proposals in this round, the issue of private sector immunization and the GAVI investment has been raised.

In the Burundi HPV demonstration project, it was noticed that there was a high proportion of health facilities in one district that were classified as private. Reviewers therefore sought clarification on how these private health facilities will be included in the project. Similarly, in the Mali HPV demonstration project, clarification was sought how both the private and education private sector would be involved in the demonstration project.

In many GAVI eligible countries, the private sector is making a contribution to immunization through private sector delivery systems. While the private sector makes a contribution to immunization

because it vaccinates a proportion of children (depending on each country), it does not always report the number and information (age, sex, etc.) of the children vaccinated and therefore information on coverage estimates, AEFI, and vaccine preventable disease cases can be lost. There needs to be very good coordination between private providers and EPI, in such a way that EPI can take advantage of the capacity of private sector for immunization, and ensure quality and safety in the private sector.

Other Issue 2 - Immunization and Urban Health

Various proposals have highlighted the challenges of managing migrations to urban areas. The main problem seems to be ensuring that these populations are registered and are included in population denominators, and most importantly have access to immunization and other health care services.

Although there is no specific recommendation on this issue for GAVI, the point is being made that in terms of the equity agenda, guideline development and monitoring attention should be focussed not only on remote rural or conflict areas, but also on the increasing populations of urban poor.

Other Issue 3 - Translation Recommendation

The IRC expressed concern about the review of applications and reports submitted in languages other than English. The quality of translation was deemed to be uneven and not all supporting documents were translated. However, in such cases where it was not possible to translate all documents, both reviewers assigned were francophone. Deficiencies in translation complicated the work of the reviewers and at times threatened the validity of their assessments. The IRC requests that at least one of the two reviewers be proficient in the language concerned (English, French, Spanish or Russian).

Other Issue 4 - IRC Report Publication Recommendation

It is recommended that, in support of transparency and dissemination of IRC findings, this report be published and **disseminated on the official GAVI website.**

Annex 1. Table 5 Key findings on Gender and Equity in proposals

Country/(vaccine)	CSO Rep on ICC Yes=1 N = 0	Sex disaggreg-ated data reported Yes= 1 No= 0 Plan to = P	Gender related barriers identified, analysed and addressed Yes= 1 No= 0		Equity related barriers identified, analysed and addressed Yes= 1 No= 0		HSS mandatory equity indicators included/linked to results chain intermediate outcomes? Yes=1 No = 0 N/A = Not applicable		Gender blind proposal Yes=1 No = 0	Comments
			Identified/ analysed	Addressed	Identified/ Analysed	Addressed	Included	Linked to intermediate outcomes		
HSS + HSS reprogramming										
Benin	1	0	0	0	0	0	1	0	1	• One mandatory indicator in M&E framework not in results chain • No explicit plan to disaggregate the data by G/E stratifiers
DPR Korea	0	P	0	0	1	1	1	0	1	• One indicator in M&E framework not in results chain • Equity related barriers identified but **not analysed** • **Explicit plan to disaggregate the data by G/E stratifiers**
Kyrgyzstan	0	0	0	0	1	1	1	1	1	• Equity related barriers identified but **not analysed** • One mandatory indicator in M&E framework not in results chain • No explicit plan to disaggregate the data by G/E stratifiers
Lesotho	1	0	0	0	1	1	N/A	N/A	1	• Equity related barriers identified but **not analysed** • M&E framework in old format without mandatory indicators
Madagascar	1	N/A	1	0	1	1	N/A	N/A	1	• Equity related barriers identified but **not analysed** • M&E framework in old format without mandatory indicators. This is a reprogramming.
Somalia	1	0	1	1	1	1	N/A	N/A	0	• 1 religious organization in ICC • Equity related barriers identified but **not analysed** • Lady health workers will be trained • M&E framework has indicators that could capture gains in G/E related outcomes if disaggregated appropriately.
South Sudan	1	1	0	0	1	1	1	0	0	• Equity related barriers identified but **not analysed** • Mandatory indicator in M&E framework not in results chain
Uganda	1	N/A	1	1	1	1	N/A	N/A	1	• Equity related barriers identified but **not analysed** • Info not mandatory for reprogramming request • M&E framework includes equity related indicator if appropriately disaggregated

