

Gavi Full Country Evaluations

2016 Annual Dissemination Report

Cross-Country Findings



Acknowledgments

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This report presents findings from the 2016 Gavi Full Country Evaluations (FCE). It was prepared by the Institute for Health Metrics and Evaluation at the University of Washington in collaboration with members of the FCE team: icddr,b in Bangladesh; University of Eduardo Mondlane University in Mozambique; Manhica Health Research Centre in Mozambique; Health Alliance International in Mozambique; the Infectious Diseases Research Collaboration in Uganda; the University of Zambia in Zambia; and PATH in the 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

Acronym	
CDC	US Centers for Disease Control and Prevention
CEF	Country Engagement Framework
CI	Confidence interval
CISM	Manhiça Health Research Centre
cMYP	Comprehensive multiyear plan
DBS	Dried blood spots
DPT/DPT3	Diphtheria/pertussis/tetanus vaccine, DPT third dose (complete vaccination schedule)
DSS	Demographic surveillance site
EPI	Expanded Program on Immunization
FCE	Full Country Evaluations
FMA	Financial management assessment
GDP	Gross domestic product
GMR	Grant Management Requirement
HHS	Household surveys
HIV	Human immunodeficiency virus
HMIS	Health Management Information System
HPV	Human papillomavirus
HSIS	Health Systems Immunization Strengthening
HSS	Health System Strengthening
ICC	Interagency Coordinating Committee
IHME	Institute for Health Metrics and Evaluation
IMF	International Monetary Fund
IPD	Invasive pneumococcal disease
IPV	Inactivated polio vaccine
IRC	Independent Review Committee
JA	Joint Appraisal
KII	Key informant interviews
LMC	Leadership, Management, and Coordination
MOH	Ministry of Health
MR	Measles-rubella
MSD	Measles second dose
NITAG	National immunization technical advisory groups
NVI	New Vaccine Introduction
PCA	Program Capacity Assessment
PCV	Pneumococcal conjugate vaccine
PEF	Partners' Engagement Framework
PIE	Post-Introduction Evaluation

SCM	Senior Country Manager
SFA	Strategic focus area
SMO	Surveillance medical officer
TA	Technical assistance
TCA	Targeted Country Assistance
TOR	Term of reference
UI	Uncertainty interval
UNEPI	Uganda National Expanded Program on Immunization
UNICEF	United Nations Children's Fund
VIG	Vaccine Introduction Grant
VTs	Vaccine serotypes
WHO	World Health Organization

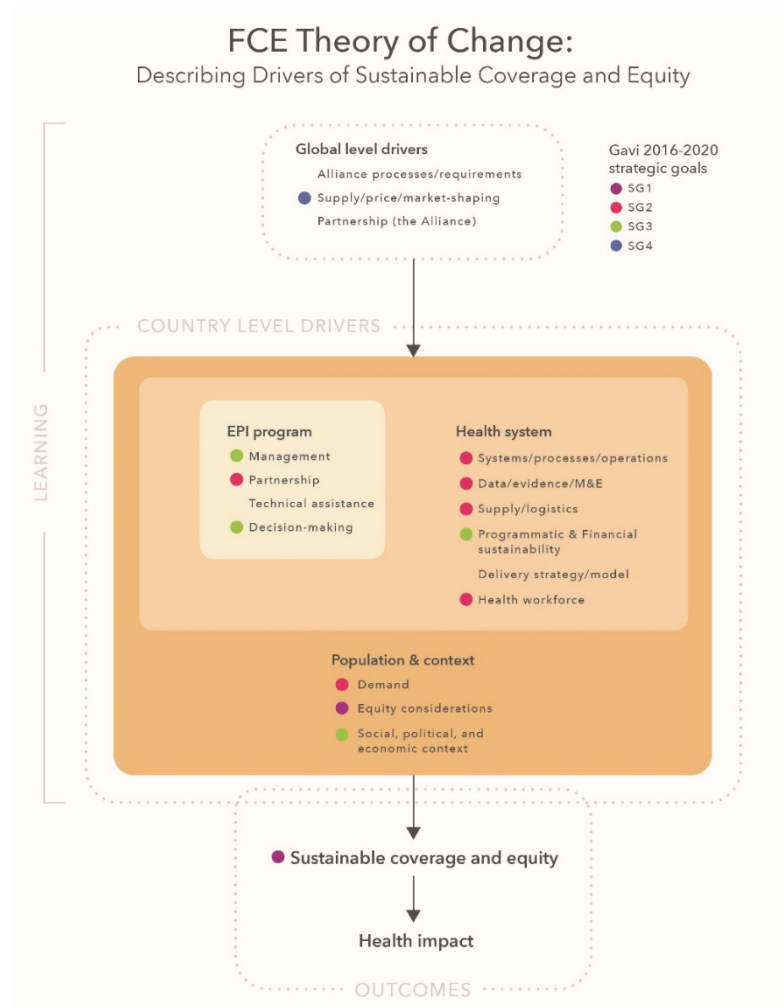
Executive summary

The Gavi Full Country Evaluations 2016 report: building evidence to achieve sustainable vaccine coverage and equity

The Gavi Full Country Evaluations (FCE) are mixed-methods prospective evaluations covering the period 2013–2016. The aims of the FCE are to understand and quantify 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 and final annual dissemination report complements previous reports by providing key findings and recommendations for the 2016 evaluation period in the four FCE countries. Mirroring the evolution of Gavi's goals in the new 2016–2020 strategic period, the FCE has evolved from the evaluation of processes, outputs, outcomes, and impacts of Gavi support streams (e.g., New Vaccine Introductions, Health System Strengthening [HSS], and campaigns) to a focus on drivers of sustainable and equitable vaccine coverage that cut across streams of support, including Gavi-related inputs such as the Joint Appraisal (JA) and Partners' Engagement Framework (PEF), and broad health systems drivers such as management performance, technical assistance (TA), and programmatic and financial sustainability. Together, these drivers support the achievement of sustainable and equitable vaccine coverage for children in countries with the greatest need.

Figure 1: Gavi Full Country Evaluations theory of change



To assist in the synthesis of multiple complex drivers and issues in 2016, the FCE team developed a high-level conceptual framework describing the drivers of sustainable and equitable coverage (Figure 1).

Methods

We used a prospective, mixed-methods approach to generate the findings included in the Gavi FCE 2016 report. This approach was driven by a set of cross-cutting evaluation questions to guide qualitative data collection at the global and country levels. Specific tools and methods included process tracking based on document review, observation, and fact-checking interviews; resource-tracking studies to generate

estimates of resource envelopes on immunization; analysis of Health Management Information Systems; analysis of dried blood spots to measure immunity in vaccinated children; analysis of primary and secondary data to generate small-area estimates of vaccine coverage and other health indicators; and vaccine-effectiveness studies to measure the impact of the introduction of pneumococcal conjugate vaccine.

What do we know about Gavi support in 2016?

The effective implementation of the two main Gavi windows of support – new vaccine support and HSS grants – continues to improve with time. Our evaluations show that *new vaccines* are having an impact on vaccine-preventable disease. In Mozambique, pneumococcal conjugate vaccine was quickly integrated into the routine Expanded Program on Immunization (EPI). We present its impact on invasive pneumococcal disease in this 2016 report. However, persistent challenges related to the routinization of new vaccines constrain their potential impact on child health. In this report, and reflected in our theory of change, we describe a variety of reasons behind mid- and long-term delays in vaccine routinization that reduce the potential impact of new vaccine introductions, including stockouts due to multiple underlying causes, inadequate attention paid to social mobilization, external macroeconomic shocks, and delayed implementation of complementary HSS activities.

HSS grants have enormous potential to increase coverage and equity, but problems with the complexity and implementation procedures of HSS grants have routinely reduced the predictability, relevance, and effectiveness of those grants. As in previous years, three of four FCE countries experienced substantial HSS delays in 2016 related to application, post-approval, and implementation. Moreover, the FCE has been unable to fully evaluate the implementation of HSS because compounding delays have pushed HSS implementation beyond the FCE end date.

What drives these findings?

Many of the root causes of challenges faced by Gavi and its partners in implementing these two main windows of support to countries are not stream-specific. Rather, they are derived from misalignments between Gavi's strategic goals, the procedures and systems of Gavi, and country systems. In this 2016 report, we cover five selected root causes, which we summarize below.

Leadership and management. Optimal vaccine delivery relies on systems and teams that are appropriately organized to manage service delivery. This includes ensuring that the EPI team is adequately staffed and structured; has the right managerial and technical capabilities; and has clear mandates, roles, responsibilities, and tools. Effective program management is weakened in FCE countries by the cumulative burden of multiple Gavi requirements and processes, which constrain EPI programs' ability to stay on top of day-to-day program needs.

Technical assistance. Relevant, effective, and efficient TA (which leads to capacity building) is one way of strengthening the capacity of EPI programs to implement increasingly complex immunization programs to ultimately improve coverage and equity. The PEF, introduced in 2015, seeks to achieve increased transparency, accountability, and country ownership of TA. The PEF, particularly Targeted Country

Box 1: 2016 findings and recommendations

GAVI FCE 2016 FINDINGS AND RECOMMENDATIONS

Table 10 on page 106 provides a comprehensive listing of the findings of our 2016 report and linked recommendations.

Assistance, is an improvement over the Business Plan in its aim to achieve country ownership, transparency, and accountability. However, some phases of the process, particularly the PEF Management Team prioritization and funding of Targeted Country Assistance activities, suffer from limited country ownership and transparency. The PEF is designed to shift accountability of TA partners from the Gavi Secretariat to countries, although we observe that this will take time to achieve in practice.

Programmatic and financial sustainability. Decisions to apply for Gavi support are not always undertaken with a full assessment of the implications on financial sustainability. In 2016, we observed that Gavi FCE countries faced challenges in meeting cofinancing requirements, concerns regarding the overall fiscal health of immunization programs, and an increasing trend to direct funds through partners instead of country systems, which may have consequences for country ownership and programmatic and financial sustainability. Lastly, in 2016, we saw limited evidence that countries were planning or preparing for entering into the accelerated transition phase and subsequent graduation from Gavi support. There is limited guidance from Gavi on what countries should be doing in the pre-transition phase to ensure a smooth transition.

Alliance processes and requirements. Donor processes and requirements have the potential to add value – both to countries and Gavi – when they are designed and implemented to balance their administrative and management burden with their potential benefits. However, Gavi changes are numerous and frequent; the Secretariat and Alliance partners must be aware of how these changes appear at the country level. We are seeing an effort to align the suite of Gavi processes and requirements, but we flag the potential short-term complexity and country-level management burden of these changes.

The Alliance partnership. The global-level Alliance partnership has evolved over time based on the changing goals of the Alliance and countries. In countries, the Alliance remains a source of technical expertise, financial resources, and coordination support. While the shift from the Business Plan to the PEF has led to improved transparency and accountability, this has been accompanied by “growing pains” in the global-level partnership. Based on global-level key informant interviews, the health of the Alliance partnership can currently be described as stable, but it should be actively strengthened as the role and function of the Alliance continue to shift.

These root causes indicate, overall, that behavioral, organizational, and institutional factors can act as significant brakes on Gavi’s – and countries’ – success. These factors can be changed. Indeed, over the course of the Gavi FCE, we observed improvements in Gavi procedures, such as the Health Systems and Immunization Strengthening framework, and changes that show the potential to improve the sustainable and equitable delivery of new and existing vaccines in Gavi-supported countries.

Looking ahead

As prospective evaluations, the FCE findings were made available to countries, partners, and Gavi over the duration of the study. FCE results have fostered refinements to vaccination systems and processes. Yet this is only the start. As the Alliance and countries continue to learn and improve vaccination programs, coverage, and impact, the remaining challenges will be increasingly complex. Moving forward, the FCE must commit to exploring the most complex, yet potentially impactful, drivers of improvement.

Contents

Acknowledgments.....	1
Evaluation Team	2
Acronyms	4
Executive summary.....	6
Contents.....	9
Introduction	11
Methods.....	12
Findings	15
New Vaccine Introductions.....	15
Finding 1.....	15
Finding 2.....	21
Finding 3.....	29
Health System Strengthening	32
Finding 1.....	34
Leadership and management	46
Finding 1.....	46
Finding 2.....	56
Technical assistance.....	59
Finding 1.....	59
Programmatic and financial sustainability.....	63
Finding 1.....	64
Finding 2.....	69
Finding 3.....	71
Alliance processes and requirements	72
Finding 1.....	72
The Alliance partnership	73
Finding 1.....	73
Use of findings	75
Bangladesh.....	75
Mozambique	76
Uganda	76

Zambia.....	76
Gavi FCE evaluation questions, 2013–2016.....	78
Summary of Full Country Evaluations, 2013–2016.....	90
Summary of findings and recommendations.....	106
References	113

Introduction

The Gavi Full Country Evaluations (FCE) are prospective evaluations that cover the period 2013–2016. The aims of the FCE are to understand and quantify 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. The FCE encompasses all phases of Gavi support, from the decision to apply, application and approval, preparation, and implementation in each of the relevant streams of support.

This fourth annual dissemination report on the FCE complements previous reports by providing key findings and recommendations for the 2016 evaluation period in the four FCE countries. Table 1 summarizes the scope of the evaluations during the 2016 period. In addition to evaluating the various streams of support active in each of the FCE countries, we address 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], Partners' Engagement Framework [PEF], and Program Capacity Assessment [PCA]) and broad organizational functions (such as the provision of technical assistance [TA] and promotion of sustainable Expanded Program on Immunization [EPI] programs) that affect the extent of Gavi's current and future success.

Table 1: Overview of streams evaluated in each country*

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

	Rotavirus vaccine		Post-introduction	Launch postponed until 2017	Post-introduction
	Pneumococcal conjugate vaccine (PCV)	Post-introduction	Post-introduction	Post-introduction	Post-introduction
	Human papillomavirus (HPV) vaccine	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

Annex 1 provides a description of the methods utilized in generating the findings covered in this report. Additional details of each method applied by country are included in each country section and in accompanying annexes. 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 Alliance, country, and EPI processes using key informant interviews (KIIs) and social network analysis;
- Resource-tracking studies to generate estimates of national-level resource envelopes on immunization in Bangladesh, Mozambique, and Uganda (submitted separately from this report);
- Analysis of Health Management Information Systems (HMIS) and EPI administrative data to understand the rollout of new vaccine introductions;

- Household surveys (HHSs) in Mozambique on immunization coverage and related key indicators;
- Analysis of dried blood spots (samples were taken in a random subset of HHS participants) to measure immunity in vaccinated children (Annex 4);
- Constraints analysis to examine linkages between health facility surveys, HHS, and dried blood spots; utilization of all primary data in tandem (Annex 3);
- Analysis of primary and secondary data to generate small-area estimates of vaccine coverage, other maternal and child health indicators, and child mortality at subnational levels (Annexes 5 and 6);
- Causal analysis of small-area estimates of vaccine coverage and child mortality to estimate the relationship between new vaccine introductions and child mortality (Annex 7);
- Vaccine effectiveness studies in Mozambique and Bangladesh, including pre- and post-introduction nasopharyngeal carriage surveys, case-control studies, and time-series analyses of surveillance data on invasive pneumococcal disease (IPD) and X-ray-confirmed pneumonia; and
- Analysis of HHS data in Bangladesh, Mozambique, Uganda, and Zambia to assess inequality in coverage for the third dose of diphtheria/pertussis/tetanus vaccine (DPT3; the complete vaccination schedule) by sex and wealth quintiles over time (Annex 8).

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

Table 2: Strengths and limitations of the Gavi FCE

Strengths
• The mixed-methods 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, monitoring and evaluation of human papillomavirus vaccine demonstration projects, or Health System Strengthening 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. The FCE also allows identification and linkage of issues earlier in the process with downstream consequences. • Data collection is designed to build on or complement other surveys and activities to minimize duplication. • The 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 the implementation process and to 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. • There is 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 good access to informal channels of communication and decision-making, there are limits to this that result in an incomplete understanding of the process.
- The absence of a prospective observation mechanism at the regional or global level and at subnational levels limits the collection of process data to retrospective, instead of real-time, methods.
- In-depth qualitative data collection relies heavily on key informant interviews that are prone to recall and respondent bias.
- In each country, a limited number of stakeholders are 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., Health Management Information Systems, surveys).

Findings

This section draws from the entirety of the evaluation 2016 findings in the four evaluation countries and at the global level. It synthesizes 12 findings and highlights cross-cutting themes that emerged from the countries. For country-specific detail, readers may reference the country reports.

Findings and recommendations are organized around five focus areas that were developed in consultation with the Gavi Secretariat Monitoring & Evaluation team. We first cover key findings across the two main Gavi support mechanisms to countries, namely, New Vaccine Introductions (NVI) and Health System Strengthening (HSS). These are followed by an assessment of key root causes that underlie the challenges and successes noted in the NVI and HSS sections of this report. These are leadership and management; TA; programmatic and financial sustainability; Alliance processes and requirements; and partnership. We conclude with a summary of the 2013–2016 findings relevant to each of the evaluation questions that were used to design the Gavi FCE and with an overall summary of the 2013–2016 Gavi FCE findings.

New Vaccine Introductions

Finding 1

FCE countries have improved the routinization of new vaccines over time, although there has been variable success across countries in the medium to long term. The underlying root causes are highly variable and emphasize the importance of post-introduction monitoring and evaluation. Robustness of finding: B^a

In previous Gavi FCE reports, we evaluated the introduction of a range of new vaccines in Bangladesh, Mozambique, Uganda, and Zambia, beginning with the introduction of pneumococcal conjugate vaccine (PCV) in three of these countries in 2013 (Table 3). In 2016, we continued to monitor and evaluate the introduction and routinization of new vaccines.

Table 3: Implementation status of new vaccine introductions in Gavi FCE countries, 2013–2016

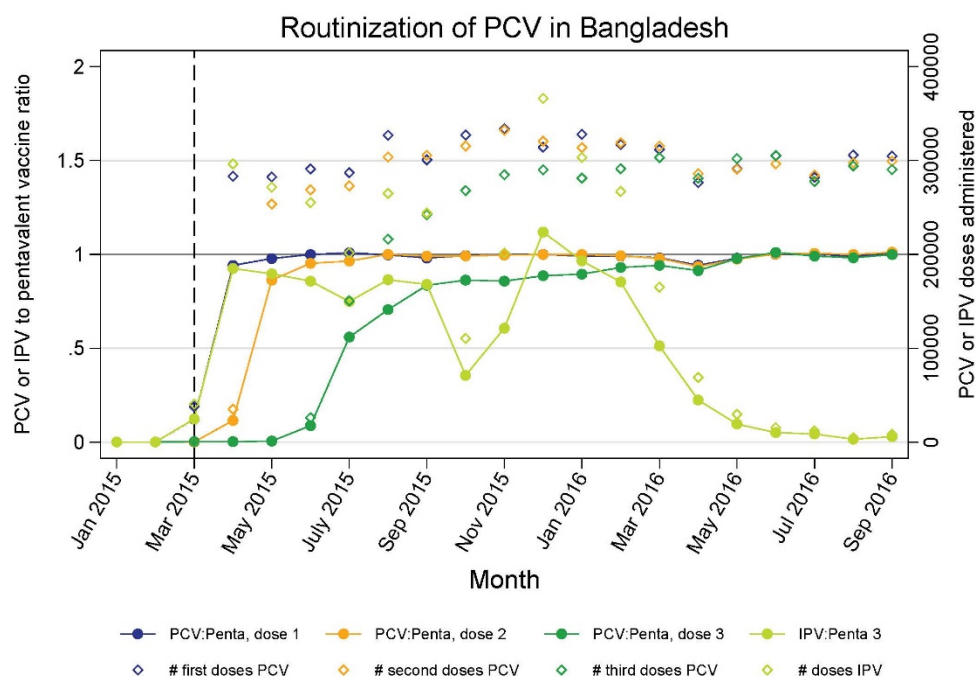
	Bangladesh	Mozambique	Uganda	Zambia
2013	None	PCV introduction (April 2013)	PCV introduction (April 2013, one district)	PCV and MSD introduction (July 2013) Rotavirus vaccine introduction (November 2013)
2014	MR campaign	PCV routinization	PCV national rollout and routinization	PCV, MSD, and rotavirus vaccine routinization

^a The robustness of FCE findings are ranked, from best to worst, as A, B, C, and D. Details on the criteria for these rankings are available in Annex 2.

2015	PCV and IPV introduction (March 2015)	Rotavirus vaccine, MSD, and IPV introduction PCV routinization	PCV routinization	PCV, MSD, and rotavirus vaccine routinization
2016	PCV and IPV routinization	PCV, rotavirus vaccine, MSD, and IPV routinization	PCV routinization IPV introduction and routinization	MR campaign

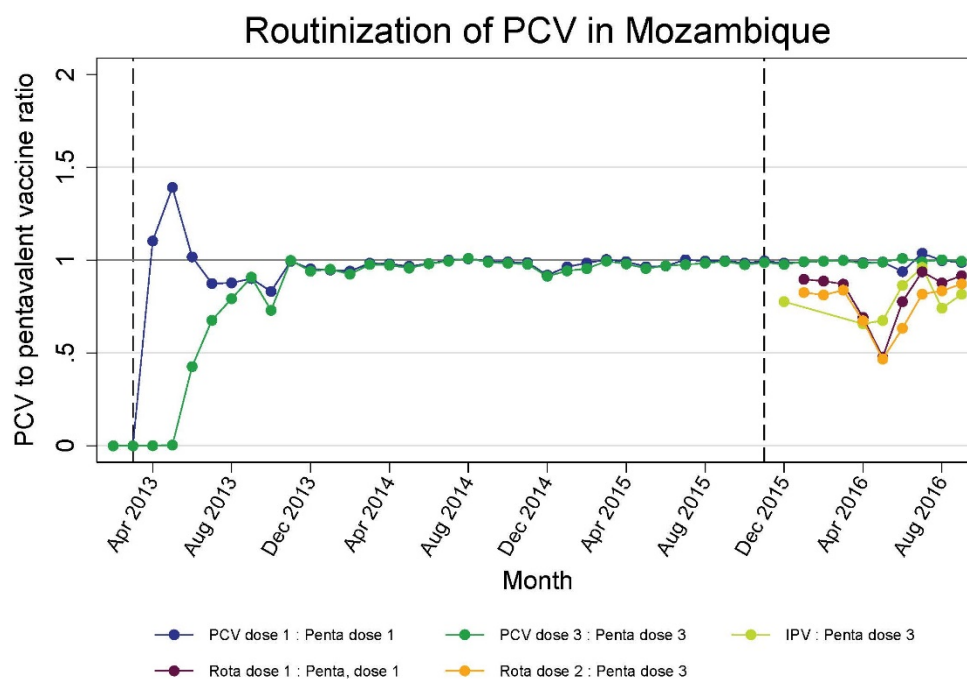
Figure 2, Figure 3, Figure 4, and Figure 5 summarize the routinization of vaccines – expressed as the ratio of new vaccine doses delivered to existing vaccines in the system (represented by pentavalent vaccine) – in the four FCE countries. As covered in the 2015 report, delivery rates of PCV in Uganda (first introduced in April 2013) and PCV (officially launched in July 2013) and rotavirus vaccine (November 2013) in Zambia remained lower than that of traditional vaccines. According to HMIS data, these problems persist to this day. In contrast to Uganda and Zambia, PCV in Mozambique was quickly scaled up (in approximately six months) to the level of pentavalent vaccine delivery; it remained more or less equivalent to pentavalent vaccine since the April 2013 launch, with the exception of the beginning of the second quarter of 2016. Rotavirus vaccine (introduced in September 2015) and measles second dose (MSD; September 2015) in Mozambique, however, have experienced suboptimal routinization to date. Initially, lower third-dose PCV coverage was recorded in Bangladesh (as a result of a separate visit that was scheduled to avoid multiple injections in the same visit). Subsequently, all doses of PCV in Bangladesh were well routinized in 2016. The introduction of inactivated polio vaccine (IPV) in Bangladesh and Mozambique has been affected by global supply issues; this is detailed further below.

Figure 2: Bangladesh routinization of new vaccines, 2015–2016



Bangladesh introduced PCV and IPV in March 2015

Figure 3: Mozambique routinization of new vaccines, 2015–2016



Mozambique introduced PCV in March 2013 and IPV & Rota in November 2015

Figure 4: Uganda routinization of new vaccines, 2015–2016

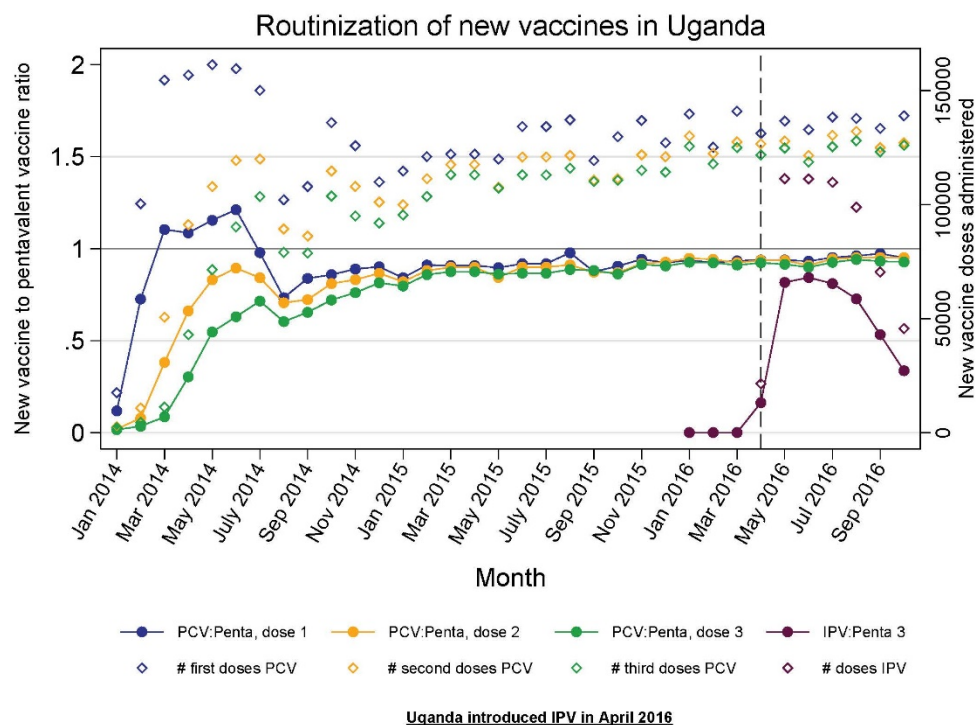
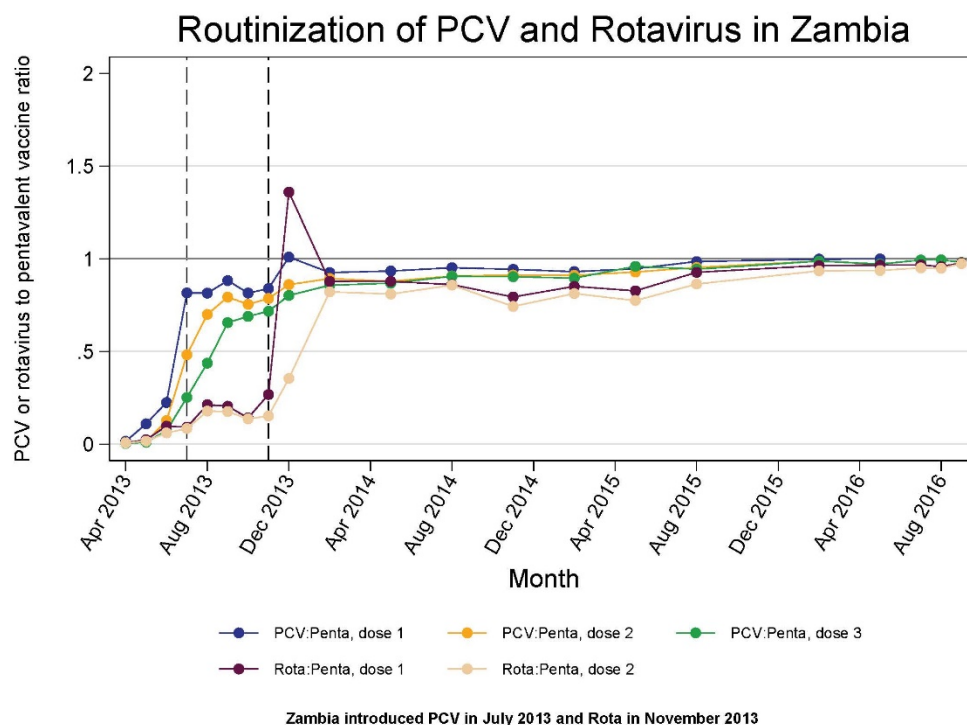


Figure 5: Zambia routinization of new vaccines, 2015–2016



Variable success was also experienced with campaign delivery of new vaccines supported by Gavi. As covered in earlier reports, the measles-rubella (MR) campaign in Bangladesh was largely successful in achieving high coverage and reducing susceptibility to rubella. The 2016 MR campaign in Zambia was implemented as scheduled but suffered challenges related to adequate vaccine supply due to population discrepancies and vaccination beyond the target age range (see Box 2 for further details).

Root causes of introduction and routinization challenges

The underlying root causes of introduction and routinization challenges were likewise variable across the FCE countries. In Uganda, challenges in routinization in 2014 and 2015 were driven by vaccine stockouts; these were covered in detail in the 2015 report. In 2016, our process evaluation findings suggest that the discrepancy in delivery between PCV and pentavalent vaccine may be due to reporting issues at the facility level, with pentavalent vaccine being better recorded as it is a performance indicator for facilities in Uganda.

