

Gavi Full Country Evaluations

2016 Annual Dissemination Report

Zambia Report



Acknowledgments

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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; Manhica 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.

This work is intended to inform evidence-based improvements for immunization delivery in FCE countries, and more broadly, in low-income countries, with a focus on Gavi funding. The contents of this publication may not be reproduced in whole or in part without permission from the Gavi Full Country Evaluations Team.

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Acronyms

bOPV	Bivalent oral polio vaccine
CHAZ	Churches Health Association of Zambia
CHU	Child Health Unit
CIDA	Canadian International Development Agency
CIDRZ	Centre for Infectious Disease Research in Zambia
CMMB	Catholic Medical Mission Board
CSO	Central Statistical Office
cMYP	Comprehensive Multi-Year Plan
DAH	Development Assistance for Health
DBS	Dried blood spot
DEBS	District Education Board Secretary
DQA	Data quality audit
DPI	Department of Planning and Information
DPT	Diphtheria, pertussis, tetanus
EOI	Expression of Interest
EPI	Expanded Program on Immunization
FCE	Full Country Evaluations
FCI	Fact-checking interviews
FGD	Focus group discussion
GBD	Global Burden of Disease
GSK	GlaxoSmithKline
HFS	Health facility survey
HHS	Household survey
HMIS	Health management information system
HPV	Human papillomavirus vaccine
HSS	Health system strengthening
ICC	Inter-Agency Coordinating Committee
ICT	Information and communications technology
IPV	Inactivated poliovirus vaccine
IRC	Independent Review Committee
ISS	Immunization services support
IST	Inter-country Support Teams
JA	Joint Appraisal
JICA	Japan International Cooperation Agency
KI	Key informant
KII	Key informant interview
MCDMCH	Ministry of Community Development, Mother and Child Health
MIS	Multiple Injection Study
MNCH	Maternal, newborn, and child health
MoE	Ministry of Education
MoF	Ministry of Finance
MoH	Ministry of Health

MR	Measles-rubella vaccine
MSD	Measles second dose
NHA	National Health Account
NHSP	National Health Sector Plan
NITAG	National Immunization Technical Advisory Group
NVI	New Vaccine Introduction
OPV	Oral polio vaccine
PBF	Performance-based financing
PCA	Program Capacity Assessment
PCV	Pneumococcal conjugate vaccine
PEF	Partners' Engagement Framework
PIE	Post-introduction evaluation
PRRR	Pink Ribbon Red Ribbon
RCA	Root cause analysis
SAGE	Strategic Advisory Group of Experts
SCM	Senior Country Manager
SD	Standard deviation
SNA	Social network analysis
STI	Sexually transmitted infection
TA	Technical assistance
TOC	Theory of change
tOPV	Trivalent oral polio vaccine
ToR	Terms of Reference
TWG	Technical Working Group
UNZA	University of Zambia
VIG	Vaccine Introduction Grant
WHA	World Health Assembly
WHO	World Health Organization
ZAMRA	Zambia Medicines Regulatory Authority
ZISSP	Zambia Integrated Systems Strengthening Program

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 Partner Engagement Framework (PEF), and broad organizational functions, such as the provision of technical assistance (TA) and promotion of sustainable EPI (Expanded Program on Immunization) 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	Implementation of demonstration project	Post-demonstration 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)	Implementation of HSS-2	Implementation 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);
- A resource tracking study to generate estimates of national-level resource envelopes on immunization in Zambia;
- Analysis of Health Management Information Systems (HMIS) and EPI administrative data to understand the rollout of new vaccine introductions;
- 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

- Analysis of household survey data to assess inequality in DPT3 coverage by sex and wealth quintiles over time (Annex 8).

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 that 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 key informant interviews.

- 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).

Status of priority research theme evaluation questions for 2016

At the beginning of the year, the FCE team reviewed findings from previous FCE annual reports and assessed what the priorities would be for the 2016 evaluation in relation to the resources and time available, Gavi focus areas, and stakeholder needs. Additionally, input was obtained through discussions with various stakeholders and feedback from meetings such as EPI TWG (Technical Working Group) and ICC (Inter-Agency Coordinating Committee) meetings. These priority themes and evaluation questions were thus arrived at in consultation with the EPI stakeholders. The priority themes were finalized at a two-day meeting held in April 2016 that included representation from EPI management.

Table 3: Status of priority research theme evaluation questions

Evaluation questions:	Statement on findings
<i>Technical Assistance</i>	
(i) What mechanisms are there for identifying TA gaps and filling them? (ii) How effective and efficient is the implementation of JA and PCA (Program Capacity Assessment) at country level and what are stakeholder perceptions of these processes? (iii) What are the current TA networks and models being utilized in Zambia and how effective and efficient are they at providing TA? [possible case studies – CIDRZ and Rota TA, Better Immunization Data TA] (iv) How effective are current TA processes (PCA, JA, PEF) at identifying long-term human resource capacity gaps and what has been done to address these capacity gaps? (v) To what extent does TA for HSS influence the design and implementation process?	Question (i) and (iii) were addressed but findings are not detailed separately in this report as the findings did not add any more detail to what was reported in the 2015 annual report. However, they are addressed within the JA section. Additionally, the unavailability of the PCA report constrained our analysis of the PCA process. Questions (ii) and (iv) were fully addressed with regard to the JA. The last question was not addressed in view of the delay in the commencement of the HSS implementation.
<i>Sustainability</i>	
(i) Description of fiscal space: expenditure on EPI program, on vaccines, etc., assess the country's revenue potential. Is the government able to mobilize domestic resources to fund a growing EPI vaccine budget at the current levels of coverage? (ii) What plans are being made for transition planning as Zambia weans off Gavi support? (iii) How sustainable are current programmatic gains in view of the Gavi support diminishing?	Questions (i) and (iii) are discussed in detail in the sustainability section and supported by findings from the resource tracking survey. Question (ii) was addressed differently in light of news that Zambia will not enter the accelerated transition phase as initially planned. In view of this, the evaluation took a more long-term view to transition planning.

<i>Suboptimal coverage of new vaccines</i>	
(i) What are the underlying causes for PCV and Rota doses delivered being less than penta even though all the vaccines are supposed to be delivered on the same schedule?	The question was addressed and discussed under the PCV Rota subsection. The evaluation has highlighted probable supply-side and data-quality factors causing a prolonged suboptimal coverage. However, more research is needed for conclusive results.
<i>Human papillomavirus vaccine</i>	
(i) How have HPV demonstration projects influenced processes for national introduction? How have demo projects been used for learning? (including costing studies) (ii) What were some of the considerations for adopting the school-based model during the pilot through to the national rollout? (iii) How is the country planning addressed the sustainability issues surrounding HPV? (iv) Who takes up the leading role in the introduction of HPV nationally? (v) How is government handling the misconceptions and beliefs around HPV?	The evaluation was able to address all the evaluation questions. The findings are detailed in the HPV section of the report as well as in the summary of findings.
<i>Health System Strengthening</i>	
(i) What are the implications of the PCA findings on the implementation schedule of the Gavi HSS grant? (ii) To what extent does Gavi's new PCA affect the whole process from approval of the HSS proposal to implementation? (iii) How does the reversal of MCH functions back to Ministry of Health (MoH) affect the implementation stage of HSS since the design stage was under Ministry of Community Development, Mother and Child Health (MCDMCH)? (e.g., coordination and synergies across all levels of the system? Allocation of resources?).	The evaluation was able to determine how the PCA process affected the commencement of the HSS implementation as detailed in the HSS section and the summary of findings. However, the PCA report has not been made public and thus a full assessment of PCA findings was not possible. Question (iii) has been addressed from a sustainability angle and so is discussed in the Sustainability section.

Summary of findings and recommendations

Table 4 summarizes the recommendations for the country findings.

Table 4: Findings and recommendations

Zambia	
Findings	Recommendations
<i>Cross-stream analysis</i>	
Finding 1. Improved JA process with greater stakeholder participation, engagement, and guidance from Gavi Senior Country Manager (SCM) compared to last year, resulting in improved identification of capacity gaps and TA needs. Finding 2. Declining fiscal space to support EPI budget threatening sustainability of the program. Finding 3. Despite strong national ownership and commitment to promoting sustainability of EPI, underlying programmatic weaknesses are undermining the sustainability of program gains. Finding 4. Limited preparation toward transition out of Gavi support is raising concerns about sustainability of current programs.	1. Technical Assistance for sustainability planning is critically needed to avert programmatic disruptions that could arise from limited attention to ensuring sustainability assessments. Gavi and country partners should ensure that available TA support mechanisms are effectively identified to address these TA needs. 2. Improving skills and capacity in costing and program management are key to enhancing the sustainability of the program and addressing the major programmatic weakness. Greater investments are needed in M&E capacity and, in particular, in reconciling data discrepancies between CSO and headcount data in population estimates. 3. The Ministry should conduct or commission a comprehensive costing and expenditure tracking assessment to determine program costs and assess funding gaps. 4. The Ministry of Health should ensure functionality of the newly constituted NITAG to facilitate strategic direction for a sustainable EPI program.
<i>Pneumococcal conjugate vaccine (PCV), rotavirus vaccine, and measles second dose (MSD)</i>	
Finding 1. Persistent/ongoing suboptimal coverage of PCV/Rota as a result of delayed and inadequate government funding and poor logistics management at the subnational level. Finding 2. MCV2 coverage very low at 48% due to low awareness and the timing of the second dose at 18 months when no other vaccines are administered.	1. There is a need to reconsider the vaccine demand forecasting process to be more inclusive and utilize local evidence; that is, disparities in population figures, wastage rates, and buffer stocks. 2. There is a need for the EPI program to evaluate the initiatives aimed at improving logistics management and data quality, such as Logistimo and BID, with a view toward expanding them country-wide. 3. EPI should strengthen second year of life interventions including measles second dose (MSD) in order to improve vaccine coverage beyond the first year. Specifically, more intensive

	social mobilization efforts for children beyond age 1 are required.
<i>Inactivated polio vaccine (IPV)/OPV switch</i>	
Finding 1. Concentrated attention on OPV leading to a successful switch and improved logistical arrangements.	
<i>Measles-rubella (MR)</i>	
Finding 1. Measles-rubella vaccine prioritized, with wide stakeholder participation and adequate planning, leading to a successful campaign despite system challenges around logistics and population estimates and delayed VIG funding.	1. Improvement in logistics during the OPV switch and MR campaign need to be assessed and learned from for application to routine vaccine logistics management. 2. To address social mobilization challenges such as those witnessed with MR, information, education, and communication materials need to be adequately pre-tested to ensure appropriate messages are disseminated.
<i>Human papillomavirus (HPV) vaccine</i>	
Finding 1. Learning from the demonstration project and greater commitment, improved leadership, and coordination leading to a smoother HPV proposal development. Finding 2. Postponement of the application submission.	1. As HPV is a nontraditional vaccine and likely to incur additional costs, the government should consider conducting a comprehensive costing exercise during national implementation using actual costs, which could be used to strengthen resource mobilization.
<i>Health System Strengthening (HSS)</i>	
Finding 1. Delayed initiation of HSS grant.	1. There is a need for Gavi to ensure that timelines for the process are agreed with the country and adhered to. 2. There is a need for effective consultation with country made in preparing the GMR.
<i>Constraints analysis</i>	
	1. We recommend that demand-generation interventions in Zambia should use reduced drop-out as a key metric of success. 2. We recommend that NVI programs focus on Facility Readiness to achieve success.

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Gavi support for Zambia

Zambia first received Gavi support in 2001. Over the following 16 years, the country has received a total of US\$130.6 million in Gavi funds for new vaccine introductions, Immunization Services Support (ISS), and Health System Strengthening (HSS). In 2013, Zambia introduced the measles second dose (MSD) and pneumococcal conjugate vaccines (PCV) jointly. It additionally introduced rotavirus vaccine in 2013. In 2015, the country's applications to introduce measles-rubella vaccine and inactivated poliovirus vaccine (IPV) were approved. The MR campaign was conducted in September 2016 and the IPV campaign has been postponed due to the global IPV shortage.

Table 5: Streams of Gavi support for Zambia

Gavi support	Period of support	Total amount of funding (\$US)
Pneumococcal conjugate vaccine (PCV)	2012–2017	38,281,440
Pentavalent vaccine*	2004, 2005–2017	60,781,335
Rotavirus vaccine	2013–2017	11,728,558
Measles second dose (MSD)	2012–2014	615,018
Inactivated poliovirus vaccine (IPV)	2016–2017	1,355,441
Health System Strengthening (HSS)	2007–2019	15,337,174
Immunization Services Support (ISS)	2001–2002, 2004, 2006	3,864,060
Injection safety support (INS)	2002–2004	689,237
Vaccine Introduction Grant (VIG)	2002, 2012–2013, 2016	2,875,183

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

*Earlier phase of support was for tetra DPT-hep B.

Methods overview

Consistent with the prospective nature of the FCE, the evaluation has reflected Gavi-supported activities, assessing implementation and related milestones by support stream. In relation to the priority themes identified in Table 3, Table 6 provides an overview of the methods used and the sources of data.

Table 6: Evaluation methods

Methods	Source consulted/study area	Topics investigated
Process tracking	- Collected and reviewed documents including IPV Switch Plan; HSS final application and GMR; MR application and budget; HPV vaccine demonstration documents; and ICC, National Immunization Technical Advisory Committee (NITAG), and TWG documents.	- Information was collected based on relevant theory of change (TOC) milestones for HSS, IPV, HPV, PCV/Rota, and MR. Additional cross cutting topics were TA and sustainability.

	- Conducted multiple fact-checking interviews with EPI stakeholders and government. - Observed four ICC meetings, several EPI TWG meetings, OPV switch meetings; MR introduction and review meetings; cMYP preparatory workshop; HPV application workshop; JA meetings; NITAG orientation meeting.	
Key informant interviews (KIIs)	- Conducted national-level KIIs with CHU and other directorates within MoH, EPI stakeholders, and Ministry of Finance (MoF).	- Information was collected based on relevant TOC milestones for HSS, IPV, HPV, PCV/Rota, and MR. Additional cross-cutting topics were TA and sustainability.
JA survey	- Conducted a JA survey with 14 respondents from among EPI stakeholders who participated in the JA.	- Respondents were asked a series of questions regarding their perceptions about the usefulness and benefits of the JA process to the country.
HMIS analysis	- Analyzed the Health Management Information System (HMIS) data.	- Estimation of vaccine coverage.

Findings

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

Table 7: Country characteristics of Zambia

Characteristic	
Demographic and economic indicators	
Total population (2016)	16,717,289
Birth cohort (2016)	659,126
GNI per capita (2015)*	\$US 1,490
Health spending and development assistance for health (DAH)**	
Government health expenditure as source (GHE-S)	\$US 723.9M
DAH channeled through government (DAH-G)	\$US 83.9M
DAH channeled through non-government entities (DAH-NG)	\$US 607.2M
Total DAH	\$US 691.1M

*GNI per capita source: World Bank World Development Indicators, 2015, reported in US dollars.

