



**REPORT OF THE NEW PROPOSAL
INDEPENDENT REVIEW COMMITTEE TO
THE GAVI ALLIANCE SECRETARIAT ON
THE REVIEW OF APPLICATIONS**

**Geneva,
Switzerland**

July 03-13, 2018

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List of Acronyms

AEFI	Adverse Event Following Immunization
BCC	Behaviour Change Communication
CC	Cold Chain
CCE	Cold Chain Equipment
CCEOP	Cold Chain Equipment Optimization Platform
EPI	Expanded Programme on Immunization
EVM	Effective Vaccine Management, an assessment tool
HPV	Human Papilloma Virus
HR	Human Resources
HSIS	Health Systems and Immunization Strengthening
HSS	Health Systems Strengthening
ICC	Inter-Agency Coordination Committee
IRC	Independent Review Committee
MCV	Measles Containing Vaccine
M&E	Monitoring and Evaluation
MNCH	Maternal Neonatal and Child Health
MoH	Ministry of Health
M/MRFU	Measles/Measles Rubella Follow up
MPRAT	Measles Programmatic Risk Assessment Tool
MR	Measles-Rubella vaccine
NITAG	National Immunization Technical Advisory Group
NVS	New and underused Vaccine Support
PCV	Pneumococcal conjugate vaccine
PEF	Performance Evaluation Framework
PIRI	Periodic Intensification of Routine Immunization
PT	Preparatory Transition
RI	Routine Immunization
RV	Rotavirus Vaccine
SCM	Senior Country Manager
SIA	Supplementary Immunization Activity
SMS	Short Message Service
TA	Technical Assistance
TCV	Typhoid Conjugate Vaccine
UNICEF	United Nations Children's Fund
VIG	Vaccine Introduction Grant
WaSH	Water, Sanitation and Hygiene Interventions
WHO	World Health Organization

1.0 BACKGROUND

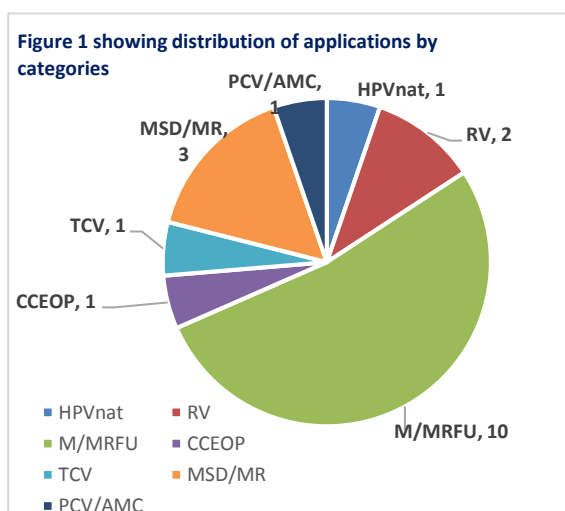
The 2nd Independent Review Committee (IRC) meeting for 2018 was held in Geneva, Switzerland from July 3rd to the 13th, 2018. The IRC session was comprised of 17 reviewers with expertise in immunization, cold chain and logistics, MNCH, adolescent health, health systems strengthening, reproductive health programme management, epidemiology, monitoring and evaluation, financial analysis, BCC and gender. Four (4) new members joined this IRC meeting bringing in additional expertise in immunization, epidemiology, health systems strengthening and programme management. The IRC also had two dedicated finance and one governance mechanism reviewers. Two members focused on in-depth financial reviews of the budgets submitted by applicant countries; and an on-site consultant reviewed ICC and NITAG functionality. *(See Annex 1 for list of members).*

The independent review committee members focused on the following specific tasks:

- Review country specific funding requests and supporting documentation for applications for vaccine introductions and campaigns to support countries through efforts to strengthen the coverage and equity of immunization.
- Review funding requests and supporting documentation, including, comprehensive Multi Year Plans, Vaccine introduction plans, Plans of actions and supporting documents as applicable to each country.
- Provide the Gavi Secretariat with evaluation reports and recommendations for each country.
- Provide the Gavi Secretariat with a consolidated report of the review, including recommendations for improving funding requests, including planning, budgeting, M&E, financial management, gender and equity considerations.
- Provide the Board and the Alliance partners with recommendations improving the processes relating to Gavi policies, governance, and structure.

2.0 REVIEW METHODS AND PROCESSES

2.1 Review process and key outcomes



Review Process: IRC reviewed **19** applications from **16** countries. **16 (84%)** were recommended for approval. (M/RFU) follow up campaigns totalled **53%** of applications. One country applied for the new Typhoid Conjugate Vaccine window. Four of the M/RFU applications were re-reviews from previous IRC meetings.

Each country application and supporting documents were independently reviewed by assigned members. This was followed by presentation of initial findings with extensive discussions during daily plenaries. Key outcomes and decisions were then consolidated into

draft country reports, which then underwent quality review and internal consistency checks. In certain instances, the IRC members adjourned decision-making to avail themselves of additional information/clarifications from SCM/Technical partners and countries. During this review window, this

was also supported by a direct phone dialogue between IRC members and Myanmar. Other countries provided clarifications through e-mails/additional documentation moderated by the SCM/TA partners.

Decisions: Two decision categories: Approval with issues to be addressed and re-review with outstanding issues/action points to be addressed by country in next iteration.

Criteria for review: These did not change from recent windows and consist of the extent to which proposals meet (a) application requirements; (b) principles of Gavi support and (c) contribution to achieving Gavi mission and strategy.

Key review outcomes: The main outcomes per country application are summarized in **Table 1** below:

Table 1: Summary of Review Outcomes

	Country	M/R support requests	Other vaccine requests	Recommendation outcome
1	Bangladesh	MR follow up		Approval
2	Bhutan		PCV AMC	Approval
3	Burkina Faso	MR follow up		Re-review
4	Comoros	MR 1+2 dose + catch up		Re-review
5	DPRK	MR 1+2 dose + catch up		Approval
6	DR Congo	Measles follow up		Re-review
7	Kenya	MR follow up		Approval
8	Liberia	Measles 1+2 dose		Approval
			HPV routine + multi-age cohort	Approval
9	Madagascar	Measles 1+2 dose		Approval
		Measles follow up		Approval
10	Mozambique		CCEOP	Approval
11	Myanmar	MR follow up		Approval
			Rota	Approval
12	Nepal	MR follow up		Approval
13	Pakistan		Typhoid	Approval
14	South Sudan	Measles follow up		Approval
15	Tanzania	MR follow up		Approval
16	Zimbabwe	MR follow up		Approval

The quality of proposals submitted by countries continues to improve, with 16 out of the total 19 (84%) proposals recommended for approval. The IRC commends the efforts of the Secretariat and Alliance partners for their technical support to countries and continued efforts to improve the process. The implementation of phone calls/email dialogue with countries provides a further opportunity to demonstrate these improvements.

2.2. Good practices and promising innovations

The IRC notes that some country applications proposed innovations that have a potential to make significant positive differences to service delivery if strategies are further refined. Gavi and its partners should provide technical support to countries to enable them to also document learnings from these innovations. Gavi can continue to encourage and disseminate promising innovations.

Country specific promising activities are listed below:

- **Use of mobile banking (e.g. e-wallets)** to pay vaccinators will encourage transparency and accountability in field payments (e.g. per diems) - **DRC**;
- **Use of mobile phones and bulk sms** communication to transmit real time data e.g. **Nepal, Bangladesh**;
- **Use of the RapidPro system** to inform, engage and mobilize communities in **Pakistan**;
- **Integrated routine and campaign immunization card** using colors for differentiation in **Nepal** (with a cost saving potential).