I realized the difference between PCV3 and DPT3 recently when the district team visited our facility for support supervision. I did not have any explanation because we have not had any PCV stockouts and every child that gets DPT also gets PCV, but we are always overwhelmed by workload so there is a problem without data. This has changed; we are now okay. (Nurse in charge of immunization at a health center, Moroto district, Uganda).

Based on subnational data collection, no stockouts of PCV were observed in facilities visited. This potential root cause highlights data quality issues in administrative and HMIS data and suggests that a population-based coverage survey or data quality audit would be necessary to confirm the discrepancy between PCV and pentavalent vaccine delivery in Uganda.

In Zambia, while discrepancies between new and existing vaccine delivery may also be a function of differential reporting related to performance measures, suboptimal routinization was also driven by a

Box 2: Zambia measles-rubella campaign

ZAMBIA MEASLES-RUBELLA CAMPAIGN

Zambia held a nationwide measles-rubella campaign in September 2016. Although the campaign was deemed successful (coverage 108% based on administrative data), it faced vaccine supply challenges resulting from the use of official population figures for forecasting, and from vaccination beyond the target age range.

Planning for the campaign started early (a lesson learned from previous new vaccine introductions) and used official population figures to forecast the necessary vaccine stock. However, the actual target population numbers differed from the official figures, and vaccine distribution to districts based on official population figures led to under- and oversupply of districts, with some districts experiencing stockouts. This required redistribution of the measles-rubella vaccine during the campaign, which was difficult without timely and reliable vaccine stock information below the province level.

Supply shortages in some districts were compounded by the fact that children outside of the target age range (9 months to 15 years) were being vaccinated. Although monitoring teams were in place and responded well to inadequate vaccines and monitoring and evaluation tools, the issue of vaccinating outside the target age range was not identified or prioritized for action during the campaign.

range of other potential root causes. A central cause was the absence of timely and reliable vaccine stock information below the province level. A Logistimo logistics system has been rolled out at the province level, but only in some districts, and there was extensive discussion during the JA on how to implement this on a trial basis in 2017. A related underlying driver was the difficulty of demand forecasting linked to inaccurate target population estimations, best exemplified by the recent MR campaign (see Box 2). These issues were also further compounded by uncertainty regarding target populations in newly created districts.

In Mozambique, rotavirus vaccine is yet to be fully routinized because its delivery was interrupted by national stock shortages and subnational stockouts during the first quarter of 2016 (see Mozambique report for a full account). While PCV suffered similar stockouts in some provinces, the PCV to pentavalent vaccine delivery ratio did not suffer since PCV was already available in the health system and thus was cushioned by buffer stocks during the first quarter when suboptimal stocks were available in the country.

For MSD, lower coverage was observed in both Zambia and Mozambique, where it was introduced with Gavi support. This is related to both lower awareness and demand among a new target age group (18 months) compared to other routine vaccines, as well as dilution of social mobilization messages, with MSD being launched with other vaccines. In Mozambique, MSD was launched at the same time as IPV, but each vaccine targets a different age group. The pre-launch social mobilization was conducted at the same time for both vaccines; as a result, the messaging was not sufficiently tailored for the new MSD target age group. Moreover, the social mobilization was conducted during a short period of only one week prior to the launch (instead of the recommended one month), and the message only conveyed a target age group of 18 months for MSD, rather than the full 18–24 month age range, which limited demand generation. Challenges with the timing of health worker training (three months prior to the launch), lack of reference materials (job aids) after training, and no supportive supervision in the initial vaccine introduction period due to competing preparation activities for the switch from trivalent oral polio vaccine to bivalent oral polio vaccine also contributed to low coverage.

Three FCE countries – Bangladesh, Mozambique, and Zambia – have been impacted by the global IPV supply shortage. Bangladesh introduced IPV in 2015 and was delivering it on a routine basis, but it was forced by the shortage to interrupt delivery indefinitely (Figure 2) until additional supplies become available (projected for the third quarter of 2017). Our evaluation findings suggest that, at this stage, caregivers or health workers have perceived limited consequences related to stockouts. Zambia also planned to introduce IPV in 2015 (and had even received the vaccine introduction grant), but because of concerns about supply, the country delayed introduction until 2016, and now likely until 2018. In Mozambique, global supply issues coupled with in-country distribution challenges led to stockouts of IPV (Figure 3). In Uganda, IPV has also not been fully routinized in the system since its introduction in April 2016, also due to issues in vaccine supply (Figure 4).

Perhaps most importantly, despite the less-than-optimal routinization of new vaccines in some FCE countries, we have observed that programs and partners have given less political priority to identifying root causes and solutions to suboptimal routinization (see Zambia report for an example). This is due to a range of root causes, including stretched capacity and other competing near-term demands; lesser attention paid to post-introduction monitoring and evaluation, particularly after post-introduction

evaluations (PIE); limited data in terms of timeliness and quality; and a sometimes limited ability to exert political pressure downward to districts/facilities in order to understand discrepancies.

Recommendations

1. We reiterate our 2015 recommendation for countries, Gavi, and partners to enhance post-PIE monitoring and evaluation of new vaccines, particularly if routinization at the time of the PIE is noted to be suboptimal. This could include activities such as placing greater scrutiny on HMIS data, conducting supervision visits to districts and facilities, as well as leveraging existing performance frameworks and the JA process with explicit linkages to Targeted Country Assistance (TCA) as a mechanism for investigating and identifying solutions. In parallel, strengthening the data-use culture and capacity in EPI programs is needed to make enhanced monitoring and evaluation of new vaccines sustainable.
2. Gavi should consider countries' past performance in introducing new vaccines and how countries intend to address previous bottlenecks as part of the approval process for new vaccine support.

Finding 2

In Mozambique, evidence from multiple vaccine-effectiveness studies suggests that the introduction of PCV in 2013, which was rapidly routinized in the country, has reduced nasopharyngeal carriage of vaccine-type pneumococcus and reduced the incidence of vaccine-type IPD and pneumonia. In Bangladesh, we also observed reductions in vaccine-type pneumococcal carriage among children who were age-eligible for PCV, but not among age-ineligible children. Our analysis of child mortality changes at the subnational level also suggests that new vaccine introductions have impacts on child mortality.

Robustness of finding: A

As part of the Gavi FCE, we conducted (led by Manhica Health Research Centre with additional support from the US Agency for International Development and the US Centers for Disease Control and Prevention [CDC]) vaccine-effectiveness studies of PCV in Mozambique. The first study aimed to estimate the direct and indirect effect of PCV10 introduction on pneumococcal nasopharyngeal carriage among HIV-infected and HIV-uninfected children. The study involved cross-sectional carriage surveys before (October 2012–March 2013) and after (first round October 2014–April 2015; second round October 2015–May 2016) PCV introduction. Carriage surveys were conducted among HIV-infected children less than 5 years old enrolled from HIV clinics in Nampula, Maputo, and Manhica. Carriage surveys were also conducted among HIV-uninfected children less than 5 years old from Manhica district, sampled at random from the demographic surveillance site (DSS).

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

there was also an increase in pneumococcal carriage of non-PCV10 VTS, including serotypes in PCV13 (i.e., 19A).

In Bangladesh, we also undertook a before-after nasopharyngeal carriage study in Mirzapur. We observed reductions in vaccine-type pneumococcal carriage among children who were age-eligible for PCV of approximately 25% but no change among age-ineligible children. There were increases in nonvaccine serotypes of 17%–20% among age-eligible children

The reduction in carriage in Mozambique was accompanied by a reduction in vaccine-type invasive pneumococcal disease. Based on a Bayesian regression discontinuity design of surveillance data from the Manhica DSS, we estimated a significant reduction in vaccine-type IPD of 94% (95% UI: 65.8, 99; Figure 6). There was also a significant reduction in X-ray-confirmed pneumonia (85%, 95% UI: 64.3, 93.7; Figure 7). There was a nonsignificant change in nonvaccine-type IPD (16.3%, 95% UI: -55.4, 203.4; Figure 8).

Figure 6: Reduction in vaccine-type IPD over time in Manhica DSS

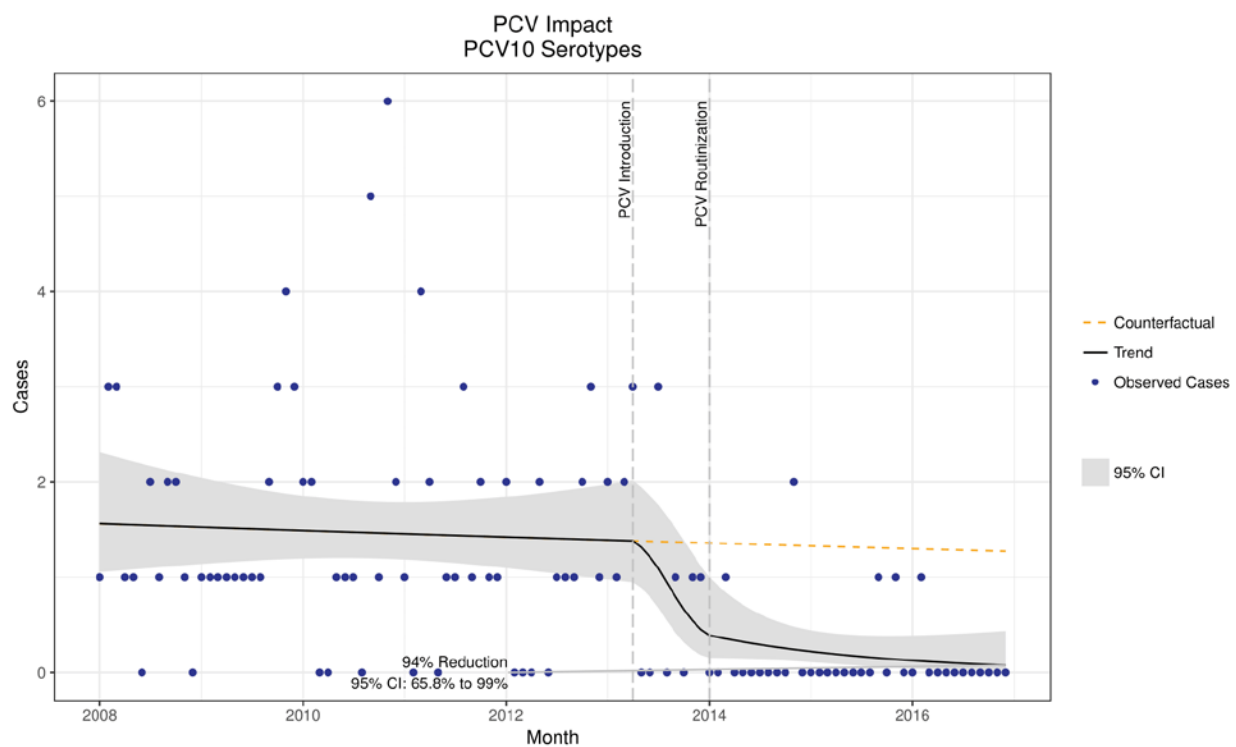


Figure 7: Reduction in X-ray-confirmed pneumonia over time in Manhiça DSS

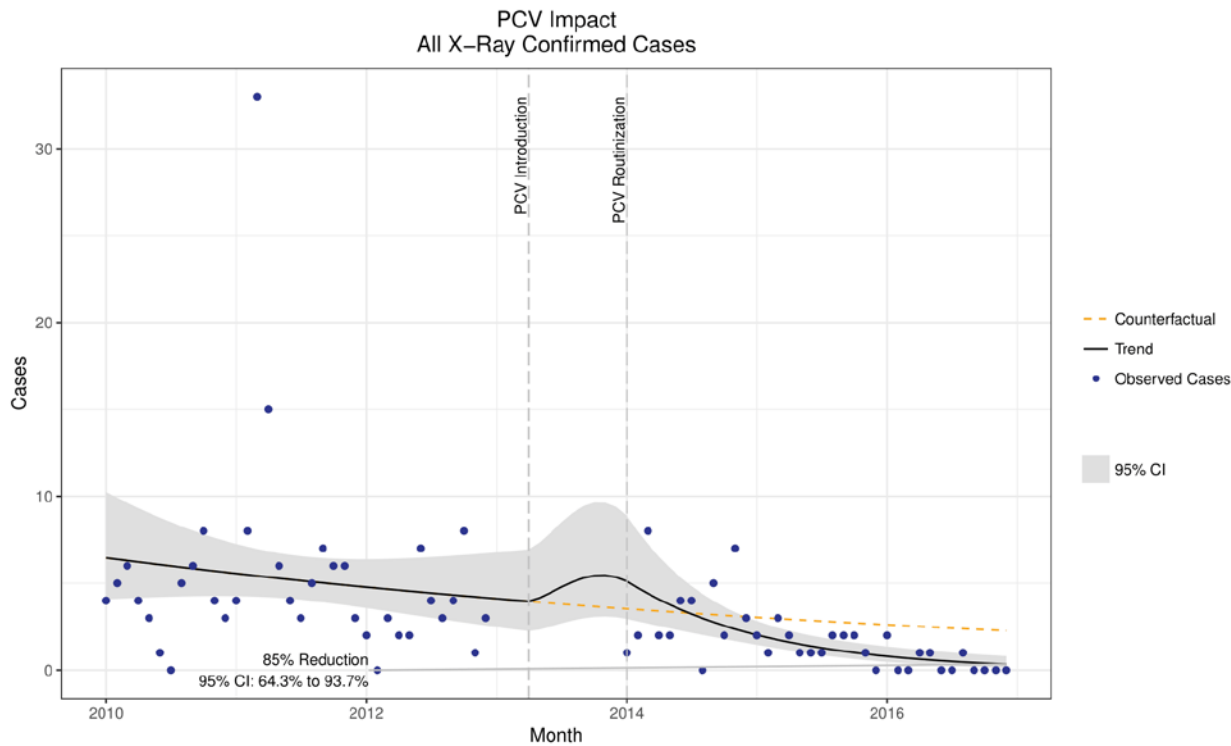
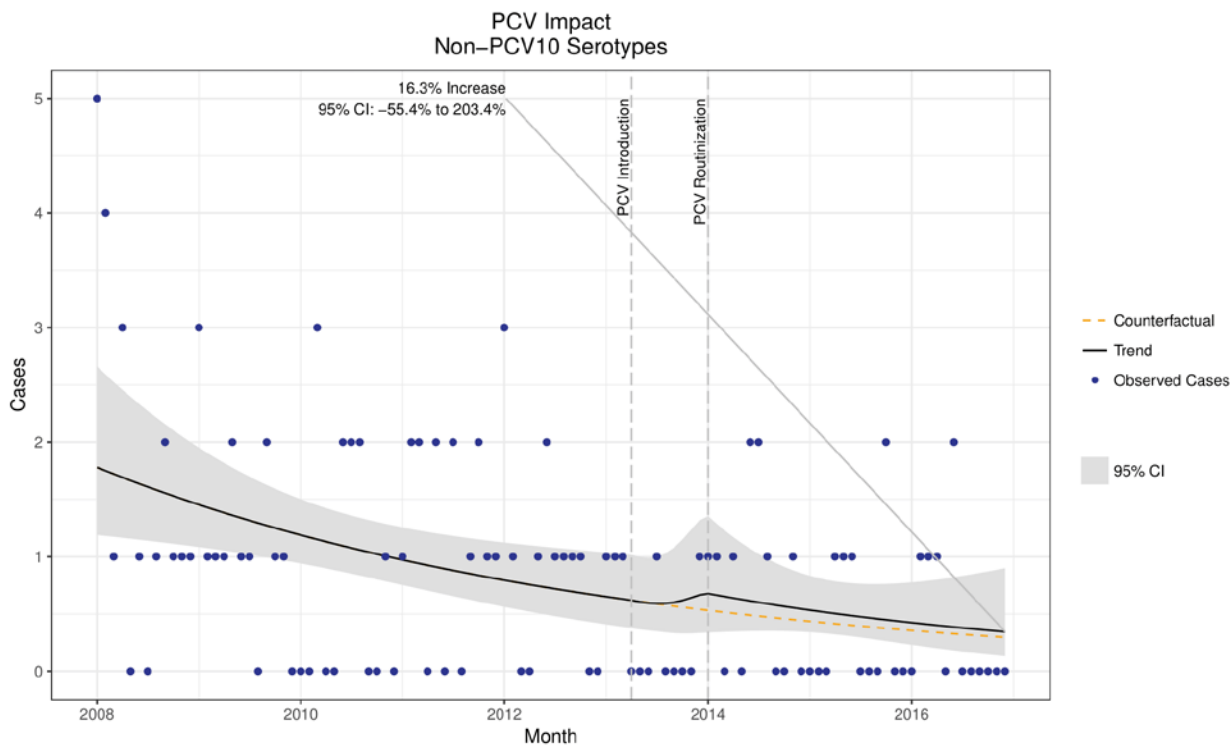


Figure 8: Change in nonvaccine-type IPD over time in Manhiça DSS



In addition to the surveillance data analysis, we also conducted case-control studies of vaccine-type IPD and X-ray-confirmed pneumonia as part of the Gavi FCE. Due to the virtual elimination of VT-IPD in the Manhiça site, we were not able to collect sufficient cases to undertake the analysis. For X-ray-confirmed pneumonia we estimated a 47% (95% UI: 22, 64) reduction associated with three valid doses of PCV. When restricting cases to X-ray-confirmed pneumonia cases that also had a nasopharyngeal swab that was positive for vaccine-type pneumococcus, we estimated 56% (95% CI 11, 79) reduction associated with three valid doses of PCV.

The high effectiveness noted in the vaccine-effectiveness studies on vaccine-type pneumococcal disease is consistent with the high coverage of the vaccine achieved in Manhiça district (our small-area estimates of vaccine indicate that coverage of three-dose PCV in Manhiça district was 89.3%, 95% UI: 85.1, 93.4 in 2016). The high coverage was the result of the rapid routinization of PCV nationwide, which has been maintained to the present date (see Finding 1 for further details). This provides evidence that the high coverage of PCV nationally in Mozambique (88.0%, 95% UI: 86.0, 90.1 in 2016) has led to considerable reductions in vaccine-type pneumococcal disease. Given the similar results seen in reducing pneumococcal disease in other studies in Africa and elsewhere,¹⁻⁵ scale-up of PCV also likely has led to reductions in pneumococcal disease in the other three FCE countries. Overall, these findings also highlight the missed opportunities for health impact due to suboptimal coverage of these vaccines, particularly at the subnational level (Figure 9 through Figure 12).

Figure 9: Map of PCV coverage in Mozambique

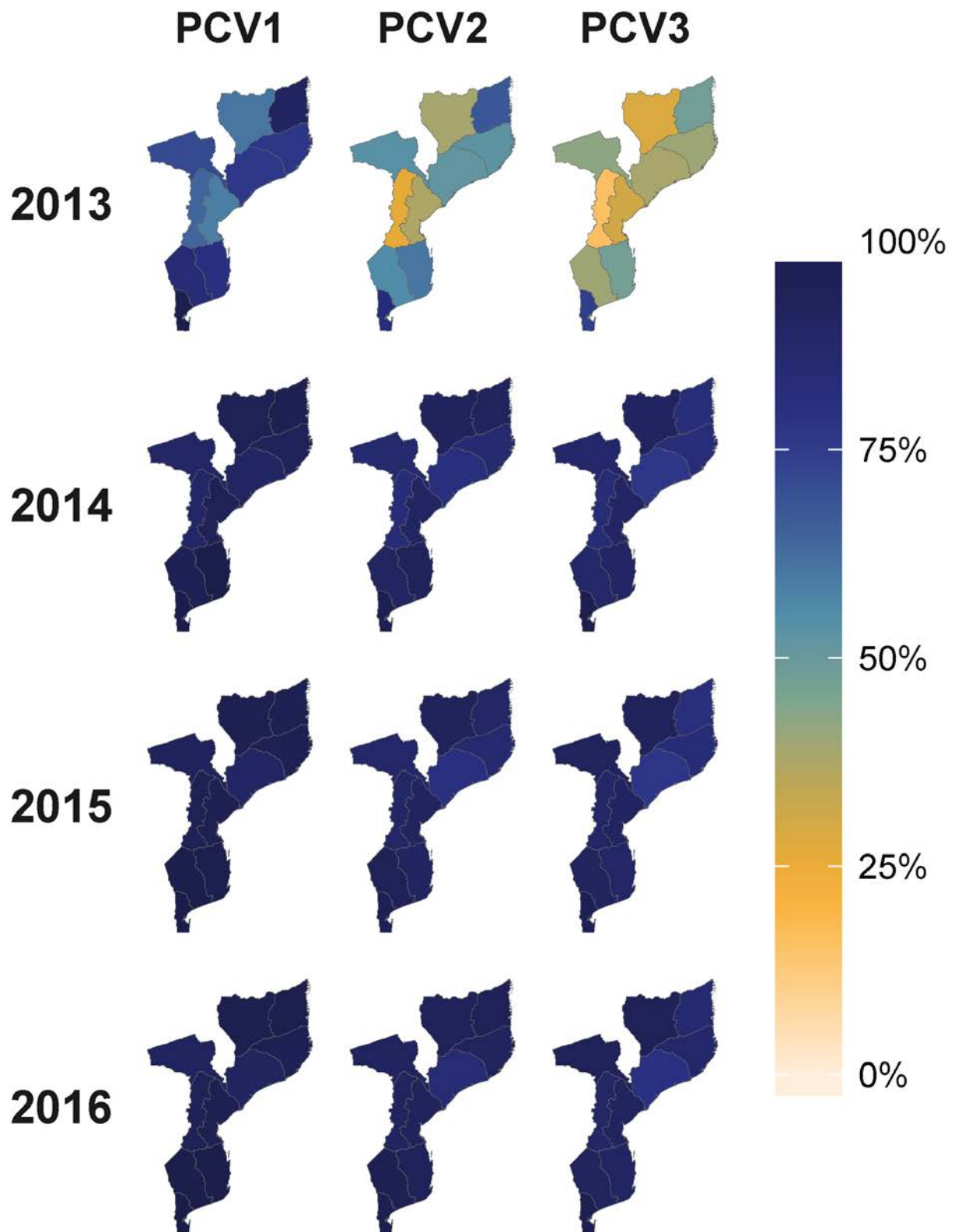


Figure 10: Map of PCV coverage in Uganda

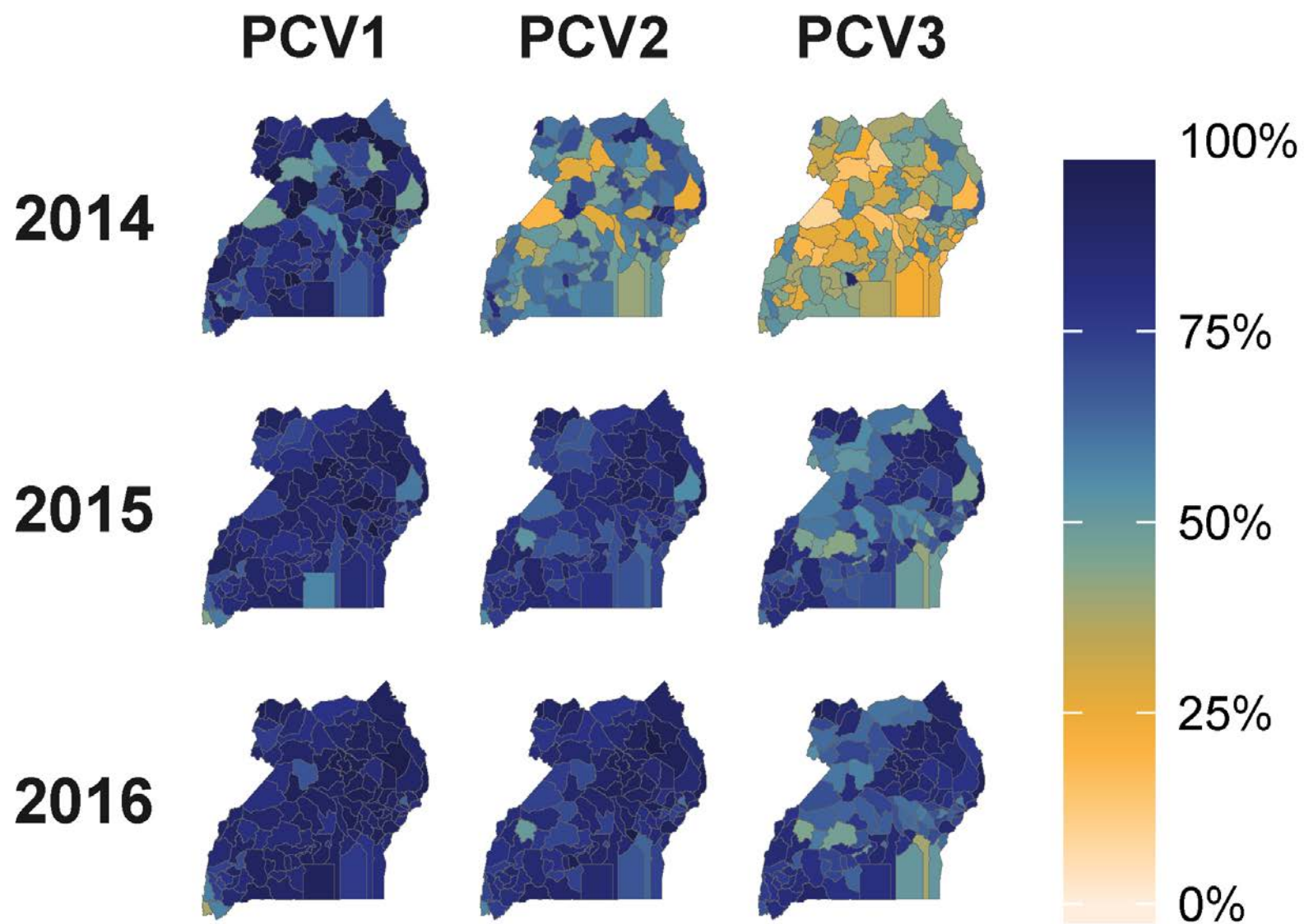


Figure 11: Map of PCV coverage in Zambia

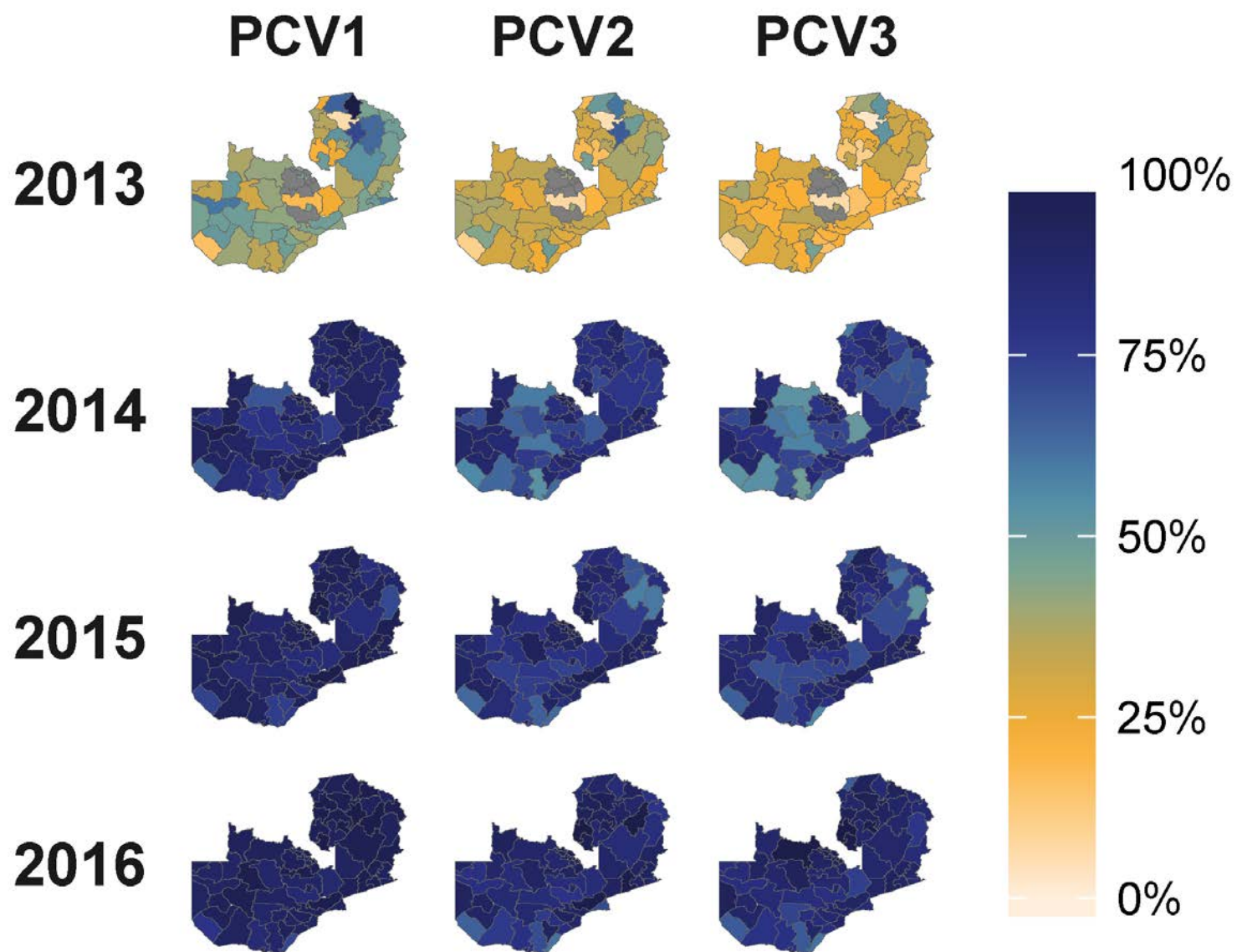
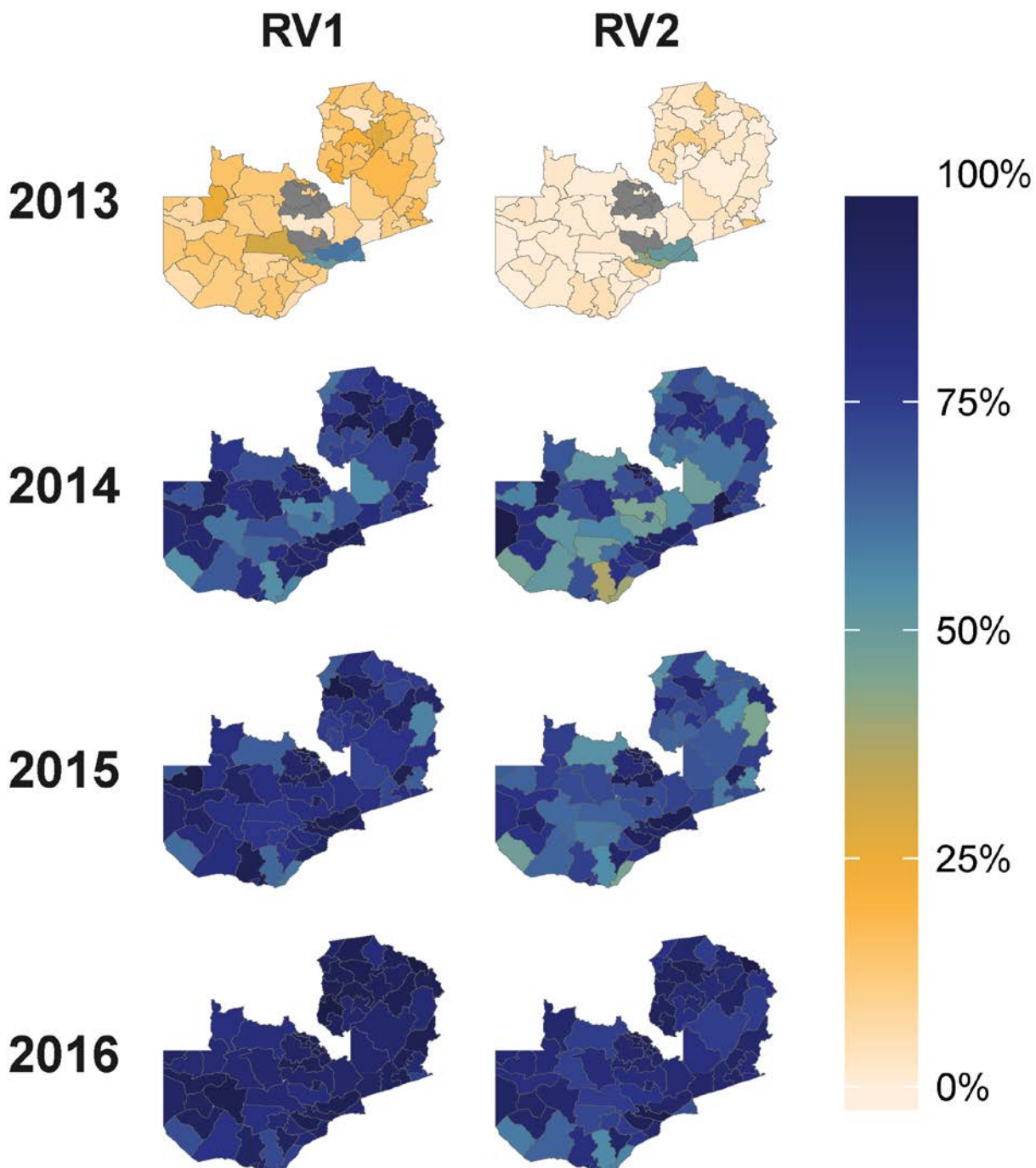