**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 8: Vaccine coverage estimates in Zambia

Vaccine coverage	Most recent survey estimate*	WUENIC 2014 **	Self-reported coverage (WHO)***
DPT/Penta3 coverage	85.8%	86%	86%
DPT1-DPT3 dropout rate	10.0%	10%	7%
BCG coverage	94.9%	95%	95%
Polio3 coverage	77.6%	78%	78%
Measles coverage	84.9%	85%	85%
Percent fully vaccinated****	68.3%	N/A	N/A

* Most recent survey coverage estimates from 2013–2014 DHS

**WHO/UNICEF Estimates of National Immunization Coverage (WUENIC) 2014 (WHO 2014)

***WHO vaccine-preventable diseases monitoring system, 2014 global summary (WHO 2014)

**** BCG, measles, and three doses each of DPT and polio vaccine (excluding polio vaccine given at birth)

Table 9: Child, adult, and vaccine-preventable disease mortality in Zambia

Child, adult, and vaccine-preventable disease mortality	GBD 2015*
All-cause mortality (deaths per 1,000 live births)	Estimate (confidence interval)
Infant mortality ($_{1q0}$)	15.6 (12.2, 19.3)
Under-5 mortality ($_{5q0}$)	41.7 (35.0, 49.5)
Female adult mortality ($_{45q15}$)	21.7 (13.4, 32.6)

Male adult mortality (_{45Q15})	30.0 (18.3, 44.1)
Cause-specific mortality: children under 5 (deaths per 100,000)	
Measles	4.2 (1.0, 11.3)
Diphtheria	0.1 (0.0, 0.3)
Tetanus	8.5 (5.2, 13.1)
Pertussis	6.1 (0.0, 30.0)
Meningococcal infection	6.1 (2.9, 11.7)
Diarrheal diseases	116.8 (72.5, 178.6)
Lower respiratory infections	175.6 (122.7, 246.4)
Cause-specific mortality: all ages (deaths per 100,000)	
Cervix uteri cancer	5.8 (2.4, 10.7)
Acute hepatitis B	1.6 (0.9, 2.5)
Cirrhosis of the liver secondary to hepatitis B	4.3 (2.4, 6.8)
Liver cancer secondary to hepatitis B	1.3 (0.7, 2.2)

* Mortality based on 2015 estimates from the Global Burden of Disease (GBD) study.

Timeline of major immunization events

Figure 1: Overview of major immunization events in Zambia

PLANNED		ACTUAL
2014	JAN	
	FEB	
	MAR	
	APR	
	MAY	Expression of Interest (EOI) submitted to Gavi ✓
		EOI submitted to Gavi ✓
		EOI submitted to Gavi ✓
		EOI submitted to Gavi ✓
	JUN	
	JUL	
	AUG	
	SEP	Application for IPV Vaccine Introduction Grant (VIG) submitted ✓
		First application for HSS grant submitted to Gavi ✓
OCT		
NOV		
DEC		
2015	JAN	
	FEB	
	MAR	IRC country report received ✓
	APR	
	MAY	
	JUN	
	JUL	
	AUG	
	SEP	Application for MR introduction submitted ✓
		Application for HSS grant resubmitted to Gavi ✓
	OCT	
	NOV	Launch of IPV ⊘ Postponed to 2018
	DEC	HSS Information Letter received from Gavi ✓
	MR Information Letter received from Gavi ✓	
2016	JAN	
	FEB	
	MAR	
	APR	Switch to OPV ✓
		PCA data collection and debriefing ✓
		Zambia receives news of entering accelerated transition phase in 2017 ✓
	MAY	
	JUN	Demonstration project phase 3 ✓
		Joint Appraisal ✓
	JUL	MR campaign ⊘ Sep 2016
		Zambia GNI figures available from World Bank ✓
	AUG	Development of Comprehensive Multi-Year Plan ✓
		HPV Proposal development ✓
		National elections ✓
	SEP	Submission of HPV proposal to Gavi ⊘ Postponed to 2017
		GMR received ✓
	OCT	Joint Appraisal ✓
	MR review workshop ✓	
NOV		
DEC		

Support streams evaluated in 2016

- Health System Strengthening (HSS)
- Human papillomavirus vaccine (HPV)
- Inactivated polio vaccine (IPV)
- Measles-rubella (MR) vaccine
- Other

✓ Implemented as planned/no delay

⊘ Delay

Support streams evaluated in 2016

- Health System Strengthening (HSS)
- Human papillomavirus vaccine (HPV)
- Inactivated polio vaccine (IPV)
- Measles-rubella (MR) vaccine
- Other

✓ Implemented as planned/no delay

⊘ Delay

Cross-stream analysis

Major finding 1: Technical Assistance

FCE findings point to programmatic capacity being strained in Zambia, which has led to reliance on technical assistance (TA) and support from partners. Such TA has not always been optimally provided for a range of reasons, including limited capacity-building as part of TA provision, restricted pool of TA providers that does not leverage local providers, and limitations in funding (Gavi FCE Team Dissemination Report 2015).

Zambia conducted a joint appraisal preparatory meeting June 8-10, 2016, at UNICEF, which was followed by a finalization workshop September 3-6, 2016, at PATH. The joint appraisal is a key step in Gavi's grant renewal process. It is an in-country, multi-stakeholder review of the implementation progress and performance of Gavi's vaccine and cash grant support to the country, and of its contribution to improved immunization outcomes. One of the objectives of the JA is to highlight areas where greater national investment and effort, as well as technical support, are needed. A survey was carried out on the last day of the final JA meeting targeted at participants in order to get their views on certain elements of the process, and 14 EPI stakeholders responded.

Finding 1

Improved JA process with greater stakeholder participation, engagement and guidance from Gavi Senior Country Manager (SCM) compared to last year, resulting in improved identification of capacity gaps and TA needs.

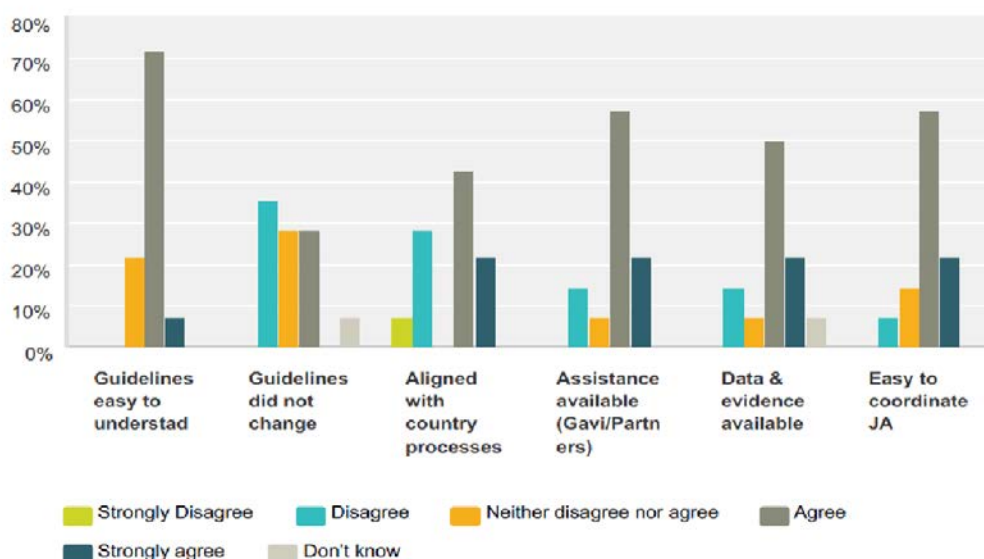
In comparison to the 2015 JA, this year's process showed improvements in a number of areas. In 2015 the JA process was found to have had relatively less participation from stakeholders with CHU, WHO, and UNICEF being the main participants. There was no involvement in-country of the Gavi SCM, and capacity gaps were found to have been inadequately identified. Thus, TA needs were not adequately addressed. In contrast, this year the Gavi SCM was more actively involved in preparations for the meetings and in leading and guiding the meetings, making Gavi more visible and accessible. The involvement of the SCM meant EPI stakeholders were better oriented to the new JA guidelines and report-writing requirements. Additionally, the SCM placed emphasis on identifying and documenting TA gaps and their possible solutions and this helped the country to be clearer about capacity gaps and TA needs. The engagement of the Gavi SCM is in itself a form of TA in understanding Gavi policies and guidelines. This engagement has markedly improved during both preparation and implementation of the JA process.

The JA meetings had wider representation from relevant EPI stakeholders which included WHO, UNICEF, CHAZ, CDC, CMMB, CIDRZ, JSI, AMP-SIVAC, GSK, and PATH. In addition to their local team, WHO also had support from two members of the Inter-country Support Team (IST), with a third member having been there for part of the process. The decision-making process was consultative and participatory. There was a balance of power among all stakeholders involved, and no particular actor seemed to have been overbearing or overpowering of others. The JA process was thus very consultative and involved rich and in-depth discussions of pertinent matters. CSO involvement in JA shows how the partnership has improved. Despite not having financial provision for CSOs to attend meetings and be part of activities, they have been there for many EPI activities, showing perceived value and strengthened partnership.

As illustrated in Figure 2 below, the majority of respondents to the JA survey indicated that the JA guidelines were easy to understand, although a substantial number did not know of any changes in the guidelines, indicating a general lack of awareness about previous guidelines. The survey revealed that 79% felt the process of completing the JA was moderately complex. Only 14% felt it was simple and straightforward and a further 7% felt it was highly complex. There was adequate assistance from Gavi and partners according to the survey. Data and evidence were largely available for the JA and it was said to have been easy to coordinate. In terms of time and effort required to complete the JA, 50% felt it was a moderate amount of time required while 36% felt it was a reasonable amount of time required. Only 14% felt an excessive amount of time and effort was required.

The JA was said to have been aligned with country processes at the time it was conducted. The country was in the process of writing the cMYP for 2017–2021. Additionally, the writing of the health strategic plan was also underway, as the plan expired in 2015 but was extended to 2016. Zambia was also going through the PCA and GMR processes that would lead to disbursement of HSS funds from Gavi. The last JA meeting in September was also utilized to discuss the HSS grant and GMR. There was, however, much debate as to when to hold the JA in future and it was agreed that the most important factor was aligning the JA with country budget cycles in order to help with securing funds. The first and second quarters of the year were thus suggested as being ideal for future purposes, although this was not conclusively decided.

Figure 2: Assessment of the JA process by participants

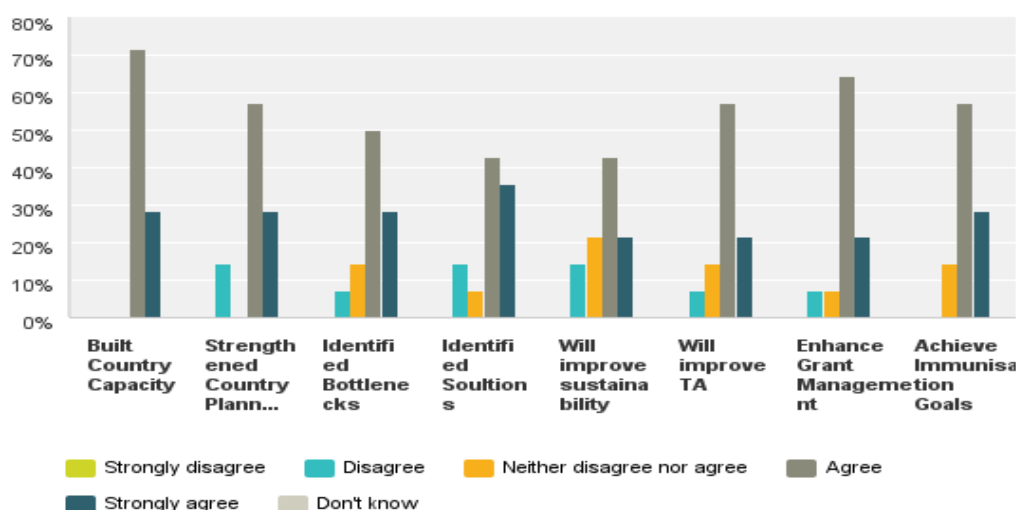


During JA discussions, emphasis was placed on identifying bottlenecks to immunization, actionable solutions, and TA needs where capacities did not exist in-house. Some of the discussions around capacity gaps and related TA needs during the two JA meetings included (1) a lack of up-to-date country research on vaccine wastage rates since the last 2005/6 vaccine sentinel surveillance survey, for which WHO was identified as currently working on and due to conduct in 2017; (2) inadequate data quality for EPI, for which CIDRZ and PATH volunteered to work on a data improvement plan; (3) a limited

understanding of current data quality challenges on the ground, suggested to be addressed through consultant desk review of existing available information or a DQA with support from WHO IST or a combination of desk review and DQA; (4) lack of dedicated M&E personnel under EPI, for which M&E support from an HSS grant position was seen as being able to assist with general data-quality and information needs of EPI; (5) procurement processes under MoH were said to be slow and thus it was suggested that UNICEF provide support to speed up the process, especially in view of the short implementation period for HSS; (6) inadequate logistics capacity for EPI with limited rollout and assessment of effectiveness of the Logistimo software that has been introduced to a limited extent at district (18 of 103 districts) and facility levels (only four of over 2,000 facilities), with suggestions for a more planned and documented approach in future to help track results, possibly with UNICEF assistance.

The JA survey showed that many respondents felt that the JA had built country capacity and strengthened country planning by participants who had improved the identification of bottlenecks and solutions at the country level. Overall, there was a sense that the JA would improve sustainability and technical assistance as well as enhance grant management and help achieve immunization goals. Overall, half of respondents felt the added benefit of the JA to the country was high and another half felt the process added some benefit to the country. No one felt the added benefit was low.

Figure 3: Assessment of the JA benefits and usefulness by participants



However, the JA report is yet to be finalized and is expected in the first quarter of 2017. Thus it is not clear yet how these issues will finally be presented in the final report and they are only preliminary findings. It should also be noted that although possible providers of TA were discussed, this was not conclusive as the emphasis, according to JA guidelines, was to identify the gaps and TA needs without specifying who should fulfill those needs. All partners appreciated and respected this guidance during the JA.

The TA needs identified are in line with observed key bottlenecks within EPI, the major ones being logistics and M&E. Much of the TA needs identified thus hinge on these two very critical areas and if addressed will go a long way toward filling many of the gaps noted.

M&E and logistics are critical and need a lot of support for evidence generation, data use and getting accurate data. Most indicators may not reflect the true picture due to data problems.
(KII)

Overall, the discussions around capacity gaps and identifying TA needs were more robust and detailed this year, with participation from a wide range of stakeholders. There was also a greater recognition of the comparative advantages of each stakeholder and who was best suited to provide the various TA required by EPI. The program is more aware of its capacity gaps and limitations and willing to get the necessary assistance, while the partnership with stakeholders is gaining strength. EPI faces major time constraints due to many activities on the chronogram and limited human resources, but the team is very dedicated. Financial resources are another constraint. The team observed that with fewer new vaccine introductions in the coming years more routine work, rather than meeting urgent deadlines, should be possible.

Recommendation

1. Technical Assistance for sustainability planning is critically needed to avert programmatic disruptions that could arise from limited attention to ensuring sustainability assessments. Gavi and country partners should ensure that available TA support mechanisms are effectively identified to address these TA needs.

Robustness of finding

Finding	Ranking	Robustness criteria
Finding 1: Improved JA process with greater stakeholder participation, engagement and guidance from Gavi Senior Country Manager (SCM) compared to last year, resulting in improved identification of capacity gaps and TA needs.	A	Findings based on meeting observations, KIIs, FCIs, and JA assessment tool and survey.

Major finding 2: Sustainability

Despite the successful launch of new vaccines, and plans to introduce additional new vaccines in the coming years, FCE findings suggest that there are increasing concerns among EPI stakeholders regarding the programmatic and financial sustainability of the EPI program. The program is relying increasingly on external support, especially from Gavi and local donors, to meet the cost of NVI. Furthermore, FCE findings indicate that domestic revenue is declining to the extent that the components of the EPI budget that are funded from government and local partner resources are increasingly getting underfunded. The economic context is adverse for the health sector with low domestic economic growth forecasts, low revenue potential, and an increasing public debt burden, all leading to diminished fiscal space for the health sector. The options for increasing domestic resource mobilization appear fairly limited. Our analysis below shows that there will be diminished ability to increase funding in order to secure adequate resources for the EPI program.

