Gavi Full Country Evaluations

2016 Annual Dissemination Report

Mozambique Report

Acknowledgments

The Gavi Full Country Evaluations team would like to thank all immunization program partners (Ministries of Health, technical partners, Gavi Secretariat, and other stakeholders) in Bangladesh, Mozambique, Uganda, and Zambia, especially those individuals who participated in workshops, were involved in stakeholder consultations, and served as key informants. We thank the Ministries of Health for facilitating stakeholder consultations and workshops. We also acknowledge and thank the contribution of the Gavi Secretariat Monitoring and Evaluation team for providing critical feedback, advice, and guidance over the course of the evaluation.

Evaluation Team

This report presents findings from the 2016 Gavi Full Country Evaluations (FCE). It was prepared by the Institute for Health Metrics and Evaluation (IHME) at the University of Washington (UW) in collaboration with members of the FCE Team: icddr,b in Bangladesh; University of Eduardo Mondlane (UEM), Mozambique; Manhiça Health Research Centre (CISM), Mozambique; Health Alliance International (HAI), Mozambique; the Infectious Diseases Research Collaboration (IDRC), Uganda; the University of Zambia (UNZA), Zambia; and Program for Appropriate Technology in Health (PATH), United States.

Citation: Gavi Full Country Evaluations Team. *Gavi Full Country Evaluations: 2016 Dissemination Report, Mozambique*. Seattle, WA: IHME, 2017.

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Acronyms

BMGF	Bill & Melinda Gates Foundation
CHAI	Clinton Health Access Initiative
CIDA	Canadian International Development Agency
CMAM	Centro de Medicamentos e Artigos Médicos
DAF	Department of Administration and Finance
DAH	Development assistance for health
DPC	Directorate of Planning and Cooperation
DPT	Diphtheria, pertussis, tetanus
DSS	Demographic Surveillance System
EPI	Expanded Program on Immunization
EVM	Effective Vaccine Management
FCE	Full Country Evaluations
FDC	Foundation for Community
FGD	Focus group discussion
FMA	Financial management assessment
FMR	Financial management requirements
GAMR	Grant Application, Monitoring and Review
GBS	General budget support
GPEI	Global Polio Eradication Initiative
HAI	Health Alliance International
HMIS	Health management information system
HSS	Health system strengthening
ICC	Interagency Coordinating Committee
IDRC	Infectious Diseases Research Collaboration
IEC	Information, Education, and Communication
IHME	Institute for Health Metrics and Evaluation
IPD	Invasive pneumococcal disease
IPV	Inactivated polio vaccine
ISS	Immunization Support Services
JA	Joint Appraisal
KII	Key informant interview
M&E	Monitoring and evaluation
MOF	Ministry of Finance
MOH	Ministry of Health
MOU	Memorandum of understanding
MSD	Measles second dose
MVI	Multiple New Vaccine Introduction
NGO	Non-governmental organization
NIP	National Immunization Program
NITAG	National Immunization Technical Advisory Group
NUVI	New and Underutilized Vaccine Initiatives
NVI	New vaccine introductions
NVS	New vaccine support

PATH	Program for Appropriate Technology in Health
PCV	Pneumococcal conjugate vaccine
PEF	Partners' Engagement Framework
PIE	Post-introduction evaluation
RV	Rotavirus vaccine
SCM	Senior Country Manager
TA	Technical assistance
TOC	Theory of change
TOT	Training of trainers
TWG	Technical Working Group
UEM	University of Eduardo Mondlane
UNZA	University of Zambia
UW	University of Washington
VIG	Vaccine Introduction Grant
VTs	Vaccine serotypes

Introduction

The Gavi Full Country Evaluations (FCE) is a prospective study covering the period 2013–2016 with the aim of understanding and quantifying the barriers to and drivers of immunization program improvement, with emphasis on the contribution of Gavi, the Vaccine Alliance in four countries: Bangladesh, Mozambique, Uganda, and Zambia. This fourth annual dissemination report complements previous reports by providing key findings and recommendations for the 2016 evaluation period in the four FCE countries. The FCE encompasses all phases of Gavi support, from decisions to apply, application and approval, preparation, and implementation in each of the relevant streams of support. Table 1 summarizes the scope of the evaluation during the 2016 period. In addition to evaluating the various streams of support active in each of the FCE countries, we have addressed issues that impact Gavi support across streams. The latter issues include both established processes that impact all vaccine streams within the four countries, such as the Joint Appraisal (JA) and Partners' Engagement Framework (PEF), and broad organizational functions, such as the provision of technical assistance and promotion of sustainable EPI programs, that affect the extent of Gavi's current and future success.

Table 1: Overview of streams evaluated in each country*

Gavi Stream	Vaccine	Bangladesh	Mozambique	Uganda	Zambia
New Vaccine Introductions (NVI)	**Inactivated polio vaccine (IPV)**	Implementa-tion interrupted by global stockout	Post-introduction	Implementa-tion interrupted by global stockout	Potential introduction postponed until 2018
	Measles second dose (MSD)		Post-introduction		Post-introduction
	Measles-rubella (MR) vaccine				Preparation for introduction
	Meningitis A vaccine			Preparation for introduction; launch postponed until 2017	
	Rotavirus vaccine		Post-introduction	Launch postponed until 2017	Post-introduction

	Pneumococcal conjugate vaccine (PCV)	Post-introduction	Post-introduction	Post-introduction	Post-introduction
	Human papillomavirus (HPV) vaccine	Implementa-tion of demonstration project	Post-demonstra-tion project	Post-introduction	Preparation of application for national introduction
Campaigns	**Measles-rubella (MR) vaccine campaign**				Implementation and evaluation
Health System Strengthening (HSS)	**Health System Strengthening (HSS)**	Implementa-tion of HSS-2	Implementa-tion of HSS-2	Completion of HSS-1 and application for HSS-2	Preparation for HSS-2

**The Gavi FCE did not evaluate pentavalent vaccine delivery, since pentavalent vaccine had been established and routinized in these countries prior to the start of the FCE. That put pentavalent vaccine outside of the scope of the FCE.*

Methods

Evaluation components relevant to this report include:

- Development of priority themes used to guide data collection at the global and country levels;
- Process tracking based on document review, observation, and fact-checking interviews;
- Root-cause analysis to identify underlying causes of identified challenges and successes;
- In-depth analysis of the process using key informant interviews (KII);
- Analysis of Health Management Information Systems (HMIS) and EPI administrative data to understand the rollout of new vaccine introductions;
- A resource tracking study to generate estimates of national-level resource envelopes on immunization in Mozambique;
- Household surveys (HHS) on immunization coverage and related key indicators;
- Analysis of dried blood spots (DBS) (samples were taken in a random subset of HHS participants) to measure immunity in vaccinated children (Annex 4);
- Constraints analysis to examine linkages between HFS, HHS, and DBS and utilize all primary data in tandem (Annex 3);
- Analysis of primary and secondary data to generate small area estimates of vaccine coverage, other maternal and child health indicators, and child mortality at subnational levels (Annexes 5 and 6);

- Causal analysis of small area estimates of vaccine coverage and child mortality to estimate the relationship between new vaccine introductions and child mortality (Annex 7); and
- Vaccine effectiveness studies, including pre- and post-introduction nasopharyngeal carriage surveys, case-control studies and time series analyses of surveillance data on invasive pneumococcal disease and X ray-confirmed pneumonia.

Strengths and limitations of the Gavi FCE approach are summarized in Table 2.

Table 2: Strengths and limitations of the Gavi FCE approach

Strengths
• Mixed-method approach allows for triangulation of findings across evaluation components to increase robustness of findings and provide more in-depth understanding. Findings from one data source also inform the design and implementation of other data collection. • Concurrent evaluation of all relevant streams of Gavi support in a country allows for timely understanding of the interactions between streams of support. • Evaluations such as Post-Introduction Evaluations (PIEs), monitoring and evaluation of HPV vaccine demonstration projects, or HSS monitoring and evaluation focus on the implementation phase. The Gavi FCE complements these by examining the full process from decision-making to application, preparation, implementation, and routinization, and allows identification and linkage of issues earlier in the process with downstream consequences. • Data collection designed to build on or complement other surveys and activities minimizes duplication. • Prospective approach allows for collection of information in real time so that key issues may be identified as they arise, allowing for the opportunity to inform implementation process and implement corrective action.
Limitations
• Due to the wide scope of the FCE, there is a limited ability to examine all issues in detail. However, the broad scope compels selective and more in-depth evaluation of critical issues that are priority areas for Gavi and countries. • Limited ability to prospectively collect information on larger-scale political-economic and social processes (e.g., priority-setting at the donor level; social displacement and migration at the country level) that affect immunization activities but fall outside the analytical scope of the process tracking of defined milestones. • Although there is a better ability to access informal channels of communication and decision-making, there are limits to this which result in an incomplete understanding of the process. • Absence of a prospective observation mechanism at the regional or global level and at subnational levels.

- In-depth qualitative data collection relies heavily on KIIs that are prone to recall and respondent bias.
- In each country there are a limited number of stakeholders involved across multiple streams, introducing significant potential for respondent fatigue in KIIs.
- The timing of surveys means that the evaluation is only able to capture relevant aspects of some, but not all, Gavi support streams.
- Secondary data analyses are subject to the availability and quality of the underlying data source (e.g., HMIS, surveys).

Summary of findings and recommendations

For each cross-country and country-specific finding described above, we developed related recommendation(s). In Table 3: Findings and recommendations, we noted the intended audience for the recommendation as well as the FCE team's assessment of generalizability based on other studies and information at hand. For brevity, we have not included the country-specific recommendations in this table, but include them at the end of each of the country-specific sections.

Table 3: Findings and recommendations

Finding	Recommendations
Multiple New Vaccine Introduction (MVI): rotavirus vaccine (RV), IPV, and MSD	
Finding 1: In 2016, the routinization of MSD has improved but remains suboptimal.	1. Rather than await the National Immunization Program (NIP) manual to be updated as the only reference material for health workers when a new vaccine is introduced, short and succinct vaccine-specific reference materials should be provided for health workers and these should be factored into the VIG budget. 2. NIP and partners should ensure that supervision for new vaccine introduction occurs within three to six months of the launch of a new vaccine. 3. In order to clarify the MSD target age group (18 to 24 months) and disseminate new strategies to improve MSD-seeking behavior, the NIP should provide a refresher training to immunization health workers, ideally embedded with in the upcoming MR training.

Finding 2. In 2016, stockouts of new vaccines impeded fast routinization of IPV and RV.	1. MOH/NIP should identify and resolve the customs-related problems that led to procurement delays for the 2016 vaccines. Additionally, beyond addressing these immediate issues, MOH should implement the Effective Vaccine Management (EVM) recommendation to set up MOUs with customs and MOH clearing agents. 2. Gavi and the GPEI should ensure that the global supply of IPV is guaranteed for countries where it has already been introduced.
Health system strengthening	
Finding 1: An initial nine-month in-country delay in accessing funds led to the late initiation of HSS grant implementation. However, MOH then prioritized and accelerated implementation in the months following.	1. NIP should adhere to DPC and MEF budget planning cycle deadlines and submit necessary activity plans and request documents on time. 2. Gavi should aim to align with government fiscal cycles when disbursing cash grants to countries. 3. NIP should consider the option of a no-cost extension (NCE) application in 2019 to make up for lost time caused by the delay in accessing funds. In order to ensure that the NCE application is timely, the NIP should begin preparations and negotiations with Gavi in 2018. Gavi policy should have the flexibility of accepting NCE preparations and negotiations earlier than the last year, after careful monitoring of the progress through JA and other reports.
Finding 2: HSS implementation is progressing with a boost in vaccination services for hard-to-reach populations, but without taking into account the prioritization stated in the approved application.	NIP and partners should consider redefining or clarifying the criteria for prioritization of allocation of HSS funds to the provinces. For example, NIP and partners could analyze vaccine coverage data from the most recently available household survey (IMASIDA) to see if provinces with lower coverage are still the same and possibly consider a cross-analysis with district HMSI data to better allocate HSS resources for mobile brigades and REC/RED strategies.
Cross-stream analysis	

Finding 1: Improvement in JA and related Gavi processes leads to stronger alignment between NIP and partners on the thematic areas that should be focused on in order to improve Gavi grants' performance.	An NIP Technical Working Group (TWG) sub-group dedicated to JA preparations should be identified to lead preparations prior to JA week, as well as facilitation of the pre-formal workshop discussions.
Finding 2: Technical assistance (TA)/PEF/TCA processes result in transparency and nascence of accountability of Gavi TA.	1. In order to support the in-country PEF-TCA milestone monitoring that the NIP and partners are performing, Gavi should develop contractual mechanisms that guarantee that PEF-TCA commitments are honored. 2. Gavi should guarantee the timely signing of contracts and disbursement of funds to Mozambique PEF partners. 3. MOH/NIP should operationalize the approved MOH TA Terms of Reference (TOR) framework in order to ensure that embedded TA through the TCA mechanism build capacity in the program.
Finding 3: Actions to ensure sustainability have begun. However, the broader macroeconomic crisis currently affecting the country may jeopardize progress toward long term sustainability.	1. Rather than await the MOH sector-wide health sector financing strategy development, the NIP, together with the tasked TCA partner WHO, should develop terms of reference for the country's actions for future sustainability of Gavi products. These should subsequently inform the health sector financing strategy.

Contents

Summary of Gavi support for country

The Mozambique Expanded Program on Immunization (EPI) was launched in 1979 under the Primary Health Care Program. Over the past 15 years, Gavi has disbursed a total of $US 135 million to Mozambique to support vaccination efforts through the EPI. Gavi support in Mozambique began in 2001 with Immunization Support Services (ISS) furthering New Vaccine Support (NVS) disbursements preceding the introduction of tetra-diphtheria, pertussis, and tetanus (DPT)-hep B. This support has been available through the ISS grant, though this stream of funding ended in 2012. Most recently, Gavi supported the introduction of PCV in 2013. Rotavirus vaccine (RV), measles second dose (MSD) vaccine, and inactivated polio vaccine (IPV) were launched in 2015 with support from Gavi. In 2016, Mozambique continued the implementation of HSS and submitted a proposal for Gavi support of measles-rubella vaccine.

Table 4: Overview of Gavi support in country

Gavi support	Period of funding	Total amount of funding ($US)
Immunization services support (ISS)	2001–2003, 2011	1,665,500
Injection safety support (INS)	2003–2005	835,881
Tetra DPT-Hep B (NVS)	2001–2007	16,897,320
Pentavalent vaccine (NVS)	2009–2017	46,627,780
Pneumococcal conjugate vaccine (NVS)	2013–2017	75,214,231
HPV demo (NVS)	2014	56,503
Health system strengthening (HSS)	2014–2018	25,041,767
Rotavirus vaccine (NVS)	2015–2018	16,426,652
Measles second dose (NVS)	2015–2018	1,688,000
Inactivated polio vaccine (NVS)	2015–2017	5,190,562

Source: http://www.gavi.org/country/all-countries-commitments-and-disbursements, accessed last November 21, 2016. Values shown represent Gavi commitments, those which Gavi intends to fund over the lifespan of the program, subject to performance and availability of funds.

Methods overview

In 2016 the FCE global team, in consultation with countries, selected priority research questions, based on the Gavi streams that each country was implementing, as well as the main FCE evaluation questions that would guide the FCE. For Mozambique, these were the routinization of all four new vaccines introduced between 2013 and 2015, implementation of the HSS grant, and Gavi processes such as JA, high level review panel, and PEF-TCA. Using these criteria, 12 questions were selected from the list of 30

questions for all countries. These were then shared with Mozambique in-country MOH stakeholders, including the NIP and the National Directorate of Public Health, for their input. Using their input, the list was narrowed to the six research questions listed below.

1. To what extent have the four new vaccines (PCV, RV, IPV, and MSD) introduced between 2013 and 2015 been routinized? What are the enabling factors and challenges for routinization at national and provincial levels?
2. How is Mozambique implementing the Gavi HSS project? What are the enabling factors and challenges at national and provincial levels?
3. Has the PEF process (planning and implementing JA, HLRP, PEF allocations, etc.) improved as compared to 2015?
4. How is immunization TA implemented in Mozambique? How has PEF changed the composition and structure of TA in Mozambique?
5. What are the current fiscal resources for EPI? What proportion comes from government compared to external sources? What has been the change over time?
6. Is the country taking any steps to prepare for sustainability of products funded by Gavi? If yes, what are they?

An overview of all major study components is described in Table 5.

Table 5: Evaluation methods

Methods	Source consulted/study area	Topics investigated
Process tracking	– Documents reviewed: MVI (RV, IPV, and MSD) training and social mobilization materials, 2016 vaccine logistics and supply data, HSS year 1 plans and monthly updated plan, HSS provinces and central budget execution data, HSS implementation monitoring template, HSS review meeting presentations and documents, DAF financial management manual, Mozambique Government Supply Unit (UGEA) guideline, provincial NIP monthly reports, comprehensive EPI review report, 2015 EVM report, JA presentations, 2015 & 2016 JA reports, 2016 PEF TCA list, NIP TWG PEF milestone document,	2016 Mozambique FCE research questions: - To what extent have the four new vaccines (PCV, RV, IPV and MSD) introduced between 2013 and 2015 been routinized? What are the enabling factors and challenges for routinization at national and provincial levels? - How is Mozambique implementing the Gavi HSS project? What are the enabling factors and challenges at national and provincial levels?

	proposed 2017 TCA list, Gavi guidance for 2016–2017 PEF process, MOH TA regulation document, several newspaper articles (on Mozambique macroeconomic situation), Netherlands donor letter to MOH, Gavi FCE program manager presentations, Gavi DAF Financial TA TORs, MR proposal, correspondences between NIP and Gavi, Gavi fragile states policy. – Participative observation events: 14 NIP TWG, 1 Interagency Coordinating Committee (ICC), 2 National Immunization Technical Advisory Group (NITAG) meetings; trivalent oral polio vaccine-bivalent oral polio vaccine (tOPV-bOPV) switch, RED/REC training; NIP review, MVI PIE (integrated within NIP review), JA, Logistic Workshop, National HSS review meeting.	- Has the PEF process (planning and implementing JA, HLRP, PEF allocations, etc.) improved as compared to 2015? How is immunization TA implemented in Mozambique? How has PEF changed the composition and structure of TA in Mozambique? - What are the current fiscal resources for EPI? What proportion comes from government compared to external sources? What has been the change over time? - Is the country taking any steps to prepare for sustainability of products funded by Gavi? If yes, what are they?
Key informant interviews	– 29 KIIs: 18 national level; 4 MOH, 4 NIP, 3 UNICEF, 1 WHO, 2 VillageReach, 2 USAID, 1 CHAI, 1 CMAM. – 11 provincial level (2 provinces); 9 district level (4 districts) and 10 health facility (HF) level (4 HFs). – 8 fact-check interviews (FCIs) at national level (1 UNICEF, 1 MEF, 1 DPC, 1 DAF, 5 EPI/MOH).	
Resource Tracking	- Administered survey questionnaires for quantitative and qualitative data to the MOH NIP and four	-

		national-level NIP partners, including two multilaterals (UNICEF and WHO), one bilateral (USAID), and two NGOs (VillageReach and CHAI). Also interviewed were the medical head, financial and NIP program managers from two provinces and four districts (10 informants).		
Small area analysis	-	Compiled and analyzed all available household survey and census data sources.	-	Estimation of national, divisional, district, and sub-district vaccine coverage and under-5 mortality.
Inequality analysis	-	Compiled and analyzed all available survey data sources with information on household wealth and vaccination coverage.	-	Estimation of vaccine coverage differences by wealth quintile and sex.

