# REPORT OF THE INDEPENDENT REVIEW COMMITTEE TO THE GAVI ALLIANCE ON THE REVIEW OF APPLICATIONS

3 – 14 June 2024

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# List of acronyms

| 2YL      | Second year of life (platform)                             |  |  |  |  |  |  |
|----------|--|--|--|--|--|--|--|
| AEFI     | Adverse event(s) following immunisation                    |  |  |  |  |  |  |
| CCE      | Cold-chain equipment                                       |  |  |  |  |  |  |
| CCEOP    | Cold-chain equipment optimization platform                 |  |  |  |  |  |  |
| COVID-19 | Coronavirus disease 2019                                   |  |  |  |  |  |  |
| CRS      | Congenital Rubella Syndrome                                |  |  |  |  |  |  |
| CSO      | Civil society organizations                                |  |  |  |  |  |  |
| EAF      | Equity Accelerator Fund                                    |  |  |  |  |  |  |
| EPI      | Expanded Programme on Immunisation                         |  |  |  |  |  |  |
| FCA      | Fragile and conflict-affected                              |  |  |  |  |  |  |
| FED      | Fragilities, Emergencies and Displaced (policy)            |  |  |  |  |  |  |
| FPP      | Full portfolio planning                                    |  |  |  |  |  |  |
| GACVS    | Global Advisory Committee on Vaccine Safety                |  |  |  |  |  |  |
| GIS      | Geographic Information System                              |  |  |  |  |  |  |
| GNI      | Gross national income                                      |  |  |  |  |  |  |
| HPV      | Human Papillomavirus                                       |  |  |  |  |  |  |
| HR       | Human resources  |  |  |  |  |  |  |
| HSS      | Health Systems Strengthening                               |  |  |  |  |  |  |
| ICC      | Inter-agency coordinating committee                        |  |  |  |  |  |  |
| ILR      | Ice-lined refrigerator                                     |  |  |  |  |  |  |
| IPV2     | Inactivated Polio Vaccine 2 <sup>nd</sup> dose             |  |  |  |  |  |  |
| IRC      | Independent Review Committee                               |  |  |  |  |  |  |
| MAC      | Multi-Age Cohort   |  |  |  |  |  |  |
| MCH      | Maternal and child health                                  |  |  |  |  |  |  |
| MCV      | Measles-containing vaccine                                 |  |  |  |  |  |  |
| MICs     | Middle-income country support                              |  |  |  |  |  |  |
| NITAG    | National Immunisation Technical Advisory Group             |  |  |  |  |  |  |
| NVS      | New and underused vaccine support                          |  |  |  |  |  |  |
| ODP      | Operational deployment plan                                |  |  |  |  |  |  |
| PAMI     | Priority areas for multisectoral interventions             |  |  |  |  |  |  |
| PCCS     | Post-campaign coverage survey                              |  |  |  |  |  |  |
| PIE      | Post introduction evaluation                               |  |  |  |  |  |  |
| PQ       | Prequalified   |  |  |  |  |  |  |
| RI       | Routine immunisation                                       |  |  |  |  |  |  |
| SAGE     | Strategic Advisory Group of Experts on Immunisation        |  |  |  |  |  |  |
| SIA      | Supplementary Immunisation Activity                        |  |  |  |  |  |  |
| TRP      | Technical Review Panel                                     |  |  |  |  |  |  |
| UNICEF   | United Nations Children's Fund                             |  |  |  |  |  |  |
| USAID    | United States Agency for International Development         |  |  |  |  |  |  |
| VCF      | Vaccine catalytic funding                                  |  |  |  |  |  |  |
| VIG      | Vaccine introduction grant                                 |  |  |  |  |  |  |
| WHO      | World Health Organization                                  |  |  |  |  |  |  |
| WUENIC   | WHO and UNICEF estimates of national immunisation coverage |  |  |  |  |  |  |

## 1. Executive Summary

The Gavi Independent Review Committee (IRC) met virtually from 3 to 14 June 2024. A total of 26 IRC members organised in 2 review panels (see Annex 1 for list of members and expertise) reviewed applications from 18 countries in four World Health Organization (WHO) regions (12 from the African Region, 3 from the Eastern Mediterranean Region, 2 from the South-East Asian Region, and one from the Region of the Americas).

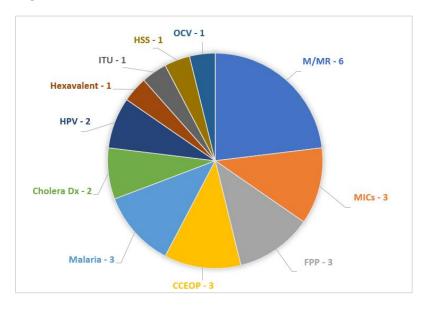


Figure 1:
Distribution of applications by support types reviewed at the June IRC meeting

Applications reviewed at the meeting included proposals and requests for various support types: three for Cold Chain Equipment Optimization Platform (CCEOP), three for middle-income country support (MICs) of which two were requests for vaccine catalytic financing (VCF) and one for one-off costs support (OOC), two for Cholera diagnostics, one for Innovation top-up (ITU) funding, one for Health System Strengthening (HSS) grant, and 13 for new and underused vaccine support (i.e. 6 for Measles/Measles-Rubella vaccine (M/MR), 3 for Malaria vaccine, 2 Human Papillomavirus vaccine (HPV), 1 for Oral Cholera vaccine (OCV), and 1 for Hexavalent vaccine). The application for operational costs to switch to a hexavalent vaccine (Mauritania) was the first application reviewed for this new Gavi support opportunity. All proposals were recommended for approval, although some countries were requested to address critical concerns by responding to action points. In addition, the IRC made recommendations to countries to strengthen their interventions and programmes in the form of 'comments for consideration' in each report.

A previously conducted remote review of the application from one country in the African WHO region, recommended for approval, included requests for 3 support types: HSS, Equity Accelerator Fund (EAF), and Targeted Country Assistance (TCA). Table 1 provides detail on requests from countries and review outcomes.

The IRC recognises consistent positive trends in the quality of applications e.g. in leveraging learnings from previous interventions, in planning, and in the quality of budgets. The IRC also notes and commends plans to effectively engage NGOs in conflict and fragile contexts to deliver services, considering the diverse challenges that affect these settings. The expanded dialogues with country EPI teams continue to prove

valuable to clarify issues identified in the review process. This, along with the technical support of the Secretariat and Alliance Partners in the preparation of country applications, is reflected in the 100% approval. In addition, the IRC values the exchanges between the IRC and the Technical Review Panel (TRP) members during reviews of Malaria applications, which has opened opportunities for collaboration. The IRC will follow with interest the gains from this active exchange.

## 2. Review methods and processes

## 2.1 Review methods

**Review methods** included independent reviews of each application by the assigned primary and secondary reviewers, as well as cross-cutting finance and supply chain reviewers as required. Reviewers presented their initial findings within the respective panels, followed by focussed discussions and consolidation of the draft report with findings, outcomes, and decisions. Before the formal sign-off, the assigned editor, the Secretariat, the vice chairs and the Chair reviewed the consolidated reports for quality and consistency.

**Decisions** were made according to two categories: 1) recommendation for approval with action points to address the identified issues, and 2) recommendation for re-review with outstanding issues and action points to be addressed by the country during revision of the application, prior to a new submission to the IRC.

**Criteria for review** remain the same as in previous review windows and are guided by IRC Terms of Reference and key criteria in line with Gavi's mission. This includes the extent to which applications meet mandatory requirements and principles of Gavi support and contribute to achieving Gavi's mission and strategy. The proposals need to demonstrate justification for the proposed activities, soundness of approach, country readiness, feasibility of plans, contribution to systems strengthening, programmatic and financial sustainability, value for money, and public health benefits of the investment. The IRC remains faithful to strict adherence to the guidelines to ensure the integrity, consistency and transparency of funding decisions, in the best interest of countries and Gavi.