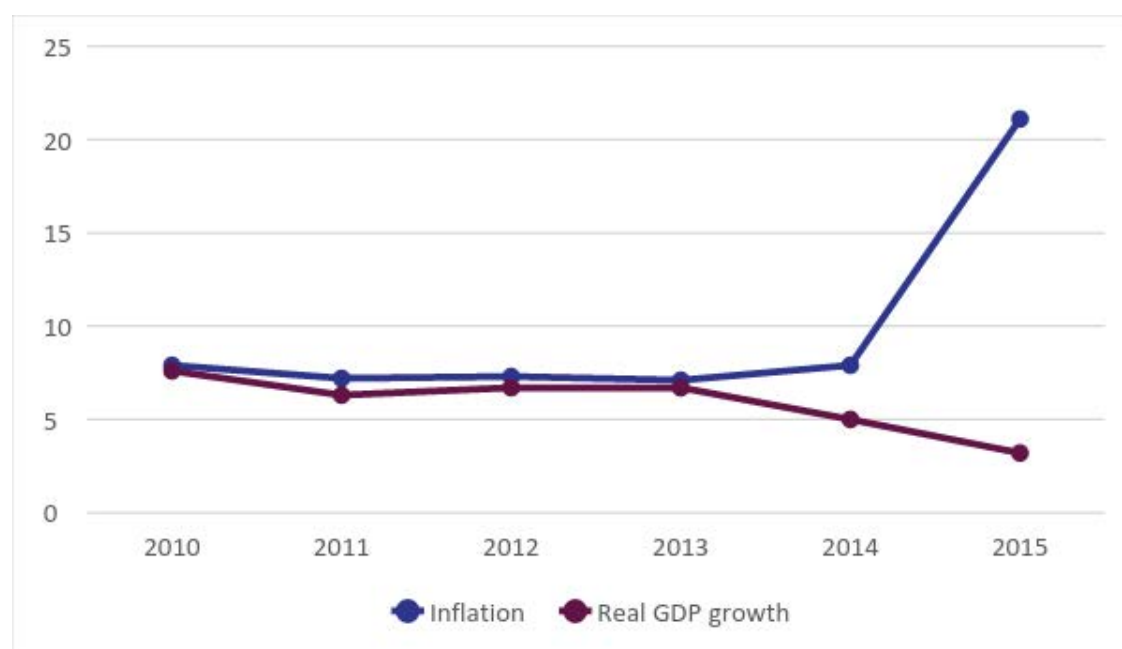
In addition, although the routine system is still fairly strong, there are potential threats to its programmatic sustainability which we have identified. The planning and budget process at the national level does not yield adequate resources to meet the operational costs for the program. The quality of costing work has some weaknesses. There is increased expenditure during introductory stages of new vaccines which are expensive and not sustained during the routine phase. Thus the benefits of such expenditure rarely carry over to the routine phase.

Finding 2

Declining fiscal space to support EPI budget threatening sustainability of the program.

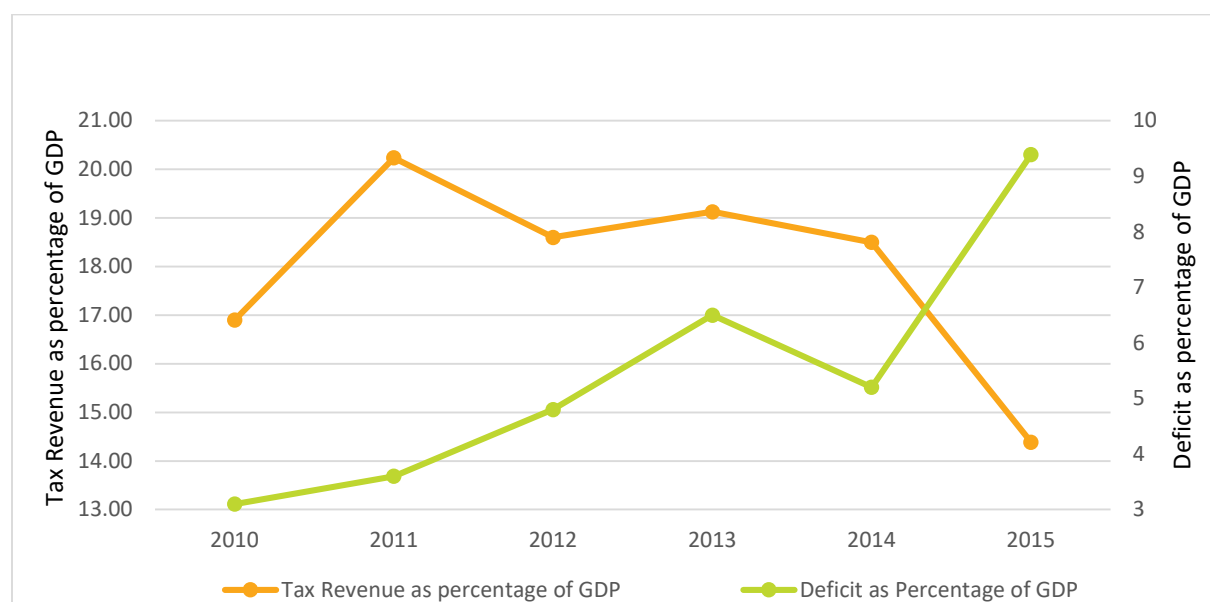
The recent economic challenges that have characterized the Zambian economy have raised questions regarding the government's ability to meet the increasing health expenditure resulting the introduction of several new vaccines. Information obtained from official government reports paints a picture of an economy in decline. The increasing inflationary levels, declining tax revenues, widening deficit levels, declining real GDP growth rate, and increasing public debt as a percentage of GDP evidence this. The diagrams below show the trends for some macroeconomic fundamentals of interest.

Figure 4: Inflation and Real GDP growth rate, 2010–2015.



Source: MoF Annual Economic Reports & BOZ Annual Reports

Figure 5: Tax revenue and deficit as a percent of GDP, 2010–2015

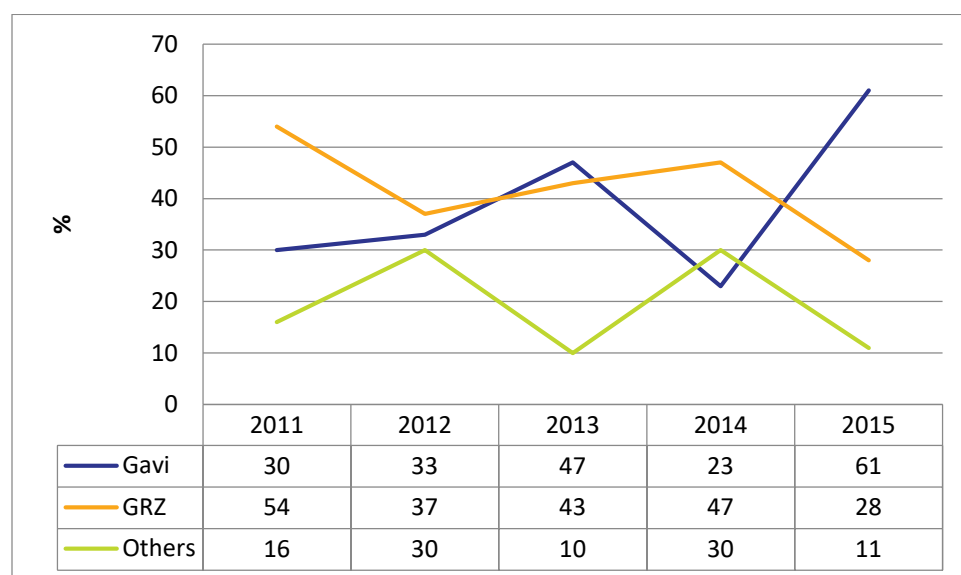


Source: MoF Annual Economic Reports & BOZ Annual Reports

From above, we note that the real GDP growth rate decreased considerably between 2010 and 2015 (Figure 4), declining from approximately 7.5% in 2010 to just above 3% in 2015. The decline in real GDP has been especially precipitous between 2013 and 2015. Figure 4 also shows that although Zambia’s inflation rate remained relatively constant from 2010 to 2014, ranging from 7.1% to 7.9%, it increased rapidly to 21.1% in 2015. Over the same time period, the deficit as a percentage of GDP climbed steeply (Figure 5). Standing at below 2% in 2012, this figure nearly reached 10% in 2015. Similarly to GDP, the increase in the deficit was especially steep between 2014 and 2015. At the same time, tax revenues as a percentage of GDP also decreased between 2010 and 2015 (Figure 5). More specifically, after peaking at 20.2% of GDP in 2011, tax revenues then fell to 14.4% of GDP in 2015. Thus, the above information suggests a declining fiscal space between 2010 and 2015. Defined generally, fiscal space is the “capacity of the government to provide additional budgetary resources for a desired purpose without any prejudice to the sustainability of its financial position.” In the context of this work, fiscal space is the government’s ability to provide resources for health, including immunization, without jeopardizing its current or future economic standing.

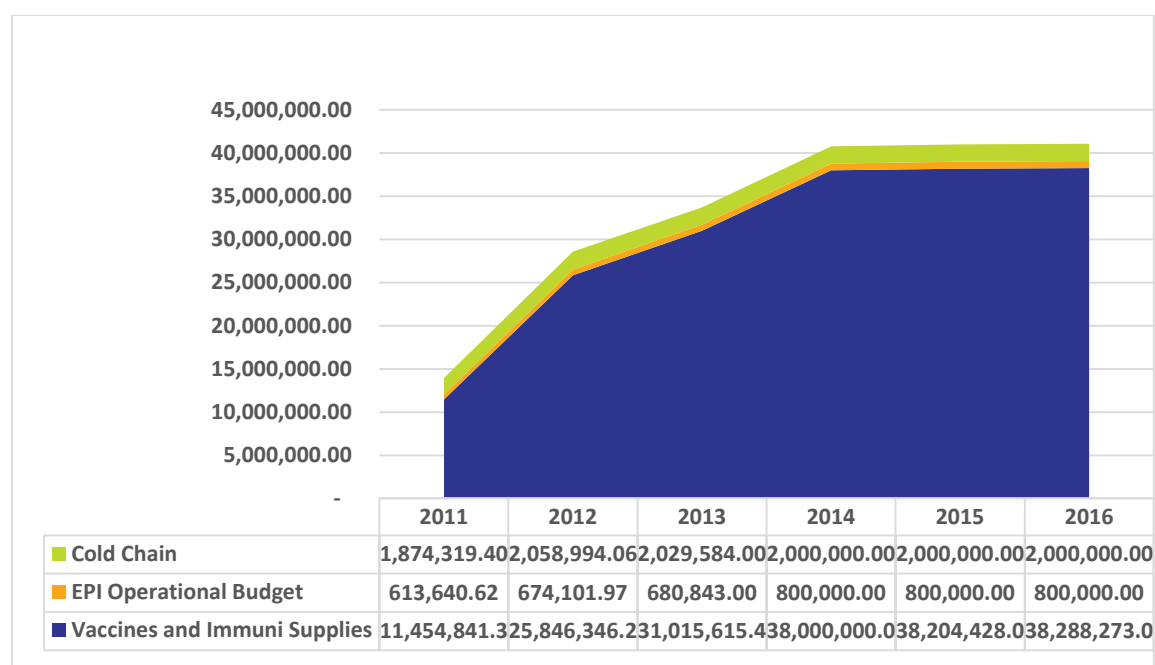
Furthermore, the resource tracking data for the period 2011–2015 suggests that the composition of funding sources for the EPI program has shifted, with Gavi’s proportion of funding for the EPI program increasing between 2011 and 2015 and the government’s proportion declining over that period, as shown in Figure 6, below. Moreover, the proportion of funding from other sources has also declined, which raises potential threats to the sustainability of the EPI program should the government fail to meet the financing gap. Therefore, the programmatic sustainability of EPI would be under significant threat should the financial support of Gavi, the main donor, decline in the coming years (Gavi FCE team Dissemination Report 2015).

Figure 6: Proportional expenditure on EPI by different funding sources



The recent poor economic performance, increasing competing expenditures, and lack of prioritization may explain the modest contributions of government toward the EPI program. Data extracted from government yellow books shows that government allocations toward the EPI program, vaccine and immunization supplies, and cold-chain equipment have remained stagnant in the last three years. The diagram below shows government allocations toward the operational EPI budget and the aforesaid EPI components.

Figure 7: Government-approved allocations, 2011–2016



Source: GRZ Yellow Books

It should be also noted that approved allocations do not necessarily imply actual disbursements. Zambia's EPI program has been characterized by underfunding from the government due to, among other reasons, relative low priority placed on EPI activities and a declining revenue base. Table 10 shows total authorized and actual disbursement to the EPI program from 2011 to 2015.

Table 10: Total authorized and disbursed allocations toward EPI for the period 2011–2015

	Activity	Total authorized provision	Actual expenditure	Variance	% of authorized funds disbursed
2011	EPI operational budget	613,640.62	-	613,640.62	0.0
	Cold-chain equipment	1,874,319.40	-	1,874,319.40	0.0
	Under-5 card printing	-	-	-	-
	Vaccines and immunization supplies	11,454,841.30	-	11,454,841.30	0.0
2012	EPI operational budget	674,102	489,992.00	184,110.00	72.7
	Cold-chain equipment	2,058,994	207,868.51	1,851,125.55	10.1
	Under-5 card printing	1,017,490	690,628.00	326,862.00	67.9
	Vaccines and immunization supplies	25,852,143.21	25,846,341.20	5,802.01	99.98
2013	EPI operational budget	476,590	474,890.00	1,700.00	99.6
	Cold-chain equipment	2,029,584	1,287,831.00	741,753.00	63.5
	Under-5 card printing	1,027,665	1,027,596.00	69.00	99.99
	Vaccines and immunization supplies	31,015,615.45	13,000,000	18,015,615	41.9
2014	EPI operational budget	800,000	776,300.00	23,700.00	97.0
	Cold-chain equipment	2,000,000	397,484	1,602,516.00	19.9
	Under-5 card printing	1,000,000	682,504.00	317,496.00	68.3
	Vaccines and immunization supplies	38,000,000	38,000,000	-	100.0
2015	EPI operational budget	800,000	66,666.67	733,333.33	8.3
	Cold-chain equipment	2,000,000	72,507.42	1,927,492.58	3.6
	Under-5 card printing	1,000,000	166,666.67	833,333.33	16.7
	Vaccines and immunization supplies	38,204,428	5,000,000	33,204,428.00	13.1

NB: The 2012 authorized allocation for vaccines and immunization supplies includes a supplementary amount of K5, 797.00

Source: MoH-CHU Immunization Financing – JA presentation and MoF-GRZ Budget Outturn Report and Yellow Book

Table 10 shows that for the year 2015, approximately 8%, 4%, 17%, and 13% of authorized funds were disbursed toward the EPI operational budget, cold-chain equipment, printing of under-5 cards, and vaccines and immunization supplies, respectively. Notwithstanding that the approved allocations fall short of the required EPI operational costs, such meager payouts are incredibly minimal and as a

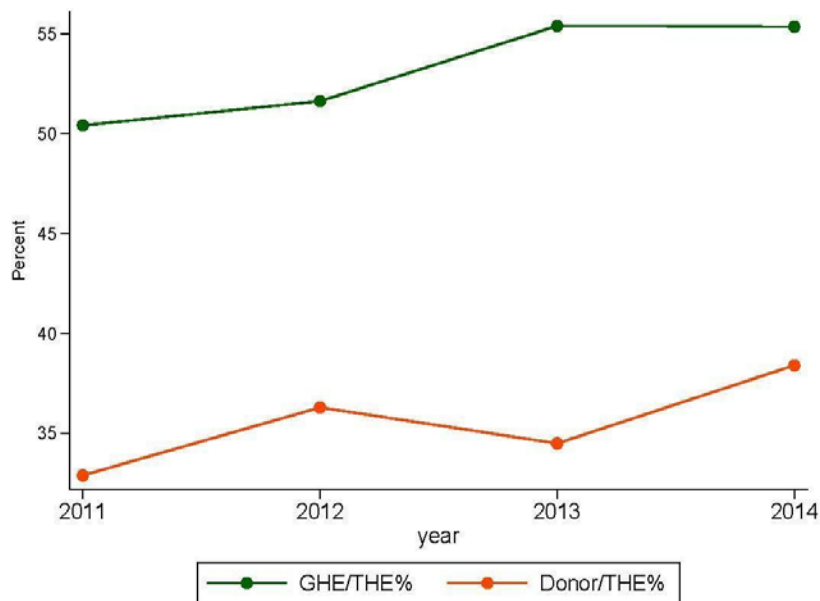
consequence may jeopardize potential future gains in immunization coverage and threaten the programmatic sustainability of the EPI program.