Uzbekistan	0	0	0	0	1	1	1	0	1	• Equity related barriers identified but **not analysed** • Mandatory indicator in M&E framework not in results chain
Yemen	1	1	1	1	1	1	1	0	0	• Equity related barriers identified **but not analysed** • One mandatory indicator in M&E framework not in results chain • No explicit plan to disaggregate the data by G/E stratifiers

New and under-used vaccines

Country/(vaccine)	CSO Report on ICC Yes=1 N = 0	Sex disaggreg-ated data reported Yes= 1 No= 0 Plan to = P	Gender related barriers identified, analysed and addressed Yes= 1 No= 0		Equity related barriers identified, analysed and addressed Yes= 1 No= 0		HSS mandatory equity indicators included/linked to results chain intermediate outcomes? Yes=1 No = 0 N/A = Not applicable		Gender blind proposal Yes=1 No = 0	Comments
			Identified/ analysed	Addressed	Identified/ analysed	Addressed	Included	Linked to intermediate outcomes		
Afghanistan (SIA)	1	P	1	0	1	1	N/A	N/A	0	• Equity related barriers identified but **not analysed** • N/A: Info not obligatory for SIA proposals
Burkina Faso (MSD; MR camp; Rubella	1	0	0	0	0	0	N/A	N/A	0	• No gender or equity barriers identified
Cambodia (PCV)	0	1	0	0	1	1	N/A	N/A	0	• Starting in 2010 Cambodia was to issue gender specific immunization card with male and female growth charts. • Groups identified: migrants, remote rural areas, ethnic minorities, urban slum dwellers/squatters.
Chad (SIA)	0	0	0	0	1	1	N/A	N/A	1	• Equity related barriers identified but **not analysed** • N/A: Info not obligatory for SIA proposals
Cote d'Ivoire (MenA)	1	0	0	0	1	1	N/A	N/A	1	• The proposal states no barriers to immunization, yet preliminary data from DHS (2011-2012) shows a 5% point (66.3% vs. 61.5%) discrepancy in male/female coverage rates.
Eritrea (PCV)	0	0	0	0	0	0	N/A	N/A	1	• No national census; no information on urban/rural, quintiles, etc. • No gender or equity barriers identified
Guinea (MenA)	1	P	0	0	0	0	N/A	N/A	1	• No gender or equity barriers identified • MenA campaign targets rural areas but IEC needs not well reflected
Kyrgyzstan (PCV)	0	0	0	0	1	1	N/A	N/A	1	• Equity related barriers identified but **not analysed**
Liberia (Rota)	1	0	0	0	0	0	N/A	N/A	0	• No information on urban/rural, quintiles, ethnic group, etc. • Refugees "are not accounted for in the projected population of the immunization program."
Malawi (MSD)	0	0	0	0	1	1	N/A	N/A	1	• Relatively even coverage of regions.

