GAVI Full Country Evaluation 2013 Process evaluation of pneumococcal vaccine introduction in Mozambique, Uganda, and Zambia

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Acknowledgements

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Acronyms

Acronym	Definition
AAR	After-Action Review
ABCE	Access, Bottlenecks, Cost, And Equity
ACADEMIC	A Comprehensive Assessment Of Diarrhea And Enteric Disease Management In Children
AIS	Aids Indicator Survey
CES	Coverage Evaluation Survey
CHERG	Child Health Epidemiology Reference Group
CHTWG	Child Health Technical Working Group
CHU	Child Health Unit
CIDRZ	Centre For Infectious Disease Research In Zambia
CISM	Manhiça Center For Health Research
CRO	Country Responsible Officer
DAH	Development Assistance For Health
DBS	Dried Blood Spot
DHS	Demographic Health Survey
DSS	Demographic Surveillance Site
DTP	Diphtheria, Tetanus, And Pertussis
EAT	EPI Expenditure Tracking
EEA	EPI Expenditure Accounts
EPI	Expanded Program On Immunization
EPITWG	EPI Technical Working Group
ERC	Ethical Review Committee
EVMA	Effective Vaccine Management Assessment

FCE	Full Country Evaluations
FDC	Fundação Para O Desenvolvimento Da Comunidade
FGD	Focus Group Discussion
FMA	Financial Management Assessment
GBD	Global Burden Of Disease
GPR	Gaussian Process Regression
GSK	GlaxoSmithKline
HAI	Health Alliance International
HMIS	Health Management Information System
HPV	Human Papillomavirus
HSS	Health Systems Strengthening
ICC	Inter-Agency Coordinating Committee
Icddr,b	International Centre For Diarrheal Disease Research, Bangladesh
IDRC	Infectious Diseases Research Collaboration
IEC	Information, Education, And Communication
IFMS	Integrated Financial Management System
IHME	Institute For Health Metrics And Evaluation
INE	National Institute Of Statistics
INS	National Institute Of Health
IPD	Invasive Pneumococcal Disease
IRB	Institutional Review Board
IRC	Independent Review Committee
ISO	International Organization For Standardization
ISS	Immunization Services Support

KAP	Knowledge, Attitudes, And Practice
KII	Key Informant Interview
LCMS	Living Conditions Monitoring Survey
LIST	Lives Saved Tool
MCDMCH	Ministry Of Community Development, Mother And Child Health
MCHIP	Maternal And Child Health Integrated Program
MIS	Malaria Indicator Survey
MMR	Measles, Mumps, Rubella
MOH	Ministry Of Health
MOHFW	Ministry Of Health And Family Welfare
MCPA	Malaria Control Policy Assessment
MPM	Multi-Partner Meeting
MR	Measles-Rubella
MSD	Measles Second Dose
NCC	National Coordinating Committee
NHA	National Health Accounts
NIP	National Immunization Program
NITAG	National Immunization Technical Advisory Group
NMS	National Medical Stores
NVS	New Vaccine Support
OECD	Organization For Economic Cooperation And Development
PAED	Programme For Awareness And Elimination Of Diarrhea
PBF	Post-Bachelor Fellow
PCV	Pneumococcal Vaccine

PETS	Public Expenditure Tracking Survey
PHFI	Public Health Foundation Of India
PIE	Post-Introduction Evaluation
QSS	Quality, Safety, Standards
RRC	Research Review Committee
RT	Resource Tracking
SIA	Supplemental Immunization Activities
TA	Technical Assistance
TOC	Theory Of Change
TOT	Training Of Trainers
TT	Tetanus Toxoid
TWG	Technical Working Group
UEM	University Of Eduardo Mondlane
UNZA	University Of Zambia
UW	University Of Washington
VIG	Vaccine Introduction Grant
WHO	World Health Organization
XRP	Radiologically (X-Ray) Confirmed Pneumonia
ZISSP	Zambia Integrated Services Strengthening Program

Process evaluation of pneumococcal vaccine introduction in Mozambique, Uganda, and Zambia

1 Executive Summary

1.1 Introduction

The GAVI Full Country Evaluation (FCE) is a prospective study that aims to understand and quantify the barriers to and drivers of immunization program improvement in five countries (Bangladesh, India, Mozambique, Uganda, and Zambia), with emphasis on the contributions of the GAVI Alliance. The scope of the study, which covers 2013 through 2016, includes GAVI's support for new and underused vaccines, cash-based support to countries and interactions between funding streams. The GAVI FCE uses a mixed-method approach that includes qualitative, semi-quantitative, and quantitative methods to understand the full results chain. The focus of this report is a process evaluation of the introduction of pneumococcal vaccine (PCV) in Mozambique, Uganda, and Zambia, including a comparative analysis across the three countries.

1.2 Methods

This process evaluation is based on qualitative data collected from document review, participant observation, key informant interviews (KIIs), and an after-action review (AAR). The evaluation team developed a theory of change to guide the evaluation and analysis.

Our findings reflect the process of introducing PCV in Mozambique, Uganda, and Zambia up to December 1, 2013. Data from other evaluation components of the GAVI FCE—including health facility surveys, household surveys, and administrative data—are still being collected and analyzed. Subsequent GAVI FCE reports will provide a more complete analysis of the PCV introductions, as well as other GAVI Alliance streams of support, including triangulation across multiple evaluation components.

1.3 Findings

1.3.1 Mozambique

A number of challenges were observedwhen PCV was introduced in Mozambique in April 2013. A central underlying challenge was a delay in receiving funds for the operational plan. Multiple sources of funding were delayed, including funding from the MOH, SWAp, and GAVI vaccine introduction grant (VIG), the latter of which formed most of the operational budget. GAVI VIG funds ultimately arrived only two weeks before the final launch date, which led to delays and suboptimal implementation of preparatory activities.

Partial contingency funding for critical preparatory activities was mobilized through partner organizations such as GSK, USAID, UNICEF, and WHO. Although this funding facilitated some key preparatory activities, the limited nature of the support meant that important activities were delayed.

For example, although training of trainers took place with contingency funding, training for district and health facility managers, in some cases, happened after the launch, raising questions about the quality of vaccine delivery. Also, because updated data collection and reporting tools for PCV10 were not available in health facilities until three months after the launch, facilities initially had to rely on improvised PCV monitoring tools. Lack of official data collection and reporting tools limited facilities' and the National Immunization Program's (NIP's) ability to accurately monitor implementation of vaccine introduction.

Funding delays were not the only challenges. A range of management, coordination, and implementation issues emerged from the process evaluation. For example, in the case of social mobilization, development of key media messages was stymied or muddled because of management and implementation issues. In particular, there was no time allotted for pretesting media messages, and this led to delivery of inaccurate and unclear messages to the population. These messages created demand for PCV outside of the target age group and had negative consequences, including an increase in providers' workload. The confusion generated by inaccurate messaging may also decrease future demand for vaccination by reducing trust in media messages.

Despite these considerable challenges, Mozambique's NIP and partners introduced PCV largely as scheduled. However, because of delayed implementation of key preparatory activities and other challenges, it may have been beneficial to postpone the launch. This would have allowed time for training at the health facility level, distribution of updated M&E tools to sites, and pretesting of social mobilization messages.

Compared to the previous introduction of the pentavalent vaccine in Mozambique, although many issues identified in the previous post-introduction evaluation (PIE) of the pentavalent vaccine were addressed in the introduction of PCV,several issues such as lack of updated M&E tools and delayed training were common to both introductions.

A positive outcome identified by the evaluation was the productive partnership between the MOH and key stakeholders, facilitated by regular meetings and good communication by the NIP prior to PCV introduction. Communication between the GAVI secretariat, NIP, and partners regarding the GAVI VIG was not as good. Key informants from both government and country partner organizations said they did not understand the reason for the delay in the GAVI VIG, and had poor understanding of the policies, procedures and timelines for disbursement of the VIG. The absence of explicitly articulated roles and accountability mechanisms may have contributed to these communications challenges.

1.3.2 Uganda

In Uganda, PCV was introduced in April 2013 in the Iganga district. Introduction was limited to Iganga because most districts had not yet held training, and were deemed not ready for introduction. After the initial launch, PCV was to be rolled out rapidly in a phased manner, countrywide (one region at a time). This had not yet occurred, however, at the time of writing this report.

Based on the results, WHO concluded that Uganda was not ready to introduce PCV, and indicated that key gaps would need to be addressed before additional vaccines would be shipped. At the time of the writing this report, Uganda has yet to be confirmed as ready, and PCV has not been rolled out countrywide.

Several factors have contributed to the lack of progress in PCV introduction in Uganda. Contextual changes, including changes in key leadership positions and implementation of a new financial system, contributed to poor planning, poor adjustment to plans, and insufficient funding disbursement to carry out essential introduction activities. At a deeper level, the relationship between immunization stakeholders in the country is delicate, though improving, as Uganda continues to recover from the country's mismanagement of GAVI funds in 2006, and the subsequent suspension of support.

Questions about the quality of training were raised in an EPI technical meeting in July 2013. One of the criticisms was that few practical demonstrations of proper handling and injection of PCV had been conducted because the vaccine was not yet widely available in Uganda. Further, the plan for cascaded PCV training assumed that the few health workers trained would in turn train their colleagues at each workstation, and there were signs that this was not consistently happening. Concerns about the quality of training in relation to specific handling requirements for PCV10 preceded WHO's formal readiness assessment in September 2013. This study indicated that only 43% of health workers had sufficient knowledge of this vaccine and its unique handling requirements.

The process evaluation also found other management challenges affecting introduction. For example, responsibility for vaccine management was shifted from UNEPI to the National Medical Stores (NMS) in July 2012. At that time, NMS lacked expertise in vaccine handling and management, and communication with UNEPI was inadequate, resulting in an insufficient transfer of critical information, knowledge, and skills to NMS.

At various points throughout the PCV introduction process, critical threats to successful introduction came to light. In some cases, the information was communicated and acted upon, but in other cases it was not. One successful adjustment was the resolution of some communication problems between UNEPI and NMS. This happened soon after new managers at MOH and UNEPI came on board.

In the midst of challenges in disbursing funds and implementing training, the lack of adjustments in preparation activities points to breakdowns in the overall management and coordination of the process. For example, although country leaders decided to scale back the launch to one district, social mobilization efforts proceeded nationwide. This resulted in caregivers bringing their children to health facilities to receive a vaccine that was not available. This brings into question whether the decision to proceed with an April launch date for any district was appropriate given the inadequate preparations.

1.3.3 Zambia

In July2013, after multiple postponements, PCV was introduced simultaneously with measles second dose vaccine (MSD).Zambia was one of only a handful of countries to have simultaneously launched multiple vaccines. Our interviews and observations suggest that this was widely perceived to be a

success, and that a number of resource and programmatic efficiencies were realized by integrating preparatory activities for introducing the two vaccines. This noted, we would caution that integrating other vaccine combinations may not be as straightforward as with PCV and MSD.

We observed a number of challenges and bottlenecks in the process leading up to the launch of PCV and MSD. First, the launch occurred in the midst of a broader realignment of ministerial functions, with the immunization program shifting from the Ministry of Health to the Ministry of Community Development, Maternal and Child Health (MCDMCH). This realignment contributed to delays in the release of funds.

Second, the launch occurred in a year with other major immunization milestones—namely, the implementation of a human papillomavirus (HPV) vaccine demonstration project in Lusaka province and the nationwide introduction of rotavirus vaccine. The implementation of so many overlapping processes was a challenge for stakeholders.

Third, there was human resource capacity constraints at the central level, with a relatively small EPI unit tasked with managing a large number of immunization-related activities. This was exacerbated by a lack of an effective alternate decision-making authority when key program managers were otherwise engaged.

Finally, country-level stakeholders lacked an understanding of the process and timing for obtaining the VIG from GAVI. This was widely acknowledged to be a slow process and was made worse when the funds finally arrived in the account of UNICEF. There were problems transferring funds to districts, and funds were transferred to the wrong account in Lusaka province. This resulted in delayed implementation of social mobilization activities and ultimately of vaccine introduction.

Following the launch of PCV in July 2013, stakeholders immediately shifted to preparations for the launch of rotavirus vaccine without a formal evaluation of the PCV introduction. This raises the question of whether it is appropriate to introduce vaccines in such close succession without an opportunity to fully evaluate and absorb lessons learned.

1.3.4 Cross-country analysis

Each of the three countries that introduced PCV faced its own unique set of challenges. All three experienced delayed introductions, albeit for different reasons, with Uganda yet to rollout PCV nationwide. Countries also faced a number of common challenges, such as (1) ensuring sufficient, timely funding for preparatory activities, including the disbursement of the GAVI Viand other funds, (2) managing health worker training, (3) updating monitoring systems to allow tracking of PCV delivery and coverage, and (4) coordinating timely and effective social mobilization and demand generation. Furthermore, there was inconsistent implementation of the PCV10 readiness requirements (training and PCV refrigerator stickers) across the three countries. In addition, although there was evidence of effective partnerships at the country level—evidenced, for example, through provision of contingency funding by partners—there were also areas of weakness, including a lack of understanding of key GAVI policies and procedures, such as those related to the VIG. The evaluation team also identified a number of common management problems which were, (1) recognizing and managing unfamiliar or unknown

processes, (2) recognizing and managing uncertainty when it is introduced into the introduction process; (3) a tendency toward reactive management rather than proactive risk management and contingency planning; and (4) poorly defined roles and responsibilities among key partners.

1.4 Recommendations

Based on the country case studies and cross-country analysis, we provide five high-level recommendations:

1. Explicitly articulate roles and responsibilities among partners, especially in relation to policies, procedures, and requirements.
2. Ensure that policies and processes specific to GAVI support are well articulated and understood by all stakeholders.
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.
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.
5. Ensure timely and sufficient operational funding for vaccine introduction through timely disbursement of VIG funds and identification of contingent funding sources.

2 GAVI Full Country Evaluation Team

This report has been written by the GAVI Full Country Evaluations team consisting of the following institutional partners: the Institute for Health Metrics and Evaluation (IHME) at the University of Washington, USA; PATH, USA; the International Centre for Diarrheal Disease Research, Bangladesh (icddr,b), Bangladesh; the Public Health Foundation of India (PHFI), India; University of Eduardo Mondlane (UEM), Mozambique; Health Alliance International (HAI), Mozambique; Manhiça Health Research Center (CISM), Mozambique; the Infectious Diseases Research Collaboration (IDRC), Uganda; and the University of Zambia (UNZA), Zambia. The following individuals contributed to the writing of this report: Jane Achan (IDRC), Joanne Amlag (IHME), Gilbert Asiimwe (IDRC), Jeff Bernson (PATH), Emily Carnahan (PATH), Benjamin Chibuye (formerly UNZA), Baltazar Chilundo (UEM), Abson Chompolola (UNZA), Sarah Gimbel (HAI), Dai Hozumi (PATH), Gloria Ikilezi (IDRC), Moses Kamya (IDRC), Stephen Lim (IHME), Felix Masiye (UNZA), Luisa Matsinhe (UEM), João Mavimbe (UEM), Kelsey Moore (IHME), Peter Mulenga (UNZA), Oliver Mweemba (UNZA), Anita Odallah (UEM), Chris Odell (IHME), James Okello (IDRC), Julie Rajaratnam (PATH), Nicole Salisbury (PATH), Catherine Seneviratne (PATH), Caroline Soi (HAI), Peter Waiswa (IDRC/MUSPH).

3 Introduction

The GAVI Full Country Evaluation (FCE) is a prospective study to understand and quantify the barriers to and drivers of immunization program improvement in five countries (Bangladesh, India, Mozambique, Uganda, and Zambia), with emphasis on the contributions of the GAVI Alliance. Covering 2013 through 2016, the GAVI FCE aims to help immunization program partners improve implementation to increase vaccination coverage. A full description of the GAVI FCE can be found on the FCE page on the GAVI Alliance website.

A key aspect of the GAVI FCE is a process evaluation to identify the processes, networks, and systems that affect vaccine delivery. In this first year of the GAVI FCE, the evaluation team focused on the introduction of pneumococcal vaccine (PCV) in Mozambique, Uganda, and Zambia. The concurrent efforts to plan and implement the new vaccine provided a unique opportunity to assess the process in different contexts, and to compare the experiences across countries. The evaluation of PCV introduction also provided a basis for process evaluation activities moving forward—that is, the evolution of issues identified through the PCV assessment can be tracked prospectively throughout the evaluation period. This basis for future evaluation applies not only to the process of vaccine introduction, but also to aspects of partnership and coordination among Alliance members, and more broadly to planning and implementation of routine immunization activities and other streams of GAVI support.

Findings from the process evaluation of PCV introductions in Mozambique, Uganda, and Zambia are predominantly based on qualitative data collected from document review, participant observation, and key informant interviews (KIIs). Data from other evaluation components of the GAVI FCE—including health facility surveys, household surveys, and administrative data—are still being collected and analyzed. Because a key feature of the GAVI FCE is triangulation of multiple data using a mixed-methods approach, the findings in this report should not be considered a completed evaluation. Subsequent GAVI FCE reports will include a more complete analysis of the PCV introductions as well as other GAVI Alliance streams of support.

4 Objectives

The objectives of this process evaluation of PCV introduction are to:

1. Document and evaluate the process through which countries prepared for and implemented the introduction of PCV with GAVI support.
2. Benchmark the current process of introducing a new vaccine, to provide a comparator for future vaccine introductions.
3. Identify questions for prospective process tracking that are relevant to the broader routine immunization system and other streams of GAVI support.

Although each country officially launched PCV in 2013, activities to support the rollout and integrate the vaccine into the routine system are ongoing. This statement applies especially to Uganda, where the

vaccine was launched initially in only one district. Thus, this report is not a complete evaluation of PCV introduction, and represents an analysis based on information gathered up until December 1, 2013.

This report has been written for dissemination to a variety of audiences, including members of the GAVI Alliance at the international level (Secretariat, WHO and UNICEF headquarters) and stakeholders and Alliance partners in each of the focal countries. The following section outlines the theory of change underlying the process evaluation, as well as the data collection and analysis methods used. Findings for each of the three countries are then described, followed by a section that analyzes the findings across the countries and provides a set of common recommendations that complement the country-specific analyses and recommendations.

5 Methods

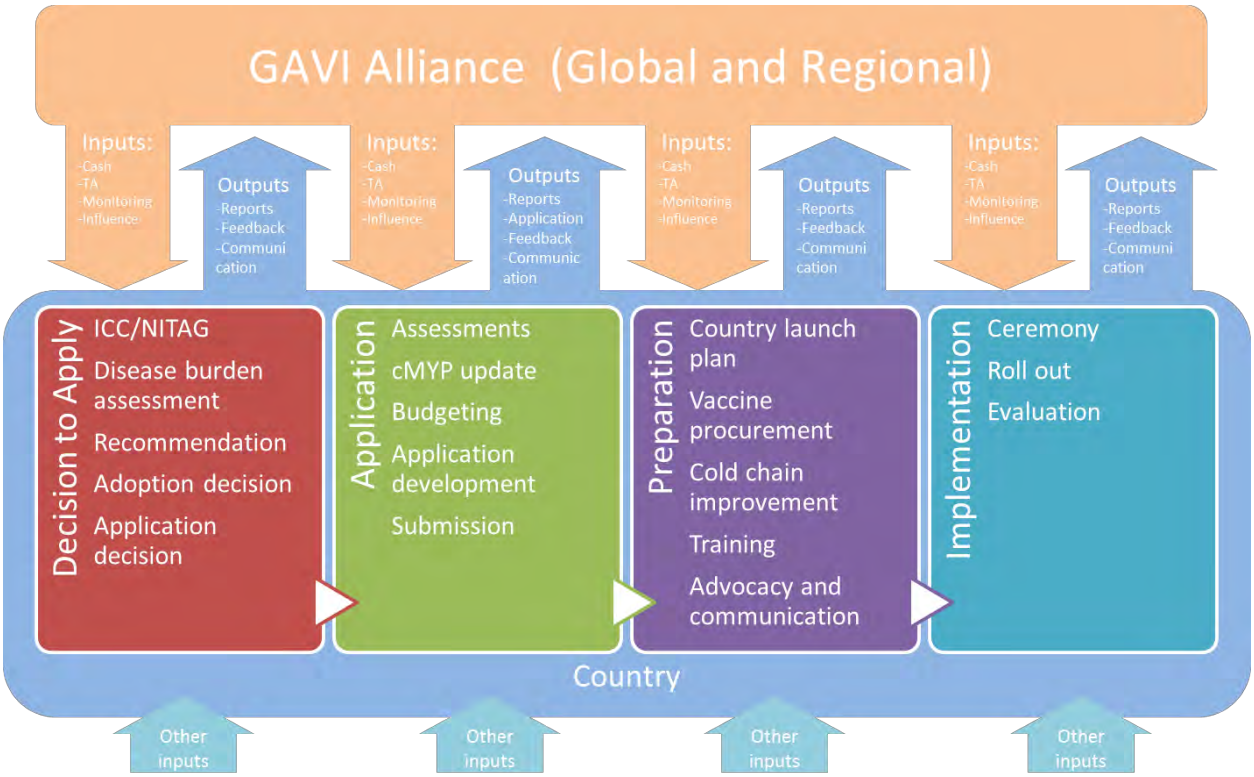
5.1 Theory of Change

Process evaluation explores the organization of existing processes, strengths and weaknesses of current management practices, and explanations for findings, and it provides recommendations for improvement. The GAVI FCE team developed a theory of change (TOC) to guide the process evaluation by comparing expected processes to existing processes. This TOC is specific to PCV10, the vaccine formulation introduced in the three countries. It describes the key milestones to be achieved and the relationships necessary for successful vaccine launch. To date, the project team has not identified any documents, including those at the GAVI secretariat, that describe an in-country TOC, and this previous lack of a TOC required us to develop one for the project. We used the TOC to organize findings in each country and to identify areas of focus for cross-country analysis.

The TOC is an evolving framework. We will continue to improve it to illuminate specific processes related to different types of GAVI assistance, elaborate tasks and milestones that must be achieved, and illustrate implicit and explicit interdependencies between elements of the TOC.

The TOC presented below corresponds to the “Preparation” and initial “Implementation” phases of the GAVI–Country Process Framework (Figure 1) that was developed by the GAVI FCE team.

Figure 1: GAVI–country process framework.



Because the process evaluation component of the GAVI FCE is prospectively oriented, and the evaluation period for PCV introduction in Mozambique, Uganda, and Zambia began after the decision to apply and application phases, the TOC does not explicitly outline these earlier processes.[1] The TOC also does not explicitly address processes specific to management of routine immunization programs, such as management of budgets for non-PCV10 vaccines or implementation of the Reaching Every District (RED) strategy. The performance of routine immunization programs is considered a contextual factor. Also, the TOC is intended to be a high-level perspective that encompasses processes across the GAVI FCE countries and does not describe detailed country-specific processes. Figure 2 illustrates the TOC.

[1] Even though the TOC does not discuss the processes for decision making and applying, we attempted to capture information on these phases where possible and incorporated that information into the country PCV case reports.

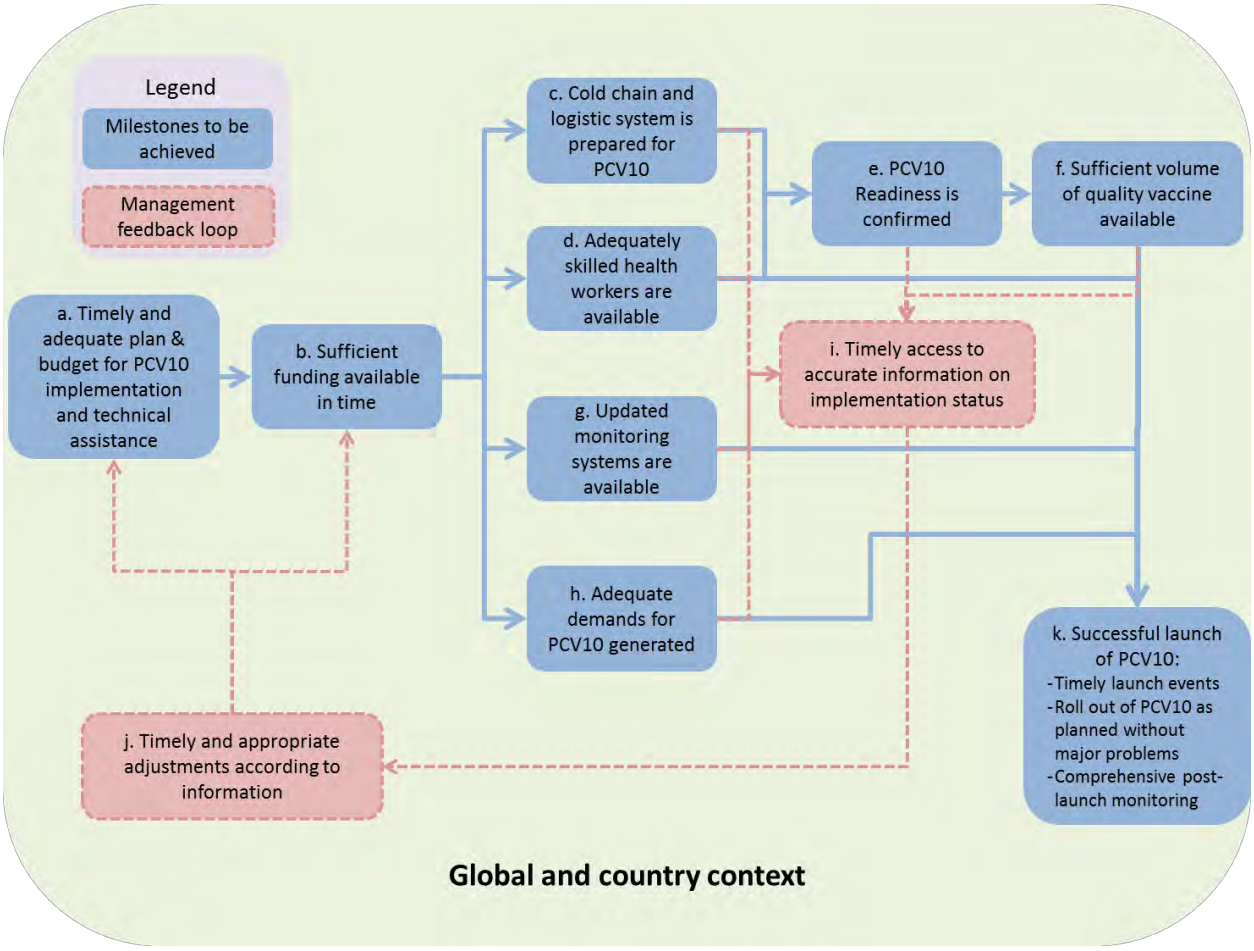


Figure 2: PCV10 introduction theory of change.

In the TOC, we define the success of a PCV launch based on three criteria: (1) implementing launch events, such as the launch ceremony, as planned;(2) achieving targets for vaccine rollout (i.e., vaccine coverage) as planned, without major problems such as stockouts or lack of demand; and (3) implementing comprehensive post-launch monitoring activities, such as post-launch supervision and a Post-Introduction Evaluation (PIE). Since the introduction process was not complete in any of the countries at the time of this report, we do not evaluate here the routinization of PCV into the immunization system, an important step to the overall success of introducing a new vaccine. Our continued efforts to track the process going forward will incorporate this critical step in the process and will incorporate additional data sources with which the qualitative findings from the process evaluation will be triangulated, such as indicators of vaccine coverage, stockouts, and wastage.

Successful introduction of PCV requires implementing various preparatory processes. The blue boxes in Figure 2 describe critical milestones for key processes. The red boxes highlight the management feedback loop that provides timely and accurate information on implementation status, so that timely corrective adjustments can be made, including the provision of additional technical assistance by government agencies and partners. We further conceived that a country's ability to manage the introduction of PCV is influenced by multiple contextual factors (the underlying green box), such as the strength of the existing immunization program, changes in competing priorities, government policies, other GAVI Alliance support (such as health system strengthening), GAVI policy/guidelines, the broader donor landscape, and the overall socioeconomic environment.

The TOC starts with development of a timely and adequate plan that includes a budget for implementation and technical assistance (Box a). Revisions of the comprehensive Multi-Year Plan (cMYP), development or adjustment of the PCV introduction plan, identification of technical assistance needs, and identification of budget requirements all need to be promptly communicated to key stakeholders—including GAVI and its partners—to ensure timely availability of needed funds and technical assistance. In response to requests, funding sources should disburse funds according to the agreed schedule (Box b) to support preparatory activities. The funding must flow as originally planned from funding agencies (the ministry of finance, GAVI, and other donors), to implementation entities (such as the EPI program, in-country partner organizations, and civil society organizations), and on down to health facilities. The TOC highlights that insufficient funding or delayed disbursement can negatively affect preparatory processes and ultimately hinder vaccine launch.

Achieving milestones in each of the following four intermediate processes (Box c [cold chain and logistic systems], Box d [skilled health workers], Box g [updated monitoring systems], and Box h [adequate demand]) are necessary for the successful launch of PCV10. PCV10 introduction may require cold chain capacity improvements (Box c) before the vaccine can be imported, properly stored, and distributed to points of delivery. Health care workers also need to be trained for proper vaccine handling and delivery, and adequately skilled health workers must be available at all vaccination points at the time of launch (Box d). In addition, existing monitoring tools such as EPI cards, registers, surveillance tools, and data summary forms, as well as data collection and management systems, must be updated in advance of PCV10 launch (Box e) so vaccine delivery can be monitored. Finally, a country needs to generate adequate and timely demand for PCV10 based on accurate information. For example, a significant time lag between implementation of demand-generation activities and the actual launch date could reduce parents' interest and motivation for bringing their children for vaccination (Box f).

Another factor influencing the launch of PCV10 is the need for confirmation of country readiness (Box e). In 2010, WHO prequalified the two-dose presentation of Synflorix™,[2] a preservative-free vaccine. However, because this presentation is new to the United-Nations-supported immunization programs,

[2] http://www.who.int/immunization_standards/vaccine_quality/synflorix_pqnote_2dose_2012/en/index.html (the last accessed Jan 1 2014)

WHO requires that each country considering introduction ensure programmatic readiness, monitor correct use, and implement any corrective training needed.

A website maintained by the Quality, Safety, and Standards (QSS) Unit of WHO's biological standardization program indicates that a country introducing PCV10 needs to certify that:

- Training materials are in place in immunization centers and training has taken place prior to the launch.
- Stickers are placed on refrigerators at all levels indicating that opened vaccine vials must be discarded six hours after opening. The stickers should be in place prior to the launch.

Shipment of the vaccine to each country, and further distribution to delivery points, is contingent upon confirmation of a country's readiness (Box f). The Ministry of Health first sends written notification of the country's programmatic readiness to the UNICEF country office, and WHO then verifies this status.[3] The readiness confirmation process involves many groups, including the UNICEF country office, UNICEF Supply Division, WHO country and regional offices, WHO headquarters New and Underutilized Vaccines Unit, WHO headquarters Quality, Safety, and Standards (QSS) Unit, and the Ministry of Health.

An effective management feedback loop (i.e., timely access to information on project execution and corrective action based on the information) is critical for successful vaccine introduction (see boxes i and j). Plans and budgets often require multiple adjustments during the preparation phase. There are multiple sources of information, including supervisory visits, reports from subnational levels, and meetings among stakeholders. For example, when a district manager identifies suboptimal vaccine quality due to prolonged temperatures outside of the specified range, this information should be immediately communicated to the national level EPI manager (Box i), and the compromised vaccine then replaced (Box j).