Figures for 2016 are not yet available, but initial indications are that actual expenditure will be much lower than previous years. It has been noted that EPI has only had less than 10% of its budget funded. The need was \$41m, of which \$6m was approved and less than \$500,000 disbursed. The immediate and future implications of the above scenario include the following: inability to maintain cold-chain equipment as well as provide cold-chain supplies such as fuel; inability to conduct program supervision and surveillance; and delayed or inadequate vaccine procurement. In addition, the ability to mobilize communities for immunization programs through outreach is likely to be adversely affected.

There is no doubt that if the above challenges and underfunding continue, gains in immunization coverage would be threatened. Taken together, the above information suggests that if the observed recent trends and poor economic conditions continue, the Ministry of Health will face a difficult financial situation in the coming years. More specifically, widening deficit levels amid declining tax revenues will result in fewer government resources and thus lead to inadequate funding for the health system. Moreover, faced with competing demands for limited government resources, the government may be forced to decrease funding for the health sector. This may threaten gains in key health indicators that have been observed in the country, including gains in immunization coverage.

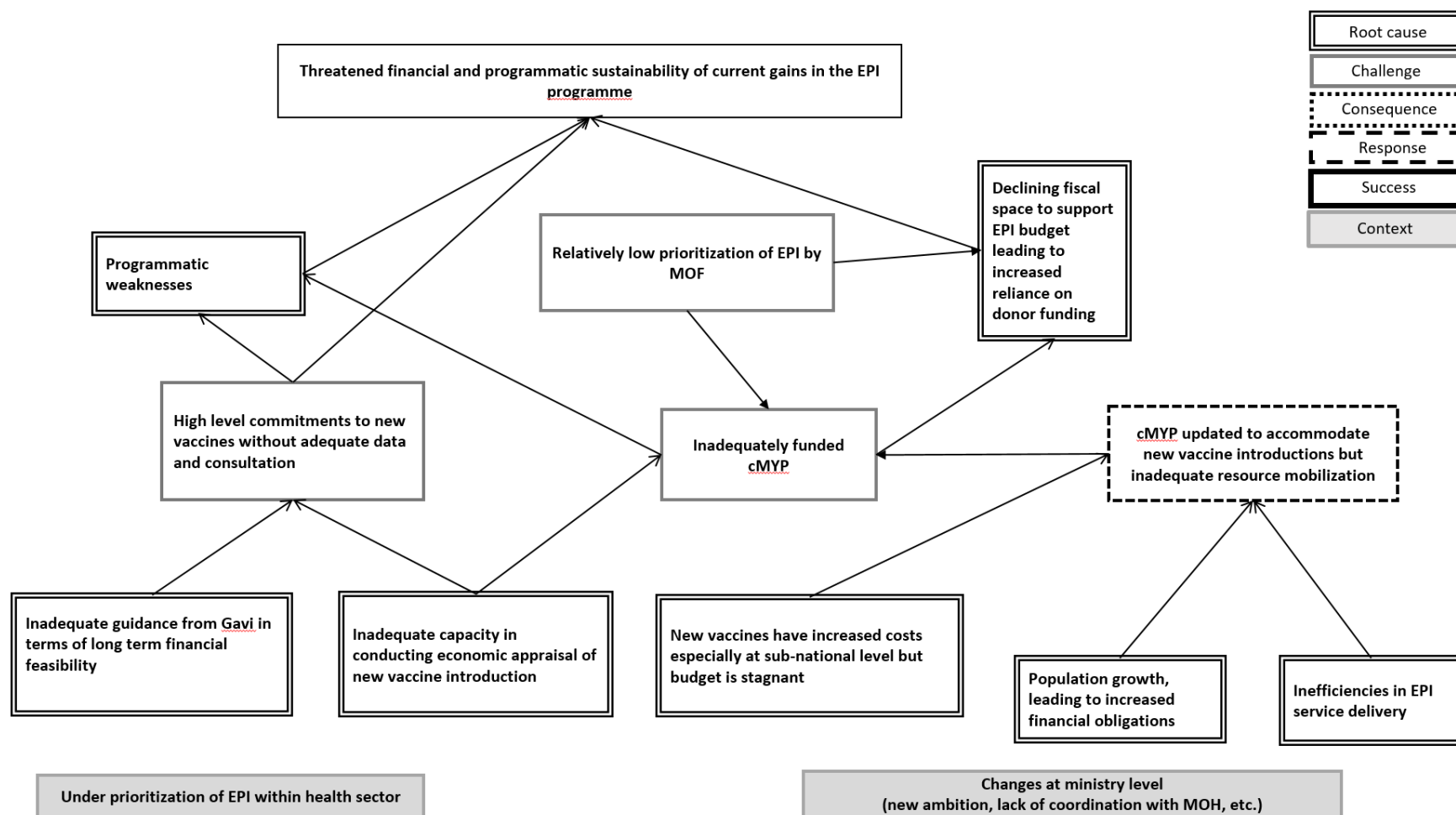
The strained economic situation faced by the government may also slow or reverse trends toward rising government health spending. Figure 8 below shows that while government health spending as a percentage of total health spending increased up to 2013, it began to slightly decline in 2014, perhaps foreshadowing future declines in the government's financial contributions. This trend is especially worrisome given the increased percentage of the EPI program that is funded by Gavi. If Gavi aid decreases in upcoming years (as it is projected to do, given Zambia's status as a preparatory transition country), the government may not be able to mobilize resources to adequately fill this gap.

Figure 8: Government health expenditure and donor health expenditure as a percentage of total health expenditure, 2011–2014



The information presented above paints a picture of an economy in decline that threatens the sustainability of the EPI program and the gains in immunization coverage. The economic challenges would make it difficult for the government to create the fiscal space needed to meet the increasing costs resulting from NVI as well as increasing health care needs resulting from a growing population.

Figure 9: RCA on sustainability



Finding 3

Despite strong national ownership and commitment to promoting sustainability of EPI, underlying programmatic weaknesses are undermining the sustainability of program gains.

The continuing high degree of national ownership and goodwill that had characterized the introduction of new vaccines is considered to be critical for sustainable integration and routine service delivery. Based on this strong ownership, it is often presumed that the government will ensure that resources are made available to ensure that the program continues to run. In addition, in 2016, the government convened the National Immunization Technical Advisory Group (NITAG), which consists of about 25 individuals with a wide range of capacities that will be crucial for sustaining the progress and gains of the EPI program. The NITAG, if well managed, will provide a resource for the government to draw upon in introducing and implementing programs. This will also fill the technical gap that exists above the EPI TWG and help improve decision-making capacity for the long term. WHO has coordinated technical support to provide orientation and technical training to members of the NITAG, which took place November 14-18, 2016. It is anticipated that the NITAG will facilitate policy debate and decision-making for a sustainable EPI program.

Despite this progress, the programmatic sustainability of the EPI program is hampered by a number of factors. In 2016, the government asked the FCE team to conduct a formal assessment of the sustainability of the country's EPI program and how the country is readying itself for accelerated transition (although the transition has been postponed). Below we outline a number of challenges that undermine the sustainability of the program.

Challenges in domestic resources mobilization framework for EPI program

We note that the cMYP, which is supposed to serve the purpose of mobilizing resources and setting priorities, is not adequately fulfilling these functions. First, in the current year and over the past few years a number of items and activities in the cMYP regularly remain without committed funding while some of the donors have not fulfilled their commitments. In Figure 10, it can be seen that not only has EPI total expenditure (from all sources) declined, as was shown earlier, but also, importantly, that the difference between the resources required by the cMYP and those actually expended has increased. This gap may be a reflection of funding commitments from the cMYP not being fulfilled or executed. This provides some evidence that the cMYP is not being adequately used to mobilize additional resources for the EPI program.

Second, our evaluation shows that once the cMYP is completed, largely by a team of EPI technocrats, efforts to mobilize resources and support from partners are led mostly by the EPI program with limited engagement of the Department of Policy and Planning, which typically is responsible for resource mobilization for the entire Ministry of Health. As evidence of the lack of policy attention to securing more resources for the EPI program, a number of key informants emphasized the importance of getting the EPI agenda to the highest policy level to ensure that more attention and resources can be mobilized to meet the increasing resource requirements as the program expands. In the midst of increasingly limited resources, having EPI tabled at the highest policy level is crucial to ensuring sustainability.

EPI is not adequately discussed at highest level of decision-making. (KII)

Despite official statements about integration, sometimes policy engagement about program funding can be an irreducible battle over limited resources.

Social insurance is being pushed to push for ARVs. What of immunization? [We are] pushing for it to be for all essential immunization services. (KII)

Another key informant even suggested that the issue of lobbying for increased funding for EPI needs to be addressed to greater national attention at the political level.

[National] Prioritization is the main challenge around financing EPI. There has been no voice to push government and inform them. Even parliamentarians do not know much and cannot discuss it with passion. So the plan is to engage more with parliamentarians and advocate for increased funding. Also educating communities on the need for increased immunization funding so they can also advocate and push for more funding. (KII)

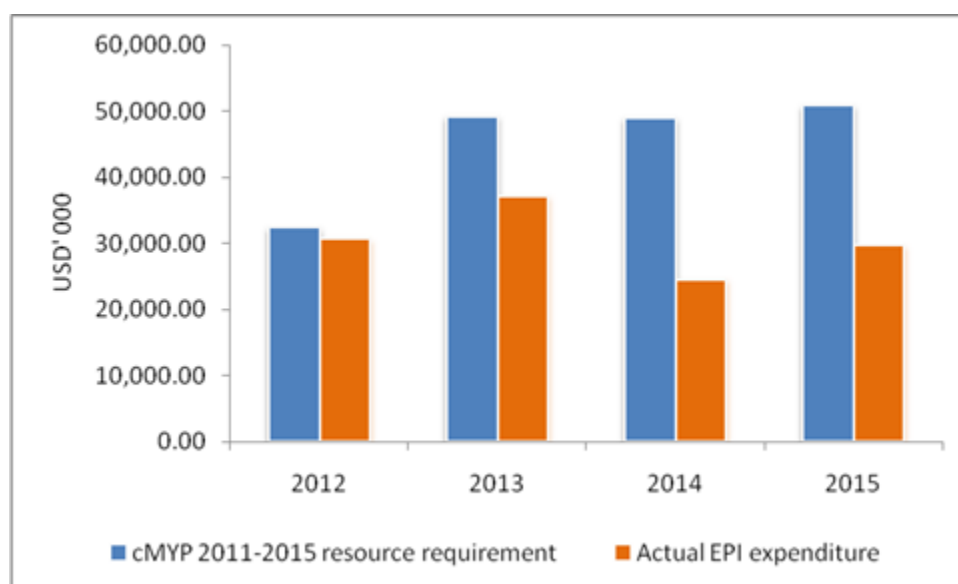
Such an approach would be unusual in terms of how the Ministry of Health allocates its national resources. But this concern probably does demonstrate a degree of frustration that business as usual is not working effectively to deliver more funding to the EPI program. For example, there are concerns which have been expressed on several occasions that requests for support from local donors are delivered late and without supporting documentation or “solid” proposals. On a number of occasions requests for funding have been presented at ICC meetings at which a new program is being approved for implementation. To ensure that recent investments in the EPI program are protected and sustained, it is crucial that the lead resource mobilization unit in the Ministry of Health places EPI at the center of planning.

The government needs to take more leadership on the issue of funding EPI in this country. The program has done a lot in terms of introducing new vaccines to prevent children from dying. But the continued success of these new vaccines requires funding. And the government is the only one which can guarantee funding because these are national programs. (KII)

A donor agency representative also noted that more serious engagement with the Ministry of Finance is required.

The only way to secure funding to the EPI program will be to have more government funding. (KII)

Figure 10: Comparison of cMYP required resources and actual EPI expenditure 2012–2015



Third, several key strategic options appear to have substantial cost implications: delivery costs through outreach, the cost of human resources (training and recruitment) to sustain coverage, and transportation and related logistics, among other costs. Although the district plans and budget proposals estimate and incorporate these implementation costs, the ultimate approved national budget does not fully take these costs into account. That is, the approved budget is less than what was proposed, and the implications of funding shortfalls are generally never negotiated or discussed. In the funding climate, the sustainability of the program in terms of meeting its coverage and quality of service delivery are susceptible to compromise. Related to this issue is the inclusion of new programs into the routine EPI program. For example, the process of revising the cMYP is not yet finalized despite introduction of new vaccines. Although discussions around HPV are still ongoing and the official position is that the revised cMYP will include HPV costs in the program funding requirements, things are not clear from a resource-mobilization perspective. A lot is dependent on Gavi support, as evidenced from this quote from a key informant.

There are no confirmed commitments for funds from partners. We are riding on Gavi contribution.
(KII)

A consequence of these challenges is that the management of the program is left to adopt an approach of “let us do what we can do with the resources we have in our hands.” Clearly, this is not an ideal situation in a case where a program is receiving so much less resources than they need. A thorough review of EPI expenditure and cost analysis is required to inform planning regarding the nature of EPI expenditure and cost. Finally, the program lacks an expenditure-tracking analysis, which would shed light on the components of the program that are receiving the available funding and facilitate analysis about where the current pattern of expenditure is contributing to sustainable EPI service delivery.

Limited investments made in building capacity for program sustainability

Despite these positive developments, some of the factors that threaten the long-term programmatic sustainability of the EPI program in Zambia relate to the inadequate investments made in developing capacities that are necessary to contribute to sustainability. We itemize several specific factors: first, over the past five years at least, neither the government nor the donors have dedicated sufficient funding to developing M&E systems. For example, the routine HMIS does not provide adequate data for planning, monitoring, and evaluation (e.g., measles-rubella campaign data on vaccine delivery, wastage rates, and coverage rates, etc.) and neither does the program collect information to understand implementation experiences and problems. Ongoing challenges with reconciling population figures between CSO and headcounts show inadequate investments in building M&E capacity. Consequences of this challenge include persistent vaccine stockouts, unreliable output indicators, and so on.

Second, because of the economic downturn in 2015 and 2016, the EPI program has been rather slow to incorporate costs borne by donors into the national EPI budget, notably cold-chain maintenance, training, M&E tools, technical supervision, and so on. As the program experienced reduced disbursement for operational funding as shown above, the EPI program at both national and subnational levels was unable to fulfill its programmatic obligations. Many activities, such as technical support for implementation, logistics, and community mobilization, were canceled.