Mauritania (Rota, MenA Camp)	1	P	0	0	1	0	N/A	N/A	1	• 80,000 Malian refugees included in proposal
Mongolia (PCV)	1	0	0	0	1	1	N/A	N/A	1	• Equity issues identified: remoteness, internal migration, poverty • Graduating country
Mozambique (Rota, MSD)	0	1	1	1	1	1	N/A	N/A	0	• Some gender and equity issues seriously addressed: rural/urban, mothers' education, geographic areas (Zambezia) – • The country always tries to address gender imbalances whenever a new intervention is offered.
Myanmar (PCV, MR camp, Rubella)	0	0	0	0	0	0	N/A	N/A	1	• No recent data from a DHS, MICS, or on early marriage. • No gender or equity barriers identified
Papua New Guinea (MSD, MR camp, Rubella)	1	0	0	0	0	0	N/A	N/A	1	• No gender or equity barriers identified • It is highly likely that gender equity barriers need to be addressed.
Senegal (Rota, MSD)	0	0	0	e	0	0	N/A	N/A	1	• No gender or equity barriers identified • 43% Senegalese population is urbanized but no other information
Sierra Leone (MSD)	1	P	1	1	0	0	N/A	N/A	0	• Sierra Leone should be congratulated for identifying gender barriers affecting rates of immunization to be addressed
Solomon Islands (PCV, MR camp, (rubella)	0	0	0	0	1	0	N/A	N/A	0	• Equity related barriers identified but **not analysed**
South Sudan (Men A)	1	N/A	N/A	1	1	1	N/A	N/A	0	• Equity related barriers identified but **not analysed** • Info already provided in HSS proposal
Tajikistan (Rota)	0	0	0	0	0	0	N/A	N/A	1	• No gender or equity barriers identified • Significant immunization coverage differences evident in regard to region, and level of education of the mother.
Tanzania (MR camp, (rubella)	0	1	0	0	1	0	N/A	N/A	1	• No gender or equity barriers identified • Sex disaggregated data from 2010 DHS
Togo (Men A)	1	0	0	0	0	0	N/A	N/A	1	• No gender or equity barriers identified • Most recent DHS 1998
Uzbekistan (PCV)	0	0	0	0	1	1	N/A	N/A	1	• Equity related barriers identified but **not analysed**
Yemen (MR camp, (rubella)	1	1	1	N/A	1	1	N/A	N/A	0	• Equity related barriers identified but **not analysed** • Info already provided in HSS proposal

Composite tables

HSS/HSS reprogramming:

		Yes (%)	Comments
1.	CSO Representation on ICC	70	
2.	Sex disaggregated data reported [1]	20	Source of data: periodic & other surveys.
3.	Gender related barriers identified [2]	40	Identified but not analyzed
4.	Gender related barriers addressed	20	Only 2 countries identified & had specific strategies to address e.g. Somalia
5.	Equity related barriers identified, analysed	90	All identified but did not analyze
6.	Equity related barriers addressed [3]	90	Good example of non-generic actions -Yemen
7.	HSS mandatory equity indicators included [4]	60	
8.	HSS mandatory equity indicators linked to results chain intermediate outcomes?	10	Most did not appropriately reflect in results chain
9.	Overall Gender-blind [5]	70	

[1] 1 country has plans; 2 are reprogramming using old format
[2] No analysis of subjects in a way to drive meaningful programming and measurement
[3] Activities described were mostly generic
[4] n = 6 because using old format or had other equity related indicators
[5] Gender blind =Ignores gender norms, roles and relations, very often reinforces gender-based discrimination; ignores differences in opportunities and resource allocation for women and men; often based on principles of being "fair" by treating everyone the same (WHO 2011 (http://www.who.int/gender/documents/health_managers_guide/en/index.html).

2. New and under-used vaccines:

		Yes (%)
1.	CSO Representation on ICC	45
2.	Sex disaggregated data reported [1]	18
3.	Gender related barriers identified [1]	14
4.	Gender related barriers addressed	14
5.	Equity related barriers identified, analysed	55
6.	Equity related barriers addressed	41
7.	HSS mandatory equity indicators included [1]	18
8.	HSS mandatory equity indicators linked to results chain intermediate outcomes [1]	18
9.	Overall Gender-blind [2]	64

[1] N/A Info not obligatory for type of proposals

[2] Gender blind =Ignores gender norms, roles and relations, very often reinforces gender-based discrimination; ignores differences in opportunities and resource allocation for women and men; often based on principles of being "fair" by treating everyone the same (WHO 2011).

Annex 2. Table 6 HPV Country-Specific Summary, Nov, 2013 IRC

Country	Main strategy	Target pop	Out-of-school girls
Benin	Mixed (Stationary schools, health facility, community & Outreach – schools, religious institutions, other)	9 y.0	9 yo (health fac, religious, oth)
Burundi	School	Grade 3	10 yo (health fac)
Cameroun (resub)	School	Grade 6	10 y.o. (health fac, mobile, outreach)
Cote d'Ivoire	Mixed (schools, health facility, mobile outreach)	10 yo	10 yo (health fac; mobile)
Gambia	School	Grade 3	9 yo (health fac)
Liberia	Campaign	10 yo	Campaign (fixed and mobile)
Mali	School	10 yo	10 yo (health fac)
Senegal	School	9 yo	9 yo (fixed and mobile)
Solomon Is.	Campaign	9 yo	Campaign (fixed and mobile)
Togo	Mixed (health fac; schools)	10 yo	10 yo (health fac; mobile)
Uganda (Re-sub)	School	Grade 4	10 y.o (health fac; outreach)
Uzbekistan	School	12 yo	Fixed

