INDEPENDENT REVIEW COMMITTEE REPORT IPV NEW PROPOSALS

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1. Background

A meeting of the Independent Review Committee was undertaken between April 27 and May 1 2014 in Geneva. The purpose of the meeting was to assess proposals for introduction of Inactivated Polio Vaccine (IPV) in 11 GAVI eligible countries. The IPV introductions arise from the Global Polio Eradication Initiative (GPEI), which was launched following a declaration by the World Health Assembly in 2012 identifying polio eradication as a global public health programmatic emergency. Three distinct stages are identified for the strategy which includes:

- 1. Introducing at least one dose of IPV before the end of 2015
- 2. Switching to bivalent OPV from trivalent OPV in 2016
- 3. Withdrawal of OPV in 2019 2020

The Polio Eradication and Endgame Strategic Plan 2013-2018 identifies 4 main objectives, of which the first two are to 1) detect and interrupt polio transmission, and 2) strengthen immunization systems and withdraw oral polio vaccine. In 2013 there were SAGE recommendations on IPV introduction planning and schedule and subsequent to this there was a GAVI Board decision to support all GAVI countries for IPV introduction. There are 126 countries currently using OPV, of which 72 are GAVI eligible countries.

2. Methods

Nine reviewers from a range of disciplines took part in the review (see Annex 1 for list of members). Background briefings were provided by WHO, UNICEF, GAVI and Country Responsible Officers of GAVI Secretariat. Two reviewers were assigned three countries each to review and a country report was generated for each submitted proposal. Two 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. In addition to the country reports, a global report was also developed focussing on main themes arising from the review.

This review was different in its approach for a number of reasons. *Firstly*, only IPV introduction proposals were assessed. *Secondly*, in view of the global health programmatic emergency context, many of the normal GAVI conditions for proposal endorsement were waived. These included multiyear planning, co-financing, coverage thresholds, and other country eligibility requirements or conditions. *Thirdly*, only two recommendation categories were under consideration (this method was also used for new HSS applications in the last proposal review). These were "Approval with comments" or "Resubmission with reasons." After discussion and reference to the last IRC meeting, the IRC team took the view that "comments" should be actionable. If a resubmission was indicated, "reasons" for resubmission should also be sufficiently practical to enable a successful application at the next proposal round. As this was a first IPV proposal round, note was taken by reviewers of the fact that that the approach to assessment would set precedents, and, in doing so, would significantly guide or influence the decisions to be made at subsequent proposal rounds in 2014.

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

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

3. Main Findings

The main findings are tabulated below according to recommendation, vial size and schedule of introduction. Overall, 11 proposals were approved for submission, all of which were "Approved with Comments." The table below summarizes the main findings from the review.

Table 1 Summary of Recommendations

COUNTRY	Recommendation	Vial	Schedule
Tanzania	Approval with comments	5	14 weeks
Yemen	Approval with comments	1	14 weeks
Afghanistan	Approval with comments	10	14 weeks
Kiribati	Approval with comments	1 & 5	14 weeks
Nepal	Approval with comments	10	14 weeks
Nigeria	Approval with comments	5	14 weeks
Ethiopia	Approval with comments	10	14 weeks
Bangladesh	Approval with comments	1	14 weeks
Sri Lanka	Approval with comments	1	6 months
Comoros	Approval with comments	10	14 weeks
Liberia	Approval with comments	10	14 weeks

There was a variety in requests for vaccine presentation, with the majority of countries (6/11) requesting a lower than 10 dose presentation principally for vaccine wastage reasons. All countries followed the SAGE recommendations for a single dose of IPV provided with pentavalent 3/DPT3. Nearly all countries will provide IPV through routine services, with the exception of Nigeria, which will also implement high risk campaigns in the northern region of the country. In accordance with the short timeline for the polio endgame strategy (with medium term targets of introduction into all countries of IPV by the end of 2015), the majority of countries propose to introduce the vaccine in 2014 as demonstrated in Table 2.