## 2.2 Focus of IRC review

Across the panels, the IRC members focussed on the following specific tasks:

- a) individual review of assigned funding requests and all other supporting documentation, which for M/MR applications also included virtual meetings with country EPI managers, country teams and core technical partners;
- b) production of country-specific review reports with findings from the evaluation and accompanying recommendations provided to the Gavi Secretariat; and
- c) development of a thematic report with recommendations to Gavi and Alliance partners for improvement of funding requests, strengthening of national immunisation programmes, and processes related to Gavi policies and governance.

## 2.3 Review process

The meeting agenda, the initial allocation of countries for review, and the country applications with supporting documentation were shared with the reviewers on 24 May 2024. The 26-member committee included reviewers with a wide range of expertise, of which 4 were cross-cutters for financial and budget reviews of applications excluding malaria. Another 5 were supply chain, logistics, and waste management specialists who served for the full review of CCEOP applications and as cross-cutters for NVS applications, excluding malaria applications. Four (4) new members joined this IRC meeting (2 cross-cutters for supply chain, logistics and waste management and 2 NVS reviewers). As roughly 50% of the committee were recently admitted members, the 'buddy system', in which the experienced reviewers support the new members, was applied to ensure support and smooth review of applications and ultimately enable the optimal use of the IRC pool.

The reviewers were organised into two panels, with panel 1 reviewing HPV, MICs, HSS and a portion of malaria applications, panel 2 reviewing CCEOP and the majority of M/MR applications, while both panels jointly reviewed the remaining malaria and M/MR applications along with OCV, Cholera diagnostics, ITU applications, and hexavalent vaccine switch application. The chairing roles were assigned to IRC Vice Chairs Pierre Corneille Namahoro and Dr Bolanle Oyeledun, and to the IRC Chair Prof. Rose Leke, who also chaired two closed IRC sessions, the final plenary session, and the debriefing/closing session.

Process and technical briefings and updates were provided to the IRC reviewers prior to the review meeting (27 May 2024). The dialogues between country EPI teams and the IRC about M/MR, OCV and HSS applications were reasonably spaced across two weeks, to allow for more focussed reviews. The FD&R team provided support and facilitated contacts between the reviewers and countries. The countries also provided their responses in writing, which helped with their consideration and inclusion in the IRC review. Gavi Secretariat continued piloting the changes of the meeting structure and process, including further modifications of the review report templates, which are now all application-specific.

Review meetings with and within panels occurred from 4 to 12 June 2024, with reporting back to the full plenary on 12 and 13 June and final debriefing on 14 June 2024. All issues requiring resolutions were solved within panels. The full IRC had two additional closed sessions for one application (i.e. Gambia application for MR follow-up campaign), to further discuss identified issues and technical standpoints, formulate additional questions for the country, and discuss country responses and clarifications, before final resolution and consensus.

Remote FPP review was conducted before, and independently, from the panel review work. The issues identified by reviewers for each proposal were summarised and included in the debriefing presentation.

## 2.4 Key review outcomes

The main outcomes of country applications reviewed during the June meeting and outcomes of remotely reviewed proposals are summarised per country in Table 1. All applications were recommended for approval. IRC recognises the efforts of the Secretariat and Alliance partners for their technical support, and commends continued efforts to improve the applications and the review process.

**Table 1:** Outcomes of country requests by country category and type of support reviewed at the June meeting

| С                 | ountry segment          | Country                   | Support request                 | Recommendation outcome |  |  |  |
|-------------------|-------------------------|---------------------------|---------------------------------|------------------------|--|--|--|
|                   | Core Priority           | Ghana                     | HPV                             | Approval               |  |  |  |
|                   | MICs                    | Tunisia                   | MICs (HPV: VCF)                 | Approval               |  |  |  |
| L 1               | MICs                    | Cuba                      | MICs (HPV: OOC, VCF)            | Approval               |  |  |  |
| PANEL 1           | Core Priority           | Togo                      | Malaria                         | Approval               |  |  |  |
|                   | Core Standard           | Comoros                   | HPV                             | Approval               |  |  |  |
|                   | Fragile and<br>Conflict | Syria                     | HSS                             | Approval               |  |  |  |
|                   | Core Priority           | Nepal                     | CCEOP                           | Approval               |  |  |  |
|                   | Fragile and<br>Conflict | CAR                       | M follow-up campaign            | Approval               |  |  |  |
| .L 2              | Core Standard           | Gambia                    | MR follow-up campaign<br>CCEOP  | Approval               |  |  |  |
| PANEL 2           | Fragile and conflict    | Yemen                     | Cholera diagnostics             | Approval               |  |  |  |
|                   | Core Priority           | Kenya Cholera diagnostics |                                 | Approval               |  |  |  |
|                   | Core Priority           | Congo                     | MR follow-up campaign           | Approval               |  |  |  |
|                   | Core Standard           | Zimbabwe                  | CCEOP                           | Approval               |  |  |  |
|                   | Core Standard           | Mozambique                | Malaria OCV preventive campaign | Approval               |  |  |  |
| IRC               | Core Priority           | Bangladesh                | ITU<br>MR follow-up campaign    | Approval               |  |  |  |
| FULL IRC          | Fragile and<br>Conflict | I South Sudan I M folio   |                                 | Approval               |  |  |  |
| Core Standard Mau |                         | Mauritania                | Hexavalent                      | Approval               |  |  |  |
| REMOTE REVIEW     |                         |                           |                                 |                        |  |  |  |
|                   | Core Standard           | Liberia                   | FPP (HSS, EAF, TCA)             | Approval               |  |  |  |

## 2.5 Good practices observed

The IRC notes that some country applications included practices and activities which have the potential to make positive impact, especially if, where applicable, they will be duly implemented and evaluated. These include:

- plans to leverage available and already supported community resources to mobilise communities for malaria vaccine introduction in Mozambique;
- use of the strong school health programme as a platform for HPV vaccine delivery alongside multiple other interventions in Ghana;
- establishment of a dedicated unit for gender, to integrate gender-specific activities across different agencies in **Comoros**;
- provision of health services through collaboration between public and non-profit private clinics in **Bangladesh** and **Liberia**; and
- transfer of the management of Gavi funds to countries in **Togo** and **Comoros**.

The Secretariat and Gavi Alliance partners should track and evaluate these practices and activities, in order to quickly scale up and share lessons learned across other countries.

## 3. Key Findings and Recommendations

## 3.1 New and underused vaccine support (NVS) and campaigns

## Measles and Rubella vaccines

During this review window, IRC reviewed applications from five countries requesting M/MR support. Congo and Gambia requested support for MR follow-up campaigns targeting children 9 to 59 months of age, while CAR and South Sudan, given their fragile contexts, applied for support for measles follow-up campaigns targeting children 6 to 59 months of age. South Sudan also applied for MCV2 introduction. Bangladesh, in an attempt to mitigate deficiencies in routine and supplementary vaccination activities, requested support for the modular MR follow-up campaign of which modules 1 and 3 will target 9 to 59 months old children, and module 2, planned to be conducted in six high-risk districts, will target wide age range from 9 months to 15 years. Except for Bangladesh, all countries have inadequate measles coverage, and all rely on SIAs to control measles (Figure 2). All applications were recommended for approval and the total funds requested amounted to approximately US\$14.4 million. While campaigns are the second opportunity for children to receive the second or the only measles vaccine dose, they should not replace a functional routine immunisation programme.

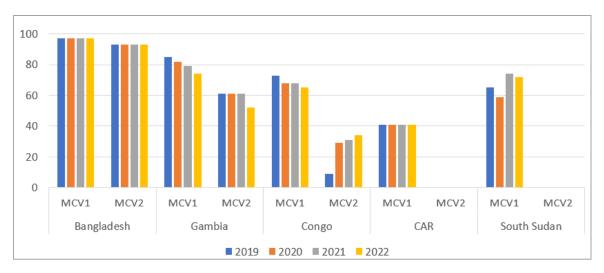


Figure 2: MCV1 and MCV2 coverage in applicant countries in 2019-2022 period (WUENIC, JRF)

The IRC notes some good practices which relate to better tailored campaign strategies observed in the revised application from Congo. The country followed the IRC recommendation from the previous submission and tailored campaign strategies specifically to urban populations. This will require close collaboration of Ministries of Health and Education to organise vaccination in public and private preschools in two urban areas, Brazzaville and Pointe Noire, where the population is concentrated, as opposed to expecting that working mothers will take time off work to bring their children to vaccination points. It will be important to ensure that a post-campaign technical report and a post-campaign coverage survey (PCCS) assess the effectiveness of this approach.