2.3 Feedback on work processes

2.3.1 The IRC commends the Secretariat for its responsiveness to enhance better work processes and especially for a well-managed transition to the new premises. It further commends the Secretariat for the active follow up on previous IRC recommendations. IRC notes that not all applications have robust WHO pre-screening; and that M/MRFU applications did not include WHO comments in the pre-screening documents. A different concern was the naming of the Technical Assistance (TA) provider as an implied degree of quality of the epidemiological reports of the Measles applications.

Recommendations

- All references to technical support/consultants to countries should not be disclosed to the IRC
- WHO should ensure that all necessary applications get pre-screened as appropriate and at the highest level of quality possible, and that comments are included in the pre-screening document/template.

3.0 Key Findings

3.1. New Vaccines Support and Campaigns

Measles and Rubella vaccines

During this review window, thirteen countries applied for measles or measles-rubella (M/MR) support. Two countries (Madagascar and Liberia) applied for second dose measles-containing vaccine (MCV2) introduction into routine, and both of these applications were recommended for approval. Madagascar requested MCV2 with a preceding follow-up campaign, while Liberia applied for MCV2 introduction only since it had recently conducted a follow-up campaign. Two countries (Comoros, DRPK) applied for MR2 introduction with a preceding catch-up campaign; Comoros was not recommended for approval. The remaining nine countries applied for M/MR follow-up campaigns: Bangladesh applied for a wider target age-range (from 9 months to 9 years) while the other eight countries (Burkina Faso, DR Congo, Kenya, Myanmar, Nepal, South Sudan, Tanzania, Zimbabwe)

requested the standard follow-up campaign target age-range (9 to 59 months). Burkina Faso and DR Congo were not recommended for approval. The recommendation for approval for Bangladesh was for standard age-range (9 to 59 months). Funds requested amounted to US\$ 54.25 million for operational costs and introduction grants, and the total amount recommended for approval for ten countries is US\$ 39.04 million¹.

Issue 01: Continued reliance on nation-wide campaigns that do not reach the unreached in the campaign or subsequent routine programmes

Following previous IRC recommendations, countries presented epidemiologic analyses to justify their requests. These analyses were of varying completeness and quality in terms of describing age-specific and subnational immunity profiles as validated by measles surveillance data. Neither the impact of prior SIA coverage (and, where applicable, MCV2 coverage) nor information on results from outbreak investigations and associated vaccination responses were typically factored into estimations of age-specific population immunity. In applications where these immunity-impacting factors were mentioned, information provided was limited. For several countries, about half of the reported measles cases had vaccination status listed as 'unknown'. No country compared the calculated immunity profiles with the age-distribution of reported measles cases.

Countries seldom reflected on stagnant (and/or inflated) administrative MCV1 coverage and low MCV2 coverage (see Figure 1). Moreover, contrary to available evidence, countries often claimed success for previous SIAs despite failing to reach at least 95% coverage, validated by post-campaign coverage surveys (NOTE: The IRC was informed by the Secretariat that only 1 of the 12 recently implemented post-SIA surveys for M/MR SIAs had reached the 95% coverage target).

During this round, the IRC continues to be strongly concerned that many countries seem to be proceeding with generic campaign planning activities, combined with lack of targeted and adequately budgeted operational strategies, that make it unlikely that these countries will reach previously un- or under-vaccinated children (0-dose and 1-dose, respectively), and to reach at least 95% coverage. While some applications described specific efforts to target persistently under-vaccinated groups, sufficient evidence of budget resource allocations to appropriately prioritising those groups were lacking.

The IRC also noted with concern that countries continue to plan for traditional nationwide SIAs in 3 to 4 year cycles as the primary means to achieve and maintain high levels of population immunity needed to sustainably control measles. This includes situations in which recent SIAs have failed to reduce measles virus circulation. While SIAs provide a second opportunity for measles immunization to children who either missed the routine dose or failed to seroconvert following previous vaccination, they are not intended to and should not replace a strong routine immunization system. It is unclear how countries are supported to ensure that the M/MR strategy is delivering the outcomes anticipated, as the current mechanisms are not improving measles control in many countries.

After countries have introduced MCV2 into their schedule, there should be strong and sustained efforts to increase MCV2 coverage so that reliance on SIAs can be reduced and eventually eliminated.

¹ This amount does not take into account reductions in target population as per IRC recommendations for several countries

SIA will have the greatest impact if they are able to reach those children not previously reached through routine immunization services. Therefore, the non-specific nation-wide SIA is of limited value when routine coverage is reaching close to 90% for both MCV1 and MCV2. Countries that are reaching 90% coverage for both MCV1 and MCV2 should work to develop innovative outreach strategies to target the groups of persistently missed unvaccinated children. If the SIA only reaches those previously vaccinated through routine services, it will have limited impact on increasing population immunity. In countries that have managed to achieve high coverage with SIAs (i.e. at least 95% validated by surveys) but continue to have inadequate coverage of routine MCV1 and MCV2, there is a risk that Gavi support may inadvertently create a disincentive to focus their efforts on increasing routine coverage.

Once MCV2 is introduced, countries should focus their efforts on developing and implementing various creative and innovative strategies to ensure that every child receives two doses of MCV. For example, school-entry checks (coupled with provisions for “catch-up” vaccinations) offer one method to do this. However, this process often requires substantial resources and accompanying changes to immunization policy and legislation, as well as to practice.

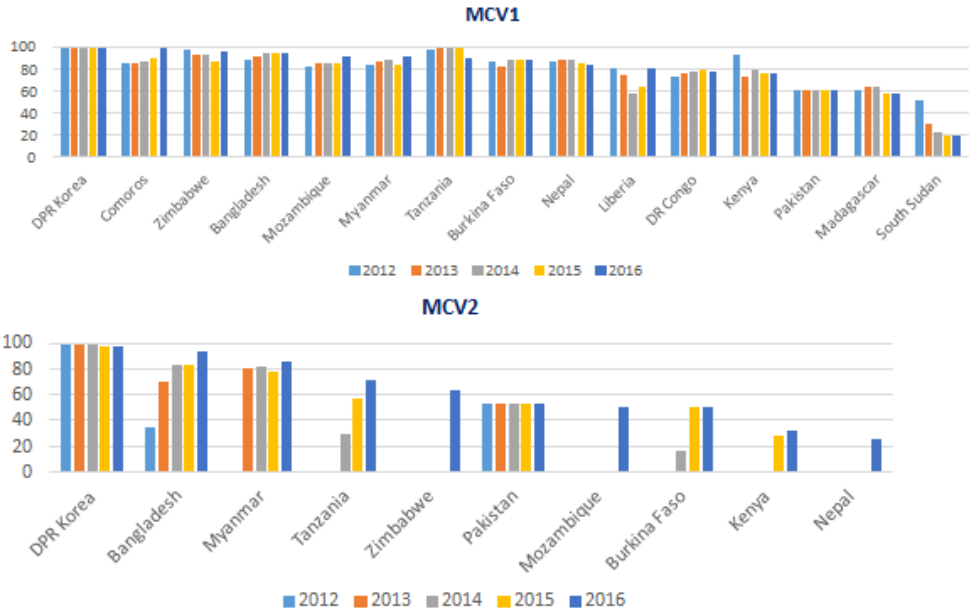


Figure 2: MCV1 and MCV2 coverage in applicant countries in the period 2012-2016

Recommendations:

