GAVI INDEPENDENT REVIEW COMMITTEE REPORT
NEW PROPOSALS JUNE – JULY 2014

AUGUST 9, 2014

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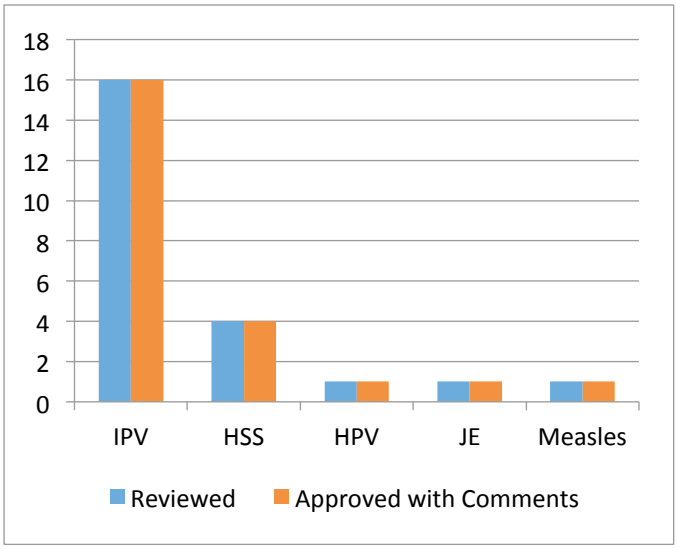
Acknowledgements

The IRC acknowledges the support of the GAVI Secretariat Monitoring and Evaluation section and the Country Responsible Officers (CROs) for their assistance in preparation of documentation, country briefings and for training / orientation support and for administrative and logistics support. Thanks is also expressed to GAVI Alliance partners WHO and UNICEF for briefings on polio eradication, vaccine procurement and supply issues.

Executive Summary

A meeting of the Independent Review Committee was undertaken between June 23rd and July 4th 2014 in Geneva. The purpose of the meeting was to assess proposals for introduction of Inactivated Polio Vaccine (IPV), new and underutilised vaccines such as Japanese Encephalitis (JE), Human Papillomavirus (HPV) and measles) and Health System Strengthening (HSS). The IRC reviewed 23 applications submitted by 19 GAVI eligible countries. All 23 applications were approved with comments. Reviewers remarked on the high quality of the applications which they attributed to the quality of technical support to countries, the introduction of waivers on certain conditions for IPV applications, and the experience of countries with preparation of GAVI proposals. Figure 1 summarises the number of proposals by funding window. The following section summarises the main themes in this IRC review.

Figure 1 Summary of Results IRC June July 2014



Critical Issues in this IRC Round

Decentralisation and Devolution: The common theme running through the HSS proposals was the attempt to sustain and improve immunisation services in a decentralisation or devolution context. The proposals from Honduras, DRC, Kenya and DRC illustrate the means by which HSS strategy is applied to adapt immunisation services to an evolving decentralisation and health reform context.

Gender and Equity and Conflict: There was significant discussion in this round on issues of gender and equity, prompted in large part by the presence of conflict in 8 countries. IRC reviewers noted that populations effected by conflict are either not mentioned in proposals ("invisible"), or strategies are not described as to how these populations will be reached. Equally, observation of the Gender Inequality Index and its links to immunisation inequities prompted significant discussion of the means by which the GAVI Alliance gender policy will be implemented. Finally, high immunisation coverage (>90%) in the context of very high maternal mortality in the same country settings (eg. >600/100,000 in Malawi) raised questions regarding the role of the GAVI Alliance in advocating for greater balance in national and international policy (between investments in CDC programmes and investments in Reproductive, maternal, Neonatal and Child Health (RMNCH). Although these are major strategic issues, the IRC did recommend some programmatic actions that the Alliance could take to make some contributions to wider global health efforts in this area (see section 3.6).

Governance Strategy: The main contextual trends observed in this review (decentralisation, system approaches and inequities) were found to have important implications for GAVI Alliance Governance strategy. Decentralisation, in conjunction with privatization, urbanization and increased complexity of the immunisation schedule (multiple vaccines and age groups), is changing the governance context at country level. Countries made frequent mention of adaptation of Immunisation Policy and in one case made reference to development of Vaccine Law (Honduras). Countries (particularly in relation to IPV) also made frequent mention of the roles of NRAs and NITAGs in licensing and in peer review of vaccine decision making. Although there is clearly a range of functionality of these institutions, policies and laws, there is clearly an evolving governance context associated with the roles of NITAGs and NRAs, as well as with the development of immunisation and health protection

policy and law. ICCs and the cMYP process has been the standard governance model to guide GAVI initiatives up until this time, but these recent developments would seem to suggest country governance is entering a new phase of development. For this reason, this IRC fully supports GAVI investment for the development of NRAs and NITAGs, and would support more careful consideration of the role of policy and law in sustaining the GAVI investment (see section 3.2 in relation to HPV vaccine). Finally, the presence of conflict in many GAVI eligible countries, and the reality of invisible or displaced populations, may require a critical rethink of the roles of CSOs in GAVI Alliance strategy in responding to the needs of these populations (see section 3.7). In particular, an important strategic and operational distinction needs to be made between a GAVI Government programme that is government led, and a country programme engaging both government and civil society representation. This led the IRC to conclude that there should be more detailed profiling of CSOs involved in the GAVI initiative, to ensure the needs and rights of vulnerable populations are adequately represented.

> *".....in relation to gender barriers to immunisation, are all types of CSOs qualified to work on this issue? …… Most of the time, inequities in health care provision are linked to legal rights or social protection. Are human-rights organizations involved in the EPI at country level to help lift some of the inequity bottlenecks to immunisation? Information provided by countries to describe the CSO work does not respond to these critical questions." See section 3.7*

System Approaches: Specialists reviewing the supply chain initiatives highlighted the challenge of evaluation of supply chain proposals in the context of a single window of support. The supply chain section (section 3.4) details recommendations and other strategies by which to improve the monitoring of supply chain performance in the context of multiple NVS introductions. Reviewers of HSS proposals highlighted the risks of sole investments in immunisation in the absence of strategic linkages to wider health sector initiatives, particularly in relation to HSS initiatives funded through other sources. This being the case, reviewers have recommended strategies for better integration of immunisation HSS with health sector strategy and other HSS development initiatives. Reviewers assessing the IPV introduction proposals in some cases still find it difficult to pinpoint how such introduction programmes cohere with introduction programmes for multiple VIG grants. This is critical for the IPV and NVS agenda, as countries endeavour to meet the managerial, communication, supply chain, waste management and resource mobilisation challenges of overlapping vaccine introductions and increasingly crowded immunisation schedules being implemented across a wider range of age groups (Measles, HPV). The consistency in these findings across funding windows and technical areas led the IRC to conclude that it would be better to assess the feasibility of proposals in the context of wider system or country programme perspectives, thereby minimizing the risk of duplications and fragmentation associated with a "window by window" approach.

Monitoring and Evaluation (M&E) Strategy: IRC reviewers commented on the detail with which countries described their immunisation safety systems. The IPV proposals also now discuss in more detail the performance of AFP surveillance. The first JE proposal was judged to be of high quality by reviewers, and in their view, sufficient surveillance and epidemiological evidence was provided to justify a vaccine introduction. There were concerns expressed however regarding the means by which the impact of this programme would be assessed, leading the IRC to recommend in future more details on surveillance system strengthening and impact assessment in future proposal rounds. Evaluation of HSS was still considered to be very light, with only 1 of 4 proposals providing an evaluation of the previous HSS grant (this is notwithstanding the fact that HSS is not a GAVI guideline requirement, and lessons learned are still documented). The lack of an in depth and rigorous HSS evaluation makes it more difficult to assess continuity in the HSS approach and restricts the capacity to develop a firm evidence base for ongoing HSS programmes. IRC reviewers did comment however

on the improved quality of the M&E frameworks and action plans, with clear links established between the HSS investment and immunisation outcomes.