Findings

The FCE compiled and systematically analyzed relevant data to estimate country performance along key indicators at the national level and, when possible, the subnational level.

Table 6: Country characteristics of Mozambique

Characteristic	
Demographic and economic indicators	
Total population (2015)	28,751,302
Birth cohort (2013)	1,104,644
Gross National Income (GNI) per capita (2015)*	$US 590.0M
Health spending and development assistance for health (DAH)**	
Government health expenditure as source (GHE-S)	$US 269.2M
DAH, channeled through government (DAH-G)	$US 225.6M
DAH, channeled through non-government entities (DAH-NG)	$US 447.1M
Total DAH	$US 672.7M

*GNI per capita source: World Bank World Development Indicators, 2015.

**Health expenditure is explained in terms of GHE-S, DAH-G, and DAH-NG. GHE-S + DAH-G gives the total government health expenditure, GHE-S + Total DAH gives total spending on health in the country. Institute for Health Metrics and Evaluation (IHME). *Financing Global Health 2015: Development assistance steady on the path to new Global Goals*. Seattle, WA: IHME, 2016. Unit is 2013 USD.

Table 7: Vaccine coverage estimates in Mozambique

Vaccine coverage	Most recent survey estimate*	WUENIC 2014 revision**	Self-reported coverage (WHO)***
DPT/Penta3 coverage	82%	78%	88%
DPT1-DPT3 dropout rate	9%	15%	5%
BCG coverage	93%	93%	94%
Polio3 coverage	73%	78%	88%
Measles coverage	83%	85%	85%
Percent fully vaccinated****	66%	N/A	N/A

* Most recent survey coverage estimates from 2015 National Survey on Immunization, Malaria and HIV indicators (IMASIDA)
** WHO/UNICEF Estimates of National Immunization Coverage (WUENIC) 2014
***WHO vaccine-preventable diseases monitoring system, 2014 global summary
**** BCG, measles, and three doses each of DPT and polio vaccine (excluding polio vaccine given at birth)

Table 8: Child, adult, and vaccine-preventable disease mortality in Mozambique

Child, adult, and vaccine-preventable disease mortality	GBD 2013*
All-cause mortality (deaths per 1,000)	Estimate (uncertainty interval)
Infant mortality ($_1q_0$)	60.1 (50.2, 70.2)
Under-5 mortality ($_5q_0$)	88.4 (76.9, 101.5)
Female adult mortality ($_{45}q_{15}$)	367.2 (344.8, 390.9)
Male adult mortality ($_{45}q_{15}$)	454.3 (423.8, 486.0)
Cause-specific mortality: children under 5 (deaths per 100,000)	
Measles	18.2 (4.4, 53.5)
Diphtheria	0.5 (0.0, 2.9)
Tetanus	6.1 (3.4, 10.8)
Pertussis	11.4 (0.0, 60.0)
Meningococcal infection	5.0 (2.8, 8.1)
Diarrheal disease	107.5 (60.9, 175.0)
Lower respiratory infections	198.9 (134.3, 273.7)
Cause-specific mortality: all ages (deaths per 100,000)	
Cervix uteri cancer	3.3 (2.5, 4.5)
Acute hepatitis B	0.6 (0.4, 0.8)
Cirrhosis of the liver secondary to hepatitis B	2.5 (1.6, 3.6)
Liver cancer secondary to hepatitis B	0.8 (0.5, 1.1)

* Mortality based on Global Burden of Disease (GBD) 2013 estimates

Figure 1: Timeline of major immunization events in Mozambique

		PLANNED	ACTUAL
2015	JAN	Weekly joint MVI (IPV, MSD, RV) preparation meetings initiated	✓
	FEB	Training of health workers, teachers, and community leaders on HPV social mobilization	✓
	MAR	HPV Implementation report including evaluation results submitted to Gavi	✓
	APR	First dose HPV vaccine implementation	✓
		National MVI joint Training of Trainers (TOT)	✓
	MAY	Effective Vaccine Management (EVM) evaluation	✓
	JUN	Installation of cold chambers at national vaccine warehouse	JUL 2015
		IPV arrived in country	JUL 2015
		Rotavirus vaccine arrived in country	AUG 2015
		MVI social mobilization activities initiated	NOV 2015
		MVI social mobilization activities initiated	AUG 2015
		Joint MVI subnational training of health workers	AUG 2015
	JUL	First HSS disbursement made by Gavi	✓
		Official start date for HSS	✓
		Joint Appraisal	✓
		Gavi officially informed country on HSS disbursement	AUG 2015
		IPV Launch (joint with Rota)	NOV 2015
		Rotavirus Launch (joint with IPV)	SEP 2015
	AUG		
	SEP	MOH officially requested inscription of HSS funds into the government electronic accounting system	✓
	OCT	Second dose HPV demo implemented	✓
		MSD launch	NOV 2015
	NOV	Two-day pre-HSS implementation meeting with provincial NIP focal points	✓
	DEC	Arrival of PCV, RV and IPV 2016 1st Trimester consignments	APR 2016 (PCV/RV); MAY 2016 (IPV)
2016	JAN	HSS funds become available in e-SISTAFE	APR 2016
		Initiation of central and provincial level HSS activities	MAY 2016
	FEB		
	MAR	Arrival of IPV 2016 2nd Trimester consignments	AUG 2016
	APR	IMF announcement of Mozambique debt problem and aid suspension. Aid suspension by government donors including Prosaude (MOH common fund).	✓
		Switch from tOPV to bOPV	✓
		Arrival of HSS motorcycles and trucks and beginning of customs process	✓
	MAY	National support supervision visits	Delayed until 2017
	JUN	National NIP supportive supervision visits to provinces for HSS implementation	✓
		Arrival of IPV 2016 3rd Trimester consignments	NOV 2016
	JUL	Mozambique government budget revision (unplanned)	✓
		EPI review	AUG 2016
		MVI PIE (integrated within EPI review)	AUG 2016
	AUG	TCA milestone review (during JA)	✓
		Joint Appraisal	✓
	SEP	Arrival of IPV 2016 4th Trimester consignments	Delayed until 2017
		Measles Rubella proposal submitted to Gavi	✓
	OCT	TCA milestone review (during TCA specific NIP TWG meeting)	✓
		Finalization of 2017 TCA table	✓
	NOV	National HSS review meeting	✓
	DEC		

Support streams evaluated
- Pneumococcal conjugate vaccine (PCV)
- Health System Strengthening (HSS)
- Human papillomavirus vaccine (HPV)
- Inactivated polio vaccine (IPV)
- Rotavirus vaccine
- Measles second dose (MSD)
- Other

✓ Implemented as planned/no delay
Delay

Funding stream: Multiple New Vaccine Introductions (MVI): rotavirus vaccine (RV), IPV and MSD

This section is a response to the following Mozambique FCE 2016 research question: To what extent have the four new vaccines (PCV, RV, IPV, and MSD) introduced between 2013 and 2015 been routinized? What are the enabling factors and challenges for routinization at national and provincial levels?

Mozambique introduced pneumococcal conjugate vaccine (PCV) in April 2013, and rotavirus vaccine (RV), measles second dose (MSD), and injectable polio vaccine (IPV) in 2015. RV (Rotarix®) was officially launched on September 4, 2015, and IPV and MSD were launched jointly on November 27, 2015. All four vaccine introductions were nationwide.

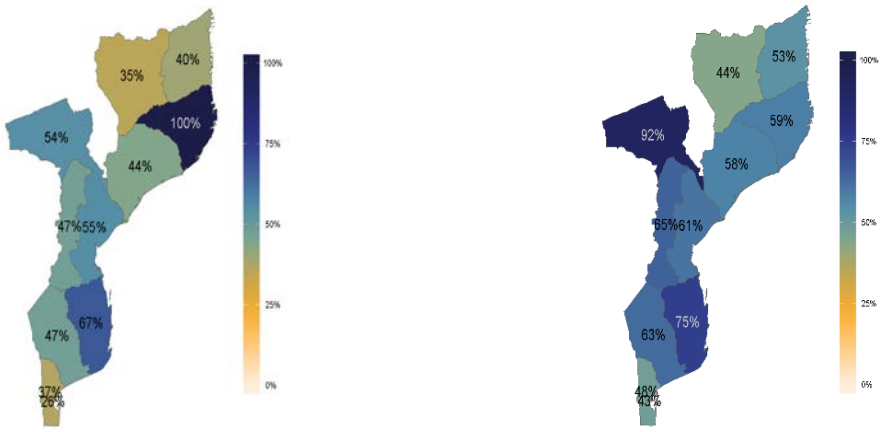
An MVI Post Introduction Evaluation (PIE) (integrated into the EPI review) was conducted in August 2016. Given these events, the country is at stage "k" of the FCE New and Underutilized Vaccine Initiatives (NUVI) Theory of Change (TOC) (Milestone "k": Successful integration of the vaccine into routine delivery). The details of progress within key TOC milestones is presented in Annex A.

The MSD target age group of 18–24 months is completely different from the usual NIP routine childhood immunization schedule that targets infants aged up to 12 months, and as such, it is a novel Mozambique NIP routine immunization target age group. This peculiarity of MSD compared to the other two new vaccines (RV and IPV) introduced in 2015 is the driver of the low coverage depicted in MVI finding 1 below.

Finding 1

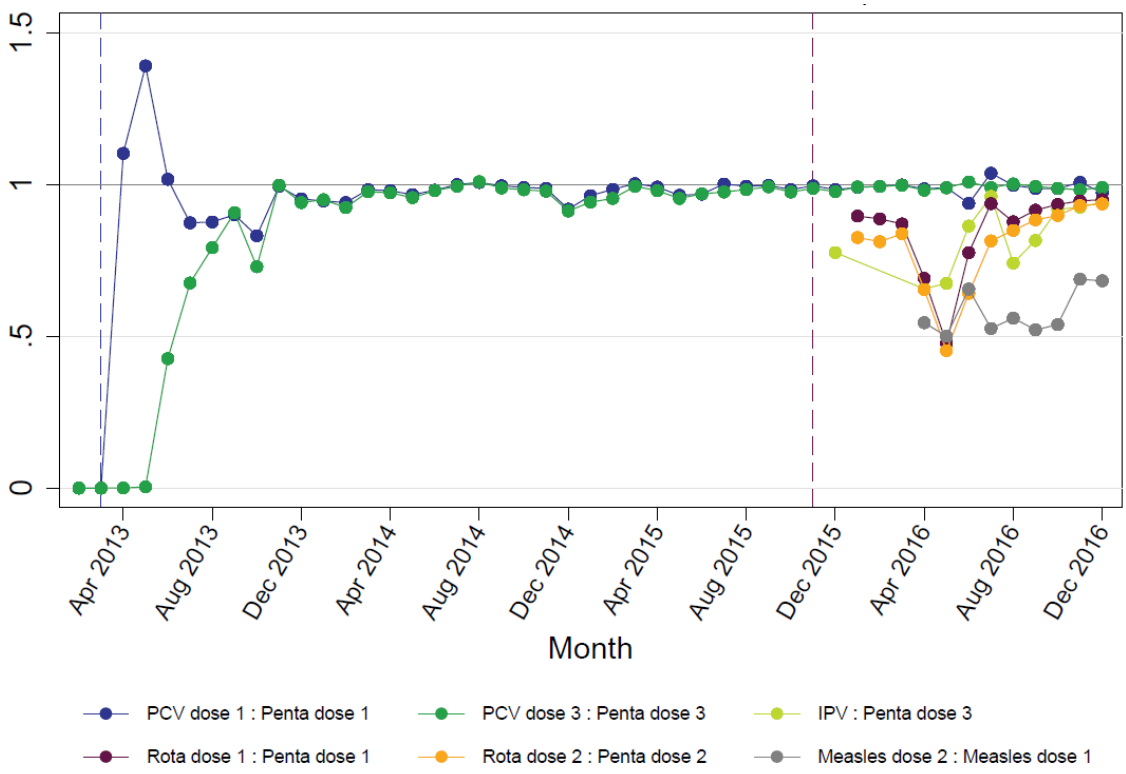
In 2016, the routinization of MSD has improved but remains suboptimal.

Figure 2: MSD coverage by province, 1st and 2nd semester 2016



1st semester 2016 2nd semester 2016

Figure 3: Routinization of MSD vaccine, 2016



The KIIs carried out by the FCE team and the MVI PIE both point to the reason for the suboptimal MSD coverage: the low awareness of mothers/caregivers of the need to bring children back for vaccination after the age of 12 months, the age that the Mozambique NIP routine immunization schedule had targeted until 2015. The root cause for this observed lack of awareness in the community was two-pronged. First, the social mobilization conducted before the official launch was deemed insufficient. Social mobilization was conducted jointly for the two vaccines (IPV and MSD) that were being launched at the same time. However, they targeted different age groups. IPV is administered to infants aged between two and six months, while measles second dose targets children aged between 18 and 24 months. During this joint launch, the disseminated message was not adequately tailored to appropriately inform mothers/caregivers of the need to bring children back for the second measles dose a year after receiving the first measles dose. The 2015 FCE social mobilization messages analysis concluded that the written IEC materials distributed to the community emphasized the benefits of measles vaccines in preventing measles disease, but did not detail the age range at which mothers/caregivers should take children to health facilities for the vaccine.

An additional problem was that message dissemination began only one week prior to the launch instead of the planned one month ahead. KIIs highlighted the fact that since the measles second dose age group was a novel target for vaccinations in Mozambique, adherence to it requires a community behavior change. For this to happen, a social mobilization strategy different from the one previously used for vaccines that targeted age groups that the community was familiar with is needed.

> *Previously it was nine months of age and a stamp was given and at least for the vaccine the mother did not have to return. She could come back for other reasons; now she has to come back*

at 18 months to get the vaccine [for the child], so we think they are still not very familiar and probably we made some errors in social mobilization. We did social mobilization through the media, posters, radio spots and even informing health professionals; but perhaps we should have had social mobilization for longer in order for them to incorporate this information and for it to become a habit, so I think this was one of the main factors. (NIP KII)

The NIP agrees with this finding and has stated that a new MSD social mobilization strategy is being formulated which will be integrated into the larger NIP communication strategy currently under development. Radio and TV spots and messages transmitted prior to the launch will be revised.

Yes, we have already started, we are in the process of revising the spot that was transmitted at the time. We are also in the process of reviewing the messages, and we have also spoken with the provinces to reinforce this information, especially at community meetings and in health facility lectures, on the need of the child to return at 18 months to do the vaccination. (NIP KII)

A contributory factor to the observed low MSD coverage is related to health workers' knowledge of the age group range for the second measles dose. During FCE provincial visits it was noted that workers in health facilities knew only 18 months as the target age group rather than the range, which is between 18 and 24 months. For this reason, they were failing to adequately mobilize all the children that should benefit from the administration of MSD. FCE in-depth investigation identified two root causes for this health worker knowledge challenge. First, MSD health worker training materials only identified the 18-month target age rather than the 18-24-month age range. Secondly, the NIP manual that is the usual reference document for health workers to consult on vaccinations in Mozambique **has not been updated since 2009** and as such does not contain information on all the new vaccines that have been introduced since 2013. Job aids that contain vaccine-specific information are not provided for health workers to consult during NVIs. The MVI PIE also recorded similar findings on health worker knowledge on MSD target age group and the lack of vaccine-specific health worker job aids during NVIs. (Note: the NIP manual is planned to be revised using Gavi HSS year-1 funds. However, this is currently one of the HSS year-1 plan activities that is delayed and has been postponed to 2017.)

We were basing ourselves on the principle that once the training was done the workers were prepared to administer the vaccines. In fact, if this was a PIE finding, I think it is a matter about which we will have to rethink and see how to make these job aids available so that they are available in the health facilities. I think we have never had such job aids available on vaccination in the health facilities, but I think it's a point that we'll take into consideration if in fact they feel the lack of this information. (NIP KII)

Additionally, there was no national-level supportive supervision accompanying the introduction of the new vaccines despite the fact that is was included in planning documents and it was also included in the budget. This is attributed to the whole NIP team being engaged in the tOPV-bOPV switch preparation activities during the first quarter of 2016, immediately following the MSD introduction.

Supervision visits were scheduled but in the end they were not undertaken. In my opinion the main reasons were the major activities that we in the country were undertaking. The main one was the tOPV-bOPV switch that all of us were involved in the first quarter. (Partner KII)

Recommendations

1. Rather than await the NIP manual to be updated as the only reference material for health workers when a new vaccine is introduced, short and succinct vaccine-specific reference materials should be provided for health workers and these should be factored into the VIG budget.
2. NIP and partners should ensure that supervision for new vaccine introduction occurs within three to six months of the launch of a new vaccine.
3. In order to clarify the MSD target age group (18 to 24 months) and disseminate new strategies to improve MSD-seeking behavior, the NIP should provide a refresher training to immunization health workers, ideally embedded with in the upcoming MR training.

Robustness of finding

Finding 1	Ranking	Robustness criteria
In 2016, the routinization of MSD has improved but remains suboptimal.	A	The robustness of findings for the evidence around this conclusion is A, because it is supported by strong data triangulation from documents review, participant observation, and KII.

Finding 2

In 2016, stockouts of new vaccines impeded fast routinization of IPV and RV.