- Gavi should consider allowing flexibility to countries to develop and implement innovative strategies, within the allowed maximum calculated budget, to target areas with high numbers of zero and one dose children. Moreover, Gavi may consider its overall investment in measles control that appropriately balances funding for both routine strengthening and appropriate SIAs.
- The Alliance needs to carefully consider how to best incentivize countries in accelerating MCV2 coverage to reduce the need for costly SIAs. This could mean providing incentives to countries for conducting high quality SIAs and for increasing both MCV1 and MCV2 coverage. Consideration should be given to earmarking a portion of the SIA application budget to fund activities for increasing MCV2 coverage as part of a second-year-of-life (2YL) platform. For SIAs, there could also be specific incentives for results achieved, such as when reaching high

numbers of zero- and 1-dose children (e.g. conditional cash transfer), and for clearly demonstrating how SIA efforts are helping to strengthen routine services (e.g. creating platforms for developing a digital vaccination register to target under-vaccinated children). Finally, there should be an accountability mechanism to reflect these objectives.

- WHO should develop guidance for countries to use an equity lens and available data to focus on efforts to reach the unreached (0 and 1-dose children), including the use of school-entry and other tools to increase MCV2 coverage. Triangulation between coverage and disease data is a key gap, and ensuring adequate resources for strengthening measles surveillance capacity is essential. Quality technical support and mentorship should be provided to countries to continue to improve collection, analysis and use of surveillance data to better inform measles control strategies, and support development of most cost-effective strategies to sustainably reduce measles virus circulation. This should include systematic reporting of 0- and 1-dose children.

Issue 02: Disconnect and overlap between MRI outbreak response preventive SIA, and routine strengthening

Lessons learned from measles outbreak investigations are seldom described in applications, and recent outbreak response activities were not clearly described and factored into the SIA applications. For example, Burkina Faso, recently submitted two parallel applications, one to the M&RI for a large outbreak response covering 26 of 70 districts and a Gavi follow-up SIA national application (reviewed by this IRC). This raises concern about duplication and the need for better coordination and integrated, cost-effective strategies for sustained measles control at country level.

Recommendations:

- Alliance partners and M&RI need to develop improved processes and procedures allowing integrated measles control strategies at country level, ensuring complementarity and value for money.
- M&RI should work closely with WHO and countries to ensure that surveillance data analysis, and outbreak response-related M&E data are collected and used to better inform measles control strategies and notably to enhance routine immunization strategies. This would involve developing epidemiological and programmatic reviews of measles outbreaks and outbreak responses to guide national measles control strategies (including a possible SIA funding request to Gavi), with a view to focusing on identifying the persistently unvaccinated, and the underlying causes for non-vaccination.

Issue 03: Continued missed opportunities to strengthen routine immunization services and to include other priority interventions within measles SIAs

SIAs offer the opportunity to boost national capacity and strengthen existing routine services through the attention given to programme components during planning and implementation phases, and can provide an excellent platform for delivering additional priority interventions, including other EPI vaccines. Only a few of the applicant countries included other interventions with their M/MR SIA. These are limited to deworming and vitamin A supplementation, and almost never include additional vaccinations (apart from Myanmar, which included catch-up of other vaccines in low-performing areas, and Nepal, which is provisionally planning to co-administer OPV).

Many countries present generic lists of routine strengthening objectives replicated from the global guidelines (i.e. list of activities that can be carried out before, during and after the SIA). In addition to their lack of specificity, the actions are not prioritised and are seldom chosen based on local routine immunization (RI) assessment, and virtually never plan to pool RI and SIA resources (e.g. refresher training courses which improve skills of health workers for both RI and SIAs) (*see Annex 2 for further analysis*).

Although integrating routine strengthening objectives and adding other interventions within measles SIAs may raise logistical challenges, they should be considered and included depending on whether they contribute to the main SIA objective of reaching the unreached at an affordable cost, and leave a legacy for the routine immunization programme.

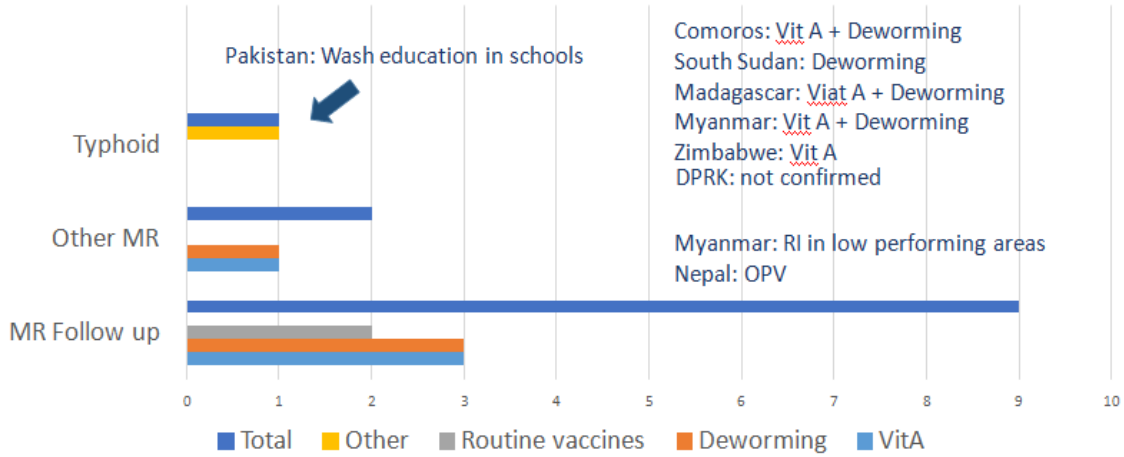


Figure 3: Integration of other interventions in SIA applications

Recommendations

Technical partners should:

- Encourage countries to use the SIA as an integrated platform to support the delivery of other vaccines and priority interventions. This could involve “catching-up” in other routine vaccines in areas of poor coverage and/or in delivering vaccinations using different strategies (e.g. Periodic Intensification of Routine Immunization).
- Ensure strengthening of routine immunization services by countries through SIAs needs to be specific, measurable and budgeted, and should include support to the second year of life platform and measurable investments in increasing MCV2 coverage.

HPV national introductions

The IRC reviewed three applications for national rollout of HPV vaccine (Zambia, Lao PDR, and Solomon Islands). All three opted to vaccinate a multiyear cohort the initial year, taking full advantage of this Gavi support window, which is in line with WHO recommendations to accelerate impact of the vaccine.

The IRC noted several “best practices” in the HPV applications. The technical support offered to countries via the vaccine focal point, Senior Country Managers, and technical partners was seen in the attention to detail and the revisions that occurred in the writing and pre-submission screening process

resulting in complete, thoughtful proposals. The structure of the Gavi HPV application form also assisted with improving proposal quality and could serve as a model for other vaccine window applications since the fine-tuned questions posed in the form prompted countries to develop thoughtful and sustainable delivery plans. Additionally, countries developed approaches that leveraged their local context. For example, Zambia chose a delivery strategy that utilizes the option for a 12-month period between the two recommended doses so that vaccination can be embedded in the well-established annual child health days. Finally, applications from this round demonstrated increased attention to the microplanning and mapping that will be required to achieve high coverage in out-of-school girls.