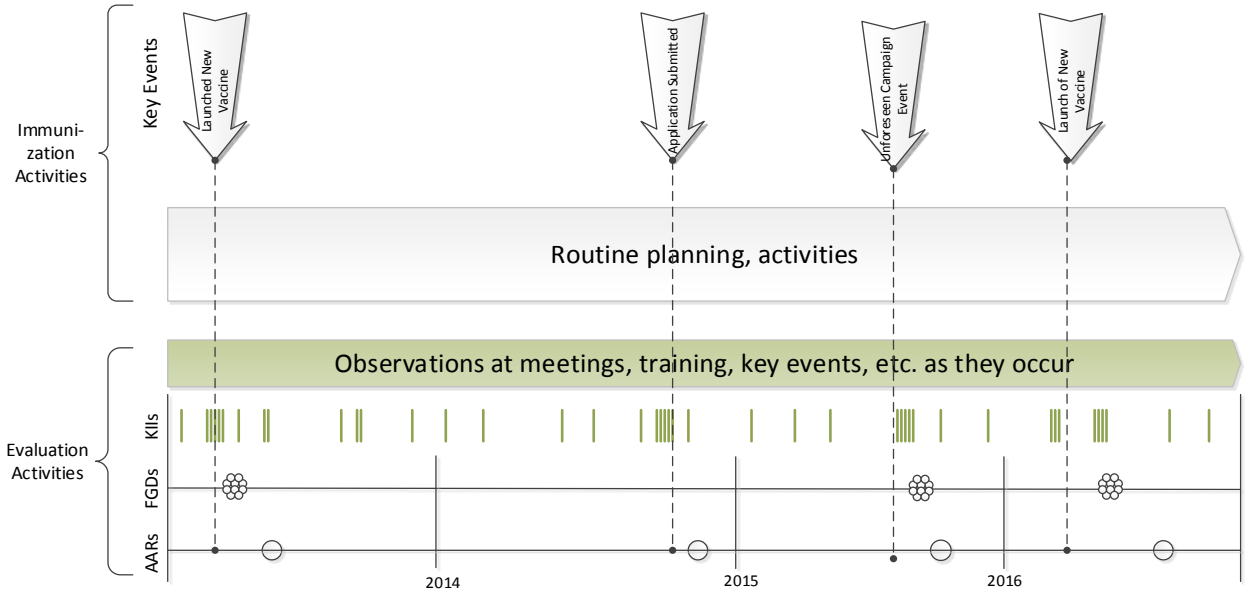
5.2 Data collection methods

Qualitative data collection informed the development of the TOC, and the evaluation of country planning, management, and implementation processes. The assessment of PCV introduction in Mozambique, Uganda, and Zambia was based on prospective, qualitative data collection carried out between February and November 2013. Evaluation activities were limited prior to Institutional Review Board (IRB) approval within each country. In Mozambique, we obtained approval in July 2013 from the Mozambican National Bioethics Committee (ethical and scientific) and the Ministry of Health (administrative). In Uganda, we obtained approval in October 2013 from the Makerere University School of Biomedical Science Research and Ethics Committee (Ref SBS 128) and the Uganda National Council for Science and Technology. Additional approval was received from the Uganda Ministry of Health (MOH) to roll out evaluation activities. In Zambia, we obtained approval in June 2013 from the University of Zambia IRB (ethical and scientific) and the Ministry of Community Development, Mother and Child Health (administrative).

[3] "Introduction of pneumococcal vaccine PCV10, two dose presentation: a handbook for district and health facility staff" June 2013 version http://apps.who.int/nuvi/pneumococcus/Rev_PCV10_Handbook.pdf

This report draws on data collected through participant observation, document review, key informant interviews (KIIs), and an After-Action Review (AAR) workshop. The data were collected at the national and subnational level within each country, and directly from GAVI and GAVI partners at headquarters. These data collection mechanisms are geared toward prospective evaluation and are intended to be complementary, as illustrated in Figure 3.

Figure 3: Illustrative flow of process evaluation activities.



5.2.1 Participant observation

GAVI FCE team members attended meetings, workshops, trainings, and other events to gather information. We took detailed notes using a journal entry form to capture details including general observations on the topics of discussion, changes to planned activities, and the decision-making process between partners. A GANTT chart was used to record activities, expected completion dates, and who is responsible, accountable, consulted, and informed for each activity.

Team members attended a variety of meetings and events related to immunization programming in each country. In Mozambique, this included (1) the PCV technical working group weekly meeting; (2) National Immunization Program (NIP) staff meetings; (3) the training of district trainers in Maputo and

Gaza provinces; (4) supervision visits conducted by NIP staff in Sofala and Nampula provinces; and (5) the central-level MOH official PCV launch.

In Uganda, evaluation team members attended (1) the national coordinating committee (NCC) meetings; (2) EPI technical working group meetings; (3) advocacy meetings (for members of parliament, religious leaders and media); (4) the inauguration of the National Civil Society Immunization Platform; (5) the national PCV launch ceremony; (6) training of health workers at the national and subnational levels; and (7) WHO's readiness assessment and district mentorship activities to improve readiness.

In Zambia, evaluation team members observed (1) the PCV10 Orientation of Health Workers; (2) National Training of Trainers; (3) Social Mobilization Subcommittee meeting; (4) Partners Advocacy on New Vaccine Introductions meeting; (5) Child Health Technical Working Group (CHTWG); (6) EPI Technical Working Group; and (7) the Inter-agency Coordinating Committee.

5.2.2 Document review

The evaluation team reviewed relevant documents for information about planned and ongoing activities related to PCV implementation. These documents included GAVI PCV-related application materials and communications, the Comprehensive Multi-Year Plan (cMYP) for each country, PCV introduction plans, annual progress reports to GAVI, GAVI committee reports, GAVI decision letters, documented cold chain assessments and strategies, Effective Vaccine Management Strategies, communication and behavioral change materials, and meeting minutes from various in-country subcommittees and technical working groups. A complete list is available on request.

5.2.3 Key informant interviews

Key issues affecting PCV implementation were identified through participant observation and document review. For issues meriting further investigation, the team hypothesized underlying causes and developed a logic model based on prior knowledge. This model was then used to identify key informants and develop topic guides (available on request) for key informant interviews (KIIs). For example, if absence of coordination among in-country partners was concern, then all relevant partners would be targeted for interviews, and the topic guide questions would explore the level of coordination.

Interviews were generally conducted by two team members: an interviewer and a note taker. Most lasted 45 minutes to one hour, but some were shorter or longer depending on key informant availability and the breadth of topics. Interviews were conducted with individuals at GAVI headquarters and at national and subnational levels in FCE countries. National key informants included government officials in the Ministry of Health or Expanded Program on Immunization (EPI) and representatives of country partner organizations such as UNICEF, WHO, or other collaborators. Subnational key informants included district health officers, cold chain focal persons, and health facility workers. Table 1 shows the number of KIIs performed in each country and at the global level. In Mozambique, we digitally recorded interviews with IRB approval and the participant's consent.

Table 1: Number of key informant interviews performed in FCE countries and at the global level

Mozambique	Uganda	Zambia	Global	Total
59	16	21	15	111

5.2.4 After-action review

An after-action review (AAR) is a structured and facilitated in-depth discussion of a specific goal or milestone event. It provides an opportunity for a group to identify and share what has worked and what has not worked in carrying out the event, in an effort to capture the lessons learned and continually improve the process. AARs have been successfully used in many areas of global development to improve processes and coordination among partners.

The AAR is structured around four key questions about the process or event of focus. Through a guided process of group reflection, participants answer:

- What was originally intended to happen?
- What actually occurred?
- What went well, and why?
- What could be improved, and how?

In September 2013, Mozambique held an AAR with 30 stakeholders that was facilitated by the evaluation team (Table 2). The AAR focused on two topics identified as areas of weakness by the National Immunization Program and the Technical Working Group, in consultation with the evaluation team: post-introduction supervision and social mobilization. The activity was documented by multiple note takers, and the findings were summarized in a final report (available on request).

Table 2: Number of AAR workshop participants in Mozambique.

Respondent type	Participants
Government (MOH)	13
Multilateral, bilateral organizations and donors	6
NGOs	7
Research/university	4
Total	**30**

5.3 Country data analysis

Data were compiled from all sources and analyzed according to the key milestones identified in the TOC, though the analysis remained open to other themes emerging from the data. Teams identified where country plans and processes differed from the process required for a timely and successful launch, and evaluated the underlying causes of the diversions where possible. We also analyzed the sequencing and timeliness of PCV launch planning and implementation activities. Where possible, data were also used to draw conclusions about the comprehensiveness and completeness of launch activities, as well as the roles and relationships of partners.

5.4 Cross-country analysis

We also identified and analyzed themes that emerged across all countries. These themes fall into two categories:

- All three countries experienced significant and similar challenges in accomplishing key tasks.
- All three countries had different experiences (different management approaches in each country seemed to contribute to the differences).

The prospective nature of the evaluation allowed these themes to be identified in real time as the data were collected, and the themes could then be explored in depth as the evaluation unfolded. For example, the importance of timely and sufficient funding emerged as a common challenge across the three countries. A topic guide was developed to further explore this theme through key informant interviews.

Based on the synthesis of information gained through the process tracking, key areas of inquiry across countries were analyzed from a management perspective. We focused on analyzing the managerial practices that might have facilitated or mitigated challenges during the PCV launch. We first identified high-quality management practices based on the International Organization for Standardization (ISO) quality management principles, and then developed analysis questions to understand whether there was evidence of strong management practices among country partners and between GAVI and countries. These analytical questions focused on common understanding of processes, clearly defined roles and responsibilities, and management feedback to make timely, information-driven adjustments.

6 Mozambique

This section describes the process by which Mozambique managed and implemented PCV introduction. Findings are presented by core steps in the TOC. We assess (1) whether the in-country process mirrored the theory of change; (2) diversions, challenges, and their consequences; and (3) underlying causes of diversions and challenges. A summary at the end of this section focuses on key issues and consequences.

6.1 Current status

Mozambique introduced the 10-valent PCV into its routine immunization program in April 2013 with support from the GAVI Alliance. At the time of this report, eight months have passed since the launch. A post-introduction evaluation (PIE) was conducted in November 2013 by the NIP and partners.

6.2 Timely and adequate planning and budgeting

6.2.1 Rationale for PCV introduction in Mozambique

The decision to introduce PCV was made in the middle of 2010. It was driven by a combination of political will and scientific evidence from burden of disease research. This decision was supported by advice from both the Interagency Coordinating Committee (ICC) and National Immunization Technical Advisory Group (NITAG), and was incorporated into the comprehensive Multi-Year Plan (cMYP) 2012-2016. According to the Mozambique Causes of Mortality Study, pneumonia was the third-leading cause of death in children under 5 years, after malaria and HIV[1]. Scientific evidence elucidating the burden of disease in Mozambique emanated from the Manhiça Health Research Centre (CISM), which conducted population-based surveillance for invasive pneumococcal disease (IPD) and pneumonia between 2001 and 2010.Data from the CISM surveillance system demonstrated that severe pneumonia accounted for 16% of hospital admissions among children under two years of age (an incidence of 45/1,000 per child-year at risk) between 2004 and 2006. Of those children with severe pneumonia, 43% had radiographic findings consistent with bacterial pneumonia according to WHO criteria for standardized interpretation. The CISM data also revealed that *Streptococcus pneumoniae* was the leading cause of bacterial pneumonia. In addition, IPD incidence rate was highest among children under two years of age from 2001 to 2010 (475/100,000 per child-year at risk)[2,3].

The decision-making process led by the MOH involved in-country consultation with partners including UNICEF, WHO, VillageReach, Fundação para o Desenvolvimento da Comunidade (FDC), the NITAG, and the ICC. It also involved consultation with the GAVI Alliance at the global level. The country selected the 13-valent pneumococcal conjugate vaccine (PCV13) based onscientific evidence from CISM. These studies indicated that the serotype coverage of the 7-valent, 10-valent, and 13-valent conjugate vaccines would be 29%, 65%, and 83%, respectively. Meanwhile, the case fatality rate among children under two years of age was higher among cases of serotypes included in PCV13 (11%) compared with those included in PCV10 (9%).

6.2.2 Setting the launch date

The cMYP was finalized in January 2011 andestablished an initial PCV launch date of January 2012. This date was unrealistic, however, given that the cMYP was only finalized in early 2011. The PCV application toGAVIwas subsequently developed, reviewed, and approved by the NITAG in April 2011 and submitted to GAVI in June 2011[2]. The application proposed thatPCV be introduced simultaneously countrywide,instead of using the phased-in approach previously used to introduce the pentavalent vaccine.

Key informants reported that the launch date was postponed for two reasons. The first was to allow time for an Effective Vaccine Management Assessment (EVMA) to be completed prior to introduction[4]. Although the PCV application stated that the EVMA was planned for September 2011, when the PCV application was approved in July 2011, the EVMA was postponed to May 2012.The second factor was thatPCV13 would not be available on the open market in 2012 and 2013[4]. GAVI consequently gave Mozambique the option to start with PCV10 or wait to introduce PCV13 at an undefined date. Mozambique opted to start with PCV10 in 2013. In December 2011,the PCV introduction plan was updated to reflect these changes in the launch date and vaccine presentation. In July 2012,the Minister of Health sent an official communication to GAVI to establish March 2013 as the introduction month[5].

Due to last-minute changes in theschedule of the Minister of Health, who was to preside over the national launch ceremony, the launch date was postponed from March 2013 to April2013.

6.3 Sufficient funding available in time

6.3.1 Budget of the PCV introduction plan

In the PCV application submitted to GAVI[6], GAVI's total Vaccine Introduction Grant (VIG) amount was originally US$306,000; this was later increased to $815,500. The total cost of introduction, including all activities and the cost of vaccines and injection supplies, was $15.2 million. In January 2012, NIP, in consultation with the ICC, developed a detailed, budgeted operational plan that identified promised funds and a gap of $1.2 million for PCV introduction activities. NIP sent the operational plan to GAVI.Table 3shows a breakdown of this plan by category of activity.

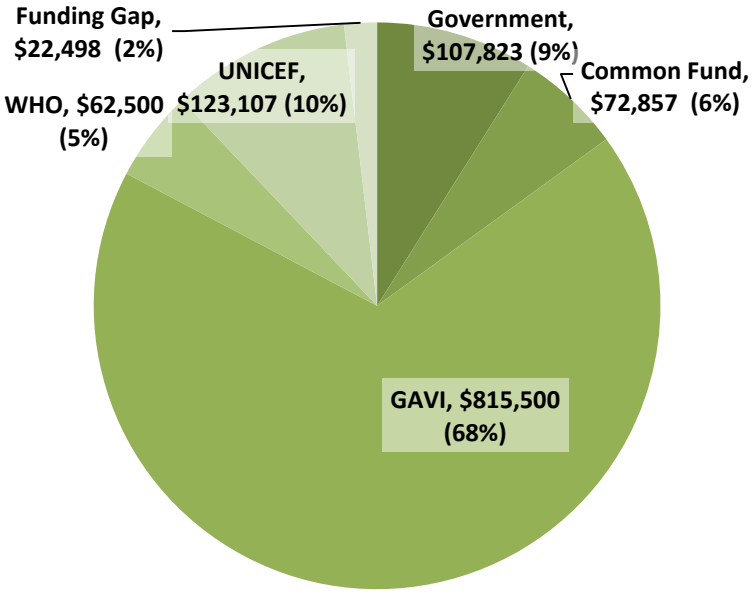
Table 3: Cost categories for PCV introduction in Mozambique's budgeted operational plan.

Cost category	Full needs for PCV introduction in US$
Training	238,210
Social mobilization; information, education and communication; and advocacy	248,767
Cold chain equipment and maintenance	149,863
Vaccine distribution	85,302
Program management	114,286
Supervision	71,429
Surveillance, monitoring and evaluation (M&E)	159,286
Post-introduction evaluation	40,000
Waste management	85,714
Technical assistance	11,429
Total	**1,204,286**

Source: Government of Mozambique (2011)

The identified funding covered 98% of country-specified needs for the introduction. Figure 4 shows the amounts promised by various sources of funding, including GAVI, MOH, SWAp common fund, UNICEF, and WHO. The funding gap of 2%was never discussed further, and the overall funding gap increased substantially when other sources of funding did not eventuate.

Figure 4: Mozambique budget for PCV introduction plan by source, in US$.



Source: Government of Mozambique (2011)

By mid-2012, most of the promised funds were still unavailable. These included MOH funds allocated for developing and printing training materials. The lack of MOH funds was attributed to a reduction in the MOH budget from 13% of the total government budget in 2006 to 7% in 2012[7].

The SWAp common fund that had been allocated to support printing costs for M&E tools was also unavailable in mid-2012, because SWAp common fund contributions in 2012had fallen to 78% of 2011levels.Donors had delayed SWAp funding because they were waiting for the MOH to satisfactorily address 2011 Global Fund audit recommendations[7,8].

GAVI VIG funds formed the bulk of the introduction plan funding; these funds were expected to be available by mid-2012. However, disbursement was ultimately delayed until March 27, 2013, two weeks prior to the launch. The reasons behind this delay are not well understood, as highlighted in KIIs with government and partner counterparts. According to one government respondent, GAVI promised to disburse the funds as soon as possible but did not do so even after all conditionalities had been met. By contrast, partner key informants mentioned that the delay of the MOH in conducting a Financial Management Assessment (FMA) may have caused the disbursement delay. Based on the data collected, both government and partner key informants do not appear to have fully understood the processes by which the GAVI VIG is requested and disbursed. One government respondent felt that the GAVI VIG followed a reactive process of countries responding to requirements at each step of requesting the VIG, rather than a process whereby all procedures are clearly set out in advance. By contrast, another government respondent felt that *"*maybe we are the ones who do not know how to read the guidelines…." Overall, a lack of understanding of the policies, procedures, and timelines around the VIG, and unclear communication between GAVI and the country program appear to have been major factors causing the delay in VIG disbursement.

In mid-2012, when the NIP was facing the challenge of limited funding availability for PCV activities (funding from MOH, SWAp Common Fund and GAVI), two new partners, GSK and USAID, joined the NIP TWG with funds to support NIP needs. Government key informants said that GSK approached the NIP to see how far it had advanced in its PCV introduction plan.GSK found that the NIP did not have funds for training or PCV refrigerator stickers (the two activities required before the vaccine could be shipped to Mozambique), and subsequently provided funding to meet these needs.

Although USAID had earmarked funds to support PCV introduction, these funds were not incorporated into the original introduction plan budget. They were ultimately used to support the national PCV launch ceremony, as well as some cold chain activities, and were disbursed via UNICEF through a previously established mechanism. In the future, USAID plans to participate in joint planning processes with NIP and other partners, and to support the NIP as a whole.

According to KIIs, GAVI informed the MOH in September 2012that it would disburse GAVI VIG funding through UNICEF and WHO because it was too late in the process to disburse the funding through the Ministry of Finance. Agreements were signed between the GAVI Secretariat, WHO headquarters, and UNICEF headquarters. The agreements included a list of budgeted activities for which UNICEF and WHO would receive funds on behalf of the MOH. The resulting budget took into consideration the profile of

each GAVI partner and is listed in Table. UNICEF and WHO expected to receive GAVI funds by January 2013. KIs reported that funding delays persisted without clear communication from the GAVI Secretariat about the timeline for disbursement. At this point, the Mozambique offices of UNICEF and WHO began to reprogram their regular NIP support funding to support PCV introduction activities. UNICEF and WHO planned to replenish the NIP funds as soon as they received the PCV funds from GAVI. These stop-gap reprogramming decisions were discussed in an NIP TWG meeting once it became clear that VIG funds would be further delayed. Ultimately, decisions on what was funded and who paid were decided between the donors and the NIP based on historical delineation of funding from the GAVI secretariat, UNICEF, and WHO. As funding became available, urgent activities were prioritized for support, first by the NIP TWG, and then by the NIP. The implication of this reprioritization is discussed further in the subsequent TOC steps.

Table 4: GAVI VIG to Mozambique, planned disbursements to WHO and UNICEF by components and activities.

Component and activity	GAVI partner	
	WHO (US$)	UNICEF (US$)
Training of Health Workers (all levels)	$228,781	
Social Mobilization, IEC, and Advocacy		$116,625
Cold Chain Equipment and Maintenance		$113,743
Vaccine Distribution		$30,943
Surveillance, Monitoring and Evaluation	$89,286	
Program management	$84,286	$55,972
Waste management		$55,862
PIE	$40,000	
Total	$442,353	$373,147
GAVI grand total	**$815,500**	

Source: UNICEF

GAVI VIG funding, which had been expected to arrive in-country by mid-2012, ultimately arrived in late March 2013, two weeks prior to the official launch. A lack of communication about the timeline for arrival of VIG funds made it difficult to solidify preparatory activities. The contingency funding provided by partners proved crucial for allowing Mozambique to conduct preparatory activities.

6.4 Cold chain and logistics system is prepared for PCV10

The Effective Vaccine Management Assessment (EVMA), a precondition for introduction of PCV[4], was planned and executed by staff from the MOH, National EPI, WHO, and UNICEF Maputo country offices in May 2012. A previous EVMA had been conducted in 2009. The main strengths noted included storage capacity, building infrastructure, equipment, and transport. Buildings, equipment, and transport were given high scores (84%) because of newly constructed buildings that met overall requirements and effective vaccine distribution plans at all levels.

The EVMA report also documented the need for increased storage capacity for PCV introduction. In response, Mozambique acquired 33 new refrigerators, which were located in provincial and district warehouses, and this distribution led to a limited increase in storage capacity[8].A related issue was that Maputo province did not have a provincial vaccine warehouse, and its vaccine allotment had to be stored in the national warehouse. This arrangement further reduced the limited storage space at the national warehouse, although it did not appear to impede PCV introduction. This will be an important area for follow-up under the future GAVI FCE process evaluation activities. According to provincial KIs, Maputo province is mobilizing resources to build a provincial vaccines warehouse.

According to the EVMA report, vaccine management, including temperature monitoring and stock maintenance, scored a low 38% due to the lack of use of vaccine vial monitors, posters, and stickers; nonreview of immunization reports; nonavailability of continuous temperature recording charts; noncalibration of system temperature mapping; and lack of a formal review process. Although the extent to which EVMA results were incorporated into PCV introduction planning is unclear, these issues appear to have persisted throughout the introduction. The PCV post-introduction evaluation (PIE) conducted in 2013 found that health workers do not have access to health facilities during weekends and holidays, and thus do not continuously monitor the refrigerators' temperature. There were also reports from KIIs of warehouse stores in two provinces being out of range, but these reports have not been substantiated further. To date, high vaccine wastage of PCV has not been reported, though this will be an important area for follow-up through the GAVI FCE health facility survey.

6.5 Adequately skilled health workers are available

A cascade approach to training was planned across the four levels of the National Health System (NHS) (central, provincial, district, and health facility). When contingency funding from GSK became available, training materials were quickly developed, and a training of trainers (TOT) for national and provincial NIP staff was conducted in August 2012.Provincial trainings for districts and health facilities occurred much later than planned(late March 2013 and early April 2013 rather than January 2013).

According to KIs, the delay in rolling out district and provincial-level trainings was due to the delay in GAVI VIG disbursement. Trainings in the northern provinces of Niassa and Nampula were only completed after the official launch after PCV delivery had commenced. According to KIs, this did not affect vaccine delivery because provincial NIP teams had instructed health workers to launch the vaccine after a general orientation on norms and expectations of vaccine delivery at the health facility level. This orientation was carried out as part of the refrigerator sticker distribution. Even for areas where training

occurred prior to the launch, district and health facility-level KIs reported that the delayed timing of the trainings impeded district and health facility managers' ability to plan effectively for the launch.

A related issue was the considerable lag time between the TOT and subsequent training of staff at district and health facility levels. This may have negatively affected the quality of the trainings at the district and health facility levels. The process evaluation cannot fully assess the effect of delays on training quality due to lack of data. The PIE reported that health workers' knowledge of the diseases prevented by the vaccine increased from 28% (documented during the pentavalent PIE) to 100% in the PCV PIE. This could be due to the fact that the pentavalent vaccine requires health worker knowledge across five diseases and PCV just two. Training quality and health worker knowledge is one of the core issues the FCE team plans to assess as part of future health facility surveys.

6.6 PCV10 readiness is confirmed

According to the KIIs, the MOH sent an official letter to GAVI in October 2012 stating that the national TOT had already been conducted and that the other trainings for provinces, districts, and health facilities were planned for January 2013. In addition, all stickers had been distributed and had been attached to all immunization refrigerators in the country. In this letter, the MOH asked GAVI to disburse vaccines in December 2012.

6.7 Sufficient volume of quality vaccine available

According to the KIs and NIP PCV report, PCV was delivered to Mozambique in December 2012. Thereafter, the PCV implementation team carried out an effective, efficient distribution within the country. According to the NIP report and preliminary PIE results, as well as conversations with KIs, all health facilities had received the vaccine by the launch date. In some cases, to ensure efficient distribution, the NIP had to deliver vaccine via road transport because the normal airline distribution system could not deliver vaccines in time for the launch. The KIs mentioned that airline delivery is often associated with delays because planes do not have enough space to transport all NIP vaccines to all locales in the designated timeframe, particularly in the Northern provinces. The national airline, LAM, primarily serves passengers and has limited cargo capacity. The PCV packaging is bulky and makes transport within the national warehouse and to and from cargo planes difficult. The country has since requested a different packaging size.

6.8 Updated monitoring tools available

NIP monitoring and evaluation (M&E) tools for vaccination coverage consist of primary data collection tools such as the child card (client-held card), tally sheets (to enter vaccines administered), and a health facility register (logbook to enter vaccination details of all beneficiaries overtime).Secondary M&E tools include monthly summary forms for reporting at the health facility, district, and provincial levels. These forms are used to collect aggregated data, which is typically entered at the district level into the electronic HMIS database known as *Modulo Básico* (MB). The M&E technical sub-working group began to update the tools in 2012 to align with the PCV introduction plan.

Most updated M&E tools, however, were available in health facilities only three months after the PCV launch. Tally sheets had still not been distributed to health facilities seven months after the launch. The electronic database (MB) was updated to include PCV information four months after the launch. KIIs emphasized that the tools were updated to accommodate PCV10, and training was done using these updated tools prior to the launch. However, printing and distribution of the tools were delayed.

> *"…that is, when we performed training, we already had the tools updated, but they were not yet printed. Then we trained our staff based on the future tools. But as we knew we would not be able to print in time due to lack of resources, we did adapt the old tools to accommodate the new vaccine."*
> – National government key informant

> *"… we introduced the [new] vaccine without register books ... there was a great inconvenience because in the register books that we had been using there is information for all other vaccines of the Expanded Program on Immunization with the exception of PCV10…. So, how to update PCV10 data on these logbooks was a little tricky. It was a big inconvenience because most of the time what happened is that there were some children receiving the 1st dose of PCV10 in April while receiving the 3rd dose of pentavalent vaccine, so as to register the information in the logbook it was too complicated ... everyone finished registering in its way ... as we were not prepared…"*
> – District government key informant

According to KIs, the primary cause of the delay was lack of funding from MOH and GAVI VIG sources. When contingency funds became available from GSK, required activities (training, refrigerator stickers) were prioritized and completed in 2012. Vaccine distribution and social mobilization were then prioritized and completed. M&E was to be addressed later once operational funds from the GAVI VIG became available.

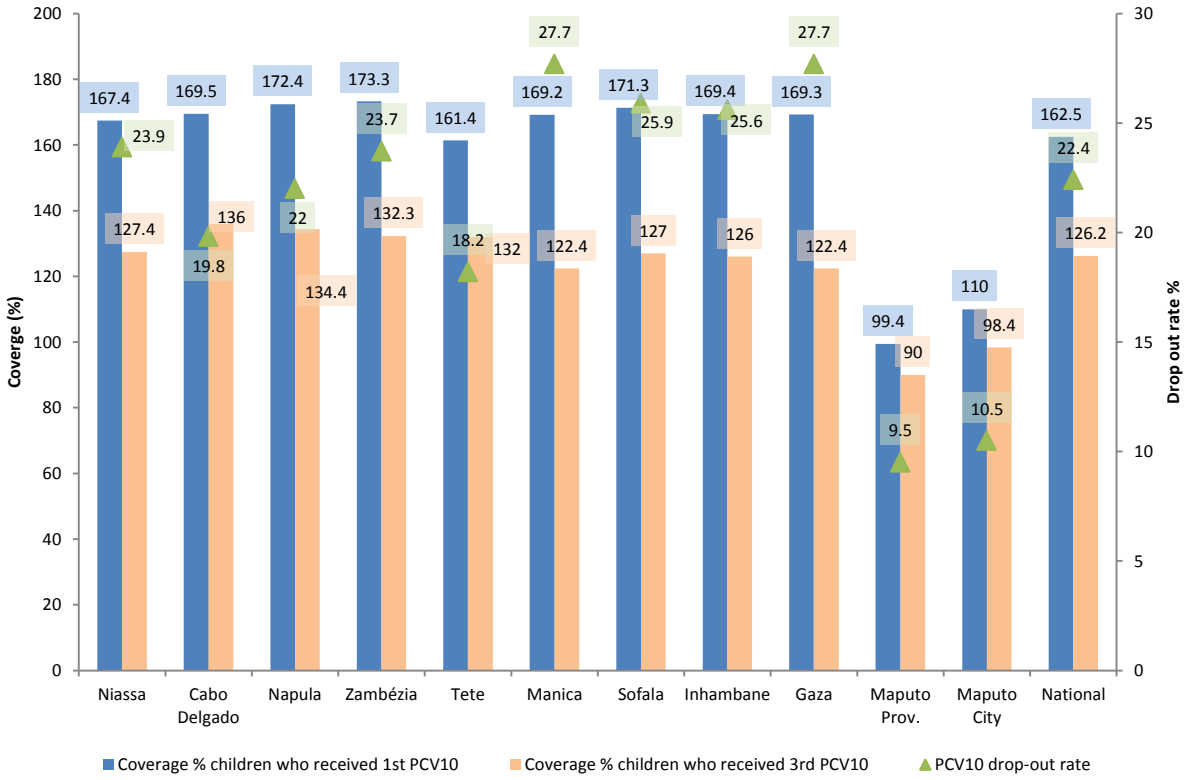
Lack of funding was not the only cause of the delays in furnishing M&E tools. Errors in the production of the M&E tools led to further delays. Logistical distribution issues also arose because the M&E materials had to be distributed through the MOH's supply system. This supply system is not located within the same section of the MOH as the NIP, and the NIP did not have the power to demand that supply system managers prioritize the distribution of the M&E materials. As a result, further delays occurred in the central supply stores before distribution.

Faced with a lack of M&E tools, health workers were instructed by NIP trainers during PCV trainings to improvise using existing registers and monthly reports. Health workers manually drew extra columns and spaces to fill in PCV data until the M&E tools were distributed. Supervision visit reports noted that this process did not work well because the improvised tools were not standardized. The lack of tools led to weak facility-level monitoring of PCV during the first six months of vaccine rollout.

Figure5 shows preliminary data from the NIP on vaccine coverage from April to September 2013, and suggests that reported coverage was well above 100% in many areas. This may reflect initial vaccination of children outside the target age group due to inaccurate social mobilization messages. It may also

reflect outdated denominator estimation. This issue of accurate estimation of vaccine coverage will be further assessed based on household and facility surveys, and assessment of all data, including administrative data.

Figure5: Mozambique coverage for children under one year old and dropout rate of PCV10 in Mozambique, April to September 2013.



Source: NIP M&E sector

6.9 *Adequate demand for PCV10 generated*

Various strategies were used to generate demand for PCV10. Radio messages were broadcast by national and local community radio stations, and SMS and Facebook were used for the first time. Other strategies included discussions with community leaders and health talks at the district and facility levels. Materials included posters, brochures, pamphlets, banners, and T-shirts.

Verbal communications with community leaders and health talks at health facilities were conducted in a timely manner beginning in January 2013 and continuing up to the launch, but other channels of communication were not as timely. Social mobilization messages for the media and IEC materials were not finalized according to plan. Message development, radio, and TV spots were not finalized until March 2013, and broadcasting began only two weeks prior to the launch. Apart from a few materials that were ready in time for the official launch ceremonies, printed IEC materials were not received in health facilities until after the launch.

AAR participants and KIs attributed delays in the development of IEC materials and media messages to several factors:

- A delay in initiating the conceptualization of messages.
- Outsourcing of the messaging work to a private company that did not meet expectations. This required the MOH to develop the final work within a very tight timeframe.
- "*Too many cooks in the kitchen*" for the subsequent messaging conceptualization discussions, which resulted in further delays.

The largest challenge encountered with social mobilization through TV and radio messaging was inaccurate messaging. Messages advised mothers to take all children under age one year to health facilities for vaccination rather than only those in the age group of two to four months, who were eligible to receive PCV. As a result, there was a high demand for PCV outside of the target age range, and many children were turned away. According to AAR participants, a direct consequence of the high demand was an unnecessarily increased workload. Health workers spent considerable time checking health cards for eligibility. In addition, many mothers whose children were turned away from health clinics were dissatisfied and felt they had been discriminated against by health workers[8]. This raises the concern that community members and mothers turned away may be less likely to respond to future mobilization messages.

