

GAVI FULL COUNTRY EVALUATION-2013 PROCESS EVALUATION OF PNEUMOCOCCAL VACCINE

INTRODUCTION

ALLIANCE RESPONSE – JULY 2014

The GAVI Alliance is a learning organisation; we take the need for independent evaluation of our funded programmes very seriously. A solid evidence-based approach is key to helping the Alliance to reach its goal of immunising an additional quarter of a billion children by 2015, averting four million future deaths. It is vital that we understand how vaccination programmes are being implemented, what they are achieving, the obstacles and constraints that individual countries face to ensure that access to and uptake of immunisation is equitable, and the impact that GAVI Alliance support is having on the lives of people in GAVI implementing countries.

In this context, GAVI welcomes the first Annual Progress Report and the process evaluation of pneumococcal vaccine introduction report from the Full Country Evaluation project, which runs from 2013 to 2016 and covers Bangladesh, India, Mozambique, Uganda and Zambia. It is important to acknowledge the different nature of these full country evaluations; the value-add, utility and outputs of these evaluations extend beyond the final reports posted on the GAVI website. As prospective evaluations, they allow for continuous learning and offer a unique opportunity to better understand programme implementation and operational challenges on a real-time basis over the life-course of the evaluation project. Actions to address emerging issues and findings need not wait until the publication of the evaluation reports themselves; the Alliance will seek to work with countries to address issues arising in a as timely a manner as practicable.

This is the first report of a series to be produced from the comprehensive full country evaluations work. This report focuses on the introduction of pneumococcal conjugate vaccine in Mozambique, Uganda and Zambia. Supporting countries on vaccine introductions is an important area of focus for the GAVI Alliance, and is vital to ensure countries set off on the right path for successful and sustained implementation. GAVI Alliance partners play a key role in supporting Ministries in defining and assessing 'readiness', identifying areas of need technical assistance and monitoring progress. We have an established business planning process that defines the roles and responsibilities of each partner, and continue to refine it to improve our operating model.

While the report highlights some of the successful aspects of vaccine introduction in these countries, it also reveals the various challenges that were experienced. Many of the challenges are consistent with observations we have made in some other countries and that has informed the Alliance efforts in the past years. These findings can serve as important lessons to further refine the direction and prioritisation of future efforts aimed at strengthening processes and collaboration around new vaccine introductions and improving the health systems of countries. The study also underlines how dynamic and changeable situations can be in countries. We already have seen major improvements in several areas since the progress reports were prepared in 2013. We look forward to the future findings of the full country evaluations that will build upon this first report and remain committed to the comprehensive independent assessment of the GAVI-supported programmes and our processes.

What is this Alliance Response?

This Alliance response was developed by the GAVI Secretariat together with our Alliance Partners, to provide contextual information on ongoing efforts and also future actions identified to address the key cross-cutting recommendations arising from the PCV case studies. While the recommendations were made based on observations in Mozambique, Uganda and Zambia, the Alliance response was developed with an aim to improve our processes which has relevance for all GAVI-supported countries. The planned actions will be monitored both as part of the ongoing full country evaluations as well as through the routine GAVI Alliance business planning processes. Country-specific findings were disseminated and discussed separately with Mozambique, Uganda and Zambia in-country partners in March 2014, to inform their preparations for future vaccine introductions. Country-specific actions will be led by in-country stakeholders and are not included as part of this response.