Finally, at the local level, we observed that because of human resource constraints, the EPI program relies significantly on community health workers to mobilize the community through various innovative ways, create demand for immunization (particularly among the disadvantaged communities), and deliver immunization services. Local ownership and community involvement have been proven to be key pillars of a sustainable EPI program in many parts of the country. In one of the districts, the MCH Coordinator emphasized the role community health volunteers play in supporting the immunization program:

Most of the outreach we do is supported by volunteers who are funded under the Sustainable Development Goals project. They really help us in reaching the community and disseminating information about child vaccination. But EPI is integrated with HIV/AIDS, nutrition, and other programs. So when we go to the community, we do everything. (KII)

However, it appears to be the case that training and incentives for community health volunteers have diminished, leading to less systematic engagement with community and compromised service delivery. Most districts lack the funding to incentivize community health workers; it is observed that the EPI program is generally doing better in areas where community health volunteers are remunerated, usually under a funded project. Most of these projects are funded by time-bound donor projects rather than the government. The challenge is that once donor funds end, these gains are quickly lost.

Finding 4

Limited preparation toward transition out of Gavi support is raising concerns about sustainability of current programs.

Zambia was expected to enter accelerated transition from Gavi support in 2017, and thus the country commenced planning for transition earlier in 2016. The engagement between Gavi and the EPI program

about transition planning started around April 2016. Initial communication was between the EPI Program Management and the new Senior Country Manager for Zambia. The first visit to Zambia by the SCM was in April 2016 to discuss a number of issues including transition planning. In addition, a number of preparatory steps were taken to help Zambia prepare for entering accelerated transition phase. A transition working group was established and planned to have monthly conference calls. The group was comprised at the global level of Gavi, WHO, UNICEF, the World Bank, the Global Fund, the Bill & Melinda Gates Foundation, and country-level EPI partners CHU, WHO, UNICEF, and CIDRZ. Unfortunately, due to communication lapses between Gavi and EPI, there was no participation on these calls from the country level, and the outcomes of these calls are unclear.

The first phase of the JA was held in early June, which was considered to be a preparatory JA workshop. The main Joint Appraisal was planned to be done together with a Joint Transition Assessment in July 2016. This meeting was postponed to October 2016. The main reason for the postponement was to allow the country to focus on preparations for the MR campaign, which was to take place in September 2016.

It can be said that the process of transition planning was delayed and did not commence in earnest and eventually was overtaken by Gavi's decision in July that the country would not be graduating into accelerated transition. Given the often protracted negotiations that are expected to take place within the government and among local EPI stakeholders, this is clearly late to start the planning process for a country which is expected to take up a significantly higher portion of the EPI budget.

The leadership over the transition planning was not clear. Leadership over the transition process both at the Gavi Secretariat level as well as within the country has been criticized as inadequate. Transition planning is a complex process that needs more time and technical support to countries. This process requires a fundamental change in the funding formula for the health sector which takes time and invariably requires reallocation of resources within the health budget.

The discussions were just beginning in April this year; there was a desk review. I think this process needs to begin not just because you are graduating. The global community are here; we need to do a case-by-case base. Every country is different. We need to show that we are increasing in our budget. We are a small country. Preparation about transition should be done on a regular basis and not when we are about to transition. (KII)

The criteria for transition are also challenged as being simplistic as they are limited to one indicator, GNI per capita. Some of the countries have recorded fairly rapid economic growth in the last few years without a corresponding increase in health sector funding and health system strengthening. Even under such conditions, adjustment takes time and is not a straightforward process for the individual sector. Many EPI programs in low- and lower-middle-income countries face systemic and capacity challenges that go beyond gross national income (GNI) indicators. Engaging government leadership at the highest level takes time. The process of transition should not be reduced to a collection of indicators.

Further, the delayed start of planning for transition invariably meant that the country was not going to be able to transition in an orderly and planned manner with the time that was left, should the decision

have been made to begin transitioning. As such, the news came largely as a relief, as one key informant indicated:

It is a tragedy for the country but for the program it is a relief that Zambia is no longer transitioning as government may not have all the funds. (KII)

Despite the postponement of Zambia's graduation into accelerated transition, the country faces concerns about how to sustain the gains achieved once the level of support begins to decline, given that the recent EPI programmatic progress is attributed to Gavi support. For the long-term sustainability of the EPI program, a clear strategy for mobilizing additional domestic revenue is considered the only viable way forward. The Ministry of Health has dedicated itself to finalizing the development of the strategy. At the moment, the country is preparing a new health financing strategy that should address ways to mobilize resources to meet the cost of health programs, including EPI. One of the most-cited specific proposals to be considered in this strategy is the introduction of Social Health Insurance (SHI). Based on interviews conducted with staff familiar with the process (development of the health financing strategy as well as the SHI), the specific proposal design and its potential to mobilize additional revenue remain unclear at this stage. It was also pointed out that some of the main proposals being reviewed have not yet been discussed with the national treasury. For example, there seems to be some reluctance among fiscal authorities to introduce earmarked taxes targeted at securing funding for specific programs. It remains to be seen how this issue will be resolved.

We can't have a [earmarked] tax for each and every program; you can imagine the chaos we would have if everybody came here to ask for earmarking their program. As much as immunization is very important, fiscal principles do not really encourage segmentation of revenues for individual programs. Our principle is consolidation. We don't want to introduce distortions into the economy. (KII)

What is also not clear is the extent to which the team that is developing the strategy is incorporating the resource needs of the EPI program. In other words, is the strategy, once implemented in full, capable of mobilizing the resources required to meet the current and future funding gaps in the EPI program? Or is the relationship between the revenue targets informing the development of the financing strategy and the resource needs of the EPI program as well as other health programs? Key informants indicated that there is a paucity of cost data, especially on program costs, including EPI. These key questions can only be answered once the strategy is completed and implemented.

Of course the costing tool that we use is standard and helpful. But I think the challenge is with the data that we put into the template. For some costs there is no data, so we have to use assumptions which may not always be accurate. (KII)

Another key informant suggested that more training is required in how to incorporate cost data for planning.

Issues of capacity in using costing information for planning are lacking. (KII)

Finally, as a process the program considers the introduction of SHI as long overdue and taking too long while the financing situation for the EPI program continues to deteriorate. Hence, although the decision

not to transition was resolved in the midst of the delay and uncertainty surrounding the country's preparedness for graduation into accelerated transition out of Gavi support, the concerns and discussions still persist.

Recommendations

1. Improving skills and capacity in costing and program management are key to enhancing the sustainability of the program and addressing the major programmatic weakness. Greater investments are needed in M&E capacity and, in particular, in reconciling data discrepancies between CSO and headcount data in population estimates.
2. The Ministry should conduct or commission a comprehensive costing and expenditure tracking assessment to determine program costs and assess funding gaps.
3. The Ministry of Health should ensure functionality of the newly constituted NITAG to facilitate strategic direction for a sustainable EPI program.

Robustness of finding

Finding	Ranking	Robustness criteria
Finding 1. Declining fiscal space to support EPI budget threatening sustainability of the program.	A	Based on quantitative data, KII, and meeting observations
Finding 2. Despite strong national ownership and commitment to promoting sustainability of EPI, underlying programmatic weaknesses are undermining the sustainability of program gains.	B	Based on quantitative data, KII, and meeting observations
Finding 3. Limited preparation toward transition out of Gavi support is raising concerns about sustainability of current programs.	C	Based on quantitative data, KII, and meeting observations

Funding stream: PCV/Rota/MCV2

PCV, Rota, and MCV2 were introduced into routine immunization in 2013. Funds for preparation and introduction were covered in the 2013 and 2014 reports. Since then, there have been no activities specific to the three vaccines.

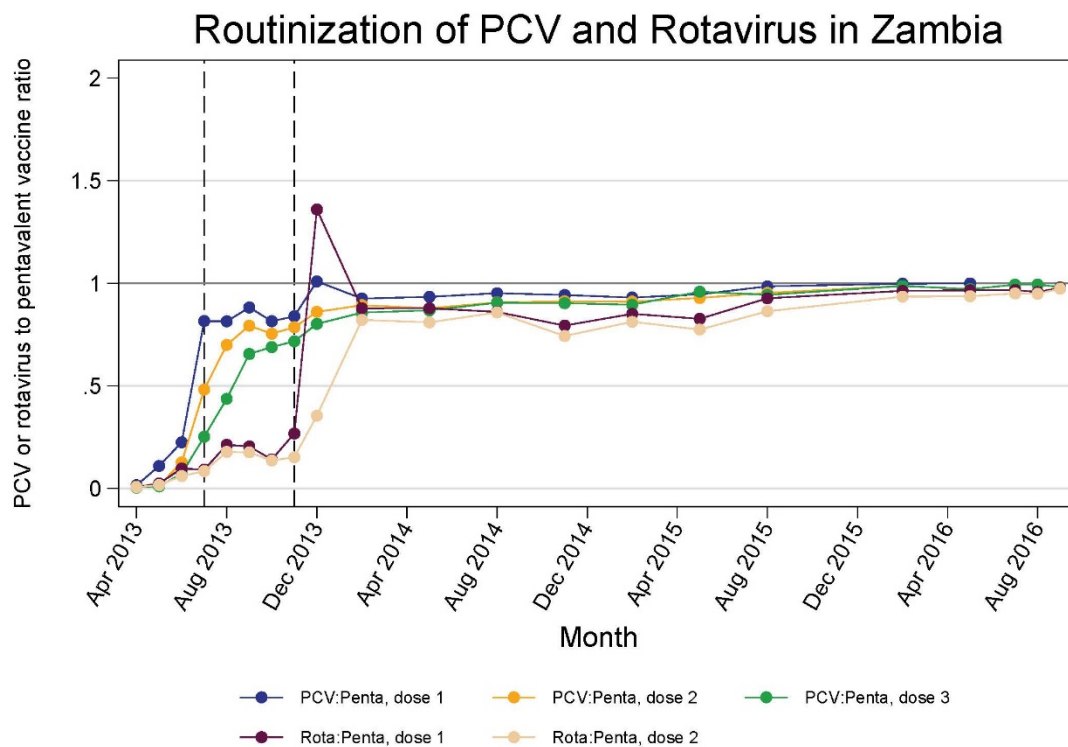
Finding 1

Persistent/ongoing suboptimal coverage of PCV/Rota as a result of delayed and inadequate government funding and poor logistics management at the subnational level.

The 2015 FCE Annual Report reported that the doses of PCV and Rota administered remained below the doses of other older vaccines despite falling due and being administered on the same schedule. Factors alluded to included subnational-level stockouts of the new vaccines caused by vaccine supply challenges as well as understatement of true demand for vaccines in many parts of the country. Three years after the introduction, administrative data show the doses of the two vaccines still remain below the comparable DPT doses. Stakeholders have shown concern over why it has taken so long for the two vaccines to catch up and the implications of such suboptimal coverage. Two factors may account for the

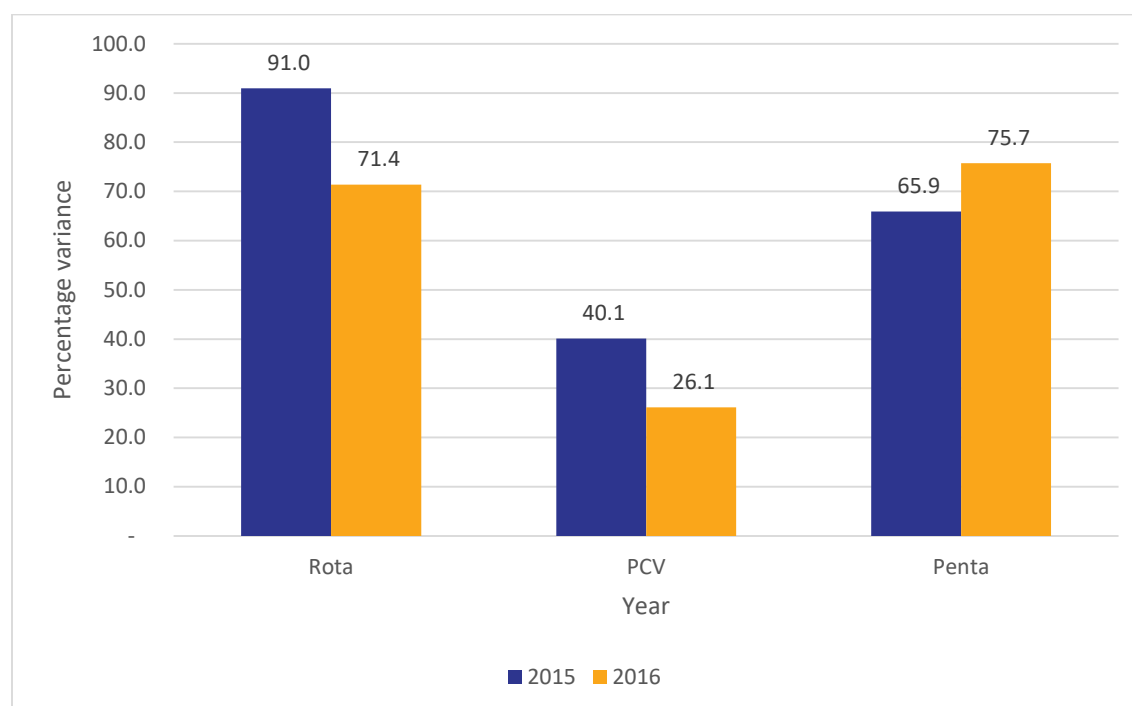
reported under-coverage of the new vaccines: supply-side challenges causing stockouts of the two vaccines and data-quality issues.

Figure 11: Routinization of PCV and Rotavirus in Zambia



At the national level there is a sense that stocks of vaccines are adequate and are often reported as such by EPI. However, comparison of vaccine forecasts with actual procurements illustrates that all vaccines are under-procured. Figure 12 illustrates this discrepancy between forecast quantities and quantities actually purchased.

Figure 12: Shortfalls in vaccine procurement versus forecast



Overall it can be seen that although all vaccine procurements were below forecast values, PCV was more severely affected. In 2015 only about 40% of PCV was procured, and in 2016, only about 26% was procured. For Rota the percentage was better, with 81% purchased in 2015 and 71% in 2016, whereas for DPT 66% and 76% were procured in 2015 and 2016, respectively. Although these data are only for two years, they illustrate a hidden problem for EPI in that it creates a shortfall that affects all the other levels of EPI delivery. There is a need to look at data for more years in order to establish the trend and differences and different antigens. The evaluation has noted many instances when there were delays in the procurement of vaccines mainly due to delays in securing government funding. Since government funding accounts for a bigger portion of new vaccines (PCV and Rota at about 66% and DPT at about 50%), delayed government funding may have a huge impact on the supply of new vaccines. The “push system” of vaccine delivery from national to provincial level further masks this problem by not considering actual demand at the provincial level. This may explain the vaccine stockouts that continue to be experienced across the country, undermining the successful routinization of the recently introduced vaccines.