Typhoid Conjugated Vaccine (TCV)

One country, Pakistan, applied for support to introduce TCV into routine EPI and a catch-up campaign including all urban areas in the country to enable rapid control, especially for the drug-resistant outbreaks. Both activities will be implemented in a phased manner over a 3-year period. The IRC recommended the application for approval.

Issue 04: Limited data on disease burden or modelling on epidemiological trends and patterns for targeting use of TCV and contribution to “learning agenda”.

The IRC was pleased to receive the first application for TCV in this round. Pakistan was proposing to introduce the routine dose of TCV nationwide, while conducting a nationwide catch up campaign in urban settings (target population estimated of 35,869,573). Despite the new WHO position paper on typhoid vaccines, there remains much to be learnt about the optimal population use of the vaccine, given the very focal nature of disease - clustered around extreme poverty, lack of paved roads, and lack of sewerage systems. In addition, there are no formal surveillance guidelines available to measure impact of the vaccine. For catch-up vaccination, in the absence of good data on risks, the control strategy selected was to be used in all urban settings, but this may not be the best use of resources. Another critical aspect of the vaccine, given that it will not prevent the other enteric infections including paratyphoid, is the need to complement the Water, Sanitation and Hygiene (WaSH) agenda. However, in countries with typhoid, including Pakistan, WaSH programmes receive a fraction of the resources.

TCV shows much promise and has the potential to reduce morbidity and mortality. For Pakistan, there is also the opportunity to see if the vaccine is an effective tool against extensively drug resistant strains. The IRC considered that as presently planned, the introduction would not sufficiently contribute adequately to the “Learning agenda” on how to deploy TCV. This partly reflects the lack of Gavi guidance on impact evaluation and the need for additional WHO guidance on assessing risk where there is limited or no surveillance data; how to use different proxies of risk that are available; and the different potential ways to monitor with a minimum required for TCV introduction in an area.

Recommendations

- The opportunity to assess the impact of Pakistan Typhoid vaccination should not be missed. An evaluation protocol should be prepared if not already considered.
- The IRC recommends that WHO and Alliance partners provide improved technical guidelines before allowing new TCV applications to be submitted to Gavi. The guidelines should include

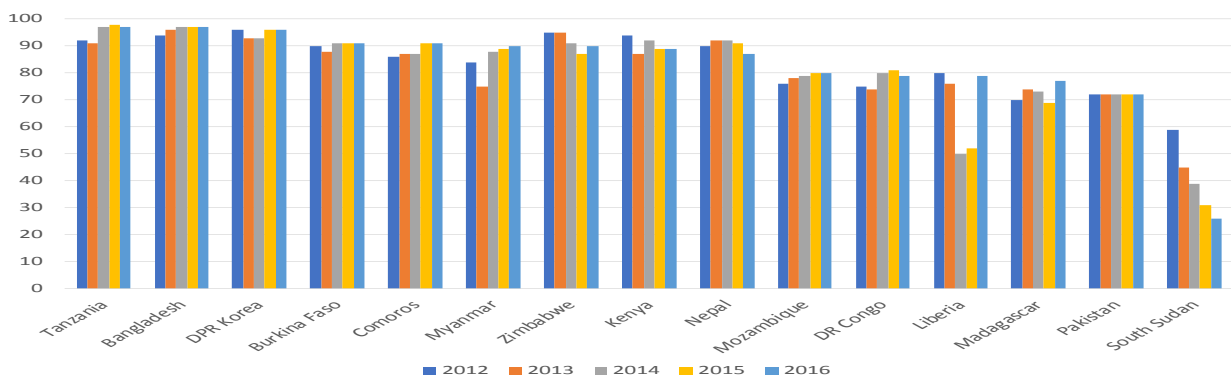
surveillance and tools to assess and interpret risk in the absence of laboratory surveillance, with the view to optimizing the “learning agenda”.

- Gavi should provide earmarked funds for typhoid surveillance as part of vaccine support, and clearly outline a strategy to monitor impact. Applications should in addition identify options for use of TCV that can help WaSH.

3.2 Coverage and Equity

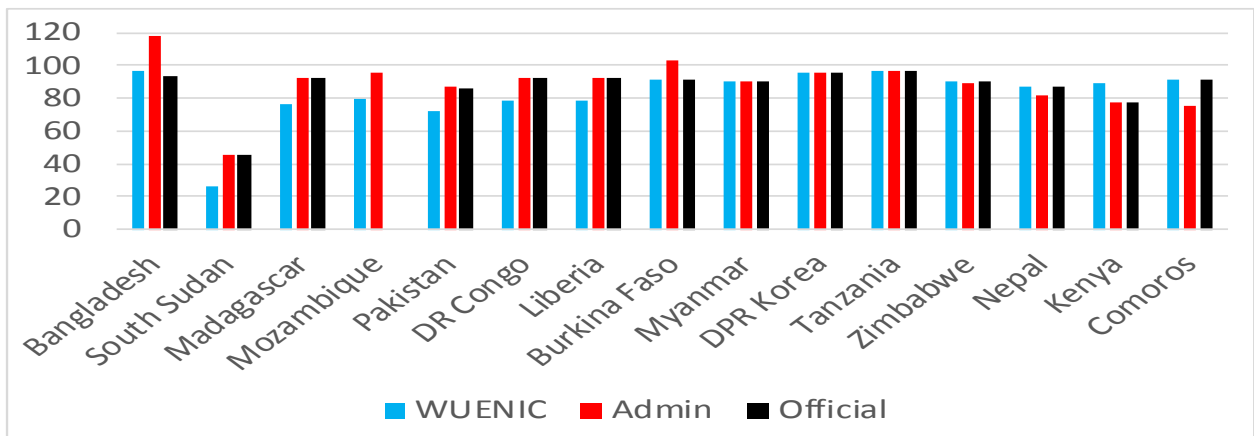
All the applications included coverage and equity data, as required. However, the way countries report these data suggest important limitations in how they understand them. Applications often fail to demonstrate how countries use available data to guide programming to increased coverage equitably. For countries applying in this round, the general trend of coverage for DTP3 shows a few countries performing well, but most have not reached the 90% national target (See Figure 4).

Figure 4. WUENIC DTP3 data, countries ranked by 2016 data



The WUENIC data on coverage are based on nationally reported data that are then adjusted based on survey and population data. WUENIC data do not provide a precise estimate of coverage, but have become the standard that is used by Gavi for eligibility and reward decisions. Yet, many countries seem to ignore these data, and instead focus on reported data (administrative coverage data), without adjusting for survey data that are often available at subnational levels (in contrast to WUENIC which is only for national level.)

Figure 4: 2016 DTP3 coverage ranked by difference between WUENIC and administrative data



Official = Country’s official estimate

Issue 05: Continuing Data quality challenges of National Programmes

The failure of national programmes to adjust reported data and the apparent consistency of the gap between administrative and survey/WUENIC data over the past decade is a concern. The efforts at improving data quality do not seem to be bearing fruit.

The failure to triangulate between data sources, including use of vaccine-preventable disease cases may reflect the lack of incentives for programmes to improve data quality. But without good data, it is hard to guide the programme.

Recommendation:

Countries to triangulate multiple data sources in reviewing and reporting national and subnational coverage data, and not limit to reported data unless this is reliable. Increased efforts/investments are needed in most countries to improve reported data quality, with the appropriate TA to guide the efforts.