Figure 4: Routinization of rotavirus vaccine (RV), Mozambique, 2015–2016

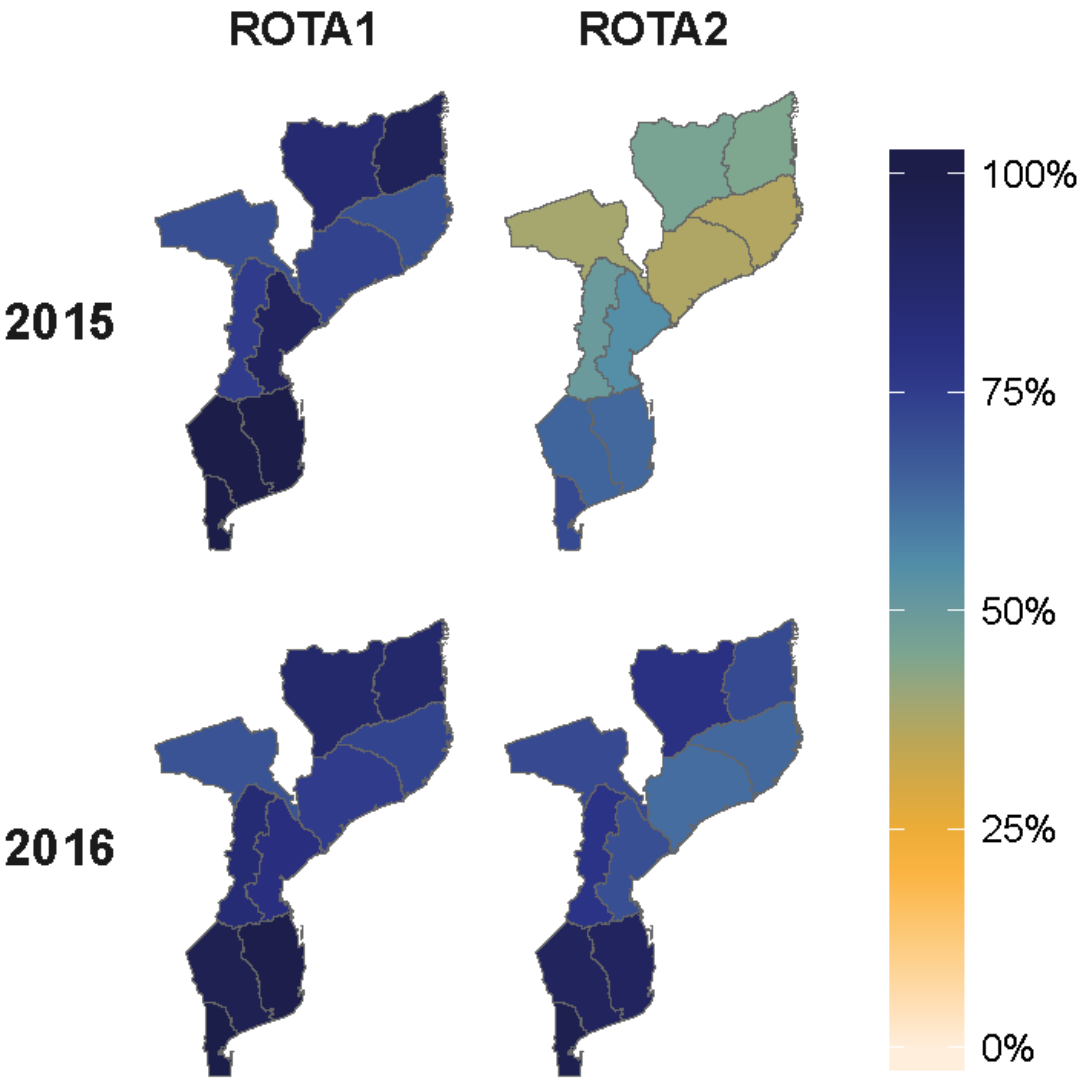
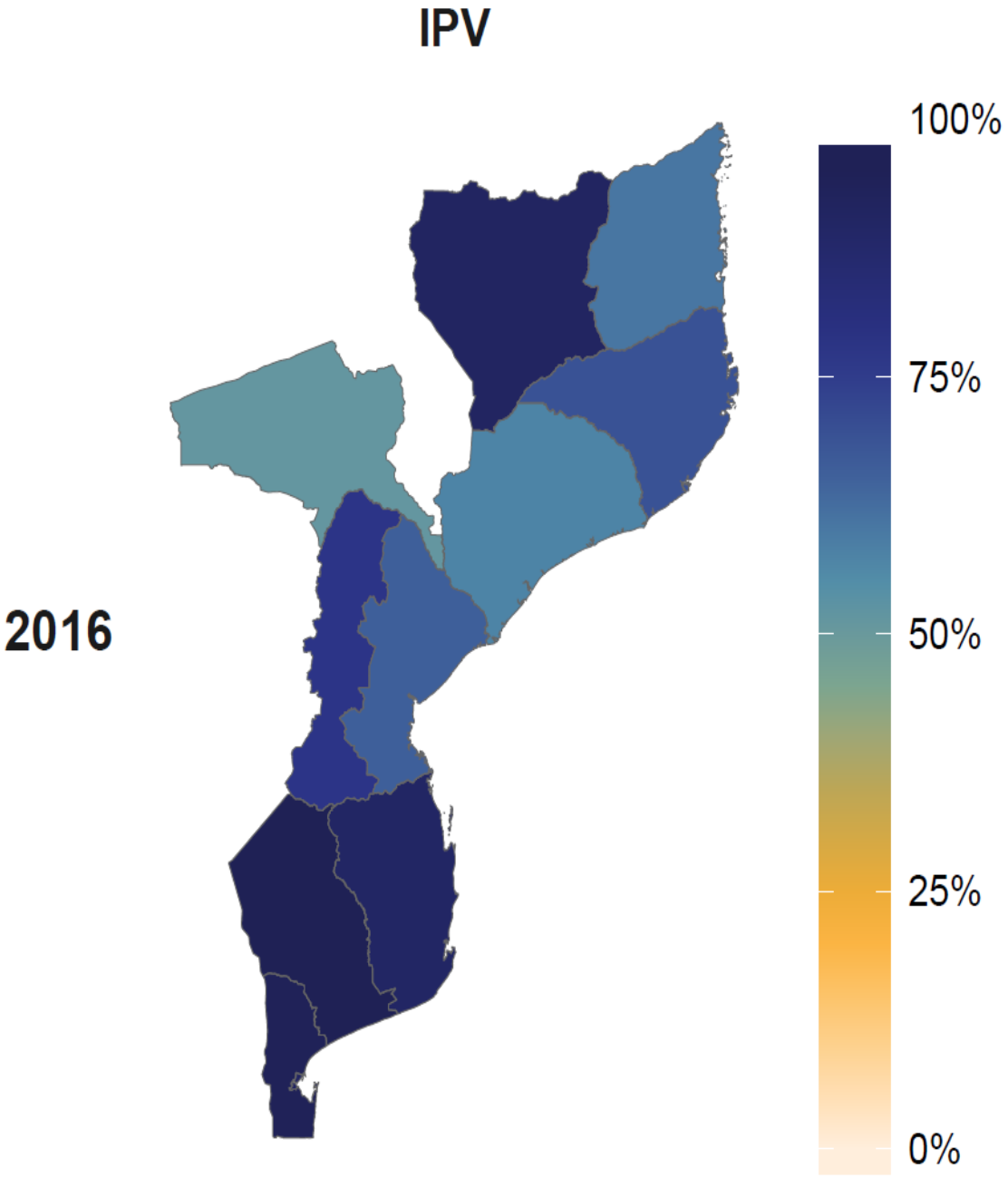


Figure 5: Routinization of IPV, Mozambique, 2016



The major factor causing the stockout problem was the late arrival of the first-quarter vaccine consignments in April (RV and PCV) and May (IPV) 2016 instead of the planned December 2015 date. The delay in arrival of these consignments was mainly attributed to customs clearance challenges which protracted the procurement process. The customs process, which is managed by the national central medical stores (Centro de Medicamentos e Artigos Medicos, CMAM), is compromised by two underlying issues that are documented in the 2015 EVM:

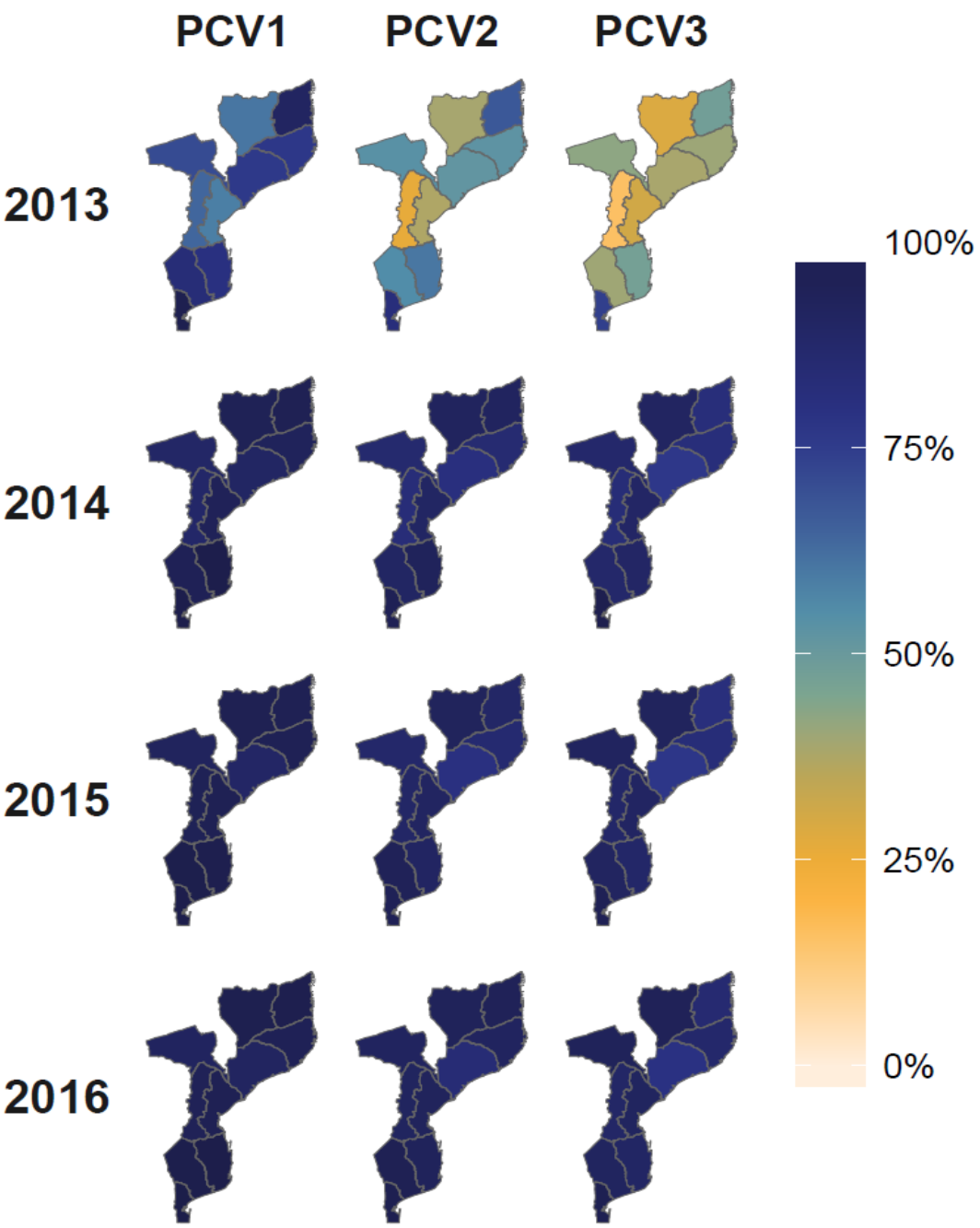
1. A lack of two key MOUs (between MOH and customs, and between MOH and clearing agents)
2. A lack of a written contingency plan in the case of delays

FCE in-depth interviews found that the lack of these EVM-identified frameworks were the key cause of these 2015 procurement delays.

More exploration need to be done to understand the root causes of delays in procurement done by partners, which could contribute to the stockouts.

Of note is that this stockout situation due to a delayed procurement process affected some non-Gavi vaccines too, namely BCG and anti-Tetanus. While PCV suffered delays in arrival of consignments at the national warehouse and stockouts in some provinces just like RV and IPV, its routinization did not suffer (Figure 6). This can be explained by the fact that PCV was already existent in the system and thus was cushioned by buffer stocks during the first quarter when suboptimal stocks were available in the country.

Figure 6: Routinization of PCV, Mozambique, 2013–2016



The stockout situation was experienced in the central and northern regions of the country. KIIs explained that this pattern of stockouts is primarily due to the inherent vaccine distribution problems. Distribution is one of the NIP 2015 EVM lowest-scoring components (49%, far below the targeted score of 80% and above). The principal root cause of the vaccine supply underperformance is the existence of just one national warehouse (located in Maputo city). This means that vaccines must be transported

long distances (1,000-2,500 km) for distribution to the central and northern provinces. While airfreight has been the main distribution mode, the local and only airline LAM (Linhas Áreas de Moçambique) has not been able to cope with the gradually increasing vaccine cargo with the introductions of four new vaccines over the last three years.

> *As you know we send the vaccines primarily by air. We have had challenges with LAM, and it is a well-known challenge that LAM does not have many flights to the provinces and we have very large volumes. When we send small volumes they were never enough for the needs of the provinces. For example, there are provinces that do not have daily flights. To carry out the whole logistics of sending the vaccine by air in such a situation where you do not have daily flights and also do not have much space is extremely difficult.* (NIP KII)

This situation is known in-country, and plans exist for the construction of central and northern regional warehouses (Logistic and Pharmaceutical Strategic Plan (PELF) and Gavi HSS plan). At present only warehouses are practically integrated between NIP and CMAM. However, the delays in Mozambique securing the Gavi HSS grant (as documented in detail in the 2015 FCE annual report) contributed to delays in the implementation of these plans. USAID HSS contingency funds have assisted in alleviating the vaccine distribution problems through the acquisition of two refrigerated trucks that are now used to distribute the vaccines to the central and northern regions. Nevertheless, the two trucks are insufficient for the required distribution needs. An additional two trucks have been acquired using Gavi HSS funds but are not yet in use due to a lack of funds to pay for the customs duty. (Further explanation on this is provided below in HSS Finding 3 describing the effects of Mozambique's macroeconomic challenges on HSS funds' implementation). USAID has also provided funds for the construction of the Nampula (northern region) warehouse that began in September 2016. Gavi HSS funds are planned to be used to refurbish the Beira (central region) warehouse in 2017. The southern region provinces collect vaccines from the national-level warehouse in Maputo city using their own transport means and thus are not affected by the vaccine distribution problems stated above.

> *But for example, the southern provinces were not affected by this situation, because these provinces come to collect the vaccines here, they may not have had a vaccine because the vaccine was unavailable at the central level, but when the vaccine became available, then they were more easily supplied, but in central and northern regions we had [stockouts].* (NIP KII)

> *What happens is that the provinces of the south are near the national warehouse. Even if there is a problem with a particular vaccine, when we receive it, we communicate to all provinces we already have the vaccine; for example, rotavirus is available, these provinces are ready to come and get it. This is not the case for the central and northern provinces that we send vaccines by air.* (NIP KII)

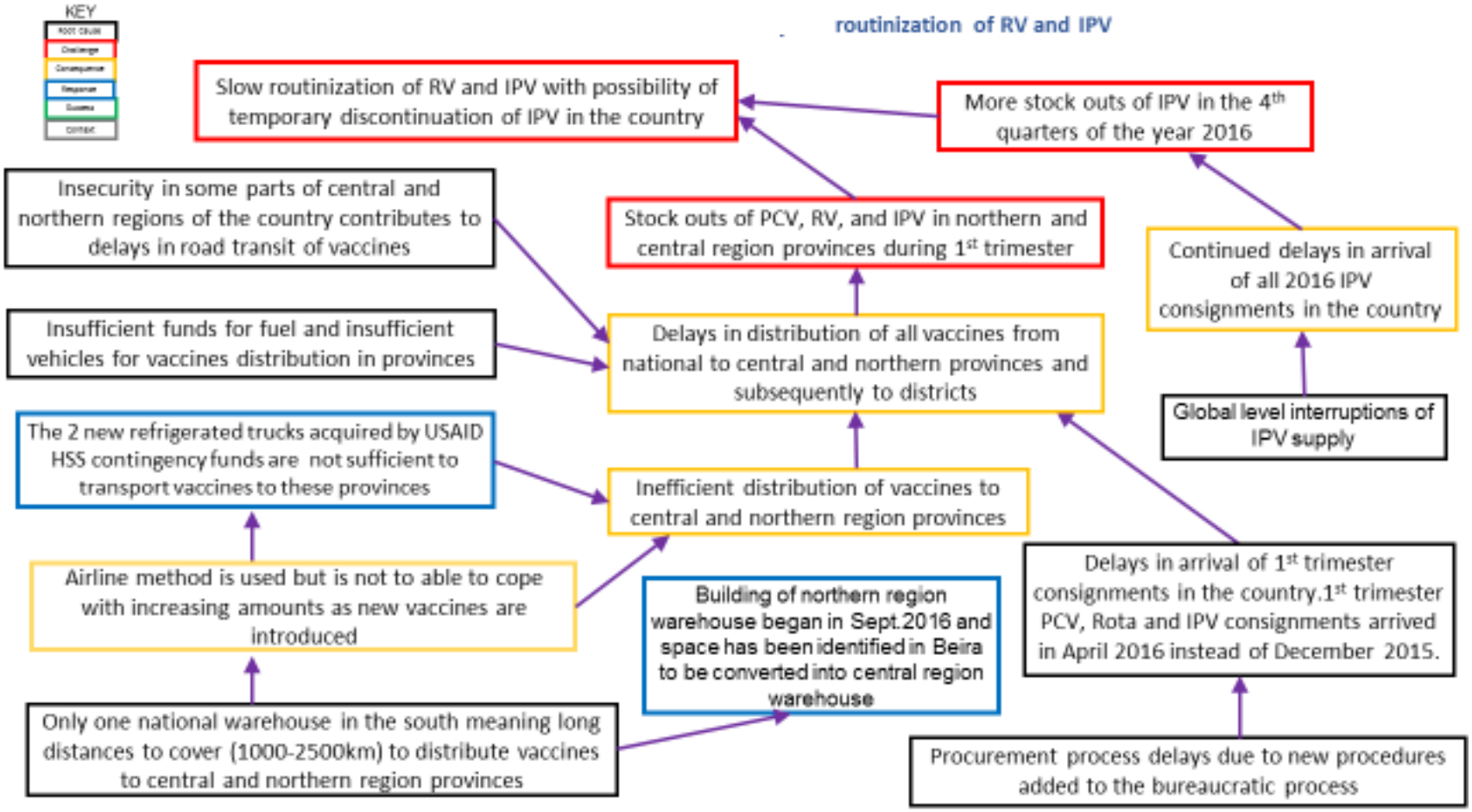
A contributing factor in 2016 was the political insecurity in some parts of the central and northern regions that has led to violent attacks on motorists and transporters on sections of the south-to-north Mozambican highway. Consequently, motorists and transporters have been forced to travel in convoys escorted by police. While the clearly labeled NIP vaccine transportation trucks have not suffered any attacks, these obstructions (due to the wait for the formation of the escorted convoys), cause delays and are contributing to the inefficiencies in vaccine distribution to the central and northern regions of the country.

> *In relation to this I am not in a position to give an exhaustive comment, but what we have observed is that for example when a truck leaves from here carrying vaccines, there are places where they have to make obligatory stops. They have to be escorted, and have to form part of a convoy. There are places where the escorted convoy happens once a day, if they get there and the convoy has already left, they have to wait until the next day. So this slows the [distribution] process.* (NIP KII)

After the first quarter, no further stockouts of RV, PCV, BCG, and anti-tetanus were experienced during the rest of 2016 because the expected quarterly vaccines consignments arrived on time to the country. The IPV situation was different, however, with stockouts being experienced in the fourth quarter of the year. The country received only six months' IPV consignments during 2016 (in May and August). The global supply shortage is the reason being given by KIIs for the non-availability of more vaccines for the last quarter of the year. During a mid-October NIP TWG meeting it was discussed that if the IPV global shortage situation continues, Mozambique may be forced to suspend IPV administration in the country until further notice. This is a worrisome situation given that Mozambique is a priority country for IPV and thus had not been expected to be affected by the global supply shortage. Initial discussion on fractional dose had taken place, but no formal decision has been made on a possible implementation at the time of report writing. During the last NITAG meeting in November, the suggestion was given to discuss in the next meeting.