RECOMMENDATION	ALLIANCE RESPONSE	RESPONSIBILITY	TIMING
<p>1. Explicitly articulate roles and responsibilities between partners, especially in relation to policy, procedures and requirements.</p>	<p>Clear articulation of roles and responsibilities between partners is at the centre of the Alliance implementation efforts and renewed efforts are dedicated to clarify this area, especially as GAVI's vaccine portfolio continues to grow and the level of technical assistance countries need on vaccine introductions and health systems strengthening intensifies. Measures underway and to be undertaken include the following:</p> <ol style="list-style-type: none"> 1. At the country level, the Inter-agency Coordinating Committee (ICC), led by the Ministry of Health, remains the core forum where partners across Ministries and agencies provide oversight on immunisation activities. GAVI Alliance partners are represented at these forums and will ensure that as activities are planned and monitored, that there is a clear delineation of roles and harmonisation of efforts. 2. The GAVI Alliance Business Plan designates technical assistance efforts to countries based on each organisation's strengths and level of resources. Continued efforts are underway to improve the process of identifying the most suitable partners to address specific country issues, the coordination mechanism, and alignment of communication flow and dissemination of information across and within agencies at the headquarter, regional and country levels. 3. With regard to coordination around the PCV10 readiness assessment requirement, WHO and UNICEF have worked and will continue to work closely with the Ministry on the conditions required for the introduction of PCV10, to ensure that all required conditions are met before the first vaccine shipment. A procedural document with roles and responsibilities defined had been developed by WHO in 2013 and are being sent to other countries in advance of PCV10 introductions. 	<p>MoH/In-country partners</p> <p>GAVI Secretariat and Alliance partners</p> <p>WHO/UNICEF/GAVI Secretariat</p>	<p>Ongoing</p> <p>Q2-4 2014 (for 2015 Alliance Business Plan arrangements)</p> <p>Development of procedural document completed in 2013; PCV-specific communication letter developed by Q2 2014, for communication to other countries for future PCV10 introductions</p>

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<p>2. Ensure that policies and processes specific to GAVI support are well articulated and understood by all stakeholders.</p>	<p>The GAVI Alliance recognizes the growing complexity of our business model and has placed concerted efforts to improve the communication of our policies and processes:</p> <ol style="list-style-type: none"> 1. The GAVI Secretariat increased the number of Country Responsible Officers (CROs) in recent years. This will ensure more frequent missions to countries and proactive dialogue with our partners. The recent institutionalisation of for example, Partnership Framework Agreement and Performance-Based Funding approach, was discussed in detail with countries, and partners were consulted on GAVI’s new Grant Application, Monitoring and Review (GAMR) process. 2. In late 2013, the Country Hub page on the GAVI website was revamped, to consolidate all policies and other resources relevant to countries on the page, for easy reference. Programme bulletins and customized letters to in-country stakeholders are developed to disseminate up-to-date information on changes in our policies, processes, and Board decisions. Feedback from countries is solicited to improve our communication approach. 3. Program Overview documents are being developed to formalise the Terms of Reference of each GAVI program, allowing the streamlining of program features and clarification of policies where required. These internal documents will serve as a base for briefing that will help with communications to countries. 4. The GAVI Secretariat and Alliance partners will intensify efforts to leverage forums such as quarterly partners calls, annual EPI Managers meetings and Regional Working Group meetings, to disseminate information to relevant stakeholders and ensure clear understanding of the materials. 	<p>GAVI Secretariat</p> <p>GAVI Secretariat</p> <p>GAVI Secretariat</p> <p>GAVI Secretariat/WHO/UNICEF</p>	<p>Increased CRO resources in 2013-2014</p> <p>Redesign in 2013; feedback survey planned for year-end 2014</p> <p>Overview documents for all programs to complete by year end 2014</p> <p>Communication of the new GAMR process started in late 2013 and will continue through full rollout in 2015</p>

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<p>3. Strengthen communication and coordination between global and country stakeholders in jointly setting realistic timeframes for the launch of new vaccines that take into account other streams of GAVI support and other country contextual factors.</p>	<p>With the increased number of new vaccines supported by the GAVI Alliance, countries are experiencing an unprecedented amount of activities taking place within the EPI programmes. While anticipation for new vaccines heightens, the GAVI Alliance recognizes the strain new activities can put on EPI and on the health system. We are committed to working with countries to jointly set realistic timeframes for vaccine introductions. Measures to be undertaken include the following:</p> <ol style="list-style-type: none"> 1. Continued dialogue through Alliance partners' participation in the ICC. Partners will provide the necessary technical guidance to countries to ensure that clearer definition of the requirements for introduction of new vaccines is shared with countries and that more realistic timeframes are set. More than half of the GAVI-supported countries have their comprehensive Multi-Year Plans (cMYPs) ending in 2015/2016. Countries' development of new strategic plans for the next planning cycle presents a good opportunity for partners to carefully plan out future vaccine introductions given the many priorities and system constraints. 2. The increased number of CROs, the establishment of dedicated team of vaccine Program Managers and the newly designed GAMR process allows for more frequent country visits and dialogues between the GAVI Secretariat, Alliance Partners and country teams, on topics including planning for new vaccines. In addition, GAVI Secretariat recently instituted a requirement for countries to submit an Expression of Interest for new vaccines support, indicating the intended timing of introduction, in advance of submitting a proposal. This will prompt earlier discussions with countries on the timeframes for new vaccine introductions. 3. WHO recently published the "Principles and considerations for adding a vaccine to a national immunisation programme", 	<p>MoH/WHO/UNICEF</p> <p>GAVI Secretariat</p> <p>WHO (guidance document development and publication)</p>	<p>As driven by the timing of countries' planning cycles</p> <p>Expression of Interest requirement introduced in Q1 2014</p> <p>Tools and guidelines published in Q1 2014</p>