Figure 12: Map of rotavirus vaccine coverage in Zambia



To assess whether the introductions of new vaccines in FCE countries have led to overall reductions in child mortality, we conducted causal analyses using the small-area estimates of vaccine coverage and child mortality (see Annex 7). These complement the results from the vaccine-effectiveness studies. To estimate the relationship between new vaccine introductions of PCV and rotavirus vaccine and child mortality, the FCE used finite distributed lag regression models that adjust for other important drivers of child mortality. These other drivers or covariates were separately estimated at the corresponding geographic level (province, district, or subdistrict), and included household wealth, maternal education, other vaccination (pentavalent and measles), breastfeeding, childhood malnutrition (stunting and wasting), and maternal health care (antenatal care, in-facility delivery/skilled birth attendance). Our analyses indicate that high NVI coverage is associated with significant improvements in child mortality. Compared to counterfactual scenarios where these vaccines were not introduced, in 2016, there were 10.1% (95% UI: 6.4, 13.8) and 11.9% (95% UI: 9.4, 14.3) reductions in under-5 mortality in Mozambique and Zambia, respectively. No significant reductions in child mortality were observed in Uganda. However, it is important that these results are not translated as an absence of an effect, given the relatively short time period post-introduction, a likely lag period between coverage scale-up and full impact, lower coverage rates, and a less-specific health outcome than for the vaccine-effectiveness studies.

Finding 3

Mozambique and Zambia have been delayed in introducing human papillomavirus (HPV) vaccine nationally. Moreover, there was an interruption in vaccine delivery in demonstration sites. The main root causes were concerns about financial feasibility and limited ownership by the EPI program. The Bangladesh demonstration program highlighted some of the challenges previously experienced, including financial feasibility and the timeliness of evaluation products to inform year two delivery. In Uganda, where HPV vaccine was introduced nationally in November 2015, the rollout was slow and varied, with 83.37% of eligible girls reported to have received one dose and 22.75% of eligible girls reported to have received two doses of HPV vaccine by December 2016. Gavi is revising the HPV vaccine window of support, which has the potential to address some of these challenges. Robustness of finding: B

Table 4: Implementation status of HPV vaccine in Gavi FCE countries, 2013–2016

	Bangladesh	Mozambique	Uganda	Zambia
2013	None	Application for HPV vaccine demonstration project	Implementation of demonstration project in several districts (not Gavi-supported) and application for national HPV vaccine introduction	Implementation of demonstration project in Lusaka province (not Gavi-supported)
2014	Application for demonstration project in September 2014, including	Completion of first year of demonstration project in three	Previously conducted demonstration, and preparations to	Implementation of demonstration project in Lusaka

	demonstration-site selection	districts (one Gavi-supported)	introduce HPV vaccine nationally in 2015	province (not Gavi-supported)
2015	Preparation for demonstration project	Implementation of second year of demonstration project	Ongoing preparation for and launch of national introduction on Nov. 24, 2015	Implementation of demonstration project in Lusaka province (not Gavi-supported)
2016	Implementation of demonstration project	Review meeting in March; expected to submit application in January 2017	National implementation and routinization	Demonstration project completed Developing application for national rollout

Table 4 summarizes the various stages of HPV vaccine support that Gavi FCE countries undertook over the course of the last four years. In 2016, Mozambique and Zambia experienced a slower than expected transition from the completion of their demonstration projects to national introduction. The root causes of this slow transition were concerns about financial sustainability of the tested delivery model during the demonstration project and limited ownership by the EPI program following the conclusion of the demonstration project. In both cases, delivery of HPV vaccine in the demonstration sites (five districts in Lusaka province in Zambia and three districts in Mozambique) has not been able to continue given the delay in application for national introduction. In Bangladesh, while the implementation of the demonstration project itself has largely been successful in terms of testing the proposed delivery model, the experience has echoed some of the issues seen in the other FCE countries. The country has focused primarily on implementing the demonstration project as designed and has not yet considered whether the delivery model being used in the demonstration project is likely to be programmatically and financially sustainable. This issue has been compounded by the coverage survey and costing evaluation studies not being ready to inform the second year of the demonstration project.

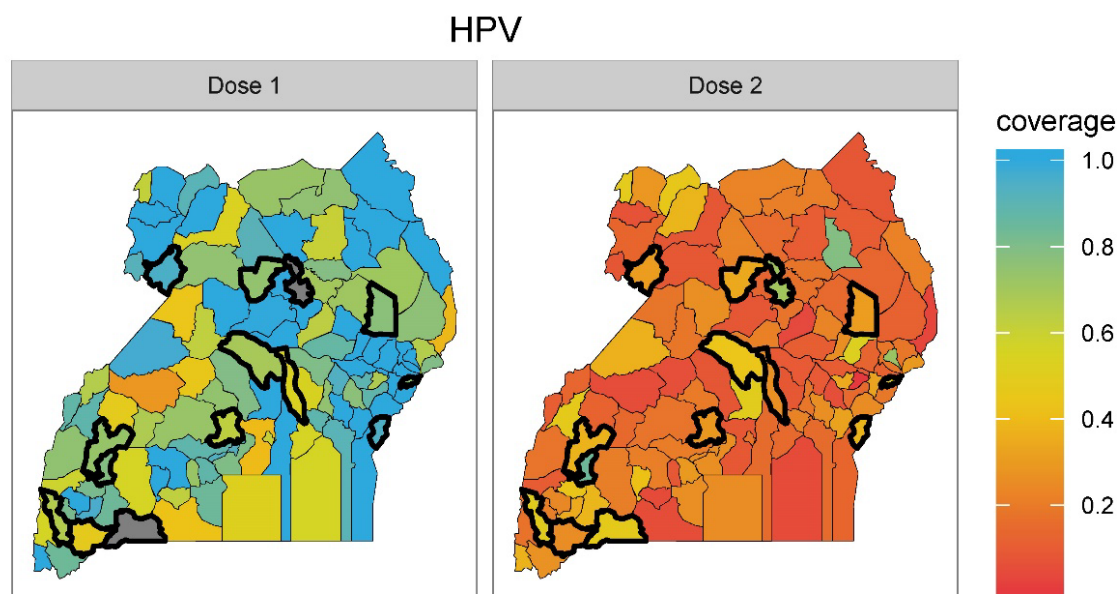
We are now focusing on the demonstration program. The sustainability of HPV program can be ensured after the coverage survey and costing evaluation. (Bangladesh KII)

Uganda launched HPV vaccine nationally at the end of 2015. Our 2015 report covered challenges associated with this launch, including delays in implementation of the HSS grant, which led to postponement of the HPV vaccine national launch, and merging of the HPV vaccine introductory activities with the measles campaign, which resulted in inadequate training and no funding for HPV social mobilization. The Uganda experience highlights some of the challenges facing the other three FCE countries – and, indeed, other countries (Uganda is one of only two Gavi-supported countries globally to have introduced HPV vaccine nationally) – as they transition from demonstration project to national introduction. Administrative data from Uganda suggest that the rollout of HPV vaccine nationally has been varied and slow (Figure 13), with national HPV2 coverage estimates at only 17% by the middle of 2016. Notably, this is a problem that persists even in districts that were earlier demonstration sites. The root causes for the slow rollout and low coverage include the shift to the health-facility-based delivery

model, inadequate planning, delayed receipt of vaccine and monitoring and evaluation tools, delayed social mobilization, and lack of clarity on the delivery model due to inadequate training.

Figure 13: HPV vaccine coverage by district in Uganda, from HMIS data, November 2015–December 2016

Bold outlined districts are HPV vaccine demonstration districts.



Drawing from the findings of the Gavi FCE and other studies, including the London School of Hygiene & Tropical Medicine/PATH review of HPV vaccine programs,⁶ the Gavi Programme and Policy Committee recommended that the Gavi Board make changes to the HPV vaccine support window. Under the proposed policy change, countries would be able to apply directly for national introduction, while maintaining the option of implementing a phased national introduction. This policy was approved in the December 2016 Gavi Board meeting.

The revision of the HPV window of support has the potential to address some of the challenges noted in our evaluation. The removal of the demonstration program step is intended to encourage countries to focus on the national introduction process and delivery models that would be financially and programmatically sustainable for nationwide rollout. Directly moving toward national introduction may also facilitate ownership of the HPV vaccine program by the EPI program and encourage broader stakeholder engagement. Our findings from past FCE reports show the limited ownership of the government for the demonstration projects, particularly in the presence of partner organizations with strong experience with HPV vaccine. The purpose of the option of the phased approach is to allow learning over time; for example, different subnational units could be used to test different approaches that could be adjusted over time. The key difference between this learning approach of phased introduction versus demonstration program is the removal of the demonstrated ability criteria — criteria that we have previously noted as impediments for countries' learning for national introduction. Notably, Mozambique will propose a phased introduction when they submit their application for national introduction of HPV vaccine. A phased introduction would also maintain momentum and avoid time lags between demonstration and national scale-up that may result in interruption of vaccine delivery, as in the case of Mozambique and Zambia.

While the revised HPV 2.0 policy has the potential to address previous challenges noted, in practice, a number of key elements would need to be in place to facilitate success. These include, for those countries implementing a phased approach, comprehensive and timely monitoring and evaluation to facilitate systematic learning (e.g., from districts implementing different models), as well as the ability to apply learnings to change strategies over the course of the phased introduction – strategies that take into account country context (e.g., finding the right balance of cost versus coverage; determining how to reach out-of-school girls; etc.). A current example of the need for strong monitoring and evaluation and ongoing refinement is in Uganda. As part of the national introduction, many districts in Uganda ended up using different specific delivery models (using varying mixes of school-based, community-based, and health-facility-based delivery), primarily due to insufficient training. These different experiences and their relative advantages and disadvantages, however, are yet to be documented and fed back to the national program or other districts to refine vaccine delivery. This aspect of phased introductions will require enhanced TA. Notably, the draft policy notes that TA will be earmarked for HPV vaccine programs under PEF-TCA, but it does not as of yet detail the nature of the TA to be provided. Such TA, as we have highlighted in previous reports, will also need to include cross-country learning.

TA will also be needed for countries early in the application process, in particular for assisting countries in preparing budgets and financial plans, a requirement that continues under the new proposed policy. Notably, the revised policy also highlights additional guidance to reduce incentives that have inflated the estimates of cost of HPV vaccine delivery (e.g., per diem rates). This issue was highlighted by the high cost estimates associated with HPV delivery in the FCE demonstration projects, which utilized per diems for HPV vaccine delivery.

The second major change to the HPV vaccine support window is that support will be provided for multiage 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. Based on our findings to date, it is difficult to predict the implications of this policy change; however, we note the potential challenges with expanded cold chain requirements for already stretched systems to meet the need for multiage vaccination.

Recommendation

In developing the HPV 2.0 policy and process further, we recommend that Gavi and partners provide clear guidance coupled with strong TA to facilitate implementation of phased introductions. This should include aspects ranging from introduction planning, monitoring and evaluation, and systematic processes for capturing learnings from phased introductions as well as from other countries.

Health System Strengthening

HSS grants are a critical component of Gavi's efforts to achieve coverage and equity targets. As of 2016, all FCE countries have been approved, and/or are in the very early stages of preparing to implement or implementing their new HSS grants. Table 5 provides an overview of the status of HSS in each country.

Table 5: Status of HSS grants in each FCE country, 2014–2016

	Bangladesh	Mozambique	Uganda	Zambia
2014	Implementation of HSS-1 grant (preliminary findings)	Preparations for implementation of approved HSS-2 grant	Implementation of reprogrammed HSS-1 grant	Preparations for submission of HSS-2 application targeted for January 2015
2015	Implementation of HSS-1 grant; submission of HSS-2 application in January 2015; and resubmission of revised application in September 2015	Preparations for implementation of approved HSS-2 grant	Continued implementation of reprogrammed HSS-1 grant	Submission of HSS-2 application in January 2015 and resubmission of revised application in September 2015
2016	Implementation of first of bifurcated HSS-2 grants (effective vaccine management and surveillance activities through the United Nations Children's Fund and World Health Organization). The second bifurcated grant will be aligned with the new Sector-Wide Approach (which is currently being finalized). An application is expected in 2017 as part of the Country Engagement Framework	First year of HSS-2 implementation; decision in November 2016 to reprogram the grant, given the implications of the macroeconomic crisis for the budget and relevance of activities	In the final stages of implementation of the HSS-1 grant. Applied and was approved for a second HSS grant. Currently in the process of fulfilling the post-approval requirements (including negotiating the Grant Management Requirement [GMR] based on findings of the Program Capacity Assessment) to enable disbursement of funds	Approved for new HSS grant in November 2015. 2016 was spent fulfilling the requirements to enable disbursement of funds. This included responding to Independent Review Committee feedback, undergoing a Program Capacity Assessment, and addressing the points outlined in the GMR.

Finding 1

If designed appropriately to target the most critical bottlenecks, HSS investments have the potential to add immense value. However, in FCE countries, we have found that regardless of design, the many complexities associated with implementation of these grants (for example, responding to Independent Review Committee [IRC] feedback, the PCA, and Grant Management Requirement [GMR] during the post-approval process) undermine this potential at all phases of the grant life cycle. These challenges diminish the predictability of Gavi HSS funds and, in some cases, the relevance of the design of the grant. Robustness of finding: B

Across all four FCE countries, 2016 was a year of continued slow progress toward HSS implementation. This was due to challenges experienced with the development of the HSS application (Uganda), particularly navigating the bottleneck analysis stage; a lack of clarity and common expectations surrounding the post-approval process (Zambia and Uganda); and slow initiation of HSS activities (Mozambique). While implementation of the first components of Bangladesh's bifurcated grant^b commenced relatively quickly in comparison to other FCE countries, the second application for a broader set of systems-strengthening activities will not be submitted until the Sector-Wide Approach is finalized. Because of the slow progress toward implementation across the four years of the evaluation, the FCE is unable at this stage to evaluate the effects on HSS program impact (from application through implementation).

While Gavi seeks to address many of these challenges through the recent Health Systems and Immunization Strengthening (HSIS) support framework and the Country Engagement Framework (CEF), as of now, these reforms do not apply to any FCE countries and, indeed, many other Gavi countries with active HSS grants.

Our findings are organized in relation to three distinct stages as they pertain to FCE countries: application, post-approval, and implementation.

Application

Uganda was the only FCE country to apply for a new HSS grant in 2016, but it experienced many similar issues to those reported in 2015. In 2015, the FCE reported on a number of root causes of challenges experienced with the HSS application process in Bangladesh and Zambia, including complex, time-consuming, and poorly understood processes of applying for HSS support. These challenges resulted in a heavy reliance on consultant support. In Uganda, the bottleneck assessment was found to be particularly difficult, which points to a need for a more standardized approach.

In Uganda, two attempts were made at developing an HSS application. The first was perceived to be inadequately consultative so stakeholders decided to start again. The second process included over 60 stakeholders who represented a wide array of organizations. Broad participation in the second process was perceived to have fostered country ownership. However, this was extremely time-consuming and

^b As noted in our 2015 report, a decision was taken to postpone submission of Bangladesh's Health System Strengthening grant so as to align the bulk of it with the new Sector-Wide Approach (currently being revised). But because some key activities implemented by the World Health Organization (WHO) and United Nations Children's Fund (UNICEF) required more immediate funding, the grant was "bifurcated." An application for surveillance and vaccine management activities to be carried out by WHO and UNICEF was submitted in September 2015. An application for the rest of the activities, to be implemented by the government, is expected in early 2017.

the lack of a structured tool for the bottleneck assessment resulted in some informants reflecting that some partners promoted their own interests or areas of comparative advantage. Although the process was widely perceived to be onerous, the bottlenecks prioritized in the HSS application were largely consistent with those identified through the FCE's constraints analysis (see Box 3), suggesting that this consultative and inclusive process was successful in identifying key bottlenecks.

Bottlenecks

In 2015, the FCE recommended that Gavi invest in enhanced data, tools, and analysis to support more robust bottleneck assessments that could inform the design of HSS grants. The experience from Uganda's application process in 2016 provided further support for that recommendation, not just to ensure the right bottlenecks are identified but also to alleviate some of the process-related burdens associated with managing the interests of partners.

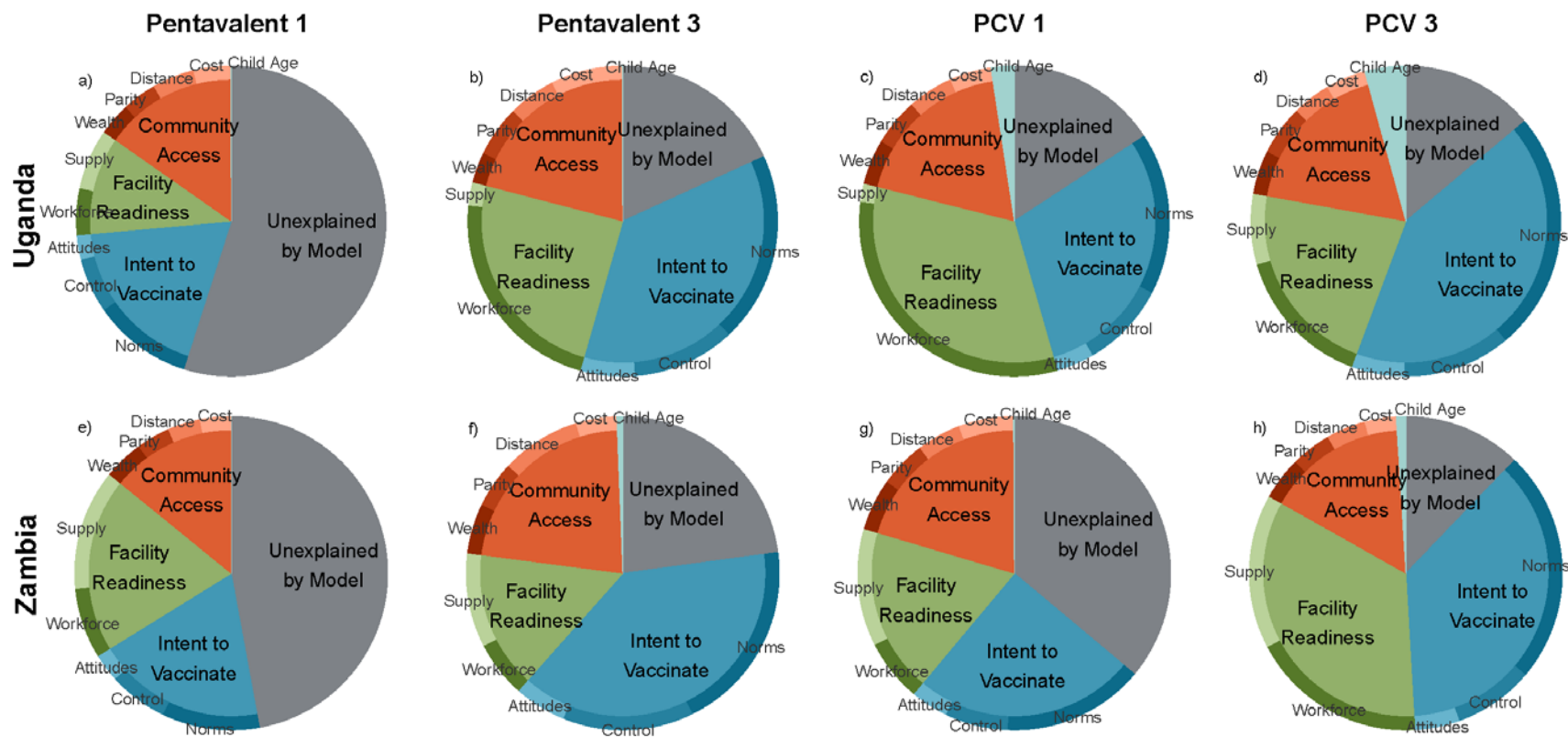
The bottleneck assessment was complemented by a constraints analysis using Gavi FCE survey data (see Box 3).

Box 3: Constraints analysis methods and recommendations

CONSTRAINTS ANALYSIS METHODS AND RECOMMENDATIONS
The linked Gavi FCE surveys provide a unique opportunity to examine constraints to vaccine coverage. Using the household survey, we evaluated community and household characteristics that correspond with vaccinated children. Linking children to health facilities, we used health facility, district health officer, 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 to assess the relative contribution of demand-side, supply-side, and access-related determinants. The constraints analysis is described in more detail in Annex 3. Recommendations 1. The data and model indicate that there are different drivers for initiation (first dose) and dropout (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 for pneumococcal conjugate vaccine than pentavalent vaccine utilization. 2. We recommend that demand-generation interventions in Zambia should use reduced dropout as a key metric of success. 3. We recommend that new vaccine introduction programs focus on Facility Readiness to achieve success.

Figure 14 displays the high-level results from the constraints analysis. For three doses of pentavalent vaccine (Figure 14 (b) and (f)), the model estimated that the largest driver of vaccination was the mother's or caretaker's "intent to vaccinate", (i.e., demand), which explained 36% of pentavalent 3 coverage in Uganda and 40% in Zambia. PCV3 utilization (Figure 14 (d) and (h)) was much more strongly influenced by health facility readiness (25% in Uganda, 34% in Zambia). For both vaccines in both countries, demand was a larger factor for the third dose (Figure 14 (b), (d), (f) and (h)) than the first (Figure 14 (a), (c), (e) and (g)).

Figure 14: Relative constraints to individual-level vaccine utilization in Uganda and Zambia.



Post-approval

All FCE countries have experienced a variety of unanticipated hurdles to HSS disbursement during the post-approval stage. Mozambique's experience with the financial management assessment (FMA) and financial management requirement (FMR) process was well documented in the 2015 FCE report. In 2016, post-approval bottlenecks fell into two processes: 1) the process for submitting clarifications to Gavi, based on feedback from the IRC, to obtain final approval; and 2) implementation of the PCA, including the GMR.

Although Gavi's application and review process no longer officially allows for conditional approvals, with final approval being contingent on satisfactory responses to issues identified by the IRC, the FCE has observed that, in practice, "conditional" approvals persist. This introduces an additional step of responding to identified issues before final approval is granted from the Gavi Chief Executive Officer. While previously these clarifications were reviewed by the IRC, now responses are assessed by the Secretariat, although this process remains opaque.

Bangladesh, Uganda, and Zambia were all required to respond to issues identified by the IRC in 2016. These included developing more detailed indicators in monitoring and evaluation frameworks (Bangladesh and Zambia), conducting sustainability planning (Bangladesh and Zambia), and updating financial gap analyses (Bangladesh). While in principle it may be reasonable to request that countries address proposal weaknesses, this step contravenes the stated process and introduces further confusion to what is already a complicated support stream. Country stakeholders expressed a lack of clarity around when they could expect final approval from Gavi, and even staff at the Secretariat were unclear on the precise

Box 4: Program Capacity Assessment

PROGRAM CAPACITY ASSESSMENT

2016 marked the first year of implementation of the Program Capacity Assessment (PCA). The purpose of the PCA is to "assess the (current or proposed) financing modality and other structures for use of Gavi support provided in the form of cash, vaccines (and related devices) with appropriate transparency and accountability." A PCA, therefore seeks to achieve the following:

- a) "Evaluate the current or proposed financing and management modality to establish its suitability;
- b) Understand other potential mechanisms, especially those used by the main development partners in the health sector in the respective country, in case they prove a more appropriate channel for Gavi support;
- c) Allow Gavi and the respective government to come to an agreement on specific modalities, mechanisms and procedures that will be used to manage cash and vaccine support from Gavi;
- d) Identify capacity gaps that need to be addressed in order to assure sound management and oversight of the Gavi-supported programs (cash and vaccines);
- e) Make recommendations on capacity building initiatives to address capacity gaps identified, indicating priority and time scales;
- f) In line with IHP+ principles which promote harmonization of country financial systems amongst the development partners, identify areas for possible harmonization; and
- g) Suggest any additional fiduciary measures necessary to strengthen the mechanisms the respective governments use including governance and anti-corruption measures."

The PCA is not an altogether new process; rather, it is an expanded process, replacing the financial management assessment, which assessed only financial management modalities. In 2016, Uganda and Zambia were early pilot countries for the new PCA.

Reference: *Gavi Programme Capacity Assessments: User Guide*. Geneva: Gavi, 2016.

steps and timing of review at the Secretariat once clarifications were received. Furthermore, while these requests may seem simple and straightforward from the perspective of reviewers, FCE observations suggest that in fact they require significant time and consideration on the part of country stakeholders and add months to the post-approval process.

2016 marked the first year of implementation of the PCA.^c The PCA is not altogether new; rather, it is a revision of the former FMA process, with added assessments of programmatic and vaccine management. Uganda and Zambia were both selected for the first wave of PCA implementation, and they were notified in early 2016 that this assessment would take place. A detailed account of experiences with the implementation of this assessment is covered elsewhere in the report (see Program Capacity Assessment section, page 56), but here we discuss it in relation to its implications for the HSS process. The PCA as a mechanism has the potential to inform the design of HSS grants *a priori* by identifying persistent systems bottlenecks, specifically as they pertain to financial, programmatic, and stock management (and increasingly through the CEF – discussed later in this section – the PCA is identified as a tool for informing design). Furthermore, the requirements outlined in the GMR have resource implications for the HSS grants, so ideally this should be reflected in the initial design and budgeting of the HSS grants. However, the timing of the PCA did not allow for this in either Uganda or Zambia (see Box 5 on PCA alignment).