> *For IPV, there is a global problem of the availability of IPV vaccine. It is true that when we were informed of the existence of this global problem, we were also informed that Mozambique would be one of the priority countries so it would not be affected much, but there were consistent delays in the arrival of the vaccine, and that influenced the issue of vaccine availability in the provinces.* (NIP KII)

Figure 7: NUVI RCA 2: Stockouts of NUVI impede routinization of RV and IPV



Recommendations

1. MOH/NIP should identify and resolve the customs-related problems that led to procurement delays for the 2016 vaccines. Additionally, beyond addressing these immediate issues, MOH should implement the EVM recommendation to set up MOUs with customs and MOH clearing agents.
2. Gavi and the GPEI should ensure that the global supply of IPV is guaranteed for countries where it has already been introduced.

Robustness of finding

Finding 2	Ranking	Robustness criteria
In 2016, stockouts of new vaccines impeded fast routinization of IPV and RV.	A	The robustness of findings for the evidence around this conclusion is A because it is supported by a strong data triangulation from documents review, participant observation, and KIIs.

Funding stream: Health system strengthening

This section is a response to the following Mozambique FCE 2016 research question: How is Mozambique implementing the Gavi HSS project? What are the enabling factors and challenges at national and provincial levels?

Gavi awarded Mozambique its first HSS grant in July 2013 after the country's third submission. Following two years of negotiations on the financial management requirements (FMR), the first-year cash disbursement was made in July 2015. After another nine-month period of in-country delays, primarily related to coordination challenges between MOF and MOH, in accessing funds, implementation of activities began in May 2016. Given these events, the country is at the "timely and comprehensive implementation" stage of the FCE HSS TOC. The details of progress within key TOC milestones is presented in Annex A.

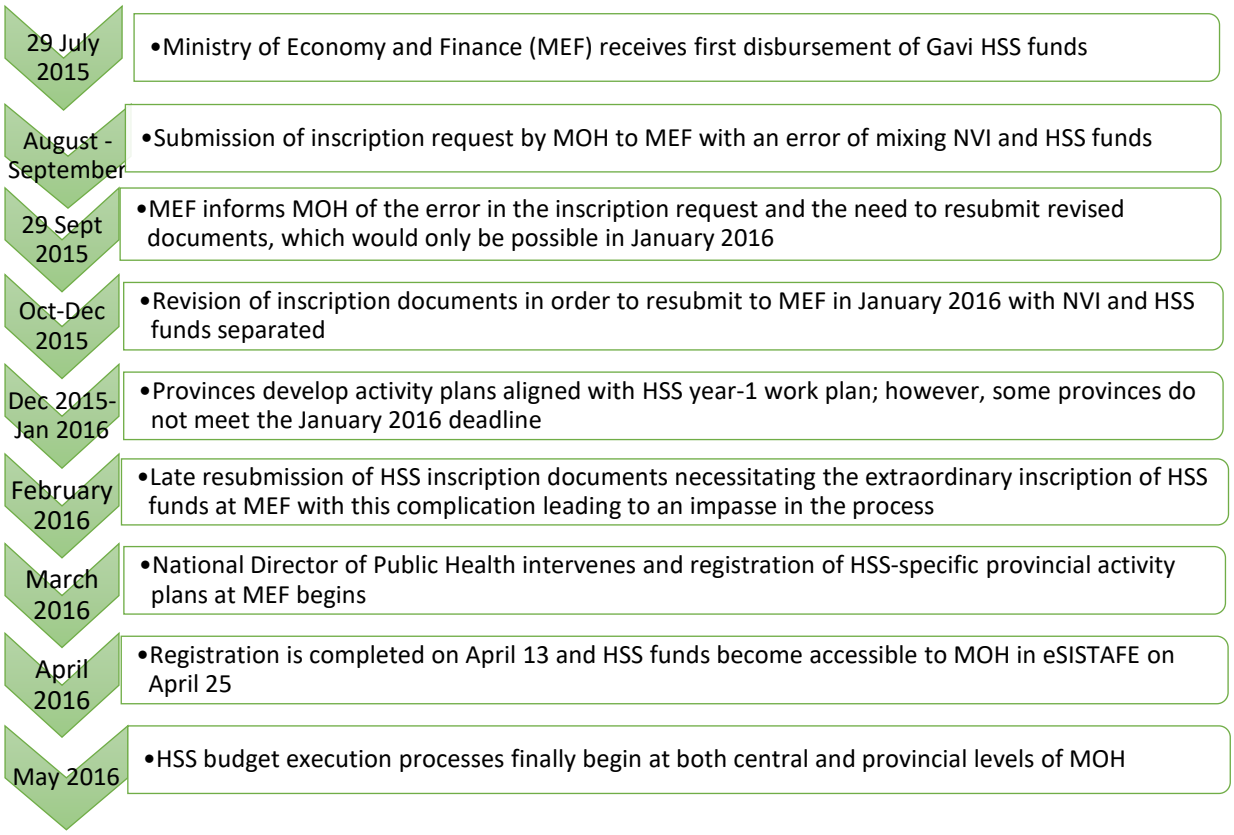
Finding 1

An initial nine-month in-country delay in accessing funds led to the late initiation of HSS grant implementation. However, MOH then prioritized and accelerated implementation in the months following.

Gavi HSS funds arrived in country on July 29, 2015. Given that Mozambique's government fiscal year is between January and December, activities for funds that are received in this period can only be inscribed at the Ministry of Economy and Finance (MEF) if the request is completed in September, the usual deadline for the government planning cycle for the following year. If the inscription request is completed on time, funds are made accessible to ministries through eSISTAFE, the electronic government financial system, for initiation of activities in January of each year. For two different reasons explained below, two critical inscription deadlines - the normal deadline in September 2015 and the extended deadline in January 2016- were missed for HSS funds and as a result, a nine-month delay was experienced with the funds only becoming accessible to MOH at both the central and provincial levels at the end of April 2016.

Based on FCE fact-checking interviews (FCIs) and KIIs, the root causes of this nine-month delay were two MOH-related inscription request challenges. First, an error was made in the initial inscription request documents submitted in September 2015, and second, there was a failure to meet the January 2016 MEF deadline in submitting inscription request documents. In September 2015, MOH submitted inscription documents to MEF, which erroneously aggregated NVI and HSS funds. At the end of September, MEF advised MOH of the error and that it would only be possible to submit another inscription request in January 2016. In order to complete the inscription process it was also required that each province submit an HSS-specific activity plan. Despite having received training/planning workshop in November 2015, some provinces had difficulties in developing HSS plans and did not meet MOH central-level deadlines. Subsequently, MOH was late in submitting inscription request documents to MEF which they finally completed in February 2016. This late submission necessitated another extraordinary inscription per MEF processes. Furthermore, it was also not going to be possible to register all HSS funds as it would cause a disequilibrium in the MEF systems. According to FCIs, these problems created an impasse and further delays were experienced. It was only after the intervention of the Director of Public Health in March that the process of registration of the funds progressed, with completion occurring on April 13. Finally, HSS funds became accessible in eSISTAFE to MOH at both central level and provinces on April 29, and the HSS budget execution processes began in May.

Figure 8: Timeline for HSS funds from arrival in country to being accessible to MOH, July 2015–May 2016



During this nine-month period, several HSS activities were implemented. These included the HSS training in November 2015 in which the provincial NIP focal point and one accountant from each province were trained. Additionally, the HSS TA recruitment process using UNICEF TCA funds was undertaken, NIP appointed an HSS focal point, and HSS reporting templates were developed in the first quarter of 2016. UNICEF also procured motorcycles, trucks, and walk-in cold rooms that arrived in country in April, and the customs process began.

Further FCE process tracking found that once HSS funds were available, bureaucratic budget execution processes at the central level and initial startup problems in provinces were experienced during the initial implementation phase. Bureaucracy challenges at the central MOH level are mainly related to the many steps in various departments that an execution request has to undergo. First, it is prepared at the NIP and signed off by the National Director of Public Health, after which it goes through various verification steps in the DAF and then further steps in UGEA and the jurisdiction department. Sometimes, depending on the nature of the budget execution request, it may require the authorization of the Permanent Secretary and Minister's offices. For this reason, MOH central level is the lowest-performing in terms of budget execution (Figure 9). One recommendation from the 2015 JA was the placement of a technical advisor to DAF to assist in facilitating the financial execution processes. In response, Gavi identified other non-TCA funds to hire a technical advisor through a local Mozambique consulting firm (MB consulting). The decision was made in July 2016; however, the TA was placed in DAF in November 2016.

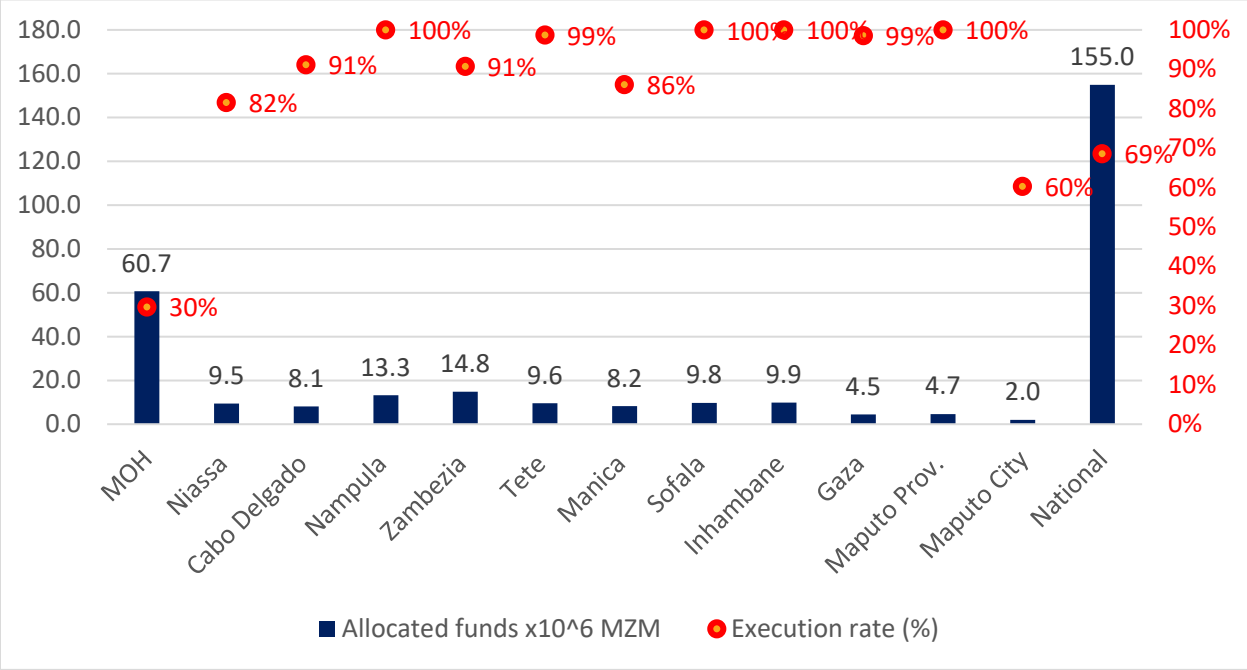
The key startup problems included inexperience with the unique processes for managing HSS funds, the complexity of the HSS grant in general, challenges in districts developing and submitting budgeted activity plans required for accessing funds, and reporting challenges using the new HSS templates. HSS funds are managed at the provincial level, and not at the district level like PES funds. This provincial-level management is aimed at ensuring accountability, as historically the districts have not had the capacity to manage and account for funds at the level required for Gavi HSS funds.

> *It is a new mechanism of funding for NIP. There is a learning curve. In every mechanism you use there are the weak and the strong points. It would have been ideal to have the districts manage the funds because that is where the activities are implemented. But we know that the districts do not yet have the capacity to manage such funds. Even the DPSs prefer the method that we have now because they are also not confident that the districts can be able to report.* (NIP KII)

> *Having these funds in the provinces is so difficult. Imagine putting them in the districts. The problem is that the capacity of the districts to account for funds is very limited.* (MOH KII)

The challenges in developing budgeted activity plans were compounded by the NIP team developing the plans without involving the administration personnel in some districts. This led to time being wasted on repeated revisions of documents before finalization. Nevertheless, some provinces performed better than others in the general budget execution rate (Figure 9).

Figure 9: Differences in provincial HSS year-1 budget execution rates, May 2016–December 2016



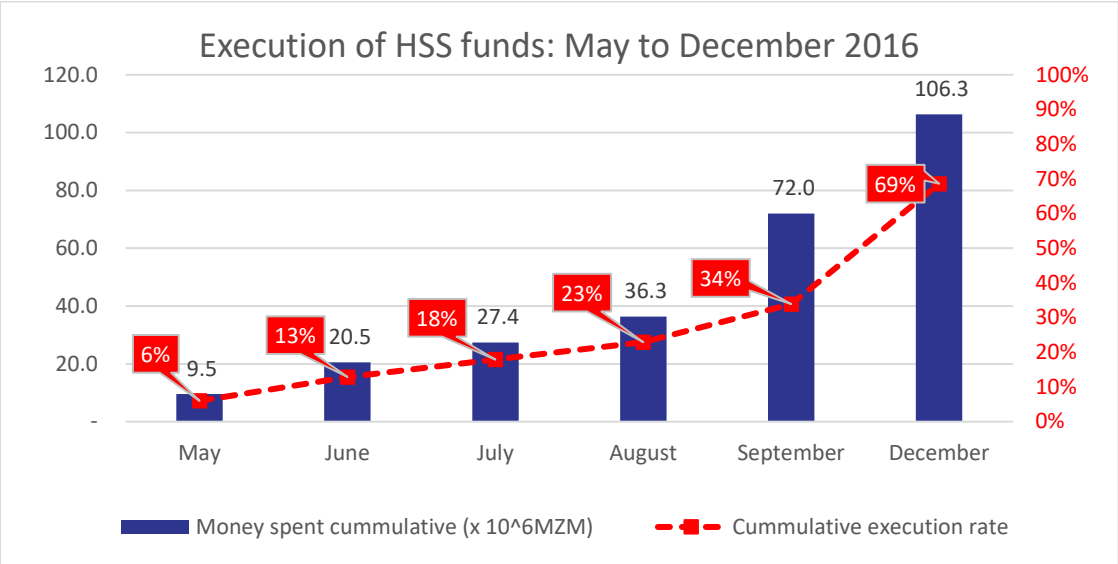
The root cause of the project reporting problem was the fact that the HSS reporting templates, including both financial and programmatic sections, were not only new but were also developed in the first quarter of 2016 *after* the training of key provincial HSS grant managers in 2015. Furthermore, they require more information than what eSISTAFE provides. While NIP focal points were oriented on the templates in May during the RED/REC training, the HSS accounts staff received them only through email. There were also no accompanying supportive supervision visits to accompany the process, though staff were supported by phone and via a WhatsApp group. (See HSS Finding 3 below for macroeconomic crisis effects on NIP supervision visits.)

> *Unfortunately, the templates were developed much later, but we presented to the provincial NIP focal points when they were here for the RED/REC training. The accountants were not here; the accountants only had a planning meeting in November. However, in all the months, this is the fourth or fifth month we have to return them as they are not correctly filled in; very simple templates, but they are always badly filled in. For almost all provinces, I think just two or three we do not have to return.* (NIP KII)

> *As you can see we have to teach people new stuff, all reporting tools are new and are different from what they are used to in eSISTAFE. If you look at eSISTAFE and Gavi reporting they are different things. eSISTAFE can explain a few things. For example, if you spent on fuel eSISTAFE does not tell you which activities the fuel was spent on. So we had to create the new tools and they are not used to this.* (NIP KII)

As of June 2016, the end of year one of HSS implementation, an 13% execution rate was reported in the Joint Appraisal (JA) and noted in the JA report. In the second half of 2016, MOH prioritized and made significant efforts to accelerate the implementation of HSS activities. The budget execution rate was only 34% in September 2016 and then it rapidly risen to 69% in December 2016.

Figure 10: HSS Budget execution, May 2016–December 2016



In September 2016, FCE observed that the NIP failed to meet the MOH's Directorate of Planning and Cooperation (DPC) deadline for submission of the necessary documents to be submitted to MEF for inscription of HSS funds for the coming fiscal year. The root causes for this delay are related to two interlinked reasons: (i) NIP needed to meet the execution rate of at least 60% of HSS year-1 budget as a requirement to solicit HSS year-2 funds at the end of year-1 (as explained in the previous page in September 2016 the execution rate was only 34%); and (ii) the costed work plan for year-2 could not be updated because it needed to be developed from the remaining budget from year-1. This is concerning as it is likely to impact the accessibility of funds in January 2017 and subsequently the implementation of HSS activities.

Recommendations

1. NIP should adhere to DPC and MEF budget planning cycle deadlines and submit necessary activity plans and request documents on time.
2. Gavi should aim to align with government fiscal cycles when disbursing cash grants to countries.
3. NIP should consider the option of a no-cost extension (NCE) application in 2019 to make up for lost time caused by the delay in accessing funds. In order to ensure that the NCE application is timely, the NIP should begin preparations and negotiations with Gavi in 2018. Gavi policy should have the flexibility of accepting NCE preparations and negotiations earlier than the last year, after careful monitoring of the progress through JA and other reports.

Robustness of finding

Finding 1	Ranking	Robustness criteria
An initial nine-month in-country delay in accessing funds led to the late initiation of HSS grant implementation. However, MOH then prioritized and accelerated implementation in the months following.	A	The robustness of findings for the evidence around this conclusion is A because it is supported by a strong data triangulation from documents review, participant observation, and KIIs.

Finding 2

HSS implementation is progressing with a boost in vaccination services for hard-to-reach populations, but without taking into account the prioritization stated in the approved application.

As stated before, the HSS proposal was conceived in 2013 and its implementation started 33 months later. The year-1 HSS plan for hard-to-reach populations has reflected activities based on this original HSS proposal. Based on data from the population-based surveys like DHS 2003 and DHS 2011, provinces with coverages of fully immunized children below 70% for the past eight years were considered priority. These provinces are Zambézia, Tete, Nampula and Manica. So, mobile brigades were to be intensified in 72 rural districts countrywide and in particular targeting 57 districts from these four priority provinces.