In some health facilities, health workers vaccinated children outside the target group. One key informant representing implementing partners at the central level said, "*In some places health workers ended up offering vaccines to children who were not eligible, but these were aspects that we managed to identify and correct….*"

District and provincial-level KIs stated that the designated age group for vaccination was clearly communicated during training. However, some health workers were no longer sure of the target population. Other health workers felt considerable pressure from the population who came to the health center expecting PCV based on the radio and TV announcements. Once this issue was identified, the NIP sent out a circular to the provinces clarifying the correct target age group for PCV. A potential consequence of the vaccination of children outside the target age group is rapid use of PCV with the potential for stockouts. According to the NIP PCV report and the PIE, there were no reports of stockouts in these areas, but the high vaccine usage necessitated re-supply sooner than planned. Stockouts and vaccine usage rates will be an important area to assess as part of the GAVI FCE household and health facility surveys.

The inaccuracy of media messaging was attributed to the absence of message piloting, which in turn was attributed to a lack of time to pretest the conceptualized messages. The time available for message development was abbreviated because of a range of issues related to a lack of timely and adequate planning, and suboptimal implementation. For example, there was a delay in initializing the conceptualization of messages. Also, the work of developing social mobilization media messages was contracted to a private group to preserve the limited time and human resources at the MOH, but the quality of the work proposed by the group was so poor that the NIP team had to step in to develop the messages with very little time prior to the introduction.

6.10 Context

6.10.1 Other GAVI Alliance support

GAVI support for the introduction of PCV10 is one in a long line of investments GAVI has made to support immunization activities in Mozambique. GAVI support in Mozambique began in 2001 with immunization support services and the GAVI-supported introduction of Tetra DTP-HepB (2001–2007). Injection safety support followed from 2003 to 2005. Pentavalent vaccine was introduced in 2008 with support from GAVI.

GAVI previously approved an HPV demonstration project to be implemented in 2014. And in September 2013, Mozambique submitted an application to GAVI proposing introduction of two-dose Rotarix. Unlike several other countries introducing new vaccines with support from GAVI, Mozambique has not yet received HSS support, having two previous applications for HSS that were not approved. Mozambique submitted a third proposal for HSS in April 2013 that was approved in July. An important area of future focus will be to examine the interactions between these different areas of GAVI support, particularly between cash-based support and new and underused vaccine support.

6.10.2 Other contextual factors

In January and February 2013, floods affected the provinces of Gaza and Zambézia, and threatened local introduction of PCV. For example, cold chain refrigerators were reportedly washed away in one health facility in Gaza, the worst-affected province. Although the TWG developed a contingency plan for postponing the launch in Gaza if necessary, the floods began to subside as the launch date approached, making it unnecessary to implement the contingency plan.

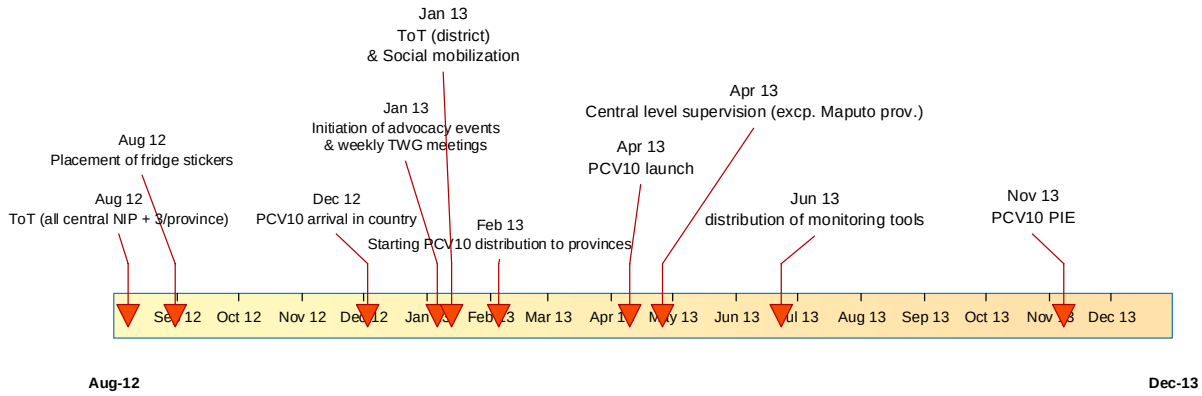
In addition, a month after the PCV launch, a nationwide strike of doctors and health workers occurred. This mainly affected the Maputo and Matola areas, with the strike reported to have disrupted vaccination services in some health facilities. Limited disruptions in service delivery were experienced in other areas. None of the health facilities visited during the process evaluation, however, reported disturbances in immunization service delivery. The limited impact of the doctors' strike was confirmed by KIs, and coverage rates did not show any decline. However, because M&E tools were still not available at the health facility level during the period, it is difficult to confirm the lack of impact. This will be an important area of follow-up for the GAVI FCE through the health facility and household surveys.

6.11 Successful introduction of PCV

The official launch of PCV10 occurred on April 10, 2013, as planned, with a national ceremony led by the Minister of Health, and UNICEF and WHO heads in-country. The GAVI Country Responsible Officer (CRO) for Mozambique also participated. The ceremony took place in Boane Health Centre, 30 kilometers outside Maputo City, and included speeches and ceremonial vaccination of children. All 11 provinces held ceremonies led by provincial governors at selected health facilities. Figure 6 illustrates the PCV10introduction timeline, including the immediate pre and post-launch interventions.

According to the information garnered from multiple mechanisms—including participant observation, KIIs, the NIP PCV report, and the PIE—all health facilities began administration on the same day. This will be an important area of follow-up as part of the health facility and household surveys.

Figure 6: Mozambique PV10 timeline, from preparation to post-launch interventions.



National and provincial NIP managers expressed surprise that the introduction went as smoothly as it did in light of coordination challenges, including coordination of vaccine delivery and technical provision of care.

In the week after the launch, the NIP central team conducted supervision visits in 9 of the 11 provinces to follow up on field implementation. This activity was implemented according to the PCV introduction plan and timeline, with the exception of Maputo city and Maputo province. Maputo city and Maputo province were not visited because the central NIP team was busy finishing the HSS application to GAVI, which was due on April 23, 2013.Some key informants said that numerous competing GAVI demands on the NIP, without due consideration of local context, planning, and human resource limitations, contributed to challenges. Other KIs, however, felt that better planning by the NIP would have allowed it to anticipate the GAVI HSS application deadline, though efforts would still be hindered by limited human resources and management capacity.

The AAR found that partner members of the NIP TWG who had actively participated in planning the post-launch supervision visits did not actually participate in the visits because of competing commitments. NIP representatives were displeased that none of the technical partners prioritized this work and felt their field-based contributions would have been helpful.

Another challenge was that PCV-specific supervision failed to include supervision of mobile outreach teams or additional follow-up visits due to insufficient funding. AAR participants felt that any additional funding should cover additional supervision visits as well as technical support for revising the MOH's integrated supervision visit model. This may involve reprogramming a portion of funds allocated for national health week to routine supervision visits. It is particularly important to ensure funds are available for district-level managers to supervise health facilities, as that is the most resource-constrained level in the area of supervision. The role of district managers in facility-level supervision is

often leapfrogged and completed by provincial managers due to funding limitations and the priorities of provincial-level partners. In Mozambique, only 6 of 11 provinces have direct support from a partner such as Village Reach or FDC.

The PCV PIE was conducted in November 2013, within the WHO-recommended period of 6 to 12 months. Activities included two days of training, eight days of field visits in four provinces, one day of preparation for the ICC presentation, and one day of debriefing the ICC. The PIE was financed by the GAVI VIG. Methods included interviews of health workers and beneficiaries as well as observations in the selected health facilities. Findings from the PIE have been included in relevant sections of this report. Overall, the FCE team found that the PIE added value to the M&E of PCV introduction by:

- Uncovering challenges that had not been identified during the NIP supervision visits, such as the lack of any written provincial and district PCV introduction plans, temperature and vaccine wastage monitoring issues, and lack of a supervision checklist for the provinces and districts.
- Including an assessment of PCV knowledge among health workers that was not included in the post-launch supervision tools.
- Including an assessment of mobile outreach services and beneficiaries that had not been included during NIP PCV-specific supervision visits.

This is a preliminary assessment of the PIE based on the GAVI FCE team's attendance at the ICC presentation. We will undertake a more detailed review when the PIE report is released.

6.12 Roles and responsibilities of stakeholders

The Mozambique MOH maintains a functioning Sector-Wide Approach (SWAp) that convenes partners on several levels. The SWAp includes technical working groups (TWGs) within and across various departments and national programs. One of the TWGs is based in the NIP and initially included WHO, UNICEF, Village Reach, and FDC. WHO and UNICEF are the principal partners who provide crucial technical and financial support to the central level of the MOH. Village Reach, an international nongovernmental organization (NGO), provides technical support at the central level and technical and financial support in four provinces. FDC, a national NGO, also provides technical support at the central level as well as technical and financial support in one province. After the first quarter of 2012, GSK and USAID joined the TWG and provided contingency funding. Save the Children joined later, in January 2013, to assist with social mobilization.

The TWG held meetings either fortnightly or weekly depending on the urgency of issues. PCV-specific TWG meetings started in January 2012, and from January 2013 to the April 10 PCV launch, PCV-specific meetings occurred weekly. Decision-making is led by the MOH, and MOH personnel chair the meetings. Depending on the subject and level of decision-making required, the NIP manager, the Director of Public Health, the ICC, or the Minister of Health may be involved. Observations by GAVI FCE team members to date showed that each partner member of the TWG participated in all meetings, with the exception of post-launch supervision visits. NIP partners also emphasized the good communication atmosphere generated by the NIP:

"…since the beginning of preparation, ministry and key program partners have always been together; there was a good division of labor and there were follow-up meetings...."
– Partner key informant at the central level

"I think what was positive is that they [NIP managers] did bring together all these partners into regular meetings."
– Partner key informant at the central level

Subgroups, chaired by NIP personnel, were created to address core thematic areas of the PCV introduction plan (Table 5). Other MOH departments are involved in the subgroups as relevant. For example, the MOH Health Promotion Department is a member of the IEC subgroup. During KIIs, all NIP staff stated that they were fully involved and had defined leadership roles as subgroup focal points during preparation. This was in contrast to the previous pentavalent introduction, where they had limited involvement:

"One of the positive aspects that happened during preparation of the new vaccine [PCV10] ... is that I am involved in all processes of the cold chain for vaccines, even in the elaboration of documents, which is a very positive thing. It's my first time. I have never participated before."
– Government key informant at the central level

This change in NIP staff involvement was attributed to the change in the NIP manager. Staff reported that the new manager had a more inclusive leadership style and was more willing to delegate to her team.

Table 5: Subgroups for planning and implementation of the PCV10 introduction.

Subgroup	Members	Roles
Training	NIP Training & IEC focal point, UNICEF, WHO, GSK	Developing training materials and all logistics for trainings at all levels.
Logistics and cold chain	NIP Logistics focal point,VillageReach, FDC, UNICEF, WHO	Developing logistical management tools and all other cold chain related issues. Quantification of all commodities needed for vaccination
Information, education, and communication	NIP Training & IEC focal point, UNICEF, WHO,GSK, FDC, VillageReach, Save the Children, MOH Department of Health Promotion	Conceptualizing IEC messages and developing various IEC materials
Monitoring and evaluation (M&E)	NIP M&E focal point, UNICEF, WHO	Updating all M&E tools

Communication with the GAVI CRO is done through the NIP manager, UNICEF and WHO. Alliance members are always copied on email communications to and from the GAVI CRO. KIs noted that the CRO role has helped to significantly improve communication around GAVI policies and procedures:

> *"…when GAVI added the country responsible officers, I think that was a really big deal. I think that made a big difference because previously what happened was that the country had to contact 15 different people for one thing and GAVI was saying to contact WHO or UNICEF and what was funny was that it was actually WHO and UNICEF who were saying I don't know who to contact. So they did a really good thing to introduce the CRO."*
> – NGO representative

Challenges in communication between the CRO and NIP and partners remain, with the GAVI VIG disbursement as a prime example. One factor identified in KIIs is the lack of an in-country or regional presence by the GAVI secretariat.

> *"GAVI seems so far…I can say that is what I don't like. GAVI is so far like in some unreachable place. Maybe it would be better if they were nearer like in the country."*
> – Government key informant

An additional impediment, related to the lack of an in-country presence, is the use of English for communication between the NIP and CRO. KIs also noted that these same linguistic challenges apply to applications and clarifications between NIP and CRO.

> *"….the language is a big challenge! We cannot submit documents in Portuguese, but the proposals are prepared by Mozambican workers, and it then becomes very complicated because people fail to convey exactly what is intended."*

– Government key informant at the central level

Data collected to date indicate that the partnership in Mozambique appears to be functioning relatively well overall. However, the evaluation team was unable to identify an explicit articulation of roles, responsibilities and accountability mechanisms at the country-level, and this may contribute to some of the problems identified previously. An in-depth analysis of partner and stakeholder roles in the NIP will be conducted in the coming year by the FCE team.

6.13 Analysis of findings

Based on our evaluation, the initial decision to introduce PCV in Mozambique was supported by locally relevant, scientific evidence and was based on consensus among partner organizations. However, the initial launch date of January 2012 was highly ambitious, given that it was set in early 2011 and the application to GAVI had not yet been finalized. Global PCV supply challenges and other issues resulted in postponing the launch date by more than a year. This highlights a need for a more realistic process for setting launch dates—a process that could include enhanced communication between GAVI and the NIP regarding global PCV supply.

After the postponement, a key impediment was the delay in making funds available for implementing the operational plan. The GAVI VIG funds that formed most of the operational budget only arrived two weeks prior to the final launch date. The lack of collective understanding at the country-level about why the delay occurred highlights a major communication issue between the NIP, country partners, and GAVI regarding the policies, procedures, and timelines of the GAVI VIG.

An important positive aspect of the PCV introduction in Mozambique is that partial funding for critical activities was mobilized through partner organizations (GSK, USAID, UNICEF, and WHO).Contingency funding, however, was insufficient to avert downstream effects, including the postponement of key preparatory activities. The effects included delayed implementation of training at the facility level and a lack of monitoring tools at facilities. The lack of monitoring tools persists in some facilities, resulting in an inability to accurately monitor implementation.

A lack of sufficient and timely funding was not the sole cause of problems. A range of management, coordination, and implementation issues were also apparent. For example, in the case of social mobilization, development of key media messages was impeded because of management and implementation issues. Consequently, inaccurate and unclear messages were delivered to the population, leading to demand for PCV outside the target age group. This inappropriate demand led to increased provider workload and may have negative consequences for future demand-generation activities because of lower population trust in the accuracy of health messages.

Overall, the multiple delays and rushed implementation associated with key preparatory activities meant that Mozambique was not fully ready to introduce the vaccine in April 2013. Notably, the present PCV10 readiness assessment officially includes only two aspects – training and refrigerator stickers – as preconditions for vaccine delivery to the country and does not include a broader set of requirements, identified in our TOC, that are necessary for a successful introduction. Full preparation would have

entailed, among other things, training completed down to the health facility level, M&E tools adequately disbursed to sites, and social mobilization messages piloted. This raises two important issues: (1) whether future readiness assessments should include a broader consideration of the status of preparatory activities and (2) whether postponement of the launch should have been considered until the country was fully prepared for introduction.

Overall, the process was well coordinated by the NIP, and there was regular communication and a relatively good understanding of partner roles. However, roles and responsibilities were not explicitly defined, and this may prove problematic in the future with personnel turnover among partner organizations. A clear barrier, however, exists in terms of the country-level understanding of GAVI policies, procedures, and timelines, with the GAVI VIG a key example. This suggests the need for enhanced communication between implementing agencies, the CRO and the GAVI secretariat.

An important aspect of the evaluation is a comparison of the PCV introduction to previous introductions of new vaccines, such as the pentavalent vaccine (Table 6). Notable improvements in the implementation process were based on the previous PIE of the pentavalent vaccine introduction. These improvements included developing an operational plan, establishing a technical working group to oversee introduction, and developing an operational budget. Although contingency funding was made available (a recommendation from the previous PIE), the funding was only partial, and funding delays remained a major challenge for the PCV introduction.

Although cold chain capacity was expanded to accommodate the new vaccine, cold chain monitoring was a persistent problem. To date, no stockouts have been reported, but the consumption rate of PCV has been very high because of inaccurate social mobilization messages. We have not yet been able to fully assess the impact of generating demand outside of the target age range on both vaccine supply and potential consequences for future demand generation. This is a critical area that will be more fully analyzed through other components of the GAVI FCE, such as the household and health facility surveys. In terms of demand generation, there were notable improvements in the scope of communication channels compared to the pentavalent vaccine introduction.

The availability of updated M&E tools for tracking vaccine delivery is an ongoing problem. This has critical implications for the program's ability to monitor progress in vaccine coverage. Notably, however, a much more timely PIE was conducted for the PCV introduction in comparison to the previous pentavalent introduction. The evaluation team has not yet had a chance to fully evaluate the PIE because the report is not yet available. Based on the comparison with the pentavalent vaccine introduction, given that some of the issues such as M&E appear to be systemic, longer term challenges, an important future consideration would be to consider health systems strengthening (HSS) support prior to new vaccine introductions.

Table 6: Comparative analysis of the pentavalent and PCV introductions in Mozambique.

Work domain	Introduction of pentavalent vaccine	Introduction of PCV10	Comparative analysis
Timely and adequate planning	• No operational plan for introduction with clear activities, timelines, responsibilities, and resources for implementation. • No subcommittee or task force designated to oversee supervision of introduction process.	• The NIP developed a PCV introduction plan. • NIP technical working group oversaw supervisory activities.	• NIP adhered to recommended improvement from the pentavalent PIE to develop an operational plan for introduction and have a group with designated responsibility for supervision.
Sufficient funding available in time	• No clearly defined budget that distinguished introduction activities. • Recommendation in the PIE suggested that EPI should advocate for and use local resources to expedite implementation of preparatory activities while waiting for GAVI funds.	• A budget specific to activities supporting introduction was developed. • Delayed disbursement of GAVI's vaccine introduction grant resulted in mobilization of funds from partners to carry out introduction activities. • VIG arrived in the country two weeks prior to launch.	• Improvement in budget development. • NIP leveraged local funding to ensure that introduction activities moved forward despite delay in VIG; this was in direct response to recommendations from the pentavalent PIE. • However, even though partners stepped in to advance funds and fill funding gaps, the delay in disbursement of the VIG resulted in delays of introduction activities such as trainings (some occurred after the launch).
Adequately skilled health workers available	• No pre-introduction training for health workers or availability of reference materials, primarily due to lack of planning.	• Training conducted for PCV; however it was rushed due to the funding delays.	• Training was an issue for both introductions, but for different underlying reasons.
Cold chain and logistics system improved	• Some equipment procured did not conform to global standards set by WHO/UNICEF. • Continuous temperature monitoring was not done on weekends and holidays.	• Continuous temperature recording charts were not available in all locations. • Continuous temperature monitoring was not done on weekends and holidays	• Although cold chain capacity was expanded to accommodate additional storage requirements, cold chain temperature monitoring remained as a persistent problem as part of the PCV introduction

Work domain	Introduction of pentavalent vaccine	Introduction of PCV10	Comparative analysis
PCV10 readiness confirmed	• Not applicable.	• New process requirement.	• Although refrigerator stickers and training of trainers was completed, the full rollout of training was not completed until after vaccine delivery. In some cases, training at the facility level occurred after the official launch date.
Sufficient volume of quality vaccines available	• Vaccine quality issues resulted in two-month stock-out.	• Vaccine was not provided to children outside the eligible age range of 2 to 4 months. However, social mobilization messages incorrectly stated that all children <1 year were eligible. • Some health workers did give vaccines to wrong target groups.	• Vaccine was not available to all who presented to receive it – for different reasons. • Presently, we do not know the full extent of demand generation outside of the target age range of vaccine supply.
Updated monitoring systems	• Updated tools that included Hib were not distributed to provinces, districts or health facilities; facilities used 3-year-old tools. • Supervisory visits were integrated with other health services, with limited focus on immunization activities.	• Tools were updated, though some errors in production process resulted in delays. • Primary tools were not available in health facilities until 3 months post-launch, with tally sheets arriving 7 months after launch. Dedicated supervision visit was made, but only one visit per province.	• Availability of updated monitoring tools remains an issue in both new vaccine introductions. • Neither had sufficient supervision visits; in the AAR, participants indicated that multiple (immunization-dedicated) supervision visits were necessary in the first six months post-introduction.

Work domain	Introduction of pentavalent vaccine	Introduction of PCV10	Comparative analysis
Adequate demand generated	• Limited messaging/activities prior to introduction of Hib vaccine. • Posters in health facilities were out of date with no information on Hib. • Media involvement in messaging was limited.	• Methods of social mobilization were expanded and included posters, brochures, pamphlets, banners, t-shirts, television, radio spots, Facebook, SMS, and verbal sensitization with community leaders. • PCV materials were not fully available at the time of the launch • Messaging was not piloted and as a result messaging was inaccurate and unclear.	• An expanded set of social mobilization methods was used as part of the PCV introduction compared to pentavalent • Although materials including PCV were updated unlike with the pentavalent vaccine they were not fully available at the time of the launch • Demand outside of the targeted age range was generated due to inaccurate and unclear media messages. • Children outside of the target age range were either turned away or vaccinated out of age range. The former has implications on future demand generation activities while the latter has implications for vaccine supply and potential stockouts.
Successful introduction	• Phased launch began in April 2009.Launch in all provinces completed by December 2009. • PIE conducted three years after the launch (March 26-April 5, 2012).	• Nationwide launch occurred in April 2013. • One round of post-launch supervision visits implemented in 10 out of 11 provinces • PIE conducted six months after the launch.	• At present it is difficult to assess the extent of the rollout. This will be an important area to examine as part of the GAVI FCE by triangulating between health facility, household surveys and administrative data. • A number of recommendations from the pentavalent PIE appear to have been incorporated into the PCV introduction • There was a great improvement in timeliness of the PIE but we have not been able to fully assess the report as it is not presently available.

6.14 Limitations

This report has four overall limitations. Firstly, this report is based on qualitative data from the process evaluation. Although these data are valuable, the overall benefit of the evaluation will be enhanced by the triangulation of findings from other evaluation components, such as the health facility surveys, household surveys, administrative data, and outcome and impact analysis.

Second, this evaluation focused on activities just prior to the PCV launch. The evaluation is therefore limited in its ability to clearly understand earlier processes, particularly during the decision to apply for GAVI support and the application phase. In addition, high staff turnover within the MOH and partners in the 12 months prior to introduction limited institutional memory of how and why certain decisions were made. For example, only two KIs were working in their current jobs when planning for the PCV introduction and application was completed. These limitations highlight the importance of prospective evaluation studies that collect data in real time using, for example, a participant observation approach.

Third, the findings reported here are based on a limited set of KIIs. In some cases, interviews were cut short due to lack of time. Scheduling challenges and interview time limits highlight the challenges of minimizing respondent burden. This will be an important consideration for the GAVI FCE evaluation as it continues. Because KIIs were conducted only in a small sample of provinces, the related findings are not generalizable.

Lastly, this evaluation is based on incomplete data on implementation processes and results. For example, although the PIE has been conducted, the complete report is not yet available to the evaluation team. We also have had limited access to other sources of data within the timeframe of this report, particularly those of a quantitative nature, such as administrative data on vaccine coverage.

6.15 Future directions

Given the challenges around demand generation and M&E tools and data, a clear priority area for future evaluation will be to track the extent of the PCV introduction across a range of quantitative indicators, including vaccine supply and stockouts, vaccine coverage inside and outside the targeted age range, and geographical and individual-level variation (socioeconomic status, gender) in vaccine coverage. We will triangulate across multiple data sources, including administrative data, health facility data, and household surveys. Important areas for follow-up will include measures of population demand for vaccination (assessed through household surveys and patient exit interviews) and assessments of cold chain integrity and health worker knowledge and skills (evaluated through health facility surveys).

We will continue to follow PCV implementation over time, including the forthcoming PIE report. Furthermore, because we were unable to examine in detail the earlier decision-making and application phases of PCV introduction, the FCE will focus on the earlier phases of other GAVI Alliance support in Mozambique. This will include the preparation and implementation phases of HSS and the HPV demonstration project, as well as the decision-making and application phases of introducing rotavirus and IPV. We will also assess changes in the implementation process between the PCV introduction and future introductions, such as the HPV demonstration project. This prospective approach will allow a more in-depth comparison than was possible with the comparison between the PCV and pentavalent vaccine introductions. The information gathered about the pentavalent introduction relied on existing documentation and limited institutional memory among the NIP and partners.

6.16 Conclusions

The Mozambique NIP and its partners managed and implemented the nationwide launch of PCV10 largely on schedule. There were, however, a number of challenges, many of which resulted from delays in funding, particularly the GAVI VIG. Although contingency funding provided by partners allowed Mozambique to complete high-priority preparatory activities, remaining funding gaps led to delays in critical activities such as the rollout of training and M&E tools. Other management and implementation challenges led to additional critical problems, such as the use of social mobilization messages that created confusion, high demand among caregivers of ineligible children, and vaccination of children outside of the defined target group.

Several important improvements were evident in the PCV introduction in comparison to the earlier introduction of pentavalent vaccine. Overall, the partnership at the country level appeared to be functioning well, although a clear challenge was a lack of understanding of GAVI policies, procedures, and timelines as a result of poor communication between GAVI and the country program. Understanding the multifaceted, multilevel complexities of the PCV10 introduction is necessary to improve the management and implementation of future vaccine introductions.

6.17 Recommendations

Our recommendations focus on the most critical challenges identified in the process evaluation, including the unavailability of funds in a timely manner, the lack of understanding of GAVI's policies and procedures (particularly around the GAVI VIG), and the lack of coordination for key preparatory activities. We begin by describing a set of high-level recommendations and end with a list of specific recommendations.

Major recommendations

Explicitly articulate roles and responsibilities of relevant partners at the country, regional, and global levels

Overall, the partnership model in Mozambique appears to be functioning relatively well, reflecting the strong communication and participatory approach of the current NIP. However, there is no explicit articulation of partners' roles and responsibilities. The partnership may benefit from a clearer understanding of roles and responsibilities, especially in light of high staff turnover at partner institutions. We therefore recommend an explicit articulation of roles and responsibilities of relevant partners at the country, regional, and global levels.

Improve understanding of GAVI policies and procedures among the NIP and country-partners, particularly with regard to vaccine introduction grants

The key factor affecting the timeliness and adequacy of funds to support PCV introduction was the delayed disbursement of the GAVI VIG. This delay was associated with a lack of understanding among government and country partner organizations of the policies, procedures, and timelines for disbursement. There was also a lack of communication between GAVI and country programs and partners on these aspects. We therefore recommend improving communication between GAVI and the NIP, and country partners concerning the policies, procedures, and timelines related to the GAVI VIG and other streams of GAVI support. This should include increasing communication to GAVI regarding the status of vaccine introduction planning and implementation over time. An underlying issue is a language barrier in communications with

GAVI, including the need to submit applications in English. A related recommendation is therefore to establish mechanisms to address the language barrier, such as by building capacity in English-language grant application processes or by allowing communications and applications to GAVI to be written in Portuguese. Other improvements in communication may include re-examining the remote CRO model, which appears to be a barrier to consistent and clear communication.

Strengthen communication and coordination between global and country stakeholders in jointly setting realistic timeframes for the introduction of new vaccines that take into account global supply issues

The launch date that was initially targeted proved to be unrealistic, and the launch had to be postponed by more than a year. Setting more realistic timeframes for introducing new vaccines that take into account global supply issues, as well as other country contextual issues, would aid in more effective planning that could be better coordinated with other GAVI Alliance support streams (e.g., HSS). We therefore recommend strengthening communication and coordination between global and country stakeholders in jointly setting realistic timeframes for introducing new vaccines.

Assess country readiness across a broader set of activities and at multiple junctions with careful consideration of changes in introduction dates

Our process evaluation found that several important preparatory activities were delayed or rushed. In some cases, such as with the rollout of the M&E tools and training, materials and assistance were not available until after the launch. For social mobilization, rushed implementation led to inaccurate messaging.

Two conditions—training and the placement of PCV refrigerator stickers—must be satisfied for delivery of vaccine. Once contingent funding was available, meeting these conditions was prioritized over other activities, such as distributing M&E tools and promoting social mobilization. This reprioritization exercise, though necessary, led to uncoordinated preparatory activities that did not time well with the vaccine launch. We therefore recommend expanding the assessment of readiness to cover the full set of preparatory activities required for a successful and timely introduction. Importantly, an expanded assessment should avoid creating unnecessary administrative burden given human resource capacity constraints at the NIP. Furthermore, given that there are multiple steps in the implementation process, we also recommend that the readiness assessment be conducted at multiple points in time and that at each junction, consideration be given to changes in the introduction schedule and launch date. This consideration should carefully weigh the advantages and disadvantages of postponing introduction.

Identify potential contingent funding sources as part of the vaccine introduction plan and assess need at specified checkpoints

Notably, the NIP and partners were able to leverage alternative sources of funding when it became apparent that funds from the MOH, SWAp, and GAVI VIG were not forthcoming. This was an important improvement over the situation with the previous introduction of pentavalent vaccine. Nevertheless, funding gaps remained, and contingent funding was not always provided in a timely manner, which led to the delay of important preparatory activities. We therefore recommend that the vaccine introduction plan identify potential sources of contingent funds and specific checkpoints in time by which those funds should be sought to help address any funding gaps and delays.

Specific recommendations

The following specific recommendations should be interpreted in light of the high-level recommendations described previously.

Recommendations to GAVI

- Enhance communication with the NIP and country partners, especially around GAVI policies and procedures.
- Strengthen communication and coordination with countries to develop realistic timeframes for vaccine introduction that account for global supply issues and other contextual factors.
- Consider a more active follow-up mechanism for ensuring that the GAVI VIG is disbursed in a timely manner.
- Consider mechanisms to address the language barrier, such as by allowing applications to be written in Portuguese. Finding qualified people with the right technical skills who understand the context and have the capacity to write in English is challenging in Mozambique.
- Consider a funding mechanism through which GAVI could provide contingent funding for vaccine introductions.
- Consider an expanded, multi-step readiness assessment that includes other key preparatory activities such as social mobilization and monitoring and evaluation.
- Consider timing health systems strengthening (HHS) support to address bottlenecks prior to new vaccine introduction.

Recommendations to NIP

- Increase the level of communication with GAVI and country partners, especially around GAVI policies and procedures and implementation progress.
- Ensure clear understanding of GAVI policies and procedures for each window of support.
- Consider an expanded, multi-step readiness assessment for new vaccine introductions with a reassessment of the introduction schedule at each step.
- Reassess the need for contingent or additional funding at multiple steps throughout the implementation process.
- Prioritize the availability of M&E tools as part of the training materials for health workers and managers at all levels.
- Minimize the period between the training of trainers and subsequent training rollout.
- Include supervision of mobile outreach teams.
- Increase the frequency of post-introduction supervision visits at all levels.
- Improve message conceptualization for social mobilization by pretesting messages prior to introduction.

Recommendations to NIP partners

- Increase assistance and facilitate communication and understanding by the NIP of GAVI policies and procedures for each window of support.
- Improve the designated role of country partners in helping the NIP navigate GAVI processes.
- Help build capacity in country for the development of applications, particularly related to grant writing in English.
- Consider a mechanism for contingent funding for vaccine introductions.

- Consider increasing the representation in all provinces to provide technical assistance needed.
- Support allocation of training, monitoring, and supervision funds for provinces with no local partner.

7 Uganda

This section describes the process by which Uganda managed and implemented the PCV10 introduction. Findings are presented by key milestones in the TOC. We assess (1) whether the in-country process mirrored the theory of change; (2) diversions, challenges, and their consequences; and (3) underlying causes of diversions and challenges. A summary of the overall process evaluation analysis is provided at the end of this section.

7.1 Current status of PCV introduction

On April 27, 2013, PCV was launched in the Iganga district. The launch was limited to Iganga even though the initial plan called for a country-wide launch. At the time of the launch, most districts had not yet conducted training for PCV and were deemed not ready to introduce the vaccine. Iganga lies in eastern Uganda and has a population of just over half a million people. It has one hospital and 47 health centers.