Regarding tailored strategies, an issue related to the use of available country data is observed.

## Issue 01: Demand-related strategies remain generic despite the availability of country-specific data.

When applying for operational support for M/MR campaigns, countries are required to outline demand- and supply-side-related tailored strategies, that address identified demand- and supply-side barriers to reach un- and under-vaccinated children. While countries strive to respond to this requirement and base the development of strategies mostly on undefined local experience and hypotheses, the demand-related strategies remain often generic and vague (e.g. 'adequate community engagement', 'engagement in demand generation', 'targeted activities'). Table 2 shows that all applicant countries have recently conducted assessments of demand-related reasons for non-vaccination and surveys of behavioural and social drivers of vaccination and indicate the presence of community engagement strategies and interventions to address under-vaccination. This is aligned with the WHO/SAGE recommendation to systematically collect and analyse data on behavioural and social drivers of vaccine uptake. However, the IRC finds no evidence in country applications that the proposed strategies to reach populations with

coverage gaps and inequities have been influenced by the new data from the behavioural and social sciences, or will address the reasons of low coverage.

| Source: JRF<br>2021-2023 | Assessment of demand-related reason for non-vaccination | Survey of<br>BeSD of<br>vaccination | Community engagement strategies to address under-vaccination | Service quality interventions to address undervaccination | Source of information for development of strategies |  |
|--------------------------|---|-------------------------------------|--|---|---|--|
| Bangladesh               | Yes (2023)  | Yes (2023)                          | Yes (2023)   | Yes (2023)  | Hypotheses  |  |
| CAR                      | Yes (2023)  | Yes (2023)                          | Yes (2022)   | Yes (2022)  | Plan de relance,<br>polio data                      |  |
| Congo                    | Yes (2023)  | Yes (2023)                          | Yes (2021)   | Yes (2021)  | Zero-dose analysis, local experience                |  |
| Gambia                   | Yes (2023)  | Yes (2023)                          | Yes (2023)   | Yes (2023)  | Local experience                                    |  |
| South Sudan              | Yes (2023)  | Yes (2023)                          | Yes (2023)   | Yes (2023)  | Local knowledge                                     |  |

**Table 2:** Availability of demand-related information as per JRF and source of information for strategy development cited in the applications

## **Recommendations:**

- Gavi and Alliance partners to encourage countries to design their vaccination strategies in line with WHO/SAGE recommendations, and to use available information from validated and field-tested tools to guide planning and prioritisation, and to develop effective strategies that would serve both campaign and routine immunisation programmes.
- Gavi and Alliance partners to assist countries in implementation research to identify when, where, and for whom the interventions were or would be successful.

## Malaria vaccines

Of three countries applying for malaria vaccine support, Togo applied for malaria vaccine introduction grant, and Mozambique and South Sudan, whose applications for introduction in prioritized areas had already been approved by the IRC, applied for malaria vaccine scale-up. The number of children targeted in all three countries surpasses 2 million and the funds requested amount to US\$1.673.238. All requests were approved.

IRC continues to note good practices in malaria vaccine introduction, such as the adoption of technologies to help identify hard-to-reach communities in Mozambique where to map the areas to target with malaria vaccination, the EPI plans to use the GIS mapping used for polio vaccination outreach in 2022-2023. Furthermore, all plans show linkages with other activities, providing examples of the complementarity of co-investments, such as leveraging community activists' networks supported by the Global Fund to

support malaria vaccine social mobilisation in Mozambique or utilizing already planned gender analyses and community health interventions funded by other Gavi grants (FPP, CDS) in Togo, or documenting lessons learned from malaria vaccine delivery in the 2<sup>nd</sup> year of life to inform roll-out of other vaccines at that time in South Sudan. As MCV2 has been only recently approved by the IRC, the country has not been vaccinating in the second year of life yet, and experience from malaria vaccination will be valuable.

All applicants presented comprehensive plans with stratification of districts according to transmission intensity, and included strategic use of other malaria interventions along with vaccination, to achieve the highest impact on disease burden reduction. The applications propose a 4-dose malaria vaccine series integrated into the routine schedule, as shown in Figure 2.

| Time (months) | 5         | 6         | 7         | 8 | 9         | 10 | 11 | 12 | 13 | 14 | 15        | 16 | 17 | 18        |
|---------------|-----------|-----------|-----------|---|-----------|----|----|----|----|----|-----------|----|----|-----------|
| Togo          | Dose<br>1 | Dose<br>2 | Dose<br>3 |   |           |    |    |    |    |    | Dose<br>4 |    |    |           |
| Mozambique    |           | Dose<br>1 | Dose<br>2 |   | Dose<br>3 |    |    |    |    |    |           |    |    | Dose<br>4 |
| South Sudan   | Dose<br>1 | Dose<br>2 | Dose<br>3 |   |           |    |    |    |    |    |           |    |    | Dose 4    |

new touch points with the immunisation programme

Figure 3. Timing and new touch points of 4-dose malaria vaccine series in applicant countries

**Issue 02:** Increased workload for health workers in routine immunisation programmes may jeopardize the quality and safety of work and care.

Following the WHO recommendation, countries opt for a 4-dose primary series and include the 4<sup>th</sup> dose of malaria vaccine in the second year of life to prolong protection. While the optimal interval between doses 3 and 4 has not yet been established, countries choose to align the malaria vaccine administration with other vaccines in the 2<sup>nd</sup> year of life to optimise delivery for dose 4. For example, Togo aligns malaria vaccination with MR and Men A vaccines at 15 months, while at 18 months, Mozambique pairs it with vitamin A supplementation and deworming, and South Sudan will do so with MCV2. However, all schedules include new touch points between the routine programme and the population: three new contacts in Togo and South Sudan at 5, 6 and 7 months, and two new contacts in Mozambique at 6 and 7 months. Because of this, Togo mentions the challenge of increased workload for health workers, and South Sudan describes a challenge of insufficient skilled health staff, high attrition, and workforce drainage. Increased workload for health workers remaining in routine immunisation programme increases a risk of fatigue, burnout, and potential programmatic errors which can ultimately negatively affect the quality and safety of work and care. These challenges should be monitored, and workload monitoring is best achieved during supportive supervision.

## Recommendation:

• Gavi and Alliance partners to encourage and support countries in monitoring the workload of health workers in routine immunisation services to ensure that challenges are identified early and addressed on a case-by-case basis.

## Other vaccines

## Hexavalent vaccines

Since December 2023, Gavi-eligible countries can apply for the switch grant to replace the pentavalent vaccine (diphtheria/tetanus/whole-cell pertussis, hepatitis B and Haemophilus influenzae type b) with the hexavalent product, or 'six-in-one' vaccine, that combines pentavalent and inactivated polio vaccine (IPV). This brings multiple programmatic and clinical benefits.

The reduced number of injections eases the burden on the child and caregivers. It may relieve potential parental concern, improve acceptance of vaccination, and increase compliance for children and parents. For healthcare workers, it reduces the time they spend on preparation, administration, and recording, as well as the potential for accidental injuries and errors.

Further, this vaccine can support polio eradication efforts by offering four doses of IPV along with the existing three doses of OPV in the routine immunisation schedule. In addition, this introduction will eliminate the need to introduce a 2nd dose of IPV at 9 months of age. With fewer doses, this introduction will also simplify the supply chain and reduce the need for commodities (syringes, safety boxes).

The fourth dose of hexavalent vaccine, administered at 12-23 months of age, reinforces the second-year of life (2YL) contact and can further strengthen the immunisation programme by maximizing uptake of vaccines provided at that time (e.g. MCV2, malaria). It can also serve as a DTP-containing vaccine booster and be the first step in EPI schedules aligning with WHO-recommended DTP-containing vaccine schedule (i.e. 3 primary doses and 3 boosters at 2YL, 4-7 years, and 9-15 years of age).