Table 2 Proposed Timeline for Vaccine Introduction

	2014					2015												
	J	Α	S	0	N	D	J	F	М	Α	М	J	J	Α	S	0	N	D
Nepal																		
Yemen																		
Bangladesh																		
Nigeria																		
Tanzania																		
Sri Lanka																		
Comoros																		
Liberia																		
Afghanistan																		
Kiribati																		
Ethiopia																		

4. Discussion

Four main themes emerged from these reviews which were discussed throughout the IRC review and in the subsequent debriefing with GAVI Alliance members. These were as follows:

- (1) Reviewing IPV proposals in the context of a programmatic emergency
- (2) Identifying the critical actions for successful introduction within next 6-12 months
- (3) Synergies should be demonstrated with other new vaccine introductions
- (4) Routine immunization strengthening in the context of GPEI

Each of these points is discussed below, with elaboration of technical findings from the review.

THEME 1 Reviewing IPV proposals in the context of a programmatic emergency

The IPV guidelines introduce waivers for certain GAVI requirements. This was in the context of a globally defined programmatic emergency, which has set a specific timeline for introduction of IPV. In order to reach a recommendation of "Approval with comments", reviewers considered that (a) the application should meet guideline requirements and (b) the intervention must still be feasible, safe and well communicated. In view of the "programmatic emergency" lens for viewing application quality, there was a 100% rate of approval, but with a list of actionable comments for each country to ensure that intervention is feasible, safe and well communicated. Other factors arising from the programmatic emergency context for proposal appraisal are as follows:

(1) Short time lines for Implementation

As figure 1 illustrates, the time lines for meeting GPEI objectives are divided into three phases.

2019-2020

2016

Before end of 2015

Switch

• tOPV to bOPV

Introduce

• at least one dose of IPV
• into routine immunization

Figure 1 Three Distinct Stages of GPEI ²

Ongoing STRENGTHENING of routine immunization services

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² Presentation WHO GPEI IRC Review

(2) Waiver of new vaccine proposal requirements

In view of these short time lines, in the current IPV guidelines, GAVI introduced a system of waiver for review of IPV applications. Some of the standard requirements for approval of new vaccine introductions were waived. These include for example co-financing agreements for vaccines, the requirement to update the cMYP and the low coverage "cut off points" for new proposal recommendation (ie. 70% DPT3).

(3) Two Decision Making pathways

As was introduced in the February 2014 IRC, there are now two decision making pathways – these are "Approval with Comments" and "Resubmission with reasons." In previous IRC rounds, the specification of clarifications and "conditional approval" was seen as providing the IRC with additional leeway or flexibility for making recommendations.

(4) New monitoring and engagement model of GAVI Alliance

Finally, the new monitoring model of GAVI (GAMR or Grant Application Monitoring Review) provides for increased focus by GAVI and Alliance partners on real time monitoring of program implementation. All of these factors served to narrow the decision making space for the IRC, as well as widen the opportunity for the IRC to provide technical and quality improvement "comments" for implementation with closer monitoring and implementation oversight by the GAVI Alliance in Geneva, regionally and in country. Despite being labelled as "comments", they provide constructive suggestions on follow up actions that should be cleared by countries and Alliance technical staff.

THEME 2 Identifying the critical actions for successful introduction within next 6-12 months

A number of "critical actions" were identified for ensuring success of the introductions. These included satisfying country requirements in terms of Immunization Policy and Licensing requirements, ensuring readiness of the cold chain and adequate supplies of vaccine, and through development of adequate communication and training plans. These steps would ensure basic "system readiness" to take on the intervention.

(1) Policy and Licensing

In all cases, countries stated they have updated policies and immunization schedules. The majority of countries indicated that the IPV will be administered at the 14 weeks immunization contact. As all countries will procure vaccines through UNICEF procurement mechanisms (issuing a WHO prequalified vaccine), no major problems were envisaged in proposals with licensing requirements (see section on governance below for more detail).

(2) Viability of Cold Chain

The cold chain specialist on the IRC indicated that IPV vaccine requirement would indicate only an additional 3% cold chain capacity expansion for the countries (although this figure can be higher for countries who have not introduced a full range of new vaccines). This being the case, it was assessed that the existing vaccine management and logistical risk was not far beyond existing management risk. However, due to the fact that most proposals were designed in apparent isolation of wider country program design, it was difficult to assess from this review the extent to which countries

actually met cold chain and logistical requirements for introduction. The IRC concluded that cold chain and logistics monitoring by the Secretariat through Alliance partners would be critical to ensure successful implementation.