Conclusion and Recommendations

The figure below summarises the main recommendations in this review. Each section highlights specific recommendations. The IRC commends countries and the GAVI Alliance for the quality of proposals in this round, and hopes that the following recommendations will enhance programme quality, particularly with regards to implementation of pro equity and systems approaches.

Selected Recommendations (Detailed Recommendations in Each Section)

IPV and Co Administration: Ensure that proposals and monitoring arrangements indicate clearly the proposals/guidelines for co-administration of vaccines at country level, as well as the communication and risk management strategies associated with the GPEI.

Systems Approach for Supply Chain: Cash based support for supply chain improvement and expansion should not be fragmented in multiple NVS and HSS windows but should be structured to enable system improvement with capacity to accommodate NVS introductions.

Health System Strengthening: GAVI and technical partners need to ensure that countries are supported to maximize opportunities for joint planning and synchronization of support using existing coordinating mechanisms and opportunities .e.g. country dialogues, PAD etc. Countries receiving multiple HSS grants must demonstrate beyond the guiding principles how these grants can be leveraged; and be clearly integrated across the different strategic plans and NHSP across the countries

Surveillance: Countries would benefit from detailed guidance on recommended JE surveillance and impact assessment activities, including national laboratory standards for confirmation of JE in the WHO guidance document

CSOs and GAVI Strategy: Given the presence of conflict and displaced populations in many GAVI eligible countries, review is required of the GAVI CSO strategy, with more attention required for (a) profiling of CSOs (b) opening of specific CSO windows of support to address the needs and rights of vulnerable or conflict effected populations

Governance: GAVI could consider if it and its partners have a role in the promotion of comprehensive health protection and promotion and immunisation policy or law, particularly in the context of decentralisation and immunisation across multiple age groups

Implementation of Pro Equity and Gender Policy: Provide input into development of global strategies for enhancing immunisation strategy and access in conflict settings: Health Worker Security; Negotiation strategy e.g. Corridors of Peace; Immunisation Delivery Strategy (campaign, mobile services, routine scheduling); internally Displaced Persons; Early warning systems; and Resource Mobilization in conflict settings. The IRC also recommends revision of the CRO checklists and GAVI application guidelines to better capture attention to gender and equity issues (SEE FIGURE 6)

HPV Vaccination: Countries are encouraged to conduct an assessment of IEC materials and acceptability of HPV vaccine prior to the initiation of vaccination.

1. Background

A meeting of the Independent Review Committee was undertaken between June 23rd and July 4th, 2014 in Geneva. The purpose of the meeting was to assess proposals for introduction of Inactivated Polio Vaccine (IPV), new and underutilised vaccines such as JEHPV and measles) and health system strengthening in 19 GAVI eligible countries. IRC reviewed 23 applications submitted by 19 GAVI eligible countries during the June/July meeting. Country applications included 16 IPV vaccine introductions, 4 HSS proposals and 1 introduction for each of the following vaccines: MSD, HPV Demo and JE. Only 3 countries did not apply for the new IPV vaccine support (Honduras, Kenya and Nepal)[1]. DRC and Madagascar applied for both IPV and HSS.

2. Methods

12 reviewers from a range of disciplines took part in the review (see Annex 3 for list of members). Background briefings were provided by WHO, UNICEF, GAVI (M& E, Policy & Performance and sections) and Country Responsible Officers of GAVI Secretariat. Two reviewers were assigned to each country, and a country report was generated for each submitted proposal. Four IRC members focussed on the cross cutting issues of cold chain and logistics and gender and equity. Proposals were assessed against application requirements as outlined in GAVI application guidelines, as well as taking into account the degree to which proposals meet the overall GAVI mission and strategic goals.[2] In addition to the individual country reports and recommendations, a global report was also developed focussing on main themes arising from the review. These theme areas are the main subject of this report.

3. Findings

3.1 IPV proposals

In this IRC round, there were 16 IPV proposals, of which all were approved with comments. In general, IRC reviewers commented this time on the generally high quality of the proposals. In particular, the quality of the introduction plans was considered to be high. The proposals provided more detailed communications plans, although countries are still presenting management and community concerns regarding vaccine co-administration. The issues of immunisation safety and supply chain were well addressed in most cases, although there were difficulties with assessment of supply chain readiness in some cases. In general, issues of gender and equity in immunisation were not well described in the proposals (discussed in section 3.6 for more detail).

Table 1 below summarises the funding allocations by country for vaccine Introduction Grants from the IPV application countries, indicating total budget of over $44 million for the grants.

Figure 2 following analyses VIG expenditures by cost category, illustrating that communication and social mobilisation was the most significant investment area for the VIG grants (45% of the total).

[1] Note: Nepal submitted an IPV proposal in the April 2014 IRC

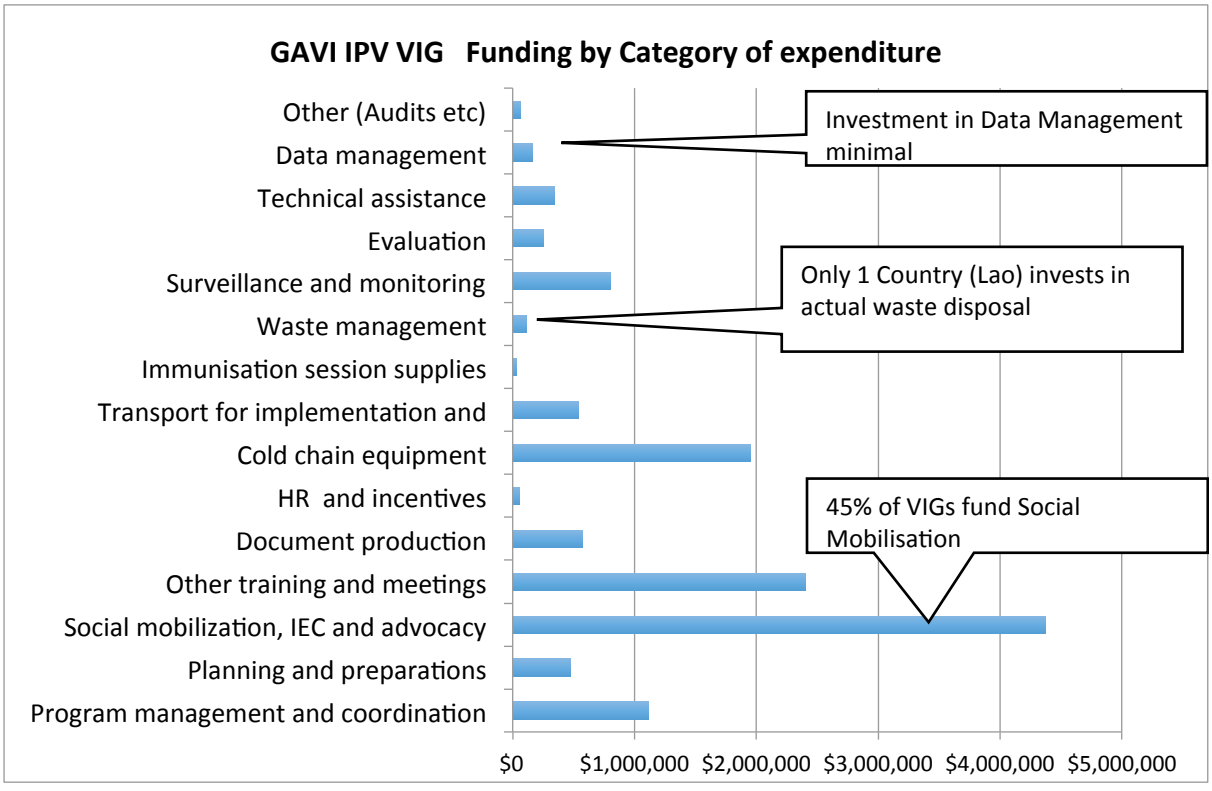
[2] a) The GAVI Alliance's **mission**: 'To save children's lives and protect people's health by increasing access to immunisation in poor countries' and

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

Table 1 Review of IPV requests during June-July review (based on mandatory Annex B and Annex D figures)