Box 5: Alignment of Program Capacity Assessment with country processes

PROGRAM CAPACITY ASSESSMENT ALIGNMENT

The Program Capacity Assessment (PCA) process could have been improved by better aligning its timing with other Gavi activities in Uganda and Zambia, including Health System Strengthening (HSS) grant applications and Joint Appraisal (JA) meetings (see Figure 15). In neither country were PCA findings and recommendations available in time to inform the recent HSS-2 applications. In Uganda, the PCA was conducted before the HSS proposal was submitted to Gavi; however, the debriefing meeting did not occur until May, after the design was finalized. In Zambia, the PCA occurred later, after approval of the HSS grant. In both countries, stakeholders participated in initial PCA debrief meetings in advance of the 2016 JA meetings, but the written PCA reports were not available to substantively inform the JA discussions.

The intent going forward is that HSS grants and/or Partners' Engagement Framework-Targeted Country Assistance can be leveraged to fill gaps identified by the PCA. However, this was not the case for the initial pilot countries due to the mistiming of the PCA. The *Health System and Immunisation Strengthening Support* report to the Gavi Board in June 2016 noted: "[I]t is critical that output from PCAs is available in time to inform countries' planning of HSIS [Health Systems and Immunization Strengthening] investments and associated Performance Frameworks." As one global key informant said, Gavi is "playing catch-up now" to synchronize the HSS proposals with the PCA.

Source: Gavi. *Health System and Immunisation Strengthening Support. Report to the Board: 22–23 June 2016*. Geneva: Gavi, 2016.

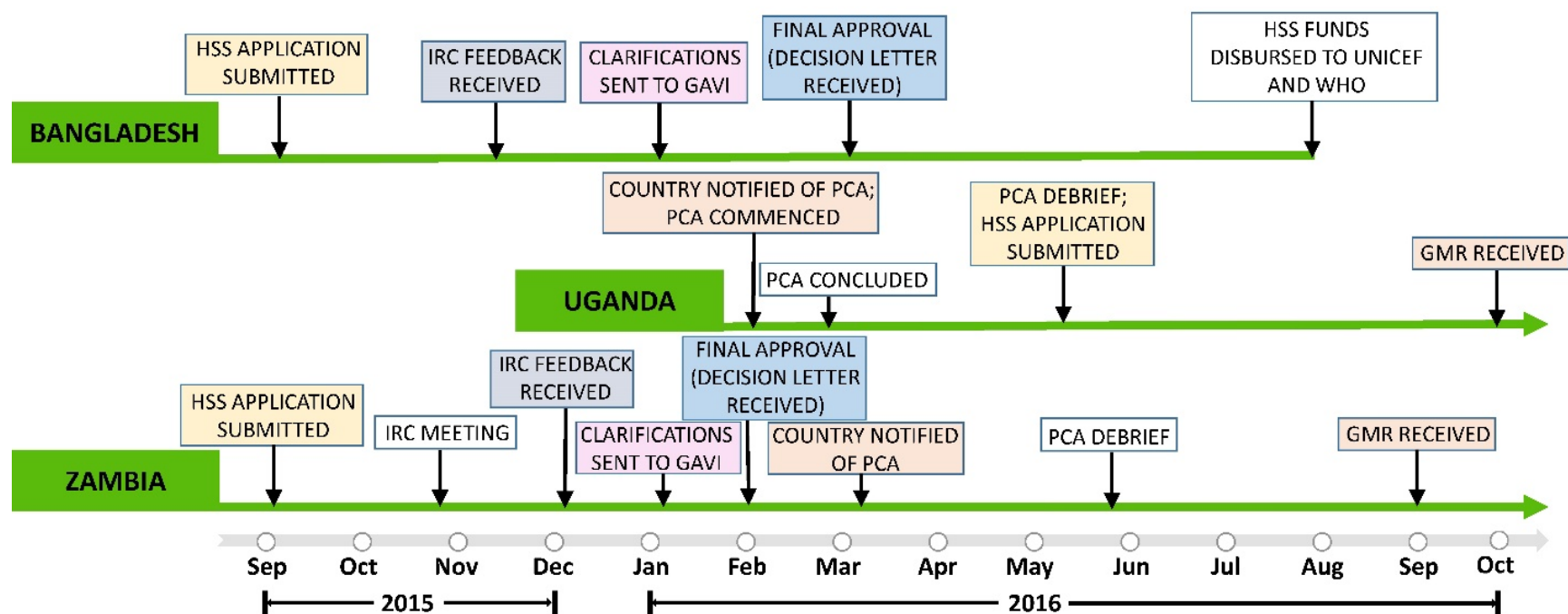
^c Please refer to the Leadership and management section on page 46 for a fuller discussion of the experience of Uganda and Zambia in implementing the PCA in 2016.

In these cases, the different steps associated with the PCA introduced additional delays and uncertainty about the timing of HSS grants disbursement, which limited the ability of the recipient countries to plan for implementation. For example, in Zambia, the PCA terms of reference (TORs) state that the GMR should have been finalized by May 18, 2016, but in reality, it was not received by the country until late September 2016. When delays such as this occur, there is a need for much clearer communication, with updated time lines, so that countries can plan accordingly. When asked about the status of the HSS grants disbursement in Zambia, key informants responded repeatedly that they were waiting on the GMR and had little insight into when it would be completed. When the timing for disbursement of HSS funds is not predictable, it is exceedingly difficult for countries to develop realistic plans for implementation. In Uganda, as a consequence of these delays, there will be a gap in funding between the first and second HSS grants, which means key outreach activities will go unfunded; this may impede progress toward improving coverage.

Figure 15 illustrates the timing of key activities, from the application submission to eventual disbursement of funds (Uganda and Zambia are yet to receive funds). It is worth noting that the post-approval process steps are different in all three countries and that they are not clearly outlined in official documentation (e.g., the Gavi website still refers to the FMA, rather than the PCA, as an HSS process step. Zambia's HSS decision letter was issued after the PCA and referred to the FMA instead of the PCA). While this may represent a tailored or "differentiated" approach, without clarity on requirements and expectations, this can hamper rather than benefit countries. Furthermore, key informants at the Gavi Secretariat noted that the target time frame from final approval by the Gavi Chief Executive Officer to disbursement is six months. This was achieved only in Bangladesh, where funds were disbursed directly to WHO and UNICEF, without conducting a PCA.

While Gavi is undergoing significant reforms to simplify processes, particularly those relevant to the HSS support stream (described below), it is worth highlighting these issues, as a significant number of Gavi countries (including all four FCE countries) already have active HSS grants and are therefore not eligible for many of the new reforms (although Bangladesh will be a CEF country in 2017). With all of the focus on the reforms that will benefit countries going forward, it is still important to ensure that countries with already active grants receive funds in a timely and predictable manner. With all of the focus on implementation of the new reforms, it is essential that Gavi and partners still actively support and not take their eyes off HSS countries.

Figure 15: HSS time lines in FCE countries



Implementation

2016 marked the first year of implementation of the current HSS grants in Mozambique and Bangladesh. The experiences of the two countries have been markedly different. The Mozambique grant is being channeled through the government, while the grant being implemented in Bangladesh is the first half of a bifurcated HSS grant and has been disbursed to WHO and UNICEF.

In Mozambique, funds were disbursed from Gavi in July 2015, but because of a number of bureaucratic delays (including inability by the Ministry of Health [MOH] to submit inscription request documents to the Ministry of Finance in a timely manner), the funds were not available to the MOH until April 2016. From that point on, implementation started slowly, in part because of a lack of familiarity with administration of Gavi HSS funds (which local stakeholders referred to as “teething problems”) as well as prolonged bureaucratic procurement processes at the MOH central level. Additionally, the freezing of all funds in the government electronic financial system for about a month in July 2016, due to a government budget revision necessitated by the wider macroeconomic financial crisis, caused the suspension of HSS activities. These issues are described in detail in the Mozambique country report.

More significantly, the current macroeconomic situation in Mozambique has slowed implementation. In April 2016, following an announcement from the International Monetary Fund (IMF) that the government had not declared over \$US 1 billion in government debts, the IMF and most other donors suspended aid disbursements, resulting in significant deficits in government funds. As a result, government funds were frozen for a period while a budget adjustment process was undertaken. During this period, inflation rose from 6.5% to 16.5%, making the budget for Gavi HSS inaccurate and insufficient. Consequently, supervision visits were postponed and the government could no longer pay customs duties on motorbikes and trucks purchased with HSS funds. Local stakeholders perceived the transaction costs associated with formal reprogramming to be high and hoped instead to simply reallocate funds as needed. While Gavi’s Fragility and Immunization Policy (currently under review) provides flexibilities for countries experiencing a number of destabilizing circumstances, Mozambique’s macroeconomic crisis does not qualify it for the country-tailored approach or other emergency flexibilities. On the week of Nov. 21, 2016, the Gavi senior country manager (SCM) visited Mozambique on mission and a meeting was convened to discuss reallocation of the HSS grant. In this meeting, it was determined that reprogramming may be required, not because of the relevance of activities but because of the impact of inflation on the budget.

By contrast, in Bangladesh, implementation commenced relatively quickly upon receipt of funds, which some global stakeholders attribute at least in part to the disbursement of funds directly to WHO and UNICEF. While this may enable more efficient progress toward implementation, it raises concerns about country ownership and sustainability, as there is no clear plan at this stage to transition these responsibilities to the government. When partners are granted support for significant implementation activities, Gavi should more explicitly require a clear plan that indicates how these capacities should be transitioned to the government; thus, it can better ensure the sustainability of investments. Furthermore, there was inadequate consultation with the ministry around recruitment of key surveillance personnel by WHO, which in itself may have slowed down implementation, as the ministry demanded more involvement in the process. While involving government in the recruitment process by forming a committee may have slightly slowed the implementation, the net benefit to country

ownership was perceived to outweigh any consequences to the time line. This issue is described further in the Bangladesh country report.

Key informants at the global level noted that many of the issues highlighted here would be addressed through Gavi's new HSIS support framework, which will be implemented through the CEF. In the next section, we provide our assessment of the extent to which these reforms will address the key issues experienced in FCE countries.

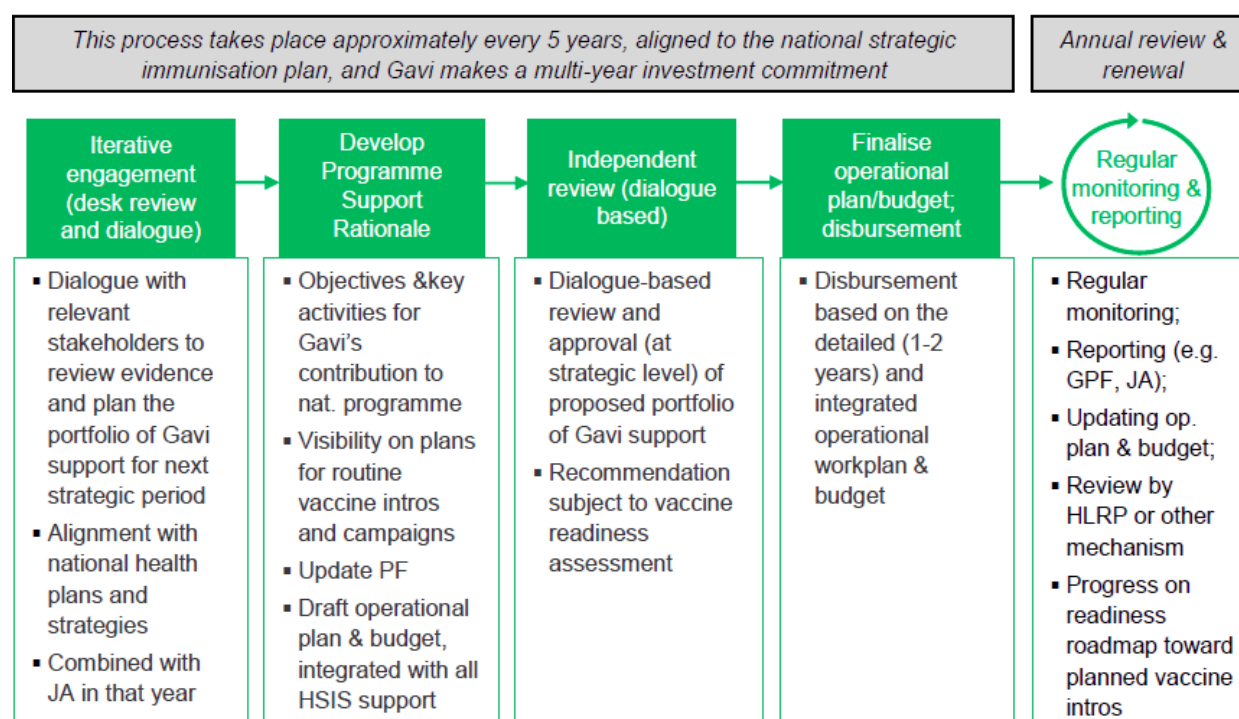
Gavi reforms to address health system strengthening challenges

In 2015 and 2016, Gavi undertook a series of significant reforms aimed at addressing many of the issues identified through the FCE. Major outputs of this process included the PEF, HSIS support framework, and the CEF. While many changes have been made to Gavi's HSS design (known now as HSIS), the effects on FCE countries will be minimal (with the possible exception of Mozambique if they reprogram and Bangladesh when they apply for the second installment of their bifurcated HSS grant) because their approvals predate the HSIS reforms.

The aim of the CEF is to "more efficiently channel Gavi support to countries, in a manner better suited to country needs and timelines, and to optimize programming to achieve more equitable and sustainable immunization coverage."⁷ Because the CEF is being rolled out in a phased manner, and 2016 implementation did not include any FCE countries, we are unable to evaluate the effect of these changes. However, because the CEF represents an important shift in Gavi's model of interacting with countries, we reflect here on its design and assess the ways in which these reforms are likely to address the HSS-related challenges in FCE countries (see Table 6). While in FCE countries there is no awareness of these changes, at the global level there exists a high degree of optimism that the CEF will simplify the process of obtaining and managing Gavi support, and in doing so reduce associated transaction costs. The increased engagement of the Gavi Secretariat (specifically the SCM) and Alliance partners is welcome and likely to reduce a lack of clarity related to Gavi policies and procedures. However, based on our assessment of the design (including the tools and processes included in the CEF), it is not clear whether the CEF will contribute to tangible improvements in the design and targeting of grants to address the most pressing bottlenecks to immunization coverage and equity. Furthermore, important questions remain about the level of effort required by SCMs, partners, and independent reviewers to engage in a meaningful way in country planning cycles.

The process steps for the CEF are outlined in Figure 16 below.

Figure 16: Country Engagement Framework process steps.



Source: Gavi. *Report to the Programme and Policy Committee; Update on Country Programmes: Country Engagement Framework*. Geneva: Gavi, 2016.

Implementation of the CEF will center around a country mission and intensive dialogue to be coordinated by the country's SCM.

Table 6: FCE observations on HSIS and CEF

FCE findings	How addressed by HSIS/CEF reforms?
<i>Application</i>	
Difficulty identifying most pressing barriers to coverage and equity, and interventions to address them	While the Gavi management response to the <i>2015 Annual Report</i> noted that this would be addressed through the HSIS/CEF, at the time of drafting the 2016 FCE report, no specific tools or guidance for bottleneck analysis were included in these reforms. ^d Instead, investments were encouraged in strategic focus areas (data availability, quality, and use; supply chain; demand generation; and in-country leadership, management, and coordination), and it was established that the PCA would inform programming. ⁷ In 2016, the timing of the PCA in Uganda and Zambia did not allow for this; in Zambia, the PCA was conducted after the HSS application had been approved, and in Uganda, recommendations were not finalized until after submission.

^d Gavi is working to develop these tools in 2017.

	The CEF also involves more intensive engagement from the SCM and other Secretariat staff and partners in developing the program support rationale, which includes the design of HSS grants. SCMs likely have varying degrees of expertise when it comes to designing complex HSS investments and conducting high-level negotiations with stakeholders and partners. Therefore, there is need to ensure that they have the necessary support to enable them to effectively support countries in this process.
Little planning for sustainability	The HSIS reforms emphasize the importance of tailoring support by transition phase. This is welcome, as sustainability was a noted weakness in the design of HSS grants in Zambia and Bangladesh, both countries that are approaching transition (see Programmatic and financial sustainability section, page 63). Further guidance is required to help countries plan effectively for transition.
Complex and time-consuming process of applying for HSS support	Rather than individual applications for HSS, new vaccine support, and all other support streams, the CEF process integrates planning and budgeting for all streams of Gavi support. The CEF process will be implemented in each country every three to five years. While it will surely be an intensive process, if implemented thoughtfully, in alignment with national health and immunization strategic plans, there is certainly great potential for it to reduce transaction costs. CEF requires on-the-ground engagement on the part of the Secretariat (specifically the SCM) and partners. Given the time and activities devoted to HSS proposal development across FCE countries, it is unlikely that a one- to two-week visit and dialogue on the part of Gavi and partners will be sufficient to generate all of the inputs required for the program support rationale. It will be important to carefully evaluate the level of effort required to determine whether processes are actually simplified.
<i>Post-approval</i>	
Unclear post-approval process contributing to slow disbursement of HSS grants	Through the CEF, the independent reviewers will engage more directly with countries (during in-country visits and/or teleconferences) during the review phase, which should reduce some of the time required to respond to comments (and may even replace this step if reviewers are able to obtain the information they require). The PCA should occur before the CEF to inform the design of investments. Simplifying the processes required for disbursement, thereby increasing the predictability of Gavi funding, represents an important first step. However, experience from FCE countries demonstrates that even after disbursement from Gavi,

	there are many bureaucratic delays at the country level. In some cases, these steps were introduced to guard against financial mismanagement, so they should not be discounted. Instead, it is important to plan realistically for these processes.
<i>Implementation</i>	
Grant not found to be sufficiently flexible as country needs change and the transaction costs associated with formal reprogramming are found to be high	The current approach requires countries to budget for three to five years (depending on the duration of their HSS grant). HSIS will leverage the JAs to instead allow for more flexible work planning and budgeting every one to two years to ensure activities are on track and aligned with new data.

Many global-level key informants emphasized repeatedly that the CEF will likely increase the burden on the Secretariat and reduce the burden on countries. According to one informant, the CEF is “more complicated for the Secretariat and partners but should be radically less complicated for countries. If it’s coherent enough, focused enough, doable enough, it may not require consultants” (KII). However, some Alliance partners expressed concerns that this is unlikely to be the case, noting the level of engagement required from country stakeholders during the country dialogue.

These reforms, and many other efforts under way at Gavi, depend upon regular and active engagement between SCMs and countries, including a larger role of the SCM in program design. While this will surely help to alleviate much confusion at the country level about Gavi processes, there is also an implicit assumption that SCMs have the appropriate expertise and experience to fulfill these expectations. According to one key informant, “This all comes down to the SCM and their approach – it should have been more standardized.” (Global-level KII, Alliance partners) Other key informants raised concerns about the many burdens being placed upon Gavi SCMs, reflecting a broader pattern observed through the FCE. Although Gavi has, over the course of this evaluation, expanded (and continues to expand) the number of SCMs, their workload also continues to grow. Ensuring they have the appropriate tools and expertise warrants careful consideration.

Recommendations

1. The Secretariat should ensure that HSS decision letters include next steps, timing of those next steps, and responsibilities of various actors, as well as the PCA process and any conditions. Gavi should make decision letters available in a timely and accessible manner by putting them on the country portals and Gavi website so that all relevant stakeholders have access.
2. Echoing our recommendations from 2015, we continue to encourage Gavi, partners, and countries to further invest in concrete and user-friendly tools and processes that support evidence-informed assessments of immunization bottlenecks (e.g., in the way that Spectrum modeling software is used to inform concept notes to the Global Fund to Fight AIDS, Tuberculosis and Malaria). Such tools and processes should be comprehensive and harmonized across HSS, the HSIS/CEF, and PCA and JA processes.
3. The Secretariat must ensure that SCMs, and other relevant teams and partners, have the appropriate technical capabilities, contextual knowledge, resources, and support that they need to

implement the CEF, as they will be required to increase their level and complexity of engagement as compared to their current role.

4. Many countries (including the FCE countries) with existing HSS grants will not benefit from the full suite of HSIS/CEF reforms in the short term, although some elements will apply to all countries. Gavi should clarify this situation and how to access certain elements, as there is limited understanding at the country level about these reforms and the potential implications.

Leadership and management

Optimal vaccine delivery relies on systems that are appropriately organized to manage all aspects of service delivery. This includes ensuring that the EPI team is adequately staffed and structured, has the right managerial and technical capabilities, has the right processes and tools, and has a clear mandate, roles, and responsibilities. Preliminary evidence in FCE countries points to gaps in organizational and management capacity at the national and subnational levels, which combined with the burden of Gavi processes, can negatively affect service delivery.

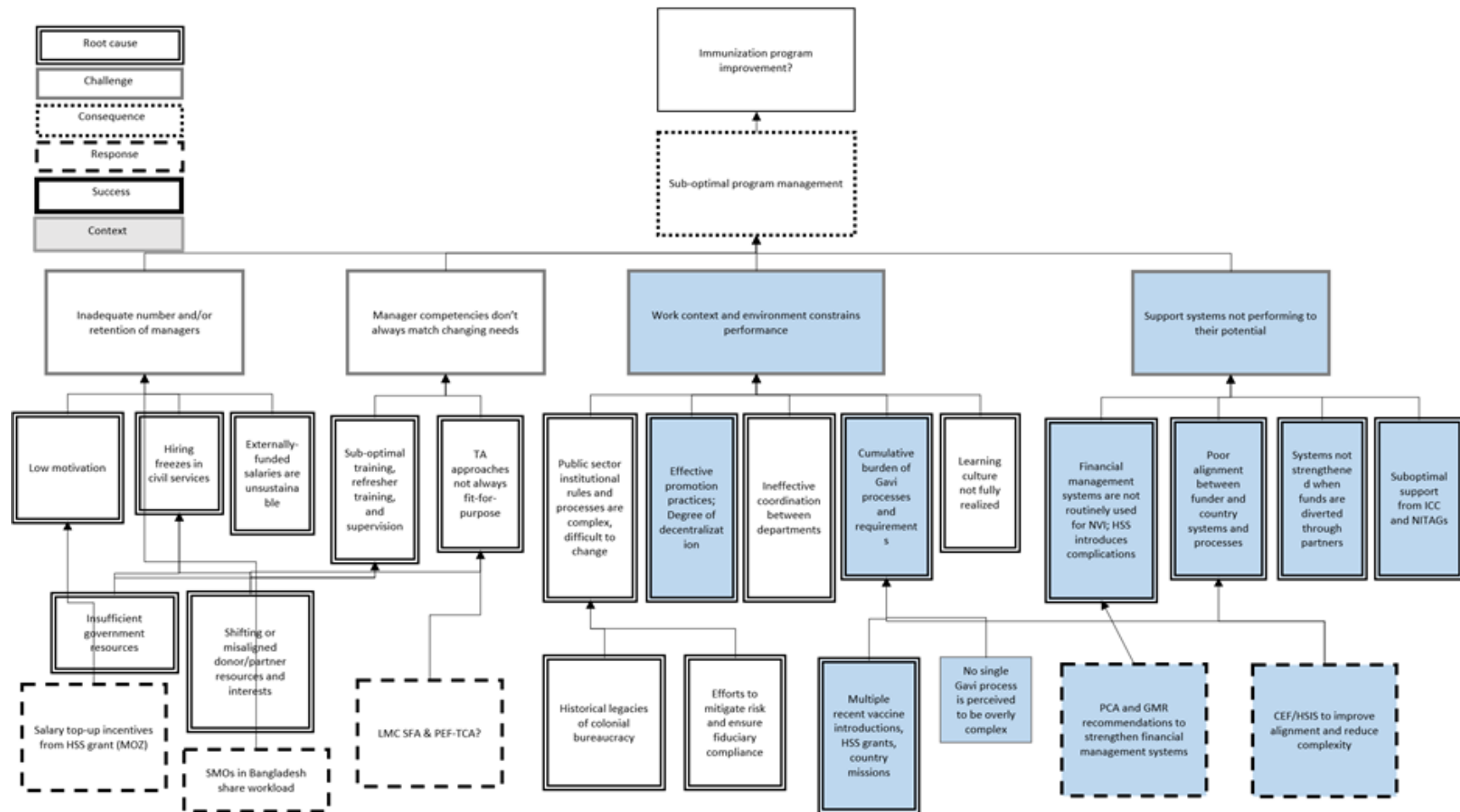
Finding 1

In 2016, we observed multiple, overlapping root causes of suboptimal program management. The most actionable short-term root cause was the cumulative burden of Gavi and other partners' processes and requirements. While no individual process itself represented an undue burden on EPI programs, the combined effect of those processes constrained EPI programs' ability to stay on top of day-to-day program needs. Robustness of finding: B

As noted in previous FCE reports, there are multiple root causes of suboptimal program performance linked to leadership and management challenges. These include the following, which are illustrated in the root cause analysis below (Figure 17):

- Inadequate number and retention of managers at all levels;
- Inadequate resources (human and financial) to effectively manage the program;
- Managers' competencies do not always match increasingly complex and changing program needs;
- Inadequate quality, timeliness, and appropriateness of training and supervision of managers at all levels;
- TA approaches related to management are not always fit for the purpose;
- Work context and environment constrain performance;
- Cumulative management burden of many donor/funder/partner requirements and processes;
- Misalignment of donor processes with country processes and systems;
- Suboptimal support systems to manage finances, human resources, planning, measurement, etc.;
- Inadequate accountability; and
- Fear of sanction instead of encouragement of learning.

Figure 17: Root cause analysis on leadership, management, and coordination challenges.



In 2016, the FCE focused on leadership- and management-related root causes, which we felt we had particular insight into, based on our country presence and rich familiarity with FCE countries' contexts. Those issues and root causes are colored in blue in Figure 17 and fall under the categories of *context and environment that constrain performance* and *support systems that do not perform to their potential*. Our aim is to add a country-driven perspective to other management-related assessments that Gavi is implementing, including through the Leadership, Management, and Coordination (LMC) strategic focus area (SFA) and the PCA.

Context and environment

Management practices are influenced by a range of behavioral, organizational, and environmental factors⁸ related to a manager's work context. Work context includes where the manager works and with whom, their roles and responsibilities, and the managerial, administrative, and financial rules and processes of their workplace. A challenging context and environment can limit the leadership and management practices of even the most competent manager.

Donor processes and requirements become a part of EPI managers' responsibilities and thus their work context. Previous FCE reports have highlighted the often unintended management burden caused by Gavi grant requirements and processes. This year, the FCE teams sought to describe *which* processes were perceived by stakeholders to be particularly complex or burdensome, and to identify possible drivers of those perceptions. Through surveys and KIIs, we asked about the perceived management burden of the JA and PCA processes, Gavi support application processes, and Gavi missions. We found that stakeholders did not perceive any given activity, alone, to be particularly complex or burdensome; however, the cumulative effect of multiple overlapping or consecutive activities led to fatigue among EPI managers and program staff and to difficulties managing the day-to-day work.

For example, the Uganda FCE team tracked 13 Gavi-related visits to the country during 2016 (Table 7). For a small EPI team, and coupled with the numerous demands from other partners and donors, there is limited time for the team to focus on routine immunization activities. The number of external missions depended on the FCE country, with Uganda receiving the greatest number of missions because of their relative high priority for Gavi and partners. Table 7 suggests opportunities for alignment or coordination across visits; for example, the Gavi Secretariat teams responsible for the PCA, JA, and program audit should consider whether elements of their visits could be combined. Ugandan KIIs expressed that, at the very least, they could be informed at the start of the year of the missions, and their purposes, for the upcoming year.

Table 7: EPI-related missions to Uganda in 2016

Mission	Date	Purpose
PCA	Feb. 22–May 3, 2016	Assess MOH's financial and program management systems for the grants
HSS grant application	April 8–10, 2016	TA support for HSS grant application
PCA debrief	May 4, 2016	Present to MOH findings of PCA
Gavi pre-visit	June 2016	Improvement of data systems
Gavi audit pre-visit	June 27–July 1, 2016	Prepare for the program audit

Joint Appraisal	July 12–15, 2016	JA report writing
Gavi audit	Aug. 8–26, 2016	Program audit
Phillips – survey	Aug. 8–Sept. 23, 2016	Information System Challenges in Primary and Community Care Service Delivery in Uganda. Focus area: Immunization
UK parliamentarians	Aug. 21–26, 2016	Look at gains from Gavi support, as well as areas of need
STEP	Aug. 29–Sept. 2, 2016	Leadership training with reference to the vaccine supply chain
Comic Relief	Sept. 28, 2016	Filming
Phillips	Sept. 28–29, 2016	Data quality improvement
Senior Country Manager	Nov. 23–25, 2016	SCM transition/introduction visit

Mozambique received fewer external missions but contended with multiple back-to-back EPI activities at the national level (e.g., the switch from trivalent to bivalent oral polio vaccine, initiation of central- and provincial-level HSS activities, and development of the MR proposal). The FCE team observed that nearly all EPI stakeholders – particularly within the central EPI team – attended all events. This lack of delegation contributed to the perceived cumulative burden of these activities.