Issue 06: Lack of in-depth analyses to understand key drivers of inequities and low coverage

The focus on equity is now well accepted as a key measure of the system's performance. However, the reports from countries in the applications only reflected the findings of the recent DHS or other survey. No deeper analyses of equity were provided, or exploration in under-served communities for the reasons for low coverage. As a result, countries do not develop specific interventions to improve the equity of coverage. Improvements in equity can follow general improvements in service delivery, but a focus on under-served communities and meeting their specific needs may be a more efficient and effective way for countries to improve coverage.

The issue was highlighted in the typhoid application by Pakistan, given its large geographical and socioeconomic differences in coverage that may mean the ones who most need typhoid are least likely to get it ('inverse care law'), thus reducing the impact of this new vaccine introduction. The opportunity to use typhoid introduction to the routine schedule appears to be a potential missed opportunity to improve equity of Pakistan's EPI – and needs to be encouraged for future applications.

Recommendations

- Increased efforts/investments are needed in most countries to improve reported data quality.
- Technical partners should actively support countries to go beyond survey data in understanding and address inequities in coverage based on specific communities and their needs, with specific pro-equity focus for reaching under-served communities as well as overall improvements in service delivery.

3.3 Data Use and Quality; AEFI

Data use and quality

Issue 07: Quality of data affects the value of situational analysis and justification for the SIA

In this IRC round 10 out of 13 (77%) applicant countries for M/MR SIA reported on data quality assessment and/or annual desk review. All 13 countries provided a measles situation analysis, with 7/13 (54%) countries including the findings from the Measles Programmatic Risk Assessment Tool (MPRAT) to support their SIA need justification. The MPRAT is an Excel-based tool that uses various data elements from the immunization and surveillance programmes to generate a risk score for future measles outbreak. The resulting risk maps were included in these applications as justification for the planned SIA, without any further triangulation with other sources of data. The tool uses the routine coverage data, despite being unreliable (10-20% point difference for WUENIC), and the IRC noted that the risk maps did not correspond well to spot maps of measles, raising the question of the utility of the measles risk assessment tool especially when not based on high quality data for the purpose of SIA justification.

Recommendation

Gavi should continue in its efforts to improve data quality and the data-literacy of programme managers. In addition, an evaluation of the MPRAT should be considered along with developing new ways to assess and address risk.

Improving the quality of the measles situation analyses and risk assessments requires data and information from multiple sources, including from post-campaign coverage surveys, other coverage surveys, outbreak investigation and responses. Triangulation of data allows meaningful analysis, which should be translated to programme actions to boost coverage.

AEFI Surveillance related issues

Issue 08: Re-emergence of preventable vaccination errors ('programmatic errors')

By definition, mass vaccination campaigns involve a large number of vaccinations in a short time period. Therefore, adverse events become more visible as they are more frequent, even if the rate of adverse events to the vaccination had not changed. Also, given the intensive social mobilization that takes place during SIAs, the increased number of adverse events receive more attention by both health care workers and the public, even if the rates of events remain unchanged.

Countries are well aware of the capacity of AEFI to derail the campaign and negatively impact the routine immunization programme as a whole, therefore in their plans of action the emphasis is on establishing AEFI committees and causality assessments trainings that would boost countries' capacity to detect, investigate and causally assess vaccine reactions. In contrast, injection practices, often considered 'solved' with the introduction of AD syringes, are not being given enough focus. The large number of injections administered during SIAs adds strain on the system and increases the likelihood of errors in vaccine handling and administration. As the events during the 2017 campaign in South Sudan proved, (and as in other countries where this has been reported) non-adherence to safe injection practices can lead to tragic consequences. These vaccination errors (formerly known as programmatic errors) are preventable. Therefore, adequate attention should be given to improving injection practices through adequate training before and close supervision during the SIA.

Recommendations:

The use of AD syringes is not sufficient to ensure injection safety, and countries need to assure correct vaccination practices through effective training and monitoring programmes. Practical skills training must be hands-on and must follow adult training principles. SIAs provide an opportunity to train vaccinators and vaccinators training should take place before every SIA even for the experienced vaccinators who contribute their skills transfer. Countries should follow WHO guidelines and plan the training in recommended timeline (2 to 4 weeks before the SIA). Digital tools can help programme fidelity; if training by cascades is appropriate, there should only be two levels to avoid dilution of messages. In addition, to ensure that proper procedures are in place and followed, close and skilled supervision during campaigns is essential.

3.4 Immunization Supply Chain Logistics (CCEOP and CCL cross cutting)

The July 2018 IRC was pleased to note the progress in implementing CCEOP and looks forward to formal evaluations of field performance and lessons.

The July 2018 IRC review identified key issues in reviewing the supply aspects of 18 NVS applications from 15 countries (routine and campaigns) and one CCEOP from Mozambique. As noted in previous IRC reports, NVS applications often report cold chain storage and transport adequacy for the new vaccines, but do not provide the assumptions and calculations to demonstrate it. In this round, the IRC again noted that calculations at subnational levels were either not done or done without reference to the population being served. Countries need to develop their data systems (CCE inventories) to be able to better manage vaccines. Gavi may wish to review the minimum data to show supply chain adequacy for new vaccines and for campaigns.

Issue 09: Warranty of cold chain equipment

Country expectations are unclear and may not be aligned with the actual support of the manufacturer's within the warranty. Countries are required to submit a maintenance plan as part of CCEOP application. A key element of this plan is budgeting the maintenance cost. This requires clear understanding of the manufacturer's warranty. For example, if spare parts are needed; how failures will be addressed under the manufacturer's warranty and how pre-maintenance and /or user's precautions should be performed to avoid dispute about causes of failures.

Furthermore, the maintenance plan reviewed did not clearly distinguish those anticipated failures that can be covered by warranty and those failures to be addressed by in-country maintenance. Nor was it clear to the IRC.

Recommendation: GAVI and technical partners to closely monitor the application of the warranty for CCE supplied under CCEOP in countries and to clarify warranty coverage and conditions. From this Gavi to follow up with Unicef Supply Division to provide clear guidance to countries on the terms, conditions and scope of warranty; and any implications on spare parts needs and the maintenance budget.

Issue 10: EVM improvement plan implementation and impact:

The EVM assessments were carried out in countries with a vision to systematically improve the immunization supply chains in line with recommended standards. The EVM assessments are used to

develop an improvement plan to achieve this aim. Both documents are required for new vaccine applications to ensure that the immunization supply chain is strong enough to support the vaccine request or campaigns. However, improvements plan are poorly tracked (once a year, outdated submissions) and show slow progress both in terms of completing the activities as tasks and completing the activities that make the big difference in performance of supply chain. EVM improvement plans are task-driven rather than results-driven, and it was not clear if implemented activities had achieved the expected results.

Recommendation: Alliance partners should ensure that EVM improvement plan is tracked and monitored by the countries, not just for completion of activities but also for the results achieved.

Issue 11: Waste Management: Weak/insufficient plan to manage waste.

Bangladesh, DRC, Zimbabwe are large countries with huge waste particularly for mass vaccination campaigns with target populations in the millions. Large quantities of hazardous waste will be generated with new introductions and campaigns. Some countries, such as the DRC and Burkina Faso, plan to use private providers to eliminate all or part of the waste from vaccination campaigns. However, there is weak/insufficient infrastructure and poor planning (and budgeting) around waste management by other countries. This has also been as illustrated in IRC global report of March 2018. The reviews of July 2018 confirmed this trend.