Country	Total Request US$	Financing of IPV Introduction Costs (US$)					Funding Gaps
		GAVI	Gov	WHO	UNICEF	Other	
Benin	473,304	310,000	32,019	91,557	39,728		0
Bhutan	132,166	100,000	4,500		27,666		0
Cameroon	749,542	681,500	36,458		49,479		17,895
DPRK	387,250	267,600	7,000	45,900	70,500		3,750
DRC	11,326,181	2,946,180	158,866	100,000	163,414	7,942,721	-15,000
Gambia	150,766	99,950	10,566	32,829	7,421		0
Guinea	401,845	401,845					0
Indonesia	16,590,444	3,787,626	9,824,531	35,000	150,000	2,793,287	0
Laos	546,858	312,553	138,080	42,600	53,625		0
Madagascar	978,110	709,360	3,750	145,000	120,000		0
Malawi	1,317,780	607,947	25,000				-684,833
Nepal	1,058,152	951,514	106,638				0
Pakistan	5,260,521	5,260,521					0
Senegal	1,260,429	451,414	653,629	6,567	148,819		0
Sudan	1,681,141	1,245,891	223,250	122,500	89,500		0
Tajikistan	123,345	99,225	24,120				0
Uganda	2,523,234	1,466,147	311,582	356,483	389,022		0
Totals	**44,961,068**	**19,699,273**	**11,559,989**	**978,436**	**1,309,174**	**10,736,008**	-678,188
%	**100%**	**44%**	**26%**	**2%**	**3%**	**24%**	

Figure 2 Analysis of VIG Costs per category



Issue: Links to Routine Immunisation and Programme Synergies

Compared to the previous round, there were by and large stronger links with routine immunisation strengthening. As with the previous round, it is at times difficult to pinpoint how various introduction grants (for PCV and MR for example) are synergized with the communication, service delivery, training and supervision strategies and activities of IPV introductions. There is also an financial risk with these proposals, as it is not always clear which source of funds support the IPV implementation plans (i.e. harmonization of IPV with other forms of cash based and vaccine support).

Recommendation

1. In future guideline developments, and in particular to ongoing GAVI monitoring arrangements, there should be increased focus on the following:
    - 1.1 How proposals link to routine immunisation strengthening, particularly with regard to immunisation equity issues
    - 1.2 How proposed investments in the proposals (such as cold chain, communication, training and supervision) are synergized with existing vaccine introduction grants and initiatives and health system strengthening programmes

Issue: Surveillance and Immunisation safety

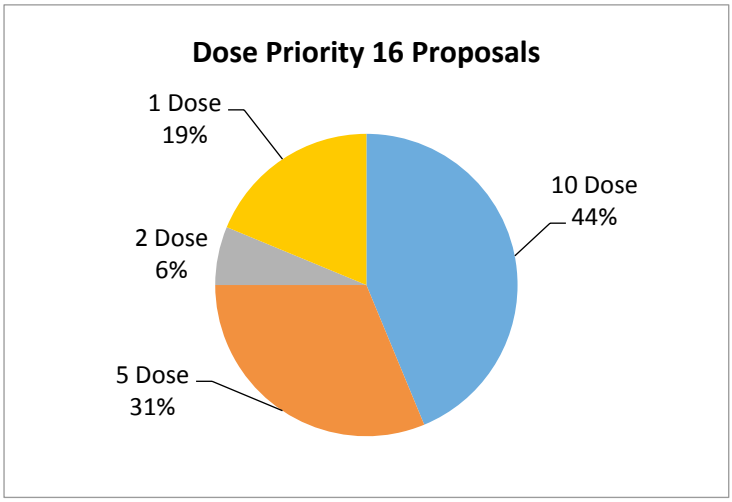
These issues are being increasingly well described since the last review, particularly immunisation safety systems. Most countries also report on the status of AFP surveillance systems.

Main Recommendations

1. The importance of immunisation and disease surveillance (including AFP surveillance) in identifying high risk populations, early detection of cases and to ensure prompt response to pockets of low coverage (including in areas of insecurity and for both remote and urban poor populations)
2. Ensure close monitoring of implementation of AEFI systems, including the monitoring of any adverse events occurring as the result of vaccine administration errors.

Issue: Supply, Policy, Licensing

Figure 3 Presentation priority for IPV Vaccine (16 countries)



A briefing by the UNICEF procurement Division indicated that the current supply situation is "fluid." For this reason, where appropriate, IRC reviewers recommended countries license all product presentations. 8 out of 16 countries report the presence of a functional NRA with the capacity to license vaccines. As is the case with Uganda, where licensing through an NRA can take up to 6 months, countries will use expedited systems of procurement of WHO prequalified vaccine through UNICEF procurement mechanisms. Only in 1 country (Indonesia) is there a proposal to locally procure IPV vaccine through a partnership between a local and international manufacturer.

Issue: Co Administration and Communication Issues:

All countries with the exception of Tajikistan and Indonesia have planned the IPV introduction for 14 weeks of age (with Tajikistan and Indonesia introducing at 4 months). A number of countries expressed concerns in their proposals regarding communication issues surrounding increasing number of childhood vaccines that are being co administered. In Pakistan, it was considered that there would be limited acceptance for giving three injections to a child in one visit, particularly with regard to co administration with the 3rd dose of pentavalent vaccine with PCV. There were also concerns regarding caregiver responses regarding providing 2 polio doses at a time. Concerns were also expressed over similar issues in the proposals from Lao and Gambia. Site of administration is also an issue in some countries.

Recommendation

1. Ensure that proposals and monitoring arrangements indicate clearly the proposals/guidelines for co-administration of vaccines at country level, as well as the communication and risk management strategies associated with the GPEI

Issue: Implementation Timelines

On a number of occasions, concerns were expressed regarding the feasibility of implementation timelines. There were a number of main issues effecting timelines for introduction. Potential delays include delays due to licensing procedures, cold chain procurements, and internal GAVI procedures. Multiple vaccine introductions (see table below for examples) could also act a constraint in terms of system capacity and may need to be monitored carefully.

Table 2 Examples of Issues of Co Administration and Schedule Changes in IPV proposals

Country	Issues of Co Administration and Schedule Changes
Gambia	Co administration with 3rd dose pentavalent and PCV, with concerns expressed regarding caregiver responses and provision of 2 polio doses at a time
Malawi	PCV and Rota introduced in 2011 and 2012 respectively, and HPV demo 2013-2014 Dual introduction of MSD and IPV
Pakistan	Co administration with pentavalent vaccine and PCV 10 (IPV right thigh with PCV) The main risks pertaining to the introduction of IPV foreseen are limited acceptance for giving three injections to a child in one visit and security risk
Guinea	Co administration of IPV at 14 weeks with DPT3 and PCV
Tajikistan	IPV, 2nd dose rota, 4th dose of OPV, 3rd dose of penta administered at 4 months
Uganda	Concern re co administration, HPV (additional districts), PCV 2015, RV in 2016 Concerns regarding multiple injections - will adapt communication strategy
Senegal	Pentavalent 3, PCV3, OPV3 and IPV co administered. PCV 2013, Rubella 2014. Administered in right thigh with pentavalent
Lao	IPV Oct 2015, Pentavalent, OPV, IPV and PCV given at one session. JE (12 months) and MR (9-11 months). Concern expressed regarding 3 vaccinations in one session. Lack of clarity on co-admin
Benin	Pentavalent, PCV introduced in 2011, IPV R Thigh, PCV L Thigh, Pentavalent
Nepal	IPV Sept 2014, PCV Nov 2014, MR Feb 2015, HPV May 2015, (JE at 12-23 months)
Indonesia	MR will be introduced 2016 & introduction of ROTA in 2017, PCV in 2018, and JE in 2019

3.2 Other NVS proposals – Measles, HPV and JE

The IRC considered an application for a HPV Demonstration Project and Measles Second Dose (MSD) from Nepal and a JE application from Lao PDR. This was the first GAVI IRC session during which a JE proposal was evaluated. The IRC congratulates GAVI on the new funding window for this neglected

disease that is especially predominant in the poor rural communities of eight GAVI-eligible countries in Southeast Asia and the Western Pacific. This session also represented the first HPV application to implement the latest WHO SAGE recommendations on the use of a 2-dose HPV vaccine schedule.