As in previous years, applications for Gavi support required a significant time investment across a range of stakeholders. In Uganda in 2016, the HSS application spanned six months and involved over 60 individuals. This case is an example of the unintended management burden of Gavi processes; while Gavi may not explicitly require, encourage, or anticipate such a high level of engagement, the design of and communication around the HSS application process incentivized implementation stakeholders to participate and express certain preferences based on their hope to receive a stake in the grant’s implementation. The root causes of this intensive engagement are documented starting on page 34 of this report and in the Uganda country report.

Mozambique, Uganda, and Zambia FCE teams administered a survey measuring perceptions of the JA process, including respondents’ perceptions of the complexity and added value of that process.^e Figure 18 and Figure 19 illustrate perceived added value and complexity

Box 6: 2016 Joint Appraisal surveys

NEW IN 2016

Full Country Evaluations teams administered a standardized survey to measure perceived complexity and added value of the Joint Appraisal process. Respondents did not perceive the Joint Appraisal process to be overly complex commensurate for its added value, yet the complexity could be reduced in future years.

^e The “complexity versus added value survey” was developed using evaluation rubrics to measure JA participants’ perceptions of multiple constructs related to the complexity and added value of the JA process. The survey instrument was adapted by each FCE country and successfully implemented. However, the adaptations make it difficult to compare across countries.

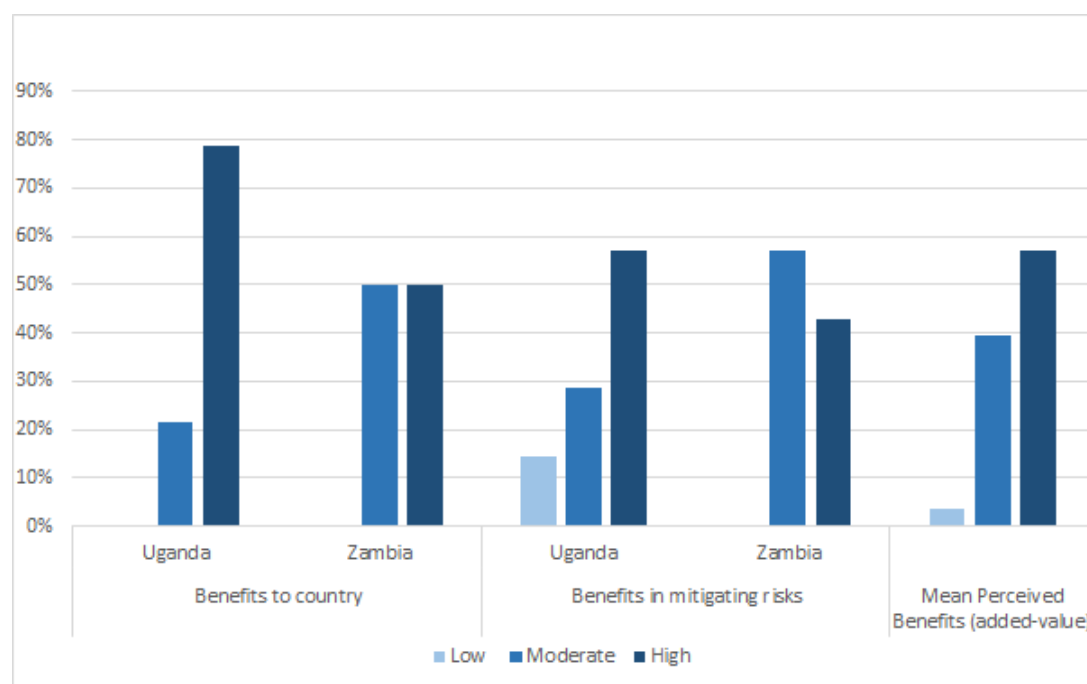
on a range of constructs for Zambia and Uganda. In Uganda, most respondents perceived that the JA had a high added value to the country and was highly useful for mitigating/controlling risks. Overall, Ugandan respondents felt that the JA's added value was greater than its complexity; the construct that was perceived to be the most complex was the "time and effort required to participate."

In Zambia, respondents were equally split between the most positive perception that "added value to the country is high" and the moderate perception that "process provides some added value to the country." Fewer respondents agreed that the process was "highly" useful for mitigating risks – the majority found it "moderately" useful. In Zambia, the majority of respondents agreed that the JA was "moderately" complex, that a "moderate" level of effort was required to complete the JA, and that it was "somewhat" challenging for the EPI team to do their daily activities during the JA. Gavi should track these responses over time, such that the majority of respondents shift from this perception of moderate complexity to a perception of low complexity.

Mozambique implemented a slightly different set of questions (see country report for additional survey results). Seventy percent of 23 respondents scored the JA as "good" in terms of its ability to contribute to management of the vaccine program. Thirty percent of respondents felt the time required for the JA process was "good," 52% felt the time needed was "normal" (neither good nor bad), and 13% (3/23) felt it was "bad."

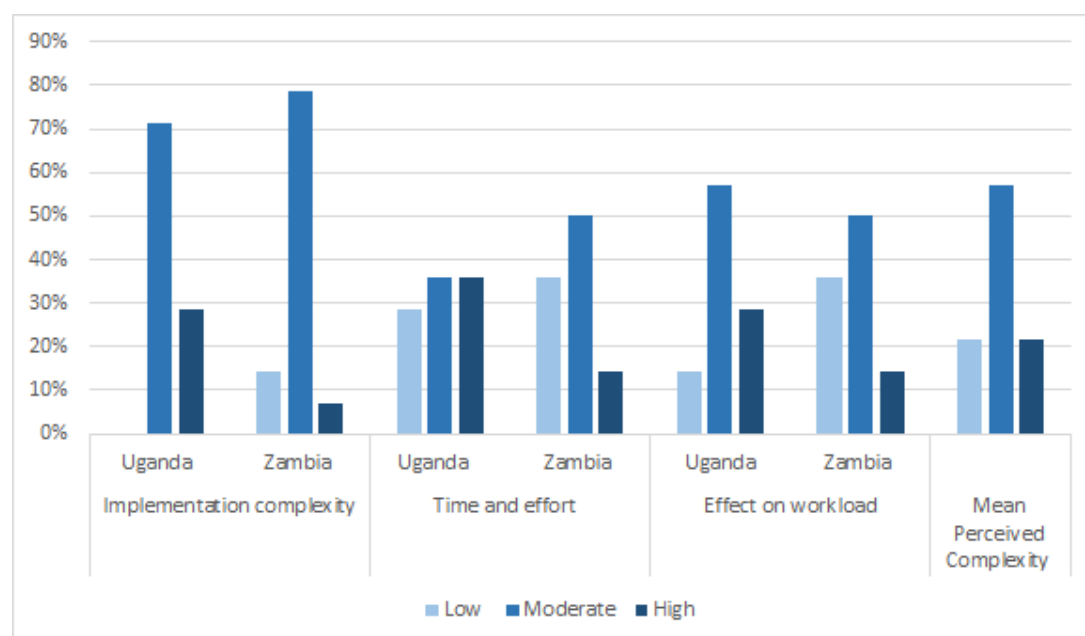
From the global perspective, there was general acknowledgement that the JA process is improving over time. Those familiar with the JA reports "can see quality improving" (Global-level KII, partner). They said that the reports reflected that the JAs were "more focused with better participation from partners" (Global-level KII, Gavi Secretariat).

Figure 18: Perceived benefits of JA process in Uganda and Zambia*



*The survey asked about perceived benefits to the country and benefits in mitigating risks. The last category is the mean of these specific benefits included in the survey, representing the overall mean perceived benefit (or added value) of the JA.

Figure 19: Perceived complexity of JA process in Uganda and Zambia*



*The survey asked about perceived implementation complexity, time and effort, and effect on workload. The last category is the mean of these specific complexities included in the survey, representing the overall mean perceived complexity of the JA.

Support systems

Support systems are a separate category of management enablers in the FCE root cause analysis. They include systems to manage money, supplies, staff, etc.;⁸ coordination and technical fora and partnerships (e.g., interagency coordinating committees [ICCs], national immunization technical advisory groups [NITAGs], ad hoc partnerships); and TA and other inputs to strengthen management performance.

Financial management systems, as in past years, caused challenges for FCE countries in 2016, largely due to the EPI programs' lack of experience in managing cash grants. Strengthening public-sector systems is not simple, and agreement rarely exists regarding the level of external intervention in such activities.⁹ For a funder such as Gavi, "weak" or "slow" management systems not only threaten the accomplishment of its mission, but also put its donors' investments at risk.¹⁰ Bearing in mind this tension between mitigating risk and achieving its mission, in 2016, Gavi introduced the PCA to expand the existing FMA tool to identify program management gaps.¹⁰ We report extensively on countries' experiences implementing the PCA in 2016 (see page 56).

The alignment of donors to country systems, according to our observations, was sometimes poor. Already strained administrative and financial management systems were further strained by complex or burdensome requirements. Each year in Uganda, misalignment between Gavi and country fiscal calendars led to challenges in meeting cofinancing obligations. In Mozambique, government processes operated on a slower time line than Gavi processes (see HSS and Mozambique sections for a detailed account and consequences). This deeply rooted characteristic of Mozambique's system cannot easily be changed or made to fit into donor processes; instead, Gavi and other partners should attempt to work

within the system and then invest in activities and actions that will strengthen the system over time. This could include activities in HSS or PEF grants or recommended through PCAs, but careful attention must be paid to *strengthening* management systems (as is the aim of Mozambique’s HSS-funded administrative advisor) as opposed to simply working around them (e.g., Bangladesh). Redirecting cash support through partners, as has happened in Uganda and is the case for Bangladesh’s bifurcated HSS proposal (\$US 33 million to WHO and UNICEF directly; 99% of the total grant), cannot by definition contribute to strengthening country financial, administrative, and management systems (see the Programmatic and financial sustainability section, page 69, for related findings and recommendation).

Interagency coordinating committees. Observation and KII data from 2016 suggest that ICCs are not as effective as they could be in supporting all aspects of the EPI program, including its management. The reasons for the suboptimal performance of ICCs include: lack of clear or updated TORs (Mozambique);

Box 7: Case study of EPI management in Bangladesh

A PLURALISTIC, YET CENTRALIZED, WORK ENVIRONMENT BENEFITS BANGLADESH

As noted in previous reports, Bangladesh’s Expanded Program on Immunization (EPI) management capacity at the central level is perceived as effective and a strong contributor to its program’s performance. In 2016, the Bangladesh Full Country Evaluations team investigated the root causes of successful EPI manager performance in Bangladesh.

Bangladesh is viewed by many as a health paradox: It has achieved tremendous improvements in its health indicators despite economic impoverishment and a weak health system. This is a paradox that has been explained variously in terms of informal innovation, a focus on pro-poor policies and equity, and pluralism. Pluralism, or the participation of many types of state and nonstate actors, exists in Bangladesh in parallel to a highly centralized health system governed by a central planning approach. We view these two characteristics, pluralism and centralization, as working together to explain immunization program performance.

Extensive centralization and enforcement of formal promotion practices following the system’s structure have resulted in highly effective central-level EPI managers. The central EPI program draws its managers from a wide pool of subnational EPI managers who must demonstrate experience and merit in a competitive environment. This hierarchical promotion system differs from other countries, where EPI managers are occasionally hired from other national posts and have less experience in directly implementing the EPI program.

At the subnational level, managers benefit from technical assistance from World Health Organization (WHO)-funded surveillance medical officers (SMOs), creating an enabling environment that may encourage retention and performance of EPI staff. These SMOs and other similar nonstate cadres are the result of years of historical legacies of donor assistance in Bangladesh. As we note elsewhere throughout this report, we observe potential long-term concerns regarding the sustainability of nonstate human resources. For example, recent shifts in donor and government priorities suggest that the level of participation of nonstate actors, including WHO, in the immunization sector may be decreasing. Partners; government; and Gavi have not invested in training government midlevel EPI managers since 2013, in part, we believe, due to the misalignment of Alliance partners’ interests with this type of a technical assistance need (see Bangladesh report for further analysis). The historically adequately staffed national program is facing reductions in staff due to retirements and a stagnating program budget. If gains are to be sustained, government, partners, and Gavi must work to ensure the survival of supportive environments to capacitate strong managers.

limited dissemination or implementation of these TORs leading to unclear roles, responsibilities, and membership (Zambia); limited or misaligned technical capacity of members (Zambia); limited management capacity or strategic expertise of members, in part due to lack of participation by the highest-level positions in member institutions (Mozambique); power imbalances within the ICC reducing government ownership; and the position within the MOH organizational hierarchy limits authority and ability to act (Mozambique). Based on observation and global KIIs, it is clear that the scope of ICC members and the body as a whole require updating to reflect Gavi and country goals, and strategies related to achieving sustainable and equitable coverage. New members or TORs should reflect strategic and leadership capabilities necessary to achieve these complex and challenging goals. This is currently being addressed by Gavi through the LMC SFA, which includes publishing new guidance and tools, and providing TA, to improve ICC functionality.

Gavi's response

Gavi introduced a number of new policies and programs in 2016 to address root causes of suboptimal program management. While implementation has generally not begun or is in early stages, we take stock of Gavi's proposals and how they will address the challenges described above. We found that the proposed reforms will address some of the root causes but that Gavi and partners must carefully monitor unintended consequences and long-term sustainability considerations.

Table 8: Management-related challenges and Gavi responses

Root cause/challenge	Gavi responses through new and revised policies/frameworks/guidelines	FCE assessment
<i>Inadequate number and/or retention of managers</i>		
• Inadequate number of staff and managers; • Limited capacity to delegate activities; • Lack of motivation of, and ability to retain, managers; • Hiring restricted for public servants; and • Externally funded salaries are not sustainable. <i>There are human resource constraints – it is a small group chugging along to keep the program going. There is no time for strategizing. ... No bandwidth or time to think, "What do we do about this?"</i> (Global-level KII referring to Zambia EPI)	Secretariat is actively encouraging the embedded TA model through PEF-TCA: e.g., surveillance medical officer model at subnational level in Bangladesh funded through HSS-2; central and regional HSS advisors (WHO and UNICEF staff) in Mozambique funded through HSS and PEF-TCA; logistics secondees from VillageReach in Mozambique funded through PEF-TCA. National staff/manager salary top-up incentives in Mozambique to motivate and retain staff funded through HSS.	Gavi should carefully explore the short- and long-term benefits and drawbacks of various models and approaches to strengthening the number of managers. For example: How will the short-term benefits of hiring managers through HSS (or embedding TA through TCA) be sustained by the government in the longer term?

<i>Manager competencies do not always match changing needs</i>		
Manager competencies do not always match changing needs. This is in part due to suboptimal timeliness and relevance of manager training, and TA approaches that are not always fit-for-purpose.	LMC SFA team developed a manager assessment tool to assess competencies, which was added to the PCA. LMC SFA team proposed set of prioritized interventions, some of which will strengthen manager competencies.	A thorough understanding of the current and future needs of managers at all levels of the health system is likely lacking, and should be invested in. This can then inform which competencies are assessed and invested in. While the LMC SFA raises awareness around management issues, the funding mechanism remains weak in that it is an opt-in model during either HSIS applications or TCA requests. As noted in Bangladesh, TA for management training was not included in the TCA requests despite the need. Although funding from Gavi is available, countries must identify the management TA needs and prioritize them in their funding requests. In the future, the PCA may be able to identify management gaps that must be acted on through inclusion as requirements in the GMR.
<i>Work context and environment constrain performance</i>		
Complexity of specific Gavi processes/requirements: • HSS application (e.g., Uganda required substantial discussion time to understand the HSS-2 application budget template); and • PCA, JA: Surveys showed these were not perceived as overly complex as stand-alone processes.	Application simplification (2016 HSS guidelines). Ongoing efforts to strengthen and simplify JA guidelines and templates.	As noted in the recommendation related to the CEF, Gavi should ensure that the early CEF pilots do not overburden countries and that lessons are learned for reducing any unnecessary complexity moving forward. The CEF does not apply immediately to all countries, and thus Gavi and partners should continue to focus on reducing complexity of requirements and processes outside of the CEF.

Cumulative burden – sheer number of requirements; cumulative processes: - Country visits (Uganda); and - Mozambique’s consecutive activities.	Through the CEF, Gavi will move away from separate application processes for all streams of Gavi support (financial and vaccine). The CEF will consolidate these into a single request for support, and an integrated operational budget and work plan, updated annually.	Same as above.
Burden: day-to-day management (too many reporting requirements). <i>We [Gavi] don’t hire staff in countries, so all this work is being done either by your EPI manager or your EPI team, and I think it’s quite a big burden. ... We can’t just keep adding work to the EPI manager’s plate ... and expect everything to go smoothly. (Global-level KII)</i>	The CEF is intended to decrease the burden on countries (noting that this may vary by country depending on capacity), which may increase the burden on the Secretariat and partners. Many required inputs for the program support rationale and performance framework will be prepopulated by Secretariat staff.	Same as above.
<i>Support systems are not performing to their potential</i>		
National financial and administrative management processes are weak or new to the EPI program (in the case of cash grants).	The PCA is intended to strengthen these processes by providing recommendations in the GMR.	GMR recommendations and conditions must be feasible, fit-for-purpose, and relevant (see PCA recommendations in the Alliance processes and requirements section, page 72).
Suboptimal alignment of Gavi processes with country’s financial and administrative processes: Uganda and Gavi have different financial years.	The CEF aims to improve alignment with country processes.	
Systems, including financial and management support systems, are not strengthened when funds are disbursed through partners.		See Programmatic and financial sustainability section, page 69.

Recommendations

1. Gavi and other partners should coordinate and align their country missions to avoid burdening EPI programs and in-country partners. The Gavi Secretariat should explore potential synergies between JA, PCA, audit, and other similar processes. Secretariat and Alliance partners should communicate

planned activities and missions, with general time lines, at the start of each year to country stakeholders.

2. Gavi should update suggested roles and functions of ICCs to capture new strategic goals and the changing landscape of immunization programs. Country ICC TORs should be updated to reflect these. Moreover, ICCs themselves should be strengthened to include the right people and skills, as well as to ensure that these people are at the right level of authority and have the appropriate level of resources, including perhaps a dedicated secretariat for a country's ICC. These reforms will ensure that these bodies serve as more than a rubber stamp on Gavi applications. In November 2016, Gavi provided new guidance and tools on ICC membership, mandate, and governance.
3. See HSS recommendations three and four (page 45, above):
 - The Secretariat must ensure that SCMs have the appropriate technical capabilities, contextual knowledge, resources, and support that they need to implement the CEF, as they will be required to increase their level and complexity of engagement as compared to their current role.
 - Many countries (including the FCE countries) with existing HSS grants will not benefit from the full suite of HSIS/CEF reforms in the short term, although some elements will apply to all countries. Gavi should clarify this situation and how to access certain elements, as there is limited understanding at the country level about these reforms and the potential implications.

Finding 2

Implementation of the PCA in Uganda and Zambia, early pilot countries in 2016, suggested that the process of implementing the PCA did not overburden countries, but it was a top-down approach that was perceived by country stakeholders to contribute to delays, particularly in obtaining funds from Gavi for HSS implementation. Robustness of finding: C

In 2016, Gavi introduced the PCA to assess countries' financial, programmatic, and vaccine stock management capacity in order to identify risks and weaknesses and make recommendations for improvements. The PCA is part of Gavi's Transparency and Accountability Policy. Through the FCE platform, we evaluated the PCA process of implementation in Uganda and Zambia, the resulting PCA findings and recommendations, and the perceived consequences.

Program Capacity Assessment process: a minimal management burden for stakeholders

Uganda and Zambia were two of the first countries to pilot the PCA. (Please refer to the HSS section on page 32 for a full description of how the PCA impacted HSS implementation in Uganda and Zambia.) Although the PCA is an expanded version of the FMA, it felt like a new process to many country stakeholders interviewed. It came as a surprise to Uganda and Zambia when they received PCA TORs shortly before the assessment was slated to begin in early 2016. The process of conducting the PCA by an external, independent assessment team reduced the implementation burden perceived by country stakeholders, although it led to certain challenges when countries become aware of the implications of the recommendations later on. In both countries, the data collection process went smoothly and was completed in a matter of weeks. A wide range of country stakeholders from the MOH and Ministry of Finance were involved, but the process required more time and commitment from the EPI team compared to other stakeholders.

Program Capacity Assessment findings and Grant Management Requirement requirements: limited country ownership from a top-down process

Country stakeholders perceived the PCA findings and recommendations to come from a very prescriptive, top-down process, as country stakeholders were not consulted in the timing or design, and felt that they did not have adequate input into the findings and recommendations. This top-down process limited the country management burden of conducting the PCA but also limited the country ownership over the findings and recommendations.

It is important to note that PCA recommendations may be used to propose terms and conditions through the GMR. Countries are legally bound to implement requirements outlined in the GMR in order to receive HSS and other financial support, but the PCA reports that informed the development of these requirements were not shared with country stakeholders in Uganda or Zambia. This was intentional in order to encourage the PCA assessment team to be “as frank as possible” in reports (Global KII, Gavi Secretariat) and to protect the independence and autonomy of the contractor. However, this calls into question the transparency of this process.

The PCA findings were shared with stakeholders through in-person debriefing meetings in May 2016 in Uganda and June 2016 in Zambia. Although the findings seemed accurate to stakeholders in both Uganda and Zambia, the requirements had mixed reactions. In Zambia, the assessment team shared findings that were generally positive, but they did not present recommendations, so stakeholders could respond only to a limited extent. They had to wait until they received the GMR and its requirements in September.

In the Uganda PCA debrief meeting, stakeholders agreed with the findings (which they felt were largely known), but the recommendations, which would inform the GMR requirements, generated heated discussion and tension among some stakeholders. Some stakeholders felt there was a disconnection between some findings and their corresponding recommendations, or that recommendations were not addressing the root cause(s) of the issues (see Uganda country report for details). For instance, one of the PCA findings was that the Uganda National Expanded Program on Immunization (UNEPI) felt disempowered because Gavi funds were being managed by the Gavi Project Management Unit within the MOH. The proposed recommendation was that the Project Management Unit should be disbanded and that UNEPI be provided with fiduciary support from an independent fiduciary management agency – which would not directly solve the challenge of UNEPI having limited control over Gavi funds. Some felt the recommendations presented were quite different from previous Gavi recommendations; these differences were attributed to a PCA assessment team that was unfamiliar with Gavi processes (they had deeper experience with similar Global Fund to Fight AIDS, Tuberculosis and Malaria assessments) and did not have the experience to make fit-for-purpose Gavi recommendations. This concern was shared by key informants at the global level; in later waves of PCAs, PCA staff from Gavi were embedded with contractor teams to provide guidance accordingly.

Although EPI program stakeholders were engaged through the PCA debrief meetings and participated in dialogue with Gavi before signing the GMR, there was still a feeling of limited ownership over some of the recommendations since they were coming from a top-down process or were not unanimously agreed to by all stakeholders. This lack of ownership may result in future challenges in implementing the recommendations. However, it also reflects the political realities and organizational hierarchies within governments:

It's a dialogue, really, and in the dialogue you need to bring all stakeholders to the table. ... In some of the cases that we have, you might suggest something and the Ministry of Finance might want to go this way, the MOH wants to go that way, the EPI unit has to go that way. So what we do is often act as a facilitator to be able to say this is [a] Gavi investment in country and what is the best way for all of us to be at the table – avoiding a lot of politics. A lot of times, the reason people want to go this way or that other way is really because of political reasons, not necessarily due to technical reasons. ... When you are managing funds for the EPI unit, the EPI unit were not created for fund management, they were created for program management. Most of the time you've got a lot of the EPI units that don't have accountants; they want to open parallel bank accounts, just weakening the whole MOH system. (Global KII, Gavi Secretariat)

Consequences of the Program Capacity Assessment: implementation delays and cost implications

According to the PCA TORs, the Zambia and Uganda GMRs were scheduled to be finalized by April 2016; in reality, the GMRs were prepared in September 2016 in Zambia and October 2016 in Uganda. This was the first time that the countries had seen the GMR requirements stemming from the PCA in detail and were required to act on them before additional funds would be released. Once the GMR was received in Zambia, the country responded swiftly. However, the delay in finalizing the GMR led to delayed HSS disbursement in Zambia, which is now tentatively scheduled for early 2017 (see HSS section, starting on page 32, for more details). Implementing GMR requirements may delay fund disbursement to Uganda for HSS-2 and the cold chain equipment optimization platform.

The GMR requirements are designed to manage risks and weaknesses in country capacity to ensure robust oversight of cash and vaccine support in the country. However, the level of risk management required must be weighed against the timing and financial implications for countries implementing the requirements. Moreover, the recommendations to channel funds through partners or fiduciary management agencies also raise questions about the implications for sustainability and capacity building of MOH staff and systems (see page 69).

In summary

It is a welcome improvement to expand the scope of the FMA/financial management requirement to recognize the importance of countries' programmatic and vaccine capacity in addition to financial management capacity. The process of implementing the expanded PCA has been iterative, and we recognize that the PCA tool has changed since it was first introduced in Uganda and Zambia, which were early pilot countries. The GMR requirements have not been implemented, so it is too early to tell whether they will improve the identified capacity gaps. However, based on the experience in FCE countries, there remains a country-level perception that the PCA is a top-down approach for risk management of Gavi funds with limited country ownership, which may undermine the implementation and sustainability of the recommendations. Moreover, as highlighted in Box 5, the PCA could be improved through better alignment with other Gavi processes occurring in countries. Gavi intends to ensure better alignment of these processes through the CEF approach.

Recommendations

1. Gavi should improve the country ownership of PCA recommendations. This could be facilitated by:
 - Selecting PCA consultants that are familiar with both country and Gavi contexts so recommendations are contextually appropriate;

- Using the PCA debrief (and/or other discussion venues such as the JA) as an opportunity to present PCA findings and to jointly develop recommendations with country stakeholders; and
 - Sharing the PCA report with country stakeholders in a timely manner.
2. Gavi should ensure that the timing and design of the PCA is aligned with other Gavi activities in country so the PCA findings can inform HSIS proposals, JA discussions, and PEF-TCA requests. The PCA report should be made available to country stakeholders in a timely manner so that the findings and recommendations can be referenced to inform these discussions.
- This is closely related to Recommendation 2 in the HSS section above, which highlights the need for tools and processes to support evidence-informed assessments of immunization bottlenecks – tools and processes that are harmonized across HSS, HSIS/CEF, and PCA and JA processes.

Technical assistance

Relevant, effective, and efficient TA (which leads to capacity building) is one way of strengthening the capacity of EPI programs to implement increasingly complex immunization programs to ultimately improve coverage and equity. The PEF, introduced in 2015, seeks to achieve increased transparency, accountability, and country ownership of TA. The overall consensus is that PEF is an improvement over the previous Business Plan model and is demonstrating progression toward its principles.

Finding 1

PEF, particularly TCA, is an improvement over the Business Plan in its aim to achieve country ownership, transparency, and accountability. However, some phases of the process, particularly the PEF Management Team prioritization and funding of TCA activities, suffer from limited country ownership and transparency. PEF is designed to shift accountability of TA partners from the Secretariat to countries, although we acknowledge that this will take time to achieve in practice. The process for implementing PEF is ongoing, and certain lessons learned from 2016 should be considered moving forward. Robustness of finding: B

Country ownership

Gavi aims to facilitate country ownership of TA by implementing a country-led process at all stages, from TA identification to monitoring and evaluation of TA activities (see Box 8). Through PEF, we have seen increased country ownership in the FCE countries of the identification of TA needs and solutions during the JA; however, there has been limited country ownership of the prioritization and funding of TA activities. Given the delayed start of TCA implementation in 2016 and the ongoing Gavi TA evaluation, the FCE has focused on the identification, prioritization, and funding of TA activities and has not comprehensively evaluated the implementation of TA activities in 2016.

Identifying technical assistance needs

In 2016, the EPI programs were fully engaged in the JAs that took place in all FCE countries. The TA discussions that took place during the JAs were generally viewed as an improvement on the Business Plan process in which countries had a limited role in designing TA. In Mozambique, there was agreement among stakeholders that the JA was the appropriate forum to identify TA needs. The JA discussion in Mozambique went more smoothly in 2016 compared to 2015 due to the change in guidance to avoid discussing specific TA providers. Although this change in the guidelines created confusion in Uganda (and they still named TA providers in the JA Report), the Uganda EPI program and many partner organizations were present for the TA discussion during the JA and the EPI Manager took an active role in leading it.

Box 8: Country ownership

COUNTRY OWNERSHIP DEFINITION

Country ownership is characterized by the full engagement and leadership of the national immunization program in identifying, prioritizing, coordinating, participating in, and monitoring and evaluating technical assistance activities.

In Zambia, the JA brought all stakeholders into the room together; it has moved more toward a demand-driven TA identification process than the previous model, which was driven entirely by TA providers.