Recommendations

- Countries need to review and analyse their current system of waste management to cope with additional quantities of waste generated in mass campaigns.
- Gavi should review application guidelines to ensure proper planning and budgeting for the management of waste generated by the campaigns and need to include incentives that reward and encourage innovative waste-management strategies.
- Countries need to be strongly encouraged and technically supported to adequately budget for strategic and specific activities to address the identified gaps on waste management.

3.5 Budget review of NVS Applications

Issue 12: Compliance with Gavi's "Guideline on supporting government HR capacity"

During this IRC round, four (4) countries in the preparatory transition phase (Bangladesh, Kenya, Myanmar and Pakistan) submitted applications, which include operational costs for 3 MR campaigns and a Typhoid campaign. Considering the expected fiscal space in these types of countries, Gavi Operational Guidelines on HR capacity include limitations to fund certain HR-related costs, such as salaries, incentives, allowances, etc. According to Gavi historical trends such costs represent between 30 and 40% of the total OPs costs of campaigns independently of the status of the applicant country. Therefore, Phase 1 countries are discouraged to budget for HR-related costs and can only do so under justified exceptional circumstances.

The budget review during this IRC session revealed that all 4 budgets submitted for campaigns did not comply with the Gavi Operational Guidelines on HR costs (HR costs as a proportion of total requested budget): Bangladesh with over 60%; Kenya budgeted up to 55% of its OPs budgets for DSA allowances;

Myanmar: 47%; and Pakistan: 46% with a total amount of DSA of \$8.7 million out a budget of \$19 million.

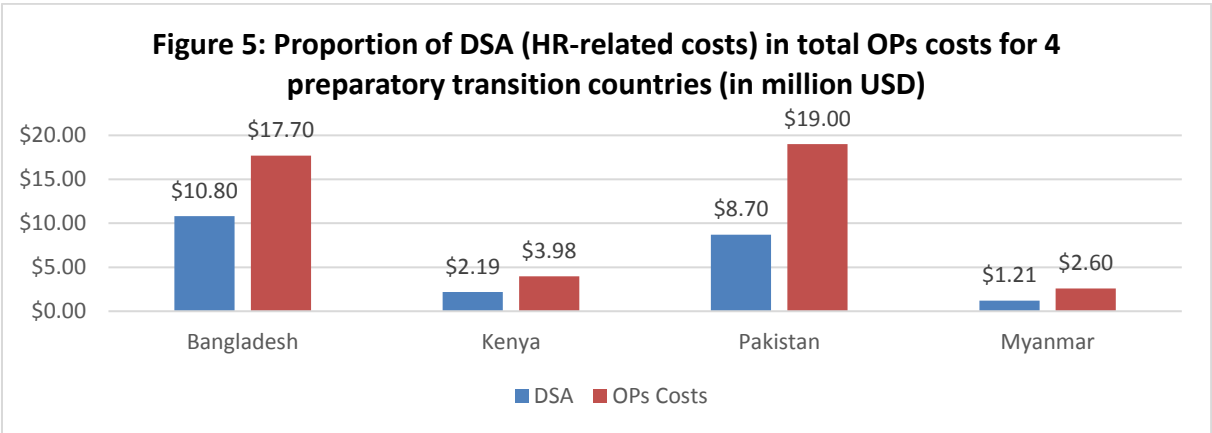
This review also highlighted the urgent need to clarify the guidance around the definition HR costs in the context of one-off campaigns which last maximum between 1 and 2 weeks. According to the majority of OPs budgets reviewed in this and previous IRC rounds (regardless of the status of the applicant country), it is apparent that some costs are related to the nature of the campaigns involving the mobilization of large number of staff and volunteers within a short time window. These include costs such as DSAs for vaccinators (whether permanent staff in front line health posts or volunteers from local communities), DSAs during trainings conducted for preparation and planning stage and DSAs for supervisors (from all levels of the health pyramid) during the active phase of the campaign.

Given that campaigns remain an important component of measles control activities at country level, Gavi guidance should be specific in listing out unallowable cost items in OPs budgets and in providing a clear definition of “exceptional circumstances” under which these costs can be accepted. With IRC advising countries to focus SIAs on hard-to-reach children, Gavi guidelines should consider whether some flexibility can be applied when targeting these populations to reach out to un-, or under-vaccinated children. Gavi should also consider whether the transitioning status of these countries would be better reflected by applying a mandatory co-financing to some of these costs, thus increasing the financial contribution and ownership of applicant countries.

Table 2: Proportion of DSA (HR-related costs) in OPs costs budgets for Preparatory transition countries (in millions of USD)

Preparatory Transition Countries	DSA Allowances (HR-related Costs)	TOTAL OPs Budget	% of TOTAL OPs COSTS
Bangladesh	\$10,80	\$17,70	61%
Kenya	\$2,19	\$3,98	55%
Pakistan	\$8,70	\$19,00	46%
Myanmar	\$1,21	\$2,60	47%
TOTAL	\$22,90	\$43,28	53%

Figure 5: Proportion of DSA (HR-related costs) in total OPs costs for 4 preparatory transition countries (in million USD)



Key Findings:

1. During this round, all 4 preparatory transition countries submitted budgets including HR-related costs above the Gavi historical trend (30% to 40%)
2. Inclusion of HR-related costs in the OPs costs budget were not justified by exceptional circumstances as required by Gavi Operational Guidelines on HR capacity;
3. The inclusion of HR costs in campaigns' budgets (such as DSA for training participants, vaccinators, supervisors, etc.) is a reflection of existing large-scale delivery strategies of disease control campaigns.

Recommendations:

1. Gavi guidance around HR-related costs in OPs budgets needs to be specific by listing out unallowable HR-cost items and clearly defining the notion of "the exceptional circumstances" under which these costs can be funded;
2. Gavi should consider the following options in relation to HR-related costs in OPs budgets:
 - a. Request countries to re-submit, at the screening phase, any budget which is not compliant with the Gavi OG on HR-related costs;
 - b. Adapt pragmatically the actual guidance on HR-related costs and align it to campaigns' implementation reality on the ground; ensure any cash payment (DSA) goes to active front line vaccinators and campaign targets are met. These checks and controls on cash payments can be done through Gavi routine internal reporting and auditing mechanisms;
 - c. Require mandatory co-financing for some defined list of most "recurrent HR-related costs" such as incentives, allowances, and per diems.

Issue 13: Budget preparation and adoption

Applications show that in many cases, the budget was prepared and adopted at the central level with little evidence of meaningful involvement of subnational and front-line health managers. This may lead to possible underestimation of field budget needs; focus on central and regional levels; and low buy-in from those delivering vaccination activities at field level.

Recommendation

In the budget design and adoption process, countries should identify mechanisms allowing involvement of sub-national level managers in budget development and adoption. This is likely to enhance budget synergies, realism and transparency.

Issue 14: Sources of funding and contributions from Government and partners

Many countries indicated that partners would fund part of the campaign expenses (in some case with a share over 30-40% or more of total cost). However, in most cases, there is no certainty that this funding has been clearly identified, confirmed and effectively budgeted. These external contributions tended to support key activities such as microplanning, surveillance, post-campaign surveys and social mobilization. This uncertainty creates a potential risk for the quality of the campaign, in the case funds cannot be found and disbursed.

Two other points deserve some clarifications:

- For some countries (e.g. DRC in this session), the government contribution is represented by the staff mobilized and paid by the public sector. This is an in-kind contribution and not additional cash resource.
- In a number of cases, contributions from partners particularly WHO and UNICEF are being funded by Gavi under the PEF/TCA.