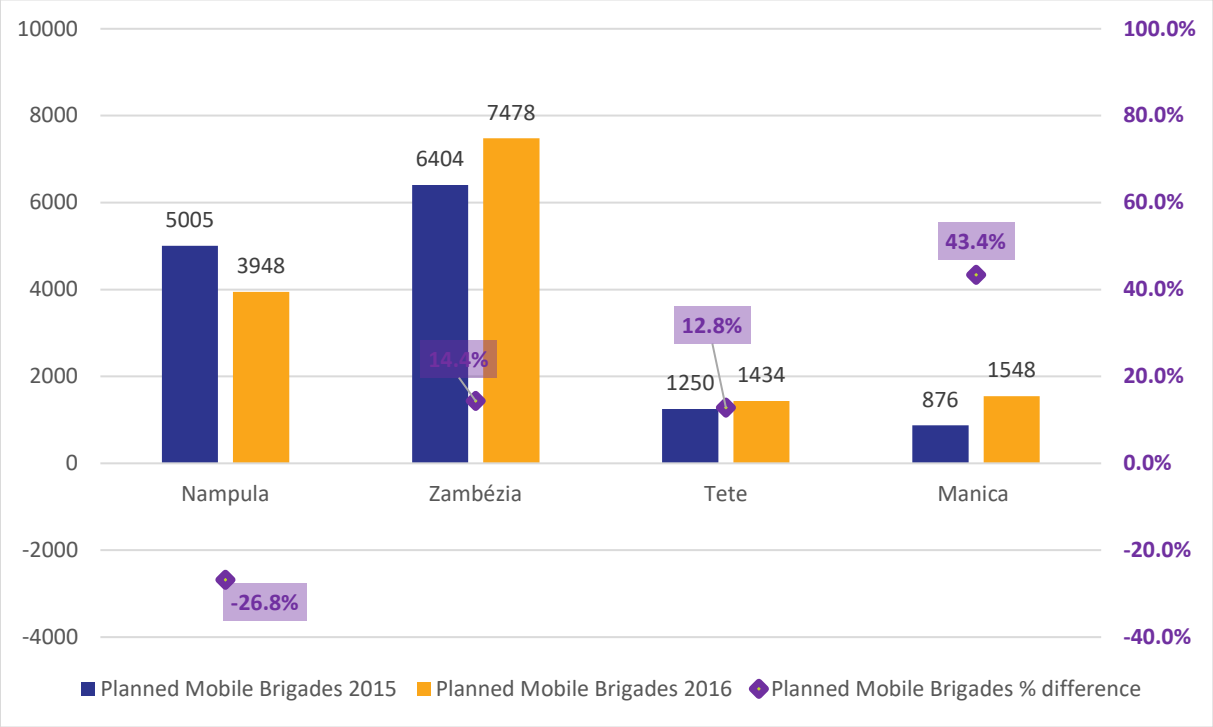
During provincial visits in the third quarter of 2016, FCE observed that provinces were focused on implementing mobile brigade activities. However, upon conducting an in-depth analysis of plans for mobile brigades by provinces, the FCE found that the prioritization of the four provinces (Manica, Tete, Nampula, and Zambézia) was not evident. Additionally, as depicted in Figure 11 Nampula had less mobile brigades being planned in 2016 (with HSS funds) than the figure from 2015 (without HSS funds). Whereas Zambézia and Tete mobile brigades' 2016 plans are quite similar to the 2015 plan. Only Manica plan demonstrates a substantive increase in the number of planned mobile brigades in 2016 compared to 2015 (Figure 11).

In addition, according to MOH KIIs, planning and allocation of funds for mobile brigades within priority provinces was conducted without prioritization of 57 districts.

> *There is this big question on the HSS funds sent to the provinces, then from there to districts. For example, for mobile brigades, the big challenge for us now is the lack of capacity to know which districts need more mobile brigades. If a district has 20 health facilities and another has 10 health facilities, but with the same area and same population, clearly the mobile brigade will make more difference in the district with 10 health facilities. So that is a huge challenge.* (MOH KII)

The concern is that without clear prioritization of mobile brigades, it may become difficult to achieve the HSS fund's first objective of equitable access to routine immunization services through sustained investment in service delivery throughout the health system and at the community level.

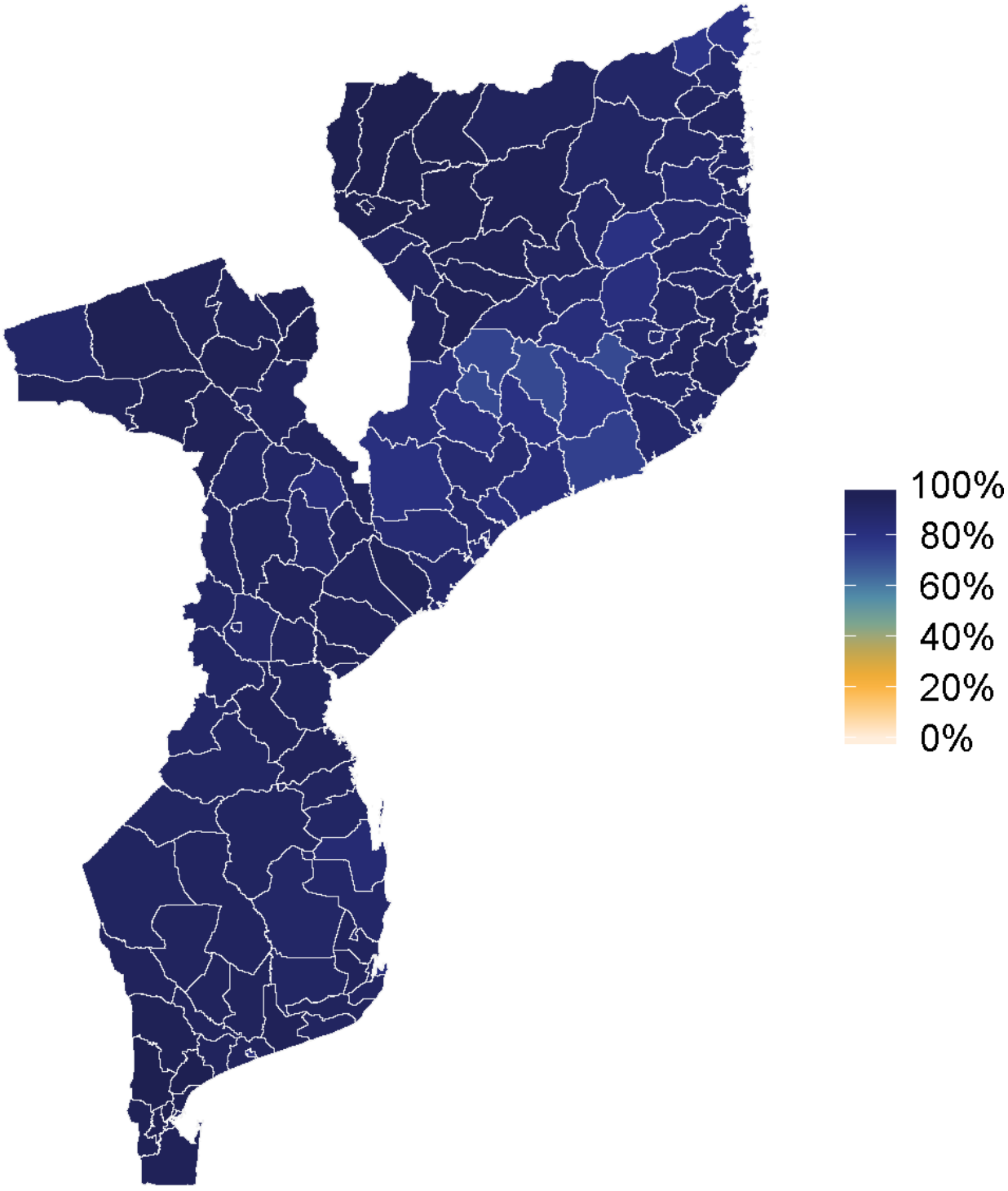
Figure 11: Mobile brigades (MB) planned with (2016) and without (2015) HSS funds



When trying to understand the root causes for a lesser intensification of MB in 2016 across the provinces of Nampula and Zambézia, managers referred to the need to adjust the plan according to the current logistical challenges they are facing, such as the limited availability of motorcycles and vehicles, as the transportation means from HSS funds are not yet available.

Vaccination coverage results from the FCE household survey that was integrated within the 2015 Mozambique HIV/AIDS and malaria indicator survey (IMASIDA) show that the low-performing provinces are Zambézia (79.7%), Cabo Delgado (86.7%), Nampula (88.2%), and Manica (89.8%). From these results, three of the lowest-performing provinces remain the same as those identified in the HSS grant proposal; however, Cabo Delgado is now one of the four-lowest performing provinces rather than Tete. The FCE additionally conducted a small area analysis that provided district-level vaccination coverage (Figure 12). The added advantage of this analysis is the possibility of identifying low-performing districts.

Figure 12: Small area results showing district coverage of DPT vaccine



Recommendation

NIP and partners should consider redefining or clarifying the criteria for prioritization of allocation of HSS funds to the province. For example, NIP and partners could analyze vaccine coverage data from the most recently available household survey (IMASIDA) to see if provinces with lower coverage are still the

same and possibly consider a cross-analysis with district HMSI data to better allocate HSS resources for mobile brigades and REC/RED strategies.

Robustness of finding

Finding 2	Ranking	Robustness criteria
HSS implementation is progressing with a boost in vaccination services for hard-to-reach populations, but without taking into account the prioritization stated in the approved application.	A	This conclusion is A because it is supported by a strong data triangulation from documents review, participant observation, and KII.

Cross-stream analysis

Major finding 1

Improvement in JA and related Gavi processes leads to stronger alignment between NIP and partners on the thematic areas that should be focused on in order to improve Gavi grants' performance.

This section is a response to the following Mozambique FCE 2016 research question:

Has the PEF process (planning and implementing JA, HLRP, PEF allocations, etc.) improved as compared to 2015?

KIIs expressed that there was an improvement in the understanding of the objectives of JA and institutional roles as compared to the first time they executed the JA in 2015. There was also unanimous agreement that the 2016 JA was a more inclusive process and ultimately better run than the 2015 process. This is supported by the JA survey results, where 87% of participants reported that they thought the JA objectives were met. NIP, however, expressed that they still need more experience to further improve their management of the implementation of the JA process.

> *Yes, this year we felt that the Joint Appraisal was practically conducted by the EPI itself and all others were giving inputs, but the process was conducted by the EPI team. For example, last year we had a full-time consultant helping with the preparation of the processes, but this year we ended up doing all of this here within the EPI team. Still our ability to conduct Joint Appraisal is not enough so we have to learn more, but there has already been some progress. We still have to learn more; I think two years is not enough to for us to have high expertise in the process.* (NIP KII)

> *I think it was definitely a better exercise than last year. We had done it before, even if nothing was said at least you knew what to do. I think the experience [compared to the previous JA] was good.* (Partner KII)

> *In terms of preparedness it was easier because we already knew what JA was and Gavi also helped a little by sharing some...what I could say was lessons learned from the previous JA. I think that last time it was too long. This time it was shorter and therefore more acceptable in terms of people participating because when it is like two long weeks of people participating in meetings all day long it is tiring. This time it was shorter.* (Partner KII)

According to KIIs, the EPI review interfered with the JA preparation phase. As such, they did not have sufficient time to prepare for the JA compared to the previous year. Given that the deliverables for the

EPI review and the JA are different, they would have preferred to have had in-depth discussions of the EPI review results as a country (NIP and partners) prior to the Gavi team joining them. They suggested an intervening period of at least a month between EPI review and the JA during an EPI review year.

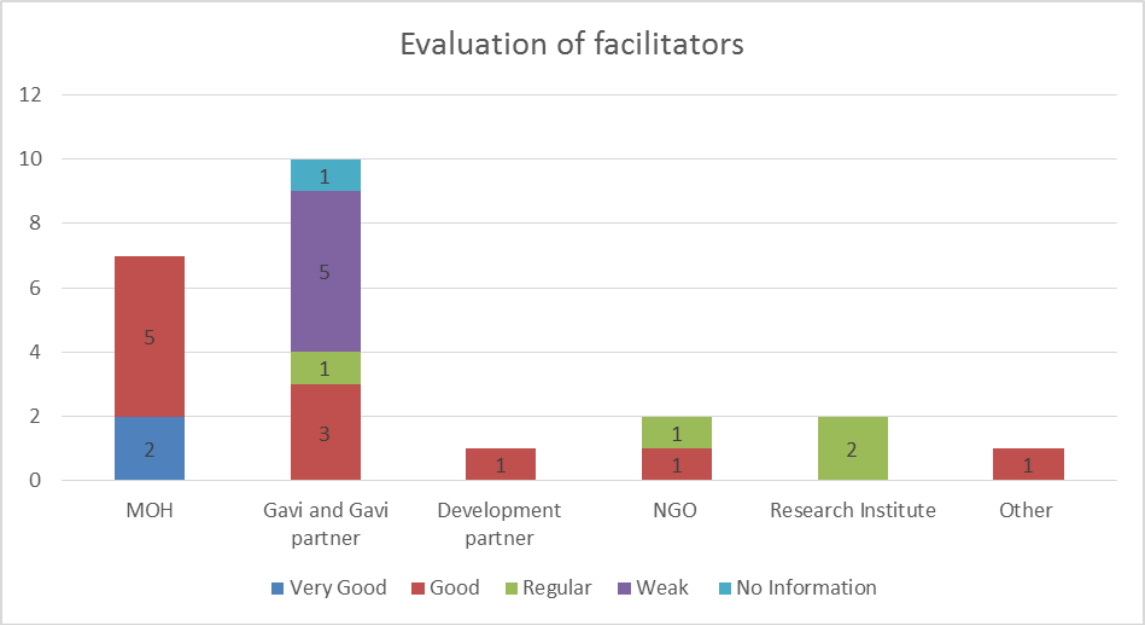
> *The Joint Appraisal occurred at a time when there was a lot of overlapping activities this year, and that this might have somehow contributed to some difficulties in carrying out the process itself, because we first made the Comprehensive EPI review, an evaluation that required a lot of the EPI team and soon after we had to do the Joint Appraisal. Initially we thought it would be a very easy thing to bridge the EPI review and Joint Appraisal. But we found that the requirements of Joint Appraisal were different from the EPI review, so that did not make the process much easier.* (NIP KII)

> *The timeline between the EPI review and the Joint Appraisal should have been longer... We only had the results of the EPI review in those two days before the Joint Appraisal so the team was getting data and using it as an input to the discussions at the same time. It would have been good to have...two weeks to one month in between to give the opportunity for us to absorb the EPI results. I mean there was so much happening.* (Partner KII)

According to KIIs, the process was country-owned because partners and NIP together managed and facilitated the whole process as compared to 2015 when an external consultant played a major role in the process.

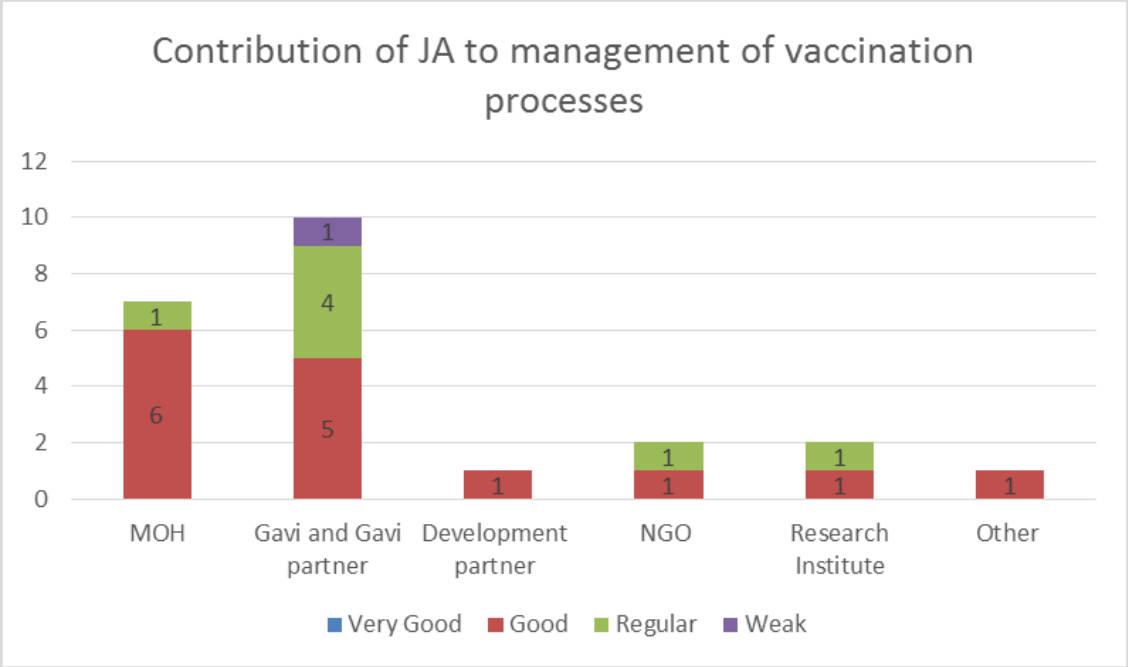
However, from the JA survey results and KIIs, there is still an opportunity for NIP to be more engaged in leading the JA. Furthermore, KIIs agreed with the FCE preliminary recommendation that there is a need for an experienced JA discussions/workshop facilitator to manage the process better and ensure a more efficient use of time during discussions. This is supported by JA results in which facilitation received the highest "weak" score of (22%) compared to the other survey evaluated areas (three areas had 4%, two areas had 13%, and one area had 0% "weak" scores) (Figure 13).

Figure 13: JA evaluation of facilitators



According to KIIs, the writing process was more inclusive compared to the previous year's writing process, which was preferred. Partners developed the draft and NIP finalized and submitted the JA report and everyone felt involved. NIP and all partners' KIIs unanimously agreed that JA is the appropriate forum for the identification of TA needs. This is additionally supported by JA results (Figure 14) showing that the JA was assessed by participants as a valuable process in terms of its contribution to the vaccine management process, scoring the highest "good" score (70%) compared to the other evaluated areas (two areas had 48%, two areas had 39%, and two areas had 30% "good" scores).

Figure 14: Contribution of JA to management of vaccination processes



Based on FCE observation and KIIs, recommendations made during the JA need to be realistic in number and timelines. Many KIs observed that recommendations from the last year could not be implemented within a year. In 2016, the FCE observed that the list of JA report recommendations had become too long and had to be shortened during a JA report consensus NIP TWG meeting held in September 2016.

An additional major constraint that was identified by the FCE and KIIs was the lack of involvement of other MOH departments, especially given that the HSS grant involves other thematic areas of the health system, such as Directorates of Finance (DAF), Human Resources (DRH), and Planning & Cooperation (DPC), as well as the Central Medical Stores (CMAM).

> *We cannot discuss items in the Joint Appraisal where we have finances, human resources without the finance people being there, without the human resources personnel being there, without the surveillance personnel. All interested parties need to be there; we cannot be only EPI and what about the processes that support the EPI.* (Partner KII)

> *I think the biggest drawback for the entire process was that it was very EPI-centric. There was nobody from other departments of MOH (such as) logistics, finance, HR. There is a need to involve other departments. You cannot discuss breaking a wall for a cold room without infrastructure and CMAM people.* (Partner KII)

The JA workshop highlighted existing tensions between partners and MOH regarding the functioning of ICC. Partners were expressing that the DNSP national director does not have authority over other directorates and that may be having an impact on the implementation of activities. They argued that the DNSP director is a peer to other directors and not their supervisor and this could limit his enforcement role. As such, they were proposing the elevation of ICC in MOH. The DNSP director, on the other hand, did not agree with this and requested specific examples. No specific examples were provided at the JA and it was agreed to continue further discussion in the next ICC meeting. During the September 7 ICC meeting the consensus reached was that the ICC TORs needed to reviewed, and if there are any items that should be raised to another level, then these should be addressed. ICC meetings have been postponed repeatedly due to competing, more critical priorities. As such the ICC TOR have not yet been prioritized but it is expected to be planned for 2017. During KIIs the FCE further established that several ICC members noted that other senior-level partner ICC members were also not attending ICC meetings as expected, and thus could not entirely heap all the blame at the level at which the ICC was placed at the MOH as a shortcoming of the ICC.