Despite being an improvement on the Business Plan, the TA discussions at the JAs were influenced by partner interests and power dynamics – and were not a completely unbiased assessment of solutions to country bottlenecks. The partners that were present were able to advocate for their interests. As a result, the 2016 JAs in Uganda and Mozambique included large contingents from WHO and UNICEF. In Uganda and Zambia, partners who were present suggested activities that fit their skill sets. And, in Uganda, representatives from WHO and UNICEF were very vocal – initially overshadowing the process until other partners cautioned them to step back. In Bangladesh, WHO and UNICEF were the only partners present at the JA, possibly due to the small envelope of TCA funds available for partners. Global key informants acknowledged the interests of partners in the TA discussions:

Difficult to have JA where traditional partners are participating who know that [the] outcome will result in resources from Gavi. Example, CDC participating in JA in Haiti: CDC person is surveillance guy, the JA will include surveillance. Where in fact the bottlenecks may be more about urban slums. Could be some bias in the way it is done. (Global-level KII, Gavi Secretariat)

Obviously, they [partners] put in a wish list. They understand that their funding comes from that. (Global-level KII, Gavi Secretariat)

The TA discussion, I think, is one of the trickiest discussions at the JA in my opinion because it does get derailed by who is going to fill TA as opposed to what the needs are. Even though we don't discuss who should fill the TA, you can tell by the TA that's being proposed that it's already been thought of as, 'OK, I'm going to propose this, but I'm potentially also the agency or individual that can fill this.' ... Becomes about who's going to get the TA. (Global-level KII, Gavi Secretariat)

The influence of partners was further exacerbated by the fact that even if countries had adequate information to identify bottlenecks, they generally did not have the evidence or time to reflect on appropriate solutions, and were thus more susceptible to activities suggested by partners. In one FCE

country, MOH stakeholders also purported not wanting to upset the working relationship they had developed with partners.

Countries also may not have been aware of the full menu of TA activities available through expanded partners that were not present at the JA and/or did not have a strong country presence. For example, in Mozambique, some expanded partners (e.g., VillageReach and Clinton Health Access Initiative) felt that participating in TA discussions in the PEF process put them on par with WHO and UNICEF. However, other partners without a presence in the country lamented that they were at a disadvantage in receiving TCA funding because they could not make their voice heard in those discussions:

Having a bottom-up, country-driven [approach] is great if you're actually at country level. ... The whole competition thing, it was clear in the first year of PEF that you needed to be present at country level when these things were discussed or you would be shut out. That was clearly a problem. (Global-level KII, Alliance partner)

Consequently, some priorities or gaps were not raised and prioritized for the TCA request, which led to suboptimal relevance of the TA provided. For example, in Bangladesh, management and human resources needs were not identified as TA needs in the past two JA reports although they were perceived as priorities through FCE investigation and included in the original HSS-2 proposal (pre-bifurcation of the proposal into two separate HSS-2 proposals). We hypothesize that this may be due to the alignment of WHO/UNICEF interests and comparative advantages with more traditional technical activities, which comprise the bulk of TA “needs” and requests in Bangladesh. All countries would benefit from improved tools and processes to support evidence-informed identification of TA needs during the JA and other processes (see HSS Finding 1, Recommendation 3, page 45).

Prioritizing and funding Targeted Country Assistance

While the TA discussions are country-led, once the TA requests are submitted to Gavi in the JA Report, the process that follows to prioritize, assign, and fund TA requests includes country input but is not country-led. This may limit the country ownership of TA activities. Following the 2015 JAs, the PEF Management Team reviewed TA requests submitted from partners and decided which activities to fund. How this process occurred was unclear to countries; in some cases, the TCA activities funded for 2016 were not TA needs identified during the 2015 JA (Uganda and Zambia), and some TA providers were not requested (e.g., the World Bank in Uganda). This implies that country stakeholders may not have been fully aware of the TA activities submitted by some partners. Similarly, in 2016, countries and partners lacked clarity in terms of how specific activities and providers would be selected and funded for 2017 TCA.

In 2016, 91% of PEF-TCA funds in Uganda went to Gavi core partners: WHO, UNICEF, CDC, and the World Bank. Across all Gavi countries, 71% of TCA funds (\$US 47 million) went to core partners.¹¹ It is important to note that Uganda is a PEF Tier 1 country, and is thereby a higher priority to receive TCA funds. Mozambique is a PEF Tier 2 country, and Bangladesh and Zambia are neither in Tier 1 nor Tier 2. In Zambia, the funds that went to WHO/UNICEF were perceived as WHO/UNICEF money by government stakeholders, not country money; this reflected the limited sense of country ownership over these TCA activities.

Transparency

The PEF is intended to increase transparency (see Box 9) through more understanding regarding TA provided by partner country offices in each country, enhanced clarity on roles and responsibilities at country level, and transparency on country-level progress through midyear reporting.¹¹

As mentioned, the process that occurs between the country's submission of the JA Report, with TA needs identified, and the dissemination of the final list of TCA-funded activities is not well understood by countries. Once TCA activities have been awarded by Gavi, at the country level, there have been mixed experiences with the transparency of partners' awards, delivery of TA, and progress on activities and expected outcomes. In Mozambique, there is an increased sense of transparency in partner activities, as the National Immunization Program technical working group now has a milestone table that includes all partners, whereas previously the country was unaware of WHO's and UNICEF's activities. However, in Bangladesh, WHO and UNICEF are still not sharing programmatic and financial information with country stakeholders (perhaps because they receive less guidance on PEF processes as a nonpriority country). In Uganda, the TCA allocation spreadsheet was not shared with the EPI program in a timely fashion so they initially had no insight into what activities were funded. But since then, the new EPI manager has taken action to more comprehensively track all TA activities conducted by partners in country (however, it is unclear whether this is as a result of the PEF or if the EPI manager's initiative is unrelated). Despite this, the EPI program still has no insight into the activities the World Bank is implementing in Uganda. With the new online "partner portal," it is expected that EPI teams will have increased insight into the activities and progress of partners against TCA milestones.

Accountability

Gavi's definition of accountability in the context of TA encourages mutual accountability between TA providers, recipients, and the Gavi Secretariat (see Box 10). Whereas, under the Business Plan, accountability was based on output deliverables at the global level, a key principle of the PEF is to measure accountability based on outcomes at country level.

Accountability for TA activities is conditional on transparency. And, as noted above, country EPI programs do not have complete insight into TA activities or a mechanism to provide feedback on the TA. This, however, has the potential to change with the new online portal and semiannual reporting. In this first year of implementation, we have observed an increased sense of accountability of TA providers to the Gavi Secretariat, but not always to the EPI programs or countries they are assisting – despite the objective that it is countries to which TA providers should ultimately be accountable. For example, among government stakeholders in Zambia, there is still a sense that WHO and UNICEF are accountable to where the money is coming from. Shifting accountability of partners from the Secretariat to the country turns the Business Plan on its head and understandably will take time to achieve:

Box 9: Transparency

TRANSPARENCY DEFINITION

Transparency is measured by the extent to which key aspects of the Targeted Country Assistance (including but not limited to planning, development of the technical assistance [TA] plan, approval of TA activities, award of partners, delivery of TA, and progress on activities and expected outcomes) are clearly documented, disseminated, and understood by all key stakeholders.

Bit of shift in mentality – partners should be accountable to countries on the TA they provide. We are shaking a bit of the status quo and admin constraints at WHO. Transparency around what has and hasn't been done forces partners to deliver beyond business as usual, as opposed to routine support in the past. That shift in mindset is taking a long time. (Global-level KII, Gavi Secretariat)

However, there is agreement that the PEF is a shift in the right direction and that “building more accountability into the system after all these years is the right thing to do. I think it’s just worth staying the course, frankly.” (Global-level KII, Alliance partner) Many of the right

pieces are now coming together at country level – the PEF functions, TCA milestones, and performance frameworks – so if the synergies between them can be realized as implementation continues, this has the potential to improve accountability to the countries.

Recommendations

1. The Gavi Secretariat should use the theory of change developed for the ongoing Gavi TA to guide a discussion during the JA on the intended outputs, outcomes, and impacts of TA, including TA funded through the PEF-TCA.
2. Gavi should require TCA providers to outline their explicit approach to capacity building and skills transfer, define how to measure progress in capacity building, and hold TA providers accountable for capacity building by having them report on these measures/indicators.
3. We reiterate our 2015 recommendations to provide country stakeholders with a menu of TA approaches and systematically compiled map of TA providers. Recognizing that Gavi may not have exposure to all national or subnational TA providers, this activity should be done together with a range of country stakeholders or through an open solicitation process.

Programmatic and financial sustainability

Gavi-eligible countries have demonstrated high demand for more vaccines to reduce the burden of vaccine-preventable disease. Funding and support from Gavi and partners have enabled eligible

Box 10: Accountability

ACCOUNTABILITY DEFINITION

Mutual accountability is the shared responsibility and answerability of the technical assistance (TA) recipient, TA provider, and the TA funder (Gavi Secretariat) for the quality and effectiveness of TA. The Partners’ Engagement Framework functions document provides further clarity on what each stakeholder is accountable for:

- TA providers are accountable for providing support in an integrated and holistic manner, systematically tracking progress, proactively identifying and addressing bottlenecks, and monitoring and reporting on progress.
- TA recipients are accountable for achieving expected outputs and outcomes.
- The Gavi Secretariat is accountable for ensuring performance across key constituents of the Alliance through performance management at different levels (Partners’ Engagement Framework performance management, Secretariat performance management, and country grant performance management).

countries to introduce many lifesaving vaccines into their immunization system. However, as a result, they are also highly dependent on external funding, calling into question the long-term financial sustainability of those programs.

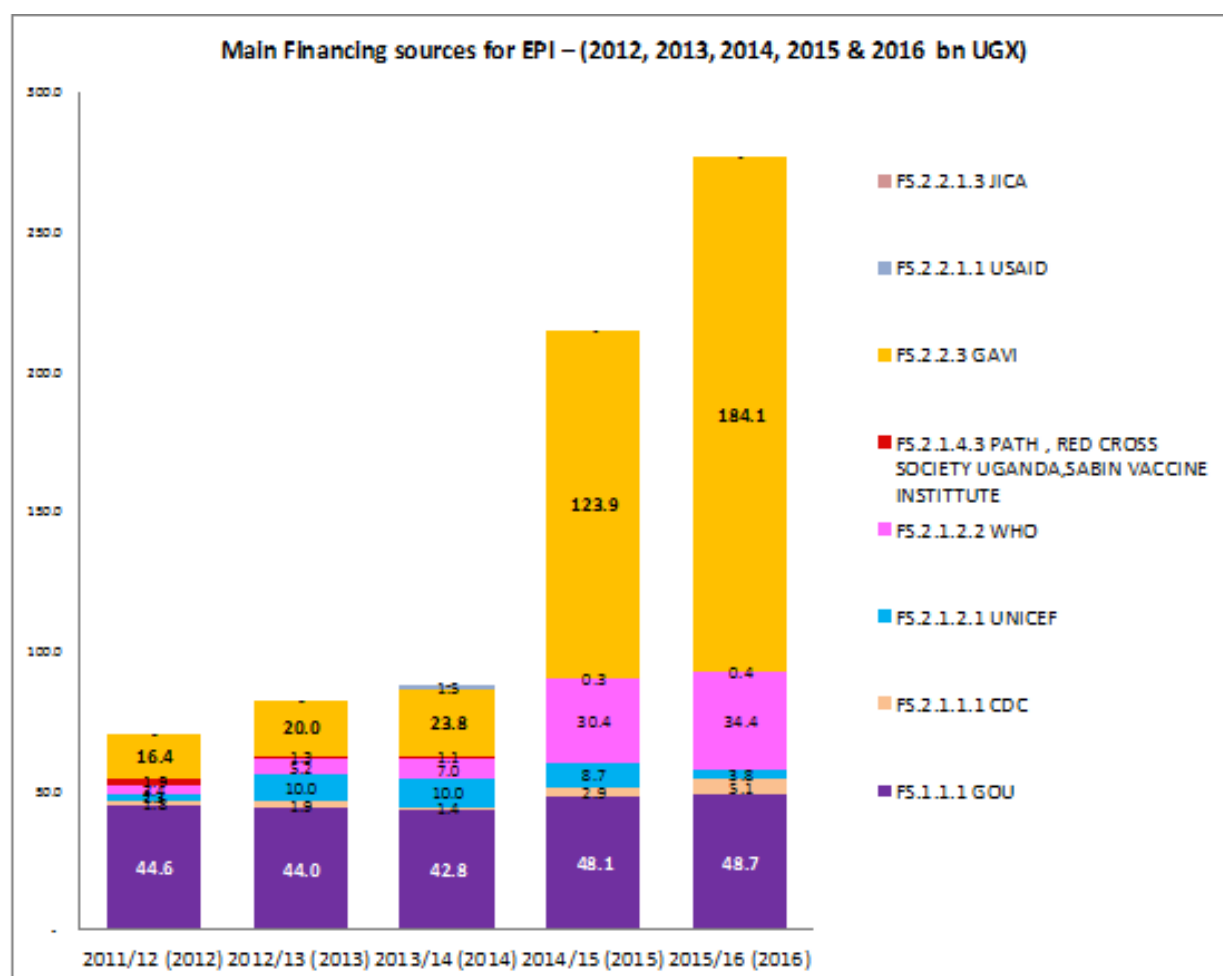
Finding 1

Decisions to apply for Gavi support are not always undertaken with a full assessment of the implications on financial sustainability. In 2016, we observed that Gavi FCE countries had challenges in meeting cofinancing requirements, as well as concerns regarding the overall fiscal health of immunization programs. Robustness of finding: B

In previous Gavi FCE reports, we covered decisions related to Gavi support that have not always been taken with a full assessment of the implications for financial sustainability. In Uganda, for example, the country highlighted the importance of balancing the health benefits of introducing rotavirus vaccine and implementing a meningitis A vaccine campaign against financial sustainability. Specifically, the NITAG called for the development of a financial sustainability plan. This recommendation was not taken into account prior to the decision to apply for Gavi support, which was subsequently approved, although steps to develop such a plan are under way. In Mozambique, applications for multiple vaccine introductions (rotavirus vaccine, measles second dose, IPV) were submitted and approved; these vaccines were subsequently introduced in late 2015. These decisions to introduce vaccines, while realizing health benefits to the population (see New Vaccine Introductions section, page 15), have also resulted in a substantial increase in cofinancing requirements in FCE countries. In the 2015 evaluation period, we noted a number of warning signs regarding countries' ability to sustain financing for newly introduced vaccines and immunization in general, some of which are the consequences of these previous decisions.

In Gavi FCE countries, we undertook resource-tracking studies to quantify the fiscal space of immunization. In Uganda (Figure 20), total expenditure for the EPI program has increased over time. Interestingly, we observe that while the government of Uganda has increased funding in absolute terms over the last two years, the government's contribution has decreased in relative terms, i.e., as percentage of total EPI expenditure. Data from Zambia show a similar pattern. While the government of Zambia's contributions to the EPI in absolute terms increased significantly from 2011 to 2014 and remained constant afterwards, the relative contribution to the EPI program decreased significantly in 2015, from 47% to 28%. Heavy reliance on external donor support is also noted in Bangladesh, where the government represents only 10% of the total EPI envelope. These figures highlight the general reliance of FCE countries on external donor funding for immunization, with comparatively smaller increases in government resources for immunization in comparison to external sources.

Figure 20: Main financing sources for EPI in Uganda



What is not yet captured in the resource-tracking results that cover the 2015 fiscal year is more recent macroeconomic instability that is threatening the fiscal health of immunization programs in some of the FCE countries, including the ability of countries to meet cofinancing requirements. In Mozambique, a currency and inflation crisis has contributed to vaccine stockouts and has raised concerns that shrinking fiscal space may lead to a risk that the government will not meet the cofinancing requirements for the multiple vaccines that have been introduced recently (PCV, rotavirus vaccine, MSD).

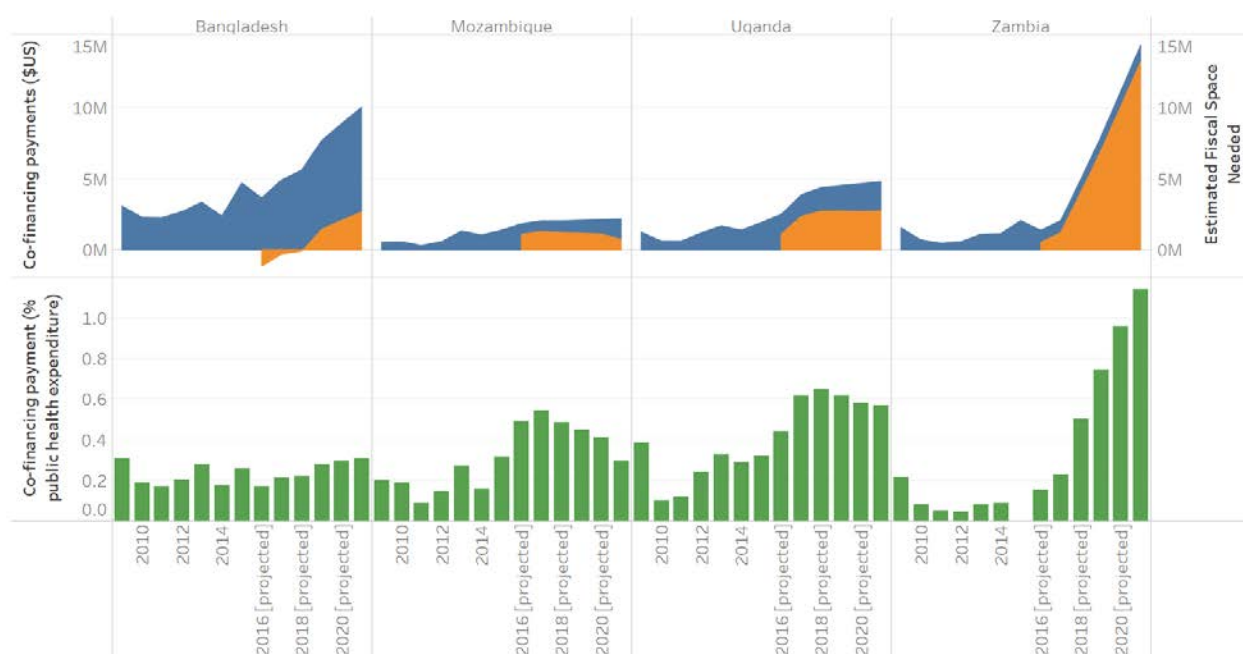
I fear that they [government of Mozambique] will not meet their 2016 cofinancing obligations. We are certainly well aware of the wider macroeconomic problems that are affecting government budgets. We are aware of very large shortfalls in many obligations that they need to meet. It's going to be hard because it's hard for them to have the budget, and then it's hard for them to access the money. (Global-level KII, Alliance partner)

If the cofinancing payment is not made by Mozambique, this may jeopardize not only the continuation of vaccine support but also future payments related to the country's present HSS grant, which the country is increasingly becoming reliant on as the fiscal space for immunization contracts. Present moves by the IMF to advocate for austerity measures may also have as yet unknown downstream consequences on the immunization program and health sector in general. In Zambia, where financial

sustainability was a core focus of the Gavi FCE in 2016, numerous factors threaten the financial sustainability of the EPI. Uganda has partly paid the 2016 cofinancing requirements and promised the remainder by the end of the year. However, the country defaulted on the 2015 cofinancing requirements. While this was largely attributed to a misalignment of fiscal calendars between the country and Gavi, it further highlights the precarious nature of immunization financing flows. Likewise, while cofinancing payments for Bangladesh have been met on time, payments were sourced from a pooled fund, which was externally funded by external development assistance and loans.

Meeting cofinancing payments is likely to be a continuing challenge for FCE countries. To investigate this, we estimated public health expenditure in the years 2015–2021 using the average percentage of government spending from 2009 until 2014, and applied this average percentage of government spending to projected gross domestic product (GDP) levels (current \$US). We then estimated GAVI cofinancing payments as a percentage of public health expenditure and compared future GAVI cofinancing payments to average payments over the period 2009–2015 (Figure 21). The first panel of Figure 21 shows GAVI cofinancing payments by FCE country, with projected values after the year 2015. We observe that GAVI cofinancing payments are expected to increase significantly, especially in Zambia and Bangladesh. These cofinancing payments are expected to represent an increasing percentage of government health spending in Mozambique, Uganda, and Zambia. In Zambia, we see the steepest increase, with GAVI cofinancing payment making up to 1.14% of total government health expenditure in 2021, compared to an average of 0.09% in previous years due to declining GDP.

Figure 21: Cofinancing in FCE countries, 2009–2021 (projected)



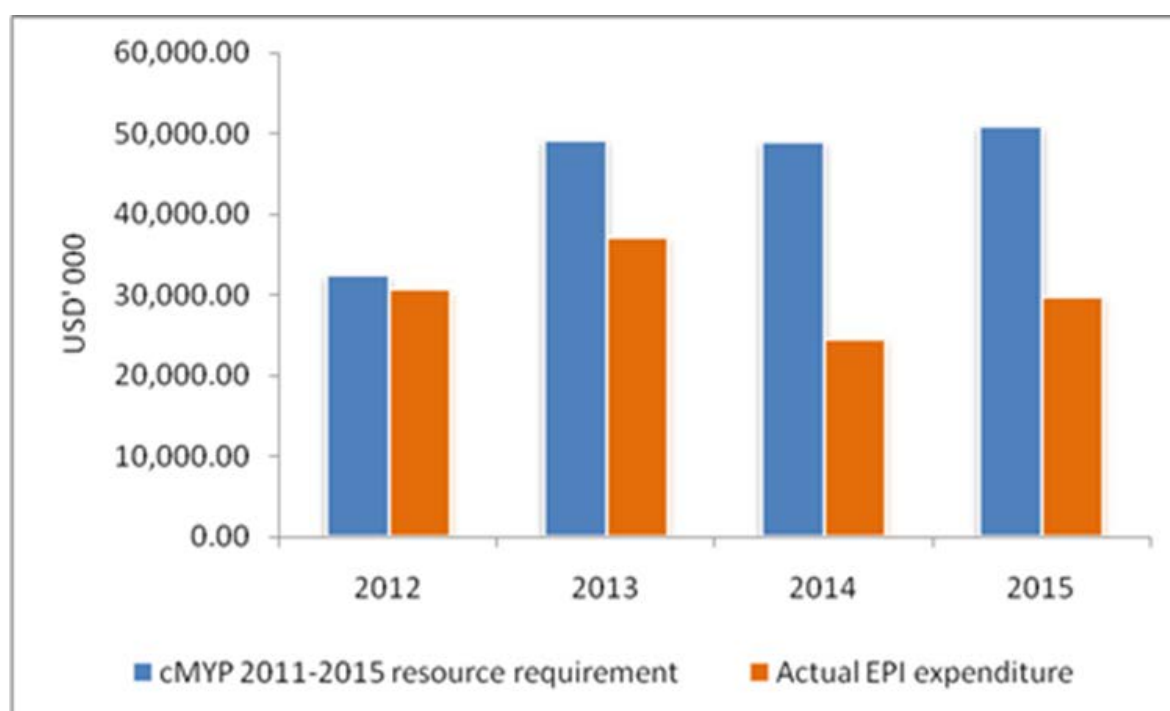
In Zambia, macroeconomic indicators – increasing inflation, declining tax revenues, widening deficit levels, declining real GDP growth, and increasing public debt – show an economy that is slowing. This has led to a delay in the country moving into the Gavi accelerated transition phase, where cofinancing payments increase but also contribute to delays in immunization financing flows. In 2015, approximately 8%, 4%, 17%, and 13% of approved budget allocations were disbursed toward the EPI operational

budget, cold chain equipment, printing of under-5 cards, and vaccines and immunization supplies, respectively. Figures for 2016 are not yet available, but initial indications are that actual expenditure will be much lower than previous years – of the \$US 41 million that was identified to be needed, \$US 6 million was approved and less than \$US 500,000 disbursed. Furthermore, at the time of this report, Zambia has yet to submit its 2016 cofinancing payment, which is later than any previous year.

Insufficient financial flows for immunization in Zambia may jeopardize potential future gains in immunization coverage and threaten the programmatic sustainability of the EPI program. Consequences could include: 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. If the observed recent trends and poor economic conditions continue, the Zambian MOH 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 to the health system.

One reason for insufficient financial flows in Zambia is that the comprehensive multiyear plan (cMYP), which is supposed to serve the purpose of mobilizing resources and setting priorities, is not adequately fulfilling these functions. In the current year and over the past years, a number of items and activities in the cMYP have regularly remained without committed funding, while some of the donors have not fulfilled their commitments. Not only has EPI total expenditure (from all sources) declined, but also, importantly, the gap between secured funds and actual expenditure has increased. The 2011–2015 cMYP and actual expenditure from the resource-tracking work show that funding commitments from the cMYP are not fully fulfilled or executed. Unfortunately, we cannot break down cMYP funding commitments by donor.

Figure 22: Secured EPI funds versus actual expenditures, Zambia, 2012–2015



A second reason for insufficient financial flows in Zambia is 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 MOH in Zambia. 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 considered at the highest policy level is crucial to ensuring sustainability.

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

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

A third issue that has led insufficient financial flows is that approved budgets are less than what is proposed or needed, and the implications of funding shortfalls are generally never negotiated or discussed. The ability of the program to sustainably meet its coverage targets and deliver high-quality service is 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 the 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 consequence of these challenges is that the management of the EPI is left to adopt an approach of “let us do what we can do with the resources we have in our hands.”

Financial sustainability is also a critical issue for current decision-making in FCE countries. Most notably, despite the unstable macroeconomic environment presently being experienced in Mozambique, the country submitted in September 2016 an application for Gavi support for an MR campaign and introduction of MR into the routine immunization system. This application was recommended for approval by the IRC in November 2016. It will further increase the cofinancing requirement (for MR in the routine system) and strain the limited fiscal space for immunization in Mozambique. In Mozambique and Zambia, as noted in further detail in the HPV section and earlier in this section, concerns regarding financial sustainability have delayed the transition from demonstration project to national introduction. The counterexample is in Uganda: With the financial sustainability concerns expressed by the NITAG, the government has put on hold for the time being additional applications for new vaccine introduction. This has also been influenced by the Ugandan Ministry of Finance requiring UNEPI to provide a cost-implication analysis before each proposed vaccine introduction.

Recommendations

1. Building on recommendations from 2015, Gavi, countries, and partners should ensure more scrutiny of financial sustainability considerations in decision-making, particularly in Phase I (preparatory) transition countries. Further checks and balances can be established as part of existing entities, e.g., NITAG and ICC.

2. As covered in the section on HSS, Gavi should expand its fragile state policy by considering the application of the country-tailored approach and/or other emergency flexibilities to countries experiencing severe macroeconomic crises (e.g., Mozambique).

Finding 2

An increasing amount and proportion of Gavi funds are flowing through partners and non-governmental sources, and there is increased reliance on non-governmental systems. The rationale for this trend includes risk mitigation and increased efficiency. We have noted short-term consequences for country ownership and flag potential consequences for long-term programmatic and financial sustainability should this trend continue. Robustness of finding: C

In 2016, we observed multiple cases where Gavi cash support was disbursed directly to partners, bypassing government systems. This trend is not unique to FCE countries; indeed, key informants referred to data presented to the PEF Management Team that indicate that, across Gavi countries, the proportion of funds channeled through partners has risen sharply in recent years, with 66% of HSIS/HSS funds channeled through partners in 2015, up from 31% in 2011.

One of the most commonly cited justifications for this disbursement pattern is the need to mitigate financial risk, whether risk of corruption or risk of inefficient use leading to reduced impact. In Uganda, where there are previously documented cases of financial mismanagement and where concerns persist that Uganda's systems are not yet robust enough to prevent corruption, a decision was taken to disburse cash funds through non-governmental channels. HSS funds will be disbursed through a fiduciary agent, with an associated administrative fee of 5%. The meningitis A vaccine introduction grant will be disbursed through WHO, with an associated administrative fee of 7%. Stakeholders in Uganda expressed concerns about the financial costs of disbursing through partners and the implications for program budgets. According to one global-level informant, these costs are considered "reasonable" in both economic and reputational terms, when partners have to "take on the financial risk and responsibility." Another emphasized that, as a general point, these decisions are taken only in cases where there is an instance of misuse of funds (identified by an audit or other assessment). In such situations, channeling funds through partners is a strategy to ensure that implementation proceeds until appropriate measures have been taken.

Partners are also sometimes perceived to have more efficient systems, which are capable of receiving funds from Gavi and disbursing within the country in a more timely fashion than government systems. Because of the slow progress toward disbursement of the HSS-2 grant in Zambia, the government may opt to use partner procurement systems, as the government's own systems are acknowledged as being bureaucratic and less efficient. There is also concern about further delays to the implementation of HSS. It is worth emphasizing that, in many cases, these inefficiencies can be attributed to checks and balances put in place to guard against risk of financial mismanagement. Furthermore, the FCE has found that channeling funds through partners is not necessarily faster. In Zambia, an initial decision was taken to disburse operational funds for the MR campaign through WHO in an attempt to speed up implementation. Because of the associated administrative fees (7%), this required rebudgeting. Ultimately, the PCA recommended channeling through the government, as channeling funds to the government allows for any unused funds to be rolled into the HSS grant. As a result, the funds were held up by the PCA process and partners had to provide stopgap funds for aspects of the campaign. It is

important to more fully assess whether partner systems are in reality more efficient than government systems. Where possible, these decisions should be taken early so that countries are able to plan and budget accordingly.

Funds are also disbursed to partners when governments are not perceived to have the capacity to implement a given activity. In Bangladesh, HSS funding for surveillance and vaccine management strengthening are being disbursed directly to WHO and UNICEF. However, with no clear plan to build the capacity of government to take over these activities, the programmatic sustainability of this decision is of concern. This concern was highlighted also by the IRC in their review of the application in 2015.