## Issue 03: Lack of a tailored plan for vulnerable groups, notably refugees, asylum seekers and migrants

The first country to apply for hexavalent vaccine switch is Mauritania, which presented a detailed training plan for healthcare providers at all levels of the healthcare system in preparation for the introduction of the hexavalent vaccine, drawing on insights from recent vaccine introductions. However, there was a lack of attention to high-risk populations in the plan of action, which may be more a reflection of Gavi Funding Guideline requirements and the proposed template for a plan of action than a disregard of the country for these issues.

In Mauritania, there is a substantial high-risk population, including asylum seekers, refugees in and out of refugee camps, and migrant populations. While the plan of action acknowledges recent diphtheria outbreaks in refugee camps, it lacks detail and a tailored strategy for introducing the new hexavalent vaccine to these vulnerable communities. The plan should capture the needs of these communities, eventually drive the immunisation efforts, and include enhanced monitoring and supervision.

## **Recommendations:**

- Gavi and Alliance partners to support countries in developing comprehensive tailored plans for hexavalent vaccine delivery to vulnerable high-risk communities.
- Gavi to ensure that the plan for addressing high-risk vulnerable communities with tailored strategies is required and included in the application.

**Issue 04:** A crisis communication plan is not explicitly required for hexavalent vaccine support and consequently is not included in the plan of action.

The process of any new vaccine introduction, including hexavalent, can be fraught with challenges, particularly when it comes to misinformation and public apprehension. The complexity and comprehensive nature of this vaccine necessitates a robust crisis communication plan to address potential technical and informational challenges. Misunderstandings or misinformation regarding the vaccine's multifaceted protection could lead to hesitancy or refusal, undermining public health efforts. Therefore, a crisis communication plan is essential for managing these challenges effectively.

This plan should outline strategies for swiftly addressing vaccine misinformation, ensuring that accurate information reaches the public before misconceptions can take hold. This includes pre-emptive education campaigns to inform the community about the hexavalent vaccine's development, its safety profile, its efficacy in preventing multiple serious illnesses simultaneously, and protocols for rapid response if adverse events or rumours arise. By having a robust crisis communication plan in place, health authorities can maintain public trust, mitigate fears, and ensure high vaccination coverage, ultimately protecting more children from preventable diseases.

## **Recommendations:**

- Gavi and Alliance partners to support countries in development of crisis communication plan and its integration into overall communication strategies when applying for support for new vaccine introduction, including hexavalent.
- Gavi to require crisis communication as a part of planning and be included in the application for hexavalent vaccine support.

## Oral Cholera Vaccine (OCV)

The IRC reviewed one application for preventive cholera campaign support, a revised request from Mozambique. As is almost always the case with resubmission, the country has significantly improved the application. The request now adequately considers lessons learned from the most recent reactive OCV and polio campaigns, including specific actions to reach under-served communities. It also now includes an analysis of updated epidemiological information from the surveillance system, including the most recent large cholera outbreak reported in 2023. The epidemiological analyses can be distorted by the resurgence of the disease, as cholera transmission may show significant variations in intensity and geographical distribution from one year to another. This complicates planning and preparation for a

multiyear campaign as the selection of priority areas for multisectoral interventions (PAMI) and strategies should be revised accordingly and updated before the initiation of the campaign.

**Issue 05:** Cholera transmission varies over time, making the selection of PAMI complex when planning a multiyear campaign.

#### Recommendation:

• Gavi and Alliance partners to encourage countries to update their PAMI analysis on a yearly basis during the implementation of multiyear OCV campaigns and state this in the Plan of action.

In addition, accurate population estimates are the cornerstone of effective preventive cholera intervention. The lack of accurate information can lead to inadequate vaccine supply, inefficient distribution, and ultimately, the failure to immunize large segments of the population who are at risk. One of the persistent challenges that Mozambique faces is a recognised underestimation of target population figures. The consequences of these misestimates are far-reaching. Communities that remain undervaccinated are not only at a higher risk of cholera but also become potential epicentres for outbreaks. This creates a cyclical problem where low immunisation coverage perpetuates the risk of cholera, demanding constant emergency responses rather than deployment of sustainable, preventive solutions. Therefore, to address this critical issue, countries need to invest efforts to adopt accurate methods of population estimation and data collection. This can be achieved through the integration of advanced demographic tools, geographic information systems (GIS), community-based surveys, recent population censuses, and pre-campaign registration of the target population. Aligning vaccine forecasts with accurate population estimates would mitigate stockouts and facilitate maximum coverage. By refining data collection processes, countries can obtain a more accurate picture of the target population, which in turn will inform a more precise vaccine forecast and campaign strategies.

**Issue 06:** Inaccurate population estimates result in stock-outs and ineffective preventive cholera campaigns

## **Recommendation:**

• Gavi and Alliance partners to support countries in triangulation of relevant data to ensure that countries provide accurate target population estimates.

## **HPV** introductions

Four countries applied for support to introduce the HPV vaccine: Tunisia and Cuba applied for vaccine catalytic financing under the MICS approach, and Comoros and Ghana applied as core countries for new vaccine introduction with an additional multi-age cohort (MAC). Tunisia and Cuba will target approximately 184,400 9-year-old girls annually. Ghana and Comoros will target approximately 447,800 9-year-old girls annually and approximately 2.07 million 10-14-year-old girls in the first year of introduction. The total funds requested amounted to approximately US\$5.7 million. All four applications were recommended for approval.

Tunisia's and Cuba's applications described the activities required for HPV vaccine introduction comprehensively and included clear plans to sustain HPV vaccine delivery long-term. Both countries submitted evidence of the government's commitment to increase the national budget for immunisations to accommodate the additional costs of HPV vaccine long-term. Cuba additionally applied for a grant for one-off-costs, which included time-limited discrete activities such as production of IEC materials, which were well-justified.

All four countries described well the elements of HPV vaccine introduction, incorporating lessons learned from prior vaccine introductions, and identifying programmatic bottlenecks and mitigating strategies. Ghana, Comoros and Tunisia provided detailed descriptions of vulnerable populations at risk of low coverage and a range of strategies that could be successful in reaching these populations with HPV vaccine and educational materials. Tunisia will use differentiated strategies and involve a wide variety of local partners to reach hard-to-reach and sparsely populated areas to raise awareness about HPV vaccine, such as 'information caravans', local community organisations, door-to-door visits, and a mix of mass-media channels. This is a commendable approach, and an evaluation of the Tunisian experience would represent a good case-study for countries in a similar socio-cultural context. Countries understand the importance of informed and targeted communication strategies for HPV vaccination. Although not a requirement of HPV NVS applications, Ghana and Comoros plan to conduct formative research to inform their communication strategy around HPV vaccine for adolescent girls. However, neither of the countries disclose detail on when and how the formative research will be done (i.e. prior to the design of an intervention or during implementation for improvement or correction as needed), who would conduct this research, and how it would be funded.

**Issue 07:** While formative research is useful to understand the characteristics of the target population for HPV vaccination and identify potentially effective communication strategies, countries that plan to perform formative research do not specify who will conduct this research, how it would be funded, nor any details on the methods and tools that will be used. This limits the ability of the IRC to understand the feasibility and utility of these plans and any complementarity of funding.

## **Recommendations:**

- Gavi and Alliance partners to request countries planning to conduct formative research to provide a high-level plan and state more explicitly where this will enable them to leverage complementary funding and/or synergies with other in-country partners and stakeholders.
- Gavi and Alliance partners to support evaluation of innovative communication strategies for adolescents in countries and share with countries of similar socio-cultural context.

**Issue 08:** Despite comprehensive plans for school-based delivery of HPV vaccination, some countries still do not consider integration with other school health programme activities.

In Ghana, HPV vaccination will be integrated into a strong school health programme which already delivers health education, deworming and tetanus vaccine. Comoros also plans a school-based delivery of HPV

vaccines but without integration with other interventions, despite the context of variable routine immunisation coverage and identified pockets of zero-dose children.