(3) Adequate Vaccine Supply

As illustrated in Table 1, there is a wide variety in vaccine presentation requests. Many countries are proposing to introduce a 10 dose vial. Other countries requested a smaller presentation in order to reduce vaccine wastage. The UNICEF procurement Division indicated that there is still a degree of uncertainty regarding prequalification and supply of certain vial presentations. UNICEF supply Division will maintain close communication with countries and with GAVI Secretariat and Alliance partners to ensure these risks of supply are managed. The wide variety of product choice seems to indicate that countries may not be applying a set of criteria for product choice.

(4) Communication and Training Plan

The provision of an adequate training and communication plan was seen as an additional critical requirement for IPV introduction. This is particularly the case given the 14 week schedule, and the likelihood in many cases that children will receive up to 3 injectable vaccines at a single immunization session (including one injectable and one oral presentation of polio vaccine). These issues are discussed in more detail under the section "routine immunization strengthening" below.

THEME 3 Synergies with other new vaccine introductions

Reviewers observed in proposals that there was lack of adequate synergy between the IPV initiative and related new vaccine introduction, routine immunization and health system strengthening initiatives. In many cases, in single countries, one or two other vaccine introductions are proposed (see Table 3), but with no firm idea given of how multiple investments in such areas as training, supervision, communication or communication are coordinated. The advantages of such synergies would be improved aid efficiency, and improved impact resulting from leveraging support from complementary immunization or health system strengthening investments. Although it was not viewed as a reason for resubmission, it was viewed by the IRC as an area for actionable comment and follow up by GAVI Alliance members globally, regionally and in country.

Table 3 New Vaccine programs and Evidence of Synergies

Country	New vaccines	Combined activities/synergies
Bangladesh	IPV: Oct 2014 PCV: Sept in 2014	Planned combined introduction, depending on supply issues
Liberia	IPV: Jan 2015 Rotavirus: 2015	Not considered
Nepal	IPV: Sep 2014 PCV10: 2014 (possibly shifting to next year)	Not considered
Nigeria	IPV: Jan 15 PCV: 4Q 2014	Synergies mentioned, but PCV phased intro and IPV nationwide intro. Costs from IPV and PCV VIGs for reporting tools aggregated

Tanzania	IPV: Jan 15	Not considered
	MSD: May 2014	
	MR: Sep 2014	
Yemen	IPV: Oct 14	Reporting tools for both introduction
	MR: Dec 2013	

THEME 4 Routine immunization strengthening in context of Endgame Strategy

In view of the fact that routine immunization strengthening is the foundation of the Endgame strategy and timeline (as well as of the GAVI Mission), reviewers observed that proposals were quite variable according to the extent to which they addressed routine immunization strengthening actions. Examples of these areas of immunization system strengthening included the following:

- (1) Gender and Equity
- (2) AEFI and Surveillance
- (3) Communication and Training Strategies
- (4) Cold Chain and Logistics
- (5) Other Issues (Governance, Urban Health, Security)

Gender and Equity

Most countries, whether or not they routinely collect sex-disaggregated data, reported parity in coverage of routine infant vaccinations, some attributing this to the fact that policy provisions of the country dictate no discrimination in the provision of care (e.g. Liberia, Ethiopia, Nigeria. However, data from periodic surveys indicate otherwise. In Liberia, for example, the preliminary report of the DHS 2013 shows gender and equity disparities in DPT3 coverage. Female/male – 74%/69%; urban/rural – 76%/67%; county disparities -high of 91% to a low of 42%; and education status of mothers (primary caregivers – no education (68%), secondary/higher (82%). This emphasizes the fact that the status of the care givers affects immunization coverage, and that sub national data as derived from periodic surveys are useful to unearth gender and equity issues buried under nationally aggregated data.