The president of Uganda presided over the launch ceremony, which was also attended by other high-level dignitaries, including the GAVI CEO, regional and country-level representatives for UNICEF and WHO, members of parliament, ministers, and other stakeholders representing key organizations.

At the launch, the MOH announced that PCV would be rolled out rapidly in a phased manner countrywide, one region at a time. As of December 1, this had not occurred, however. In September 2013, WHO conducted a readiness assessment and concluded that Uganda was not ready to introduce PCV. It determined that key gaps needed to be addressed before additional vaccines would be shipped to the country. At the time of writing of this report, Uganda has yet to be confirmed as ready. As a result, PCV has not been rolled out in the rest of the country. Uganda was working with support from partners to meet a mid-December 2013 deadline for establishing readiness.

7.2 Context

7.2.1 Management and organizational changes

One factor affecting the PCV launch and rollout was management and organizational changes within the MOH.

Key personnel at UNEPI, including the program manager, changed twice. The first change occurred in April 2012, when critical preparations for PCV introduction were underway. The second change happened in July 2013 when the current EPI manager was appointed. In the interim 15 months, an acting EPI manager oversaw preparations for PCV introduction. Further, in June 2013, when the vaccine had still not launched nationwide, the Minister of Health and her deputy who had played a critical role in PCV introduction were assigned to other roles.

Another organizational change that affected process management was the transfer of responsibility for vaccine logistics management and vaccine quality and safety from UNEPI to the National Medical Stores (NMS) in April2012. The change was implemented swiftly, with little preparation for NMS. Stakeholders indicated this change was abrupt and carried out without adequate consultation, planning, or training. This resulted in an insufficient transfer of critical information, knowledge, and skills to NMS. These issues led to disharmony among some top managers whose positions in the Ministry were crucial for PCV introduction.

These management issues became regular topics of discussion among stakeholders concerned about the worsening performance of the immunization system and were even covered in the Ugandan media. Two weeks after the PCV launch in Iganga, a new wave of managers were brought into the MOH. These included two ministers and a new UNEPI program manager. These changes have resulted in an improved working relationship between UNEPI and NMS and a more normalized process of vaccine management and distribution for the immunization program. The working relationship between NMS and UNEPI has reportedly improved, and the two groups meet regularly under the auspices of UNICEF with technical assistance provided by WHO.

7.2.2 Financial system changes

In 2012, the MOH introduced a computerized, integrated financial management system (IFMS) as part of a phased government rollout. The system was intended to improve financial management by streamlining financial flows, improving efficiency, and promoting accountability by spending units; it was also intended to speed the transfer of GAVI funds between the Ministry of Finance, Planning and Economic Development (MOFPED) through the MOH and on to districts. However, several aspects of the implementation of this system caused delays in the financial disbursement process.

First, it took time for people to become familiar with the new system. Second, per diem payments to health workers were required to be sent directly to individual health workers' accounts, but the MOH accountants did not have all the health workers' details and account information. This information had to be gathered and manually entered into the system before payments could be processed. Third, several upgrades to the system forced it to be offline for an extended period during which payments could not be made. According to one stakeholder, "IFMS was practically closed between May, June, and July, 2013." Finally, the accountants who were most familiar with the IFMS were transferred to other roles when funds were supposed to be disbursed to the districts, slowing the entire process as new staff came on board.

7.2.3 Other GAVI Alliance support

GAVI support in Uganda began in 2001 with Immunization Services Support (ISS). New Vaccine Support for the introduction of pentavalent vaccine began in 2002, and is anticipated to continue through 2015. Injection Safety Support (INS) was disbursed from 2002 to 2004. In 2006, as a result of mismanagement of ISS funds, GAVI suspended all cash transfers to Uganda. Uganda was approved for Health Systems Strengthening (HSS) support in 2007, conditional on the establishment of an agreement between GAVI and the Government of Uganda on a process to ensure the appropriate use of cash funds and the reimbursement of misappropriated ISS funds. In 2008, the GAVI Secretariat and Government of Uganda signed an aide memoire that outlined these processes and recommended lifting the suspension of GAVI support. A formal memorandum of understanding was signed, and the suspension was lifted in June 2012. Reprogramming of the remaining ISS funding and of approved HSS funds was required before these funds could be disbursed. ISS funds were reinstated in 2012, and $4.5 million in HSS funds was disbursed in 2013. New Vaccine Support for pentavalent vaccine continued throughout the suspension of cash support.

A proposal for reprogramming the remaining HSS funds is currently under review by GAVI. In addition, Uganda has applied and been approved for New Vaccine Support to introduce HPV country wide in 2015, and it is planning an application for IPV.

7.3 Timing and adequate planning and budgeting

The MOH, MOFPED, UNICEF and WHO were key decision-makers involved in the application seeking support for the introduction of pneumococcal vaccines from the GAVI Alliance. At the operational level, all technical and planning aspects were handled by the NCC, including the writing of GAVI applications.

Uganda's decision to introduce PCV was influenced by many factors. First, immunization is a key policy and strategic plan issue for the Uganda MOH as highlighted in the National Health Sector Strategic Plan (HSSP), which stresses new vaccine introduction as a key priority. Studies in Uganda also show a high burden of pneumococcal disease: 21% of deaths are estimated to be due to pneumonia, of which 7% are caused by *Streptococcus pneumoniae* infection[9]. The WHO estimates that 18,995 deaths each year among children under-five years of age are attributable to *S.pneumoniae.* Other studies have shown that *S. pneumoniae* accounts for 35% of all confirmed etiologies with an overall case fatality ratio of 19%[10]. It was also estimated that a pneumococcal vaccination program would save 2.565billion Ugandan shillings (US$1.245million) in direct medical costs annually and that introducing PCV would prevent 94,071 cases of *S. pneumoniae* and save 10,796 lives per year in children under-five years of age. As a result, Ugandan leaders chose to introduce pneumococcal vaccines to reduce disease burden in children.

The Government of Uganda submitted the PCV introduction proposal to GAVI in May 2011, and GAVI approved the grant in September 2011. The approval came with standard terms and conditions that were reviewed and approved by the Government of Uganda.

PCV was originally planned for introduction in January 2013, but the launch date was changed twice. It was first rescheduled for April 1, 2013, and was later changed to April 27, 2013. Factors related to financing and management likely led to the first postponement. Delays in the transfer of funds from the MOFPED to the MOH and further to districts were compounded by use of the new financial management system. The final launch date was determined in the NCC meeting on March 3, 2013, and was scheduled to coincide with the celebration of African Vaccination Week.

Findings of this assessment reveal that initial planning for the PCV introduction, at least up until funding approval, went relatively well. For example, a PCV introduction plan was in place at the time of the application for GAVI support, an update of the comprehensive Multi-Year Plan (cMYP) was completed, and the PCV application was submitted in time to meet the GAVI deadline. Also, the PCV application was approved well before the initial launch date. Plans appeared comprehensive, they were developed on time, and funding sources were identified to meet budgeted needs. As the launch date approached, however, activities became rushed to meet the impending deadline. The rush was attributed to delays in the financing process due to the new IFMS. The planning failure was the failure to account for the dynamic context and, specifically, how changes in the financial system would affect the ability of UNEPI and partners to carry out the introduction plans.

7.4 Sufficient funding available in time

According to the PCV Introduction Plan submitted by the Government of Uganda to GAVI with the PCV application in June 2011, the budget supporting PCV introduction was initially $816,000, with $514,500 of this total to come from GAVI in the Vaccine Introduction Grant (VIG). The VIG funds were to support training; some aspects of social mobilization, IEC and advocacy; some aspects of surveillance and monitoring; micro-planning at central and district levels; and supportive supervision. By early 2013, however, a progress report on the introduction of PCV indicated that the full cost of introduction had

increased to more than $2.9 million (Table 7), including $1.37 million to come from GAVI funds, $26,000 from WHO, and $1.5 million from the Government of Uganda and Health Development Partners. The GAVI funds supporting the introduction activities were noted in the progress report as coming from the VIG, HSS and ISS budgets.

Table 7: January 2013 budget for PCV10 introduction activities, Uganda.

ESTIMATED PCV10 INTRODUCTION BUDGET BY ACTIVITY				
	Full cost/needs for new vaccine introduction	Proposed utilization of GAVI	WHO	GOU&HDP
Activities planned	Costs in US$	in US$	in US$	Gap US$
Training	697,423	697,423		-
Social Mobilization, IEC and Advocacy	759,138	*99,999*		659,139
Cold Chain Equipment Maintenance	80,844	80,844		-
Vehicles and Transportation	75,608			75,608
Programme Management	192,916	192,916		-
Surveillance and Monitoring	546,395	157,002	26,178	363,215
Human Resources (Supervision)	290,721			290,721
Waste Management	182,333	-		182,333
Technical assistance				
Other (please specify)Micro planning	143,816	143,816		-
Other (please specify)				
Totals	2,969,194	1,372,000	26,178	1,571,016

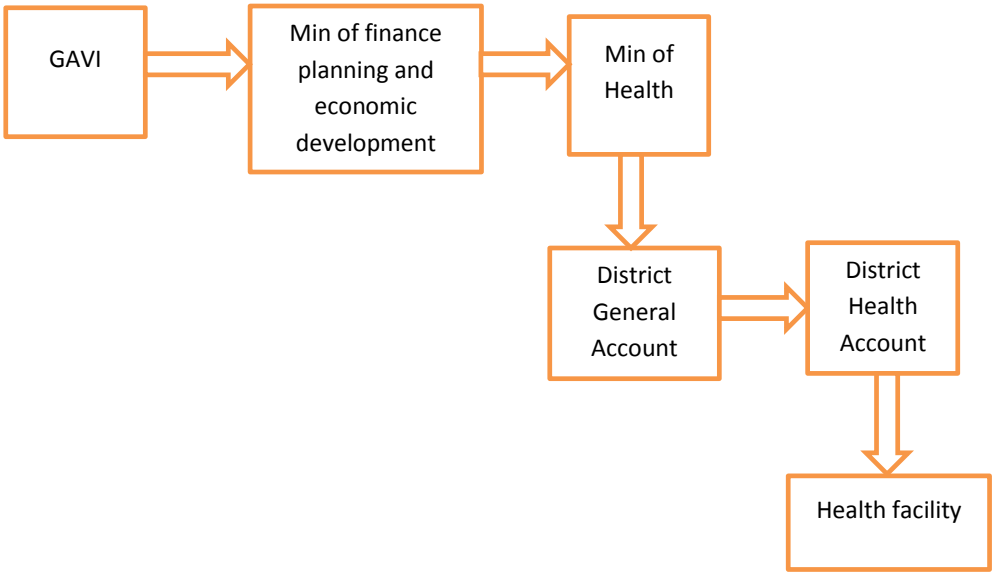
Source: Government of Uganda, 2013. "Progress Report on the Introduction of Pneumococcal Conjugate Vaccine in the Uganda Routine Immunization Programme"

The VIG funds from GAVI arrived in Uganda in September 2012. However, the process of disbursing funds from the principal recipient, the MOFPED, to districts was delayed. According to a key informant at the MOH, the VIG funds were received by the MOFPED in September 2012 but were not sent to the MOH until March 2013. Although some districts received funds in May 2013, other districts have still not received funds. The delays in the transfer of funds from the MOFPED to the MOH, and from the MOH to the districts were attributed to a number of factors, including the IFMS as mentioned previously.

> *"The introduction of IFMS ... has only solved the problem of accountability and record keeping, but [it] does not facilitate faster transfers for payment and spending by other departments."*
> – Key informant, subnational level

Funds earmarked for immunization activities at the district also have to pass through a prescribed channel as shown in Figure 7.

Figure 7: Process flow of funds from GAVI to districts and health facilities in Uganda.



This disbursement process is considered lengthy. Money is sent from the MOFPED to the MOH GAVI account. From the GAVI account, it is sent to each district's general account. When funds are disbursed to districts, the Permanent Secretary of the MOH sends a circular to all district chief administrative officers (CAOs) detailing how the funds are to be used. The CAO then notifies the district health officer (DHO) when money is reflected on the district general account. The DHO then makes a requisition to the CAO through the chief finance officer. Upon verification of the requisition, money is then wired to the health account in the DHO's office. The DHO then distributes the money to different health facility accounts, or in the case of training, to the individual accounts of the health workers attending the training. Several steps can become bottlenecks in this process, as one key informant's response exemplifies:

> *"No other person apart from the CAO can approve payment. It is only he who has the password and that means when he is not in office, the activity has to wait."*
> – Key informant, subnational level

Many respondents considered the new IFMS to be the underlying cause of the delay in disbursement not only for GAVI funds but also for all funds coming through the government. Most national and subnational-level informants cited the IFMS as a factor hindering implementation of activities in the districts. According to one key informant from the national level, most health workers who were trained in April (regional training) and July (district level and lower-level training) had not been reimbursed as of December 2013. There were delays in disbursement of funds to entire districts as well.

> *"Our district has not received money meant for training health workers for PCV and even some of us who attended the national-level training have not received our transport refund and per diem up to now. The reason they give is that our district is not in the IFMS and so money cannot be wired."*
>
> – Key informant, subnational level

Another issue was lack of timely instructional notes accompanying the release of funds. All funds that are transferred from the national MOH account to the district general account are required to have an accompanying instruction note from the Permanent Secretary that indicates how those funds are to be expended. However, respondents reported these notes are sometimes received late, after funds have been transferred. Without timely instructions, it is difficult to assign particular funds to intended activities.

For several specific funding shortfalls, Uganda was able to muster contingent sources of funding. In Iganga where PCV has already been rolled out, subnational key informants reported direct financial support from the following organizations:

- UNICEF has a separate account at the district level where they channel funds for activities they support. For example, UNICEF provided funds for advocacy and social mobilization in the Iganga district.
- The US Agency for International Development (USAID), through the Maternal and Child Health Integrated Program (MCHIP), supported training of health workers at district levels. Their support has been expended to four other districts (Kabale, Kapchorwa, Rukungiri and Busia districts) in addition to Iganga. The success in training sufficient health workers in the five districts is attributed by informants to MCHIP support.
- The US Centers for Disease Control and Prevention, through the African Field Epidemiology Network (AFENET), supported training in 10 districts (these districts are different from those supported by MCHIP).

These organizations make direct transfers to districts without using the government IFMS system. As a result, districts could implement activities in a timely manner.

7.5 Cold chain and logistics system is prepared for PCV10

In preparation for general strengthening of the immunization system, a national cold chain review and inventory were conducted in all health facilities providing immunization in 2008. As a follow-up, an Effective Vaccine Management Assessment (EVMA) was done countrywide in July 2011. The inventory and assessment provided vital information on the number and status of cold chain equipment at all levels. USAID and Japan International Cooperation Agency (JICA) supported procurement of cold chain equipment to bridge the gaps identified at national and subnational levels.

However, an update of the cold chain inventory in October and November 2012 found that only 65 out of the 122 districts (53%) had a functional cold chain system in place, in contrast to the findings from the EVMA that estimated this indicator to be 88%. This gap was attributed to lack of periodic maintenance and repair of the equipment. Periodic maintenance had been scheduled to occur twice every year. Since then, an approach of preventive maintenance was adapted at the district level to ensure that the refrigerators are checked and maintained on a regular basis.

In preparation for the introduction of PCV, refrigerator stickers were distributed to all districts with the intention of placing them on all refrigerators in health centers. However, a PCV readiness assessment conducted by WHO in September 2013 showed that 31% of refrigerators in randomly selected facilities lacked refrigerator stickers, several health facilities lacked a second gas cylinder on standby, and some refrigerators were nonfunctional. According to these criteria, the districts were not ready. By contrast, 90% of refrigerators in Iganga were functional thanks to support from MCHIP.

The distribution of vaccines was also a reported challenge. Respondents reported that logistics management was affected by the transfer of the vaccine distribution role from UNEPI to NMS. At the time of the transfer in April 2012, NMS lacked adequate expertise in vaccine management, and communication with UNEPI was inadequate. This resulted in problems during the PCV launch and rollout. For instance, our data from Iganga revealed that there was a PCV stockout from the last week of May to the second week of June 2013. One informant attributed this to NMS distributing vaccines once every two months as they do for other essential drugs instead of doing it monthly as UNEPI previously did. However, following improved communication with UNEPI and districts, the situation has improved and no further PCV stockouts have been reported. The turnaround in NMS performance is attributed by national-level informants to several rapid capacity-building efforts conducted since the appointment of the new program manager at UNEPI. NMS staff have undergone training in vaccine management with support from UNEPI, WHO, and UNICEF. In addition, to improve communication between NMS and UNEPI, a high-level transition committee was established in September 2013. It consists of representatives from NMS, UNEPI, UNICEF, WHO, PATH, and CHAI and meets monthly. Multiple key informants report that working relations between NMS and UNEPI have greatly improved.

7.6 Adequately skilled health workers are available

Health workers were trained at the national and regional levels and in some districts. The intention was to train health care workers before introduction of PCV. The preparation for training began with development of training materials at national level, and the training material was adapted from the WHO PCV training manual. Most partners reported having been fully involved in the process of material development. However, not enough copies of the field training manual were available for trainers and supervisors.

> *"Training at the national level went well. However, training materials were not enough due to poor coordination, and at times, the funds were not adequate."*
>
> – Key informant, national level

According to the initial introduction plan, when the launch date was to occur in January 2013, all health managers, health workers and staff who handle EPI vaccines were to be equipped with knowledge and skills to ensure smooth introduction of PCV by December2012. National-level training (training of trainers) took place in March 2013 in three phases. By the end of March, 92% (111/122) of the first-tier of trainers had been trained at the national level, and subnational trainings had not yet begun.

The regional training began in late March 2013. By the April 27 launch date in Iganga, regional staff from 21 of the 23 regions had been trained. Although national and regional trainings had been done by the time of PCV launch, district and HSD trainings had been conducted only in Iganga, Kabale, Kapchorwa, Rukungiri and Busia districts. These lower-level trainings resulted from direct support provided by MCHIP.

As of November30, 2013, seven months after the training of trainers began, 98 of 112 districts had trained health workers at the facility level in preparation for PCV introduction. The other 14 districts have not yet trained health workers. In Iganga and Tororo districts, respondents at the HSD reported that trainings at lower levels were handled in a satisfactory manner with adequate supervision. For district-level training to be valid, a national supervisor needed to witness the training. At lower levels, supervision was done by district supervisors. Many respondents expressed satisfaction with the training efforts.

"I am very satisfied with the training because at least three staff per facility were trained for PCV and the training covered the key messages about PCV. All the participants appreciated the training they were given."

– Key informant, health subdistrict

However, this perspective contradicts the results of the readiness assessment conducted by WHO, which found that health workers were not knowledgeable (see below). WHO found that only 43% of health workers could indicate five key messages related to PCV. These findings are presented in more detail in the next section.

7.7 PCV10 readiness is confirmed

We learned from KIs that WHO sent a formal communication on the need for a readiness assessment prior to PCV introduction, and that the readiness assessment was discussed in the surveillance, monitoring and evaluation subcommittee meetings. However, the requirement and the reasons to undertake a formal district-level readiness assessment were unclear to most in-country stakeholders. Varied perceptions of how this decision was made emerged in KIIs. Some stakeholders thought that the district-level readiness assessment was a directive or a condition from WHO headquarters, whereas others thought that it was a directive from the MOH Director General of Health Services. The third explanation was that it could have been a requirement of the vaccine manufacturer (GSK), although this latter reason was denied by GSK country office.

The requirements for readiness certification stipulated in this country-wide assessment were:

- Availability of training materials at health facilities providing EPI services.
- Evidence of training of operational health workers through knowledge of five key messages.
- Presence of a sticker on the EPI refrigerators.

The five key messages health workers were required to know were:

- Do not return opened vials to the refrigerator.
- It is safe to give a child more than one injection or antigen at the same time.
- Vaccines are administered in the right upper thigh.
- This is a two-dose vaccine with no preservatives.
- Discard opened vials after six hours or at the end of the immunization session, whichever occurs first.

Health workers were asked "*What specific messages related to the administration of PCV10 were provided during the training?*" and were expected to list the five key messages above without prompts. As noted previously, in an assessment after training, only 43% could name the five key messages, and stickers were found on only 69% of refrigerators, far from the 80% target. When the PCV readiness report was made available to the MOH in September 2013, the EPI technical team met and developed a plan to address the identified gaps. Approaches to fill gaps included:

- The MOH leveraging ongoing immunization activities like SIAs and Child Health Days to pass key PCV messages to health workers and distribute refrigerator stickers.

- The MOH sending a circular to all DHOs detailing findings of the readiness assessment and instructions for filling gaps.
- The MOH sending out text messages to most health workers containing key messages on how to handle PCV.
- WHO providing technicians to repair non-functional refrigerators in all districts.
- Partners like the Uganda Pediatrics Association, CHAI, MCHIP and AFENET providing mentorship and reorientation of health workers in some districts.

Not all of these approaches had been implemented at the time of this report. Subnational interviews revealed that PCV messages were not communicated within the setting of the SIAs and Child Health Days in the districts visited. A circular was sent through email to all DHOs, although its effectiveness has been questioned. Text messages were sent to health workers. Support for cold chain repair has yet to occur. Finally, partner organizations including UPA (with support from GSK and CHAI) and AFENET have provided mentorship in 36 districts. At the time of report writing, a second readiness assessment was underway.

Although most respondents at national and subnational levels appreciated the importance of the readiness assessment, many were dissatisfied with the process. One issue identified by respondents was that the assessment criteria were not shared with some of the stakeholders. The assessment was based solely on the ability of health workers to spontaneously list the five key messages and on the observed presence of stickers on refrigerators. In Iganga, it was reported that the readiness assessment team had observed whether the refrigerators had stickers on top, per instructions. However, respondents reported that some stickers had been put on the doors of refrigerators, with good reason, because the refrigerator was so tall that placing a sticker on top would have impaired its visibility. Interviews with respondents revealed that the process of assessment in the field and analysis of variables used to determine readiness were not clear to stakeholders.

> *"Some fridges are so high that when you put the stickers on top as emphasized in the training, it will not be seen by health workers. In the training, it was emphasized that the stickers should be put on top of the fridge but not all facilities have the low-level fridges. The WHO assessment wanted to see stickers on top of the fridge."*
>
> – Key informant, subnational level

In addition, the need for a country-wide readiness assessment was not clear to in-country stakeholders, so respondents indicated that it was not a planned activity in the PCV introduction plan. Nevertheless, it was clear through observation that stakeholders understood the importance of being ready because some concerns about readiness were raised in one of the NCC meetings prior to the launch. In that meeting, attendees decided to shift the venue from Nakapiripiriti to Iganga district, which they deemed to be more ready for vaccine introduction.

7.8 Updated monitoring systems are available

Monitoring of coverage of the PCV was integrated within the existing routine health management information system (HMIS) tools. Monitoring tools (tally sheets, child health cards, monthly reporting forms, and monitoring charts) were updated to include PCV in 2011. Mass production and distribution of the revised HMIS tools to all districts occurred well before launch.

Nevertheless, there was a severe shortage of most of the tools in all districts visited. In addition, since the PCV launch in Iganga, the country has lacked immunization cards, except for a few districts that have Mother and Baby Passport cards, which capture antenatal and postnatal information.

> *"We do not have the Child Register Control book and have decided to improvise by drawing columns in counter books, and therefore we have our record up to date. Even the Child Health Card is lacking and for that we cannot improvise. They were only delivered when we were about to go for the Family Health Child Day and that was that."*
> – Key informant, health subdistrict

7.9 Adequate demand for PCV10 generated

With support from UNICEF, Uganda developed a comprehensive *Advocacy and Social Mobilization Strategy and Plan*. Most of the social mobilization efforts were completed prior to the launch. However, the lack of coordination between this activity and other key launch milestones was a problem. Communities were mobilized to get immunized with PCV even though no vaccine was rolled out beyond the Iganga district. Health workers in the Tororo district reported that community members visited health facilities to request PCV as advertised in the media, but the facilities did not have it. By contrast, Iganga registered an influx of people from neighboring districts coming for PCV, which resulted in rapid use of existing supplies. This meant that there was a high unmet demand for PCV.

> *"We were even receiving children from the neighboring districts, which was really something we did not plan for. The parents from the neighboring district learned that there was vaccine for pneumonia in Iganga and that Iganga was the only district to benefit so they had to rush in with their children to get that service."*
> – Key informant, subnational level

Even though some social mobilization activities occurred prior to the launch, respondents reported that development of social mobilization information, education, and communication (IEC) materials was not completed on time. Mass production and dissemination of IEC materials in various languages was scheduled to take place from May to July 2012. However, by April 2013 when PCV was launched, only the PCV poster had been developed, and few copies had been printed because of financial constraints. Other mobilization efforts to create public awareness were:

- Advocacy meetings with members of Parliament, religious leaders, and the media, which were held in April 2013. These meetings had originally been scheduled for August and September2012.
- Mass publicity through radio and television programs and print media was planned to start in October 2012 and run throughout 2013. With help from UNICEF, radio notices and advertisements started airing on 38 local stations in March 2013 in different languages. Other advocacy and social mobilization activities were completed on time. For example, the PCV introduction seminar for all stakeholders was organized as planned in February 2013.

7.10 Sufficient volume of quality vaccines available

Distribution of vaccines to the districts and delivery of injection materials for the new vaccines was planned to start in November 2012 and run throughout 2013. However, the first shipment of PCV (250,000 vials) and injection safety materials arrived in Uganda in April 2013, a few days prior to the launch ceremony. The

vials were shipped for the launch ceremony in Iganga and four other districts that MCHIP had prepared and were considered ready.

At the time of training at the national, regional, and district levels, the country had not yet received any PCV supply. PCV was not available during the trainings, which resulted in "theoretical trainings," as explained by one stakeholder:

> *"The major problem with the training was that it was too theoretical and the practical aspects were not emphasized. Imagine not even a single bottle of PCV was shown to the participants. How can you train someone on something that you have not shown him?"*
> – Key informant, subnational level

Health workers at the HSD level reported a lot of vaccine wastage. They cited the newness of the vaccine and the unique instructions for administration as reasons for the high levels of wastage.

> *"Another possible reason for the vaccine stockout could have been that there was too much wastage on the side of the health workers. PCV was a new vaccine and had its own instructions for how it should be administered."*
> – Key informant, health subdistrict

7.11 Successful Launch of PCV10

The launch ceremony in Iganga was a well-organized and well-attended event. It was presided over by the President of Uganda and attended by many key dignitaries, including the CEO of GAVI, regional and country representatives of UNICEF, and the WHO country representative. There were numerous dances and drama performances by cultural groups and schools. The launch also featured a leading Ugandan musician who is the UNICEF ambassador for immunization. The ceremony was covered by both local and international press.

The introduction of PCV was limited to Iganga because most districts had not yet conducted training for PCV and were deemed not ready to introduce the vaccine. Under support from MCHIP, five districts (Iganga, Busia, Kapchorwa, Bushenyi and Kabale) had trained health workers and were ready for PCV introduction. However, according to one country partner, because of operational difficulties in undertaking an introduction for five districts in different regions, the MOH deemed it better to restrict introduction to Iganga, with an assumption that the other four districts would rollout PCV shortly after.

The decision to launch PCV in Iganga before the rest of the country was ready was not well regarded by some stakeholders. One national-level respondent described the launch as "rushed" and premature:

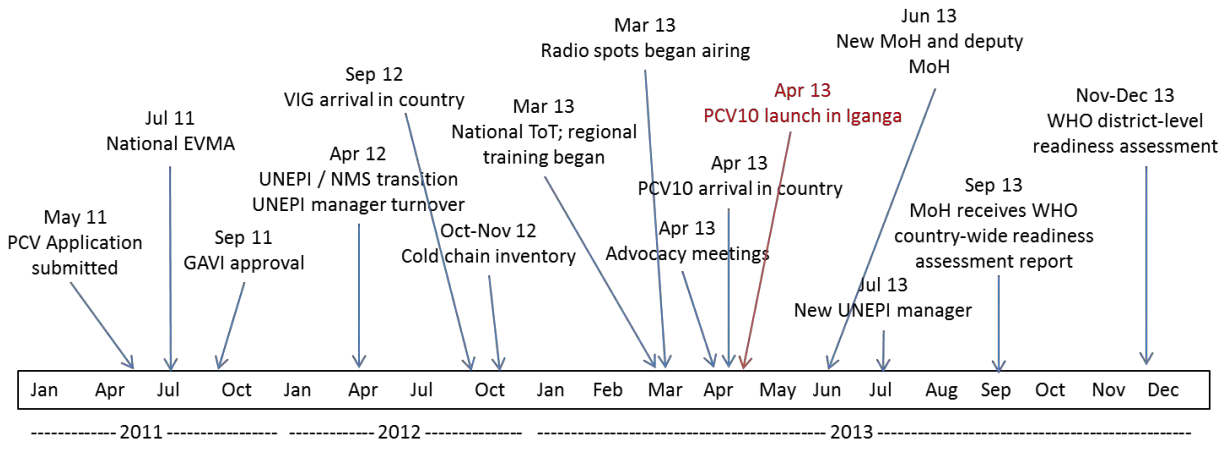
> *"At the time of the launch, only 5 out of the 112 districts had provided adequate training for health workers, and that is a clear sign that the country was not fully prepared for the introduction of PCV."*
>
> – Key informant, national-level stakeholder

Another respondent viewed the decision to maintain the April launch date as a nearly unilateral decision made by top leadership for political reasons. "Political readiness" seemed to outweigh technical readiness in the decision to launch the vaccine.

MCHIP is currently conducting quarterly supervision with the MOH in Iganga district. The supervision is supportive, focusing on strengthening implementation of all vaccines in the routine immunization system, including PCV10. Surveillance is expected to continue within the existing Integrated Disease Surveillance and Response framework. The existing mechanism for reporting and investigation of adverse events following immunization is already being used by UNEPI for the new vaccine in Iganga.

Figure 8shows the timing of key events leading up to the launch and afterwards.

Figure 8: Timeline of key events in the introduction of PCV in Uganda.



7.12 Roles and responsibilities of stakeholders

The introduction of PCV was intended to be undertaken as a partnership between the MOH, partners and districts. Table 8summarizes the roles and responsibilities of stakeholders, committees, and subgroups that participated in the introduction at the national level. Key stakeholders included the MOH, UNICEF, WHO, NMS, MCHIP (funded by USAID), UPA, CHAI, GSK, civil society organizations, and other private partners. The stakeholders worked through recognized committees such as the Top Management Committee of the MOH, the Health Policy Advisory Committee, the Senior Management Committee, the National Coordination Committee, and the EPI Technical Committee. Each committee was charged with different functions such as proposal development, endorsement of the proposal, making decision on the launch date, and monitoring the implementation of introduction activities. The focus of the process evaluation was on the work carried out by the members of the EPI technical committee during the planning, launch, and rollout of PCV. The EPI technical committee was the most active structure throughout the process.

Table 8: Roles and responsibilities of stakeholders, committees, and sub-groups involved in the PCV introduction process in Uganda.

Structure	Role	Chair	Membership
Top management committee	• Endorsed the application	Cabinet Minister of Health	• Ministers of Health (Cabinet and State ministers) • Permanent Secretary (PS) • Director General of Health Services (DG) • Heads of Directorates
Health Policy Advisory Committee (HPAC)	• Reviewed and approved application	Permanent Secretary	• Health Development Partners (HDPs) • Civil Society Organisations (CSOs) • Private partners • Heads of Directorates National Medical Stores (NMS) • Ministry of Finance, Planning and Economic Development (MoFPED) • Ministry of Education • Ministry of Public Service • Ministry of Health
Senior management committee	• Reviewed and forwarded application to HPAC • Endorsed the launch date	Director of General Health Services	• Heads of Departments in the Ministry of Health • Commissioners in the Ministry of Health
National Coordination Committee (NCC)	• Endorsed the proposal • Decided the launch date • Coordinated the launch ceremony	Director of General Health Services	• Ad hoc consultative committee (not structural) • Technical officers • Health Development partners (WHO, UNICEF, GSK, SABIN, JICA, MOH)

Structure	Role	Chair	Membership
EPI technical committee	• Developed proposal, work plans and budget • Monitored implementation of introduction activities	EPI manager	• UNEPI technical officers • CSOs • Health Development partners • Private sector partners

Formal communications from GAVI are addressed to the Permanent Secretary or Director General of Health Services. The CRO communicates regularly with the EPI manager and the GAVI technical advisor and the MOH through email on programmatic issues. GAVI communicates with in-country partners (WHO and UNICEF) through a weekly call. The partners give regular updates on what is happening in the country.