Recommendation

Gavi to clarify process to ensure that Government and partners funding is appropriately requested, with a clear timeline. If other contributions do materialize by a set date, consider re-budgeting Gavi funds to ensure that critical vaccination activities are adequately funded (e.g. microplanning, social mobilization, survey). Gavi Secretariat to clarify what should/could be considered as *additional funding* both from Government and from Partners.

3.6 Technical Assistance

The IRC note that the technical partner inputs have improved over the years and most especially with the introduction of the PEF. Some of the applications especially for the HPV National Introduction demonstrate clear strategic focus and feasible interventions. However, this is not crosscutting for all applications reviewed and in particular, the M/MR applications.

Issue 15: Applications do not reflect the investments around PEF/TCA support

A number of the M/MR follow up campaign applications did not demonstrate sufficient strategic interventions that would reflect the investments made over time. Gaps in applications as highlighted under the MR section 3 above further buttress this fact. The IRC is especially concerned about the timeliness, depth and quality of technical assistance available to support countries. An illustrative example is presented as follows: ***“Country XX has submitted two detailed proposals attempting to strengthen efforts to further control measles. In order to continue strengthening routine immunization, for this 6th periodic mass campaign, the country is requested to develop specific strategies to finally tackle the issue of the 20% always missed. If this is not done, the need for mass vaccination will continue forever even if the 2nd dose is introduced. As campaigns are always referred as “supporting routine”, this has to be translated in activities and measurable impact, not just lip service”...***

Given that the PEF has been operational for some time now, it is unclear what the transparency, accountability and output measurement rules and approaches are around the resources.

Recommendations

- Gavi should institute a rapid response system around PEF/TCA support to enable countries to maximize its benefits.
- TA partners need to focus on timely and robust technical support to countries especially on campaigns. This will enable them to develop strategic and well integrated interventions that can rapidly improve and sustain coverage.

3.7 Governance

Gavi is in the first year of a more deliberate engagement in technical assistance for ICCs and NITAGs. Strong country fora demonstrate country ownership and political will. They are an important contribution to EPI sustainability as partner countries move towards transition. As countries' socio-economic situation improve and they move closer to transition from Gavi support, less donors and partners are present in-country and the importance of NITAGs to facilitate evidence-based decisions that implicate domestic resources become more relevant. In addition, the establishment and strengthening of NITAGs requires time and cannot be left to the last years of Gavi support. NITAGs offer value to ownership and stewardship across the transition spectrum of countries (initial – accelerated – fully co-financing). In the following analysis, Bhutan, as a graduate country without an ICC, is excluded.

3.7.1 ICC Functionality

All of the 15 countries presenting applications in July 2018 had either an HSCC or an ICC. Most had a long experience while one (Comoros) had only started functioning in 2017. Only two of the ICCs (DPRK and Myanmar) had no CSO/NGO participants.

In this review, six of the countries (South Sudan, Pakistan, DRC, Kenya, Tanzania, and Nepal) are devolving health sector delivery to the **sub-national level** (province, state, county). There are different approaches to sub-national participation on the ICC. For example, in Kenya, there is a technical representative of County Governments while, in Pakistan, the NICC includes membership of both national and provincial staff responsible for managing immunization programmes. In Pakistan, they will be testing the use of video conferencing to ensure provincial voices are heard at the NICC. It may be useful to assess the success of these two approaches in ensuring sub-national levels on the IRC.

Issue 16: The IRC was concerned to observe that none of the 4 applications coming back from re-review had been endorsed by their national ICCs before resubmission.

Recommendation

ICCs should be involved in re-review and this should be reflected in the 2019 Gavi guidance by the Secretariat.

3.7.2 Functionality of NITAG

Only 13 of the 15 countries had established NITAGs. Two are to be formalized in late 2018 (Liberia, Madagascar). Five of the 13 were set up in the period 2016 to 2017 and are not yet fully established. Only 7 meet all six WHO criteria.

NITAGs remain “works in progress” intended to provide independent local scientific and technical knowledge to national EPI strategies. It was suggested that it would be useful to add ICT expertise (Information and communication technology) to the list of skills needed in NITAGs.

Issue 17: Need to maximise use of independent local knowledge to ensure high quality programme approaches.

The IRC is concerned that local independent knowledge is not being used to best advantage. For example, at this session, 13 countries presented measles, MCV2, or MR proposals. Of these proposals, only 4 were presented to a NITAG for review; in the case of Burkina Faso, this was specifically at the request of the Minister of Health. Some countries considered that a NITAG review was unnecessary since these particular vaccines are not new introductions. However, the IRC considered that such a review would help situate the proposals in the context of the country's overall immunization strategy.

As well, members flagged the fact that CCEOP applications are often not reviewed in tandem with the broader immunization strategy.

Finally, it was noted that none of the Proposals resubmitted after re-review had been endorsed by NITAGs or ICCs before resubmission to Gavi. This means that the IRC concerns are not discussed by the NITAG to determine whether such concerns have all been addressed.

Recommendations

- Where NITAGs are established and functional, they are strongly encouraged to sign off on re-reviews to ensure IRC concerns especially where technical have been fully addressed;
- Gavi and partners to reflect on how NITAGs can benefit CCEOP applications and the design of the cold chain strategy
- Gavi and partners to reflect on how, in the context of countries' broad strategies, can NITAGs contribute to the Plans of Action for measles and MR applications. Gavi guidelines for 2019 to consider reflecting this;
- Technical partners especially WHO and Global NITAG Network should support countries add ICT expertise (Information and communication technology) to skills set on NITAGs.

4.0 Conclusions

Whilst the IRC further commends Gavi and its Alliance partners for the strides towards TCV introduction, it is critical that Gavi and its partners (especially WHO) to ensure the availability of clear technical guidelines including surveillance and tools to assess risk in the absence of laboratory surveillance to support countries develop robust TCV applications. Gavi should further provide earmarked funds for typhoid surveillance as part of vaccine support, and clearly outline a strategy to monitor impact. The IRC strongly recommends that these need to be in place before further TCV applications are submitted for review.

The IRC remains strongly concerned that many countries seem to be proceeding with generic campaign planning activities that are least likely to reach previously un- or under-vaccinated children (0-dose and 1-dose, respectively) or reach at least 95% coverage, and continue to plan for traditional nationwide SIAs in 3 to 4 year cycles as the primary means to achieve and maintain high levels of population immunity needed to sustainably control measles. The IRC reiterates that while SIAs provide a second opportunity for measles immunization to children who either missed the routine dose or failed to seroconvert after previous vaccination, they should not replace a strong routine immunization system. There is an urgent need for Gavi and its technical partners to reassess how countries are supported

technically to apply the M/MR strategy in their specific epidemiological and system context so that SIA would achieve proposed results and contribute to overall M/MR global outcomes. Gavi and its partners should further consider how to incentivise more integrated campaigns; and better support countries to understand and address inequities with a focus on the routine MCV2 and 2YLP.

The IRC reiterates the need for the urgent completion and dissemination of the Gavi operational guidelines on HR capacity especially in respect of preparatory transition countries. Gavi should strongly consider encouraging mandatory co-payments for recurrent HR-related costs in transitioning countries.