Table 4 Key findings on Gender and Equity-IRC-IPV April 2014

	Yes
CSO/NGO Representation on ICC	9 *
Sex disaggregated data reported	4
Plans to collect SDD in future	3
Gender related barriers identified	1
Gender related barriers addressed	1
Equity related barriers identified	6
Equity related barriers addressed	6
Fragility issues being addressed	2

* Not clear in two proposals

Given the limitations of the application forms and guidance, the IRC would like to commend Afghanistan for identifying gender/equity-related barriers and making efforts to address them by planning to develop appropriate communication and social mobilization interventions targeted at men and women in their various roles in the family and extending the hours of service to

accommodate women's roles and recognizing that these are measures to promote gender equality. Bangladesh also identified the challenges of reaching the undocumented urban slum dwellers and proposed strategies to reach them

Compared to the November 2013 IRC, the proportion of applications identifying equity barriers has dipped (approx 55%) compared to 90%.

The guidelines for application for IPV introduction support do include good guidance on gender and equity analysis. However, many of the countries did not follow these guidelines. During this round, many applications gave only scarce attention to analyses of gender & equity barriers. It is apparent that many of the applications could benefit from technical support to strengthen their capacity for identifying gender and equality issues and developing strategies to address them.

This being the case, the following is recommended:

- 1. GAVI to consider revising/amending the application template to ask countries to provide, where available, vaccine coverage information comparing the measures below, suggesting to countries the sources that could be consulted to get such data:
 - Urban/rural
 - The richest/poorest quintiles
 - The provinces or /districts with highest/ and lowest coverage
 - Caretakers' (Mothers') education from lowest and highest levels
 - Gender Inequality Index

AEFI and Surveillance

Many countries applying for IPV introduction have initiated surveillance of adverse events following immunization (AEFI). Countries, however, are still at varying stages of implementation of AEFI systems. Plans to strengthen and conduct AEFI capacity building activities and response to AEFI for health workers are underway. Only a few countries have established 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 had a risk communication plan in place, therefore, there is a need to develop a clear strategy for risk communication to prepare health professionals, and to provide credible to information to caregivers and the public. In addition, preparedness plans are needed to address any vaccine safety issues that may emerge.

Communication and Training Strategies

The IRC would like to highlight two key communication challenges that were identified during the proposal reviews that face countries introducing IPV into routine immunization programs previously providing only OPV. While most proposals discussed the importance of a communication strategy, there was very little detail provided regarding the specific communication strategies that will be implemented to deal with these two key issues. Supporting partners need to work with countries to ensure that these communication challenges are being adequately dealt with at the country level.

Issue 1: Administration of multiple vaccinations at the 14-week visit

• Country concerns around the acceptability of multiple injections occurring during one visit were flagged in most of the submitted proposals.

- Countries require field-tested communication messages, using local acceptability data, on the safety and benefits of multiple immunizations at the same visit (i.e. earlier protection, fewer vaccination visits, etc.). These messages should be appropriately tailored to different target audiences.
- •It will be important to ensure that training materials and tools on best practices for the administration of multiple vaccinations are provided to countries. Administration of multiple vaccines at one visit poses the potential for increased vaccine administration errors. There were several applications that failed to indicate best practices for administration of multiple vaccines (i.e. separation of injection sites by at least 2cm if given in the same limb, giving penta in one limb and IPV/PCV in the other limb due slightly increased local reactions to penta, etc.).

Issue 2: Rationale for the use of both OPV and IPV

- Very few countries addressed the importance of communicating the rationale for the administration of both IPV and OPV in their vaccine introduction plans.
- Field-tested communication messages based on local social data that clearly explain the
 rationale for IPV introduction need to be developed ahead of the launch. Tailored messaging
 is required for health care workers, caregivers, social mobilizers, opinion leaders and the
 general public. The introduction of IPV should not be communicated as a failure of OPV.
 Neglecting to prepare appropriate communication messages may inadvertently undermine
 the use of OPV.

Cold Chain and Logistics

Key issues arising from the cold chain and logistics review of the IPV proposal are described below.