Both applications were approved with comments. 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 came through during the IRC meeting with these proposals to assist with further strengthening, planning and success for MSD, HPV Demo and JE applications.

Measles Second Dose

Issue 1: Leveraging the 15-18 month visit

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

Recommendation

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

HPV Demo

Issue 1: Obtaining Parental/Guardian Consent

The Nepal application indicated that parental/guardian consent was not required for vaccinating the ten-year-old girls target but no information was provided on the legal basis for this statement or any potential issues that may arise from not obtaining consent.

Recommendation:

1. Countries should be encouraged to consider issues of parental permission or/and assent of the preadolescent girls, as appropriate in their cultural and legal contexts.

Issue 2: Selection of Districts

Nepal selected two accessible districts in different geographic areas of the country for the HPV Demo Project. The country may have benefited from experiences gained by conducting a project in a less accessible area of the country.

Recommendation:

1. The IRC continues to encourage countries to "learn by doing" by selecting districts that represent the varied populations and contexts in the country.

Issue 3: Assessment of IEC materials and vaccine acceptance by girls, parents and communities

The HPV demonstration project guidelines mandate coverage assessments but also encourage assessment of vaccine acceptance and messaging to girls, parents and communities due to the unique reproductive health nature, age, and gender of the target group for this vaccine. As was seen in previous applications rounds, assessment of messaging and vaccine acceptability was not included in the proposal submitted.

Recommendations

1. Countries are encouraged to conduct an assessment of IEC materials and acceptability of HPV vaccine prior to the initiation of vaccination.

2. 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.

Japanese Encephalitis

Issue 1: Guidelines for JE

At the current time WHO guidance is on conducting JE campaigns followed by introduction of JE into the routine immunisation programme. An updated WHO SAGE Position Paper on JE will not be released until 2015.

Recommendation

1. Countries would benefit from detailed WHO guidance on recommended JE surveillance and impact assessment activities, including national laboratory standards for confirmation of JE.

2. WHO JE guidelines should include minimum standards for campaigns including coverage assessments, population estimation validation, and AEFI surveillance measures.

3. GAVI JE application guidelines should be updated as relevant once the revised WHO position paper on JE is released.

3.3 Health System Strengthening

Four country applications from Madagascar, Honduras, the Democratic Republic of Congo and Kenya were reviewed during the June 2014 IRC meeting. The first three countries as fresh applicants used the current forms and guidelines, while Kenya, a re-submission from June 2013, applied using the common form. Of the four country applications, Honduras is a graduating country and applying for two years funding. DRC was given flexibilities under the country tailored approach, and an additional $53 million was allocated for cold chain.

Table 3 describes the country request by country, and the agencies through which the funds are channelled (government, CSO or implementing partners).

Table 3 Review of HSS requests during June-July review (based on mandatory HSS Budget Template)

Country	Total Request (US$)	Implementing Partners				Funding
		Gov	CSO	WHO/UNICEF	Other	Gaps
DRC	144,991,152	72,293,337	12,245,471	60,452,344		0
Honduras	5,450,434	2,705,088		2,749,346		0
Kenya	32,839,115	27,280,262	5,558,853			0
Madagascar	16,639,999	10,882,609	1,459,340	4,298,050		0
Totals	**$199,920,700**	**$113,161,296**	**$19,263,664**	**$67,495,740**	**0**	0
%	**100%**	**56%**	**10%**	**34%**	0%	

Table 4 summarises the main findings of HSS as well as the recommendations

Table 4 Main Findings HSS

Country	Windows	Outcome (100% approval)	Key Findings/Recommendations
Madagascar	HSS, IPV	Approval with comments	Programmatic resilience in the face of compelling political challenges, CSO interface with community agents, PBF complementarity with other partner input and incentive mechanisms
Honduras	HSS	Approval with comments	Mechanisms to safe guard vaccines despite a 10% reduction in overall budgets
D.R. Congo	HSS, IPV	Approval with comments	Consider as focus country for an Equity Plan in partnership with other donors
Kenya	HSS	Approval with comments	Role of GAMR in closer monitoring of the country implementation especially during the first year of grant implementation
Model Practice		Madagascar	GAVI and Alliance Partners to document and disseminate evidence informed lessons learned in maintaining immunisation coverage under challenging conditions such as political crises/conflicts
Model Practice		Sudan	Harmonization of HSCC and sub-CCM for better planning, coordination and leveraging of HSS resources at country level
Model Practice		Honduras	Sustainability Strategy of Honduras – Enactment of a Vaccine Law in 2014 that legislated Ministry of Finance to vaccine financing as well as financing of operational costs. Also development of a Transition Plan to support graduation process

Key Issues identified and recommendations during this review meeting for HSS are detailed below.

Issue: Quality of the proposals:

There is an increasing level of technical coherence seen in proposals submitted. There is a clearer focus and better attempts by countries in linking strategic objectives through relatively well defined activities with intermediate result indicators that link to immunisation outcomes more clearly. However, there is need to further help countries focus on the need to have well defined strategic

interventions linked to M and E frameworks with better defined indicators that really can better measure intermediate results and intended outcomes.

Recommendation

The IRC commends the Secretariat and the Technical Partners for the increased commitment and support to countries during the proposal development process. Further support need to be provided to countries especially in prioritizing evidence informed, measurable and cost effective interventions.

Issue: Harmonization/Leveraging of Existing investments

HSS grants from other sources especially GFATM and the WB are available in most eligible countries. There is often no well-defined attempt to harmonize HSS components with other existing GAVI cash support grants and/or in- country HSS grants from other donors especially the GFATM and WB. There are several missed opportunities to integrate service delivery and activities e.g. RMNCH, trainings, procurements, etc.

Recommendation

GAVI and technical partners need to ensure that countries are supported to maximize opportunities for joint planning and synchronization of support using existing coordinating mechanisms and opportunities .e.g. country dialogues, PAD etc. Countries receiving multiple HSS grants must demonstrate beyond the guiding principles how these grants can be leveraged; and be clearly integrated across the different strategic plans and NHSP across the countries.

Issue: Strategic linkages of immunisation outcomes with broader system investments: e.g. RMNCH. Is this happening or is there a systemic verticalisation of immunisation for HSS deliberately or as an unintended consequence? Countries are still struggling with this and need more input from Alliance partners.

Recommendation

The guidelines and road shows through the Secretariat and technical partners should provide better clarity on this to countries. Immunisation outcomes should not mean stand-alone and often capital investments in the EPI unit.

Issue: Human Resource Issues:

Countries still continue to apply for salary support and top ups for their staff. In the case of one particular country, GAVI resources will pay for top ups and salaries of the EPI specific staff while considering that these staff are already in the system.

Recommendation

GAVI and Alliance Partners to reiterate through guidelines and road shows etc. that HR support is the primarily responsibility of the country. Essential salaries and HR allowances will only be supported when it is absolutely crucial and would not replace country responsibilities. Performance based strategies should be linked to HR policies and procedures, or commitment to develop such policies and procedures when considered.

Issue: Closer grant monitoring through GAMR

The development of the GAMR initiative means that the IRC has now focussed increasingly on comments to support the quality of implementation.

Recommendation:

Possibility of evolving role of GAMR in closer scrutiny during grant monitoring especially in specific country contexts e.g. Kenya as a pre-requisite for subsequent year allocations.

Issue: Decentralisation at country level and implications for immunisation coverage:
Immunisation coverage declined in the case of Kenya following constitutional changes leading to decentralisation. This has been seen in cases of other countries in the past (e.g. Honduras, Colombia, Indonesia, and the Philippines). How can countries be supported to ensure that health and development gains made are sustained when countries undergo significant political/economic changes?