## **Recommendation:**

• Gavi and Alliance partners to continue to encourage countries to integrate HPV school-based delivery with other school health programme activities. In contexts with very variable routine coverage, schools could be used as a fixed outreach point for local mothers to access vaccination services on the day of HPV vaccination.

## 3.2 CCEOP

**Issue 09:** Lack of an integrated supply chain strategy that benefits from effective donor coordination and addresses all RI distribution costs.

In its MR application, one country (the Republic of Congo) outlined supply chain issues and limitations related to a lack of funding and donors' coordination that could disrupt supply chain operations, especially vaccine distribution. This may compromise the MR campaign, other vaccine campaigns, and routine immunisation.

#### Recommendation:

• Gavi to discuss with Alliance partners (World Bank, UNICEF, WHO, etc.) how to optimise the distribution and other supply chain functions, as well as cover the funding gaps to minimise the immunisation supply chain disruptions and interruption of health services.

**Issue 10:** Incorrect segmentation of health facilities, inadequate selection of CCEs, inaccurate ODP (Operational Deployment Plan) and uninstalled CCEs.

Nepal requested 47 CCEs (SDDs of the same size and exact same model) for various health facilities with differing needs, which is the least effort and one-size-fits-all solution. This resulted in some health facilities having storage overcapacity and others facing under-capacity issues. Nepal had 93 unutilised or idle CCEs (42 ILRs and 51 freezers) left over from CCEOP1. There was also a lack of integration between the two grants (CCEOP 1 versus CCEOP 2) and issues with accurate Operational Deployment Plans (ODP) for both CCEOP applications.

## **Recommendation:**

• Gavi and Alliance partners to ensure a detailed segmentation of targeted health facilities for CCE distribution at all times, with accurate and **time-bound** ODP based on exact needs, to avoid idle CCEs. Once procured CCEs are delivered in the country, they should not be idle for more than six months. UNICEF, in collaboration with the EPI team, should establish a RACI (Responsible, Accountable, Consulted & informed) matrix with specific timelines to ensure that there are no idle or uninstalled CCEs in any country beyond six months after delivery.

**Issue 11:** Lack of alignment between various grants of FPP portfolios.

While Liberia submitted a CCEOP application (at 58% of the allowable CCEOP ceiling) that was reviewed and approved by Gavi IRC back in March 2024, the country requested an additional 60 CCEs *via* HSS/FPP application in June 2024 and without any decommissioning plan.

#### Recommendation:

• Gavi and Alliance partners to provide clear guidelines to countries to ensure that CCE requests are optimised and not fragmented across CCEOP and HSS components during the same period, and that a decommissioning plan is consistently required for all CCEOP applications.

**Issue 12:** Lack of details on passive cold chain (vaccine carriers, cold boxes and ice packs) gap analysis for campaigns.

In the Gambia and Bangladesh, IRC noted a lack of inventory gap analysis for vaccine carriers, cold boxes, and ice packs, especially for campaigns. This may lead to inadequate capacity for implementing campaigns, which can lead to missed children, communities, and populations. This may also pose a risk of campaigns not achieving the objective of covering the target and exposing children to further outbreaks of vaccine-preventable diseases (VPDs).

## **Recommendation:**

• Countries should provide passive cold chain gap analysis in their applications and plans of action for campaigns to determine adequacy and capacity to implement the campaign, especially at the peripheral level, where arrangements for fixed immunisation sites, school-based, and outreach require different passive cold chains in different volumes. The analysis should provide clear plans to bridge any identified gaps.

**Issue 13:** Underestimation of spare parts for CCEs and lack of consistency in budget allocation across three recommended options (A, B, and C).

In the CCEOP applications for Gambia and Zimbabwe, there were discrepancies between the number of spare parts requested in the comprehensive CCE needs document and the number specified in the budget template that was submitted. The spare parts were underestimated for both countries and did not align with the Gavi guideline of 1 kit of spare parts per 10 CCEs. This could potentially lead to the redundancy or non-functionality of CCEs. Furthermore, certain budget items such as RTMDs, RTMD subscriptions, and training costs were not consistently included in all budget options.

#### **Recommendation:**

• Gavi and its Alliance partners should assist countries in estimating spare parts based on Gavi's guidelines. Countries should ensure that the items in the budget are consistent across budget options A, B, and C to maintain uniformity in the overall budget assessment.

## 3.3 Gender issues

IRC reviews every application to confirm if gender-related barriers to immunisation have been identified, and whether gender responsive or transformative interventions have been considered, planned, and budgeted for.

Issue 14: Gender analysis has not been conducted or it is not being used in the programming

In this review round, the IRC found that gender analysis was not presented in applications by some countries e.g. Mauritania, Tunisia, or Yemen. In other countries, gender analysis was conducted but incorporating this into clear actions and the plan of action (POA) was challenging e.g. South Sudan, Mozambique malaria application.

In addition, IRC reiterates that there is a missed opportunity for utilising existing gender analysis from other public health programs in the country in the immunisation program.

#### **Recommendations:**

- Gavi and partners to assist countries to conduct gender analyses.
- Gavi and partners to share clear examples of incorporating gender-responsive and transformative activities into the POA and immunisation program.
- Countries to utilise recent gender analyses conducted for any health program, e.g. MCH programs, in immunisation programs.

## Issue 15: Budget is not allocated to gender-specific activities in some applications

The immunisation budget missed allocation for gender activities e.g. Gambia MR, Liberia FPP.

## **Recommendations:**

- Gavi and partners to encourage and support countries to allocate appropriate funding to gender activities.
- Gavi to require that gender-related activities be included in the application, workplan and budget.

## 3.4 CSO engagement

IRC reviewed applications from 18 countries for 26 support types. Only one country, Liberia, submitted a full planning portfolio (FPP) application, and it successfully met the Board mandate of at least 10% of the combined funding ceilings (HSS, EAF, TCA) allocated for Civil Society Organizations (CSO). The Liberia FPP has 13% of the total HSS, EAF and TCA funds allocated to CSOs. The CSO role is well-described for demand generation, advocacy for health financing, addressing gender barriers and data tracking.

**Issue 16:** Engagement of CSOs is often weak, except in fragile and conflict-affected countries.

IRC notes that in fragile and conflict-affected countries, non-governmental organisations were found to be key for the functioning of the immunisation programs. E.g. in the CAR application for measles follow-up

campaign support, the engagement of NGOs for service delivery is described, where NGOs serve as intermediaries between nomads, pigmies or similar groups and the EPI program. Also, South Sudan's application for a measles follow-up campaign and MCV2 introduction support notes that the immunisation program is heavily reliant on NGOs, including for routine immunisation. The rest of the applications (more than 20) describe limited engagement with CSO.

## **Recommendation:**

• Gavi and partners to further support countries to consider engaging CSO platforms for all aspects of the immunisation program as appropriate, including to drive innovation and for integrated service delivery, and aligned with the country context. The engagement of CSOs in immunisation could be modelled around the successful CSO engagement in other public health programs, e.g. HIV, malaria programs.

## Issue 17: Difficult to assess from current available information, whether local partners are prioritised

Per Gavi guidance, civil society engagement encompasses the full range of formal and informal, non-governmental and not-for-profit organisations that represent the interest of the communities. These include community-based organisations, faith-based organisations, international NGOs, civil society networks, local professional associations, and not-for-profit advocacy organisations. In 2021, the Gavi Board mandated at least 10% allocation for CSOs for combined funding ceilings for (HSS, EAF, TCA) for all FPP applications, and this encompasses the breadth of partners described above. In the review process, IRC found that a description of CSO is scarce, and the capabilities of CSO are not described in the application materials. It is also not possible to determine whether international or local CSOs are utilized.

## **Recommendations:**

- Gavi to require detailed information on CSO engagement in all applications, to include names of CSO and their capabilities.
- Gavi to provide a clear definition of local partners for all applications, and countries should utilize this in their implementation and applications.
- Countries to prioritize local partners where applicable and in accordance with the country context.

## Issue 18: The budget for CSO is missing or is inadequate for the country context.

Countries often include CSO engagement in the application narrative; however, no budget is allocated to it. This is the case in the HPV application from Comoros, where collaboration with different leaders, influencers, and CSOs is described in the narrative, but no budget is allocated to CSO engagement.