> *The ICC needs to be saying this themselves and I think this is the opportunity where we can discuss whether we need times when we should have an ICC plus that may involve other senior MOH people and not just MOH but all other member organizations because it becomes awkward to suggest that the ministry should be bringing the minister to be discussing with technical people. So this question should be across the board.* (Partner KII)

Some KIIs expressed that ICC may benefit from some kind of secretarial support (for example, one staff fully or 50% dedicated) for ICC. The reason they gave was that all ICC members are very busy people, holding many responsibilities at their various institutions, and thus have very little time left to dedicate to ICC. As a result, ICC is not able to play more of a strategic and oversight role beyond reviewing and endorsing applications. In conclusion, as part of the 2016 JA report, a decision was made to have an ICC review undertaken, and TCA for this has been included in the proposed 2017 Mozambique TCA table to be submitted to HLRP. Note in 2016, the ICC only met three times.

Recommendation

An NIP TWG sub-group dedicated to JA preparations should be identified to lead preparations prior to JA week, as well as facilitation of the pre-formal workshop discussions.

Robustness of finding

Finding 1	Ranking	Robustness criteria
Improvement in JA and related Gavi processes leads to stronger alignment between NIP and partners on the thematic areas that should be focused on in order to improve Gavi grants' performance.	A	The robustness of findings for the evidence around this conclusion is A, because it is supported by a strong data triangulation from documents review, participant observation, and KII.

Major finding 2

TA/PEF/TCA processes result in transparency and nascence of accountability of Gavi TA.

This section is a response to the following Mozambique FCE 2016 research question:

How is immunization TA implemented in Mozambique? How has PEF changed the composition and structure of TA in Mozambique?

Existing TA models in Mozambique include the following:

1. Technical Advisors outside the MOH that are based in organizations
2. Technical Advisors seconded to the MOH that are based at NIP or appropriate departments
3. Transfer of funds to MOH at central level and provinces
4. Implementation partners providing direct support to provinces and districts
5. Short-term consultancies that could be either Mozambican or non-Mozambican.

In general, KIIs expressed that having a mix, as in the current scenario, is optimal because each model has both advantages and disadvantages and all are therefore complementary to each other.

According to the Public Health Director, the MOH terms of reference for TA that provide a framework for TA to MOH to build local capacity were approved last year. The regulation outlines responsibilities for both the provider and recipient of TA. However, many KIIs were not aware of these TORs, and those who were aware of them said their implementation had not begun. Many KIIs expressed their opinion of the perception that existing TA is not building capacity and there is a need to better understand why this is so and enable the creation of an environment where NIP members can meaningfully gain from TA on, for example, monitoring and evaluation tools. Capacity-building mechanisms, for example the inclusion of clauses that guarantee that capacity-building happens in bilateral agreements, are some suggested mechanisms. In quarter four, the FCE team observed the passing of a new Government of Mozambique (GOM) labor regulation for hiring foreign workers that takes effect in December 2016. In this regulation there is a clause that states that "the employer will be obliged to ensure that the foreign employee, after gaining three years of work experience, transfers his knowledge to the local employee in order to engineer the foreign employee's replacement by the local one." This regulation will, however, not apply to embassies and diplomatic missions.

When asked to assess the usefulness of the current TA, both the NIP and the directorate of Public health responded that the TA was performing well. The director of public health specifically highlighted the example that after the HSS TA had visited the least-performing HSS budget execution province (Inhambane), he had been able to resolve the underlying issues. An improvement in budget execution was observed after his visit in this province.

> *This advisor also has some ability to help in the financial area and I remember that when we had a low execution, in Inhambane, he went to Inhambane, stayed there a week, working with people and this had some impact in terms of execution.* (MOH KII)

Both welcomed the temporary assignment of two more TAs that were being expected to be placed at the MOH: logistics TA through Village Reach to NIP, and financial TA through MB consulting to DAF in

November 2016. Of note is that although the ICC agreed to monitor the TA effectiveness, this has not been made official.

> *But the question of the financial area I think will be resolved because the DAF (Directorate of Administration and Finance) has already agreed to technical assistance. There is a technical assistance from MB Consulting, we have already created conditions for someone from MB Consulting to come here, he will work with our EPI administrator and the accountant.* (MOH KII)

In general, KIIs agree that the JA/PEF process is a much better process than the APR/Business Plan process that was in place previously. This is because of the joint planning and identification of needs. There is more transparency and accountability than the previous system because PEF activities and budgets with milestones for each PEF partner are now presented in NIP TWG meetings and monitored together by both NIP and partners at regular intervals. A concrete example was the specific NIP TWG TA/PEF meeting to review 2016 PEF milestones and plan for 2017 that was held in October. In this meeting, FCE observed that WHO was late on the two 2016 TCA activities they had been tasked with (development of sustainability and HR TORs).

According to KIIs a major constraint of the PEF system is that funds for all organizations arrived late (April for WHO and UNICEF while VillageReach, the new partner, had not signed the contract with Gavi as of October 2016). This has resulted in the delay of implementation of some TCA activities (for example, the assignment of a logistic TA to NIP by VillageReach). Some partners are suggesting a multiannual rather than an annual approach aligned to the Gavi grant cycle.

Recommendations

1. In order to support the in-country PEF-TCA milestone monitoring that the NIP and partners are performing, Gavi should develop contractual mechanisms that guarantee that PEF-TCA commitments are honored.
2. Gavi should guarantee the timely signing of contracts and disbursement of funds to Mozambique PEF partners.
3. MOH/NIP should operationalize the approved MOH TA TOR framework in order to ensure that embedded TA through the TCA mechanism build capacity in the program.

Robustness of finding

Finding 2	Ranking	Robustness criteria
TA/PEF/TCA processes result in transparency and nascence of accountability of Gavi TA.	A	The robustness of findings for the evidence around this conclusion is A, because it is supported by a strong data triangulation from documents review, participant observation, and KII.

Major finding 3

Actions to ensure sustainability have begun. However, the broader macroeconomic crisis currently affecting the country may jeopardize progress toward long term sustainability.

This section is a response to the following Mozambique FCE 2016 research questions:

What are the current fiscal resources for EPI? What proportion comes from government compared to external sources? What has been the change over time? Is the country taking any steps to prepare for sustainability of products funded by Gavi? If yes, what are they?

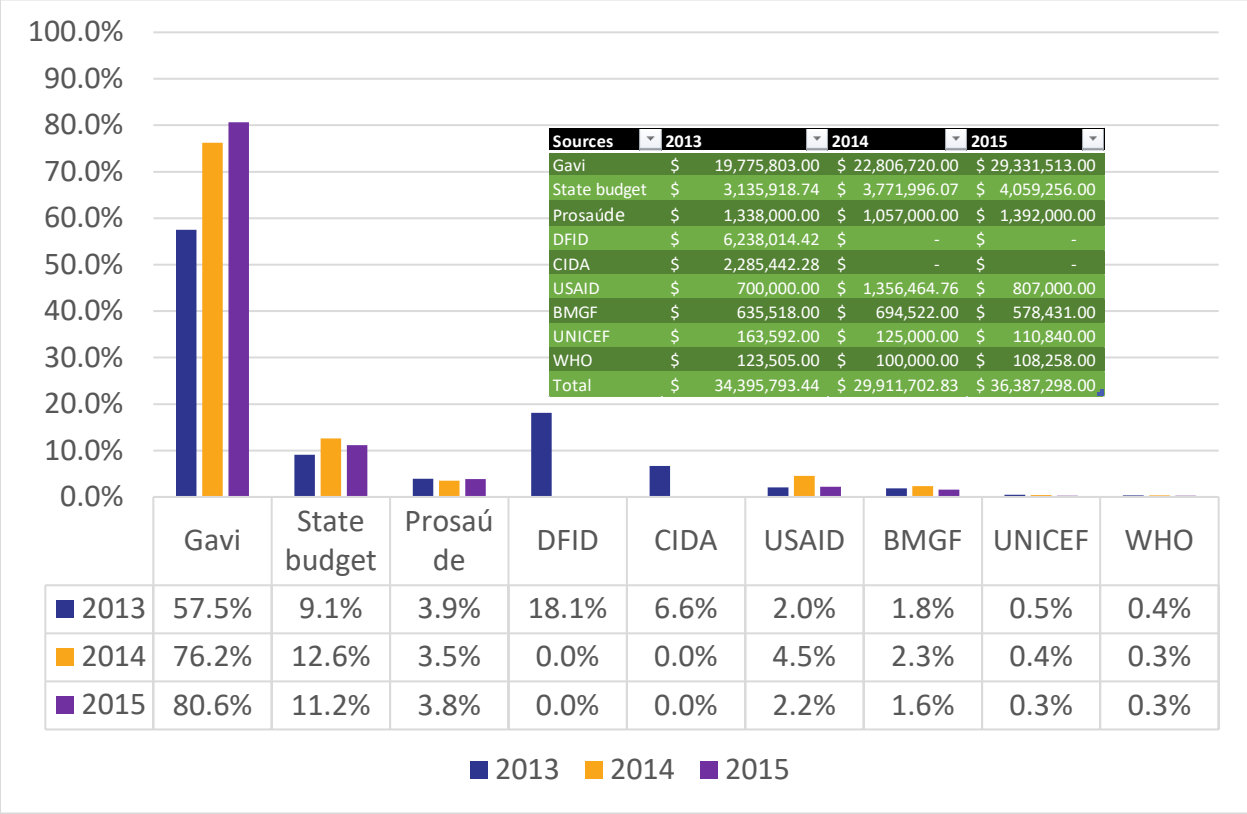
The FCE has tracked the resources that support the Mozambique NIP during 2013, 2014, and 2015 in order to identify the principal funding sources and agents (organizations that manage funds between donors and service delivery points) for immunization services in Mozambique. Similar to previous years, organizations and institutions identified through the NIP were requested to provide data using collection forms that were emailed to them. Given this approach, the results presented here are limited to sources of funding known to the NIP and projects reported by participating organizations and institutions. Because not all institutions/organizations reported all funding streams, the annual total amounts are likely to be underestimated. Also not captured were the government's personnel and direct non-medical costs for immunization service delivery. Document review provided supplementary data.

Our findings (Figure 15 and Figure 16) show that the most consistent financial sources for Mozambique's NIP were Gavi, Government of Mozambique State Budget (GOM SB), Prosaúde, USAID, CIDA (Canada), BMGF, UNICEF, and WHO. Each of these entities provided funding every year of this three-year survey. Descriptions of the GOM state budget and the Prosaúde are provided below.

> *The GOM state budget: In Mozambique a group of aid partners contribute directly to the state budget through the Program Aid Partnership (PAP) mechanism. During the resource-tracking period (2013-2015) the PAP donors were AfDB (African Development Bank), Austria, Canada (CIDA), Denmark, EU (European Union), Finland, France, Ireland, Italy, Portugal, Sweden, Switzerland, UK (DFID), and the World Bank.*
>
> *The Prosaúde: Prosaúde is the health-sector-specific common fund. Donors who contributed during the resource tracking period (2013-2015) were Canada (CIDA), Denmark, UNFPA, Netherlands, Ireland, UK (DFID), Switzerland, UNICEF, and Belgium.*

This demonstrates that some donors, namely Canada (CIDA) and DFID, contributed to immunization delivery in Mozambique through three mechanisms, 1) the GOM state budget, 2) the Prosaúde, and 3) funding of specific projects through UNICEF. In the NIP, the GOM state budget is annually utilized for procurement of traditional vaccines and vaccine distribution through the domestic airline (LAM) and the Prosaúde for co-financing payments. CIDA and DFID funds that were transferred to UNICEF in 2013 were used for SIAs during the National Health Week. This activity that did not occur in 2014 and 2015.

Figure 15: Mozambique immunization funding sources 2013, 2014, and 2015

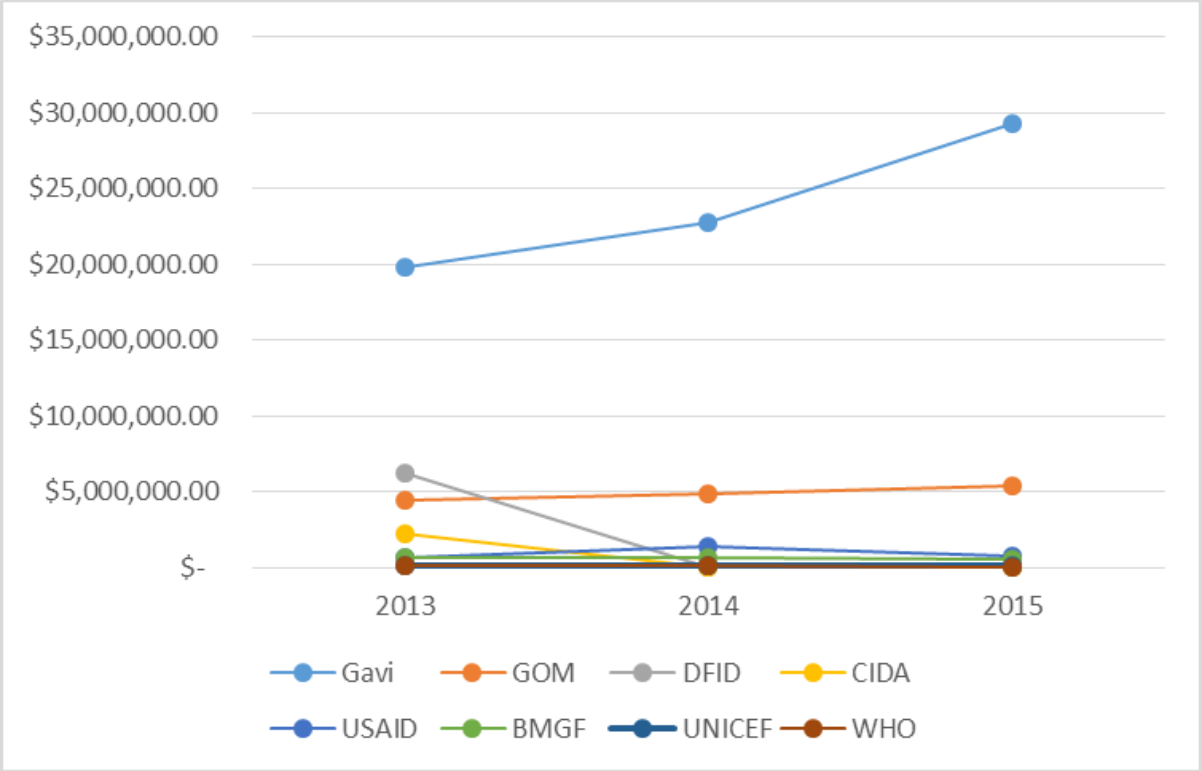


Sources	2013	2014	2015
Gavi	$ 19,775,803.00	$ 22,806,720.00	$ 29,331,513.00
State budget	$ 3,135,918.74	$ 3,771,996.07	$ 4,059,256.00
Prosaúde	$ 1,338,000.00	$ 1,057,000.00	$ 1,392,000.00
DFID	$ 6,238,014.42	$ -	$ -
CIDA	$ 2,285,442.28	$ -	$ -
USAID	$ 700,000.00	$ 1,356,464.76	$ 807,000.00
BMGF	$ 635,518.00	$ 694,522.00	$ 578,431.00
UNICEF	$ 163,592.00	$ 125,000.00	$ 110,840.00
WHO	$ 123,505.00	$ 100,000.00	$ 108,258.00
Total	$ 34,395,793.44	$ 29,911,702.83	$ 36,387,298.00

Other funding sources which were more intermittent included DFID, Ireland, Norway, the government of Barcelona, the Aga Khan Foundation, and IS global. The DFID and Irish government funds were used for supplementary immunization activities (SIAs) during the National Health Week in 2013. After 2013, SIAs were no longer conducted during the national health week and this substantial amount of funding ($7.9 million) was directed to other activities. Other examples: the government of Barcelona and Aga Khan Foundation were specific funders of HPV demo project-related activities. Funds were disbursed in 2014 and the majority of activities were conducted in 2014. Further HPV demo project activities implemented by the Manhiça research center (CISM) in 2015 were funded through Gavi funds. These funds contributed less than 1% of immunization spending in that year.

The total annual financial inputs that immunization funding sources provided for Mozambique increased from approximately $34.4 million in 2013 to $36.4 million in 2015 (Figure 16). Over the three years the largest source of funding was Gavi, whose contributions to the total budget were 35%, 71%, and 75% in 2013, 2014, and 2015, respectively. This Gavi funding was the driver behind the increased spending on immunization, with a steep rise being observed in 2015 when three new vaccines (RV, IPV, and MSD) were introduced and the first HSS grant disbursement of $5.5 million was made.

Figure 16: Mozambique immunization funding sources, Mozambique, 2013–2015



Financing agents are the organizations that manage funds between donors and service delivery points and include both the MOH and NGOs. In 2013, UNICEF was the largest financing agent; however, MOH overtook it in 2014 and 2015 (Figure 17 and Figure 18). This is primarily due to a large volume of funds that UNICEF received from DFID and the government of Ireland ($7.9 million), which were not available in 2014 and 2015 because the activities that they supported were halted after 2013 (SIAs during the Mozambique National Health Week). However, UNICEF continued to be the largest NGO financial agent and received funding from Gavi, USAID, CIDA, and its own UNICEF HQ sources. The other consistent NGO financing agents during the three years were VillageReach and WHO. The local NGO FDC received immunization funding from Norway in 2013 and from Gavi in 2014 but had no immunization funding in 2015. Another NGO, CHAI, was slated to receive Gavi HSS funds in 2015 through a subcontract with UNICEF and joined the group of financing agents handling immunization funding in Mozambique.