Recommendation
There is a need for GAVI and Alliance partners to need to pay increased attention to implications of devolution and decentralisation plans at country level especially on immunisation outcomes and overall GAVI HSS investments going forward. Early warning signs and processes to ensure that where there are significant constitutional/political changes that may impact on gains made on immunisation and other health outcomes, there should be a response support by GAVI and other technical partners to plan with existing structures to put in place mitigating measures and forestall a system decline/ collapse.

Issue: Evaluation
Evaluation of existing HSS grants and use of lessons learned to inform subsequent HSS application: Most of the countries did not attempt to evaluate recently completed HSS grants nor clearly document lessons learned.

Recommendation:
While this was not a requirement for HSS grants prior to 2014, according to the current guidelines all countries must plan for end of grant evaluation and at least one coverage survey as part of the grant application.

Issue HSS Model Practices

Madagascar: Madagascar has continued to maintain impressive immunisation coverage levels despite its weak economy and political crisis. How do countries manage to keep systems running and with high immunisation coverage during political crises/conflicts?
Sudan: Harmonization of the HSCC and the sub-CCM for a holistic approach following JANS team recommendations.
Honduras: Mechanisms to safe guard vaccines against economic forces by enacting a vaccines safeguard law which has protected earmarks for vaccine procurement despite a 10% reduction per ministry in overall national budget.

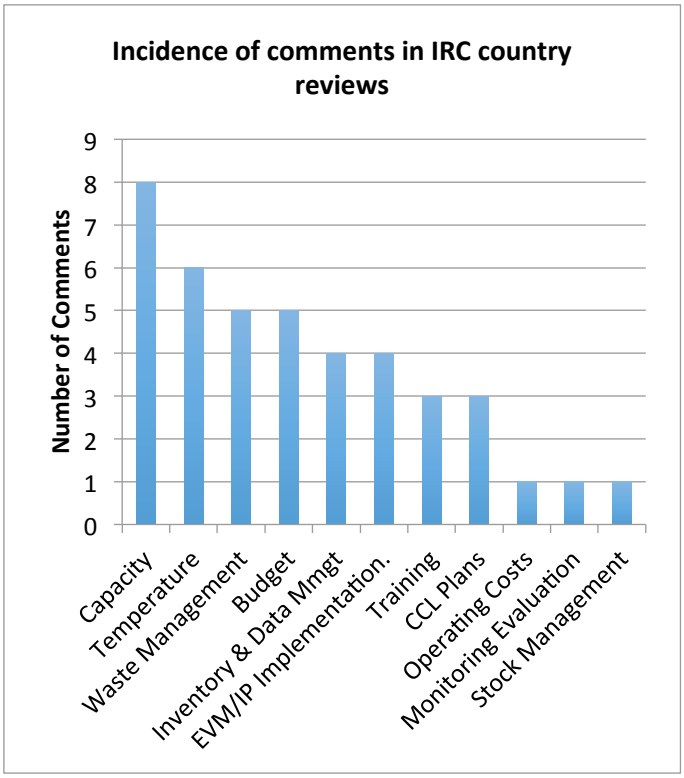
Recommendations
GAVI and Alliance Partners should support these countries to document lessons learned and share with other countries to better improve processes.

3.4 Supply Chain

The 19-vaccine introduction grant applications and 4 health system strengthening applications reviewed by the IRC highlight a number of systemic weaknesses in immunisation supply chains. Supply chain logistics bottlenecks and ambiguities are evident in most of the country applications reviewed by the IRC. A total of 41-supply chain related comments were necessary in the reviews of the 23 applications ranging from storage capacity to stock management issues as indicated in Figure 4.

Key measures proposed to mitigate supply chain related risks to programme performance are described below.

Figure 4 Incidence of Comments in IRC Country reviews



Issue: Supply Chain is Country Specific and not Window specific

The GAVI shift to a country based rather than funding window approach enables the process of a country vision rather than isolated window visions. Supply chain is a window in itself servicing the needs of NVS windows and should be viewed as such to support a country funding approach.

Recommendation

Cash based support for supply chain improvement and expansion should not be fragmented in multiple NVS and HSS windows but should be structured to enable system improvement with capacity to accommodate NVS introductions.

Issue: The 2016/2020 GAVI Strategic Plan includes a focus in improved effectiveness and efficiency and enhanced innovation

The absence of a focused GAVI approach, particularly in guidelines, to support the development of global improved data management systems and supply chain equipment innovation will impede progress towards improved effectiveness, efficiency and innovation.

Recommendation

The gestation period to improve effectiveness and efficiency through innovation or otherwise in supply chain systems is long. The Secretariat should be building mechanisms into guidelines and applications that will today trigger the thought process for future improvement in programmatic effectiveness efficiency and the introduction of innovation and innovative strategies..

Issue: EVM Assessments are not a monitor of supply chain readiness

EVM's are but one partially effective element of a process that can lead to a quantitative determination of supply chain readiness. GAVI should tailor its guidelines and application process to ensure that other essential elements to determine supply chain readiness are included in cash based support windows and implementation status is reported in the IRC/GAMR review process.

Recommendation

The Secretariat to work more closely with UNICEF/WHO to transform the Joint Statement "Achieving Immunisation Goals with Effective Vaccine Management" into an actionable process through mandating that:

- Supply chain inventories are maintained and status is reported in application submissions
- Supply chain upgrade (rehabilitation plans) are included in application submissions and implementation status reported, and
- EVM secretariats are established within existing NITAG or equivalent frameworks to monitor the implementation of EVM recommended and adopted improvement actions.

Issue: Bridging loans to address supply chain bottlenecks

The introduction of IPV and ambitious targets for introduction, do not provide sufficient time for countries to assess supply chain readiness and implement improvements to reduce risks to vaccines during storage and distribution. A bridge loan facility triggered by an IRC "Approval" or "Approval with Comments" would lengthen the time available to countries to improve supply chain readiness by several months. This would be of particular value where countries need to improve temperature monitoring or complete equipment inventories for example.

Recommendation

The Secretariat considers introducing a "Bridge Loan" facility to countries approved for support for IPV introductions. This "Loan" would then be debited from VIG amounts eventually transferred to countries. Specific bridge loan needs could be indicated in IPV applications.

Issue: Civil Society Organization

CSO involvement in the implementation of new vaccine introductions, health system strengthening and even PBF management is strongly encouraged by GAVI. CSO's in many instances lack appropriate professionalism and are not technology savvy to be effective in supply chain related activity. This may include the right technical decision for appropriate cold chain equipment selection or oversight of installations or training users in monitoring temperatures with 30-DTRs or electronic Freeze indicators. The Secretariat should establish a mechanism to reinforce the professionalism of CSO's involved in cash based support programme implementation.

Recommendation

The Secretariat provide a framework to enhance the technical and operational knowhow of CSO's involved in the use of GAVI funds through the establishment of an externally managed center of excellence, where CSO's would attend orientation programmes as a prerequisite to involvement in GAVI investments. This should also provide guidance in accountability practices. Costs of CSO participation in the orientation should be built into budgets for programme implementation.

Issue: Data Management Standards and EPI Data integration

A handful of different Logistics Management Information System (LMIS) packages are being adopted by countries as systems become computerised and more and more people become computer literate. Because of the inherent vertical nature of EPI programmes, EPI parameters which generate appropriate data to monitor EPI performance is frequently poorly or partially integrated with the net result that countries operate 2 parallel systems in some cases. Efforts to fully and effectively integrate or include comprehensive EPI data modules into LMIS architecture are sporadic and often country specific. A substantially more global and professional approach is required to provide countries with a readymade but flexible package for EPI data management.

Recommendation

As an advanced step towards setting in place systems to achieve certain goals in the 2016-2020 Strategy, the Secretariat should spearhead an initiative to respond to the present shortcomings of EPI data integration into, or complimentary modules of LMIS packages, in such a way that countries

are able to select a readymade package (As most countries have done across Africa for the last 15 years with SMT/DVD-MT) suited to or readily adapted to their needs. The package(s) should provide countries with an EPI management tool for stock management, wastage monitoring and supply chain readiness and include provision for channelling essential data to GAVI (and partners) for purposes of management of vaccine shipments.