7.13 Analysis of findings

This section summarizes the critical factors contributing to the current state of PCV introduction in Uganda (as of December 1, 2013), tracing the connections between them and making comparisons with prior experiences with vaccine introduction. Currently, Uganda is stalled at the point of establishing readiness to receive and introduce PCV to the entire country.

Contextual changes, including changes in key leadership positions and implementation of a new financial system, contributed to poor planning, poor adjustment to plans, and insufficient disbursement of funding to carry out essential introduction activities. At a deeper level, the country is in many ways still recovering from the financial mismanagement and subsequent suspension of GAVI cash support that occurred in 2006 and lasted until 2012. Though the misappropriated funds have been reimbursed, the IFMS system is just being put into place for improved transparency and accountability. Work is ongoing to rebuild trust within the MOH, between the MOH and MOFPED, and between the government and partner organizations. Renewed yet tenuous relationships create a context in which it is difficult to address challenges.

In the past few years, significant changes at UNEPI have had a negative impact on the introduction of PCV as well as immunization activities as a whole. In addition, changes in top management of EPI left an acting manager as head at the time of vaccine introduction. There was no permanent appointment in place until June 2013, two months after the launch.

Early plans for PCV10 introduction did not factor in the simultaneous implementation of the IFMS. The effect of the system conversion on the timing of funding disbursement was not well anticipated. Delays in IFMS implementation subsequently delayed introduction plans and resulted in hurried and incomplete activities to meet what ultimately became an unrealistic launch date.

The delays with IFMS affected the timing and quality of training in many districts. Funds were not sent to districts to conduct trainings until well after the April launch, except in the districts that were supported directly by MCHIP. When funding finally did go through to districts, the activities were rushed. Disbursement of funds remains an ongoing problem; for example, many health workers who attended trainings (including trainings of trainers) still have not been paid.

Questions were raised about the quality of training in an EPI technical meeting in July 2013. One of the criticisms was that the training curriculum was theoretical; no practical demonstrations of proper handling and injection of PCV were conducted because the vaccine was not yet in the country. Further, the cascaded process of PCV training assumed that the few health workers trained would in turn train their colleagues at each workstation. Subnational interviews revealed, however, that this never occurred in some districts. Also, the wrong health workers were sometimes apparently sent for training (i.e., they were not responsible for handling or administering vaccines). The failure to complete the cascaded training plan as intended was likely influenced by a number of factors, and we see a probable connection between this

incomplete training process and the challenges that emerged with compensating trainers and health workers attending the trainings.

Establishing nationwide readiness to safely introduce PCV is currently the most important and direct barrier to nationwide rollout. This includes many aspects of programmatic readiness, aside from refrigerator sticker placement and health worker knowledge, such as availability of monitoring tools and needed cold chain repair at some facilities. These failures to achieve programmatic readiness are directly connected to the management, funding, and training problems described previously. Several informants acknowledged the importance of being well prepared before implementing such a costly vaccine with unique safe handling requirements. There was some indication from respondents that measures to fill the readiness gaps have been inadequate and ineffective. For example, the strategy to integrate PCV mentoring (re-communicating and emphasizing the key training messages for handling PCV with health workers) into SIAs and Child Health Days did not occur, according to respondents in one district. One key informant stated that sending a circular by email to DHOs was ineffective because most of them have no immediate Internet access.

At the same time, the process of assessing readiness has itself been problematic. According to interviews at the global level, WHO was responsible for the assessment and for certifying that the country met the criteria for programmatic readiness. However, several in-country respondents said they were unaware of this requirement and of the process for confirming readiness when they were preparing for launch and rollout.

Country stakeholders cited the importance of using the readiness assessment as an opportunity for capacity-building. One key informant suggested that when assessors found lack of knowledge among health workers, for example, they should have taken the opportunity to build capacity by reminding the workers of key messages for PCV10. Although all assessors were given PCV field guides, and they strengthened programmatic readiness by using the field guide and checking for refrigerator stickers, one key informant did not believe the readiness assessment adequately emphasized capacity building:

> *"[The assessment] should be a process improvement exercise, not a fault finding mission."*
>
> – Key informant, national level

Most in-country immunization partners said they were not involved in planning or implementing the readiness assessment. They also questioned the timing of the assessment in relation to the training, given that it was conducted three months later and health workers had not had a chance to practice and apply what they had learned. The larger question, in our view, is why the readiness assessment was not more explicitly included as part of the introduction plan.

Because the placement of refrigerator stickers is a vital component of readiness, it is important to note that this requirement has still not been satisfied in many districts. It is not clear why refrigerator stickers did not reach all facilities. Because training had not occurred for staff in these facilities, information about the importance of the sticker on the refrigerator may not have been effectively relayed to all facilities.

Given the challenges identified in Uganda, one respondent commented that "*the wrong vaccine was introduced at the wrong time*." This raises the question of whether it may have been wiser to introduce a

different presentation of PCV than the two-dose vial of PCV10. The 13-valent presentation would not have required the same unique handling procedures to maintain safety because it comes in a single-dose vial. Selecting this vaccine presentation could have avoided the complexities of training health workers to meet the PCV10-specific safe handling requirements. The conclusion that PCV was introduced at "*the wrong time*" appears to be accurate, based on our process evaluation.

Although the management and funding disbursement challenges and their effects on training of health workers were major underlying problems, other contextual issues also contributed to introduction difficulties. For example, the shift of vaccine management responsibility from UNEPI to NMS was sudden and occurred while planning for PCV introduction was underway. Many stakeholders commented that NMS was unprepared for the new role, and the sudden transfer was not well received by UNEPI. The result was a challenging transition. Some effects were observed with PCV distribution to Iganga, notably a nearly three-week stockout period. The lack of experience at NMS could have resulted in much broader consequences for vaccine supply had all districts launched the vaccine in April.

Comparing the introduction of PCV to the previous introduction of pentavalent vaccine in 2002underscores the major impediment posed by the new IFMS (see Table 9). The pentavalent vaccine was introduced nationwide in June 2002, three months later than originally planned. No post-introduction evaluation (PIE) was conducted, and detailed information about the process introduction is limited. However, a review of annual performance reports submitted to GAVI in 2002 and 2003 and of the application for PCV introduction gives no indication of any major financial disbursement issues with respect to activities directly supporting the pentavalent introduction. However, concerns were expressed about the financial sustainability of the vaccine as part of routine immunization, and in subsequent years there were well-known financial mismanagement issues associated with GAVI funds. Also, some planned activities related to monitoring and surveillance and sensitization of NGOs, hospitals, and the private sector were delayed and did not occur prior to the launch of pentavalent. The reason cited for these delays was a diversion of attention to competing priorities rather than funding issues.

Table 9: Comparison of lessons learned in the process of introduction of pentavalent vaccine[4] to the process of introducing PCV10 in Uganda.

Work domain	Introduction of Pentavalent Vaccine	Introduction of PCV10	Comparative synthesis
Timely and adequate planning	• Vaccine introduction plan and budget was developed • Launch was in June 2002, three months later than originally planned • Some activities for introduction were not completed as planned due to competing priorities (e.g. expansion of monitoring and surveillance for HepB and Hib, and sensitization of NGOs, hospitals and the private sector)	• Vaccine introduction plan and budget was developed • Launch in one district was in April 2013, and rollout to other districts has still not occurred. • Insufficient planning to account for the implementation of the integrated financial management system (IFMS) which introduction activities depended upon • Unforeseen factors including changes in leadership positions within the MoH also contributed to the delays.	• Early stage planning was well done for both vaccine introductions. • In both cases, foreseeable factors affected the timely completion of plans
Sufficient funding available in time	• No major funding issues were raised in with respect to activities supporting the introduction • GAVI vaccine introduction grant was $100,000 and supported a narrower range of activities	• GAVI vaccine introduction grant was larger ($514,500), supporting a broader range of activities, and was received six months prior to the launch. • Challenges with funding disbursement from the MoFPED to the MoH and on to districts and health care workers due to the new IFMS.	• Delays in funding disbursement due to the IFMS were a major underlying reason for the incomplete launch and rollout of PCV; these issues were not present prior to IFMS during the launch of pentavalent vaccine. • The GAVI introduction grant increased from pentavalent to PCV introduction
Adequately skilled health workers available	• Adequate training of health workers was cited as a critical lesson learned	• Cascaded training plans were thorough and detailed; however they were not implemented as planned • Questions around the quality of training led to the countrywide readiness assessment	• Quality of training was a consistent issue in both pentavalent and PCV introductions, though for different underlying reasons
Cold chain and logistics system improved	• Lessons learned included many related to cold chain and logistics, especially with regard to cold chain storage capacity for low-dose vials suggesting that capacity was an issue	• An effective vaccine management assessment was conducted in July 2011 and an update in October 2012. The first concluded there was adequate storage capacity. The second identified only 65 of 122 districts with functional cold-chain.	• Storage capacity may have been effectively addressed for PCV10; however, the equipment was not well maintained.

[4] A post-introduction evaluation (PIE) was never conducted for the pentavalent introduction. Therefore, lessons learned from the pentavalent introduction have been gathered from review of other documents, including annual progress reports to GAVI and subsequent applications for GAVI support.

Work domain	Introduction of Pentavalent Vaccine	Introduction of PCV10	Comparative synthesis
PCV10 Readiness confirmed	• Not applicable	• Readiness confirmation was unique to the introduction of PCV10	• Stakeholders implementing PCV10 did not fully understand the requirements for readiness confirmation. This new but significant step in the process was a major factor in the launch of the vaccine in only one district.
Sufficient volume of quality vaccines available	• Projections for estimated doses required were too low and the country ran through a 6-month supply in less than 4 months; formulas to estimated doses did not account for a substantial dropout rate between doses 1 and 3	• New formulas for estimating doses required accounted for dropout between doses 1 and 3 • The country has only received 250,000 vials to date.	• Formulas were revised and the underestimation of doses was not an issue; however fewer doses were approved than were requested, and due to readiness, even fewer were shipped to the country. • Because of the readiness requirement, no vaccines were in the country for practical training for PCV.
Updated monitoring tools available	• One recommendation coming out of the pentavalent introduction was that monitoring tools needed to be revised prior to training of health care workers	• Monitoring tools were revised in 2011 to include both PCV and Rotavirus vaccines • Distribution occurred well before launch • Iganga and other districts have severe shortages of these tools	• Revision and distribution of monitoring tools to include PCV was done well in advance of the launch. However, at the time of the launch in Iganga, the updated tools were not available and had to be improvised.
Adequate demand generated	• IEC materials were developed, pre-tested and distributed • Advocacy meetings were conducted with policy-makers and were seen as important activities for ensuring country ownership of the new vaccines	• The full set of IEC materials was not produced as planned • Advocacy meetings with parliament, religious leaders and the media were conducted, however, this was done much later than planned, in the same month as the launch occurred.	• The timing of advocacy meetings with parliament may have resulted in less political support for PCV10 compared to pentavalent.
Successful introduction	• Launch occurred 3 months after initially planned, presided over by the President. • Rollout was countrywide and generally viewed as successful. • A PIE was not yet conducted	• Launch occurred in April 2013, three months later than planned. • Launch was limited to one district. Nationwide rollout has yet to occur. • A PIE has been planned for 2014.	• Both introductions were postponed; the launch of PCV10 probably should have been postponed again given the lack of readiness. • The lack of the PIE for pentavalent limits the lessons learned for this introduction process for PCV.

The revision and use of updated monitoring tools to track coverage and adverse events may have been problematic in the pentavalent introduction. This is indicated by one of the documented lessons learned, which noted that monitoring tools needed to be revised before training health care workers. While this lesson seems to have been internalized by stakeholders in the case of PCV introduction (monitoring tools were updated and an initial supply was distributed more than a year prior to the launch), consistent supply of the tools to facilities was an issue for PCV introduction. These tools were in short supply or missing in all three districts visited during the process evaluation.

At various points throughout the PCV introduction process, critical threats to success appeared. In some cases, these threats were communicated and acted upon; in other cases, they were not. There was room for improvement in the role of the management feedback loop (see the theory of change). The paragraphs below discuss key moments where this feedback loop was successful and times when it failed.

One successful adjustment was made following changes in management at the MOH and UNEPI in June 2013. A special committee was formed to improve communication between UNEPI and NMS, and to improve vaccine distribution. In addition, NMS quickly recruited new staff who were trained with support from the new UNEPI management.

In August and September, competing priorities—such as SIAs conducted in response to a polio outbreak and the preparation and submission of the HSS proposal—hindered UNEPI and partners' ability to adjust plans, and reinvigorate the stalled introduction process.

In the midst of the challenges in disbursing funds and implementing the training cascade, the lack of adjustment in other preparatory activities suggests breakdowns in the feedback loop. For example, although decisions were made to scale back the launch to one district, social mobilization efforts proceeded nationwide. This resulted in parents bringing their children to health facilities to receive a vaccine that was not available. At a higher level, this brings into question whether the decision to proceed with an April launch for any district was appropriate given the delay in preparations.

Finally, after the decision was made to launch only in Iganga district, and a clear problem with the quality of training was identified, the length of time that it took (and is still taking) in-country partners to address the issue suggests a breakdown in the management feedback loop. KIIs revealed a lack of understanding of the process for assessing readiness; this may have contributed to a slow response because partners were not clear about roles and responsibilities, and who was responsible for addressing the problem. The readiness assessment was not conducted until September 2013, despite the decision to do a partial introduction in April 2013. Further, after the readiness assessment was conducted, it was not until a meeting in late October that the results were presented and plans began to form for how to address the findings. This suggests a need for greater communication and coordination across partners. Better communication of GAVI policies and processes, particularly with respect to the

introduction of PCV10, would have improved the planning for this introduction. It is interesting to note that none of the decision letters sent to Uganda from the GAVI Secretariat, from the initial approval of pneumococcal introduction support in September 2011 to the last decision letter received in December 2012, mentioned the requirements for confirming readiness before the vaccine supply could be shipped.

7.14 Limitations

This evaluation has a number of limitations. First, because the national rollout has been delayed in Uganda, we are evaluating an incomplete process. The rollout experiences we have evaluated have occurred in only 1of 112 districts.

Second, the focus of our prospective evaluation began with activities just prior to the launch. Data collection mechanisms such as KIIs were possible only after ethical approval was granted in October 2013, and are ongoing. The evaluation is therefore limited in its ability to clearly understand processes prior to these dates, particularly during the decision to apply for GAVI support and application phases. Within UNEPI, there was significant staff turnover during the introduction process, and there is limited institutional memory of how and why certain decisions were made. For example, the new EPI manager was appointed in July 2013. Additionally, some staff involved in earlier phases of the introduction process were transferred out of UNEPI, and we have been unable to include their perspectives. These limitations highlight the importance of prospectively oriented evaluation studies that collect data in real-time.

Third, the findings reported here are based on a limited set of KIIs. In some cases, interview lengths were reduced due to lack of time. The scheduling challenges and interview time limits highlight the challenges of minimizing respondent burden. This will be an important consideration for the GAVI FCE evaluation as it continues.

Fourth, this process evaluation employs qualitative data collection mechanisms. It does not tell us about the coverage levels achieved in the one district that is currently implementing PCV. This and future process evaluations will be more meaningful as they are linked with quantitative data to be gathered as part of the FCE, and from secondary sources. This includes data from health facility surveys, household surveys, and administrative sources. Triangulation against these other sources is a key aspect of the GAVI FCE.

7.15 Future directions

The findings to date and associated limitations of the evaluation highlight a number of future priorities for the GAVI FCE, which we summarize here. A clear priority area is to track the continued process of rolling out PCV to all districts and subsequent monitoring and supervision activities. In addition, we will begin to triangulate our qualitative findings with a range of quantitative indicators, including vaccine supply and stockouts, vaccine coverage both inside and outside the targeted age range, and geographical and individual-level variation (socioeconomic status, gender) in vaccine coverage. We will

triangulate across multiple sources—including administrative data, health facility data, and household survey data—that constitute components of the GAVI FCE. Other important areas of follow-up are measures of population demand for vaccination (assessed through household surveys and patient exit interviews), cold chain integrity, and health worker knowledge and skills (evaluated through health facility surveys).

We will continue to follow aspects of the PCV implementation process over time, including monitoring and supervision and the PIE. Furthermore, because we were unable to examine the earlier decision-making and application phases of GAVI Alliance support in detail in this report, we will focus on the earlier phases of other GAVI Alliance support in Uganda, which will include:

- Preparation and implementation phases of HSS,
- Countrywide introduction of HPV, and
- Decision-making and application phases of introducing IPV and rotavirus vaccine.

This will also allow for an assessment of changes and improvement in the implementation process between the PCV introduction and future introductions such as HPV. The prospective approach will allow a more in-depth comparison than was possible with the comparison of the PCV and pentavalent introductions.

7.16 Conclusions

Although Uganda had initially carried out adequate planning for PCV introduction, the process later faced various challenges that led to a delayed rollout. Delays in financial disbursements, turnover of key leadership positions, and other management problems derailed the introduction process. These were compounded by inadequate management of the process to ensure readiness. Iganga's experience suggests that once the vaccine is introduced in ready and supported districts, it can be effectively integrated into the routine immunization system. However, months of delay in rolling out the vaccine nationwide are costing the country valuable time, resources, and most importantly, children's lives. As of December 1, 2013, it is not yet clear that efforts to re-train health workers on the safe handling of the vaccine are working. Given the confluence of complications that arose as the country was attempting to introduce the new vaccine, it may have been wiser to postpone the launch entirely, so investment in health worker skills acquired through training could immediately be put to use protecting children from pneumococcal disease.

7.17 Recommendations

This section describes recommendations focused on the most critical factors contributing to the delayed rollout. These factors include the concurrent introduction of a new financial management system and related challenges with the timely availability of funds, poor coordination and quality of training, and a lack of understanding of GAVI's policies and procedures, particularly around the specific readiness requirements for this vaccine. We begin by describing a set of high-level recommendations and end with a list of specific recommendations.

Major recommendations

Clearly articulate the roles and responsibilities of each stakeholder involved in carrying out or supporting the implementation of a new vaccine, and more generally, of immunization initiatives as they are planned.

A clearer articulation of roles and responsibilities of partners involved in the planning and implementation process may have substantially improved clarity and structure during critical staff transitions and as partners determined how to respond to the challenges in achieving readiness.

Ensure that policies and processes related to GAVI support are well articulated, communicated, and understood by in-country stakeholders.

Prior to the launch, stakeholders were not clearly aware of the requirements for programmatic readiness for the PCV10 vaccine. Broader articulation of these requirements and the processes to meet them would have facilitated greater understanding of and planning for programmatic readiness, and could have occurred through formal communication methods such as decision letters, as well as informal communication from GAVI Alliance partners. This would have allowed for integrating the readiness assessment with other activities, such as training and supervision, to more effectively bolster program performance.

Ensure that planning, timelines, and sequencing of activities takes into account national-level processes and structural changes upon which the introduction process depends.

The main underlying cause of the delay in training, and therefore of the prolonged delay in roll out of PCV to all districts in Uganda, was the simultaneous introduction of the IFMS to manage the financial disbursement of MoH activities. The lengthy process of implementing the new system, including manual entry of health worker account numbers for payment, coupled with the lack of pre-testing to ensure smooth operation, were all factors in this critical system conversion; this could have been foreseen and coordinated with the planning and timeline for PCV introduction activities. Similarly, the planning for introduction of new vaccines ought to consider the implications of organizational transitions, as happened with the critical transfer of responsibilities for vaccine management in this case.

Strengthen the relationship, communication, and coordination between partners in Uganda to ensure effective response to challenges as they arise in the introduction process.

The management feedback loop depicted in the theory of change did not adequately address challenges that arose during the introduction process. This has been especially true as Uganda has struggled to ensure programmatic readiness to introduce the vaccine nationwide. Turnover in key leadership staff exacerbated this problem, further highlighting the importance of strong relationships, communication, and coordination processes and structures to buttress partnerships during times of transition. Given the difficult history in Uganda and previous distrust among partners, rebuilding these relationships and trust should be a high priority. Clearer roles and responsibilities are an important structure around which trust can be nurtured as partners fulfill their roles. In addition, regular meetings should be carried out as

planned, and information regularly and systematically shared. These important communication and coordination structures must be used to identify challenges and make adjustments to plans so challenges are addressed in a timely manner.

Ensure standards for quality training of health workers are clearly identified and met prior to launch. Several breakdowns in the training process have contributed to the current state of affairs in the introduction of PCV. Aside from funding disbursement issues, the quality of training was identified as problematic, and a lack of essential knowledge for PCV10 administration was apparent from the WHO readiness assessment. We recommend a comprehensive effort to identify a core set of components and criteria for training that should be planned and met as countries prepare to introduce a vaccine. Essential elements include: hands-on practical components of training, formal evaluations of training sessions to ensure learning has occurred, monitoring to ensure all health workers responsible for vaccine handling and administration are trained, and proper timing so the training occurs immediately prior to launch to avoid loss of knowledge over time. Training should also include activities to ensure continued retention of knowledge through monitoring and supervision.

Specific recommendations

The following specific recommendations should be interpreted in light of the high-level recommendations already noted.

Recommendations for GAVI:

- Allow enough vaccine to be shipped to the country prior to launch so that training can include a practical component. This amount of vaccine should be made available regardless of any required verification of readiness. Adequate supervision of practical training would be necessary to ensure safe handling, and this could be included in training plans.
- Engage and collaborate with in-country stakeholders when developing process criteria, tools, and assessment methodologies to ensure buy-in and ownership of key milestones in the implementation process.
- Ensure that readiness criteria are met before a universal launch.
- Ensure that sufficient plans and funding are in place to support the monitoring and surveillance of new vaccines. In both the pentavalent and the PCV introductions, availability and use of up-to-date monitoring tools was an issue. Because these tools and activities are not essential for the actual launch, they tend not to be prioritized.

Recommendations for UNEPI:

- Plan flexibility into timelines and resources to allow for meeting urgent needs, such as responding to disease outbreaks with SIAs, without stalling the process for vaccine introduction.
- Launch and rollout vaccines immediately after training to avoid a loss of acquired knowledge and skills.
- Include a hands-on practical component using the actual vaccine in the training curriculum.

- Prepare and test key system components affecting introduction, such as financial management systems, prior to introduction.
- Continue to find ways to build relationships between partners at the lower levels of management so there is more trust between organizations and experience working and solving problems together.
- Monitor performance of the IFMS over time to ensure it fulfills its purpose of streamlining funding disbursement.

Recommendations for in-country partners:

- Coordinate the readiness assessment with training activities so both are completed just prior to launch. Programmatic readiness should continue to be monitored through post-launch supervision.
- Continue to find ways to build the relationships between partners at the lower levels of management so there is more institutionalized trust and experience working and solving problems together.

8 Zambia

This section describes the process by which Zambia managed and implemented the PCV10 introduction. Findings are presented by key milestones in the TOC. We assess (1) whether the in-country process mirrored the theory of change; (2) diversions, challenges, and their consequences; and (3) underlying causes of diversions and challenges. A summary of the overall process evaluation analysis is provided at the end of this section.

8.1 Current status of PCV launch and implementation

After five postponements, Zambia officially launched PCV on July 9, 2013. The causes and timing of postponements are discussed in subsequent sections of this report. In summary: first, a measles outbreak in the country necessitated an urgent measles campaign, and the launch was postponed until November. At that time, CHU recommended that PCV and measles second-dose (MSD) be launched simultaneously. PCV arrived in Zambia in October 2012, but the launch was postponed again because the GAVI vaccine introduction grant (VIG) had not been received. After two additional postponements, PCV and MSD were finally launched on July 9, 2013.

Informants described the launch ceremony as "colorful and well attended." The launch was intended to kick-off national roll-out. However, information collected later suggests that vaccines were actually administered in districts in nine provinces prior to the launch; this is discussed in greater detail below.

PCV10 is administered as part of routine immunization in all facilities. Data on the number of children receiving the vaccine are being collected by the health management information systems (HMIS) unit. At report writing, nationwide results were unavailable; Table 10 provides available data from selected districts. It is important to note that this data has not yet been checked and shows clear discrepancies. In Kitwe and Livingston, for example, more children received the second and third dose than the first. In the future, the GAVI FCE team will review data after the HMIS unit has confirmed them with districts.

So far, PCV vaccines in Zambia have been available without any disruptions or subnational stock outs. There is enough stock for the last quarter of 2013, and reportedly enough for distribution in the first quarter of 2014.

Table 10: Number of children who received pneumococcal vaccine (PCV) from selected districts in Zambia.

District	Time	PCV1 (6 weeks)	PCV2 (after 10 weeks)	PCV3 (after 14 weeks)
Copperbelt Province				
Kitwe	April-June 2013	80	670	640
	July-Sept 2013	4,083	3,288	2,027
Ndola	April-June 2013	0	0	0
	July-Sept 2013	1,481	3	4
Eastern Province				
Chipata	April-June 2013	0	0	0
	July-Sept 2013	4,055	2,000	831
Luapula Province				
Mansa	April-June 2013	0	0	0
	July-Sept 2013	197	13	0
Lusaka Province				
Lusaka	April-June 2013	33	34	5
	July-Sept 2013	9,891	7,891	3,128
Kafue	April-June 2013	21	0	0
	July-Sept 2013	1,047	569	303
Northern Province				
Kasama	April-June 2013	0	0	0
	July-Sept 2013	1,115	14	0
Southern Province				
Livingstone	April-June 2013	0	0	0
	July-Sept 2013	796	856	899
Western Province				
Mongu	April-June 2013	0	0	0
	July-Sept 2013	864	0	0

Source: HMIS data, MOH, 2013

8.2 Context

In September 2011, a new ruling party was elected in Zambia. This brought a number of structural changes to government institutions. One change was the creation of a new Ministry of Community Development, Mother and Child Health (MCDMCH), to increase focus on the provision of mother and child health (MCH) services. The new ministry merged the duties of the Ministry of Community Development and Social Welfare and of a department in the Ministry of Health (MOH) that was in

charge of maternal and child health services and primary health care in general. The change placed CHU and all primary health care facilities under the jurisdiction of the new ministry.

Capacity building for the new MCDMCH is ongoing. In 2011, planning, preparation and submission of the PCV request to GAVI took place under the MOH. For the fiscal year 2012, the government budget for PCV and MSD introduction was also under the MOH. Requests for government funds by CHU had to go to the Ministry of Finance through the MOH. Similarly, the funds for PCV went through the MOH and then to MCDMCH. All functions related to health policy, standards, disease surveillance, training, and related activities also remained in the MOH. A new HMIS unit for primary-level care has been set up in MCDMCH, but is not yet fully functional; MCDMCH still relies on the HMIS unit of the MOH for its data management.

In addition to support for PCV and MSD, Zambia was granted support from the GAVI Alliance to introduce a rotavirus vaccine. This occurred soon after PCV and MSD introduction in November 2013. The country is also likely to apply for a second phase of Health Systems Strengthening (HSS) support in 2014, and has received such support in the past.

8.3 Timely and adequate planning

8.3.1 Rationale for PCV introduction

Zambia has long battled high mortality rates among children. Under-five mortality rates are still above 100 deaths per 1,000 births. The decision to introduce pneumococcal vaccine was based on the desire to reduce national infant and child mortality, in line with the Millennium Development Goals and the Comprehensive Multi-Year Plan 2011–2015.

The government decided to introduce PCV in 2007. The proposal was presented to the Interagency Coordinating Committee (ICC) which, by consensus, agreed on introduction. An application for new vaccine support was submitted to GAVI in 2009. In 2010, Zambia received approval from GAVI, conditional on the scale-up of cold chain facilities. Preparations began for PCV and for two other new vaccines: MSD and rotavirus vaccine.

8.3.2 Planning for the introduction of PCV

Zambia intended to introduce PCV in April 2012. As noted, the launch was postponed several times for a variety of reasons. Before the first anticipated launch in April, a high-level workplan to guide introduction-related activities was developed. Once the launch had been postponed, however, the plan was not updated to reflect the new timelines. Our observations suggest that it was not referenced during planning meetings. The CHU tasked subcommittees with the development of workplans outlining key activities and timelines leading up to the launch; however, only the social mobilization and service delivery subcommittees developed a work plan and accompanying budget.

One important aspect of planning to introduce PCV in Zambia was the decision to launch PCV and MSD simultaneously. After the November 2012 postponement due to a measles outbreak in the country and

the urgent need for a measles campaign, CHU made the recommendation that PCV and MSD be launched simultaneously. The rationale for this recommendation was as follows: Measles vaccine is not a new vaccine thus the level of training required for health workers was relatively minimal. Furthermore, rotavirus and HPV vaccine introductions were also scheduled for the same year, and four separate launches was thought to be unmanageable. Finally, CHU management believed that introducing multiple vaccines simultaneously was both efficient and convenient because all of the work could be done at once. One informant noted:

"All these introductions have had a lot of challenges with uncertainty of funding both from GAVI and government and other partners. It helps to do these activities jointly rather than separately. The time invested in each process yields better benefits if the processes are combined given that we wanted to implement both PCV and MSD almost within the same year. The processes involved are also cumbersome, and I would choose to go through this once rather than twice."

8.4 Sufficient funding available in time

8.4.1 Overview

Most activities in preparation for the launch were funded by the GAVI VIG and government funds. Other donors provided funding for discrete activities; for example, GlaxoSmithKline (GSK) supported social mobilization and demand generation. A budget was developed for the introduction (see Table 11), and revised in March 2013 to account for an upward revision by government on civil servants' daily subsistence allowance (DSA) for attending training sessions. It is important to note that the budget does not include other activities related to the PCV and MSD launch, such as cold chain improvements, which were budgeted separately.

Transfer of funds, from GAVI and from the government, was characterized by delays and uncertainty. One informant indicated that even after the launch and roll-out, people did not know whether funding commitments made by various partners had actually been met. One key informant remarked that, for future launches, they will not set a date until they are certain all funds are in place. This change in practice was evident in the recent launch of the rotavirus vaccine: Until funds for the launch were received (in September 2013), stakeholders were extremely reluctant to commit to a launch date.

Table 11: Budget for Introduction of PCV and MSD, Zambia.

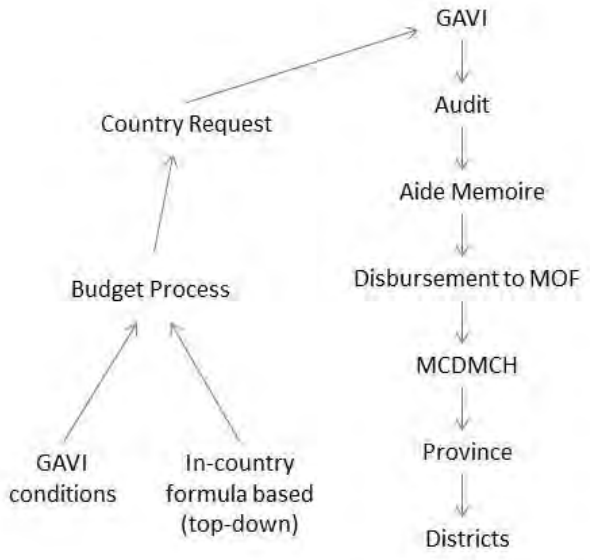
Budget for new vaccine introduction pneumococcal and measles second dose			
Item	**ZMK**	**USD**	**Source**
Service Delivery	**4,924,485,000**	**1,025,934**	
Central level meetings	12,945,000	2,697	GRZ
Training/orientation of health workers	480,510,000	100,106	GSK+MCDMCH
Training/orientation of health workers	853,030,000	177,715	GAVI
Community orientation	220,800,000	46,000	UNICEF
Printing of updated under five cards	530,371,200	110,494	GAVI
Printing of updated under five cards	1,919,628,800	399,923	GRZ
Printing of guidelines	300,000,000	62,500	GAVI
Stickers for vaccine refrigerators	25,000,000	5,208	GAVI
DVD development	50,000,000	10,417	GSK
Production of DVD training materials	31,200,000	6,500	GSK
Preparedness and implementation checklists	1,000,000	208	WHO
Updating of monitoring tools (HMIS)	500,000,000	104,167	GAVI
LOGISTICS	**437,323,800**	**91,109**	
Vehicles/transportation	29,952,000	6,240	GAVI
Distribution to provinces	4,818,000	1,004	GAVI
Distribution to health facilities	402,553,800	83,865	GAVI
Social mobilization	**1,461,407,624**	**304,460**	
Social mobilization at national level	701,407,624	146,127	GAVI
Social mobilization at district level	760,000,000	158,333	GAVI
Monitoring and evaluation	**1,190,167,941**	**247,952**	
District supervision	870,345,741	181,322	GAVI
District supervision	-	-	MOH
Central and provincial monitoring	105,195,000	21,916	WHO
Post-introduction evaluation	214,627,200	44,714	GAVI
UNICEF administrative cost (7% of additional GAVI Funds)	231,504,000	48,230	
Administrative cost (USD 689,000)	231,504,000	48,230	GAVI
GRAND TOTAL	**8,244,888,365**	**1,717,685**	

8.4.2 GAVI vaccine introduction grant

According to our global-level interviews, the flow of GAVI funds to countries (in this case, Zambia) would typically follow the process outlined in Figure 9. First, GAVI should conduct a financial audit of

MCDMCH. Second, upon successful audit, the government, specifically the Ministry of Finance (MOF), and GAVI should sign an aide memoire, or memorandum of understanding (MoU). Third, GAVI should disburse funds to the MCDMCH through the MOF.