One person from UNICEF sits with one or two from MoH, so there is a big gap [in forecasting and quantification]. The process needs to be more inclusive and should involve other players as well. For example, medical stores as well could help, as can GSK and JSI. Going forward we will work on this to make it more inclusive. At central level, stocks look fine. The challenge is logistics management. Provinces are laid back and simply store, but do not distribute actively. Therefore, the responsibility is on the district and facilities to pull. Thus stocks get stuck at provincial level. The plan is to set up Logistimo tool to check on this, focusing in a few districts first, test these,

and expand after. Another area of TA need is therefore logistics. More numbers and technical capacity for logistics is needed. (KII)

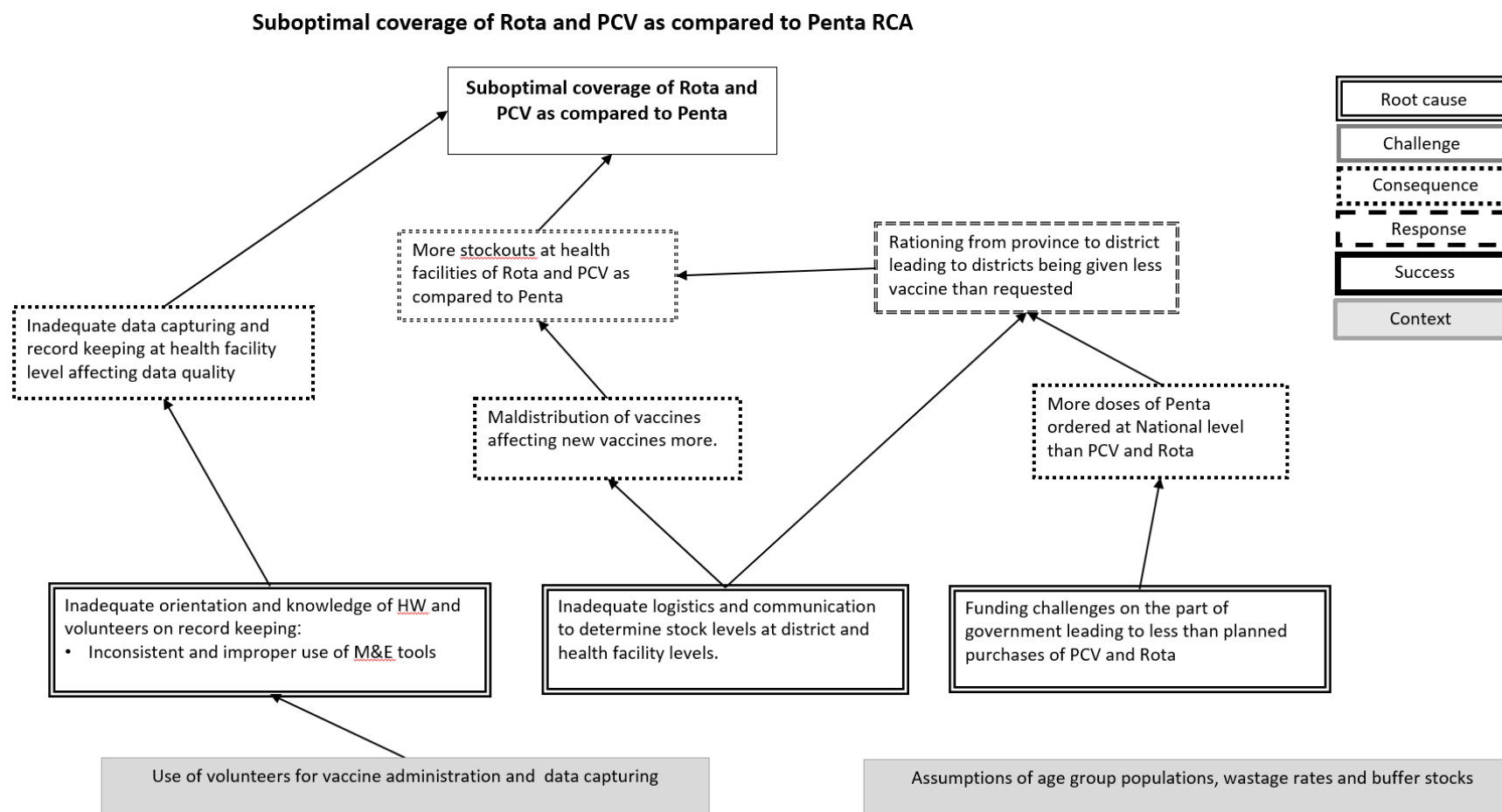
In addition, vaccine stocks at the district and facility levels are being managed mainly by MCH coordinators and the Health Facility In-Charge. The lack of specialized logisticians at these levels may contribute to some facilities not receiving vaccine quantities as requested, contributing to stockouts. Though this may affect all vaccines, including DPT, there is reason to believe that the effect will be higher for new vaccines. This is based on the following reasons: First, the people managing vaccine stocks may have built experience in managing old vaccines and may be skeptical of the stocking of recently introduced vaccines. Second, the performance of health facilities on immunization is measured based on DPT coverage. It is likely that they pay more attention to DPT at the expense of new vaccines. This is also compounded by the use of inadequately trained volunteers and support staff such as Community Health Assistants (CHAs) and Classified Daily Employees (CDEs) in conducting vaccination and record-capturing coupled with limited and irregular supportive supervision, thereby undermining record-keeping.

We have few qualified staff and therefore use CHAs and CDEs. Maybe they are not recording properly. For example, Rota is sensitive and has a cutoff point and maybe they are not giving when [the child] is over age. (KII)

Some facilities use CHAs. There are challenges with vaccine administration and record-keeping. Data capturing is a challenge. They are in health posts and so data management is lacking, but we have tried to train them. (KII)

Although procurement and distribution of vaccines appear to be the main challenges around routinization, there is a need for further research in this area. Factors such as data quality issues around vaccine reporting, vaccine administration practices, and population figures used for forecasting could also have a bearing on the coverage figures for vaccines.

Figure 13: RCA on suboptimal coverage of Rota/PCV



Finding 2

MCV2 coverage very low at 48% due to low awareness and the timing of the second dose at 18 months when no other vaccines are administered.

Zambia introduced the second dose of Measles Containing Vaccine (MCV2) jointly with PCV in July 2013. The second dose was necessary to comprehensively control measles and allow for a progressive reduction in the frequency of measles supplemental immunization campaigns [PCV/MSD Training Report]. The dose is administered at 18 months of life which is nine months after the first dose. Since introduction, however, the coverage rates for MCV2 have remained too low, raising concerns among EPI stakeholders.

The coverage for MCV2 for the 2014 and 2015 periods was only 33% and 48%, respectively. When compared with the MCV1 coverage for the same periods, at 85% and 90%, respectively, we note very high dropout rates. It means only about half of the children that get the first dose also get the second dose. Many factors may have contributed to the low coverage rates. First, the dose is given at 18 months. This falls in the second year of life and long after all the other vaccines are administered. It is possible that mothers will pay little attention to this vaccine which is isolated time-wise. EPI has recognized that less attention is paid to child health activities in the second year of life, including immunization, and has therefore developed a strategy focusing on promoting health intervention in this age group starting in 2017.

Second, low levels of awareness of MCV2 may also contribute to laxity with which mothers and caregivers approach the dose. Since the introduction of the dose was done jointly with the new PCV, more attention was paid to the “new” PCV. It was argued that MCV2 is an already administered vaccine and therefore would not need much attention and publicity. This may have overshadowed the MCV2 dose, resulting in a coverage rates below initial targets, which were set at around 90% in the same periods (See PCV/MSD proposal and APR (2013)). As noted in the MR section of this report, the plan is to replace MCV with MR.

Robustness of finding

Finding	Ranking	Robustness criteria
Finding 1: Persistent/ongoing suboptimal coverage of PCV/Rota as a result of delayed and inadequate government funding and poor logistics management at the subnational level.	A	Based on quantitative data, KII, and meeting observations
Finding 2: MCV2 coverage very low at 48% due to low awareness and the timing of the second dose at 18 months when no other vaccines are administered.	A	Based on quantitative data, KII, and meeting observations

Recommendations

1. There is a need to reconsider the vaccine demand forecasting process to be more inclusive and utilize local evidence; that is, disparities in population figures, wastage rates, and buffer stocks.

2. There is need for the EPI program to evaluate the initiatives aimed at improving logistics management and data quality, such as Logistimo and BID, with a view toward expanding them country-wide.
3. EPI should strengthen second year of life interventions including measles second dose (MSD) in order to improve vaccine coverage beyond the first year. Specifically, more intensive social mobilization efforts for children beyond age 1 is required.

Funding stream: IPV/OPV switch

Zambia planned to introduce IPV by the fourth quarter of 2015, but due to a global vaccine supply shortage the launch was postponed. Given the new information about IPV availability, the vaccines are expected to be delivered in the last quarter of 2017 and thus the tentative plan is to launch IPV during the first quarter of 2018.

The postponement may have implications for the sufficiency of the VIG given that budget assumptions on unit costs may not hold until 2018. This is likely to exert more pressure on local resource mobilization. The government and local partners may need to fill a bigger gap in funding. In 2015 we reported that IPV was not considered a country priority, despite the global significance as part of the Polio Endgame Strategy. As such, the government faced significant challenges in mobilizing partner and broader government support for preparatory activities. Because of the delayed introduction, IPV risks falling off the radar of partners as a priority. This was evidenced by the lack of progress during EPI meetings as stakeholders are unable to make decisions on the way forward given the uncertainty of the global vaccine supply. This is likely to erode gains made in the initial phases of IPV introduction.

The official launch of the OPV switch from tOPV to bOPV, which took place on April 21, 2016, was held indoors at Mwachisompola Health Demonstration Zone in Chibombo District. The explanation for holding the launch indoors was because the launch placed little emphasis on informing the community about the switch because the vaccines would be the same in the eyes of the community. According to MoH, “the community does not expect to see any difference between the two vaccines” (MO April 21, 2016).

Finding 1

Concentrated attention on OPV leading to a successful switch and improved logistical arrangements.

The switch from tOPV to bOPV was considered successful. First, the delivery of vaccines to all health facilities was done before the switch. This came as a result of an improved logistical arrangement in which distribution of the bOPV was done directly to the districts, bypassing the usual route of going through provincial centers. It was observed that this more decentralized model was more effective in delivering an adequate number of doses in a timely manner. It was reported that the country had enough stocks of tOPV to last up to the switch in April and had already received 1 million doses of bOPV out of the 3 million that were ordered for the remaining three quarters of 2016. Second, the switch exercise was mainly on the supply side, with no demand-generation activities executed. Finally, the time at which the switch happened was when there were no competing activities that would create constraints on the staff and resources. The post-launch validation exercise was also carried out and results shared. The validation showed that all districts were oriented, supported, and had the switch

done on the same day. The validation exercise also showed that tOPV was successfully withdrawn. This signified a successful switch (MO, ICC, May 11, 2016).

Robustness of finding

Finding	Ranking	Robustness criteria
Finding 1: Concentrated attention on OPV leading to a successful switch and improved logistical arrangements.	B	Based on MOs, FCI, and document reviews

Funding stream: MR campaign

Zambia decided to apply for Gavi support to introduce the bivalent vaccine that contains measles and rubella (MR). The introduction into routine immunization was planned to be preceded by a preventive campaign targeting children of 9 months to below 15 years. The nationwide campaign was conducted in September 2016. A post-campaign review was conducted involving all 103 districts. The national coverage was reported at 108%. The above-100% coverage rate was attributed to the differences between the CSO population estimates and the headcount data in the denominator. In addition, there was also a possibility of immunizing over-age children given the national-level miscommunication on the upper age limit as discussed below under Finding 1. At the time of writing this report, the country was in the process of conducting a coverage survey to inform the EPI program on the campaign. MR is planned for introduction into routine national immunization to replace monovalent measles vaccine at a later time.

Finding 1

Measles-rubella vaccine prioritized, with wide stakeholder participation and adequate planning, leading to a successful campaign despite system challenges around logistics and population estimates and delayed VIG funding.

The Ministry of Health, through the Child Health Unit, conducted a nationwide measles-rubella preventative campaign for four days, September 19-23, 2016. The campaign was determined to be successful by the FCE team that visited five provinces of Zambia during the campaign, as the vaccine was launched countrywide during the planned period and managed to achieve the target coverage. Several factors were found to have contributed to the successful campaign.

First, measles-rubella was prioritized considering the risk of a measles outbreak due to the missed opportunity to conduct a measles campaign in the previous year. The last campaign was carried out in 2013 together with the launch of PCV, and the follow-up campaign scheduled for 2015 did not occur as the country decided to wait instead for the MR vaccine. As a result of this prioritization, preparations for the MR campaign began early in the year and plans and budgets were finalized early. Some activities such as IEC material preparations, drafting guidelines, Terms of Reference (TORs) for training and post-campaign, and development of a micro plan, communication plan, and M&E plan were conducted before the VIG was received. The VIG was disbursed late owing to Gavi and MoH working on funding modalities during the period, which took longer than expected: funds were only released in August 2016 rather than around the first quarter of 2016 as expected. These activities were supported by the government and local partners. Additionally, a request for TA was sent to WHO. Other lessons from

previous campaigns and introductions were timely procurement and distribution of supplies, and more detailed planning for logistics and transport. Additionally, as was experienced with the OPV switch, EPI opted to distribute vaccines directly to districts, bypassing provinces in order to improve on timeliness and efficiency.

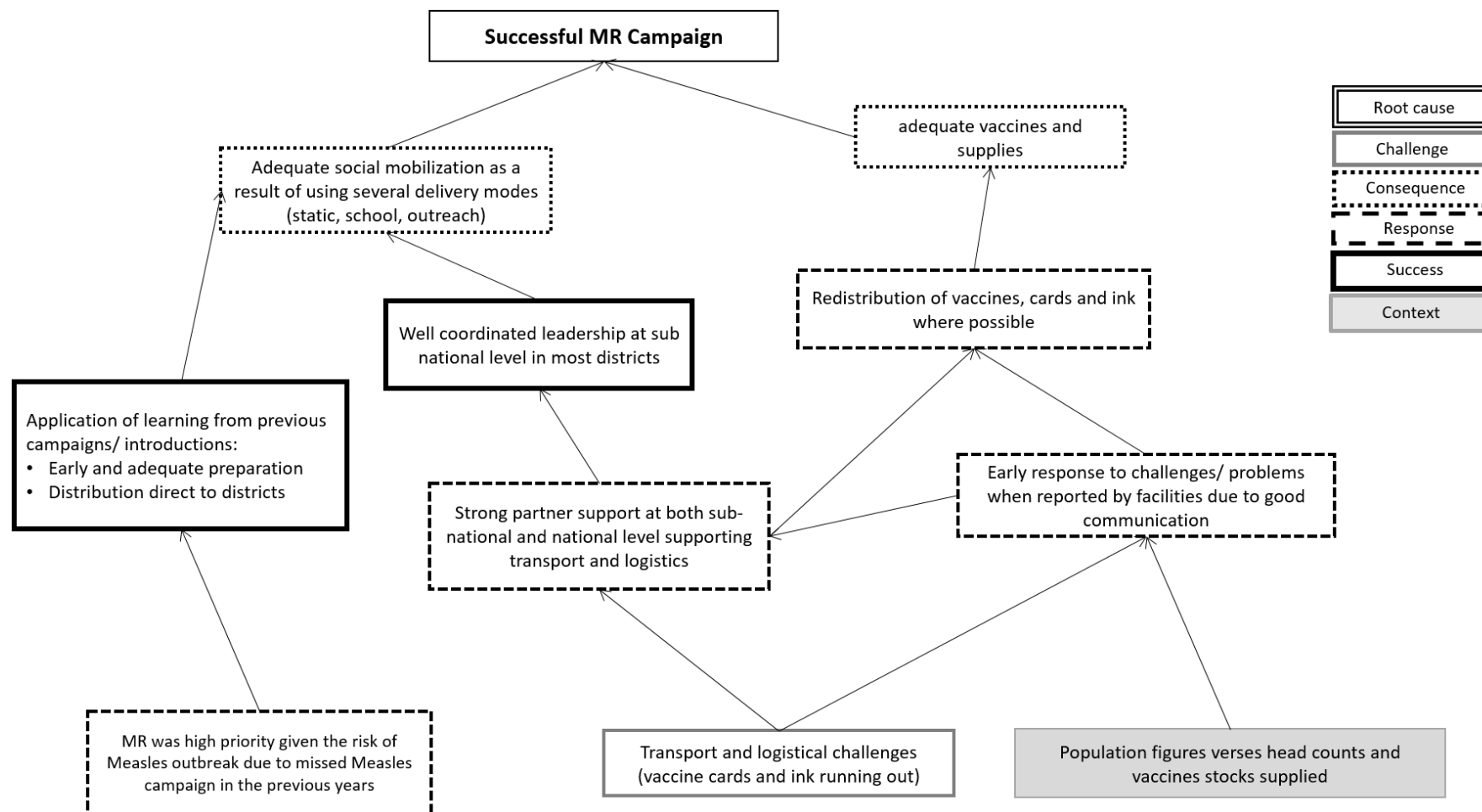
Distribution was directly to districts, bypassing provinces in order to save time and improve efficiency. (MO)

The campaign started on September 19, 2016, with most districts starting vaccination at the start of the day. The campaign utilized three avenues of delivery – school-based, facility-based, and outreach – in order to capture the targeted groups. Strong partner support was received during the campaign, both at national and subnational levels, through other government departments at provincial and district levels, as well as Civil Society Organizations present in various districts. For example, partners provided transport (vehicle, boats, fuel) and drivers. Civic, traditional, and religious leaders also supported the MR campaign through social mobilization.