In some cases a budget is provided, however it is minimal and may not be appropriate for the context, e.g. in the Mauritania Hexavalent application, the role of civil society organisations is described for demand generation and service delivery, and the budget allocated is only US\$5K and will likely be inadequate. Similarly, in the Gambia MR application, the CSO budget is 4.5% of the total budget, which appears inadequate for the activities described.

#### **Recommendations:**

- Countries to make a concerted effort to engage CSO and provide appropriate funding for their engagement. The funding should be evident in the submitted budget tables.
- Countries could utilise the Gavi CSO funding window if applicable, to ensure direct funding to CSOs.

Issue 19: The Gavi Board mandated that 10% CSO allocation is required only for FPP applications.

IRC reviewed 26 application support types + 1 FPP application. Only the FPP applications were required to have the CSO allocation. The Board mandated a 10% CSO requirement for FPP applications (HSS, TCA, EAF), which was monitored by IRC through the review process. IRC notes that the FPP funding for 2022-2023 represented 47% of the total amount approved by Gavi, and 53% of the funding in the same time period was not required to have a CSO allocation.

## **Recommendations:**

- Gavi to identify a minimum appropriate allocation for CSO in all applications and require prioritisation of local partners where applicable.
- Gavi to request that CSO allocations are included in the budget and that this is evident in the budget presentation.

## Issue 20: Unclear or sub-optimal private sector engagement in immunisation service delivery

As the introduction of a new vaccine brings in various challenges of acceptance at the community level, participation of the private sector in generating buy in and addressing communities' concerns is instrumental. The participation of the private sector can also help in expanding the outreach and coverage across communities. Of the 26 application support types submitted this round, only two applications appear to have robust collaboration between the public and private sectors for the provision of health services. These were described well in the Bangladesh and Liberia applications. However, in the example of Mauritania, only 14% of the private sector and 42% of the public sector are currently engaged in immunisation service delivery across the country. Increased private sector involvement would expand the immunisation service network and strengthen the overall immunisation infrastructure.

IRC notes that private clinics are considered CSO engagement only if they are not-for-profit. IRC recommends that Gavi consider revisiting the definitions of local partners and CSO, and to include local private sector collaborations where applicable.

## **Recommendations:**

- Gavi and partners to encourage countries to enhance public-private partnerships for equitable immunisation service delivery across all tiers of the healthcare system. This includes mapping the private sector and incentivising private players to participate in the launch of new vaccines.
- Gavi to consider revisiting the definitions of local partners and CSO, and to include local private sector collaborations within these, if applicable.

## 3.5 Fragile and conflict-affected countries

In this round, fragile and conflict-affected countries requested support for malaria vaccine introduction (South Sudan, Mozambique,), measles follow-up campaigns (CAR, South Sudan), MCV2 introduction (South Sudan), health system strengthening (North-West Syria, NWS), cholera preventive campaign (Mozambique), and cholera diagnostics (Yemen).

**Issue 21:** Due to funding constraints and security considerations, fragile and conflict-affected countries often prioritise select interventions and do not explore integration and complementarity with already operating activities.

As fragile and conflict-affected countries have unique operational contexts and challenges, Gavi developed the Fragilities, Emergencies and Displaced (FED) policy, intended to enable Gavi to extend support where greater flexibility, tailored support and stronger partnerships are needed. Such flexibilities often require trade-offs that weaken sustainability, systems thinking, and cost-efficiency. For instance, the context may require investing in temporary health service delivery structures in refugee camps instead of strengthening primary health facilities that might be unavailable or destroyed. In the example of NWS application, there was an appropriate emphasis on demand generation and zero dose children (ZDC) but insufficient funding was requested to re-open or strengthen existing primary health care (PHC) facilities at a time when donors previously supporting PHC left, leaving Gavi as the sole immunisation donor in that territory. This kind of imbalance needs to be avoided, and equal prioritisation of demand generation and ZDC can be made while also investing to maintain existing PHC facilities.

#### **Recommendation:**

• Gavi and Alliance partners to request and support fragile and conflict-affected countries to combine demand generation and interventions to address ZDC, with efforts to maintain open and operational PHC facilities.

**Issue 22:** While some fragile and conflict-affected countries are cognizant of the importance of people-centred integrated service delivery, others are lagging behind in applying integrative strategies across PHC services in their implementation.

The CAR application clearly states its intention to continue the integration of vaccination efforts with nutrition and communicable disease control. However, there appears to be little coordination between the EPI and the nutrition sections of CAR's ministry, evidenced in shortage of vitamin A and albendazole in a number of districts where integration with vaccination was conducted. Nevertheless, it remains important for FCA countries and partners to demonstrate the best efforts to synergise Gavi investments with those made by humanitarian response partners, to attempt systems development, and to adopt the most cost-effective approaches to achieve their objectives within the constraints and circumstances of their unique operational environment. There may also be good opportunities for integrating vaccination with other primary health care (PHC) services or a greater ability for CSO partners to expand their roles.

## **Recommendation:**

• Gavi to request fragile and conflict-affected countries to demonstrate integration with other PHC services as a key element of intervention design, particularly PHC interventions that serve the same target population (e.g. nutrition, other child health and antenatal care for women). If not possible/realistic, fragile and conflict-affected countries need to provide adequate justification as to why that is the case in their specific context.

**Issue 23:** Lack of guidance on allowable funding above Gavi budget ceilings for fragile and conflict-affected countries

While the FED policy's higher programmatic and financial risk appetite is noted, and certain flexibilities indeed need to be accorded to the fragile and conflict-affected countries in unique operational circumstances, there needs to be some parameters for the IRC to judge how far these flexibilities can be extended, what to exempt and what to apply. For example, whether exemptions should be granted for: the high proportion of human resource budgetary allocation within the overall total budget amount requested in South Sudan, or the event-related and vehicle rental unit costs which were higher than Gavi ceilings and above Gavi threshold guidance in CAR and Mozambique. While the IRC expects applicant countries to provide valid justifications for such costing, there is no specific guidance upon which the IRC can base its judgement on whether justifications are within reason. Gavi could establish margins of flexibility for each budget component or cost type (e.g. stating that "with sufficient justification relevant to each application's FCA context, Gavi allows a margin of X% for vehicles and transport, Y % for travel, Z % for human resource-related costs).

## **Recommendation:**

• Gavi to further elaborate the budget allocation flexibilities in the FED policy, so that the IRC review of fragile and conflict-affected countries applications is based on clearer benchmarks, while remaining flexible.

## 3.6 Budget, financial management and sustainability

## Limited alignment with on-going grants, Partners and Government

IRC Financial crosscutters reviewed fifteen applications from 11 countries which consisted of one FPP, one HSS, one ITU, one hexavalent vaccine, one OCV, two HPV, three malaria and five MCV applications. The applications (excluding HSS, FPP and ITU) had a total budget of US\$ 39,611,496 out of which Gavi funding accounted for US\$ 34,256,322 (86%), Government funding for US\$ 2,110,989 (5%), Technical Partners funding for US\$ 1,308,888 (3%), other sources of funding for US\$ 865,638 (2%) and a funding gap of US\$ 1,069,659, representing 3% of the total budgets submitted by countries.

The figures below show the percentages of overall budget by funding source and budgets by country and funding source.

Figure 4: Overall budget by funding source

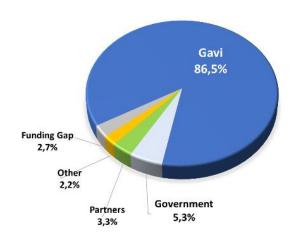
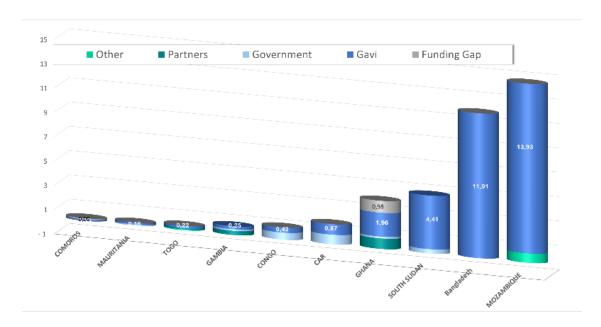


Figure 5: Budgets by country and by funding source



Nine of eleven countries presented a budget with different funding sources including two FED countries. Bangladesh (MR and ITU) and NW Syria (HSS) requested 100% Gavi contribution. As a country in transition from Gavi support, Bangladesh is expected to have already identified other potential funding sources and started implementing synergies.