Issue: Country Estimates of required vaccine storage volumes

Volumes estimated by countries are frequently imprecise and erroneous. This combined with the uncertainty in countries of quantities of correctly operating vaccine storage equipment makes any assessment of supply chain readiness a guessing game. Application forms and guidelines for the introduction of any NVS should include a protected template with mandatory fields that generates data of required storage capacity at catchment population hubs when target coverage and wastage rates and vial presentations of existing and new vaccines are considered. WHO already has computerised tools that perform these functions for purposes of planning and vaccine forecasting. A simplified template in GAVI NVS/VIG applications would facilitate rapid accurate appraisal by IRC/GAMR committees and CRO's managing country programmes.

Recommendation

The Secretariat to review the WHO tools for FIC determinations and in coordination with WHO logisticians, to introduce a simple protected template with mandatory fields so that vaccine volumetric estimates are correct in submitted applications and Secretariat personnel are made aware of supply chain storage bottlenecks.

Issue: Planning Timelines

The budget and timeline templates included in VIG guidelines and application forms require improvement and would benefit if part of an on line submission process. This would ensure completion, compliance with mandatory information, rational sequencing of events and consistency across applications to facilitate in house analysis.

Recommendation

The Secretariat to determine the added value of this approach and to introduce measures accordingly.

3.5 Financial Management and Sustainability

The total introduction costs budgeted for the 16 countries that applied for IPV is US$ 45 million. Funding requested from GAVI represents 44% of these introduction costs. The rest of the vaccine introduction budget is split between Government 26% (with Indonesia contribution representing 22% of this total), EPI traditional partners (WHO and UNICEF for 5%) and HSS existing grants (DRC and Indonesia for 24%). Two countries: Indonesia (60%) and Senegal (52%) fund from government budget more than half of their IPV introduction costs. Although GAVI format requested information on how resources from existing HSS grants will complement new vaccine introduction plans, only DRC and Indonesia provided that information. In the case of DRC, costs to be covered from active HSS grants represent 70% of the total IPV vaccine introduction budget. This indicates that if GAVI cash support to country is consolidated and provided in one single application package, reviewers may have better sense of programme complementarity and oversee how duplication is avoided at country level. This is particularly essential for GAVI when countries that have been granted HSS resources attempt to use opportunities of new vaccine introductions to fix health system or EPI chronic issues likes cold chain (DRC), human resource development or transportation/logistic (Cameroun).

The HSS proposals submitted by 4 countries (DRC, Honduras, Kenya and Madagascar) request a total grant of US$ 200 million. The HSS proposals have dedicated objectives and activities for specific immunisation related areas: cold chain, health care delivery: availability and accessibility of quality health services, health information system, demand creation/stimulation, programme

strengthening, etc. The grant implementation arrangements outlined in the proposals show the HSS funding is e-marked for Government entities (56%) and development partners (34%). This HSS budget allocation between implementing partners leaves only less than 10% of the financial resources for CSO work in DRC and Madagascar. Kenya has identified HENNET (CSO) for implementation of the grant and 17% of the proposed budget is allocated to CSOs. Honduras does not include CSOs in the implementation of the grant.

Furthermore, in 2 countries (DRC, Honduras), WHO and UNICEF have been allocated almost half of the HSS grant (42% in DRC and 50% in Honduras). Although it is critical that some key and sensitive procurement tasks (UNICEF) or technical assistance needs (WHO) be handled by these two GAVI Alliance partners, it is also essential to factor into the contractual arrangements with the international institutions some kind of capacity development mandate and skills transfer requirements to national entities, so that gains on health sector investment are sustained in the long term.

The 4 HSS proposals contain concrete action points for improving health information systems; studies, surveys, mid and end of project evaluations should collect sufficient data to inform future HSS investments in these countries.

Main Issues

Many VIG calculation errors and other mistakes in the IPV applications: due to fluctuating birth cohort and population figures in the documentation provided; figures in Annex B do not match the ones in the introduction plan or those used to calculate the VIG grant in Annex D.

Training, IEC materials and document production account for the most part of the VIG requests compared to other vaccine introduction budget line items: cold chain, surveillance/monitoring, etc.

Specific gender-related activities are still not easily identifiable among the HSS planned activities. There's no budgetary allocation to appraise the priority given to this area at country level.

Completing the HSS budget template poses challenges for some countries. None of the 4 HSS proposals have all the sheets adequately filled in. This may require more training or technical assistance to be provided to countries prior the submission of the applications.

Despite very difficult and challenging contexts, some countries (DRC, Madagascar, Pakistan, etc.) manage to maintain EPI services functioning at an acceptable level. There may have been some resilience/emergency/contingency plans in place that are not properly captured and documented by these countries in their proposals.

Recommendations

1. Conduct enhanced refresher trainings on the use of GAVI standard budget templates (for Cash and NVS support) in collaboration with Alliance in-country partners;
2. Develop additional guidance on better and efficient use of vaccine introduction grants during mass campaign (at least for the portion of the introduction budget requested from GAVI);
3. Reinforce in GAVI guidelines and templates tracking of gender-related activities and budgets so that countries are able to show distinctly any gender sensitive HSS investment;
4. Consider documenting and sharing resilience and contingency plans developed by EPI programmes that have managed under challenging situations (security, social, political, etc.).

3.6 Gender and Equity

Main Issues: Integration of Immunisation with Other Health Interventions

The IRC welcomes the Principles that have been restated in support of GAVI Alliance Strategy 2016-20. In particular, it wishes to support the principle of integration of immunisation with other health interventions. There is increased scope for developing collaborative networks among GAVI, the Global Fund and PMNCH partnerships to ensure equitable investments (policy and investment balance) in public health / HSS (CDC, Immunisation, maternal and neonatal health).

Recommendations

1. GAVI should use the new joint assessment system (GAMR) to assess how its contribution to strengthening health systems overall is making immunisation more effective and efficient.
2. The GAVI Alliance at the country level, building on RI successes and child health days with integrated packages of services, should encourage in conversation on health interventions beyond EPI in order to strengthen services for the mother and for a minimum package in support of MNCH as is observed in the Sudan IPV application or child health days.

Main Issues: Immunisation in Conflict Settings

Over half the countries reviewed at this IRC session have risks associated with conflicts on or within their borders. Most of these conflict-affected countries are dealing with populations displaced internally and/or cross-border(s). In some situations, the displaced populations will be housed in camps and receive services from UNHCR or similar providers where they can be served on an acute basis. But in other cases, the fleeing populations are crossing an undefined border, staying temporarily with relatives/friends and then moving on to settle as “undocumented” residents. This is particularly the case for the countries where eradication is a challenge because of the risk of a polio outbreak (DRC, Pakistan, Cameroon, Kenya, Sudan, and Uganda) all of which are dealing with internal or external conflicts or both. Unregistered cross-border migrants are a burden on the receiving health systems but are not counted in the denominator for the purpose of immunisation. Indeed, the receiving country may need technical assistance to survey this population and to determine how to reach them in a way that is not politically threatening, that is, that make the migrants hide from health services.