Despite the successes, some challenges were encountered during the campaign. These include official population figures not matching the actual targeted population, resulting in maldistribution of vaccines and other supplies; vaccine cards and ink running out in some places; late start of the MR campaign in some places; and overall transport challenges. However, these challenges were mitigated through timely communication and response at national, provincial, and district levels to the challenges relating to supplies. Availability of help from partners assisted with the timely response.

In addition, there was some miscommunication around the target age group. Most of the IEC materials and communication to the health workers indicated that the eligible age group was from 9 months to 15 years, rather than indicating from 9 months to below 15 years. It was also difficult to verify ages as most children did not have any identity documents. Thus in many places children who were 15 years old were also vaccinated. This might increase the coverage figure beyond the target coverage as extra children were captured; this could also have implications for the coverage survey.

Figure 14: RCA on MR campaign



Robustness of finding

Finding	Ranking	Robustness criteria
Finding 1: Measles-rubella vaccine prioritized, with wide stakeholder participation and adequate planning, leading to a successful campaign despite system challenges around logistics and population estimates and delayed VIG funding.	A	The finding is based on meeting observations, document review, observation of the campaign, and KIIs

Recommendations

1. Improvement in logistics during the OPV switch and MR campaign need to be assessed and learned from for application to routine vaccine logistics management.
2. To address social mobilization challenges such as those witnessed with MR, information, education, and communication materials need to be adequately pre-tested to ensure appropriate messages are disseminated.

Funding stream: HPV

Taking advantage of about 60,000 doses of HPV vaccine that remained from the first two phases (2013 and 2014), the country decided to do a third phase of the demonstration in Lusaka district. The targets for this phase were 20,000 for round 1, 17,242 for round 2, and 15,269 for round 3. The coverage achieved was 86% for round 1, 88.5% for round 2, and 94% for round 3. The demonstration has therefore achieved a 72% coverage rate of target children receiving 3 doses of HPV. A key difference from the other phases in 2013 and 2014 was the active involvement of Civil Society Organizations (CSOs) for social mobilization. For instance, CHAZ, with financial assistance from Gavi, conducted social mobilization in selected areas of Lusaka.

In 2016, Zambia started developing the HPV national introduction proposal. A number of stakeholders were involved in the application process with the lead organizations being MoH through CHU. The reproductive health unit (RHU) and M&E unit at MoH were also involved. Other key organizations involved were MoE, UNICEF, WHO, PATH, CHAZ, and GSK. PATH supported with a consultant to help with the application process. The application process was endorsed by the ICC on August 25, 2016, targeting the September 9, 2016, submission window. However, the submission was postponed to January 2017.

Finding 1

Learning from the demonstration project and greater commitment, improved leadership, and coordination leading to a smoother HPV proposal development.

Sustainability of the HPV vaccine has been a major concern among stakeholders and a point of discussion at several ICC meetings. However, the country is committed to national introduction despite these concerns. This commitment is evident by the push from MoH to have the application completed this year and to proceed swiftly from the demonstration phase. In addition, two week-long workshops were conducted in July and August 2016 to work on the HPV application with support mainly from UNICEF, WHO, and PATH.

The country has learned a number of lessons from the 2013, 2014, and 2016 demonstrations which were used for the purposes of improving the application for HPV national rollout. Leadership of the application process was a concern from the demonstration program. It was decided during the application that CHU should lead the application process, as it was the custodian of immunization programs in the country and had the necessary infrastructure and expertise. This contributed to better coordination and wider stakeholder involvement during the proposal development process.

As a lesson from the first and second phases of the demonstration, social mobilization was strengthened during phase three of the demonstration by giving the responsibility to civil society organizations through CHAZ. This was one strategy to address misconceptions and beliefs around HPV vaccine that were encountered during the first and second phases of the demonstration. CHAZ conducted the baseline survey at the beginning of this phase and adjusted their approach to social mobilization according to the findings of the survey. An endline survey was also conducted, and both reports are yet to be shared.

Social mobilization will include CHAZ through BMGF. They have a very good social mobilization package and strategy. We had the highest coverage as a result [during phase 3 of the demo] and can use the same approach [for national introduction]. (KII)

The cost implications of the school-based model of delivery were appreciated from the demonstration program. In order to try to mitigate this, the school-based model was still adopted, but was planned to be utilized during child health week. Although vaccination is currently not part of child health week, it is hoped that combining it with child health week will ultimately reduce the cost of HPV vaccination. Additionally, the country opted for two doses of vaccine per child to be administered a year apart as opposed to the three doses given during the demo.

As far as sustainability, cost, and delivery model, I think it is a good plan. The target group is mostly in school, hence the need to stick to this model and out of school at health facilities. The cost would be lower if delivered during CHW as districts are funded during CHW. They use schools as their posts, though not all, but the plan is to have all schools covered. Sustainability will be helped by this as well. There are no confirmed commitments for funds from partners. We are riding on Gavi contribution. (KII)

In order to address sustainability concerns, the government stated that in addition to the general MoH budget, funding would be complemented by SHI. SHI is intended to generate more funding for the health sector by allowing a wider cross-section of the population to make monthly contributions toward health insurance. However, it is not clear when and how the SHI will be implemented and how much funding will be realized. The country still needs considerable support from Gavi for the operational cost of the HPV program beyond the introduction.

Finding 2

Postponement of the application submission.

A number of factors led to the postponement of the submission of the HPV application. The main one was the number of competing priorities within the EPI program, which included the MR campaign, cMYP development, and JA preparations, which were all taking place around the submission deadline. This

was compounded by limited access to the Gavi portal, as only one person at CHU had writing access and delegation was not possible. As of October 2016, Gavi has since allowed more EPI members to have access to the portal as requested by the country. In addition, the country had an incomplete cMYP which was a requirement for the HPV application. Two workshops were held to work on the cMYP, and the application for HPV will be submitted to Gavi in January 2017. Additionally, EPI received information from Gavi about pending changes relating to support for a multi-age cohort and also allow a phased introduction approach. These factors led to the country's decision to apply in January.

All have access to the portal but only one could edit. There were so many activities like MR and others. Others needed to review but were very busy to review what went into the portal. There were too many activities at the same time. The draft cMYP also needed to accompany the application and was also incomplete. The process is quite involving although we had all the necessary support from government and all interested stakeholders. Other than the cMYP other components are complete. (KII)

New HPV 2.0 guidelines were shared with the country in November 2016. The major changes from previous guidelines were that countries can apply directly for national introduction, while maintaining the option of implementing a phased national introduction, and they could apply for support for multi-age cohort HPV vaccinations (9–14 years of age) in year one of introduction of the vaccine, including support for 100% of vaccine costs for the additional cohorts, and operational support of up to US\$0.65 per targeted girl of those cohorts. These changes support earlier assertions by the country that more funding would be available in the January 2017 window, which was another reason for the postponement.

KIIs further revealed that the decision to introduce HPV was also delayed because the level of support from Gavi for the operational costs was not known until November 2016. Although Gavi has provided for \$0.65 per targeted girl, it remains to be seen to what extent this will be within the expected level of Gavi support for operational costs for HPV implementation, especially for reaching the out-of-school girls. Further amendments to the Gavi requirements for the HPV introduction, as noted above, have made it easier for countries to introduce HPV, although this information was made available by Gavi after the finalization of the national HPV proposal.

Robustness of finding

Finding	Ranking	Robustness criteria
Finding 1: Learning from the demonstration project and greater commitment, improved leadership, and coordination leading to a smoother HPV proposal development.	A	Document review, KIIs, meeting observations. Unlike in 2015 the FCE team followed the HPV funding stream closely in 2016.
Finding 2: Postponement of the application submission.	A	Document review, KIIs, meeting observations. Unlike in 2015 the FCE team followed the HPV funding stream closely in 2016.

Recommendation

1. As HPV is a nontraditional vaccine and likely to incur additional costs, the government should consider conducting a comprehensive costing exercise during national implementation using actual costs, which could be used to strengthen resource mobilization.

Funding stream: HSS

Zambia started the HSS application process in 2014 and after a resubmission in 2015, the proposal was approved in February 2016. The current HSS support is being sought for the purpose of reducing the major health system bottlenecks inhibiting performance of the EPI program in seven districts in the northern region of Zambia. These bottlenecks include a shortage of HRH, lack of outreach, lack of transport, poor data quality and availability, inadequate supervision, inadequate funding, inadequate IEC, and limited private sector involvement. Bottleneck assessment was complemented by the constraints analysis using Gavi FCE survey data (see “Constraints Analysis,” page 53).

Application

The IRC provided feedback on the HSS proposal in March 2015, requiring the country to attend to weaknesses in the following areas: district selection M&E, the RBF, etc. All the comments raised by the IRC on the HSS proposal were addressed. District selection was one point that needed more clarity. In response, the district selection criteria were better defined and justified as being poor-performing and lacking key development partners funding any health and immunization system interventions in these districts. The M&E framework was strengthened to make it more complete by the inclusion of more intermediate indicators and detailed measurement for all indicators. The PBF plan was also updated to include a detailed results framework and budget. This involved providing a detailed description and justification for all planned activities and linking them to the M&E framework and budget. Lastly some adjustments were made to the budget. These include a reduction of the budget from \$US 14.7 million to \$US 9.1 million and the provision of budgetary allocations and justifications for the PBF section.

The corrected proposal was resubmitted in September 2015, and an IRC decision to approve the proposal was communicated to the country in December 2015. Although the proposal was approved, the IRC suggested further refinement and clarification of the following issues before final approval could be granted: human resource sustainability, budgetary support for vehicle maintenance after expiry of HSS support, district-level PBF activities, and the M&E framework. Final approval of the proposal was granted in April 2016.

Post-Approval

A Program Capacity Assessment (PCA) was carried out between April and June 2016. The PCA is a prerequisite to disbursement of HSS funds by Gavi to the government and was conducted to assess the financing modality and other structures for use for Gavi support provided in the form of cash grants, vaccines, and vaccine-related devices. The PCA led to the preparations of the Grants Management Requirement (GMR) in September 2016, which detailed measures that the country has to undertake before HSS funds will be released. There two main requirements in the GMR which need to be met to enable the disbursement of HSS funds from Gavi are:

- Submission of an updated Annual Procurement Plan, Workplan, and Budget – these documents need to be endorsed by the ICC before submission to Gavi for review; and
- Opening of dedicated Gavi bank accounts in the seven target districts for the HSS-2 grant.

Because of steps and requirements associated with the PCA, implementation of the HSS grant is now tentatively scheduled for early 2017, subject to fulfillment of the two requirements above. There is also a set of other requirements which have to be met during the implementation period, among which are the recruitment of an HSS coordinator, HSS Senior Accountant, and M&E Specialist within three months of the first disbursement.

Finding 1

Delayed initiation of HSS grant.

Communication to the country from Gavi about timelines and processes leading up to HSS funds disbursement remained unclear to some key stakeholders within EPI. Early in 2016 the country learned a PCA was to be carried out in Zambia. The scope of the PCA was to review capacities, structures, and past performance and make recommendations for strengthening the following key pillars: (1) program management capacity, (2) financial management capacity, and (3) vaccine and cold-chain management capacity. The PCA is a new requirement and Zambia was one of the early pilot countries. The PCA was conducted in April 2016 and finalized in June. The level of engagement of EPI stakeholders with the PCA process was largely restricted to being interviewed by consultants and attending the debriefing meeting, with limited understanding of the details of the process. According to the PCA TORs and the consultant, it was also indicated that the PCA report would be made available to country stakeholders, but this did not occur and further hampered understanding of the PCA process. The PCA guide states that the PCA report should be shared with the government and discussions should be held to agree on the GMR. However, the country EPI stakeholders did not receive the PCA report. In addition, the draft GMR was prepared by Gavi and presented to the country for comments and input. However, no feedback was provided to Gavi owing to communication challenges with MoH. These events evidently challenged the intended participatory nature of the PCA process. This presents another lost opportunity for the country to fully appreciate the programmatic challenges outlined and come up with long-term solutions.

Additionally, the GMR was only communicated to the country at the end of September 2016, much later than originally planned, giving the country little time to respond in preparation for the HSS implementation start date of January 2017. The period following the approval of the grant can therefore be characterized as a period of uncertainty and inaction on HSS resulting in concerns about the reliability of Gavi funds.

The communication is not clear on the process. We don't know if it will be this year or next year.
(KII)

According to the GMR, funds will be released once the country has submitted an updated Annual Procurement Plan, Workplan, and Budget, and dedicated Gavi bank accounts have been opened in the seven target districts for the HSS-2 grant. There was, however, a concern expressed by government and partners on how to expedite procurements once implementation has started, as experience has shown that government processes are bureaucratic and lengthy. UNICEF and CHAZ were being considered as

possible solutions to this problem as they have adequate and expedited procurement systems. The country has since worked on the two major GMR requirements which are the submission of updated work plan and budget and opening of Gavi HSS dedicated bank accounts.

Robustness of findings

Finding	Ranking	Robustness criteria
Finding 1: Delayed initiation of HSS grant.	A	Based on document review, meeting observation, FCI and KIIs

Recommendations

1. There is a need for Gavi to ensure that timelines for the process are agreed upon with the country and adhered to.
2. There is a need for effective consultation with country made in preparing the GMR.