While some key informants emphasized that disbursing through partners is only intended to be a temporary solution until government systems are strengthened, others expressed misgivings:

More and more funds going through partners instead of through MOH systems – that to me is the wrong direction. I think we are not doing any favors to our Ministries of Health by taking on these funds. In some cases it is essential, but in some, Central African Republic, absolutely. But in some countries, if we really want to have credible exit strategies for these interventions, then we have to invest in the systems, the financial systems, and try to make them robust. (Global-level KII, Alliance partner)

Still others noted that this is in effect an effort to transfer fiduciary risk from Gavi to partners in response to pressure from some Gavi donors. According to one Alliance partner:

If you're building capacity, ultimately you need to have funds flow through the government system and building on those systems. The minute you actually set up a parallel system, don't think you can, in good honesty and faith, say that you are building government capacity – on anything actually, because you've created a parallel stream. I think that the conundrum we have ourselves in right now is that many of the sovereign donors really want to see Gavi, and the Alliance, really help countries improve coverage and equity – and these are some of the highest-risk countries in the world, and suffering some of the most difficult situations. At the same time, saying, "But we have zero acceptance of fiduciary risk" – I personally don't believe you can do that. I think you have got to accept that there's going to be some fiduciary risk if you are going to work in these difficult settings. I think this is actually a real conundrum ... one that I raised, that I'd like actually raised at the Board level. (Global-level KII, Alliance partner)

This reflects a broader tension between country ownership (a key tenet of the Gavi 2016–2020 strategy) and concerns about mitigating risk of financial mismanagement. While undoubtedly there are country circumstances that require disbursing funds through partners, this should not become the norm. In the case of the FCE, it is particularly concerning to note this is happening even in Zambia and Bangladesh, both Phase I (preparatory) transition countries. This trend warrants further discussion and careful consideration at the highest levels within Gavi (and other donor agencies).

Recommendation

Gavi should formally assess whether it is actually more efficient in the short term to channel funds through partners versus government systems, and the long-term consequences of this trend on country ownership and sustainability. Gavi should also review other best practices in mitigating risk of financial mismanagement of donor funds, while still strengthening country systems.

Finding 3

There is limited evidence that countries are planning or preparing for entering into the accelerated transition phase and subsequently graduating from Gavi support. There is limited guidance from Gavi on what countries should be doing in the pre-transition phase to ensure a smooth transition. Robustness of finding: B

None of the Gavi FCE countries have entered or will be entering the accelerated transition in 2017. This provided an opportunity for the Gavi FCE to evaluate the extent of planning for accelerated transition and the extent of engagement and support by Gavi and the Alliance partners, particularly for those where entry to the accelerated transition phase is expected in the near future.

Zambia was originally scheduled to enter into the accelerated transition phase in 2017. Based on revised gross national income per capita, the country was informed on Aug. 26 that they would no longer be entering into the accelerated transition phase. Prior to the August communication, however, we did not observe significant planning for the accelerated transition phase, particularly how the additional cofinancing requirements would be met. During this period, we also observed limited TA from partners and the Secretariat. According to one key informant, had the gross national income figures been high enough for Zambia to enter accelerated transition next year, there would have been a “mass state of panic.” However, among key informants at the global level, there is acknowledgement that Gavi lacks the capacity to support countries in the earlier stages of transition, and engagement prior to countries actually entering accelerated transition has been extremely limited. So while, ideally, planning should happen while a country is in the preparatory transition phase, in reality, the sustainability group at Gavi is focused on those countries already in accelerated transition. The Board has mandated that Gavi engage earlier, with an initial focus on immunization financing.

We have also observed minimal planning for the transition phase in Bangladesh, which is expected to enter into the accelerated transition phase in coming years. Notably, again, there has been no dialogue between Gavi and the country on issues of sustainability. A similar situation is present in Mozambique. While a PEF-TCA activity specifies TA from WHO to develop a concept note regarding financial sustainability, we have observed no progress on this to date. In contrast to other countries, Uganda has been demonstrably more proactive in terms of planning for financial sustainability, having passed a parliamentary bill on financing for immunization and requested TA to develop a financial sustainability plan through the PEF-TCA and guidance from the NITAG on planning for financial sustainability. This is notable, particularly considering Uganda is not slated to transition from Gavi support as early as some other countries.

Recommendation

We recommended earlier dialogue between countries, Gavi, and partners, including clearer guidance and processes for Phase I transition countries that could be implemented as part of the CEF. This ideally would include tools and local resources for assessing and planning for sustainability that should include lessons learned from other countries. This could be part of the sustainability SFA.

Alliance processes and requirements

Donor processes and requirements have the potential to add value – both to countries and Gavi – when they are designed and implemented to balance their administrative and management burden with their potential benefits.

Finding 1

Gavi changes are numerous and frequent. The Secretariat and partners must be aware of how these changes appear at the country level. We are seeing an effort to bring them together and to simplify, which may lead to increased short-term complexity. Robustness of finding: C

There is nothing novel in our 2016 observation that Gavi changes are frequent and numerous – it has been a finding of nearly all the FCE reports. In 2016, changes included ongoing JA and PEF implementation, the HSIS/CEF reform, proposed changes to the HPV vaccine program, and changing guidelines related to IPV.

How do these changes feel to in-country stakeholders? At Gavi's HSIS country consultation hosted in Geneva, one country participant noted that by the time the country or partners are aware of a change, it has changed again. This was echoed last year in Zambia, where an interview respondent recommended that Gavi should slow guidelines changes so that they can learn from one year to the next. On the other hand, the relative continuity of the JA process from 2015 to 2016 enabled learning and improvement.

In Zambia, the FCE team reported that stakeholders were not always aware of changes (e.g., the changes to the HSS application guidelines). One observed coping mechanism is to request TA or rely on consultants to deal with the changes. In Uganda, it is most often the FCE team who informs stakeholders about changes. These approaches are neither sustainable nor do they strengthen program capacity. A more positive example comes from the SCMs, who are primarily responsible for communicating changes. Their effectiveness depends on their overall workload and relationship with the country. Gavi should continue to strengthen their capacity to be effective change managers.

Unplanned changes can have unintended consequences, as occurred with the PCA (see Leadership and management section, page 46). Confusion or potential misinformation regarding HPV program changes led Zambia to delay their HPV vaccine application; the country believed additional operational funds would be available if they waited. In turn, this led to halting of delivery in the demonstration districts.

In the presence of these many changes, and the growing number of policies overall, Gavi resolved in 2016 to improve its policy development, implementation, and change-management approaches. Whereas in the past, new policies were handed over to country programs to implement, the new approach involves policy development as a joint activity between the policy and implementation teams, with continual reflection on the operationalization of the policy to ensure a smooth handover. Another important procedural change is the increased inclusion of country voices in designing and planning meetings (e.g., the HSIS and HPV country consultations):

With HSIS, we really consulted a lot. And we had to, because we can't redesign those frameworks from Geneva. (Global-level KII, Gavi Secretariat)

The Secretariat also recognizes the need to provide an overarching theory of change or map describing the causal pathways between Gavi policies/inputs and their intended outputs, outcomes, and impacts,

with an explicit discussion of the assumptions (a recommendation from the 2015 report). The Secretariat is in the process of developing such a map.

In terms of specific policies to reduce complexity, HSIS and CEF grew out of the Board-level discussions related to simplification. Paradoxically, CEF implementation has the potential to be quite complex and burdensome initially; this must be carefully monitored and managed. Global stakeholders suggested that the burden felt by countries would largely depend on the capabilities of SCMs to support the CEF implementation process. Another element of complexity, which is built into the HSIS process, is the need to bring donors together around the table in planning for HSIS. One respondent argued that this was a necessary step, although likely to increase delays or complexity initially and also risk potential conflicts of interest or reduced country ownership:

It's supposed to be collaborative. ... This is really supposed to be the country's proposal. ... The proof will be in the pudding, quite frankly, when it starts being implemented and the MOH says, "Well, the Gavi Secretariat will just do it." Where has the ownership been in the program?
(Global-level KII, Alliance partner)

As noted in recommendations above, the CEF early learning approach, as well as other opportunities for evaluation, should focus on unpacking these complex issues and the likely unintended consequences of this significant change.

Recommendations

1. Gavi should continue to include country participation in Gavi-/global-/regional-level policy development and design processes.
2. Gavi should slow changes to policies and guidelines and ensure new policies/guidelines are monitored and evaluated so that Gavi and countries can learn from one year to the next.
3. See also the HSS section recommendations, page 45, above, regarding CEF.

The Alliance partnership

Finding 1

The global-level Alliance partnership has evolved over time based on changing Alliance and country goals. The single largest driver of change has been the process of designing and implementing the PEF, which has improved transparency and accountability but has also affected perceptions of the partnership's function, level of trust, and performance in countries. Based on global-level KIIs, the health of the Alliance partnership at the global level can currently be described as stable but with room for improvement. Robustness of finding: C

In 2015, we reported on the PEF's potential effects on the Alliance partnership. The Secretariat commissioned an Alliance Health Survey in 2016 to measure core partners' (WHO and UNICEF) satisfaction, pride, and mutual appreciation in being a part of the Alliance partnership. The FCE team conducted supplementary global-level KIIs to explore the Alliance partners' perceptions of the health of the partnership and drivers of recent changes in trust and performance.

The design and implementation of the PEF have affected the Alliance in intended and unintended ways. Intentionally, the PEF increased partners' accountability to Gavi, although some donors felt that the

Secretariat could have gone further in challenging the “business as usual” model of the partnership. The shift from a partnership to contractual model did not always align with partners’ reasons for participating in the Alliance. Smaller Alliance partners expressed concern over the size of transaction costs to engage through the PEF, preferring to collaborate in the original “partnership” spirit:

We value the relationship, the collaboration. The financial aspect is actually much less important to us than the operational relationship, which also introduces some interesting dynamics when we start talking about the actual PEF process – what the level of effort is to participate in that process in relation to the amount of money that we get out of the process. ... The PEF process and forcing this relationship into that paradigm I think actually reduces our ability to collaborate effectively with Gavi. (Global KII, Alliance partner)

The PEF has also introduced an element of competition between partners, which was reported to be difficult at first, and certainly caused tension in some countries’ JA processes in 2015. In at least one case this has improved: The CDC reported that Gavi’s decision to set aside funds for them in 2017 means they are no longer perceived to be in competition with other partners for funding during country JA processes.

When asked about trust in the Alliance, many global respondents differentiated trust among partners and trust between partners and the Secretariat. Among partner-to-partner relationships, trust is fairly stable, which was attributed to the long-standing relationships between the core partners that extend beyond Gavi. However, the growing influence and changing role of the Secretariat in the Alliance has led to diminished trust from partners to the Secretariat – which is partly to be expected and somewhat necessary to achieve the paradigm shift of the PEF. In the partnership overall, there have been “growing pains” experienced in the transition to the PEF that should not be ignored, with one respondent reporting that trust is at “an all-time low” (Global KII, Alliance partner). Respondents felt that careful steps would need to be taken by the Secretariat, Board, and others to build trust and to prepare for difficult years ahead, as the core role and function of the Alliance continue to shift:

A re-evaluation at some point of roles and responsibilities [is required] in Gavi. Fifteen years ago, Gavi, it was very clear, wasn’t an organization: It was an alliance; everyone worked to their comparative advantage; WHO did their normative thing; and Gavi was simply the financing

Box 11: The country perspective

HOW DO THE GLOBAL SHIFTS FEEL TO COUNTRIES? AN EXAMPLE FROM JA PROCESSES.

By design, the JA process is a participatory and transparent process. Thus, it has had overall net positive effects on country partnerships. In Uganda, respondents felt the partnership was stronger now that core partners were more accountable to the government for technical assistance activities. Similarly, government stakeholders have felt a sense of empowerment vis-à-vis other partnership actors thanks to these principles.

But the process is not perfect. Its rules – both formal and informal – and the path dependency created by the existing rules and partnerships have led to further entrenchment of core partners. We anticipate that without significant changes in the JA process and incentives to include expanded partners or other stakeholders, country partnerships will remain relatively dense and closed.

mechanism to grease the wheels of everyone's collective goals. You really can't say that anymore. ... We'll see the Secretariat continue to grow, somewhat regrettably. The more you grow, the more contact you have with countries, the more knowledgeable you become, the more competition there is with some traditional partners who have worked in a country. ... There's potential for sort of more erosion of trust than I think perhaps we've seen to date if we're not careful. (Global KII, Alliance partner)

These results from global KIIs should be interpreted in light of the Alliance Health Survey, which will provide additional information on this issue, both at global and country levels.

Use of findings

In 2016, we observed many instances of FCE findings and recommendations being used for program and policy decision-making. Most often, as is the case with all research and evaluation evidence, FCE findings are used “conceptually” to add to decision-makers’ understanding of issues, root causes, and potential solutions. FCE findings are often taken together with other evidence, or sometimes provide just enough weight to tip the balance from uncertainty to action.

When and why are FCE findings most likely to be used? As with all other evidence, FCE findings were used when they were timely, relevant, and trusted. FCE findings can be produced and disseminated in a timely manner because of the prospective evaluation approach and because of the FCE teams' awareness of and access to policy windows. These windows may only be open for a matter of days (e.g., a planning meeting) or weeks (the JA process). Knowing when these windows will open is essential if FCE findings are to inform resulting decisions.

FCE findings are relevant also because of the evaluative approach, namely, the broad lens of the process evaluation component, which ensures that all aspects of Gavi support are being tracked. This enables the FCE teams to identify the most important issues and to contextualize and describe them in a way that is both actionable and likely to lead to impact. Over time, growing familiarity with the issues and context has enabled the increasing relevance of all FCE findings.

One of the most compelling predictors of evidence-informed decision-making is the existence of relationships between evidence producers and users.¹² Over time, country and global FCE teams have cultivated relationships with potential users of findings, which in turn enabled timeliness of exchanges and a relevant set of evaluation questions. As well, relationships help bolster the credibility of the independent evaluation teams. At all levels, the FCE evaluators are perceived as neutral and credible technical experts. It should be noted that FCE evaluators are not always fully resourced or trained to play this “knowledge-broker” role; however, it is a growing area of interest for the teams if we wish to increase the use of FCE findings.

In the case studies below, we present an illustrative example from each FCE country showing how FCE findings were used to inform programmatic and/or policy decision-making in 2016.

Bangladesh

The Bangladesh FCE team’s most recent salient example of the use of their findings occurred during the development of the 2015 HSS-2 application. The FCE team participated as members of an application development working group, as requested by the Bangladesh Ministry of Health and Family Welfare.

The FCE team provided examples of lessons learned from the HSS-1 grant utilization process, which were included in the submitted application in the hopes of informing and improving the HSS-2 implementation process.

The FCE findings were also addressed in the JA 2016 report. The report presented the FCE findings on uptake of immunization coverage in the districts supported by the HSS grant, as well as findings on constant improvements that have allowed PCV coverage rates to approach the target of DPT3 coverage.

Mozambique

In 2015, the Mozambique FCE team reported on the HPV vaccine demonstration project. However, they missed opportunities to inform a national introduction, due in part to the unrealistic time lines that meant that the evaluation products were not available at the end of the first year for a discussion on the testing of other delivery models. While 2015 findings were detailed in the report, the team paid extra attention in meetings with stakeholders to the issue of non-generalizability of the tested delivery model and the Gavi-funded demonstration site. The FCE team attended an HPV vaccine planning meeting in early March 2016, where their findings were incorporated in the analysis of the demonstration site contexts. Informed by FCE findings and other sources, the EPI program decided that their application for national introduction should incorporate a phased approach, as well as assessments of the different delivery models undertaken in various contexts.

Uganda

The Uganda team has many examples of how FCE findings inform decision-making in both direct and indirect ways, but this case study focuses on a recent request that highlights the FCE team's progression from producers and providers of findings ("producer push") to the recipient of requests ("user pull").¹³ In mid-2016, UNEPI requested guidance from the NITAG on the new vaccines that were proposed for introduction into routine immunization for 2017–2020, which included yellow fever, MR, hepatitis B, tetanus, and meningitis A vaccines. To inform its recommendations, the NITAG asked the FCE team to develop a report on UNEPI's capacity for immunization. The FCE report highlighted the need to develop a long-term immunization financing sustainability plan, as well as strategies to overcome immunization inequalities, ensure sustainable cold chain maintenance, and strengthen human resources capacity to deliver immunization services.

The request was facilitated by factors related to the FCE team's credibility, their strong relationships with potential users, and their status as an "honest broker" of information. The fact that the report was requested by the NITAG ("user pull") suggests a higher baseline likelihood that the findings and recommendations within will be used. The team will continue to track how its findings inform NITAG recommendations.

Zambia

In Zambia's 2015 report, the team reported that PCV and rotavirus vaccine coverage had stabilized but were slightly lower than that of pentavalent vaccine. The team continued to track this issue into early 2016 and was able to present near real-time findings based on HMIS data at the dissemination meeting for the FCE report (April 2016) and at other meetings during the year. The causes of the suboptimal routinization are presented in greater detail in this report.

The FCE team's attention to this issue brought it to the forefront for EPI stakeholders, who commented that they had not been closely tracking or analyzing PCV and rotavirus vaccine coverage; they had

assumed that the vaccines had been successfully introduced. The issue also brought to light concerns related to future new vaccine introductions and the importance of understanding and addressing existing system bottlenecks before further new vaccine introductions. The issue was discussed during the JA process.

Gavi FCE evaluation questions, 2013–2016

The design of the Gavi FCE was guided by a set of high-level evaluation questions that were posed by the Gavi Alliance in 2013. In the table below, we briefly summarize our findings across each of these evaluation questions, drawing from this year's report and previous reports. These findings are further synthesized in the Summary section, page 90, that follows.

Table 9: Gavi FCE evaluation questions

Gavi FCE evaluation questions	Comment
<i>Relevance</i>	
1) To what extent is the design of Gavi support and its implementation at the country level aligned with Gavi priorities and principles?	The 2011–2015 operating principles are as follows, with a summary of relevant findings from the Gavi FCE. Many of these questions are discussed in further detail under separate questions. 1. Advocating for immunization in the context of a broader set of cost-effective public health interventions As part of the Gavi FCE, we find that there is both country- and global-level advocacy for new vaccine introductions, which has contributed to introductions of vaccines such as PCV and rotavirus vaccine. IPV, in particular, has had a more notable global-level push, in conjunction with a time-limited window for applying for support. We have limited findings on advocacy for vaccines within the broader set of public health interventions, with the exception of HPV vaccine, for which there is a requirement that HPV vaccine be considered as part of a comprehensive cervical cancer prevention program. 2. Contributing to achieving the Millennium Development Goals Our findings on vaccine effectiveness and child mortality (covered in this table under the Impact section, Questions 2 and 3) summarize the contribution of Gavi support to achieving the Millennium Development Goals for child health. 3. Supporting national priorities, integrated delivery, budget processes, and decision-making In general, applications for Gavi support have been well aligned with national priorities, as described further below in this table under the Relevance section, Question 2. In this table's section on Effectiveness, Question 5 describes the alignment with national budget processes and decision-making.

	4. Focusing on innovation, efficiency, equity, performance, and results Our findings from the Gavi FCE are described further under this table's section on Impact, Question 5. 5. Maximizing cooperation and accountability among partners through the Secretariat Our findings regarding partnership are discussed under this table's section on Program implementation and context, Question 3. 6. Ensuring gender equity in all areas of engagement. We discuss this in further detail under this table's section on Impact, Question 5.
2) To what extent is the design of Gavi support and its implementation at the country level relevant to the country's needs and aligned with the country's priorities and systems?	The introduction of new vaccines is well aligned with FCE countries' priorities to reduce child mortality, with pneumonia (PCV) and diarrhea (rotavirus vaccine) in particular being major causes of death in those countries. HPV vaccine demonstration projects and national introduction in Uganda are also well aligned with country priorities around reduction of HPV infection and cervical cancer. IPV is also aligned with country priorities as signatories to the Global Polio Eradication Initiative, although this vaccine is driven to a greater extent by top-down push, in line with the Global Polio Eradication Initiative Strategic Plan. The slow progress in implementation of HSS, relative to the pace of new vaccine introduction, has limited the potential to increase vaccine coverage in these countries. This could further contribute to improving health outcomes and reducing health inequalities. The design of these grants helps to facilitate consideration of key bottlenecks to immunization delivery. More recently, Gavi support mechanisms were revised (or are in the process of being revised) to target leadership, management, and data quality as key bottlenecks, as well as cold chain investments. These are all generally well aligned with a country's needs and priorities. As noted, Gavi has also reformulated the JA process for technical assistance identification to be country-driven.
3) How do Gavi's process, products, and resources work at the country level to influence immunization-related outcomes? Are they improving over time? What are the intended and unintended consequences?	All findings for this evaluation relate to this overall research question, and we do not attempt to summarize them here. Unintended consequences are present in all thematic areas and are covered under this table's section on Impact, Question 6.

<i>Effectiveness</i>	
1) To what extent does Gavi support to countries contribute to meeting the goals and objectives outlined in the Gavi Alliance Strategy 2011–2015 and Business Plan?	1. Accelerating the uptake of new and underused vaccines Over the course of the Gavi FCE (2013–2016), the four FCE countries introduced a wide range of new vaccines with Gavi support, including PCV (all countries), rotavirus vaccine (Zambia, Mozambique), MSD (Zambia, Mozambique), IPV (Mozambique, Uganda, Bangladesh), and MR (Bangladesh, Zambia). As noted in this (page 15) and previous reports, there has been variable success in preparing for, introducing, and routinizing vaccines into country systems. These findings also relate to Gavi’s 2016–2020 strategic goal to accelerate equitable uptake and coverage of vaccines. 2. Strengthening the capacity of integrated health systems to deliver immunization In this (page 32) and previous reports, the Gavi FCE has highlighted the broader set of challenges and slower progress in implementing Gavi’s HSS window of support in comparison to new vaccine introductions. Gavi’s HSS window of support is the primary mechanism to strengthen immunization and health systems. Over the time period of the Gavi FCE (2013–2016), there was limited implementation of HSS, meaning that the contribution of Gavi support in FCE countries to health and immunization systems was small. These findings also relate to Gavi’s 2016–2020 strategic goal to increase effectiveness and efficiency of immunization delivery as an integrated part of strengthened health systems. 3. Improving the sustainability of national financing As noted in our resource-tracking results, countries are highly dependent on external donor financing for immunization, reflecting the increased support from Gavi, particularly for new vaccine introductions. In this and the 2015 report, we note a number of immediate challenges for FCE countries in terms of financial sustainability, both in terms of the goal-level indicators of fulfillment of cofinancing commitments and fiscal space for immunization. These findings also relate to Gavi’s 2016–2020 strategic goal to improve the sustainability of national immunization programs.
2) To what extent does Gavi support provided through each window of support meet the window’s objectives at the country level?	For new vaccine support evaluated in the FCE countries (the window of support’s objectives are underlined): • Our assumption is that the introduction of new vaccines with Gavi support has <u>accelerated uptake and use of new and underused vaccines</u>. However, it is difficult to quantify by how much this has accelerated introduction. While new vaccines have

	largely been scaled, routinization has not been optimal when compared to other traditional vaccines within FCE countries. • There was indication of <u>evidence-based decision-making</u> with regard to decisions to introduce these vaccines, with all countries indicating high burden of the corresponding disease. For polio, where disease burden is low, the decision to apply for Gavi support to introduce IPV is in line with the Global Polio Eradication Initiative. • Considerations of <u>sustainability of national financing for immunization</u> have been more variable. Evidence shows that financial sustainability considerations are being assessed more seriously in Uganda than in other countries. For cash-based support (the window of support's objectives are underlined): • We have noted challenges and delays in the implementation of HSS in all Gavi FCE countries, which have resulted in limited implementation over the course of the Gavi FCE. For the earlier HSS-1 grant in Bangladesh, there is evidence that the grant has contributed to improvements in coverage and <u>increasing equity</u> (see 2015 report, page 69). • For the remaining countries, due to limited implementation, HSS outputs have not contributed substantively to <u>resolving the major constraints to delivering immunization, increasing equity, and strengthening civil society engagement</u>.
3) To what extent does Gavi support to countries contribute to helping countries meet the goals outlined in their national health strategies and plans?	• The introduction of new vaccines, as documented by the Gavi FCE, has likely contributed to improvements in country priorities around child health and child mortality (see also this table's section on Impact, Questions 2 and 3). Although there has been a range of challenges associated with HPV vaccine delivery, this has also likely contributed to future reductions in cervical cancer, which is also a major country priority. • The slow implementation of HSS, as noted above, has likely limited the potential for improvements in health systems. • The more recent Gavi support mechanisms that target leadership, management, and data quality as key bottlenecks, as well as cold chain investments and the overall realignment of technical assistance, are generally too nascent for us to determine the potential impact on country priorities.

4) What is the added value of Gavi as a partnership in contributing to results achieved at the country level?	As part of the Gavi FCE, we have noted several instances in which the Alliance has added value as a partner at the country level. These include but are not limited to: • The added value of the partnership at the country level has been noted for new vaccine introductions, for example in Bangladesh with the MR campaign, but also in other FCE countries across a range of other vaccines (e.g., Zambia with the rotavirus vaccine, Mozambique with PCV, and improvements in the partnership for the PCV rollout in Uganda). • In general, across all FCE countries, we have seen a broadening of partnerships for the HPV vaccine support stream (see 2014 and 2015 reports). • In HSS, particularly in the application phase, we see some evidence of partnerships adding value (for example in Uganda), but this may come at the cost of efficiency of the process.
5) To what extent do the Gavi funding mechanism at the country level (e.g., HSS, ISS, new vaccine support, and technical assistance) and its implementation reflect country-level ownership, alignment, harmonization, managing for results, and mutual accountability?	Over the course of the Gavi FCE, we noted both challenges and improvements in country ownership and alignment related to Gavi support. These include: • As noted in this report (page 69) and previous reports, the Gavi FCE observed an increasing reliance on non-government systems for fund disbursement and procurement. While this may help to mitigate risk and increase efficiency, there are negative consequences for country ownership and long-term programmatic and financial sustainability. • The Gavi FCE has also observed misalignments between country systems and Gavi requirements. This includes misalignments between financial calendars in terms of reporting in Uganda (see 2014 report, page 178), as well as issues affecting the payment of cofinancing requirements (see 2015 report, page 192). • The PCA process (see page 56) was seen as a top-down approach, with prescriptive findings and recommendations that led to reduced country ownership. • The evolution of the Gavi Business Plan to the Partners' Engagement Framework has been accompanied by a country-led process that is an improvement in terms of country ownership, transparency, and accountability. As noted on page 73 of this report, some aspects of the process at this stage continue to suffer from limited country ownership and transparency.