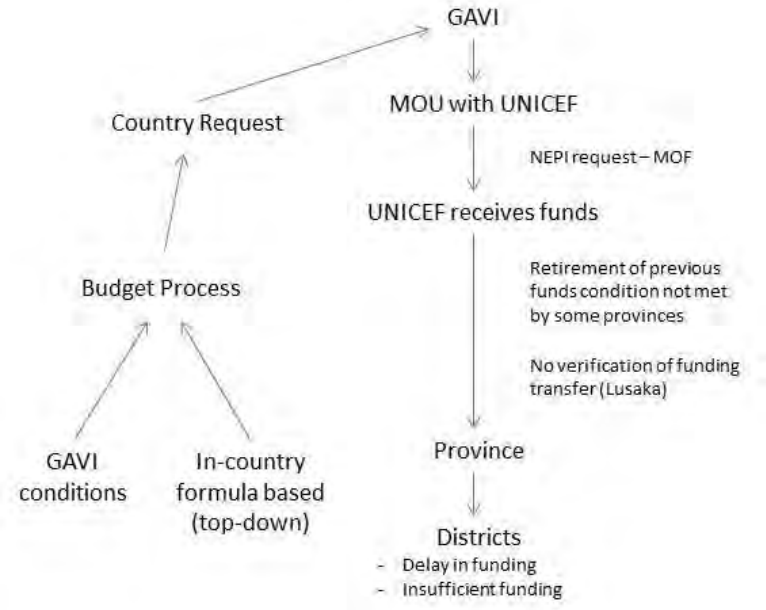
Figure 9: Ideal funding request and disbursement process to Zambia, based on the typical funding process as described by global-level key informants.



The actual flow of funding in Zambia did not follow the ideal process. In the case of PCV, MCDMCH anticipated that they would not qualify if GAVI were to conduct an audit as a condition of award. At that time, issues around the financial mismanagement of HSS funds in MOH were still unresolved. Instead, MCDMCH management followed another process (Figure 10).

MCDMCH designated UNICEF as the recipient and manager of funds, requiring UNICEF headquarters to sign a MoU with GAVI. The disbursement of funds from UNICEF required the government to submit requests to GAVI. GAVI would disburse funds to UNICEF as the principal recipient. UNICEF would then disburse the funds directly to provinces.

Figure 10: Actual (in-practice) funding request and disbursement process, Zambia.



Informants said that initially they were unsure of how much time GAVI required to process VIG requests; retrospectively, they estimated that the process took about six months. There were, however, funding delays due to various causes. These included GAVI's decision in 2012 to increase the amount of the VIG, requiring a new MOU between GAVI and UNICEF, a process that took several months. The funds finally arrived in country in December 2012, but there were further delays in the disbursement of the VIG to the subnational level.

For example, in April 2013, UNICEF unsuccessfully attempted to transfer funds to districts in seven provinces (Western, Southern, Eastern, Lusaka, Copperbelt, Northwestern, and Luapula). The transfer could not be completed to some districts because they had unretired funds for activities previously supported by UNICEF (these included funds for other program areas under the CHU and not just immunization), and the UNICEF system would not allow transfer of any funds to districts with unretired funds. Prior to the VIG disbursement, UNICEF corresponded with CHU regarding the issue of unretired funds, with CHU in turn communicating to the relevant districts and provinces. This was not resolved prior to the GAVI VIG transfer, leading to a delay. A further delay was caused when money for Lusaka province was transferred to the wrong account. These disbursement delays contributed to postponement of the launch date until July 9.

8.4.3 Transfer of government funds to MCDMCH

The ministry realignments, combined with delays, also tangled the release of funds. Because the PCV introduction had originally been scheduled for 2012 (when CHU was still part of the MOH), MOF had earmarked government funds for the introduction for MOH. By late 2012, however, the CHU had been

moved to MCDMCH. Key informants acknowledged that obtaining the remaining funds was a slow process: first, funds were transferred from MOF to MOH (January 28, 2013), and then from MOH to MCDMCH (February 18). This should not be an issue for subsequent launches, as the budget for immunization now resides within MCDMCH.

8.4.4 Distribution of funds to the subnational level

According to interviews, funds are distributed from national to subnational groups through a "top-down" process. Districts wait for national leaders to disburse the funds in line with the plan and budget for the year. Because districts are not included in planning for the launch of new vaccines, they do not actively follow up on the timing of disbursements.

The PCV preparation and launch encountered a number of challenges related to this national/district relationship. In particular, communication about disbursements between the two levels was poor; provinces and districts were unaware that funds were in accounts; and the purpose of the funds was not clear. For example, the grant for monitoring was sent to provinces without accompanying documentation, resulting in delays in these activities.

8.5 Adequately skilled health workers available

Rollout of PCV10 training followed a cascade model, moving from a national level training-of-trainers (ToT) for key representatives from provinces and districts, to training for frontline workers in districts and health facilities.

The national ToT was conducted in Kabwe district between March 25 and April 6, 2013. The training included cold chain officers and MCH coordinators from each of the provinces and districts in the country. Training was divided into three groups: the first from Northern, Muchinga, Central, and Lusaka provinces (March 25–26); the second from Copperbelt, Luapula, and Northwestern provinces (March 27–28); and the third from Southern, Western, and Eastern provinces (April 5–6). The training included sessions on how to handle vaccines, vaccine storage, and age criteria. A manual and video communicated key messages. The manual also included frequently asked questions, adverse events following immunization (AEFI) forms, supervisory visit checklists, and HMIS forms. CHU staff, provincial medical officers, and cold chain officers facilitated trainings.

Afterwards, staff who had attended the ToT facilitated at district level training for both health staff and community health workers. District-level training started around April 17–19, except in Lusaka, where training was conducted on June 19–20, 2013. Initially, trainings were delayed by a lack of funding, largely a result of the complexities discussed above. Because of the revised DSA rates it was necessary to request unspent funds from 2012, but those funds needed to be sent through the MOH, which was a prolonged process. As a result, stop-gap funds were requested from GSK.

A number of informants also raised concerns about the arrangements and coordination of training at the district level. For example, in one district, the cold chain officer who was designated to attend the training had gone on leave. As a result, a representative attended the training in the officer's absence.

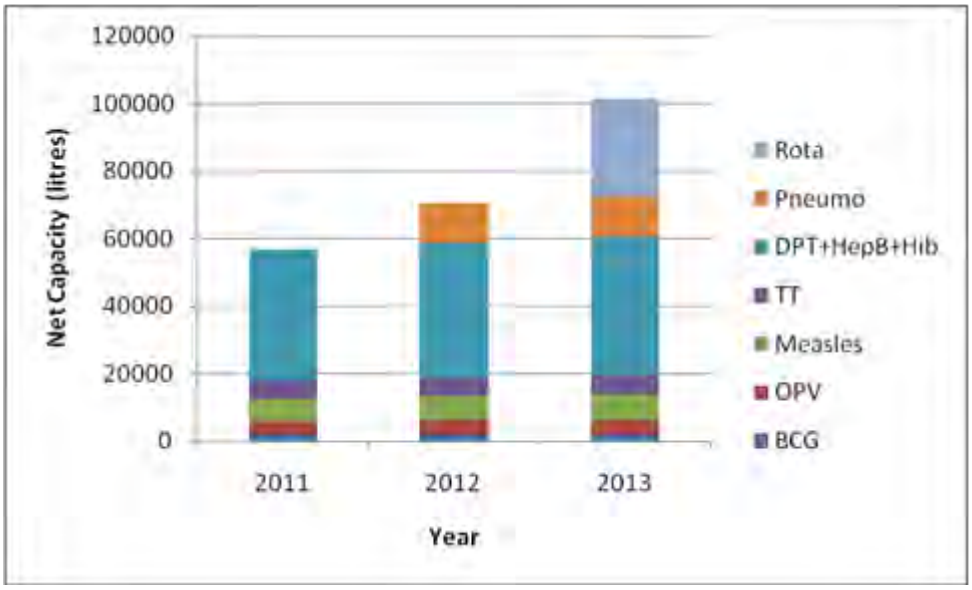
The cold chain officer then returned and took over from the delegate without a proper handover between the two. The officer, with no orientation, collected the vaccines for the district and ended up freezing them.

This problem was identified by district level managers who reported to the relevant authorities. The district was supplied with new vaccines. There were no reports of the frozen vaccines being administered. At writing, we are not able to fully assess the quality of training that was conducted. This will be an important area of follow up for the GAVI FCE.

8.6 Cold chain logistics system improved

As noted, Zambia's application to GAVI for support to introduce new vaccines, including PCV, was approved on the condition that the country expand its cold chain capacity. Figure 11 shows estimates of the required increase in cold chain capacity storage requirements based on increased vaccine volumes from the introduction of pneumococcal, MSD and rotavirus vaccines. It also shows cold chain capacity requirements at national and other levels of the Zambian health system.

Figure 11: Increased cold chain capacity required for new vaccines in Zambia, 2011–2013.



Source: Zambia Cold Chain Scale up Strategy[11]

The estimates of cold chain capacity requirements are based on projections obtained using the WHO cold chain forecasting tool. To scale-up the cold chain in preparation for the new vaccines, the national vaccine store was first prioritized and strengthened, followed by the provincial and district-level vaccine stores, and finally the systems at the health facility level. Resources for this work were mobilized through the ICC. To meet requirements, the Zambian government introduced a specific budget line for the cold chain in the national budget. From this budget line and with assistance from cooperating partners, the government installed five additional 40m^3 cold rooms at the national level, and five 30m^3

cold rooms at the provincial level. This allowed Zambia to meet the GAVI condition for cold chain expansion.

Table 12: Net cold chain capacity requirements at national, provincial, district, and health facility levels, Zambia.

Level	Current net capacity (liters)		Additional net capacity required (liters)	
	Positive (+2 to +8°C)	Negative (-25 to -15°C)	Positive (+2 to +8°C)	Negative (-25 to -15°C)
National	10,000	11,024	41,447	N/A
Provincial	7,776	9,504	20,244	N/A
District	19,008	8,508	18,305	N/A
Health facility	33,600	N/A	16,800	N/A

Source: Zambia Cold Chain Scale up Strategy

One informant cited these cold chain improvements as an area of success; however, another worried that there could be future challenges in maintaining the expanded cold chain. Failure of some appropriate cold chain personnel to attend PCV training, as discussed above, does suggest a vulnerability to the maintenance of the cold chain and oversight vaccine storage at the subnational level. A more detailed assessment of the cold chain is an important area of follow-up for the GAVI FCE through the health facility survey.

8.7 PCV10 readiness confirmed

Because PCV10 has special safety and storage considerations, GAVI requires that countries' readiness to introduce PCV10 is confirmed in advance of vaccine shipment to country. In order to be ready, countries must demonstrate that: (1) training materials are in immunization centers prior to the launch of the vaccine; and (2) stickers are on refrigerators at all levels, indicating that opened vials of vaccine must be discarded six hours after opening. Our observations indicate that PCV10 was shipped to Zambia before these two specific readiness requirements had been met. KIs indicate that the reason for this was to secure PCV supply due to limited global availability of PCV. The requirement for shipment of the supply to Zambia was agreement that vaccines would not be distributed sub-nationally until programmatic readiness was met. Upon receipt of PCV in October 2012, CHU kept custody of the vaccine in the central store until April 23, 2013.

8.8 Sufficient volume of quality vaccines available

PCV arrived in Zambia in October 2012, in advance of the second scheduled launch in November 2012. Vaccines are kept in the national store and move to the provincial stores on a quarterly "push" basis. The provincial health office then sends the vaccines to the districts on a monthly "pull" basis, based on consumption needs. District vaccine data is compiled by the district EPI/cold chain technician or the district MCH coordinator. Districts send this information to the provinces, who feed it back to the National Directorate of Planning within MCDMCH.

As of late October, there were no reports of stock-outs in Zambia. According to one informant in Zambia, GAVI had indicated wanting to postpone the next shipment of vaccine from December 2013 to around March 2014. The informant suspected this was related to efforts to manage a global shortage of PCV10, but cautioned that the delayed shipment could lead to a national shortage and stock-outs in Zambia. This is a key area of follow-up for the GAVI FCE for the future.

8.9 Updated monitoring tools available

Monitoring tools, including updated under-five cards and vaccine registers, were created in advance of the launch. In planning meetings, however, members reported insufficient stocks of the updated tools. As a result, many facilities were reported to be using old registers without space for the new vaccines. According to one informant, *"The only way they are capturing the information is using the tally sheets. What I observed is that people are not improvising to go around the shortcoming in the old registers."* The shortage was partly due to the failure by MoH to provide adequate supplies of the revised tools; MoH retained the mandate for revision of tools after the ministerial realignment. Additionally, there were some women from previous years who did not have cards, and these women were not included in calculations for the number of cards to produce. There was also concern about the quality of the new under-five cards, which reportedly tore easily.

In addition, some informants said that inadequate supply of the cards has led to reports that cards are being sold privately. In response, CHU has requested a "not for sale" label on all cards. Details of these reports are not yet known and will be followed up as part of the FCE.

8.10 Adequate demand for PCV10 generated

A social mobilization subcommittee was responsible for the following:

- Preparing a budget for social mobilization and demand-generation activities for PCV
- Agreeing on key messages and required materials
- Overseeing the printing and distribution of those materials
- Orienting partners and the media
- Planning for the launch ceremony

The subcommittee planned to hold the media orientation first, and then begin the radio, television, and newspaper social mobilization campaign at least one or two weeks prior to the launch date. They planned to inform health workers about social mobilization plans and messages during their training on PCV administration.

Although many informants highlighted social mobilization as an area of great success for PCV, in practice the committee's activities had to be continually rescheduled as the national launch date was postponed. The team also overcame several additional challenges, outlined below.

Radio and television spots were filmed by February 2013 for review by the social mobilization committee. However, the committee was concerned that because the PCV and MSD spots used the same voice, the public might not be able to differentiate between the two vaccines. This concern, and the cost implications of changing the spot, was presented to the Child Health Technical Working Group, who ultimately decided that the spots should be separated.

By March 2013, the information, education, and communication (IEC) materials for the PCV launch had been printed and delivered to districts, including posters, brochures, and launch materials (e.g., banners). Although there was only enough budget to print 20 brochures for each district, the Church of Latter Day Saints offered to print and distribute 100,000 additional brochures.

The primary bottleneck in the implementation of social mobilization and demand-generation activities was problems with the transfer of funds from UNICEF to districts with unretired funds, described above, and the erroneous transfer of funds. Because these problems were not immediately recognized, they contributed to a delay in the implementation of some activities, and ultimately, postponed launches. There were also challenges in the distribution of IEC materials. During district visits, evaluation team members observed that some facilities did not have PCV posters. The full extent of such shortages is unknown and will be further examined through health facility surveys.

In addition, the same subcommittee was responsible for managing both PCV and HPV demand generation. Partly because of this, the team also observed that when the April 23 PCV launch date was postponed, social mobilization for HPV (launched in May, 2013) was given significantly more time and attention.

Despite these challenges, one key informant applauded the campaign messages for their ability to *"convey the message to the people."* Another informant noted that, unlike the HPV vaccine, PCV did not encounter resistance from the public. This may be attributable, in part, to the success of social mobilization and sensitization activities. However, it is worth noting that the vaccine and target populations are very different for PCV and HPV.

Finally, the bulk of effort and resources for social mobilization were for activities immediately surrounding the national launch. One informant recommended that in the future, ongoing resources be put toward social mobilization to sustain demand for PCV:

> *"Social mobilization is so important that it should not be done as a once-off activity but rather a regular program using different types of media to help keep the momentum. That way, our activities will not look like campaigns but ongoing/routine activities. Continuous social mobilization is important because if people are informed about a service, they will demand for that service."*

8.11 Successful launch of PCV10

According to stakeholders, the ceremonial launch of PCV on July 9, 2013, was itself a successful event. Equally, informants felt that the simultaneous launch of PCV and MSD represented a more efficient use of time and resources than launching the two vaccines separately, and noted this strategy would be considered for future launches. Indeed, preparatory activities for the two vaccines were almost entirely integrated (the only exception being the radio and television spots), and the evaluation team did not identify any notable challenges resulting from this approach.

Postponements, however, hindered the process of introducing PCV in Zambia. A total of six launch dates were set, from April 2012 to the eventual ceremonial launch (and subsequent national scale-up) on July 9, 2013. Table 13 outlines the primary reasons for the postponed launches.

Table 13: Pneumococcal vaccine launch dates and postponements, Zambia.

Date	Primary reason for postponement
April 2012	Outbreak of measles required urgent measles vaccination campaign.
November 19, 2012	Delay in receiving necessary vaccine introduction grant from GAVI: result of delay in memorandum of understanding between GAVI and UNICEF New York.
March 25, 2013	Funding shortage: conditions of service for health workers modified, resulting in a significant increase in Daily Sustenance Allowance.
April 23, 2013	UNICEF funds transfer system did not allow funds to be transferred to provinces due to unretired funding. Delay in the transfer of funds from UNICEF to Lusaka Provincial Health Office: funds were erroneously transferred from UNICEF to an account at University Teaching Hospital.
July 8, 2013	Minister for Ministry of Community Development, Mother and Child Health was unavailable to officiate the launch.
July 9, 2013	PCV launched.

The postponements did, however, have consequences for the national roll-out. First, some districts launched PCV before the national launch due to a lack of communication between national and subnational levels. These included districts in Luapula, Northern, Muchinga, eastern, Central, Western, North-Western, Southern, and Copperbelt provinces, although the full number of districts has not yet been determined.

In addition, some health care workers felt that delays eroded their credibility and sparked distrust in the population. Social mobilization messages had been rolled out at the subnational level in April (long before the launch finally occurred), and demand for the new vaccines was high. Health facilities in some districts reported that caregivers visited health facilities and requested PCV before the launch, and so had to be turned away. District- and facility-level staff felt that their credibility, and that of the immunization program, was under threat, and that there was risk of low uptake if they delayed any further. According to one informant:

> *"Women would come to clinics asking for PCV vaccinations. We reached a point where we ran out of excuses as the uncertainty [about launch date] went on. We started receiving informal reports that people were saying that we were lying about this new vaccine, that someone had sold the vaccines out of the country, to Zimbabwe. In the meantime, the only instruction we got from MCDMCH was to continue with sensitization and mobilization until the launch date was to be confirmed. But these activities cost us money, which we didn't have. In the end we were getting more worried that the misinformation would affect the core message we had delivered. So the biggest threat was that our campaign was going to lose credibility and momentum."*

Furthermore, one informant suggested that the postponements contributed to declining confidence in the government's ability to manage vaccine introductions, and the required planning and communication among stakeholders.

Supervisory visits were not conducted following PCV launch, but postponed until after the launch of rotavirus vaccine. There was some disagreement among informants about the reason for the wait. Some KIs thought supervision had not been budgeted for; another explanation provided was that funds were sent to provinces for supervision, but there was a miscommunication and provincial officers were initially unaware of the funds. By the time this was realized, preparations were already heavily underway for rotavirus introduction. Other KIs simply attributed it to multiple delays in the launch and roll-out which resulted in conflict with the preparatory activities for rotavirus. Still others saw it as the result of a strategic decision to combine the visits with supervision for the rotavirus vaccine. Either way, many expressed concerns about the wisdom of introducing rotavirus vaccine without having conducted any supervisory visits for PCV.

To date, there have been no reports of AEFIs in any districts. Health facilities are required to use a specific form to report AEFIs. Based on data collected to date, however, the forms are not readily available. Even when they are available, there are reports that health workers do not fill them out. Some stakeholders were concerned that this indicated weakness in the reporting system. Others suggested that it was actually the result of effective social mobilization efforts: because caregivers were more aware of potential adverse reactions to PCV, they were less likely to report mild AEFIs, such as fever. Because monitoring and supervision have not yet been conducted, it is difficult to draw any conclusions about why AEFIs have not been reported. We will continue to monitor this situation through the FCE

process evaluation. One informant suggested that supervisory visits will begin in January 2014. At writing, PIE is tentatively scheduled for the first quarter of 2014.

8.12 Roles and responsibilities of key stakeholders

Planning for PCV and MSD introduction was the responsibility of several technical working groups and related committees. These roles and responsibilities are outlined in Table 14 below.

Table 14: Immunization planning and coordination architecture, Zambia.

Stakeholder group	How does the group affect the PCV launch?	Member organizations
Interagency Coordinating Committee (ICC)	Makes policy decisions to apply for new vaccines	MCDMCH, WHO, UNICEF, CIDA, UNZA, CIDRZ, UNFPA, ZISSP, USAID, DFID, PATH, CHAI, MOH, UTH, Malaria Consortium, HPCZ, UNFC, CARE, World Vision Zambia, CDC, SAFAIDS, MEDMCH, HIP MAMAZ, MCHIP, CSH, GSK
Child health technical working group (CHTWG)	Advises on the development of policy and coordinates the implementation of child health related issues	MCDMCH, ZISSP, UNICEF, UNZA, CIDRZ, WHO, PATH, Lusaka School of Nursing, World Vision Zambia
Expanded Program on Immunization technical working group (EPITWG)	Sub-group of CHTWG focusing on immunization-related issues	MCDMCH, UNICEF, WHO, Lions Club, Church of Latter Day Saints
Social Mobilization subcommittee	Develop a strategy to create demand through production of information, education, and communication (IEC) training materials for health workers	MCDMCH, CIDRZ, WHO, UNICEF, ZISSP, CSH, NPNC, GSK, UTH
Logistics subcommittee	Procure the vaccines, organize transport to deliver vaccines, and manage the cold chain	MCDMCH, WHO, UNICEF, CIDRZ
Monitoring & Evaluation subcommittee	Develop plan for monitoring and supervisory support	MCDMCH, WHO, ZISSP, CIDRZ
Service Delivery subcommittee	Train health workers and facilitate the roll-out exercise at the district level	MCDMCH, WHO, UNICEF, CIDRZ

Within these structures, each organization played a specific role in supporting the CHU to prepare for vaccine launch. UNICEF provided support for procurement of vaccines; forecasting PCV needs; assisting with budgeting, social mobilization, and training of health workers; and managing the vaccine introduction grant from GAVI. WHO provided technical and financial support in the cold chain assessment, cold chain installation, and the training of technicians; it also conducted ongoing surveillance on vaccine preventable disease. The Center for Infectious Disease Research, Zambia (CIDRZ) played a role in supporting the implementation of social mobilization activities; CIDRZ also played a substantial role in the roll-out of rotavirus vaccine in late 2013.

8.12.1 Challenges

Overall, informants felt that multiple coordination mechanisms and regular meetings strengthened preparation and implementation for PCV and MSD. However, a few expressed frustration that some partners wielded more influence than others. They noted that the process for including partners was not transparent. As a result, areas of in-country expertise—particularly academic insight—went untapped. Coordination mechanisms at the national level are also not replicated at the subnational level, where they could improve management and coordination and support better national/subnational communication.

8.12.2 Accountability

Some informants also indicated that country-level partnerships would benefit from strengthened accountability. For instance, because the CHU lacks any enforcement power to sanction external partners, there is little the unit can do if partner institutions fail to achieve a deliverable. In addition, CHU and MCDMCH have to balance the (sometimes competing) agendas of different partners. Informants noted that this compromised preparations for the launch of PCV, because some partners were more interested in the HPV demonstration project, and others were focused on rotavirus introduction. As a result, some partners were selective about which coordination meetings they attended, making participation less consistent and predictable than desired.

8.13 Analysis of findings

In interviews, many key informants cited the national launch and rollout as a success, though in our broader assessment which included participant observation and other data collection mechanisms, we noted several challenges. Clearly, the process leading up to the launch was characterized by postponements and repeated delays, resulting in uncertainty and frustration among stakeholders.

8.13.1 Cause of delays

Our analysis points to several key factors that contributed to delays. These range from issues affecting the Zambian health system as a whole to concerns relating specifically to the PCV10 implementation process.

Ministerial realignment

Preparations for the launch of PCV10 occurred in the midst of a ministerial realignment. The Maternal and Child Health units initially under MoH were realigned to the now Ministry of Community Development, Mother and Child Health. This resulted in the transfer of immunization authority from MoH to MCDMCH. Some informants expressed optimism that this shift will ultimately benefit child health, which has in the past received relatively little attention within MOH. They were also worried, however, that this new arrangement may, in the short term, affect the implementation of a program as large as EPI. One key informant from a partner organization stated that some challenges during the introduction of PCV were the result of the CHU learning to do things for the first time under the MCDMCH.

Other delays attributable to the realignment include the lag in funding to cover the higher DSA rates for training participants which was not budgeted for in the budgeting cycle as at that time this was not yet in effect. Informants also indicated that because of the realignment CHU had to deal with new administrative departments within MCDMCH.

Competing priorities

Other challenges, such as competing priorities and multiple vaccine introductions during a short period of time, were more specific to immunization systems. During 2013, CHU and partners prepared for the simultaneous launch and roll-out of PCV10 and MSD, an HPV vaccine demonstration project in Lusaka province, and the national launch and roll-out of rotavirus vaccine (then scheduled for the last two quarters of 2013). The HPV demonstration project was a significant competing priority, as its timeline overlapped with preparations for PCV10 and MSD. In April and May we observed, and informants reported, planning meetings at which PCV roll-out was not discussed at all because participants ran out of time after long discussions on preparations for the HPV demonstration project. Introduction of HPV vaccine may have also been prioritized over PCV and MSD for two reasons: firstly, because the HPV demonstration project was contingent on the school calendar, and secondly because it was being championed by the First Lady of Zambia. PCV and MSD lacked a similarly high-profile champion.

Some informants said that they were not concerned about the rotavirus launch because CIDRZ was leading the process. Despite this optimism, one informant lamented that they were not even able to begin preparatory activities for the rotavirus launch because of PCV/MSD delays.

The recommendation for conducting a post-introduction evaluation (PIE) is within 12 months post-launch. Because the PCV/MSD and rotavirus launches occurred so close together, however, there was no PIE conducted of the PCV/MSD prior to the rotavirus launch. As a result, lessons from the PCV introduction were not systematically collected or incorporated into plans for the rotavirus vaccine launch.

In the future, simultaneous introduction may be a successful model for introducing multiple vaccines. According to our interviews and observation, the simultaneous launch of PCV and MSD resulted in a

more efficient use of time and resources. As noted, the majority of preparatory activities were integrated, and no reports emerged of any confusion stemming from introducing the two new vaccines at the same time. Informants were unequivocal in stating that this is an approach they would consider, and even prefer, for subsequent introductions. This said, careful consideration should be given for joint launches as synergies between PCV and MSD may also vary from those of other vaccine combinations.

Overall, it is clear that the number of major immunization milestones occurring in such close succession, and the significant overlap in planning processes, was a monumental challenge for program managers and partners in Zambia.

EPI program capacity

EPI resides within the CHU in MCDMCH. Only five staff were dedicated exclusively to immunization during the time of the PCV launch. In late 2013, a key position of logistician which had been vacant for a long time was finally filled. The EPI manager is the head of CHU as a whole, and his or her portfolio is not limited to immunization. As a result, the manager and other CHU members are frequently called away to represent CHU in other forums, even in the midst of critical EPI-related activities such as the launch of a new vaccine. In their absence, there was no effective alternate decision-making authority. As a result, decisions with major programmatic implications, such as whether to delay a launch date or not, were not reached.

Planning, Communication and Coordination

A number of challenges in the PCV10 planning process also contributed to delays. Although an introduction plan was developed as part of the GAVI application dossier, the work plan was never updated. Furthermore, program managers did not have a realistic understanding of how long it would take GAVI to release the VIG. That process took about six months, but because the timeframe was not well understood in Zambia, it was not factored into the planning process.

This confusion has persisted. For example, despite the government's and partners' experience with the PCV VIG (and the knowledge that it took six months to obtain the VIG), uncertainty remained as they prepared for the introduction of rotavirus vaccine. Even though they planned to launch in early October, CHU was not aware of the need to submit a request for VIG until August. CHU assumed that since the VIG was part of overall application approved by GAVI, the VIG would be transferred without need for a specific budget request. Hence, the request was only made at the end of August. (The VIG for rotavirus vaccine arrived in late September 2013; the vaccine was not launched until late November.)

Communication also posed challenges. Postponement of activities, and eventually launches, was not always communicated well among stakeholders. As noted above, this was perhaps most apparent during the period leading up to the April 23, 2013 launch date. One of the most widely identified reasons for the delay in that launch was challenges in transferring funds for social mobilization and training to the districts. As discussed earlier, because a number of districts had unretired funds from previous UNICEF-funded activities, UNICEF's financial system was unable to effect the transfer. Although

both CHU and UNICEF had sent several reminders to concerned districts to retire the funds, some districts did not comply. CHU had assumed at the time of application that the concerned districts had retired the funds, when in reality they had not. This issue was compounded by the organization issues noted above. One meeting to determine a revised launch date could not happen because key CHU staff were away and no other staff were available to coordinate.

8.13.2 Comparison between pentavalent and PCV vaccine introduction

A retrospective look at the introduction of the pentavalent vaccine in Zambia provides useful perspective on the PCV launch. Pentavalent vaccine was introduced in 2005 in a liquid-lyophilized form and later in 2007 as a fully-liquid form. Comparing lessons from the pentavalent and PCV introductions, organized by the steps in the theory of change (Table 15), clarifies that despite clear improvements, some systemic weaknesses remain.

Expansions to the cold chain, particularly at the central level, reflect a clear and arguably successful response to recommendations from the pentavalent PIE. Progress on systemic issues has been more uneven. For instance, in both introductions, the quality of health worker training was said to be compromised by a lack of funds. For the PCV launch, this was partly attributable to the increase in DSA rates. However, both introductions show a lack of contingency funding for such issues. Similarly, weaknesses in AEFI reporting appear to persist.

Notably, some challenges for the pentavalent vaccine have not emerged for PCV. However, the pentavalent PIE was conducted two years after launch, while PCV was launched less than six months ago. Although the pentavalent PIE raised concerns about the quality of supervisory visits and supervisors' ability to identify issues, for example, PCV supervision is yet to be implemented.

Table 15: Comparison of lessons learned during pentavalent vaccine and PCV10 introduction in Zambia.

Work domain	Introduction of pentavalent vaccine	Introduction of PCV10	Comparative analysis
Timely and adequate planning	• The Child Health Technical working group, with guidance from the ICC, developed a detailed national plan for the launch. • District-specific plans with concrete activities and timelines for implementation were not evident at the lower levels.	• PCV master implementation work plan was developed in advance of the April 2012 launch date, but was not updated once the launch had been postponed to reflect the new timeline. • A national budget was developed, but required later revisions due to an increase in the Daily Sustenance Allowance for health workers. • Each subcommittee was to develop a work plan and budget, but only the social mobilization subcommittee did. • The launch date was pushed back several times due to various reasons.	• National work plans were developed in advance of both launches, but in the case of PCV the national plan was not updated, and detailed work plans were not developed at lower levels (districts, subcommittees).