- 1. CCL measures to support the hard to reach group wealth quintiles, gender, and readiness focus are not specifically addressed in the CCL information provided in applications.
- 2. The IPV supplementary guideline for IPV applications (2014) addresses:
 - Pre-introduction activities that can be funded through the GAVI vaccine introduction
 grant may include but are not limited to health worker training, information, education
 and communication (IEC) and social mobilization, micro-planning, expansion or
 rehabilitation of some cold chain equipment and additional vehicles if needed, printing
 and purchase of materials (such as immunization cards), technical assistance, and
 modifications to the surveillance systems.
 - The checklist of mandatory documents to be submitted with the application also includes a progress report on the implementation of any effective vaccine management (EVM) assessment conducted in the preceding 36 months or a description of the vaccine management system in place and a commitment to conduct an EVM within 6 months of the the application being approved.
 - The Annex A template of the IPV Introductory plan also clearly defines the supply chain logistics information applicants are expected to provide in terms of adequacy, gap, budget and evidence of funding for O&M costs.
 - The Annex C template for the Timeline of activities includes an activity "Confirm space at regional and district cold stores" but does not include provision to program CCL activities in the event of lack of adequacy.

 The 2 worksheets of the budgetary template (Annex D) includes cost categories for "cold chain equipment" and "waste management", but the summary sheet cells are not referenced to the detailed sheet and sheet versions used are not consistent across all applications.

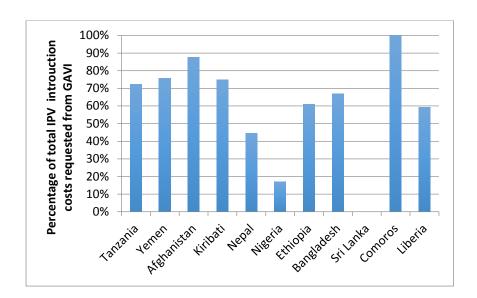
Guidelines do not address:

- The 2 worksheets of the budgetary template (Annex D) includes cost categories for "cold chain equipment" and "waste management", but the summary sheet cells are not referenced to the detailed sheet and sheet versions used are not consistent across all applications. Guidelines do not address the following:
 - Equipment Inventory status
 - Additional CC equipment need specifically related to IPV introduction:
 - That adequate temperature management and monitoring is in place to ensure vaccine is stored correctly.
 - Maintenance adequacy to ensure equipment is functioning correctly, and
 - Planned vaccine distribution and stock management arrangements and measures to modify the supply chain to accommodate IPV.
 - WHO/PQS Compliance of new equipment requested
 - CCL Data management standards and consistency
 - Justification and intended use for vehicles
 - Program readiness (Last EVM performance summary)
 - Synergies with CCL requests for the introductions of other new vaccines/campaigns or HSS except for a budgetary reference in Annex D.
- 3. There are no clear synergies to the process of achieving the 6 rights³.
- 4. 9 of the 11 applications include some form of EVM improvement plan, although not always in a tabulated format (Nigeria provide a descriptive narrative).
- 5. Most of the 11 countries provide sufficient information on supply chain status to provide confidence that adequate storage capacity is available to introduce IPV. There is lack of clarity however on supply chain readiness when other new vaccines are also scheduled for introduction in 2014/2015 and when it is not clear whether a single dose or 10 dose presentation of IPV will be supplied
- 6. Requests for GAVI support amount to \$16.08m. This represents 32% of the estimated total cost. (Note: Sri Lanka total cost is not provided in proposal). Support requested from GAVI for IPV introduction varies from 100% in the case of Comoros to 17% in Nigeria. A graph showing percentage of GAVI funding by country is shown below.

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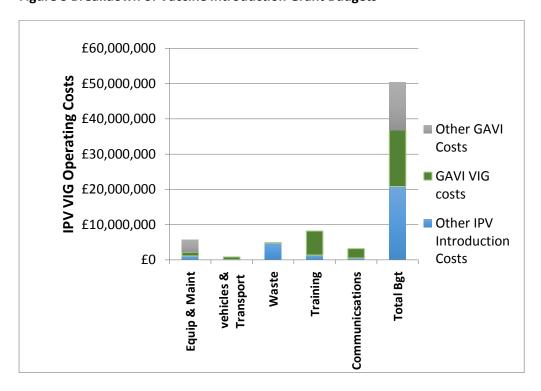
³ Right vaccine, right place, right time, right quantities, right condition and right cost.

Figure 2 % IPV Introduction Costs Requested from GAVI



7. The repartition cost elements relating to equipment and maintenance, vehicles and transport, waste, training and communications requested through GAVI support to IPV introduction, other GAVI cash support (HSS), and other non GAVI supported IPV costs are shown below.