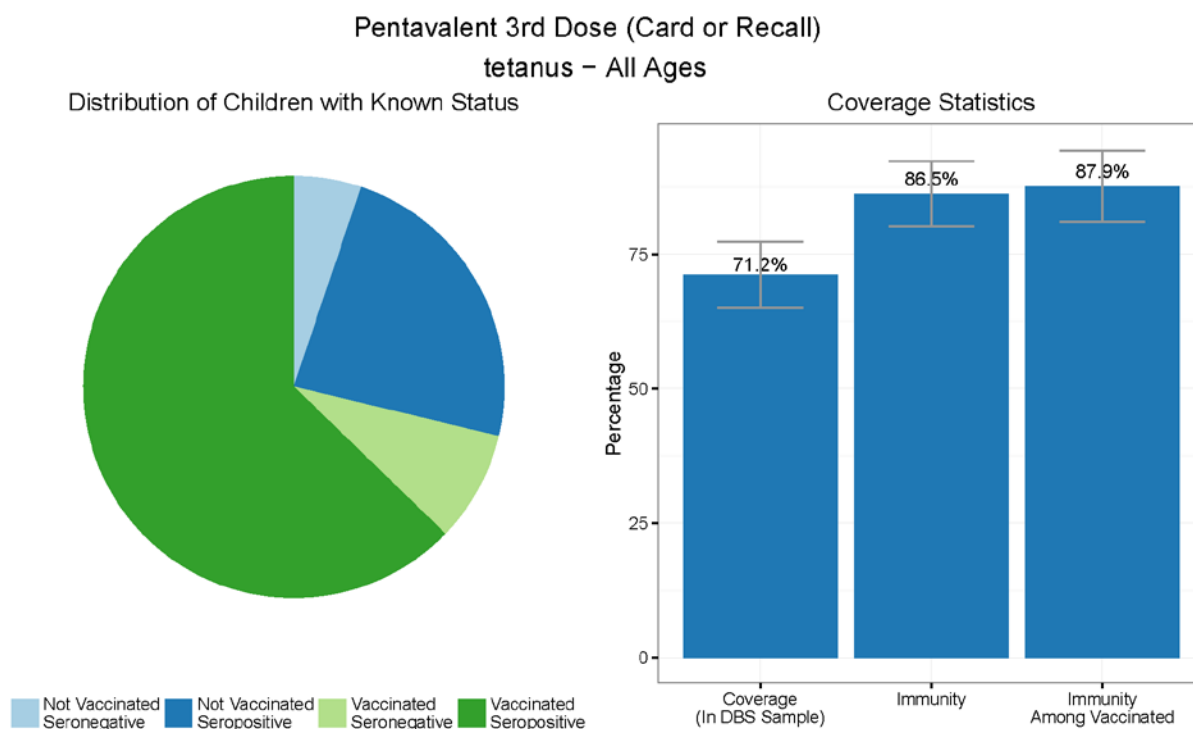
Dried Blood Spot analysis results

During the Gavi FCE household survey, 970 children were randomly selected for blood tests to determine whether they are immune to hepatitis B and tetanus. Trained health workers absorbed five drops of blood from consenting participants onto specially designed filter paper by pricking their finger. Blood spots were dried and sent to a laboratory for antibody testing. The antibodies allow us to determine which children are immune to hepatitis B and tetanus. Laboratory methods and data processing methods are described in Annex 4. We also compared children's immune status to their vaccination status, which allows us to assess which of the vaccinated children have actually gained immunity, and which have not.

Based on the DBS results, 56.2% of children (95% uncertainty interval [UI]: 46.8–68.0%) were immune to hepatitis B, and 86.5% (95% UI: 82.2–90.6%) were immune to tetanus. According to control samples, sensitivity and specificity were to be higher for tetanus than hepatitis B.

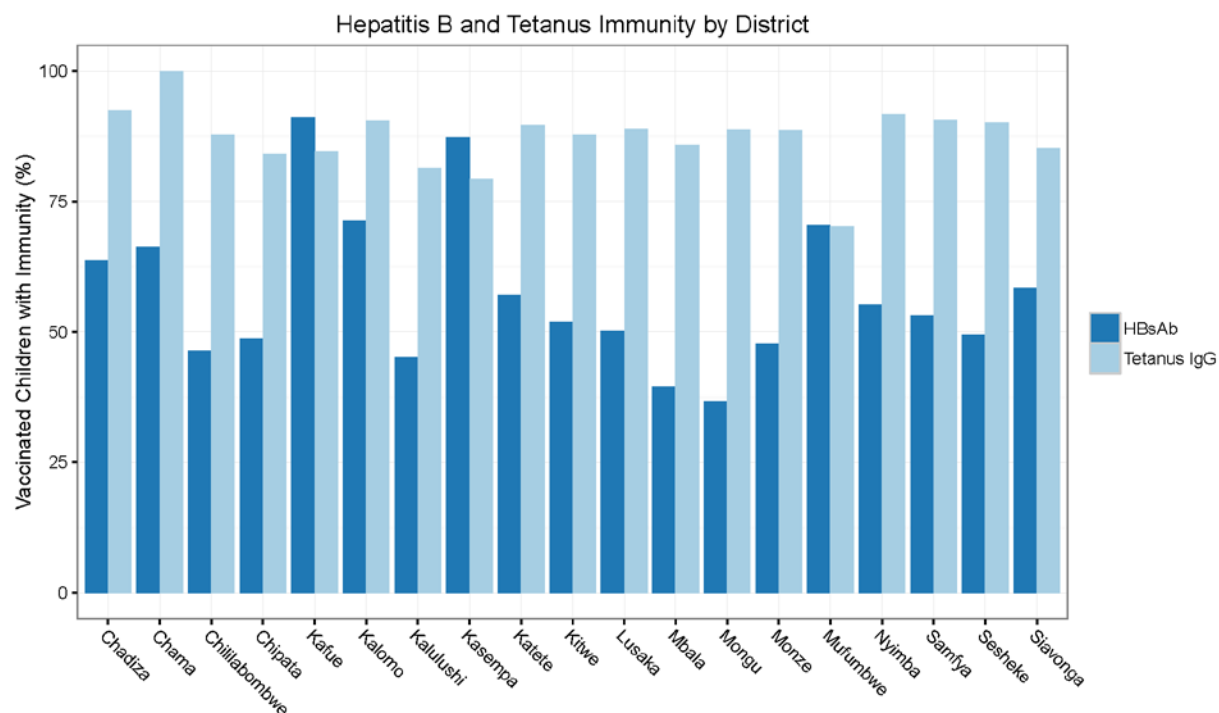
Comparing the DBS results to children's pentavalent vaccine status ("vaccinated" being defined as receiving three doses, according to either maternal recall or vaccine card), only 59.5% of vaccinated children (95% UI: 50.2–70.7%) were immune to hepatitis B, and 87.9% (95% UI: 83.6–91.8%) were immune to tetanus. Figure 15 displays this comparison for tetanus. We caution against interpreting these as estimates of vaccine effectiveness, as the study was only designed to measure seroprevalence.

Figure 15: Comparison between pentavalent vaccination and tetanus immunity among children selected for DBS



The Gavi FCE surveys can also help understand explanations for immunization success. As shown in Figure 16, immunity among vaccinated children varies considerably by district. In Chama, for example, 100% of vaccinated children were successfully immunized for tetanus, meaning that all vaccinated children gained immunity. Other districts, however, such as Mufumbwe and Kasempa, had a low percentage of vaccinated children successfully immunized for tetanus (<80%). Also notable, children who were vaccinated more recently were more likely to gain immunity; only 63% of children vaccinated during 2013 were immune as compared with 74% in 2015. Other variables, such as adherence to dosage schedule and age at first dose were generally not correlated with vaccine success (or failure). We caution that these are preliminary results and do not account for all confounding or uncertainty.

Figure 16: Percentage of vaccinated children who are immune, by district



Constraints analysis

Using the household survey, we evaluated community and household characteristics that correspond with vaccinated children. Linking children to health facilities, we used the HFS, DHO, and patient surveys to assess the influence of supply-side constraints on vaccine coverage, and how they interrelate with demand-side factors. We used systematic review, thematic analysis, interpretive synthesis, and Bayesian structural equation modeling (BSEM) to assess the relative contribution of demand-side, supply-side, and access-related determinants. Constraints analysis is described in more detail in Annex 3.

Figure 17 displays the high-level results from the constraints analysis. For three doses of pentavalent (Figure 17 (b)), the model estimated that the largest driver of vaccination was mother or caretaker's "Intent to Vaccinate," i.e., demand, which explained 29% of pentavalent 3 coverage. PCV-3 utilization (Figure 17 (d)) was much more strongly influenced by Health Facility Readiness (34%). For both vaccines, demand was a larger factor for the third dose (Figure 17 (b) and (d)) than the first (Figure 17 (a) and (c)).

Figure 17: Relative constraints to individual-level vaccine utilization in Zambia

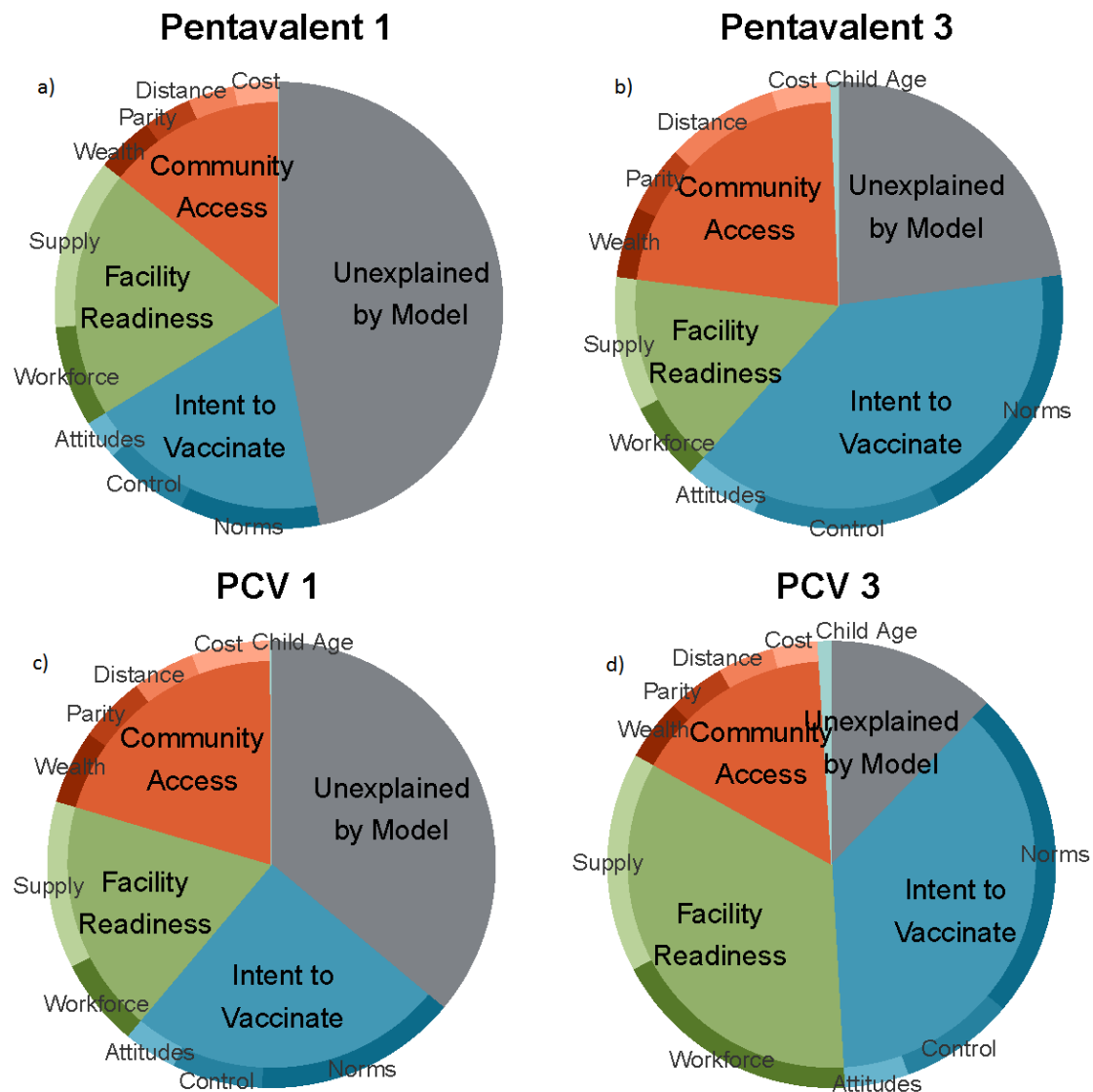
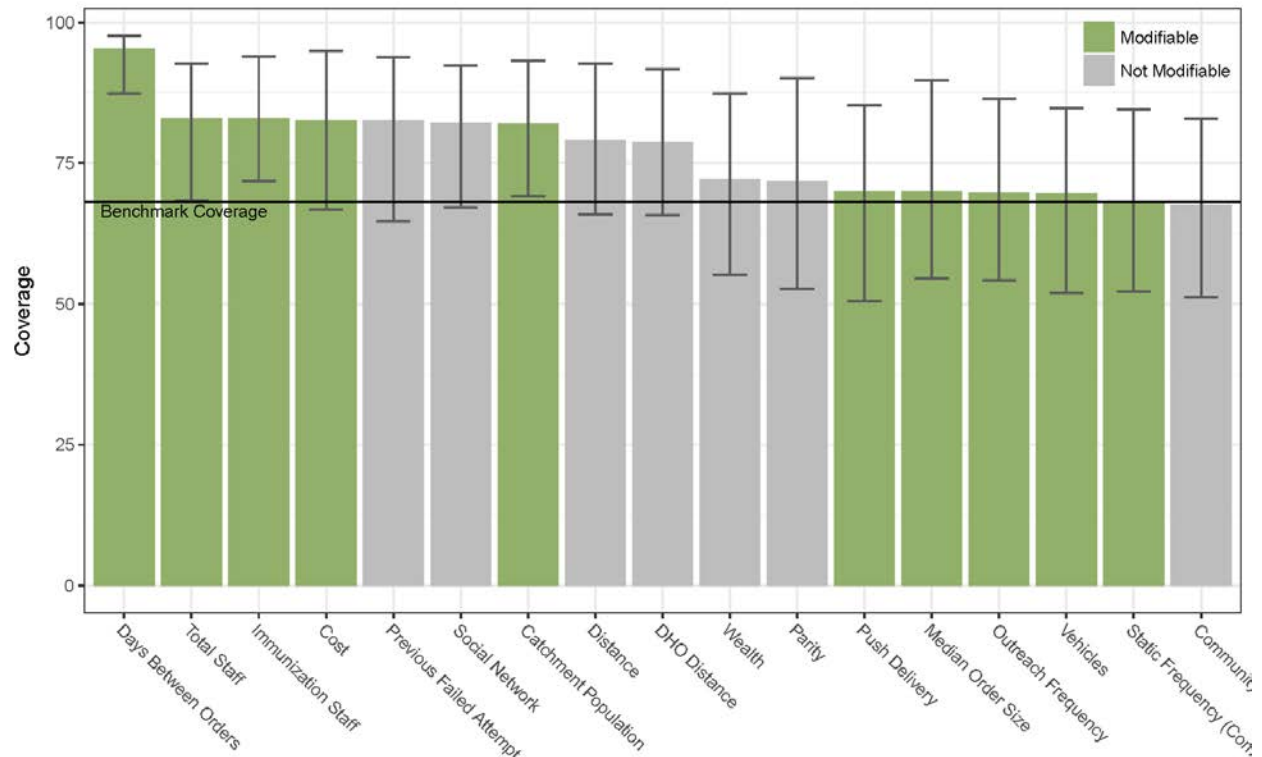


Figure 18 shows detailed results from the constraints analysis for PCV-3 coverage. Certain bottlenecks were correlated with coverage more strongly than others in the data, taking mediating factors into account. Frequency of ordering supplies (days between orders), total staff, immunization staff, and cost of vaccination (incurred by the mother or caretaker) were all strong constraints. In Figure 18, the model estimates that PCV-3 coverage would increase to the height of each bar if the associated barrier was removed.

Figure 18: Expected PCV-3 coverage if an individual barrier was removed



Recommendations

The data and model indicate that there are different drivers of initiation (first dose) and drop-out (third dose), and different drivers for new and routine vaccines. For example, Intent to Vaccinate (attitudes and perceptions) is a larger driver of three-dose coverage than one-dose coverage, and Facility Readiness is a larger driver of PCV than pentavalent.

1. We recommend that demand-generation interventions in Zambia should use reduced drop-out as a key metric of success.
2. We recommend that NVI programs focus on Facility Readiness to achieve success.

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