Despite other funding sources being presented in the applications, IRC identified a lack of integration of activities between the budgets with other ongoing Gavi supports and/or with other donor sources. For example, Mauritania has a newly approved FPP which was to start in 2024, but the Hexavalent vaccine introduction application did not mention any complementarity with this Gavi funding. Similarly, the

Comoros HPV application described in the narrative the integration of funding with other donors (especially The Global Fund) but did not formally indicate those synergies in the budget. South Sudan has an approved EAF/HSS grant, which was not integrated to support the current application.

**Issue 24:** Countries presented budgets with different funding sources, but budgets still do not include clear details on integration with other donors nor consider integration of activities with other ongoing or planned Gavi funding.

## **Recommendations:**

- Gavi and partners to ensure that countries disclose all other non-Gavi committed resources.
- Gavi and partners to ensure inclusion in the budget of all activities described in the narrative and disclose the related funding source.
- Gavi to encourage countries to explore and align the multiple funding streams to maximize efficiencies.

## Lack of sustainability arrangements in accelerated transition countries

In this round, there are 3 countries in accelerated transition phase (Ghana, Bangladesh, and Congo) that requested Gavi support. While their budgets provided sufficient details on assumptions and calculations, the IRC identified that some countries did not provide any detail about their plans to sustain their programs beyond Gavi support. Congo presented an application with no information on sustainability (i.e. no EPI plan of action for 2023 and an outdated cMYP). Bangladesh provided a cMYP and the NIS (National Immunisation Strategy) that showed some EPI long-term planning, however, the IRC noted that recurrent costs are still part of Gavi budget e.g. HR related costs for Bangladesh were 26% of the budget (and were 69% for the Congo campaign application). Ghana presented a budget with a funding gap of US\$984k, representing 25% of the budget. This significant share of unfunded activities limits the IRC's ability to assess the feasibility of the plans proposed. This risk is particularly critical as Ghana still relies on partners to fund core programme functions for vaccine introduction e.g. logistics, waste management, and microplanning.

**Issue 25**: Countries in accelerated transition are still not sufficiently prepared to transition out of Gavi support and continue to present technical and financial gaps.

#### **Recommendations:**

- Gavi to consider updating guidelines for countries in accelerated transition phase to require inclusion of sustainability plans as a part of all support requests to Gavi.
- Gavi to potentially consider providing specific thresholds for recurrent costs and/or minimum funding for core functions by Governments as part of all requests to Gavi.
- Gavi to work with accelerated transition countries to formalise transfer of responsibilities to MOH/ equivalent.

## Inconsistencies in use of unit costs

The overall quality of budgets presented was satisfactory, which is a consistent trend noted in several rounds. Most of the budgets were adequately linked to appropriate worksheets with all the details. This is commendable as it reflects the tremendous effort put in by countries to support their budget requests and make their investment case convincing and appealing to IRC reviewers. IRC has identified some exceptions related to unit costs in this round. These issues were minimal in previous rounds. For Ghana, IRC identified disparities in the use of unit costs for Vaccine Ledgers and Vaccine Registers, which has the potential of a budget overstatement of US\$101k. The two applications by South Sudan presented three different unit costs for stationary, and unit costs used in the March and June review meetings are not aligned. Some countries still do not present an official document for DSA rates.

**Issue 26**: Countries present budgets with inconsistent unit costs across the same budget or compared to a recent previous application.

## **Recommendation:**

• Gavi and partners to ensure consistency of unit costs and request that countries present justification for material items and related unit costs.

## 3.7 Cross-cutting issues

The IRC observed several recurring cross-cutting issues highlighted below.

**Issue 27:** Post-campaign coverage surveys (PCCS) planning and budgeting issues jeopardising timely implementation

The IRC has repeatedly emphasised the importance of timely and well-executed post-campaign coverage surveys, which require detailed planning, preparation, specialised professionals, and adequate budgeting. Post-introduction evaluations (PIE) should also be timely and carefully planned, either as standalone evaluations or as a part of the overall EPI review. Their importance stems from the fact that introduction of a new vaccine introduces significant changes to current practice. Evaluations therefore rapidly identify areas that need improvement or correction, providing lessons for the continued use of the vaccine and improved practice. In this round, the IRC notes that budget allocations and funding sources are not strictly followed by the countries. This particularly relates to the countries in transition phase. For example, Bangladesh charges 100% of its PCCS budget to Gavi, while Congo charges the entire PCCS budget to the Government. However, PCCS remain either non-conducted (as is the example of Bangladesh after the previous MR campaign), or not finalized in time to inform the planning and preparation of the new campaign (as is the example of Gambia). With regard to PIE, Comoros included it in the budget but without the identification of a donor, which represents a funding gap and puts in jeopardy the implementation of this important activity.

#### **Recommendations:**

- Gavi to propose clear guidelines on budget allocations of financing for certain key campaign activities such as PCCS.
- Gavi and partners to continue encouraging countries to adhere to the WHO guidance, and plan for the PCCS 9 to 6 months prior to the campaign, to allow for timely implementation.

Issue 28: Lack of triangulation of data from sources other than the census for target population estimation

IRC continues to note difficulties that countries are facing with the estimation of the target population due to multiple context-related factors, but at the same time, seldom endeavour to triangulate data from other sources (e.g. data from recent SIAs). For example, Mozambique's target population estimate based on the census data is not accurate due to an outdated census, frequent cross-border movement and internally displaced populations. Lack of accurate target population estimates affects planning for logistics and supply chain, leading to frequent stockouts of essential supplies including vaccines and gaps in coverage.

## **Recommendation:**

• Gavi and Alliance partners to support countries in strengthening data management and encourage the use of multiple sources of service level data to triangulate and generate operational level estimates of the target population.

## Issue 29: Continuing issues in governance mechanisms

The IRC has repeatedly emphasised the importance of the presence and functionality of governance mechanisms for the functioning of immunisation programmes. In this review window, the IRC again notes gaps relating to NITAGs and ICCs. For example, the request of Mozambique for support of malaria vaccination scale-up includes the application endorsement of ICC, but no NITAG meeting minutes that would provide evidence on endorsement of a national technical body. IRC also notes that NITAG and the 'Immunisation Technical Working Group' in South Sudan have the same scope of work, which may lead to confusion and conflict, while the establishment of NITAG in Mauritania appears to be a continuous issue and a recurrent IRC action point.

## **Recommendations:**

- Gavi and Alliance partners to ensure that countries adhere to governance practices.
- Gavi and Alliance partners to support countries to establish their national immunisation advisory groups with clear terms of reference.
- Gavi Secretariat to continue to ensure that countries provide adequate endorsement for their requested support type.

## 4. Conclusions

During the June 2024 IRC meeting, all 26 applications (23 applications reviewed across 2 panels or plenary and 3 in previously started remote review) were approved. This extraordinary result indicates a continued improvement of applications through a joint effort of countries and the Alliance. It also confirms that countries returning to the IRC with revised requests come back with significantly improved applications, as was the case with Congo MR follow-up and Mozambique OCV campaign requests, increasing thus the possibility for robust plans to be translated to well-implemented interventions that should achieve high coverage and reach those most in need.

In this round, the IRC has approved the first-ever request for a switch of the pentavalent vaccine with the hexavalent vaccine product. Along with benefits for health workers and vaccine recipients, this 'six in one' vaccine will support polio eradication efforts.

The IRC also appreciated the value of dialogue by increasing the exchanges between the IRC and the Global Fund's Technical Review Panel (TRP). Cross-collaboration between the two review groups materialised in IRC and TRP attending respective malaria application reviews. This has proven valuable in clarifying questions and identifying issues, but also in identifying areas of integration. Significant Global Fund investments can help malaria vaccine introduction and the immunisation programme in general, for example, in capacity-building efforts which target the same health workers.