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	<p>which includes guidance on vaccine planning and implementation, as well as detailed templates for work planning. These tools are referenced in GAVI's New Vaccine Support guidelines and countries are encouraged to adopt these tools to carefully plan for all the activities for new vaccine introductions and time required.</p> <p>4. Recognising that global PCV supply constraints had created uncertainties for countries' planning of introductions, the GAVI Secretariat and UNICEF (Programme and Supply Divisions) have ensured earlier dissemination of information on vaccine supply status where possible to better inform countries' decisions around vaccine introduction dates.</p> <p>5. The Independent Review Committee (IRC) will be requested to provide specific feedback on a country's proposed timeline of pre-introduction activities, highlighting potential areas of bottleneck that require attention and implications on introduction timing.</p>	<p>In-country and regional partners/MoH (utilisation of tools)</p> <p>UNICEF/GAVI Secretariat</p> <p>GAVI Secretariat</p>	<p>Ongoing</p> <p>Earlier dissemination of supply information where possible in effect immediately</p> <p>Future rounds of new applications</p>
<p>4. Adopt a management approach based on continuous improvement, proactive risk assessment, and contingency planning to better implement and coordinate critical launch activities and adapt when necessary.</p>	<p>Recognising that the time between new vaccine applications and launches can be as long as 12-18 months and countries' plans may change since the time of application, the GAVI Alliance will take a more active role in drawing attention to a monitoring framework with countries reporting progress against activities and milestones. The issue of readiness is an ongoing area of discussion at the senior management team of the Alliance, to develop a systematic approach to identify and manage risks, by directing technical assistance to areas which require support.</p> <p>Ministries of Health are accountable for driving implementation of programme activities. A number of measures are being undertaken to support a better management approach:</p> <p>1. Capacity building at the MoH is needed to strengthen the in-</p>	<p>MoH/Alliance partners/GAVI</p>	<p>Ongoing coordination;</p>

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	<p>country mechanisms currently used for decision-making and coordination between stakeholders for introduction planning, implementation and monitoring. We recognize that mechanisms such as the ICCs and Immunization Technical Advisory Groups (NITAG) function at varying levels across countries. The GAVI Business Plan allocates resources to strengthen such mechanisms. In addition, Coordination meetings and calls at the global, regional and country levels exist between Alliance Partners to discuss strategic and operational issues. These include, for example, WHO-led partner calls by region, regional working group meetings, Vaccine Implementation Management Team and vaccine-specific sub-teams calls. Technical assistance needs and allocation of resources across agency partners and countries will be re-assessed for the next business plan cycle, to ensure proper support to the Ministries.</p> <p>2. Since mid-2013, the WHO Immunisation Repository has been rolled out to provide a unified platform to monitor bottleneck areas and progresses in countries' implementation of vaccines. This supports better information sharing between global, regional and country stakeholders. Other tools have also been developed to support better risk management. In addition, the GAVI Secretariat recently completed an analysis on the pneumococcal and rotavirus vaccine introductions in recent years, to gather lessons on the common reasons that contribute to delays in vaccine introductions. This contributed to the design of a customized reporting tool for the Alliance sub-team to track progress of implementation.</p> <p>3. More CROs in the Secretariat now allows for more routine monitoring and review, and improved communication between the Secretariat and regional/in-country partners. Country Programme Risk Registers are being developed to proactively identify and mitigate key risks to program results.</p>	<p>Secretariat</p> <p>WHO (refinement of tools and development of reports)</p> <p>All partners (provision of inputs and monitoring of progress)</p> <p>GAVI Secretariat/Alliance partners</p>	<p>Q2-4 2014 (for 2015 Alliance Business Plan arrangements)</p> <p>WHO Immunisation Repository and the HSS Live Monitoring tools instituted in 2013; WHO New Vaccine Introduction Checklist revised in Q1 2014; Development of customized report for PCV in Q2-3 2014</p> <p>Risk register development to complete by year end 2014; GAMR Joint Appraisal</p>