Finally, the IRC commends the efforts of the Secretariat staff especially the A & R team, the focal points and SCM managers for their technical support to the review process. During this window, the IRC particular noted; and identified proposed innovations in country applications with a potential to make significant positive differences to service delivery. It enjoins Gavi and its partners to provide technical support to countries to fine tune the innovations and also document learnings from these innovations for scale-up and experience-sharing purposes in the near future.

Acknowledgements

The IRC acknowledges the Gavi executive team for their continued responsiveness to key IRC recommendations; the A & R Team especially Adrien de Chaisemartin, Patricia Kuo, Sonia Klabnikova, Verena Oustin, Elodie Sarreau; Friederike Teutsch, Ebun Okunuga, the Country Programme Team especially the Senior Country Managers/key members for invaluable insights into the country activities and progress. The IRC further acknowledges the role of the CCEOP/HSIS Team especially Hamadou Dicko in ensuring that the lessons learned from the roll out of the CCEOP platform continue to be rapidly integrated and shared through revised guidelines. Finally, the IRC particularly thank the WHO and all the Alliance partners for their invaluable technical inputs and increasing attention to quality technical support to countries.

ANNEXES

Annex 1: List of IRC Reviewers; July 2018

No	Name	Nationality	Profession/Specialisation	Gender	French Speaking
1.	Aleksandra Caric	Croatia	Independent Consultant	Female	X
2.	Art Reingold	USA	Head, Division of Epidemiology & Biostatistics, School of Public Health, University of California	Male	
3.	Benjamin Nkowane	Zambia	Independent Consultant	Male	
4.	Bolanle Oyeledun – CHAIR	Nigeria	CEO, Centre for Integrated Health Programs	Female	
5.	Bradley Hersh	USA	Independent Consultant	Male	X
6.	Clifford Kamara	Sierra Leone	Health Sector Coordinator, Ministry of Health and Sanitation, Sierra Leone	Male	
7.	Diana Rivington	Canada	Independent Consultant	Female	X
8.	Jean-Marc Olivé	France	Independent Consultant	Male	X
9.	Linda Eckert	USA	Professor, University of Washington (Gynaecology)	Female	
10.	Mario Stassen	The Netherlands	Independent Consultant	Male	
11.	Miloud Kaddar	Algeria/France	Independent Consultant (ex WHO)	Male	X
12.	Osman David Mansoor	New Zealand	Public Health Physician, Regional Public Health, New Zealand	Male	X
13.	Ousmane Amadou Sy	Senegal	Independent Consultant	Male	X
14.	Philippe Jaillard	France	Independent Consultant	Male	X

15.	Ranjit Dhiman	India	Independent Consultant	Male	
16.	Sandra Mounier-Jack	France/UK	Lecturer London School Hygiene and Tropical Medicine (Health Policy)	Female	X
17.	Zeenat Patel	Canada	Independent Consultant (JSI outside of the IRC)	Female	

Annex 2: ANALYSIS OF INTEGRATION OF CAMPAIGN ACTIVITIES BY COUNTRY

Country	Request	Integrate the campaign with other intervention	Multi-antigen	Strengthening of routine
Tanzania	MR follow up	No <i>(2014 SIA OPV, deworming, Vit A)</i>	No	Inclusion of a chapter on routine MR2, further information about AEFI and specific surveillance guidance will be added to the training manual . Will build on microplanning to reach out under-immunised communities MR SIA messaging will include messages about routine vaccination Engagement with school authorities to screen immunisation and identify defaulters, training on wastage.
Pakistan	Typhoid catch up + routine	Educational wash intervention in schools	“Routine EPI services for other antigens will also be offered to eligible children in these communities during the typhoid campaigns.” Co-administration of (MR) discussed and discounted (AEFI, complexity, age range, new vaccines). “Measles-rubella campaigns in 2020, targeting children aged 9 months to 15 years”	Strengthen the existing AEFI surveillance system, micro plans, training, advocacy, Detailed urban routine immunization plans, Use of technology (android based applications for tracking of vaccinators in out-reach service delivery) is being rolled out across the country. E-VACC in Punjab has ensured equitable coverage across the province by monitoring the attendance of vaccinators as per their micro-plans. No details on the introduction routine plan.
Burkina Faso	MR follow up SIA	No	No	The data collected will allow to strengthen the routine vaccination through activities such use of updated micro-plans; developing adapted strategies for hard to reach populations; organisation of targeted PIRI in areas of low coverage and systematic search for defaulters with community support. Other strengthening activities listed include co-administrating MR2 with MenA vaccine, integrating MR with nutrition activities and more largely

				communicating with the new schedule, with involvement of CSOs, parents, and schools
Comoros	MR catch up SIA + routine	Vit A and Albendazole	No	Plans to strengthen RI listed including using micro planning to identify under vaccinated children; advocacy; training includes routine
South Sudan	MR follow up SIA	Deworming <i>It is expected that the March and Nov Polio SIA round will be integrated with Albendazole and Vit A.</i>	No <i>In 2019 the country has planned for 3 rounds of Polio SIA and 2 rounds of PIRI with the Polio SIA in Feb, March, and Nov while the PIRI will be planned for March, April, May round 1 and Sept, Oct and Nov for the 2nd round.</i>	Mentioned, as campaign are using the same approach for routine (no routine) - PIRI service delivery approach accounted for 66% - 74% of all antigens provided to infants in 2017 in the country – The SIAs coverage data and data related to the number of zero dose children reached in specific counties will be factored into any future plans for routine immunization and PIRI activities.
Bangladesh	MR follow up	No	No	Update RI micro plan based on SIA micro plan and identification of hard to reach areas, drop-out and left-out children, include RI message during SIA training, capacity building of health workers on injection safety, AEFI management, cold chain and vaccine management, use of supportive supervision technique and tools, include RI message in SIA posters, RI invitation card and using RCM to identify drop outs/lefts out. All identified zero dose and 1st dose MR receiving children will be vaccinated through routine immunization considering the 28 days interval.
Madagascar	M follow up , MCV2	Vit A, Albendazole	No	Training, microplanning, AEFI, 0 dose follow up, communication and messages. Added PIRI into the budget!
Myanmar	MR follow up ,	VitA, deworming in low performing and hard to reach areas	Yes - routine immunisation catch up in Kachin and Shan State and EHOs from Shan, Kayin and Kayah	Surveillance strengthening, advocacy, providing information on routine immunization through MR invitation cards for referrals
Zimbabwe	MR follow up	Vit A <i>(Mebendazole will be done at other time)</i>	No	Training on REC, microplanning, safe practices, surveillance, Information on children for follow-up will be given to community based health workers for further follow up

DRC	MR Fu	No	No	Microplanning, surveillance, data analysis. Organise activities for Periodic Intensification of Routine Immunization (PIRI) against measles in the towns identified at risk based on the new risk analysis tool. During the immunization campaign, a team will be assigned so that routine immunization is not interrupted.
DPKR	MR catch up	Considering Vit A , Mebendazole. Not confirmed	No	MICRO PLANNING, COMMUNICATION & SOCIAL MOBILIZATION, SUPERVISION & MONITORING and TRAINING
Nepal	MR Fu	No	OPV is mentioned as possible inclusion	Efforts to identify unreached children, including sending SMS to defaulters, training advocacy, surveillance, use of information from post campaign coverage survey on zero-dose children to cross-check with previous estimates of coverage
Kenya	MR Fu	No	No	Augmenting demand for measles-rubella vaccine among communities, strengthen staff capacity
Total		5 Vit A + 4 deworming + 1 wash intervention	2 in low coverage areas + 1 considered	All to different degrees