While the IRC continues to emphasise the opportunities related to strengthening routine immunisation and increasing efforts to reach those consistently missed, another important opportunity stemming from this review round relates to leveraging Gavi investments across its grants and beyond. This should ensure programmatic synergies, reduce duplication of efforts, and ultimately, reach more children through better integration of Gavi and partners' efforts. This can be illustrated with a positive example of Congo, where an approved EAF grant will be used to strengthen the 2YL platform to help overcome the challenges of reaching children after their first birthday.

The IRC remains concerned that countries seem to disregard available country-specific information, such as recent analyses of demand-related reasons for non-vaccination, surveys of behavioural and social drivers of vaccination, or gender analyses. Failure to use the latest country-specific data will mean that planning, prioritisation, and strategies will not be evidence-driven and will not achieve the expected results for campaigns and the routine immunisation programme.

The IRC is pleased to see a consistent trend in countries presenting satisfactory budgets and making their investment case convincing for reviewers. It is also reassuring to witness Gavi funds management being transferred to countries to be managed locally after extensive TA provision from Gavi. The IRC also reiterates that the Gavi FED policy should be further developed to provide guidance on allowable funding above Gavi budget ceilings for FCA countries related to their contexts.

Finally, the IRC commends the Secretariat's and, in particular, the FD&R team's ongoing efforts to further improve processes with an aim to increase review differentiation and efficiency.

## 5. Acknowledgments

The IRC would like to thank the Gavi Executive Team for their continued support of its work and the FDR team for organising the meeting.

The IRC also thanks the Gavi Secretariat, SCMs, VPs, HSIS, and PFM team members for their continued important input during pre-review screenings and clarifications on country-level perspectives during review sessions.

The IRC also acknowledges the contribution of the Alliance partners in supporting country applications and their participation in sessions during the IRC's deliberations.

# Annex 1: IRC members participating in the June 2024 meeting

| #  | Name                            | Nationality | Profession/Specialization   | Sex | Review<br>language | Expertise  |
|----|---------------------------------|-------------|---|-----|--------------------|--|
| 1  | Rose Leke –<br>CHAIR            | Cameroon    | Emeritus Professor of<br>Immunology and Parasitology,<br>University of Yaoundé,<br>Cameroon                                 | F   | EN, FR             | Malaria. Global Health, HSS, training of the next generation of scientists   |
| 2  | Abdul-Aziz<br>Garba<br>Mohammed | Nigeria     | Pharmacist/Supply chain<br>management, Ministry of<br>Health Yobe State, Nigeria  | М   | EN                 | Health supply chain management, immunisation supply chain, vaccine and cold chain logistics  |
| 3  | Aleksandra<br>Caric             | Croatia     | Independent consultant  | F   | EN, FR             | Measles, SIAs, AEFI surveillance and vaccine safety, programme management, primary health care   |
| 4  | Dah Cheikh                      | Mauritania  | Independent consultant  | M   | EN, FR             | Health and immunisation system strengthening, vaccine introduction, disease surveillance   |
| 5  | Akram Ali<br>Eltoum<br>Mohamed  | Sudan       | Independent Global Health<br>Consultant   | М   | EN, FR             | IRC Thematic Lead for Fragile & Conflict-affected countries, health systems strengthening, health sector governance, human resources for health  |
| 6  | Dominique<br>Legros             | France      | Independent consultant  | M   | EN, FR             | Epidemiology of infectious diseases in developing countries, surveillance and early warning systems, vaccinology, operational research, management of outbreaks and of complex emergencies |
| 7  | Rochika<br>Chaudhry             | USA         | Advisor, Johns Hopkins Medical Institution  | F   | EN                 | Immunisation services, global health security, outbreak response, HSS, health finance and policy, malaria, HIV   |
| 8  | Kate Gallagher                  | UK          | Associate Professor of Epidemiology, London School of Hygiene & Tropical Medicine, and the Kenya Medical Research Institute | F   | EN                 | HPV and PCV epidemiology and vaccine delivery, behavioural and social drivers of immunisation, supply and demand interventions   |
| 9  | Henry Katamba                   | Uganda      | National Facilitator, GF at the<br>Ministry of Health in Uganda   | М   | EN                 | Epidemiology, M&E of health projects, health research and advisory   |
| 10 | Wassim Khrouf                   | Tunisia     | Auditing and Consulting Worldwide, Partner  | М   | EN, FR             | Financial and budget analysis, audits, project assessment  |
| 11 | Viviana<br>Mangiaterra          | Italy       | Associate Professor, SDA<br>School of Management,<br>Bocconi University, Milan  | F   | EN, FR             | specialist in international public health<br>HSS and infectious diseases programs,<br>Maternal and Child Health, Malaria,<br>HIV and TB  |
| 12 | Tony Mugasia                    | Kenya       | Independent Consultant  | М   | EN                 | Malaria, HSS, Epidemiology and disease surveillance, Immunisation  |
| 13 | Mutuku<br>Stephen<br>Mutinda    | Kenya       | Health economist and health financing specialist  | М   | EN                 | Economic modelling, expenditure and costing analysis, efficiency and productivity, Value for Money -VfM analysis, Return on Investment (ROI) and Impact analysis                           |
| 14 | Pierre-<br>Corneille            | Rwanda      | Director of Public Health,<br>Global Supply Chain & HSS,<br>Fascinans Ltd.  | М   | EN, FR             | HSS, Supply Chain Management and Cold-Chain Logistics  |

|    | Namahoro –<br>VICE CHAIR       |            |  |   |                   |  |
|----|--------------------------------|------------|--|---|-------------------|--|
| 15 | Villyen<br>Nkengafac<br>Motaze | Cameroun   | Associate Professor of Epidemiology, Medicine Usage in South Africa (MUSA), Noth West University, South Africa                       | M | EN, FR            | Vaccinology, epidemiology, systematic reviews, evidence-based practice   |
| 16 | Natasha<br>Howard              | Canada, UK | Associate Professor, NUS School of Public Health and LSHTM   | F | EN, FR,<br>SP, AR | Immunisation service delivery, Health Policy, HPV, measles, malaria, COVID-19, EAF, FER settings               |
| 17 | Chioma Nwuba                   | Nigeria    | Independent consultant   | F | EN                | Supply chain management and cold-<br>chain logistics   |
| 18 | Bola Oyeledun – VICE CHAIR     | Nigeria    | Chief Executive Officer at<br>Centre for Integrated Health<br>Programs (CIHP), Nigeria   | F | EN                | HSS, MNCH, immunisation, adolescent reproductive health & HPV, programme assessment and evaluations            |
| 19 | Sehrish<br>Tehreem             | Pakistan   | Independent consultant   | F | EN                | Health and immunisation system strengthening, vaccine management, disease surveillance                         |
| 20 | Ousmane<br>Amadou Sy           | Senegal    | Independent consultant   | М | EN, FR            | Grant management, financial management and internal control mechanisms   |
| 21 | Pierre de<br>Vasson            | France     | Independent consultant   | М | EN, FR            | Supply chain management and cold-<br>chain logistics   |
| 22 | Kondwani<br>Msampha            | Malawi     | Deputy Global Director for<br>Corporate Services & Human<br>Resources Director at the<br>World Scout Bureau Global<br>Support Centre | M | EN                | Finance & budget management  |
| 23 | Sophie<br>Newland              | USA        | Independent consultant   | F | EN                | Supply chain, medical waste, and cold chain equipment management   |
| 24 | Anne<br>McArthur-<br>Lloyd     | UK         | Independent consultant   | F | EN, FR            | HPV Expert, New vaccine introduction, immunisation system strengthening/assessments and community engagement   |
| 25 | Beena<br>Varghese              | India      | Independent consultant   | F | EN                | Health systems, health economics, health equity  |
| 26 | Julie Pasquier                 | France     | Independent consultant   | F | EN, FR            | Health and immunisation systems strengthening, supply chain management & resilience, Monitoring and Evaluation |