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	<p>Newly designed Joint Appraisals missions as part of GAMR are being conducted in partnership with countries to assess program performance on an annual basis. Continued dialogues with ICCs will ensure that they monitor and report back to GAVI Secretariat on pre-introduction status against country-submitted timelines.</p> <p>4. Partners will continue to work together with the Ministries on contingency plans to address certain risks. For example, on cold chain readiness WHO and UNICEF have set up the immunisation supply chain hub to lead efforts in this area with the objective to strengthen in-country supply chains. The Alliance is also developing an immunisation supply chain strategy, to be reviewed by the GAVI Board in June 2014, which should positively impact cold chain readiness. Also, increasingly, funds from GAVI Health Systems Strengthening are being used to strengthen immunization supply chains.</p> <p>5. GAVI Business Plan supports the conduct of Post Introduction Evaluations (PIEs) which are typically conducted within 6-9 months of new vaccine introductions. The PIEs help to rapidly identify problem areas needing correction within the immunisation programme, and also provide valuable lessons for future vaccine introductions. In the case of Mozambique, a PIE was conducted around the same time as the full country evaluation team conducted their assessment. Findings from the two assessments were consistent. Results from the upcoming PIEs in Uganda and Zambia are expected to inform further actions in countries and the continued evaluation efforts within the full country evaluation project.</p>	<p>Alliance partners/GAVI Secretariat/MoH</p> <p>Alliance partners/MoH</p>	<p>missions started in Q1 2014 in selected countries and will be rolled out to all countries in 2015</p> <p>Board review of supply chain strategy in June 2014; implementation plan for 2015 to be finalized in Q4 2014</p> <p>Zambia PIE – July 2014; Uganda PIE – late 2014/early 2015; Other countries – timing dependent on vaccine introductions</p>
<p>5. Ensure timely and sufficient operational funding for vaccine introductions, which includes: ensuring VIG disbursed on time and</p>	<p>Ensuring early availability of funding for vaccine introductions and the development of a contingency plan requires actions both from Alliance partners, the GAVI Secretariat and the countries:</p>		

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ensuring sufficient contingent funding sources are identified.	<ul style="list-style-type: none"> The GAVI Secretariat is taking a number of steps to improve the timeliness of operational funds, including incorporation of more stringent internal timelines for the processing of Decision Letters and Vaccine Introduction Grants (VIG), and development of a pre-defined template to provide better guidance to countries on the budget details required for VIG disbursements. Furthermore, these budget details are now required at the application stage, rather than after IRC recommendation for approval as done in the past, allowing for a more thorough review of the planning and budgeting processes. Alliance partners will also provide support in the development of the VIG budget itself, ensuring that costs are reasonable and realistic. The funding levels in the GAVI VIG and operational cost policy will be reviewed this year to determine if policy revisions are necessary to be recommended to the Board. Before the VIG is disbursed, each country needs to ensure that the financial management system is in place to disburse funds in a timely manner to sub-national levels and to the entities in charge of implementing the required steps to prepare the vaccines roll out. This will be checked as part of a readiness assessment for launch. The Alliance partners at headquarter, regional and country levels are working with countries to ensure that new vaccine introductions are adequately planned and budgeted for in the New Vaccine Introduction Plan (NVIP), the comprehensive Multi Year Plans (cMYPs) and the annual work plans. Where needed, Alliance partners work on contingency plans to address shortfalls, including use of locally available resources, mobilization of additional resources through partners both in-country 	<p>GAVI Secretariat/In-country partners</p> <p>GAVI Secretariat</p> <p>MoH/MoF/In-country partners</p> <p>MoH/MoF/Alliance partners</p>	<p>VIG budget template disseminated as part of NVS guidelines in Jan 2014; VIG disbursement process improvements ongoing</p> <p>Q4 2014</p> <p>Ongoing</p> <p>Ongoing</p>

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	<p>and from headquarter. For example in Uganda, UNICEF headquarters provided additional funds for communication and cold chain activities. UNICEF Country Office in Mozambique mobilized additional local resources to cover similar areas.</p>		