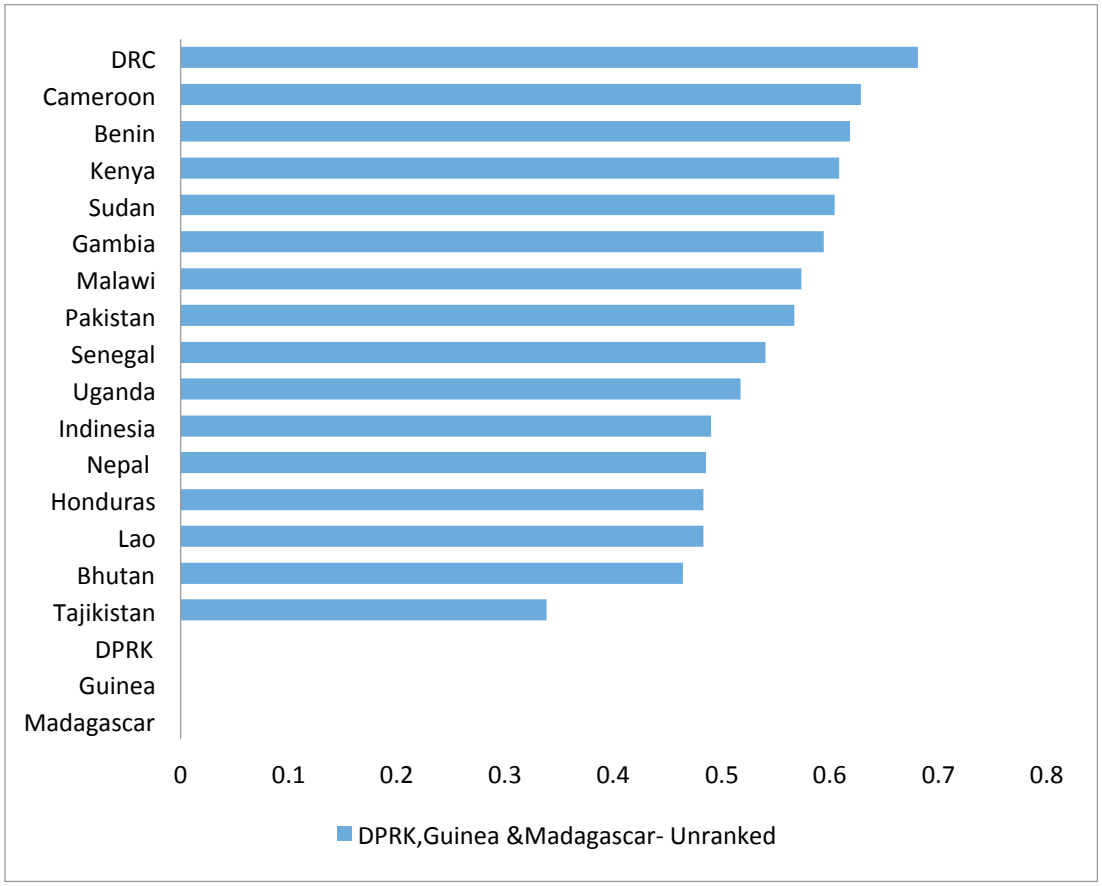
None of the current applications, whether HSS or IPV, contained explicit information on conflict affected populations, security risks to health system staff, and the potential need for more vaccines and operational costs. In its discussions, the IRC considered these populations as a chronic yet invisible risk for the achievement of immunisation objectives, particularly polio. Not being proactive about this invisible population is a missed opportunity. GAVI and partner organizations can help push for mapping these groups and develop a plan for their inclusion in HSS and VIG applications.

Recommendations

1. GAVI to add questions related to internally displaced and cross border displaced populations to applications forms and review the related guidelines. CROs should be prepared to engage in conversation with governments that may not recognized conflict as an immunisation related issue.

2. GAVI to be prepared to support technical assistance, additional components in the VIG, or other contingency support as part of a country tailored approach affected countries.
3. Support GAVI as a learning Alliance by funding case studies in programmatic resilience (Madagascar) and operational strategies in conflict settings (Pakistan).
4. Provide input into development of global strategies for enhancing immunisation strategy and access in conflict settings: Health Worker Security; Negotiation strategy e.g. Corridors of Peace; Immunisation Delivery Strategy (campaign, mobile services, routine scheduling); internally Displaced Persons; Early Warning Systems; and Resource Mobilisation in conflict settings

Figure 5 Gender Inequality Index of Proposal Countries IRC June July 2014 [3]



Main Issues: Countries with Equity Plans

Only two of the ten countries selected by GAVI for priority equity plans had applied before the June/July 2014 IRC. In the case of Madagascar, the findings of the equity analysis and plan, conducted with the support of UNICEF, were clearly reflected in both the HSS and IPV applications. The IRC welcomed this evidence of the political will to address equity issues by the Government of

[3] * Gender Inequality Index : Women and girls face disadvantages in health, education and the labour market. There is no country with perfect gender equality – hence all countries suffer some loss in their HDI achievement when gender inequality is taken into account, through use of the GII metric. GII is a percentage loss to potential human development due to shortfalls in the dimensions including reproductive health, empowerment and labour participation. Gender inequality varies tremendously across countries—the losses in achievement due to gender inequality range from 4.5 percent to 74.7 percent. Higher GII values indicate lower achievement. The world average score on the GII is 0.463, reflecting a percentage loss in achievement across the three dimensions due to gender inequality of 46.3%.

Madagascar. The equity analysis and plan for Pakistan is still incomplete and was not reflected in that country's IPV application.

Recommendation

1. The IRC recommends that the DRC be considered as a country for an equity plan.

Issue: GAVI Revised Gender Policy Revision

The IRC has some recommendations for the HSS and IPV application forms to reflect the revised policy and the need for better information on gender and equity issues, including the status of conflict-related internally displaced/cross border migrant populations. These proposals are included in the attached application guidelines.

Recommendations

1. The IRC also recommends revision of the CRO checklists to capture attention to gender and equity issues.

Figure 6 Recommendations on Implementation of New GAVI Alliance Gender Policy Guidelines

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

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

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

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

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

3.7 Monitoring and Evaluation (AEFI, Surveillance, Evaluation)

Issues AEFI & Surveillance

The risk of perceived adverse events may cause significant parental or community concern and sensational media coverage may seriously undermine immunisation activities.

A great progress and response was observed in 16 GAVI eligible countries in the surveillance of adverse events following immunisation (AEFI), AFP. The main findings are in (Tables1). However, countries are still at varying stages of implementation of AEFI systems.

Almost all countries reported Pharmacovigilance Capacity, and a national AEFI expert review committee that is able to provide technical assistance on causality assessment of serious AEFIs/clusters of AEFIs, so that risks can be managed effectively. Only one country (Lao) had a risk communication plan in place. In this review, there was increased reporting of AFP surveillance from countries.

Table 5 Status of AEFI surveillance in 16 countries in 2014

Questions	Response	
	Yes N (%)	No N (%)
Pharmacovigilance Capacity	15 (94)	1 (6)
National Expert Committee	13 (81)	3 (19)
Injection Safety Policy (main components):		
• Vaccine administration	16 (100)	0(0)
• Waste management	16 (100)	0(0)
• Open vial policy	Not reported	
Sharing of Vaccine Safety Data AEFI integrated into VPD surveillance	15(94) 12 (75)	1(6) 4(25)
Risk Communication Strategy	1(6)	15(94)

Recommendations

1. The function of AEFI surveillance should be technically monitored and supported by the member states.
2. The injection safety policy components should be integral part of the supplementary guideline for NVS.
3. Countries should be required to demonstrate the presence of a strong and integrated AEFI system with strong committee and crisis management capacity as well as preparedness plans to address any vaccine safety issues that may emerge prior to introduction of vaccine and launch of campaigns.
4. There is a need to develop in advance a clear national strategy plan for the risk communication regarding Adverse Event Following Immunisation (AEFI) to prepare health professionals, to provide credible information to caregivers and the public.
5. GAVI Alliance along with partners to develop benchmarks for strengthening surveillance within the new vaccine introduction and campaign support grant to assess readiness for new vaccine introduction

Issues Coverage & Data Quality

In view of the global health programmatic emergency context of the GAVI conditions for IPV proposal endorsement, coverage thresholds were waived. A great emphasis was needed on data quality in the country applications, and indeed the whole process of reviewing, judging and making recommendations to the IRC depended critically on having reliable information upon by which the decisions were made.

In terms of data quality, out of the 16 IPV proposals, 38% reported birth cohorts and populations that differ from WHO/UNICEF estimated levels, out of total 19 countries 47 % conducted independent DQS during the last 3 years. Another issue that has been observed in proposals is denominator issue due to the lack of available reliable sources for calculation (census, civil registries, immunisation data flow, etc.)