Figure 3 Breakdown of Vaccine Introduction Grant Budgets



Other Issues

Governance mechanisms - Role of ICCs-NITAGs-NRAs: Three main governance mechanisms and roles were evident in proposals – these were coordination roles (ICCs), scientific roles (NITAGs) and

regulatory roles (NRAs). Overall, countries demonstrated effective leadership and oversight of proposal initiatives, particularly through ICC mechanisms. Other countries illustrated innovative high level leadership support. In *Nigeria* for example, the application explains that Nigeria subscribed to the decision to use IPV in September 2013 at the WHO-Afro regional Committee of Health Ministers. The NPHCDA led the decision making process on behalf of the ICC and recommended applying for GAVI support. The Core group of the ICC oversaw the plan development. In Yemen, a task force consisting of the MoH (Family Health, EPI, Surveillance), WHO, UNICEF and chaired by the deputy minister will be the main entity for planning and oversight of IPV introduction. The task force meets monthly but will increase frequency of meetings during the introduction process.

Most countries do not see licensing requirements as a factor delaying or impeding timely introduction. This is mostly due to the fact that as IPV is a WHO prequalified vaccine procured through UNICEF procurement mechanisms, most countries are able to fast track registration requirements. In Nigeria for example, the introduction of other presentations will require national licensure and the plan provides appropriate information on a process that involves expedited registration and the use of a waiver to import WHO prequalified vaccine, which has been used in similar situations in the past. Nevertheless, despite the stated claims for fast track licensure, the process may need to be monitored closely. In Ethiopia for example, the country has a functional National Regulatory Authority which is under FMHACA and is responsible for vaccine licensure. In addition to being WHO pre-qualified, all new vaccines must be licensed and registered in the national drug list before arrival to the country. However, the country plan is silent about the time required for this to happen.

Where the IRC considered there was limited information was in relation to the role of NITAGs in advising or guiding decision making and implementation. Clearly, the role of scientific data (particularly surveillance data) will be critical for sustaining quality of information, guiding immunization strategy and validating eradication. Also, the discussion of immunization schedules, co administration, and adverse events will all need to be carefully monitored by a scientific committee.

Urbanization and privatization: As noted increasingly in previous IRCs, the issues of rapid urbanization (and privatization) will increasingly impact on the reach and quality of GAVI supported programs. In this round of proposals, the issues of the urban poor and immunization access were noted or discussed in the cases of Nepal, Bangladesh and Yemen. In future proposals, more attention will be required to be placed on determining "hard to reach" not only in terms of geographically remote populations, but also in terms of un registered urban poor populations who reside quite close to public health facilities but who may not be accessing them, be using private sector services, or who may not be included in urban coverage population denominators.

Security and coverage: The IRC noted that remaining polio cases are occurring in security compromised locations including Pakistan, Nigeria, and Syria. In order to keep the focus on the longer term goals of the endgame strategy, more attention will be required on support for immunization strategy in security compromised situations.

5. Conclusion

Although the proposals are of variable quality, the IRC indicated that all meet the minimum requirements for IPV introduction. The proposals can be further strengthened however through improved focus on routine immunization systems development (including surveillance and equity

concerns) in order to focus investments not only on short term goals (such as IPV introduction) but also on the longer term goals for high coverage and eradication.

Some of the proposals illustrated careful planning, sound governance mechanisms, and comprehensive approaches to routine immunization strengthening (Bangladesh, Yemen). Others will require very careful monitoring, more detailed planning and ongoing technical support (Afghanistan, Nigeria, Tanzania in particular). Given the very tight timeline for some, GAVI should be ready to review implementation plans with countries and partners to avoid rushing and overlooking some critical actions or immunization systems that may not as yet be well addressed (such as communication, training, guidelines on co administration, surveillance and AEFI)

In conclusion, the IRC commends and acknowledges Alliance partners for their successful engagement with countries for working towards achieving global health goals for polio eradication.

6. Summary Recommendations

- 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 immunization strengthening, particularly with regard to immunization 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 programs
 - 1.3 The importance of immunization 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)
- 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

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