Figure 17: Institutions managing funds between donors and service delivery points (financing agents), 2013 and 2014

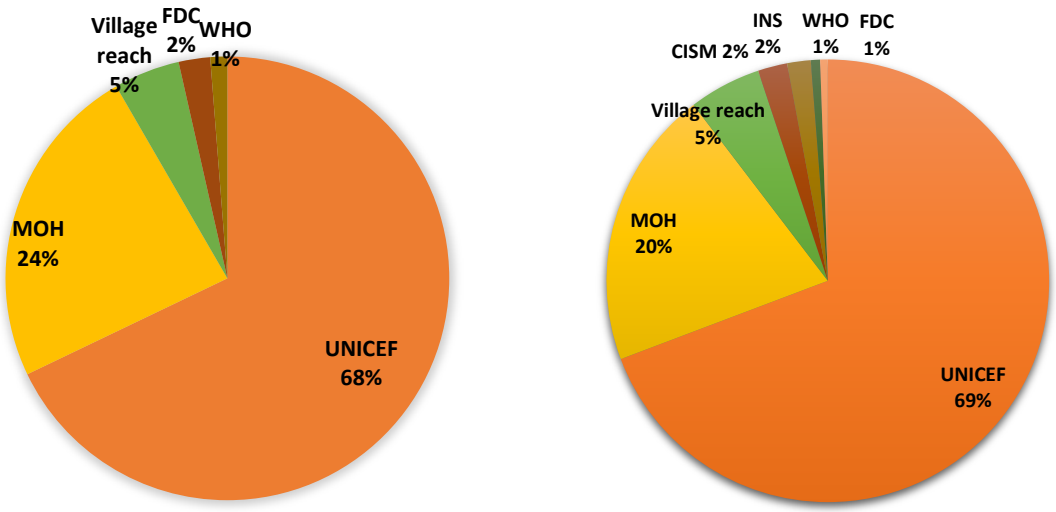
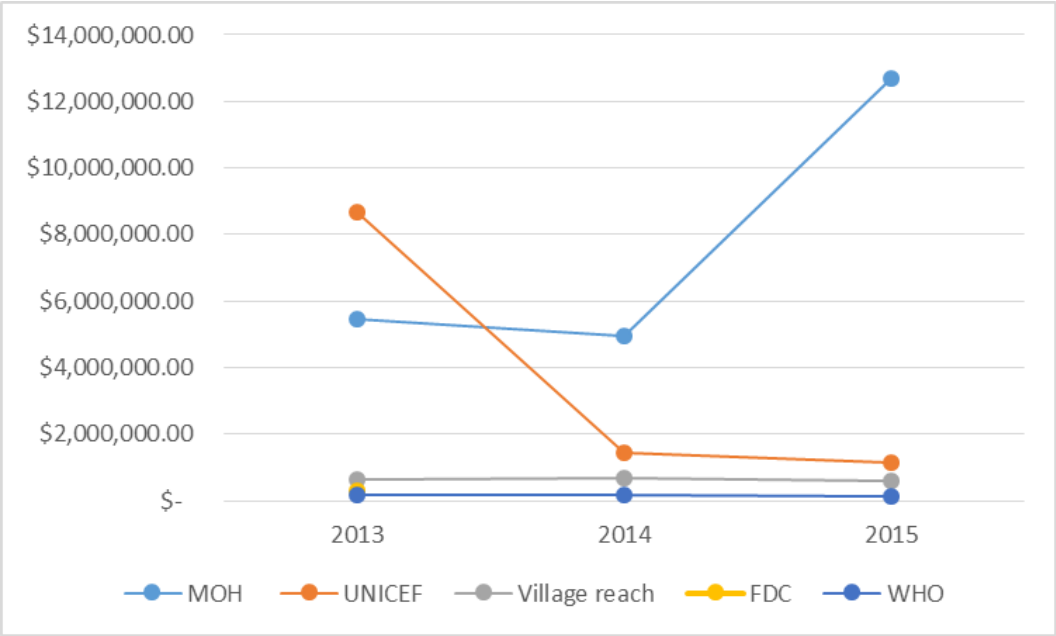


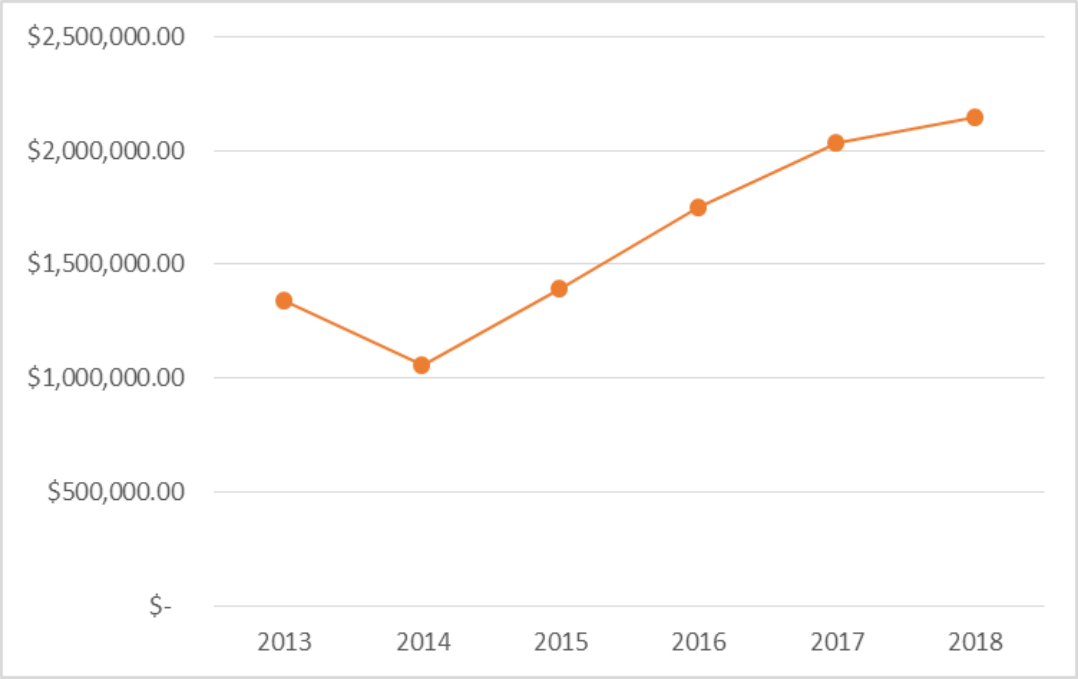
Figure 18: Institutions managing funds between donors and service delivery points (financing agents), 2013–2015



The FCE established that the MOH had annually earmarked Prosaúde funds to pay for co-financing obligations and State Budget funds for procurement of traditional vaccines including their distribution through the domestic airline (LAM) (see above for description of the difference between Prosaude and State budget). Figure 19 demonstrates that Mozambique annual co-financing obligations increased in 2015 and the rise is expected to continue in 2017 and 2018. The reason for the expected increase is that

there are plans to introduce two new vaccines in 2017 and 2018. Mozambique's measles-rubella proposal application was approved in November 2016 with clarification requests, and the vaccine is planned for introduction in the form of SIAs in the last quarter of 2017. The national introduction of HPV vaccine is planned for 2018.

Figure 19: Mozambique co-financing obligations



*Source cMYP 2015–2019 (Does not include expected HPV co-financing obligations. As at the time of writing, the NIP is planning to complete the HPV demo costing exercise in 2017 and subsequently make projections.)

While there are no NIP-specific activities for sustainability, there are currently wider MOH efforts toward future sustainability of Ministry of Health activities including human resources, data, supply chain, etc. These also include the development of a health sector financing strategy and the Global Financing Facility (GFF) process for maternal and child health. KIIs revealed that NIP is considered one of the important components of these processes.

> *Well, we have this process of developing a financing strategy within the health sector, clearly the NIP is an important element, and the strategy is not only to mobilize more resources but to use well and allocate well, so there may be, say, a light at the end of the tunnel. We also have this GFF where EPI is a central element and clearly in the GFF we are discussing about domestic resource mobilization, both for communities and the private sector. So it may be that this can also push this discussion of sustainability.* (MOH KII)

Furthermore, the FCE established that following discussions in the 2015 JA, a recommendation was made for the development of sustainability TORs. WHO was tasked to develop TORs, but as of the October 2016 TWG meeting to review partner PEF milestones they reported that they had not begun the activity. This activity has now been revised and included in the proposed 2017 TCA. WHO will now be tasked with ensuring that the NIP is included in the health sector financing strategy initiative. Additionally, NIP and other government KIIs mentioned that there has been a discussion within the

MOH for NIP to make a presentation in parliament in the near future (no specific date) regarding the current and forecast financial responsibility given that further new vaccines are expected to be introduced in coming years (MR and HPV in 2017 and 2018, respectively). Some KIIs, however, expressed that there is a need for guidance from Gavi on the development and implementation of a sustainability mechanism including a forum for learning from countries who are in the process or have completed the process.

> *We are aware of the need to think of sustainability, but I think that, well we probably need an exchange of experience to know, those countries that have already done this. How did they show sustainability, because I do not know if sustainability is to reserve a fund so that in five years, everyone knows that, hey, Mozambique can do it. I do not know if the sustainability that Gavi talks about is for me to every year or every two years say, look, I'm going to cut down on what you [Gavi] are paying for from the 100% of the vaccine purchase in addition to the co-financing. Gavi has to create mechanisms for sustainability, if they want the countries do it ... if not, we will get a situation like that of Angola, which suddenly stopped and has no way out. I think they [Gavi] should say, look, you have to create a reserve or for example they could say, annually you have to show a commitment of, for example, 2%, 7%, 10%, which could be even mandatory if need be.* (MOH KII)

Mozambique has been meeting its co-financing obligations on new and underutilized vaccines to date (2016). In 2016, Mozambique encountered a macroeconomic decline which is described in detail in HSS Finding 3 of this report. During the EPI review this was raised as a threat to Mozambique's ability to meet its co-financing obligations in coming years as well as to undertake activities toward future sustainability of Gavi-supported products. FCE noted similar sentiments among KIIs.

> *Ask me next year. I fear that they will not meet their co-financing obligations. We are certainly well aware of their wider macroeconomic problems that are affecting budgets. We are aware of very large shortfalls in many obligations that they need to meet. So it's going to be hard because it's hard for them to have the budgets, and then it's hard for them to access dollars.* (Partner KII)

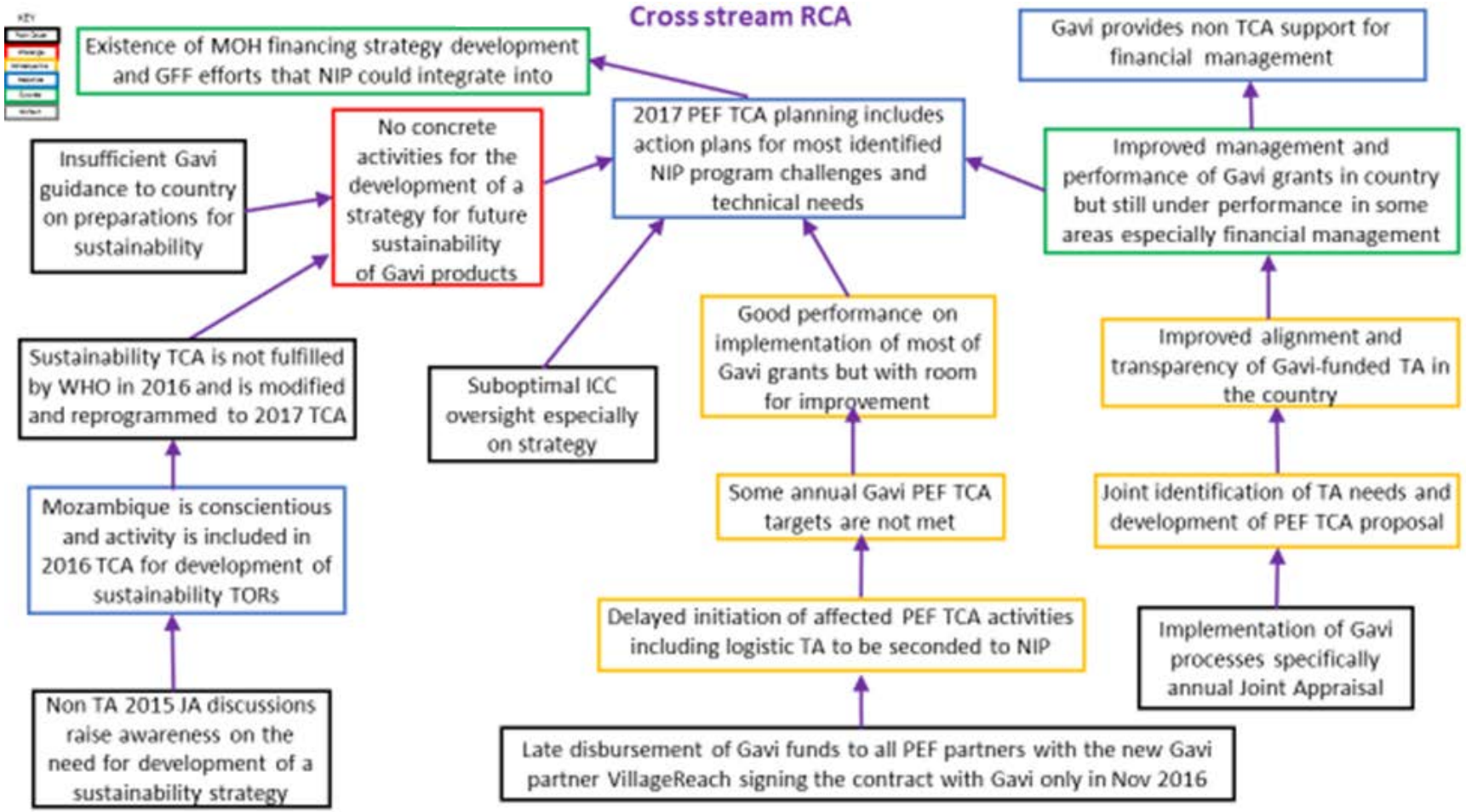
Recommendation

Rather than await the MOH sector-wide health sector financing strategy development, the NIP, together with the tasked TCA partner WHO, should develop terms of reference for the country's actions for future sustainability of Gavi products. These should subsequently inform the health sector financing strategy.

Robustness of finding

Finding 3	Ranking	Robustness criteria
Actions to ensure sustainability have begun. However, the broader macroeconomic crisis currently affecting the country may jeopardize progress toward long term sustainability.	A	The robustness of findings for the evidence around these conclusions is A, because they are supported by a strong data triangulation from documents review, participant observation, and KII.

Figure 20: Cross-stream RCA



Vaccine effectiveness analysis

In Mozambique, evidence from multiple vaccine effectiveness studies suggests that the introduction of PCV in 2013, which was rapidly routinized in the country, has reduced nasopharyngeal carriage of vaccine-type pneumococcus and reduced the incidence of vaccine-type invasive pneumococcal disease (IPD) and pneumonia.

As part of the Gavi FCE, we have conducted (led by the Manhiça Health Research Centre with additional support from USAID and CDC) vaccine effectiveness studies of PCV in Mozambique. The first study aimed to estimate the direct and indirect effects of PCV10 introduction on pneumococcal nasopharyngeal carriage among HIV-infected and HIV-uninfected children. The study involved cross-sectional carriage surveys pre- (October 2012–March 2013) and post- (first round October 2014–April 2015; second round October 2015–May 2016) PCV introduction. Carriage surveys were conducted among HIV-infected children under 5 years old enrolled from HIV clinics in Nampula, Maputo, and Manhiça. Carriage surveys were also conducted among HIV-uninfected children under 5 years old from Manhiça district, sampled at random from the demographic surveillance site (DSS).

Based on this study, a direct effect of the vaccine on PCV10 serotype-specific (VTS) pneumococcal carriage was observed at the first round (within 18 months) and the second round (within 30 months) after PCV introduction. Among HIV-uninfected children receiving three doses, a 44% (95% confidence interval [CI]: 33, 59) reduction in VTS pneumococcal carriage was observed at the first round and a 70% reduction (95% CI: 57-78) at the second round. In HIV-infected children receiving three doses, a 60% (95% CI: 25, 95) reduction was observed at the first round and no additional decline was observed at the second round. There was also an early signal of an indirect effect among HIV-infected children, with a 31% reduction (95% CI: 11, 46) among HIV-infected children receiving no PCV doses. As expected, there was also an increase in pneumococcal carriage of non-PCV10 VTS, including serotypes in PCV13 (i.e., 19A).

The reduction in carriage has been accompanied by a reduction in vaccine-type invasive pneumococcal disease (IPD). Based on a regression discontinuity design of surveillance data from the Manhiça DSS, we estimated a significant reduction in vaccine-type IPD of 94% (95% CI: 65.8, 99; Figure 21). There was also a significant reduction in X-ray-confirmed pneumonia (85%, 95% CI: 64.3, 93.7; Figure 22). At this point we did not observe evidence of serotype replacement, with a non-significant change in non-vaccine-type IPD (16.3%, 95% CI: -55.4, 203.4; Figure 23).