Table 6 Data Quality Activities from Country IPV Proposals

M&E data	IRC-June-2014	
	Yes (%)	No (%)
Household Survey for IPV (last 5 years)	12 (75%)	4 (25%)
Independent DQS for 19 countries (last 3 years)	9 (47%)	10 (53%)
Data Discrepancy (IPV)	6 (38%)	10 (62%)
Denominator issue (IPV)	4(25%)	12(75%)

Recommendations

1. GAVI to consider revising/amending the application template to ask countries to provide vaccine coverage information considering:
    a. Country to address the strategy to identify low coverage areas and plans to reach them
    b. GAVI to provide technical and/or financial support to countries for the conduct of coverage surveys and independent DQS evaluations

For new vaccines introductions

Evaluation is a part of proposal requirement. 19/19 countries conducted the EPI's review during last 5 years. All the countries had cMYP. 9/16 countries have already integrated new vaccine activities, while 3 planned to do so in the next coming months. EVM was conducted in 13/16 countries for the past 5 years and 03 planned to do it prior to new vaccine introduction. EVM improvement plan progress reports were provided (10/16 country) PIE was planned in all countries within the period of 6 to 12 months. Others activities like evaluation meeting, progress reports were planned in 50% of countries.

For HSS (4 countries)

Review of the previous HSS round was done in the four countries. However, detailed reports or findings of these evaluations are not provided. M&E framework were providing in the four HSS proposals, including data sources, baseline and targets for each indicator. Strong linkage between HSS implementation and EPI's performances were well established. All the four Countries indicate plans to independently assess the quality of administrative data and track changes in data quality over time. Iindependent and household surveys and evaluation are planned to be conducted in the four countries.

Progress reports and evaluations reports are not always submitted with proposals. The level of recommendation's implementation and lessons learned from programme evaluations are not clearly established and well integrated to proposals. In only 1 of 4 countries was evaluation undertaken of the previous HSS round.

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

Main Issues: Institutional Development (Institutions, Policies and Laws)

National Regulatory Agencies existed in 8 of the 16 countries presenting IPV applications and were not a source of delay in most countries. According to WHO data on the minimum requirements for functionality of NITAGs, 4 out of 16 countries currently meet the standards (see Annex 2).

Although there were no major concerns about ICCs, the structure and level of ICCs varied across countries. This may be an area for GAVI guidance.

EPI policies are often in draft or seem to be staying in "final draft" so the policies are not binding. A question about the status of country policy or legislation governing immunisation could be reflected in the CRO checklist.

The IRC recognises a need for comprehensive health protection and promotion policies or legislation, particularly in the light of how many countries are decentralising health responsibilities to the provincial, district, or municipal level. It noted the positive example of Honduras national legislation. Such policies or legislation need to take into account the many more vaccines and technologies being introduced and the variety of players in the sector including private sector health players (private health insurance, traditional healers, for profit organizations, national and international NGOs). In particular, such policies or legislation could structure the role of all players in surveillance, mobilisation, IEC, and reporting. For example, in the review of certain countries, it was not clear whether there was low coverage of the urban population or whether vaccinations had been administered outside the public system but not reported through the EPI system.

Recommendations

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

Issues: Civil Society participation

CSO have a long history with GAVI since the initial cash grants: CSO Type A, CSO Type B. Almost all of the country proposals acknowledge the vital role of community organizations in achieving and sustaining immunisation results. Minutes of ICC/HSCC meetings indicate that CSOs are invited and participate to the deliberations of these EPI governing bodies. They endorse all applications and proposals from countries as participants to the meeting. However, programmatic space and budget allocations assigned to CSOs within the HSS proposals and even with the VIG grants demonstrate that their added value to the entire EPI system is still not well perceived at country level. Although countries start to involve CSOs in demand generation activities or as frontline service providers in some difficult settings (conflict, post conflict, hard to reach areas, disadvantaged urban areas, suburbs, etc.), their work remains basic and classic such as outreach or sensitization work among local communities. Participation and involvement of CSO in early stages of EPI planning and budgeting process are not documented and captured in the narrative of cMYP or introduction plans. Selection/recruitment process of suitable CSO representatives at the ICC/HSSC meeting table is not clearly defined and described in the ToR of these governing bodies. Countries use different approaches: DRC has a consortium/platform representing several groups with SANRU as a lead NGO, Kenya with HENNET as one single lead NGO and Madagascar which has not defined the CSO implementers at the time of submission. Another issue is the type of CSO needed for certain thematic or locations. For example, talking about gender barriers to immunisation, are all types of CSOs qualified to work and deliver on this issue? Or are women organizations better placed? Most of the time, inequities in health care provision are linked to legal rights or social protection. Are

human-rights organizations involved in the EPI at country level to help lift some of the inequity bottlenecks to immunisation? Information provided by countries to describe the CSO work does not respond to these critical questions.

Recommendations

1. Encourage innovative and bold strategies in the CSOs' interventions rather than classic outreach and community mobilisation work, especially in difficult health system settings;
2. Involve CSOs in early stages of EPI planning and budgeting process, including development of cMYP, introduction and mass campaign plans;
3. Define profile of CSOs that are capable to add value to the EPI programme at country level according to their programmatic areas of expertise;
4. As per previous IRC recommendations, consider the opening of specific windows for CSO support, targeted towards the needs and rights of vulnerable population groups in known high risk settings (populations effected by conflict, the urban poor).

Annex 1 Table of Main Findings

Country		Support requested	IRC recommendation
1	Benin	IPV	Approval with comments
2	Bhutan	IPV	Approval with comments
3	Cameroon	IPV	Approval with comments
4	DPRK	IPV	Approval with comments
5	DRC	IPV	Approval with comments
		HSS	Approval with comments
6	Gambia	IPV	Approval with comments
7	Guinea	IPV	Approval with comments
8	Honduras	HSS	Approval with comments
9	Indonesia	IPV	Approval with comments
10	Kenya	HSS	Approval with comments
11	Lao	IPV	Approval with comments
		JE	Approval with comments
12	Madagascar	IPV	Approval with comments
		HSS	Approval with comments
13	Malawi	IPV	Approval with comments
14	Nepal	MSD	Approval with comments
		HPV demo	Approval with comments
15	Pakistan	IPV	Approval with comments
16	Senegal	IPV	Approval with comments
17	Sudan	IPV	Approval with comments
18	Tajikistan	IPV	Approval with comments
19	Uganda	IPV	Approval with comments

Annex 2 List of Functional NITAGs in IPV eligible Countries

Afghanistan	EMRO	Least developed	Low income
Bhutan	SEARO	Least developed	Lower middle income
Côte d'Ivoire	AFRO	Developing	Lower middle income
Democratic People's Republic of Korea	SEARO	Developing	Low income
Indonesia	SEARO	Developing	Lower middle income
Mozambique	AFRO	Least developed	Low income
Nepal	SEARO	Least developed	Low income
Pakistan	EMRO	Developing	Lower middle income
Republic of Korea	WPRO	Developing	High income: OECD
Sudan	EMRO	Least developed	Lower middle income
Uzbekistan	EURO	Economy in transition	Lower middle income
Zambia	AFRO	Least developed	Lower middle income

Annex 3 List of IRC Review Members

Name	Current Role
Salah Al Awaidy	Advisor at the Ministry of Health, Oman
Ousmane Amadou Sy	Independent consultant
Gabriel Carrasquilla	Founder and Director of ASIESALUD
Jean Marie Edengue Ekani	Immunisation specialist MoH, Cameroon
John Grundy	Independent consultant
Terence Hart	Independent consultant
Bolanle Oyeledun	Chief Executive Officer at Centre for Integrated Health Programs (CIHP), Nigeria
Zeenat Patel	Independent consultant
Diana Rivington	Senior Fellow in the Faculty of Social Sciences at the University of Ottawa, Canada
Rafah Salam Aziz	Independent consultant
Gayane Sahakyan	National Immunisation Program Manager, Republic of Armenia
Malek Sbih	Independent consultant
Shamsa Zafar	Head of Department, Centre of Excellence in MNCH at the Health Services Academy, Pakistan