Annex 3. Table 7 HPV Gender and Equity Detailed Report

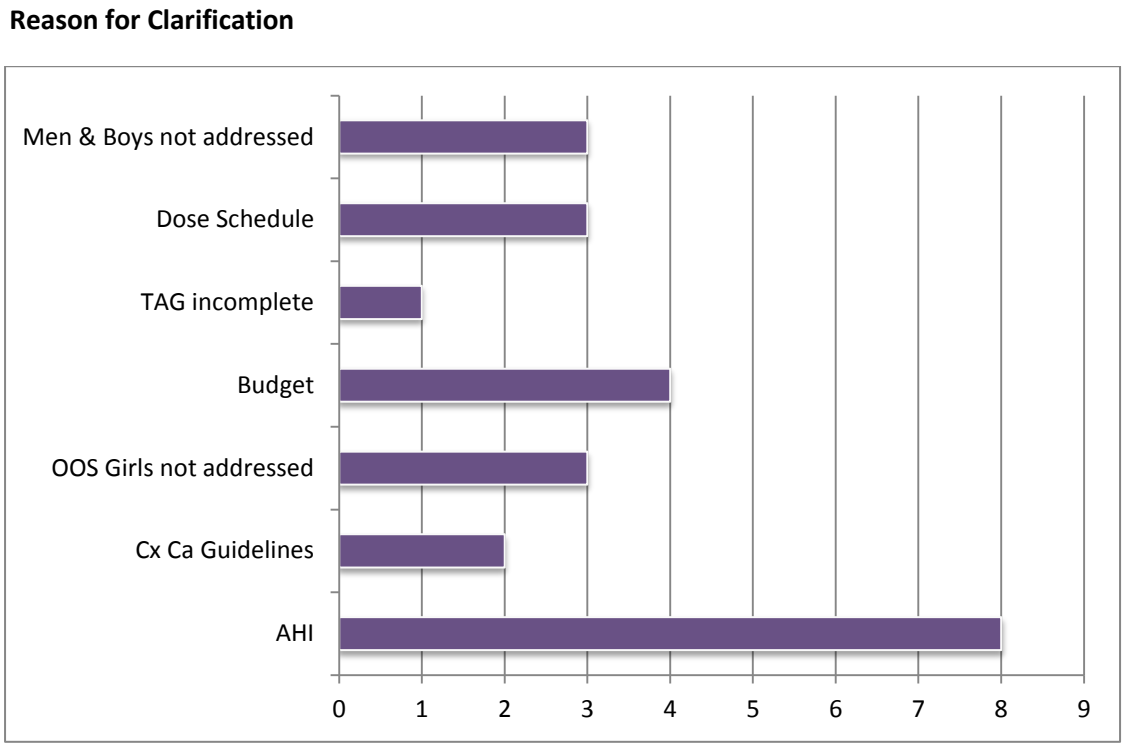
Country	% target group OOS	Services/ engagement of men/boys e.g. targeted info on HPV (Yes=1; No=0)	Reaching OOS girls ** (Yes=1; No=0)	Cultural/religious issues identified & addressed		CSO Rep on ICC/TAG (Yes=1; No=0)	Other issues	Notes
				(Yes =1; No= 0)	(Yes =1; No= 0)			
Bénin	36	1	1	1	1	1	+ Some level of details provided for reaching OOS girls + No information about OOS girls besides %	No Women's, youth groups in TAG
Burundi	9.2	0	1	1	1	1	+ No information about OOS girls besides % + Minimal detail provided for reaching OOS girls	No Women's, youth groups in TAG
Cameroon	11	0	1	1	1	1	+ No information about OOS girls besides % + Minimal detail provided for reaching OOS girls	No Women's, youth groups in TAG
Côte d'Ivoire	43	1	1	1	1	0	+ No information about OOS girls besides %: + 1st location, 52.7% of 10 year olds OOS; 2nd location 34%	No Women's, youth groups in TAG
Gambia	2	0	1	1	1	0	+ No information about OOS girls besides % + Minimal detail provided for reaching OOS girls	No Women's, youth groups in TAG
Liberia	30	0	1	1	0	1	+ No information about OOS girls besides % + Some level of details provided for reaching OOS girls + No mention of men and boys	No Women's, youth groups in TAG
Mali	45	0	1	1	1	0	+ No information about OOS girls besides % + Some level of details provided for reaching OOS girls + No information about OOS girls besides %	No Women's, youth groups in TAG