Figure 21: Reduction in vaccine-type IPD over time in Manhiça DSS

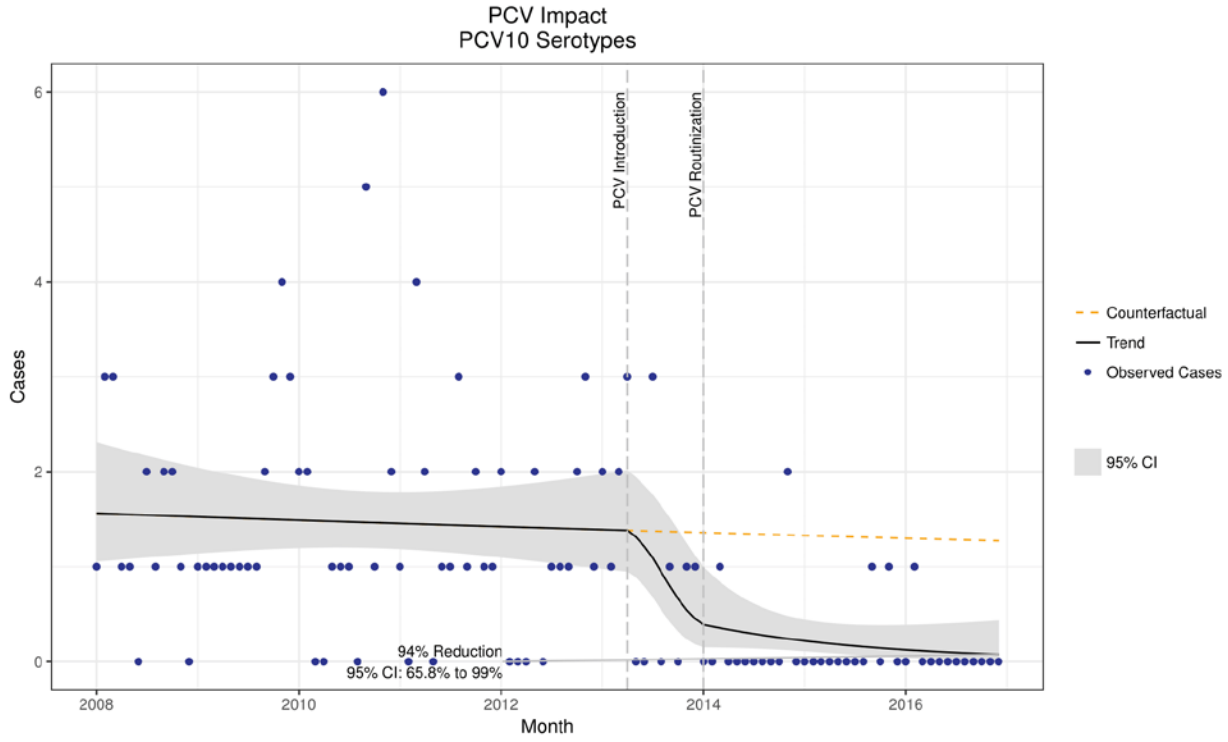


Figure 22: Reduction in X-ray-confirmed pneumonia over time in Manhiça DSS

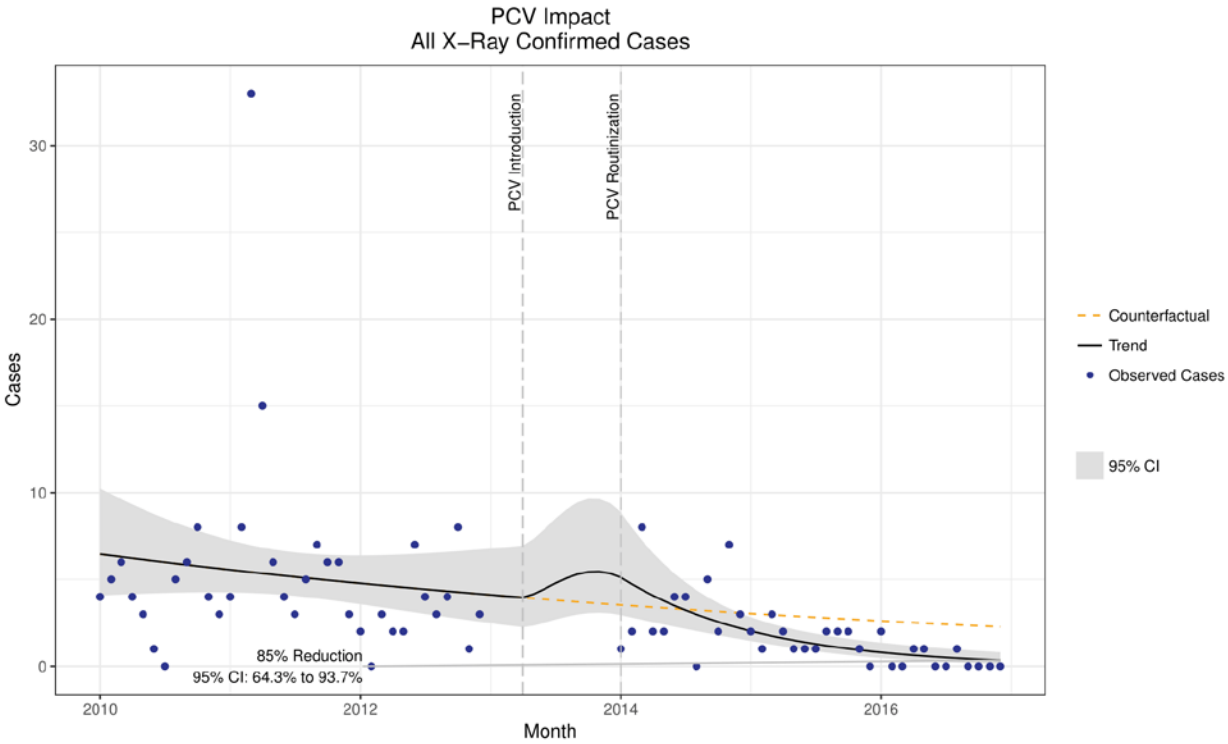
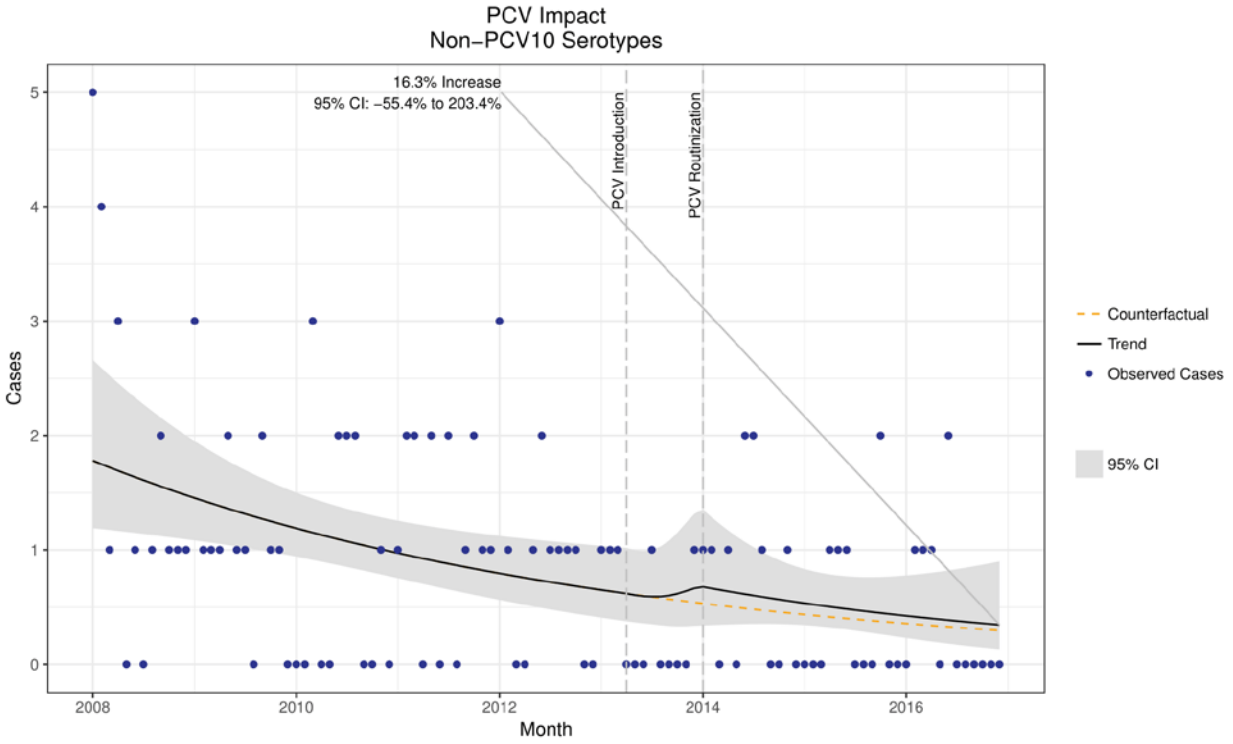


Figure 23: Change in non-vaccine-type IPD over time in Manhiça DSS

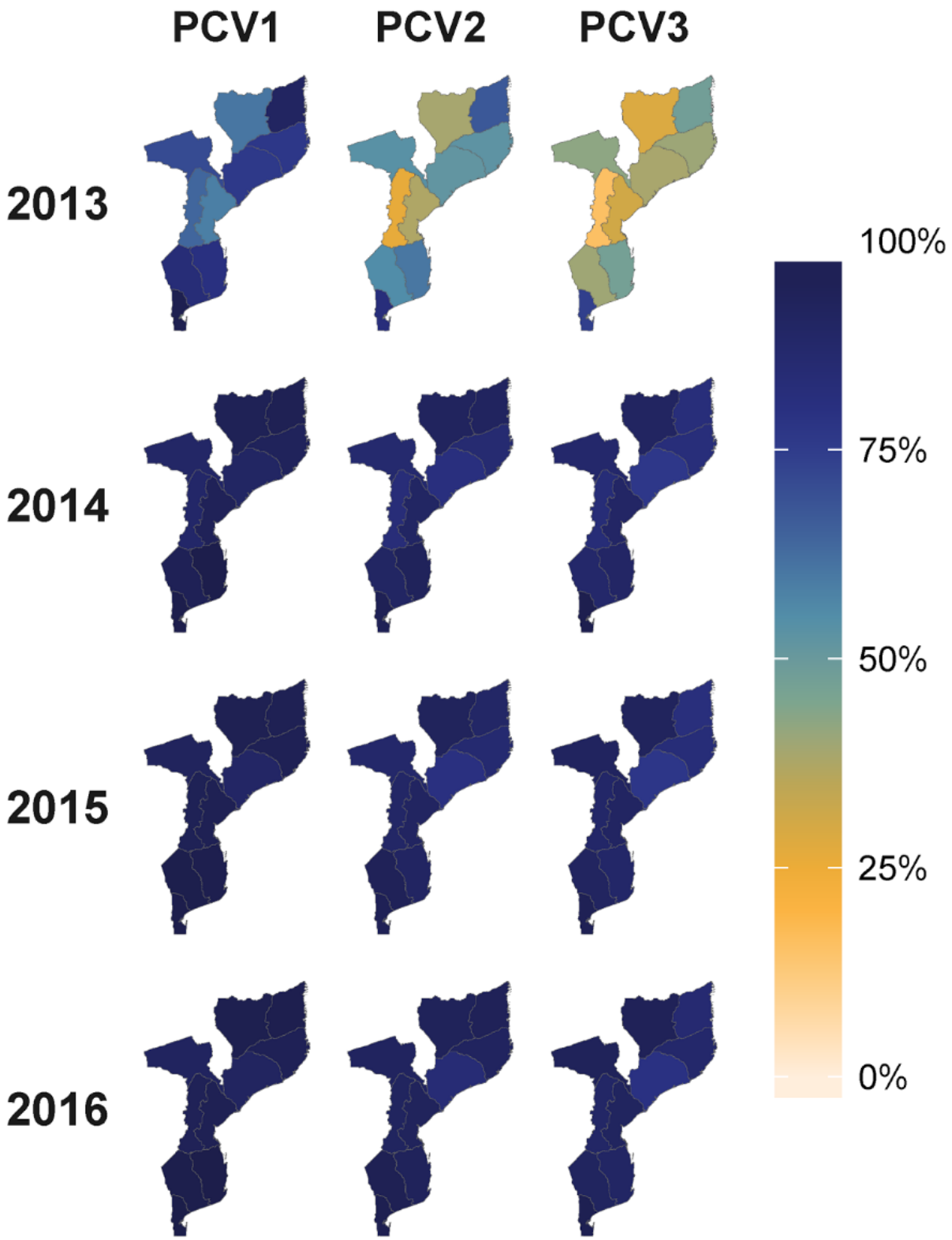


In addition to the surveillance data analysis, we also conducted case-control studies of VT-IPD and x-ray confirmed pneumonia as part of the Gavi FCE. Due to the virtual elimination of VT-IPD in the Manhiça site, we were not able to collected sufficient cases to undertake the analysis. For x-ray confirmed pneumonia we estimated a 47% (95% CI: 22, 64) reduction associated with three valid doses of PCV. When restricting cases to x-ray confirmed pneumonia cases that also had a nasopharyngeal swab that was positive for vaccine type pneumococcus, we estimated 56% (95% CI: 13, 78) reduction associated with three valid doses of PCV.

The high effectiveness noted in the vaccine effectiveness studies on vaccine-type pneumococcal disease is consistent with the high coverage of the vaccine achieved in Manhiça district (our small area estimates of vaccine indicate that coverage of PCV in Manhiça district was 89.3% (95% uncertainty interval [UI*]: 85.1, 93.4) that was the result of the rapid routinization of PCV nationwide. This provides evidence that the high coverage of PCV nationally in Mozambique (88.0%, 95% CI: 86.0, 90.1 in 2016) has led to considerable reductions in vaccine-type pneumococcal disease. Given the similar results seen in reducing pneumococcal disease in other studies in Africa and elsewhere,[1–5] this also suggests that the scale-up of PCV has led to reductions in pneumococcal disease in the other three FCE countries.

* UI – Uncertainty Interval. UI (uncertainty interval) is a better term in this context than the CI (confidence interval), as the interval include statistical uncertainty and uncertainty from the data processing used in the DBS data processing algorithm.

Figure 24: Map of PCV coverage in Mozambique



To assess whether the introduction of new vaccines in Mozambique has led to overall reductions in child mortality, we have, in addition to the vaccine effectiveness studies, conducted causal analyses using the small area estimates of vaccine coverage and child mortality (see Annex 8). These inputs were survey-based estimates (using all available data), and are subject to the same biases and inaccuracies described in the Gavi FCE Cross-Country Report annexes, "Annex 6: Small area analysis methods," and "Annex 7: Causal analysis methods and results." To estimate the relationship between new vaccine introductions of PCV and rotavirus vaccine and child mortality, the FCE uses finite distributed lag regression models that adjust for other important drivers of child mortality. These other drivers or covariates were separately estimated at the corresponding geographic level (province, district, or subdistrict), and include household wealth, maternal education, other vaccination (pentavalent and measles), breastfeeding, childhood malnutrition (stunting and wasting), and maternal health care (antenatal care, in-facility delivery/skilled birth attendance). Our analyses indicate that high NVI coverage is associated with significant improvements in child mortality. Compared to counterfactual scenarios where these vaccines were not introduced, in 2016 there was a 10.1% (95% UI: 6.4, 13.8) reduction in under-5 mortality in Mozambique.

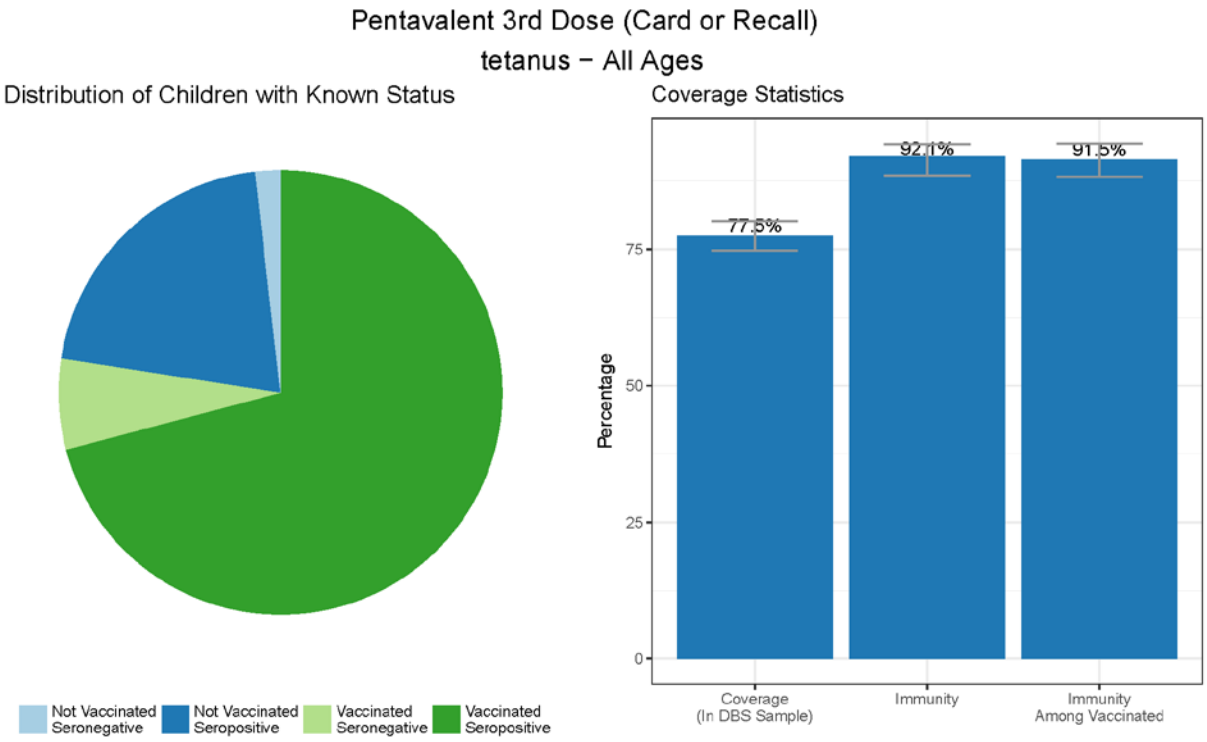
Household survey dried blood spot (DBS) analysis

Full analysis of DBS samples acquired through the IMASIDA (Mozambique AIDS Indicator Survey) is currently delayed, pending final MOH and study partners' approval to share with the FCE team the variables necessary to link DBS assays with household survey data. Some preliminary DBS analyses appear below, but these analyses are subject to change following receipt of additional data.

During the Gavi FCE household survey, 2,117 children were randomly selected for dried blood spot (DBS) sampling. Trained health workers absorbed five drops of blood from consenting participants onto specially designed filter paper via a finger prick. Blood spots were dried and sent to a laboratory for antibody testing. Antibodies examined were those related to hepatitis B (three separate antibodies) and tetanus (IgG), though hepatitis results were not prepared in time for this report. Laboratory methods and data processing methods are described in Annex 4. The DBS results allow us to assess which of the vaccinated children have actually gained immunity, and which have not.

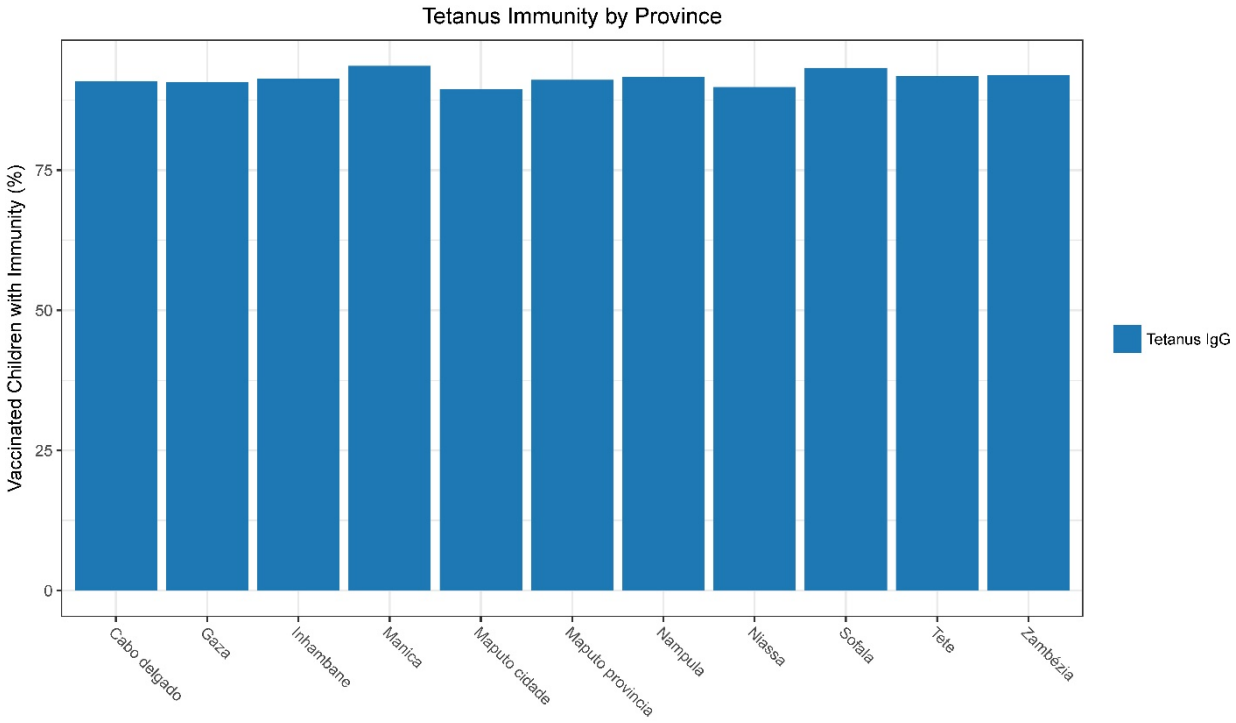
Based on the DBS results, 92.1% (95% UI: 89.6, 94.2) of children were immune to tetanus. Comparing the DBS results to children's pentavalent vaccine status (three doses according to either maternal recall or vaccine card), 91.5% (95% UI: 88.7, 93.9) of vaccinated children were immune to tetanus. Figure 25 displays this comparison. We caution against interpreting these as estimates of vaccine effectiveness, as the study was designed to measure seroprevalence, not effectiveness.

Figure 25: Comparison between pentavalent vaccination and tetanus immunity among children selected for DBS



The Gavi FCE surveys can also help explore explanations for vaccine success. As shown in Figure 26, tetanus immunity can be stratified by province. We found very little variability between provinces in terms of immunity to tetanus among vaccinated children. This is consistent with findings from other FCE countries, where hepatitis B immunity was seen to vary widely between districts, but tetanus immunity was relatively constant. We caution that these are preliminary results and do not account for confounding or uncertainty.

Figure 26: Percentage of vaccinated children who are immune, by district



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