Work domain	Introduction of pentavalent vaccine	Introduction of PCV10	Comparative analysis
Sufficient funding available in time	• Training and pentavalent vaccine introduction were funded from GAVI ISS funds. • Zambia met its commitment for co-financing pentavalent vaccine. The only factor cited in the 2007 APR that slowed and/or hindered mobilization of resources for co-financing was delayed release of funds from the treasury. • Financing for cold-chain expansion was a challenge according to the 2008 APR due to the high cost.	• The funds from GAVI were not adequate after per diem rates increased, so a request for additional funds from MoH was made. Funds from the 2012 CHU budget were transferred from the MoF to MoH to MCDMCH, but this process took time and resulted in a delayed launch. • Other partners (e.g. GSK, CIDA, CIDRZ, government) provided funding for discrete activities, such as cold-chain expansion and training. • VIG process not clearly understood which resulted in routing of GAVI funds through UNICEF. • UNICEF funds transfer system did not allow the transfer of funds to provinces (for onward transfer to districts) for which the system reflected unretired funding. • District-level training funds were inadequate to conduct the required level and quality of training.	• The pentavalent PIE noted that future vaccine introductions should be co-financed from the outset and the MOH should ensure that resources are mobilized well in advance of the launch to ensure sustainability. However, there were many delays in obtaining the VIG funds for PCV and disbursing funds to the subnational level; consequently, in many cases resources were not mobilized well in advance of the PCV launch.
Adequately skilled health workers available	• Training for the liquid pentavalent vaccine was done before the launch at all levels by cascade • Not all relevant staff members of the health facilities received training. • Training manuals were not available at sites. • Health workers at 6 (24%) sampled facilities did not know all 5 antigens that comprise the pentavalent vaccine. Health workers at 9 (37%) facilities did not know which diseases the Hib vaccine prevents. There was poor knowledge among facility staff regarding Vaccine Vial Monitor stages.	• Cascaded training was implemented with trainings at the national level (ToT) and district level. • District-level training funds were inadequate to conduct the required level and quality of training. • Stakeholders have raised concerns about administrative arrangements at the district level for staff to be trained and reports of the freezing of vaccines suggest that in some cases the appropriate individuals were not trained.	• Cascaded training was used in both launches. • Lack of knowledge among HCWs pointed to issues with the quality of training in the pentavalent launch; a key recommendation of the pentavalent PIE was to improve the quality of training. • There were reports following both introductions that the relevant health workers had not been trained.

Work domain	Introduction of pentavalent vaccine	Introduction of PCV10	Comparative analysis
Cold chain and logistics system improved	• Insufficient cold-chain capacity at central level – some limited capacity for cold chain and dry storage at province and district levels. • No standard protocol to address how often to monitor temperatures during power failures; some provinces and districts not recording temperatures on weekends. • No freeze-watch monitors • Stock registers are not generally well maintained • Several issues around waste management protocols and standards reported.	• Zambia met the GAVI condition for cold-chain expansion: cold-chain storage capacity was expanded at the national level and in 5 of the 10 provinces. • A case of frozen vaccines found in one district due poor handover between the trained staff and the designated cold chain officer. This was attributed to weak administrative arrangements at the district level.	• A key recommendation of the pentavalent PIE was to increase the cold storage capacity at the central store; this was done in time for PCV. • Although the cold-chain equipment was improved, there were issues with procedures related to cold-chain logistics in both launches. Strengthening vaccine and cold-chain management practices was another key recommendation from the pentavalent PIE that appears to not have been comprehensively addressed for PCV, since there were still issues with cold-chain training.
PCV10 readiness confirmed	• Not applicable	• Interviews and observation indicate that PCV10 arrived in country before the training was implemented. CHU did not disburse PCV10 to the lower levels until after the training and the distribution of refrigerator stickers.	• Readiness was not applicable for pentavalent and although PCV was shipped to the country prior to the confirmation of readiness, the vaccine was not distributed subnationally.
Sufficient volume of quality vaccines available	• Health facilities did not report any interruption of immunization services as there was no gap between arrival of the liquid pentavalent vaccine and phasing out of excess lyophilized pentavalent vaccine. • Stock-outs were rare at all central and health facility levels, but there were occasional stock-outs at the district level due to poor forecasting. • No expired vaccine at the central level; some provinces and health facilities had expired vaccines. • No standardized method for forecasting vaccine needs; many vaccine requests from health facilities are not based on data or need.	• Vaccines arrived in country before the official (revised) launch date • PCV was distributed to districts after trainings had been conducted • No reports of stock-outs at the subnational level	• Occasional stock-outs at the district level for pentavalent; so far there have been no reports of stock-outs for PCV. • Adequate supply of vaccines was available for both launches.

Work domain	Introduction of pentavalent vaccine	Introduction of PCV10	Comparative analysis
Updated monitoring tools available	• All health workers completed tally sheets and monthly summary sheets, but there was not a consistent use of standard immunization charts and data were not readily available. • AEFI procedures were in place and facilities had copies of AEFI reporting forms and guidelines, but health workers were not aware of what AEFIs to expect and report. • At the time of the PIE, no AEFIs had been reported at any level.	• Inadequate supply of monitoring tools at facilities • So far no AEFIs reported. There are reports that facilities do not have the correct forms; when forms are present, they are not always filled out correctly.	• A key recommendation of the Pentavalent PIE was to assess and strengthen the AEFI monitoring system prior to the introduction of new vaccines. This recommendation does not appear to have been adequately addressed for PCV since concerns have been raised about the quality of AEFI monitoring. • Following both launches, no AEFIs were reported. This may reflect a lack of understanding of what AEFIs to report or how to fill out the AEFI forms correctly.
Adequate demand generated	• Used a variety of communication tools including radio, newspaper, posters, daily health talks at health facilities and outreach sites, and community-based social mobilization activities. • High profile launches at the national and district levels. • Pentavalent vaccine was well accepted by the community. • Adequate health education messages provided to community about pentavalent vaccine. • Excellent acceptance of vaccine by community and health care workers.	• Used a variety of social mobilization techniques, including printed materials, radio and television spots, and advocacy meetings. • "Colorful and well-attended" national launch ceremony. • Inadequate supply of brochures; partners had to step in and print more. • Some challenges in distributing materials to districts. • Continual rescheduling of social mobilization activities to coincide with the delayed funds and launch dates.	• Generally an area of strength for both launches. Both launches relied on a variety of communication tools and held high profile national launches to generate demand.
Successful launch	• The PIE reported a smooth transition between the liquid pentavalent vaccine and phasing out of excess lyophilized pentavalent vaccine with no interruption of immunization services. • Facilities received frequent supervisory visits, but the visits did not identify and	• The process of introducing PCV was fraught with postponements; a total of 6 launch dates set. • Vaccine administration began in some districts prior to official launch date of July 09, 2013. • No post-launch supervision visits have	• Issues were identified with the quality of supervision visits after the launch of pentavalent vaccine. Despite numerous recommendations in the PIE for increased quality of supervision visits, supervision visits have not yet occurred for PCV. • A PIE should be conducted 6-12 months

Work domain	Introduction of pentavalent vaccine	Introduction of PCV10	Comparative analysis
	correct many obvious problems regarding coverage, vaccine management, and cold chain. • The post-introduction evaluation (PIE) was conducted 2+ years after the launch.	occurred. They were postponed until after the launch of rotavirus vaccine. • The PIE has not occurred	after vaccine introduction, according to WHO PIE guidelines[5]. The pentavalent PIE was conducted late, and a PIE for PCV, MSD, and rotavirus is tentatively scheduled for the first quarter of 2014.

[5] See: http://whqlibdoc.who.int/hq/2010/WHO_IVB_10.03_eng.pdf

8.14 Limitations

There are several limitations to the findings in this report. First, the report is based on data from the qualitative data mechanisms of the process evaluation. Although these data have proven very valuable, the overall benefit of the evaluation will be enhanced with triangulation of findings from other evaluation components, such as health facility surveys, household surveys, and administrative data.

Second, it is important to note that this prospective evaluation focused on activities just prior to the PCV launch. Also, some data collection, such as key informant interviews were only possible after institutional review board (IRB) approval. This limits the evaluation's ability to clearly understand processes from earlier stages, particularly the decision to apply for GAVI support and the application process. This limitation highlights the importance of prospectively oriented evaluation studies such as the GAVI FCE, which collect data in real-time.

Third, given the short timeframe of the evaluation study, the findings reported here are based on a limited set of key informant interviews; some of these were shortened due to a lack of time. The evaluation team also encountered difficulties scheduling interviews. Some key informants were unavailable. These issues highlight the challenges of minimizing respondent burden, which will be considered as the GAVI FCE evaluation continues.

Fourth, although the evaluation is reporting on findings, some implementation processes for the PCV introduction are incomplete. For example, the PIE of the PCV/MSD launch has not been conducted and post-launch supervision has not been implemented.

Finally, it is important to note that this is an ongoing, prospective evaluation that will continue with aspects of the implementation process over time. The GAVI FCE will also assess the relationship between the PCV introduction and the rotavirus vaccine introduction.

8.15 Future directions

The team will use facility surveys to better assess the full extent of the early PCV launch. At the time of writing, reports suggest that the early launch was widespread. However, no systematic effort has been made to estimate the number of districts that began administering PCV and MSD before the national launch, identify when these districts began, or assess any consequences. Surveys will also be used to determine distribution of materials (IEC materials, AEFI forms, etc.).

Follow-up activities will examine the decision-making and application phases of other streams of GAVI support. This includes phases for the upcoming HSS support and HPV vaccine. We also will continue to track ongoing implementation phase activities for rotavirus vaccine introduction.

8.16 Conclusions

Despite repeated delays and postponements, PCV10 and MSD were eventually launched on July 9, 2013. Zambia is one of only a handful of countries to have undertaken a simultaneous launch of more than one vaccine. Our interviews and observations suggest that leaders achieved resource and programmatic efficiencies by integrating preparatory activities for the two vaccines. To date, data suggest that, in the case of these two specific vaccines, this approach was appropriate.

Challenges for the launch of PCV and MSD are attributable to several factors. These include, in particular, the relocation of the CHU from the MoH to the newly created MCDMCH; the number of immunization milestones competing for the attention of a relatively small set of program managers and supporting partners; and the CHU's inability to manage complex processes without adequate human resources. These were exacerbated by delays in the transfer of funds from government and GAVI, and gaps in communication between partners.

Following the launch, country stakeholders did not have time to reflect on the introduction of PCV because they immediately shifted attention to the launch of the rotavirus vaccine. There was no formal assessment of the successes and shortcomings of the PCV launch; monitoring and supervision, and the PIE, are not scheduled until early 2014.

Some informants noted lessons that were applied directly to the rotavirus launch. For example, the pre and post-training evaluation of participants to ensure that they had absorbed key messages and knowledge which was used in the PCV training was adapted to the Rotavirus training. Other lessons were interpreted in a less constructive way. For example, because of issues with the transfer of funds for PCV, some informants noted a reluctance to set a launch date for the rotavirus vaccine until the VIG was in country accounts. The absence of a clearly communicated launch date is likely to severely compromise efforts to effectively plan for and implement preparatory activities. In our recommendations section, we suggest a number of opportunities to improve this process in the future.

8.17 Recommendations

Recommendations in this section are organized around key areas. They proceed from high-level recommendations to more specific suggestions.

Major recommendations

Better articulate the roles and responsibilities of stakeholders at the country level.

Preparatory activities for the launch and roll-out of PCV in Zambia involved a host of stakeholders representing government and partner institutions. Stakeholder involvement was loosely coordinated through the technical committee and sub-committee structures, but membership in those groups—and the expected contributions of members—were not formally articulated or understood. This undermined efforts to coordinate activities in the run-up to the launch.

Strengthen communication between global and country stakeholders so that they can set realistic time frames for the launch of new vaccines and other streams of GAVI support.

Vaccine launch dates are often set in isolation, without crucial knowledge about the availability of vaccine supply and VIG funds. This issue commonly begins with the GAVI application process. Countries set an *aspirational* date for the launch of a new vaccine, which often creates an expectation in-country that they will indeed be able to introduce at that time. In the case of Zambia, it is not clear that any of the dates set were the result of communication between the country and GAVI, despite critical dependencies, including the VIG and the actual supply of PCV. To avoid raising unrealistic expectations, stakeholders and planners on both sides should communicate proactively as they set dates.

Critically assess decisions to launch multiple vaccines within a short period of time, and the appropriate spacing of these major milestones.

2013 was a major year of milestone events for Zambia's immunization program. It included the simultaneous launch of PCV10 and MSD, an HPV vaccine demonstration project in Lusaka province, and the national launch and roll-out of rotavirus vaccine. According to our interviews, the simultaneous launch of two vaccines, in this case PCV and MSD, is a strategy that will be considered for future launches given resource and planning efficiencies in Zambia. However, informants also noted that other major immunization milestones, particularly the HPV vaccine demonstration project and rotavirus vaccine launch, often took away from time needed for PCV/MSD planning (and vice versa). The impact of all of these activities was somewhat mitigated by the role of a trusted partner, CIDRZ, in supporting preparations for rotavirus vaccine launch. However, the number of launches undertaken by Zambia in 2013 clearly presented a significant challenge to the capacity of program managers and partners.

We recommend that GAVI and partners work with countries to assess their capacity to undertake multiple launches in quick succession, and consider developing specific guidelines on the conditions in which multiple vaccine launches are appropriate. Furthermore, though stakeholders were unequivocal that simultaneous launches represent a more efficient use of resources, the synergies between PCV and MSD may be quite different from other vaccine combinations, and as such, careful consideration should be given to decisions to launch simultaneously.

Improve understanding of GAVI policies and procedures among the CHU and country partners, particularly with regard to vaccine introduction grants.

Overall, stakeholders identified the delay in the release of the VIG from GAVI as the key factor in the timing (and delay) of the PCV launch. In Zambia, it took about six months to obtain these funds, resulting in a postponed launch and roll-out. Although global-level interviews suggest that obtaining these funds can take up to one year, it is clear that there is a lack of understanding of the policies, procedures, and timelines surrounding disbursement. Although the VIG represents a relatively small investment on the part of GAVI, it plays a crucial role in allowing countries to implement required activities before vaccine introduction. We recommend that GAVI and the national EPI and country partners work to improve communication around these processes and other streams of GAVI support, and develop of clear

written guidance that is easily accessible to country planners. This should also include increased communication to GAVI regarding the status of vaccine introduction planning and implementation over time.

Identify potential contingent funding sources as part of the vaccine introduction plan and assess need at specified check points.

The most commonly identified explanation for the multiple delays in PCV10 were delays in the release of funds, including the VIG and government funds. In Zambia, this became an issue with the increase in DSA rates for public service workers, including health workers. In this case, the country was fortunate to have some unspent government funds, in addition to stop gap funds from partners. Nevertheless, trainings, and ultimately launch dates, were postponed. Our recommendation is to include an identification of sources of contingent funds, and specific checkpoints in time by which such support should be sought, in the vaccine introduction plan. This will help address any funding gaps that may arise. Once the MCDMCH is in a position to receive the funds themselves, instead of having them routed through UNICEF, delayed disbursement of the VIG may also be less challenging.

Emphasize the importance of post-launch activities, such as supervisory visits and post-introduction evaluations, which provide critical feedback on needed programmatic improvements.

Despite all the time and resources dedicated to activities leading up the launch of a new vaccine, PCV10 post-launch activities, such as supervision, were overlooked. In Zambia, this was likely because after the many delays in the launch of PCV, program managers and partners had to immediately shift to prepare for rotavirus vaccine launch, which occurred just a few months later. As a result, country leaders missed an important opportunity to learn from the launch of PCV and to apply those lessons learned to the introduction of rotavirus vaccine. GAVI should consider requiring that such learning takes place prior to the next vaccine launch, by mandating a PIE or, at a minimum, extensive supportive supervision.

Specific recommendations

The following specific recommendations should be interpreted in connection with the high-level recommendations above.

Recommendations for GAVI:

- Increase the level of communication with the national EPI and country partners, especially around GAVI policies and procedures, and any changes to those policies and procedures.
- Consider a funding mechanism through which GAVI could provide contingent funding for vaccine proactively with countries to develop realistic timeframes for introductions from as early as the development of the GAVI application.

- Provide explicit guidance to countries on the appropriate spacing of major immunization activities, specifically new vaccine launches, making sure to leave space for needed monitoring and supervision to take place between launches. Because such activities are not essential for the actual launch, they tend not to be prioritized.
- Invest in strengthening central-level capacity to manage and plan new vaccine introductions and immunization more generally.
- Consider a more active follow-up mechanism to ensure that the GAVI VIG is disbursed in a timely manner.

Recommendations for CHU:

- Increase the level of communication with GAVI around GAVI policies and procedures.
- Work proactively with GAVI to develop a realistic timeframe for introductions; this should begin as early as the development of the GAVI application.
- Prioritize the implementation of post-launch monitoring and supervisory visits, and the implementation of a PIE before the launch of the next vaccine.

Recommendations for in-country partners:

- Provide assistance and facilitate communication to increase the CHU's understanding of GAVI policies and procedures for each window of support.
- Improve the designated role of country partners in helping the CHU navigate GAVI policies and processes.

9 Cross-Country Findings

This section presents a cross-country analysis of findings. It focuses on key issues and managerial practices that might have addressed or mitigated challenges during the PCV launch. While not exhaustive, the cross-country findings are meant to identify critical process challenges and underlying causes that should be monitored and further analyzed as FCE activities progress.

Key areas for cross-country analysis fall into two categories:

Category 1: Topic areas in which all three countries experienced significant and similar challenges in accomplishing key tasks.
This category focused on the following topics:

1. Ensuring sufficient funding is available in a timely manner at all levels
2. Managing training of health workers
3. Ensuring availability of updated monitoring systems
4. Coordinating timely and effective social mobilization and demand generation

Category 2: Topic areas in which the countries had different experiences, likely due to differences in their management approaches.
This category focused on the following topic:

5. Implementation of the PCV10 readiness requirements

In addition to the five topic areas, we discuss management and coordination leading to the successful PCV10 launch, with a focus on the management of postponements. We also offer preliminary observations regarding partnerships.

9.1 Analytical questions for cross-country analysis

The theory of change suggests that the successful launch and rollout of PCV10 relies on a complex series of interrelated processes. These demand sophisticated management and coordination capacity. We understand the following management principles to be necessary. Stakeholders must:

- understand the purpose of each process, as well as the interdependencies between processes,
- understand specific activities needed to complete each process,
- understand the responsibilities and accountability needed for managing the defined processes,
- ensure that resources are available to complete processes and address constraints prior to action, and
- continuously monitor and evaluate their own performance and improve their actions.

Using these assumptions, the FCE evaluation team developed the following analytical questions and sub-questions for cross-country analysis, and sought evidence for each.

1. **Is there evidence indicating that relevant partners commonly understood the importance of the process and specific activities needed to achieve milestones?**
2. **Did partners commonly understand the interdependencies between processes, and thus coordinate these activities?**
3. **Were roles and responsibilities clearly established and understood among partners?**

4. **Did the management feedback loop function such that timely adjustments could be made to the plan and the associated budget, which included addressing resource constraints?**

9.2 Analysis

The following section discusses results from the cross-country analysis of the Mozambique, Uganda, and Zambia case studies. We begin with a summary of country experiences related to each topic area, followed by analysis. Findings presented here reflect a limited time frame of data collection. As the GAVI FCE is an ongoing prospective evaluation, we also identify important areas for further inquiry.

In this section, "manager(s)" and "partners" refer to all officials of government and in-country partners that are directly involved in management of the introduction. "Government manager(s)" refer to the national government official(s) responsible for the PCV10 introduction, which is often the national immunization program and its managers, but may include other senior government officials. "In-country partner(s)" refer to the key in-country stakeholders that are directly involved with implementation, which are often UNICEF and WHO country offices, as well as other donor and technical agencies, and civil society organizations. "Global level partners" refer to GAVI secretariat partners such as WHO and UNICEF. "Stakeholder(s)" are used to describe a broader group of entities and people concerned with the introduction.

9.2.1 Topic 1: Challenges in ensuring timely availability of sufficient funding at all levels

All three countries faced challenges in ensuring the availability of funds to support preparatory tasks for PCV10 introduction. Funding delays and shortfalls led to a range of negative consequences. In Zambia, delays in funding disbursement resulted in postponement of the implementation of social mobilization and training, and ultimately a delay of the launch date. In Mozambique, funding delays resulted in some districts conducting training after the launch, and a lack of updated M&E tools until well after the official launch.

We identified four types of challenges associated with the funding availability. Table 16 provides an overview.

Table 16: PCV10 funding challenges by category and country.

Challenge	Zambia	Uganda	Mozambique
Delays in obtaining the GAVI VIG by country	Yes	Not identified	Yes
Delays in in-country disbursement of funds	Yes	Yes	Not identified
Shortfalls in available funds	Yes	Yes	Yes
Uncertainty of timing of GAVI VIG disbursement	Yes	Yes	Yes

Even though GAVI provides small amounts of cash support for introduction activities relative to the cost of the vaccines, they are the major funding source for operational activities as compared to other donors and government sources. For example, GAVI's introduction grant for Mozambique was $815,000, yet the amount was two-thirds of the planned budget. Therefore, any delays of GAVI's cash support had a significant impact on the country's ability to manage introduction activities.

Another significant funding challenge was uncertainty around the timing of the release of the GAVI VIG. Because of its significance, not precisely knowing when the funds would be released put introduction activities on hold and frustrated government managers and in-country partners.

Is there evidence indicating that relevant partners commonly understood the importance of the process and specific activities to needed for process completion?

Case reports suggest that government managers and in-country partners understood the importance of delays of the GAVI VIG. However, there is limited evidence that they developed a clear understanding of, or familiarity with, the processes and requirements for accessing and disbursing the VIG. Interviews with government and in-country partners consistently showed that they struggled to understand the process, status, and timing of the VIG. In both Zambia and Mozambique, key informants repeatedly indicated that they were not familiar with GAVI's funding release process. Furthermore, no informants could articulate GAVI's transparency and accountability policy (TAP), or its associated processes in relation to funding disbursements. The report to the GAVI Programme and Policy Committee on Oct 2013 supports our findings that countries showed mixed levels of knowledge and capacity related to the TAP policy.

Significantly, funding availability problems were not limited to the VIG. Countries also experienced challenges with other funding sources and their own government processes. For example, the process for obtaining funds through the new integrated financial management system in Uganda was affected by several issues related to the new system. The implications of this new system were not clearly understood by national-level planners (e.g., manually entering health worker account information) and, as a result, significant delays occurred in accessing funding at the subnational level. In Zambia, when the GAVI VIG was finally released through UNICEF, Zambian sub-national stakeholders were not familiar with UNICEF's fund-release requirements, resulting in further delays and confusion. This lack of familiarity and experience with fund management meant that managers were unable to estimate the timing of funding disbursement or proactively make adjustments for subsequent activities.

Did partners commonly understand the interdependencies between processes and coordinate these activities?

Interviews suggest that the GAVI Secretariat and global partners do not give due attention to how the GAVI VIG affects preparation for the vaccine introduction. The VIG may not always receive the highest priority at the secretariat level. This can create a delay in processing, especially given competing priorities of CROs and the relatively small cash amount. As noted, however, our analysis demonstrates

that the VIG is a centrally important funding source for preparatory activities and is needed for a successful vaccine introduction.

When making decisions regarding funding allocations, it is important that managers make a conscious evaluation of potential risks and consequences. When faced with a funding shortfall, countries addressed the gap in a piecemeal fashion. This approach risks losing sight of the overall coordination and implementation of various processes. For example, in Mozambique the allocation of stop-gap funding prioritized activities related to programmatic requirements set by the global partners, such as the placement of PCV stickers and training for vaccine supply, over other activities, such as the distribution of M&E tools. Further investigation of countries' decision-making processes and practices with regard to prioritization during a funding shortage is an important area for future study.

Our case studies suggest that there is a potential mismatch between the channels of information about financial procedures available from GAVI and global level partners (such as WHO) and the way in-country managers access and use this information. For example, interviews from the three countries point to a lack of familiarity among in-country managers with GAVI's transparency and accountability policy, and procedures for release of funds. Furthermore, there appears to be a lack of familiarity with how these polices and processes affect and are relevant to these countries. GAVI's website includes several pages that discuss the policy and link to a 2009 policy document, but this channel of information leaves room for interpretation and does not clarify what happens if countries do not complete the process. Global-level partners often view CROs as the key communication channel with countries, but the way they are accessed to clarify information seems to vary by country. We will seek to learn more about government managers' and in-country partners' access to and use of these information and communication sources as well as other channels such as WHO and UNICEF as part of future GAVI FCE activities.

Were roles and responsibilities clearly established and understood among partners?

In managing complex interactions such as the PCV10 launch, roles and responsibilities should be clearly identified and aligned with capacity and resources. This will facilitate a coordinated reaction to changes and can help involved parties to know each other's roles and anticipate next steps. Country cases suggest that having a history of collaboration has allowed in-country partners to operate without formally defining and documenting the roles and responsibilities of in-country partners in managing funds; this includes communication surrounding funding processes and progress, decision-making, and disbursements). Because the VIG was channeled through partners rather than government agencies in Zambia and Mozambique (UNICEF in Zambia, and UNICEF and WHO in Mozambique), we expected that roles and responsibilities on fund management would be reflected in those partners' terms of reference. However, there was limited evidence that roles were defined, revised, and communicated among in-country and external partners. Despite this lack of formal arrangement, in-country partners were largely able to adjust their roles, as needed, and drew on close collaboration to identify individuals responsible for fund management at each organization. In Zambia, for example, stakeholders could name the position and individuals who were handling bank information.

At the same time, it is important to emphasize that this arrangement was not necessarily ideal. Without defining specific tasks and how they would be accomplished at the beginning, inefficiencies may have been introduced as partners learned about each other's processes through informal communication, by trial-and-error, and under significant time pressure.

Certainly, country case studies highlight that this informal arrangement is ineffective in the management of processes that go beyond the country-level, such as communication between the GAVI Secretariat and in-country partners. It is clear from interviews that the national EPI manager is often the key point of contact with GAVI, especially with CROs. However, several key informants were not clear about the roles that in-country partners should play in communicating with GAVI and in support of the national manager. In-country partners were reportedly copied on email communications between GAVI and the national manager for each country. In addition, Uganda established a weekly call between in-country Alliance partners and GAVI CRO. At the same time, key informant interviews suggest that partners were not necessarily proactive when communication between the national manger and GAVI stalled. Our interviews and country case studies suggest that communications between CROs and countries are affected by several factors, including the number of countries that each CRO supports, the language of communication, and familiarity between CROs and in-country managers. If neither side is proactive, authorization processes can slow down significantly, introduce uncertainty, and lead to subsequent problems (as evidenced by the challenges around the GAVI VIG). We will pay close attention to communication between countries and GAVI through subsequent process evaluation.

Did the management feedback loop function such that timely adjustments could be made to the plan and the associated budget, including addressing resource constraints?

All three countries faced funding gaps while preparing for introduction. Case reports indicate that government managers and in-country partners tried to revise the introduction plan and budget in accordance with the funding situation, and also mobilized resources when the funding shortfall became apparent. Countries took a range of actions to address funding gaps, including mobilizing stop-gap or contingent funding, reprioritizing activities, and changing or reducing activities for example, shortening training duration and frequency.

The case reports highlight the importance of contextual factors in funding availability and timing. In Zambia, establishment of a new human resource policy significantly increased training costs and resulted in a shortfall of funds to complete training. In Mozambique, the contribution from the sector-wide approach contribution was reduced, and with it, the overall amount of funds available for the PCV introduction. In-country partners assisted the ministry by mobilizing stop-gap funding and temporarily reprogramming existing funds. USAID (Mozambique and Uganda), and GSK (Zambia, Mozambique, and Uganda) were listed in the country case reports as sources of stop-gap funds. In Mozambique, both WHO and UNICEF reprogrammed regular support channels to fund introduction activities.

In Zambia, UNICEF disbursement procedures were proactively incorporated into the management of funding for rotavirus vaccine introduction; this is a positive example of how Zambia has used lessons

learned from the PCV10 launch. Thanks to an improved understanding of UNICEF's requirements for the retirement of outstanding accounts, the ministry was also able to instruct districts to submit accounts in advance.

9.2.2 Topic 2: Challenges in ensuring availability of skilled health care workers

As discussed in the theory of change, the availability of skilled health care workers at vaccine delivery points is crucial for safe vaccine administration. It is considered one of the two programmatic readiness requirements that preclude vaccine shipments to countries. All three countries experienced challenges in implementing effective training programs. Table 17 below summarizes the challenges and issues associated with this topic area.

Table 17: Challenges in the implementation of effective training programs.

Key Issue	Zambia	Uganda	Mozambique
Status of training at the time of launch	• Training was done but there was inconsistency in training program across districts.	• Only districts supported by MCHIP had training completed at the launch.	• Training of HCWs was not completed before the launch.
Issues with funding for training	• Funding delay contributed to a delay in training implementation. • Funding shortfall.	• Funding delay contributed to delay in training implementation.	• Funding delay contributed to delay in training implementation.
Issues associated with training session quality	• Training program varied across districts. • Appropriate personnel did not attend the trainings. • Use of training DVD was considered a success.	• Time lag between TOT and HCW training, • Training had no demonstration vaccine for practice and was considered "theoretical."	• Time lag between TOT and HCW training.

Did partners commonly understand the importance of the process and specific activities needed for process completion?

In-country partners clearly understood the importance of training and its relevance to the PCV launch. As the case of Mozambique suggests, establishing programmatic readiness requirements may have

elevated the importance of training and influenced the prioritization of training activities. In Zambia, some districts mobilized their own operational funds to conduct training, which indicates the perceived importance by subnational stakeholders.

On the other hand, perceived importance did not necessarily translate into high-quality training. Based on interviews, it appears that training quality suffered because it was rushed to meet the launch date. Other concerns about training quality included *"considerable time lag between TOT and training,"* "*theoretical nature of training without practice," "no supervision after training," "inconsistency in implementation,"* and *"wrong cadres of HCWs attended."* In subsequent activities, we will investigate the quality of training by combining health facility survey and qualitative research methods.

Were roles and responsibilities clearly established and understood among partners?

It is generally understood that government managers took the lead and were assisted by in-country partners such as WHO and UNICEF in relation to the design and implementation of training programs. In addition to WHO and UNICEF, other technical agencies such as MCHIP (a USAID-funded project) provided assistance in this area. In the case of Uganda, MCHIP was instrumental in facilitating training of districts in preparation for the PCV launch, although MCHIP only covered a small number of districts. Data collected do not allow us to elaborate on the roles and responsibilities of partners in relation to the design and implementation of training programs.

Did the management feedback loop function such that timely adjustments could be made to the plan and the associated budget, including addressing resource constraints?

Training implementation was significantly influenced by funding availability and the need to meet launch dates. Despite expressed concerns about training quality, countries appeared unable to proactively address problems and sequence activities. These issues were most severe in Uganda. Although questions on training implementation arose before the launch, adjustments occurred well after.

9.2.3 Topic 3: Challenges in ensuring availability of updated monitoring systems

Activities to address monitoring systems included updating and distributing EPI data-collection tools, such as vaccination cards, vaccination registries, and monthly data summary sheets; updating information systems and surveillance systems; and establishing and implementing post-launch monitoring and supervision. Without these updates, it is difficult to monitor vaccine introduction or obtain information critical for making necessary adjustments and ensuring safe vaccine use.

All three countries experienced challenges ensuring that monitoring tools would be available at health facilities for the launch. Uganda successfully updated, produced, and distributed tools in 2011-12 in anticipation of both the PCV10 and rotavirus vaccine launch. However, when PCV was launched in Iganga district in 2013, many facilities still lacked tools. Zambia also updated its monitoring tools, but many facilities reported using old registers at the time of launch. Mozambique started working on production monitoring tools in 2012, but errors and lack of funding delayed finalization and distribution

to facilities. In the absence of updated monitoring tools, the national program instructed facilities to improvise existing tools to accommodate data on PCV.

Implementation of post-launch monitoring and supervision was poor in all countries. In Zambia, the vaccine was launched in July 2013, but post-launch PCV supervision had yet to begin as of early December. Zambia indicated that it would implement joint supervision with the rotavirus vaccine in January 2014. In Mozambique, post-launch supervision was implemented in 9 out of 11 provinces due to competing priorities in completing the HSS application. In-country partners in Mozambique also failed to prioritize their participation in supervisory visits over other competing priorities, even though they participated in planning these visits. The table below summarizes key challenges associated with the monitoring systems. We plan to further examine the availability of monitoring tools through the facility survey planned in each country.