Senegal	25	0	1	1	1	1	+ No information about OOS girls besides % + A CSO (Fédération des Associations Féminines du Sénégal (FAFS) engaged in IEC + Target is 9 year olds + No mention of men and boys	No Women's, youth groups in TAG
Solomon Islands	35	0	1	1	1	1	+ No information about OOS girls besides % +Target is all girls aged 9-12 in selected districts which makes sense in country context + No mention of men and boys	
Togo	8	1	1	1	1	1	+ No information about OOS girls besides % + Target is 10 year olds + Will establish district management committees with CSO participation	

** For OOS girls, mostly generic description of community mobilization, etc. Scanty information and unconvincing strategies for delivering the vaccination.

OOS girls in target group %	0.1 - 59
Planning to engage boys e.g. targeting information to them	31
Plans to reach OOS girls % *	92
Cultural issues/barriers identified %	77
Plans to address cultural issues/barriers %	69
CSO represented on ICC/TAG %	46

Annex 4. Table 8 Reasons for Clarifications on HPV Proposals



Note: TAG = Technical Advisory Group, OOS = Out of School, AHI = Adolescent Health Interventions, Cx CA = Comprehensive Cancer Control Strategy

Annex 5. Table 9 Characteristics of HSS applications November 2013

Country	Type of application	Cash support requested (US $)	GAVI budget ceiling (US $)	Potential to strengthen the health system	HSS approach	Outcome	Comment
Benin	HSS new application	8,374,702	8,380,000	+++	Support to extend Results-Based Financing approaches in 2 health districts, in full alignment and partnership with other key development partners	Approval with Level 1 clarifications	69% of the budget is for Objective 1 on strengthening the coverage and quality health services and immunization in two particular health districts through the implementation of Results-Based Financing
DPR Korea	HSS new application	26,064,463	27,530,000	+	Strengthen HR, planning, surveillance & financial management with support for logistics, service delivery & demand generation.	Approval with Level 2 clarifications	The biggest component of the budget, 30%, is allocated to improvements in cold chain. Request support for a vertical grant management unit.
Ethiopia	HSS APR	75,000,000	N/A	+	GAVI's HSFP funds are put into Ethiopia's MDG Performance Fund (MDG PF).	Insufficient Information	Funds within the MDG PF are not earmarked therefore limiting accountability for HSFP funds
Kyrgyzstan	HSS new application	4,596,655	4,620,000	+	Apart from addressing infrastructural issues, the proposal emphasises the need to increase knowledge trust and demand for MCH services; it therefore allocates significant resources to IEC activities.	Approval with Level 1 clarifications	Most IEC activities funded with approximately 23% of the total budget focus on immunization, but a broader MCH perspective is intended.