Table 18: Challenges involved in monitoring systems.

Challenges	Zambia	Uganda	Mozambique
Monitoring tools	• Tools were updated but not consistently available at facilities at the time of launch.	• Tools were updated but not available at facilities at the time of launch.	• Tools were not available at facilities until several months after the launch.
Post-launch monitoring and supervision	• PIE not implemented prior to the next rotavirus launch but planned as part of rotavirus post-launch supervision in January 2014.	• In the one launch district, post-launch monitoring supervision is being facilitated by MCHIP. We have not presently identified issues with these activities.	• Occurred in 10 out of 11 provinces. • Occurred without participation of partners. • Did not include mobile outreach teams.

Is there evidence indicating that partners commonly understood the importance of the process and specific activities to needed for process completion?

Country case reports indicate that monitoring systems, which include post-launch monitoring and supervision, are generally not prioritized by the government and partners relative to other preparatory activities. Based on our observations of the PCV launch, especially in Mozambique, other areas were consistently given higher priority over the work on monitoring systems. We hypothesize that this happens because the weaknesses of monitoring systems are not often apparent until after a vaccine is

launched–especially because having the monitoring system in place and updated does not impede a vaccine launch.

Is there evidence that roles and responsibilities were clearly established and understood among relevant partners?

Case studies consistently indicate that the predominant modes of coordination among in-country partners are informal. This includes coordination related to updating, producing, and distributing M&E tools. Countries established technical working groups to update monitoring systems, but interviews to date indicate that the groups have not explicitly developed terms of reference.

Did the management feedback loop function such that timely adjustments could be made to the plan and the associated budget, including addressing resource constraints?

The fact that health facilities still lack proper monitoring tools, often without a clear explanation, suggests the absence of analysis and a management feedback loop. Significantly, monitoring systems are themselves the foundation of the management feedback loop, especially for post-launch adjustments and safety. In all three countries, continued weaknesses in monitoring systems will result in poor feedback loops for immunization program management.

9.2.4 Topic 4: Challenges in coordinating timely and effective social mobilization and demand generation

These reports indicate that the three countries were successful in generating demand for the new vaccine. At the same time, they encountered challenges during the implementation of social mobilization, primarily related to uncoordinated and inaccurate demand generation activities (Table 19).

Table 19: Challenges in preparation and implementation of social mobilization activities.

Challenge	Zambia	Uganda	Mozambique
Coordination of timing and sequencing of activities	• Difficulty in coordinating activities due to uncertainty around the launch date, which resulted in some social mobilization activities occurring well ahead of the launch.	• Misalignment between coordinating social mobilization activities and the actual implementation of the vaccine launch. Social mobilization was conducted nationwide, even though the launch happened only in one district. Districts without the vaccine had caretakers demanding it.	• Management and implementation challenges led to reduced time for preparation of social mobilization materials. Messages were broadcast later than planned.
Inaccurate messaging	• Not identified	• Not identified	• Rushed implementation led to inaccurate messages. This led to demand for PCV outside of the targeted age group, resulting in a combination of vaccines being delivered outside of the target group and unmet demand.
Availability of materials	• A shortage of materials emerged, especially at the facility level.	• Shortage of materials at the facility level.	• Materials were not available in facilities until after the launch.

All countries experienced some form of unmet demand for PCV, whether due to early social mobilization or inaccurate messaging around the target age group for the vaccine. Downstream consequences of this challenge included an increased workload for health workers, as well as a potential longer-term effect of reduced population trust in media messages about vaccines

Did partners commonly understand the importance of the process and specific activities needed for process completion?

Across countries, partners and stakeholders prioritized social mobilization even though it was not part of the programmatic readiness requirements. In Zambia, the subcommittee on social mobilization was seen as the most active group for the PCV launch. In Mozambique, when contingency funds became available and after the readiness requirements were addressed, social mobilization was prioritized.

Nonetheless, there were clear challenges associated with articulating and managing the process for developing and implementing social mobilization activities within a short period of time, as well as coordinating these activities with others (for example, the lack of media message piloting in Mozambique).

Did partners commonly understand the interdependencies between processes and coordinate these activities?

Even though the importance of social mobilization was clearly acknowledged, the coordination between social mobilization and other processes has been challenging for countries. In Uganda, social mobilization took place nationally, but since the vaccine was launched in only one district, an unmet demand for the vaccine was created. In Zambia, the official vaccine launch took place well after the planned period of social mobilization, because the official launch experienced a penultimate postponement when Lusaka province was not prepared.

Were roles and responsibilities clearly established and understood among partners?

While UNICEF was seen as the key partner in the strategic support of social mobilization activities across countries, other partners also played important roles. Because social mobilization activities entailed a wide variety of activities (such as television and radio messaging, paper-based media, development and distribution of educational materials, and mobilization of community members), it also involves a large number of partners and stakeholders. One informant in Mozambique described it by saying “there were too many cooks in the kitchen” at times, which resulted in the duplication of roles and responsibilities, and made the coordination of activities difficult.

Did the management feedback loop function such that timely adjustments could be made to the plan and the associated budget, which included addressing resource constraints?

There is evidence from the three cases that the management feedback loop did not function in an optimal way. In Mozambique, missteps in outsourcing social mobilization development, and other management and implementation issues, led to the absence of pre-testing of messages. Recognizing the problem that media messages created, Mozambique managed to make corrections via updating guidance to facilities and media messages clarifying the target range but not until after the launch. The consequences of the inaccurate message are likely to persist in terms of the potential effects on demand generation. When social mobilization activities were not well synched with the roll out of the vaccine in Zambia and Uganda, the available information suggests that corrective actions were not taken by in-country partners.

The three cases indicate that mistakes in social mobilization activities are difficult to retract; therefore, careful and well-timed preparation is important for the successful launch. The findings also highlight that, in all cases, social mobilization activities were condensed within a short time frame and hastily implemented very close to the launch date, which then did not give enough time for well-timed preparation and management.

9.2.5 Topic 5: Inconsistent implementation of PCV10 readiness confirmation

As discussed in the TOC section, a process was established for confirming country's programmatic readiness prior to shipment of PCV10 to the country. The objective of the process is to ensure that the vaccine will be safely handled, and to minimize adverse events that may occur due to vaccine contamination. The process starts with a country's MoH confirming its programmatic readiness, which is completed by writing to the UNICEF country office. WHO is then responsible for verifying the readiness status before the vaccine is shipped.

Although the word "programmatic" may imply broader immunization program-wide readiness for the new vaccine, it is only concerned with the verification of HCW training and placement of stickers on refrigerators and does not address other programmatic issues such as cold chain capacity, social mobilization, or M&E. These three country case reports highlight the inconsistent interpretation and implementation of the "programmatic readiness" process with varying consequences. The most significant repercussion was documented in Uganda, where the verification exercise continued eight months after the official vaccine launch (as of December 2013). Table 20 summarizes challenges in implementation of program readiness.

Table 20: Challenges in programmatic readiness implementation.

Challenge	Zambia	Uganda	Mozambique
Training readiness	Training was not completed before vaccine shipment.	Training quality was identified as a problem before the launch, which contributed to the decision to have a limited introduction. During the post-launch assessment, the level of HCW's knowledge was used as a criterion, but there was a lack of understanding of and disagreement over what was considered "passing" score among stakeholders. WHO has indicated that 80% of health workers tested should have correct knowledge in order to be verified.	Completion of training- of-trainers was used as the standard for training status. In some cases, training at the facility level was not completed until after the launch.
Refrigerator stickers	Stickers were distributed after the vaccine shipment.	Thirty-one percent of refrigerators were found without stickers at the post-launch verification by WHO. The standard is that 80% of refrigerators assessed should carry stickers to be considered ready.	Stickers were distributed to health facilities and placed on refrigerators prior to vaccine supply.
"Programmatic readiness" implementation	Vaccine shipment to Zambia occurred before two criteria met. MOH held the vaccine at the national store waiting for training and sticker distribution.	No plans existed for verification prior to the launch. There was a lack of knowledge among stakeholders concerning readiness assessment. The vaccine shipment was halted while waiting for confirmation. After the official launch in one district, the verification process started but is taking a long time. The rollout to the rest of the country will occur after verification is completed.	The shipment of the vaccines occurred before health workers were trained at the facility level. Interviews indicate that no formal verification of readiness was conducted in the country.

Our process evaluation did not assess the training quality and use of refrigerator stickers; however, we will verify them through the quantitative facility survey in 2014.

Did partners commonly understand the importance of the process and specific activities needed for process completion?

One global-level key informant mentioned that "*while it is an added process and may slow down the introduction process at times, the readiness requirements of PCV10 introduction is a novel mechanism to ensure that countries are ready and the investment will not be wasted*." The importance placed on the

readiness assessment by the global partners is evident in WHO Quality, Safety, and Standards' (QSS) immunization updates. It is also apparent in the verification process; two key GAVI partners, WHO and UNICEF, play prominent roles at the country and global levels.

Despite the importance given to the process, case reports reflect inconsistent interpretations and implementation of "programmatic readiness." This indicates that countries did not translate global-level guidance into action. For example, in Mozambique, the training-of-trainers was used as the requirement criteria. After the limited initial launch of the vaccine, Uganda, following more stringent criteria, made the target for readiness "80% of health care workers with correct knowledge". In Zambia, shipment of the vaccine occurred prior to health worker training, although the vaccine was held at the national store while training was being completed.

We also noted that stakeholders lacked accurate understanding of the objective of the readiness requirements. As stated earlier, the objective is narrowly focused on the safe use of the vaccine, rather than a broader confirmation of a country's readiness for introduction. There are signs that in-country stakeholders interpreted the objective as the latter.

Did relevant partners commonly understand the interdependencies between processes and coordinate these activities?

Our analysis could not explain why such major differences of interpretation existed among countries. Our interviews suggest, however, that not all stakeholders were aware of the rationale and process behind readiness confirmation. This was the case even though there was a fairly clear understanding that vaccine shipment depended on confirmation of readiness. Some informants felt these conditions were another hurdle imposed by GAVI. Our observations show little evidence that programmatic readiness was part of an active meeting agenda item, except for post-launch in Uganda. In Uganda, verification of readiness has become a dominant theme and concern in post-launch meetings.

Based on these early observations, we suspect that poor understanding partially stems from a lack of specificity at the global level. During our process evaluation, we identified guidelines on programmatic readiness for countries in two resources: (1) the WHO website, on a page titled "Update on two-dose presentation of preservative-free 10-valent pneumococcal conjugate vaccine from GlaxoSmithKline (GSK) (Synflorix™)" (published on May 14 2012); and (2) a WHO handbook titled "Introduction of pneumococcal vaccine PCV10, two dose presentation: a handbook for district and health facility staff." The two resources explain the definitions on readiness in the exact same language, but do not offer elaboration on assessment criteria and how countries should operationalize them. According to interviews at the global level, communication on readiness is considered the responsibility of WHO. The June 2013 version of the WHO handbook for districts and facilities[12] describes the process steps to confirm readiness, and indicates that the WHO country office, in consultation with the regional office

and headquarters, should verify the state of readiness in the country.[6] One interviewee indicated that "*UNICEF and WHO, through their close collaboration with the country, should be able to determine the status*." The confirmation process expects that WHO will conduct a rapid assessment to physically verify the readiness status. To date, however, no standardized rapid assessment method or set of instructions on how country readiness should be verified exists.

Our studies suggest that the global-level partners, including GAVI, WHO, and UNICEF, have not done enough to assist countries in understanding the programmatic readiness and its implementation. This is akin to issues surrounding the financial process. We will investigate this further in subsequent study.

Were roles and responsibilities clearly established and understood among relevant partners?

According to one guidance document, "WHO QSS Requirements for PCV10: the process for confirming country's programmatic readiness," which was included as an appendix in the June 2013 version of the aforementioned handbook, the country is responsible for confirming programmatic readiness to the UNICEF country office. WHO's role is to verify and provide advice on readiness in the country. However, we could not find any documentation identifying the organization(s) accountable for overseeing overall implementation of the programmatic readiness process.

Country stakeholders' understanding of roles and responsibilities must be confirmed. Based on the level of understanding of the readiness confirmation process, we suspect that the roles and responsibilities of global and in-country partners are not well understood at the country level.

Is there evidence that the management feedback loop functioned such that timely adjustments could be made to the plan and the associated budget, including addressing resource constraints?

Although neither Uganda nor Mozambique met the WHO QSS requirements prior to the official launch, they still decided to move forward with shipping vaccine to the country. In Mozambique, the launch happened as planned. In Uganda, the vaccine was launched in only one district, followed by a lengthy process of country re-verification. This had significant ramifications, including the emergence of competing priorities; an inability to meet demand for the vaccine; and an increased cost of introduction because health workers had to be retrained. Programmatic readiness requirements could serve as an important management feedback loop. In Uganda, this loop likely saved the country from introducing a vaccine before it was prepared. As noted above, however, the process for confirming readiness needs further elaboration, instruction, and orientation. It will need to be well understood and consistently implemented by in-country stakeholders before it can function as an effective management tool.

[6] We also noted that the October 2013 version of the WHO handbook has eliminated description of the process for confirming the country readiness. Based on our discussion with GAVI, the process is still valid as at the time of this report.

9.3 Management and coordination of work domains leading to the successful PCV10 launch

A variety of challenges contributed to the postponement of the PCV10 launch in all three countries. How much the launch was postponed and the frequency of postponements varied, as did the reasons underlying each decision. Postponement is not unusual; according to one global-level key informant, postponement by three to nine months is typical for a new vaccine introduction.

In Zambia, there were two major postponements of the official launch, with frequent changes that occurred near the scheduled launch date. In Uganda, there were two relatively small postponements in one district, but the vaccine has not been introduced to the rest of the country. In Mozambique, there was one major postponement, and one minor change occurred near the launch date.

One negative consequence of a significant delay in a vaccine launch date is that children who were eligible for PCV vaccination at the original launch date may be missed at the rescheduled launch. Delays can also impact the global strategic forecast of vaccine supplies.

From a process evaluation perspective, postponement of a PCV launch date may indicate the presence of inadequate planning and mismanagement. At the same time, we must be careful in making judgments that the postponement itself constitutes an inherent process problem, especially if the delay occurred to allow for adequate preparation for a successful introduction (i.e., training of health workers, improvement in logistics, and availability of vaccines and other commodities).

The experiences of the three countries elucidate management practices that may have contributed to unnecessary postponements or aggravated consequences. These include:

- Setting an ambitious or unrealistic launch date during the application process because of inadequate planning or lack of understanding of the process and requirements.
- Frequent adjustments of the launch date without clear and proactive communication.
- Lack of coordination of preparatory activities after postponement decision.
- Inability to adjust the launch date when postponement was desirable or necessary.

Setting an ambitious or unrealistic launch date during the application process

Key informant interviews revealed a predominant understanding that postponing vaccine introductions is a normal occurrence. This is a concern. For all three countries, the application process for PCV introduction support preceded the starting date of this study. Thus, we have an incomplete understanding of how the original launch date was set by the country stakeholders, what information was considered, and what instructions were given. As noted, one potential reason is that country stakeholders may not have had a complete understanding of processes and procedures pertaining to the vaccine introduction. We noted that countries underestimated the time and effort required to receive financial assistance from GAVI and other sources. Similarly, we identified a lack of understanding of "programmatic readiness." There is also evidence of poor understanding of the timeframe needed to complete necessary conditions.

Our investigation **suggests** that significant postponements are both within, and outside of, a country's immediate control. For example, Mozambique's postponement was influenced by the need for an Effective Vaccine Management Assessment (partially *within* the country's control) and a PCV13 shortage (an external factor). Zambia's initial seven-month postponement was due to a measles outbreak (external, although related to routine measles coverage). Zambia's next eight-month postponement was due to delays in funding (internal and external). Subsequent adjustments were due to inadequate management of competing priorities (internal). Uganda, after a three-month postponement largely due to fund-management reasons (internal), launched the vaccine in one district. At writing (December 2013), introduction to the rest of the country has not happened, which constitutes a nine-month delay.

During the subsequent phase of the FCE project, we will have opportunities to investigate the process of application and the factors that influence its key contents. This is particularly relevant as countries apply for new vaccine support from GAVI. We will pay close attention to the ways in which countries determine their initial launch dates.

Frequent adjustments of the launch date without clear and proactive communication

The way global stakeholders viewed postponements in terms of management differed markedly between Mozambique and Zambia. Mozambique's postponement was not seen as a problem, while Zambia's case was viewed as a sign of management weakness. For Mozambique, this interpretation may be because the country communicated the date and stuck with the decision—despite adjustments as the launch approached and some training after the launch. In Zambia, some launch changes happened without communication to stakeholders in and outside the country. These experiences have prompted a sense of caution among stakeholders regarding any subsequent decisions made by the country.

Lack of coordination of preparatory activities after postponement decision

The successful launch of a new vaccine requires the management of a complex system with multiple and interdependent processes. The theory of change illustrates these interdependencies among several factors, such as the availability of skilled health workers, the availability of potent vaccines at all vaccine delivery points, a population's demand for the vaccine, and the availability of updated monitoring systems. Processes to meet these conditions need to be coordinated across different partners and stakeholders. Adjusting to changing contextual environments can add to management challenges. Our case studies show that a lack of coordination can result in issues such as time lags between the training-of-trainers and health workers, between social mobilization and availability of vaccines, and between training and health workers providing the vaccine. When the launch dates shift, it is important to assess the overall situation and make adjustments to the whole plan rather than focusing on the immediate challenges at hand.

Inability to adjust the launch date when postponement was desirable or necessary

Finally, our cases found that countries might have decided to go ahead with the PCV10 launch even when postponement may have been more desirable. The prime example of this is Uganda. Uganda's

training status, both in terms of coverage and quality, was questioned before the launch. Some areas did not have required cold-chain stickers in place. In Mozambique, sticking to the launch date shortened the timeline for social mobilization, which led to additional challenges. In-country stakeholders speculated that political pressure may have led to maintaining the official launch date. Decisions on setting launch dates will be one of areas that the process evaluation will continue to focus on.

9.4 Partnership

One of the important overarching process evaluation questions in the GAVI FCE is how partnership contributes to the successful implementation of GAVI support, and, in this case, a successful PCV10 launch. This is one of the areas in which we are preparing to conduct in-depth analyses in 2014. Nonetheless, this report points to potential strengths and weakness for the GAVI Alliance partnership.

Notable examples of effective partnership include:

- In-country partners provided stop-gap funds and reprogrammed resources to provide contingency funding when Mozambique was faced with funding shortfall.
- Zambia and Uganda also received contributions from in-country partners when funding shortfalls became apparent.
- UNICEF's role in social mobilization was recognized in all countries.
- In post-launch, Uganda, WHO has taken a technical lead role in assessing programmatic readiness.

Weaknesses include gaps in:

- Clearly communicating and assisting countries to navigate GAVI's policies, processes, and procedures, especially in areas where government managers have less experience.
- Facilitating proactive communications between the global and in-country levels.
- Providing preemptive assistance to prevent crisis or emergencies.
- Providing broad perspectives and coordination of interrelated processes throughout the implementation of new vaccine introduction.
- Explicitly defining and updating the roles and responsibilities of partners.

Our observation suggests that current partnerships are key to managing crisis during vaccine implementation; stop-gap funding is a key example. On the other hand, there is no evidence to suggest that partnerships can prevent crises. Many challenges might have been mitigated or reduced through proactive risk management and contingency planning with partners. Partnership and its performance will be one of the key process evaluation activities in 2014.

9.5 Unintended consequences from the PCV launch

A key focus of the GAVI FCE is to examine positive or negative unintended consequences of GAVI support. Findings to date are based primarily on qualitative data collection and the FCE has not triangulated across multiple evaluation components. Therefore, it is too early to identify consequences such as effects on the routine immunization system or the broader health system.

For example, as part of the GAVI FCE we will examine the relationship between the PCV introduction and delivery of other selected health services. Given the challenges that have arisen as part of the PCV introductions in Mozambique, Uganda and Zambia, we highlight three selected areas where there are potential unintended consequences which we will continue to monitor as the GAVI FCE proceeds.

Demand generation. A key consequence that we will track as part of the GAVI FCE is whether demand generation activities for PCV have led to increased demand for other vaccines supplied by the routine immunization system and/or other health services. We will examine this through analysis of administrative data, health facility including patient exit interviews, and household surveys. There are also potential negative unintended consequences that may stem from problems with PCV demand generation that we have observed. In Mozambique, inaccurate social mobilization messages related to age groups eligible for PCV led to demand outside of the target population. In Uganda, the lack of coordination between demand generation activities and other key launch steps resulted in demand generation nationwide, but PCV delivery being restricted to a single district. In Zambia, uncoordinated demand generation with the launch date also resulted in demand generation occurring prior to the official PCV launch and delivery. These problems may lead to negative effects on future demand generation activities due to unmet demand; we will track this through health facility and household surveys.

Health worker training quality. Across the three countries, implementation of training was characterized by delays due to funding and truncated schedules. In Mozambique, training in the districts did not occur until close to launch or after launch of PCV. In Uganda, training at the district level was initially only in five districts and after the training rollout nationwide; the readiness assessment suggests sub-optimal health worker knowledge. In Zambia, the allotted training time was reduced. Given the challenges in training roll-out across the three countries, the FCE will track the potential unintended consequences of reduced quality of service delivery at the district and facility levels and potential safety issues that could have occurred as a result.

Competing vaccine and health delivery priorities. In each of the three countries, there is some evidence of competing multiple priorities that may have unintended consequences. In Zambia, for example, multiple vaccine launches (HPV, rotavirus) may have negatively affected the introduction of PCV10 or vice versa. In Uganda, SIA activities for polio appear to have had an effect on stalling the ongoing introduction of PCV. In Mozambique, competing priorities appear to be less of an issue; however, HSS applications affected the completion of PCV post-launch supervision in one province. The broader unintended consequences of these competing priorities are presently not well known but will be an important area of focus as the GAVI FCE proceeds.

9.6 Conclusions

Our cross-country analysis aimed to illuminate insights into challenges that countries faced and learn from their management practices. We focused our review of the cases on five areas where countries

faced common challenges or, in one case, where the process in each country was notably different. These areas were: timely availability of sufficient funding, availability of skilled health care workers, availability of updated monitoring systems, coordination of timely and effective social mobilization, and implementation of PCV10 readiness requirements. Overall, this analysis notes that countries consistently struggled in managing processes that were unfamiliar to them and/or less standardized with considerable room for interpretation. Requirements such as GAVI's transparency and accountability policy, WHO QSS requirements for a country's programmatic readiness for PCV10, policies and processes around the GAVI VIG, and new financial management systems all created varying degrees of challenges for the countries. From a management perspective, managing an unfamiliar process is a common challenge faced by organizations and agencies. The challenge can become exacerbated when the lack of proactive management is coupled with poorly defined roles and responsibilities among in-country partners, and limited availability and use of effective communication channels to exchange and feedback information. In addition to reducing or eliminating unknown or unfamiliar processes, common principles of management emphasize the importance of minimizing uncertainty. For example, uncertainty around the release of the GAVI VIG funding was problematic. The long time lag in some cases between application and disbursement introduced uncertainty in the decision-making environment in countries and increased the presence of competing priorities that took focus away from preparatory PCV launch activities. This combination of factors lends itself to a set of recommendations based on these findings, which are covered in the next section.

Four management challenges across countries:

- Recognizing and managing unfamiliar or unknown processes.
- Recognizing and managing uncertainty when it is introduced into the introduction process.
- A tendency toward reactive management rather than proactive risk management and contingency planning.
- Poorly defined roles and responsibilities among key partners.

9.7 Recommendations

Given the four challenges we highlight above, in this section we describe a series of recommendations arranged around a number of the cross-country analytical points presented above. In developing recommendations, we note that these are based on our evaluation team's view of contextual factors such as political environment, resource availability and institutional operations, which we acknowledge is limited. As a result, we refrained from developing a set of specific action items, rather, we highlight areas that would bring improvement in implementing PCV and other new vaccines introductions based on our findings. To illustrate how these recommendations might be considered for process improvement, we elaborate on each recommendation's relevance to the process of ensuring programmatic readiness for PCV10. As we have noted, this part of the process was particularly challenging and inconsistent in its implementation across all three countries. Our intention is that GAVI,

countries and partners consider these recommendations and further develop steps to operationalize them that are commensurate with their resources and context. We emphasize that these are not meant to be exhaustive but rather to reflect the findings in this section, and are intended to complement the recommendations contained in the country reports.

Recommendation 1: Explicitly articulate of roles and responsibilities between partners, especially in relation to policy, procedures, and requirements.

Launching a new vaccine is a complex endeavor that involves a large number of partners. Our recommendation is based on the fact that, beyond broad language in the introduction plans around partner contributions and broad activities that they will support in country, there was minimal explication of terms of reference that articulated roles, responsibilities, and commitments by each partner. The lack of such terms had an impact, especially in relationship to understanding the implementation of existing requirements, such as the TAP, or the introduction of new ones. Given that traditional and familiar demarcation of roles and responsibilities among in-country partners might not be sufficient to address the lack of understanding of existing and new requirements, it is critically important that partners and national EPI managers understand them and establish terms of reference according to each organization's defined strengths and resources. Formally establishing roles and responsibilities will not solve all issues related to collaboration. That said, their articulation will be a first step to ensure better coordination among partners and adjustments if necessary.

Relevance for programmatic readiness:

To better articulate roles and responsibilities for achieving programmatic readiness, the process could be better elaborated and institutions identified that are accountable for each step. Specifically, we note that the process outlined in WHO's "the Introduction of pneumococcal vaccine PCV10, two dose presentation: a handbook for district and health facility staff" does not explicate responsibilities for communicating the need for the readiness assessment, implementation of the process, supervision and technical assistance, and communication of results.

Recommendation 2: Ensure that policies and processes specific to GAVI support are well articulated and understood by all stakeholders.

This is applicable not only to new policies and procedures but also for ones that might have existed for some time. For example, GAVI's transparency and accountability policy has been in place since 2009, but there appeared to be little understanding of it among countries. It is important to ensure understanding of relevant policies and procedures by not just the country EPI manager, but also by a broader set of in-country partners. This will facilitate common interpretation of the necessary operational steps and implementation of key introduction activities. GAVI has indicated upcoming procedural changes in 2014

in relation to how they work with and monitor countries. It is important that GAVI prepares well-developed communication and assistance plans in advance of the implementation of new changes. Some specific actions that GAVI could take are listed below for consideration:

- Assess accessibility, readability, and the level of ease in understanding GAVI policies and procedures with country audiences and incorporate their suggestions.
- Standardize processes, procedures, and metrics associated with how these processes are ideally assessed and the potential decision points, consequences, and trade-offs. Increase opportunities for exchanges among countries of their experiences, knowledge, and lessons learned, especially for new policies and procedures.
- Improve the ability of countries to track the status of GAVI assistance either through email, website, or other means.

Relevance for programmatic readiness:

To better articulate the programmatic readiness policy, a standard set of tools including assessment protocol and operational procedures for countries to plan and implement the readiness assessment could be developed. We also recommend assessing the accessibility, consistency, and effectiveness of the existing guidance materials and communication channels to inform countries of the purpose, procedures, and consequences of the readiness process, to inform their improvement. Finally, global partners need to ensure that developed tools and procedures are well aligned with in-country capacity and available financial resources.

Recommendation 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.

Associated with putting in place better articulated and understood policies, communication and subsequent coordination channels among partners and stakeholders require strengthening. The relationships between the national EPI managers and GAVI Alliance partners need to strengthened, and communication needs to be made clearer, more frequent, and proactive, especially in setting dates for launch, status of vaccine introduction, and communicating potential delays. Countries must also adopt a position of proactive communication with GAVI and other partners to increase confidence that executing activities will take place in an efficient and effective manner. GAVI and partners should look at diversifying approaches to building relationships and communication. Currently, GAVI relies on a model of remote assistance, but should consider other options especially in countries that have an aggressive investment-implementation schedule, have struggling EPI managers, or historically weak collaboration with in-country partners.

Relevance for programmatic readiness:

Communication and coordination between global and country stakeholders can be improved by standardizing information channels to ensure consistency and ease of understanding of the purpose, procedures, as well as the planning and resource implications of achieving programmatic readiness. Further, the rules and consequences of the readiness process should be applied in a consistent manner; e.g., if a country fails to meet the readiness criteria, the vaccine should not be shipped. Inconsistency signals to countries the lack of importance of the readiness process, which will not serve countries well in planning realistic timeframes for future new vaccine introductions.

Recommendation 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.

In each of the PCV10 country case reports, there is little evidence that potential delays and postponements were explicitly identified in the planning and timeline documentation. Whether it was managing competing demands from multiple vaccine launches in Zambia, addressing implementation and approval bottlenecks with the IFMS in Uganda, or managing delays in funding in Mozambique, interviews and observations rarely highlight a proactive risk management or contingency planning approach. These approaches take a long time to cultivate within organizations and agencies where work culture is firmly ingrained. For a shift from a reactive to a continuous improvement environment to occur, trained leaders and champions are required both internally and externally. The GAVI FCE will need to further investigate potential facilitating factors that support improved management capacity and the feasibility of influencing these issues through existing mechanisms. It is still early in the FCE, but potential opportunities may exist and will be further explored in follow-up study activities. These opportunities include:

- Increasingly champion proactive approaches with country counterparts.
- Increased focus on highlighting lessons learned and best practices from new vaccine introductions and other streams of funding.
- Formal and informal points of reflection with country partners to ensure adaptation of management practices between launches that could include existing mechanisms, such as EPI reviews and post-introduction evaluations, or new/modified mechanisms such as an expanded readiness requirement that includes, for example, monitoring and evaluation and social mobilization.

- More frequent communication and follow-up to ensure the country is fixing not only temporal issues such as those addressed through the PCV10 readiness assessment, but putting in place processes and problem-solving approaches to address complex systemic challenges.
- Using HSS support or other streams of support more explicitly to strengthen central-level management capacity to plan and coordinate new vaccine introductions.
- Strengthen practical management approaches, tools, and processes for identifying potential risks and managing critical milestones for national EPI program managers and countries to deploy.

Relevance for programmatic readiness:

It is important to shift from the perception that the readiness process is a one-time hurdle to overcome to understanding readiness assessment as ongoing and integral to the process of vaccine introduction and the immunization system as a whole. This shift in understanding also suggests a re-examination of whether the current readiness criteria meet the purpose of ensuring safe vaccine use. For example, our case studies revealed weakness of the post-launch monitoring system across countries, which is critical to ensure vaccine safety.

Recommendation 5: Ensure timely and sufficient operational funding for vaccine introductions, which includes: ensuring VIG disbursed on time and ensuring sufficient contingent funding sources are identified.

This major finding from the cross-country analysis related to the importance of the management of funding. Funding availability and timing was, not surprisingly, a critical driver to ensure the other vaccine introduction processes flow. The fact that all three countries experienced a delay in the VIG disbursement, needed contingency funding, and struggled to fill in funding gaps indicates that the current process of planning, budgeting, and executing funds is suboptimal. Although there were positive contributions from in-country partners to fill funding gaps, contingency funding was never sufficient to completely bridge the gaps, and the process of identifying contingency funding further delayed and fragmented the implementation of introduction activities. A future priority of the GAVI FCE team is to investigate in more depth the causes of delays in the VIG disbursement. Additionally, the FCE will explore where the breakdown in a country's financial management process occur, including in instances where: countries intentionally or unintentionally under-budget for introduction activities, countries do not plan for contingencies, or GAVI's VIG calculation is not sufficient. While our study will pay close attention to the future planning and budgeting by countries, we suggest GAVI and its partners review their internal process for disbursing the VIG as well as the contingency financial plans across a broader set of countries to understand if and how risk is assessed and whether it is adequately addressed. This kind of review would inform the more specific practices that GAVI can support in this area as well as explore whether a formal mechanism for contingent funding is something that would feasibly address

this challenge. At the country level, our recommendation is to reexamine the budget and financial assumptions and the steps in the preparation process, with the aim of identifying specific stage-gates that could be put in place for considering whether contingent funds should be more proactively

Relevance for programmatic readiness:

Addressing weakness identified through the readiness process might require additional financial and/or technical resources and could result in a delay in vaccine introduction. It is important to identify implications of failing to fulfill the readiness criteria and to develop a contingency plan to address them.

mobilized to address potential delays.

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