Country	Type of application	Cash support requested (US $)	GAVI budget ceiling (US $)	Potential to strengthen the health system	HSS approach	Outcome	Comment
Lesotho	HSS new application	2,719,999.94	3,360,000	+++	Support for MCH	Approval with Level 1 clarifications	51% allocated to strengthen MCH interventions aimed at reaching hard to reach populations. Another 26 % will be utilized to improve health sector capacity through training health workers
Madagascar	HSS Reprogramming	Total US$ 11,216,500 (requested and approved USD 3,549,249.80)	N/A	++	HSS funds to be used for the employment and deployment of 65 paramedics to provide primary care services –including EPI	Approval with clarifications	Lack of data on contribution of HSS grants to date
Somalia	HSS Repro-gramming Request	Total approved grant: 11,544,180 Funds spent: 2,934,621 Funds remaining for reprogram-ming 8,610,880	N/A	+	HSS strategies integrate immunization activities into MCH platforms of service delivery that are also strengthened.	Approval with clarifications	Proposed activities operate in tandem with the GFATM HSS grant, each focusing on strengthening different levels of the health care system through interfaced strategies;
South Sudan	HSS New Application	29,400,000	29,400,000	+++	HSSC/ICC embedded in the Health Sector Working Group therefore it is linked to national health sector priorities	Approval	Strong participation of CSO - including Council of Churches, Islamic Council, South Sudan Red Cross etc.
Uganda	HSS Reprogramming	Total 19,241,700 (requested & approved 15,192,133)	N/A	+	Clear alignment of immunization services to national health sector development plans	Approval with clarifications	Narrow focus on immunization outcomes

Country	Type of application	Cash support requested (US $)	GAVI budget ceiling (US $)	Potential to strengthen the health system	HSS approach	Outcome	Comment
Uzbekistan	HSS new application	17,218,480	17,220,000	++	Mainly strengthening of the cold chain.	Approval with Level 1 clarifications	64% of total budget mostly for infrastructure, cold chain equipment and vehicles. Vertical implementation unit proposed.
Yemen	HSS new application	17,637,380	17,640,000	+++	Focus integrated into all three objectives: improved integrated delivery through capacity building, improvement of integrated HIS, and community empowerment and CSO participation in the provision of immunization and essential health services.	Approval with Level 1 clarifications	Based on the bottleneck analysis, this proposal allocates a large share of the total budget to capacity building.

Annex 6. Table 10 Summary of IRC Recommendations by Country

Country		Type of support							
		Rota	PCV	HPV Demo	Men A campaign	MR campaign	HSS	MSD	Measles SIA
1	Afghanistan								Clarifications
2	Benin			Clarifications			L1 Clarifications		
3	Burkina Faso					Clarifications		Approval	
4	Burundi			Clarifications					
5	Cambodia		Approval						
6	Cameroun			Clarifications					
7	Chad								Clarifications
8	Côte d'Ivoire			Clarifications	Clarifications				
9	Eritrea		Clarifications						
10	Gambia			Clarifications					
11	Guinea				Conditions				
12	Korea DPR						L2 Clarifications		
13	Kyrgyzstan		Approval				L1 Clarifications		
14	Lesotho						L1 Clarifications		
15	Liberia	Clarifications		Clarifications					
16	Madagascar						Clarifications - HSS Reprogram		
17	Malawi							Clarifications	
18	Mali			Clarifications					

Country		Type of support							
		Rota	PCV	HPV Demo	Men A campaign	MR campaign	HSS	MSD	Measles SIA
19	Mauritania	Clarifications			Clarifications				
20	Mongolia		Clarifications						
21	Mozambique	Clarifications						Clarifications	
22	Myanmar		Conditions			Conditions			
23	PNG					Conditions		Conditions	
24	Senegal	Clarifications		Clarifications				Clarifications	
25	Sierra Leone							Resubmission	
26	Solomon Islands		Clarifications	Clarifications		Clarifications			
27	Somalia						Clarifications - HSS Reprogram		
28	South Sudan				Conditions		Approval		
29	Tajikistan	Approval							
30	Tanzania					Clarifications			
31	Togo			Clarifications	Clarifications				
32	Uganda			Clarifications - HPV national			Clarifications - HSS Reprogram		
33	Uzbekistan		Clarifications	Clarifications - HPV national			L1 Clarifications		
34	Yemen					Clarifications	L1 Clarifications		

APRs:

Country		HSS	Penta – Scale up
1	Ethiopia	Insufficient information	
2	Indonesia		Clarifications

Annex 7. IRC Members

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4. Alejo Bejemino
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