	• Another example of a positive shift in country ownership was the shift in roles and responsibilities in Mozambique for the HPV vaccine demonstration toward the MOH as the lead entity and funding recipient, increasing country ownership and alignment with subsequent national HPV vaccine introduction (see 2014 report, page 111). There is potential for increased country ownership with the revision of the HPV policy to allow countries to begin with a phased or simultaneous national rollout of HPV. • Other changes – for example, the Country Engagement Framework – have the potential to increase country-level ownership, alignment, harmonization, and mutual accountability; however, it is too early to properly evaluate them.
<i>Impact</i>	
1) What is the immunological evidence of effective vaccination?	As part of the Gavi FCE, we undertook a range of biomarker data collection that assessed directly the immunological evidence of effective vaccination. • In our evaluation of the MR campaign in Bangladesh, we noted that high coverage achieved by the campaign led to large reductions in the susceptibility to rubella, as measured by dried blood spot-based rubella antibody seroprevalence. Measles susceptibility was already low prior to the campaign, reflecting historically high, sustained coverage of measles vaccination. Further details are provided in the Gavi FCE 2014 report (page 69). • As part of HHS conducted in Mozambique, Uganda, and Zambia, we have assessed biomarkers of tetanus, which indicate immunological protection generally commensurate with levels of vaccination.
2) To what extent have reductions in morbidity and mortality of vaccine-preventable diseases occurred? To what extent has Gavi contributed to such reductions?	As part of the Gavi FCE, we undertook PCV-effectiveness studies in Mozambique and Bangladesh. • In Mozambique, nasopharyngeal carriage surveys conducted among HIV-infected children under 5 years enrolled from HIV clinics in Nampula, Maputo, and Manhica, and among HIV-uninfected children under 5 years from Manhica, showed reductions in PCV10 serotype-specific (VTS) pneumococcal carriage observed within 18 months after PCV introduction. Further details are provided in the Gavi FCE 2015 report (page 44) and this report on page 21. • In Mozambique, before-and-after surveillance conducted in the Manhica demographic surveillance system (DSS) also showed significant reductions in vaccine-

	type invasive pneumococcal disease, overall IPD, and X-ray confirmed pneumonia. Further details are provided in this report starting on page 21. • In Mozambique, case control results showed significant reductions in invasive pneumococcal disease and X-ray confirmed pneumonia. Further details are provided in this report starting on page 21. • In Bangladesh, nasopharyngeal carriage surveys showed reductions in vaccine-type pneumococcal carriage among children who were age-eligible for PCV but not among age-ineligible children. Further details are provided in this report starting on page 21.
3) To what extent have reductions in child and adult mortality occurred in Gavi-supported countries? To what extent has Gavi contributed to such reductions?	As part of the Gavi FCE, we conducted causal analyses using the small-area estimates of vaccine coverage and child mortality. To estimate the relationship between new vaccine introductions of PCV and rotavirus vaccine and child mortality, the FCE used mixed-effects multivariate regression models that adjust for other important drivers of child mortality. These showed significant reductions in mortality associated with vaccine introductions in Zambia and Mozambique (see New Vaccine Introductions section, page 15). Gavi has contributed to these reductions by accelerating the introduction of these new vaccines. We do not provide a quantitative attribution of the Gavi impact, which would necessitate an estimate of when the FCE countries would have introduced these vaccines in the absence of Gavi support. The results from our resource-tracking studies provide a crude estimate of the contribution of Gavi to the overall resource envelope for immunization in these countries (see the discussion starting on page 63).
4) To what extent has Gavi support contributed to social and financial risk protection for populations in countries supported by Gavi?	In collaboration with the Manhica Health Research Centre and the London School of Hygiene & Tropical Medicine, we undertook a study to estimate the inpatient costs of treating pneumococcal disease. This study estimated the reduction in direct health care costs that would be borne by families and the system due to the introduction of PCV averting cases of pneumococcal disease.
5) To what extent does Gavi support contribute to improved equity between and within countries, including, but not limited to, gender equity and equity between the poor and the nonpoor?	We measured, through systematic analysis of surveys combined with appropriate statistical models, changes in equity of vaccine coverage by geography (district, subdistrict), household wealth as measured by asset ownership, and gender. Further details of these results are shown in Annex 8; in summary, our results suggest: • Vaccine coverage was largely equitable with respect to gender in all FCE countries in 2015. Bangladesh, in particular, has demonstrated notable declines in female-male

	inequality since the early 1990s, with other countries showing largely equitable distribution by gender of vaccine coverage over the last 20 years. • Vaccine coverage by household wealth is largely equitable between the richest and poorest quintiles in Uganda, with notable declines in inequality since the 1990s. In other FCE countries, the richest quintile has a 10% to 20% higher probability of being vaccinated than the poorest quintile. This is despite declines in rich-poor inequality over time. • Geographic inequity in terms of DPT3 coverage and full vaccination at the district and <i>upazila</i> levels declined markedly in Bangladesh. Geographical inequity between 2000 and 2015 remained more or less the same in Mozambique, Uganda, and Zambia. The extent to which Gavi support has contributed to improvements in equity is likely to be limited, given that in three of the FCE countries (Mozambique, Uganda, and Zambia), there has been limited to no implementation of the HSS support window (the main mechanism by which Gavi support will contribute to improved equity). In Bangladesh, there is evidence that Gavi support has contributed to reductions in district-level inequality in vaccine coverage (see Gavi FCE report 2015).
6) What positive or negative unintended consequences have occurred as a result of Gavi support to countries?	A range of positive and negative unintended consequences were observed over the course of the Gavi FCE, including but not limited to: • Gavi support has encouraged and served as a catalyst for partnership at the country level. In Zambia, stakeholders meet more frequently and work together more, while in Uganda, partnership has cross-pollinated technical assistance and best practices. • Aspects of Gavi support have led to strained capacity of EPI programs. For example, in Mozambique and Uganda, substantial time and resources were spent on the HSS application and approval process. • Proposed solutions to transfer responsibility to non-government partners have led to reduced country ownership and at times greater bureaucratic burdens. • There were a range of consequences due to delayed HSS implementation, including the need to reprogram grants and implement activities with other resources. • New vaccine introductions also helped to identify system bottlenecks in countries.

<i>Efficiency</i>	
1) To what extent is Gavi support cost-effective?	We did not undertake a formal cost-effectiveness analysis of Gavi support as part of the Gavi FCE, given the challenges of attribution. This table's section on Impact, Question 3 covers the potential costs and benefits of Gavi new vaccine support.
2) To what extent have the following occurred in a timely manner: a) approval of cash support from Gavi, b) disbursement of money from Gavi to countries, c) utilization of funds and implementation of activities by countries, and d) achievement of objectives?	Our findings from the Gavi FCE demonstrated challenges and lessons learned over the course of the FCE related to the timely approval, disbursement, and utilization of Gavi's cash-based support: • Delayed approval and/or disbursement by Gavi of some of the vaccine introduction grants have had subsequent consequences on the ability of countries to adequately prepare for vaccine introduction: ○ Approval of MR campaign Vaccine Introduction Grant (VIG); ○ Disbursement of VIG (e.g., PCV in Mozambique and Zambia); and ○ Uncertainty about the timing and procedure for the HPV VIG arrival in Uganda (Gavi FCE 2015, page 162). • Over the course of the FCE, we also documented evidence of lessons learned. For example, the disbursement of HPV vaccine demonstration VIG funds from Gavi to Mozambique occurred well ahead of the launch date, in contrast to the previous experience from PCV. • Slow utilization of VIG funds has also been due to in-country disbursement. For example, the MOH's onward disbursement of HPV vaccine demonstration VIG funds to implementing partners in Mozambique was late (Gavi FCE 2015 report, page 111). • Slow approval, disbursement, and utilization of HSS funds have been common themes throughout the course of the Gavi FCE. ○ Approval-to-disbursement time lines have been lengthy, with the Bangladesh HSS-1 grant taking two and a-half years to disburse funds post-approval (see Gavi FCE report 2015, page 88). In Mozambique, funds took two years to disburse post-approval (Gavi FCE report 2015, page 130). These delays were caused by post-approval procedures, including the FMA/financial management requirement, as well as clarifications required to the HSS grant.

	○ In 2016, lengthy post-approval procedures, particularly related to PCA, also delayed disbursement of funds in Zambia and Uganda (see 2016 report, page 56). ○ Implementation of grants has also been lengthy, due to challenges in subnational disbursement of funds to implementers, as well as bureaucratic processes involved with procurement and hiring (see 2015 report page 252 and 2016 report page 56).
3) To what extent have the following occurred in a timely manner: a) approval of new and underused vaccine support from GAVI to countries, b) shipment and delivery of GAVI-supported vaccines, c) utilization of supply and implementation of immunization programs, and d) achievement of objectives?	Gavi FCE findings suggest that the approval process for new and underused vaccine support has been achieved in a timely fashion. Several challenges have been noted with the shipment/delivery and utilization of vaccines by countries, including: ● Delays in the PCV readiness assessment process led to delays in PCV introductions in Mozambique, Zambia, and Uganda. Uganda, in particular, experienced lengthy delays in rolling out PCV to the remainder of the country (see 2013 and 2014 reports for further details). ● Global supply issues delayed the introduction of PCV in Bangladesh; however, issues around the communication of the PCV readiness assessment were avoided as part of the Bangladesh introduction, showing evidence of learning. ● Global supply issues for IPV interrupted delivery of IPV in Bangladesh and led to delays in introduction in Uganda and postponement in Zambia. Supply issues contributed to incomplete routinization of IPV in Uganda and Mozambique (see 2016 report for further details). ● Countries have experienced variable success in routinization of new vaccines into their systems (see 2015 and 2016 reports for further details).
<i>Sustainability</i>	
1) To what extent are the benefits of Gavi support to countries likely to continue after direct support has ended?	Gavi FCE countries are not scheduled to graduate from Gavi support for some time; however, we have noted a number of financial sustainability issues in the short term, including: ● Difficulty in meeting vaccine cofinancing payments in Uganda (defaulted in 2015), and potential difficulties in Mozambique and Zambia in 2016 (see 2016 report, page 64 for further details);

	• Variable consideration of future financial sustainability related to decisions to apply for Gavi support (see 2016 report, page 71 for further details); • Financial sustainability issues related to the ability to deliver HPV vaccine to a new target population in all FCE countries (see 2016 report, page 29 and 2015 report, page 250 for further details); • Macroeconomic conditions having downstream consequences on the ability of EPI programs to finance delivery of vaccines in Mozambique, with potential consequences in Zambia (see 2016 report, page 64 for further details); • A presently heavy reliance on external donor financing as evidenced by resource-tracking studies (see 2016 report, page 63 for further details); • Limited preparation or planning for countries, such as Zambia, that are nearing the Gavi-accelerated transition phase (see 2016 report, page 71 for further details); and • Channeling of funds through third parties, while mitigating risk and potentially improving efficiency, has negative consequences on sustainability and country ownership (2016 report, page 69).
<i>Program implementation and context</i>	
1) What are the most important factors that affect program implementation, effectiveness, efficiency, and sustainability?	In the summary section of this report (see page 90), we cover the factors that we have identified through a high-level theory of change that are most important in affecting program implementation, effectiveness, efficiency, and sustainability. We also provide further details on the main contributors to population-level coverage of vaccination.
2) To what extent has Gavi support been responsive to changes in context? In other words, to what extent have Gavi stakeholders used an adaptive management approach to learn from experience where appropriate?	We have noted a number of instances of Gavi stakeholders using an adaptive management approach to learn from experience: • In terms of new vaccine introduction, we have noted several instances of learning from previous vaccine introductions, particularly in the preparatory and launch phase. Examples range from the setting of launch dates only after arrival of the VIG, early disbursement of VIG funds, and improved communication around the PCV readiness assessment. Importantly, there is scope for further improvement in this area for NVI during the post-introduction and routinization phases. • For HPV, we have noted ongoing reforms by the Secretariat to address limitations noted in previous Gavi FCEs around tensions between demonstrated ability and learning for national rollout objectives. We do note, however, that these were not

	implemented in time to address similar limitations observed in the Bangladesh HPV demonstration project. • For HSS, we have also noted a range of reforms that are under way to address the generally slow implementation of Gavi's HSS support window, although we have not yet had an opportunity to evaluate them. • Evidence of adaptive management is also present with the reform of the Gavi Business Plan and changes to the PEF and JA processes.
3) To what extent do the main stakeholders at the country level contribute to the planning, implementation, monitoring, and evaluation of Gavi support? To what extent are their activities coherent and complementary?	Our findings on the extent to which the partnership is working together in a complementary and coherent fashion are mixed. This year's report (page 73) addresses the question of partnership in detail. In summary, as seen in previous years, partnership composition, structure, and roles are largely determined by Gavi rules and who stands to gain or lose. This leads to a variety of partnerships across applications, implementation activities, ICCs, and JA processes. In turn, the composition, structure, and roles of partnerships affect their effectiveness, efficiency, and country ownership/legitimacy.

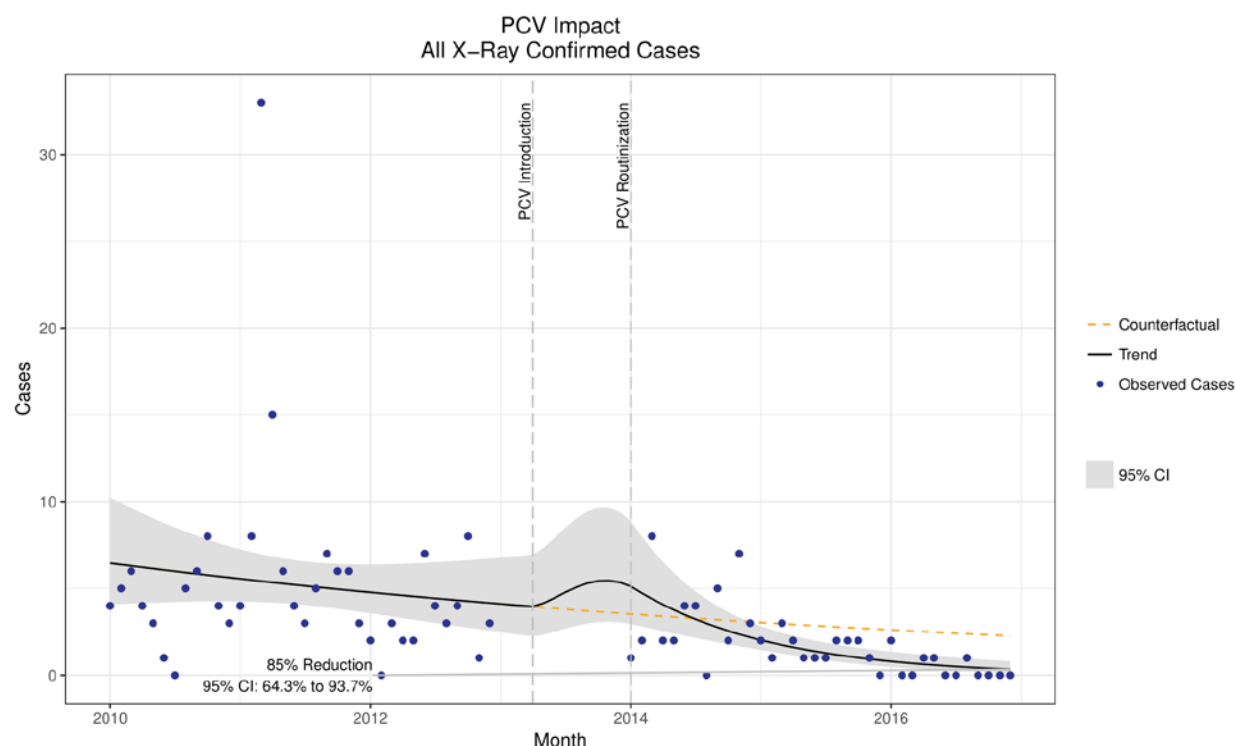
Summary of Full Country Evaluations, 2013–2016

Looking back and moving forward: using the FCE theory of change to describe drivers of sustainable and equitable coverage

In this final year of the first phase of the four-year prospective FCE, we take this opportunity to summarize what we have learned about the key global- and country-level drivers of sustainable and equitable vaccine coverage.

As covered in the section on NVI, between 2013 and 2016, the four FCE countries introduced a wide range of new vaccines into their systems, including: PCV (all), rotavirus vaccine (Zambia, Mozambique), MSD (Zambia, Mozambique), IPV (Bangladesh, Mozambique, Uganda), MR campaign (Bangladesh, Zambia), and HPV vaccine (Uganda nationally, demonstration projects in Bangladesh, Mozambique, and Zambia). Although success in routinizing these vaccines has been variable, these introductions have likely led to reductions in vaccine-preventable disease and child mortality, as has been the case for PCV introduction in Mozambique (Figure 23).

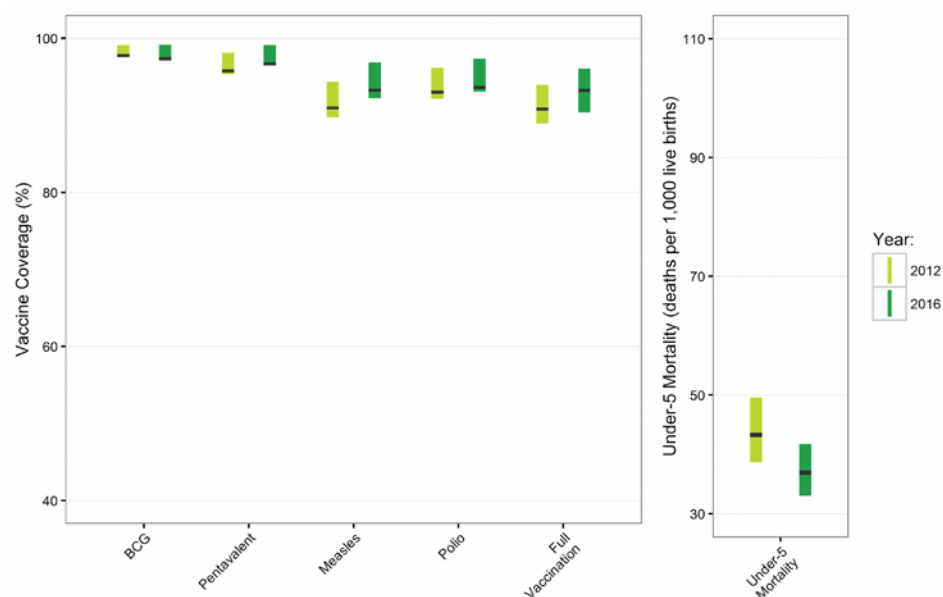
Figure 23: Impact of PCV vaccine in Mozambique, 2010–2016



Over the same time period, implementation of HSS – the primary mechanism for Gavi support to increase overall coverage and improve equity – was fraught with challenges (see the sections on HSS in this and previous reports). Our findings suggest that, in the case of Bangladesh, HSS likely contributed to improvements in vaccine coverage (see 2015 report for further details). Minimal implementation of HSS meant that the HSS window of support did not realize its potential in the other FCE countries. Our small-area estimates of vaccine coverage and child mortality showed that, over the period of the FCE, vaccine coverage improved at the national level. That said, geographic inequities in subnational coverage (as measured by the interquartile range by district [or subdistrict in Bangladesh]) remained more or less the

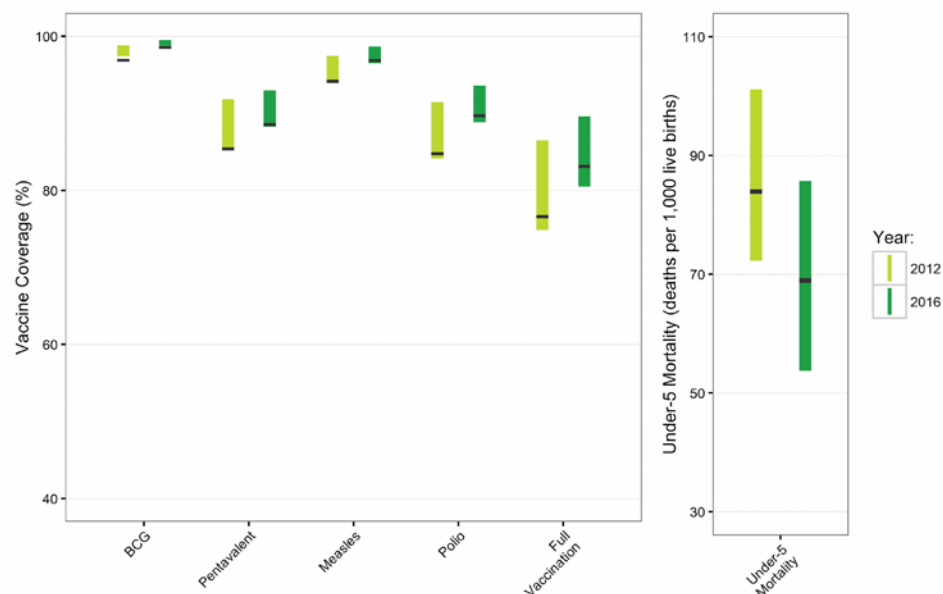
same in Bangladesh and Mozambique and somewhat worsened for children receiving the full vaccination schedule in Uganda and Zambia (see Figure 24 through Figure 27). In these figures, the black horizontal bar represents median coverage of full vaccination (fully immunized child), comparing 2012 (light green) to 2015 (dark green). The size of the green bars represents the interquartile range or difference between the first and third quartiles; a larger bar represents greater inequality.

Figure 24: Changes in vaccine coverage and geographic inequity in Bangladesh, 2012–2016*



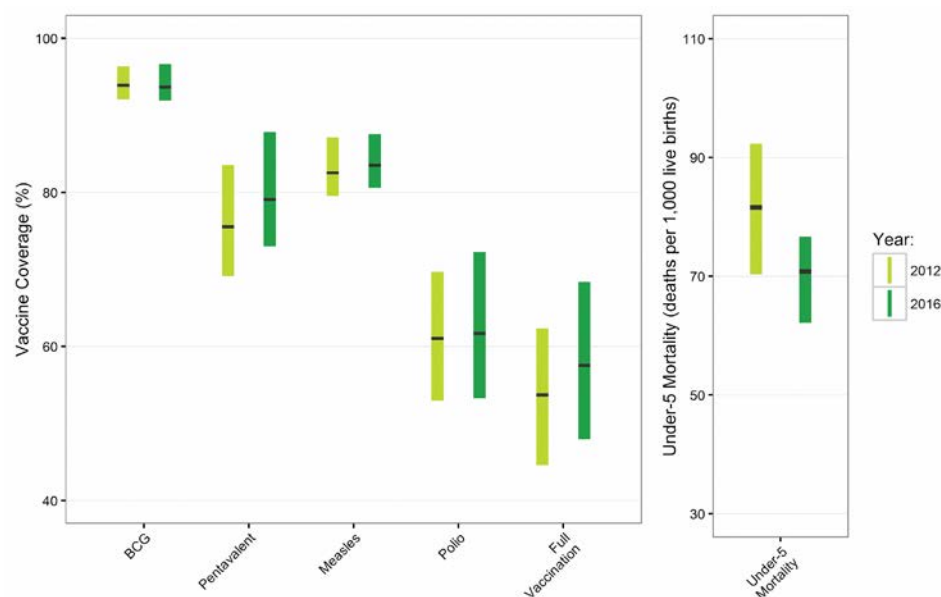
*Colored boxes indicate the interquartile range of coverage or under-5 mortality among all upazilas. Black dashes indicate the corresponding national estimate. Coverage represents the completed schedule for each antigen.

Figure 25: Changes in vaccine coverage and geographic inequity in Mozambique, 2012–2016*



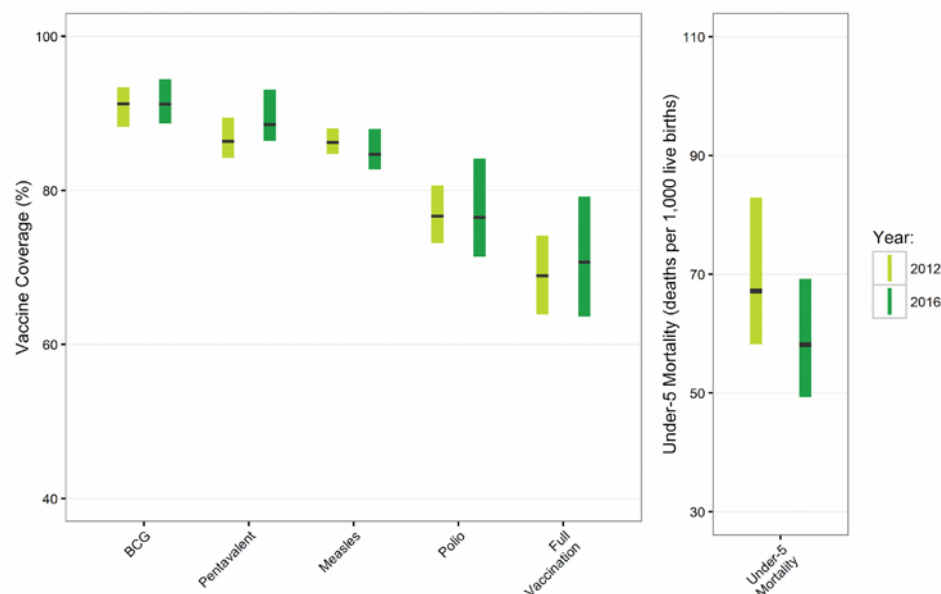
*Colored boxes indicate the interquartile range of coverage or under-5 mortality among all districts. Black dashes indicate the corresponding national estimate. Coverage represents the completed schedule for each antigen.

Figure 26: Changes in vaccine coverage and geographic inequity in Uganda, 2012–2016*



**Colored boxes indicate the interquartile range of coverage or under-5 mortality among all districts. Black dashes indicate the corresponding national estimate. Coverage represents the completed schedule for each antigen.*

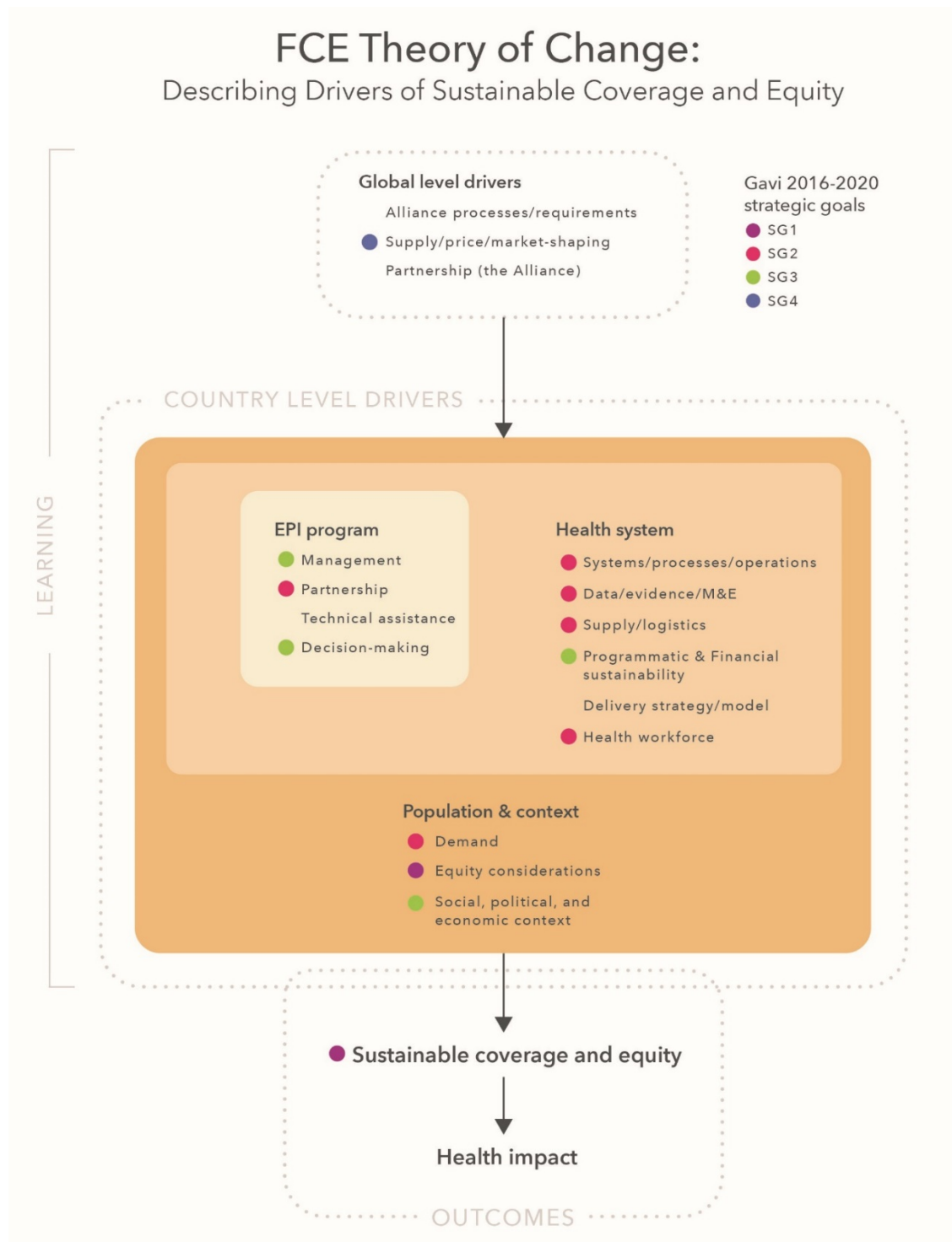
Figure 27: Changes in vaccine coverage and geographic inequity in Zambia, 2012–2016*



**Colored boxes indicate the interquartile range of coverage or under-5 mortality among all districts. Black dashes indicate the corresponding national estimate. Coverage represents the completed schedule for each antigen.*

To understand the drivers (many of which are cross-cutting) of this performance – both in terms of introducing new vaccines and, in line with the 2016–2020 Gavi strategy, improving coverage and equity – we propose a high-level conceptual framework (Figure 28) describing the drivers of sustainable and equitable coverage.

Figure 28: Gavi FCE theory of change.



Levels of drivers

At a high level, we observe that sustainable and equitable coverage is determined by drivers at the global, national, subnational, and community levels. The operationalization of Gavi's strategy has shifted – both “vertically” and “horizontally” – over the course of our evaluation. Vertically, we observe shifts in resources from the global and regional to country levels through the PEF. Moving forward, additional functions (e.g., IRC) will be devolved to the regional or country levels, and there is a growing rhetorical emphasis on country ownership. Yet, we also observe the growing role of SCMs and the Secretariat more broadly. Overall strategy and priorities are highly influenced by the Alliance Board, which has clear consequences in countries. Considering the changing nature of global politics and economies, investing in resilient and country-owned EPI programs is a strong bet toward sustainable coverage and equity.

Box 12: 2016 FCE recommendation

2016 RECOMMENDATION

This year we make a new recommendation for a specific way the Secretariat can ensure that Gavi systems, processes, and requirements are well translated from global to country level:

The Secretariat must ensure that SCMs, and other relevant teams and partners, have the appropriate technical capabilities, contextual knowledge, resources, and support that they need to implement the CEF, as they will be required to increase their level and complexity of engagement as compared to their current role.

The FCE also observed sideways shifts, both in *how* and *where* resources were allocated as well as *who* gained and lost. Over the course of the FCE, we observed changes in how HSS grants were targeted toward immunization versus broader health systems issues and more recent shifts in who received HSS funding, with more cash disbursed directly to partners (see the section Programmatic and financial sustainability, Finding 2). A growing positive emphasis on strengthening the capacity of EPI programs was counterbalanced by the continued resourcing of and reliance on TA.

Global-level drivers and trends

A common theme over the FCE was the consequences, often unintended, of **Alliance and Secretariat systems, processes, and requirements**. Their alignment, content, and implementation all influence whether they will help or harm progress toward increasing coverage. For example, slow HSS implementation, in part attributable to poorly aligned Gavi requirements (e.g., the timing of the PCA leading to delayed distribution of HSS funds to Zambia and Uganda), likely impeded potential increases in vaccine coverage during the FCE. A major finding of the 2014 report, echoed in 2015, was how the design of HPV vaccine demonstration projects constrained real opportunities for learning. The Secretariat and partners used these findings to inform the HPV program's redesign in 2016. Indeed, Gavi is listening. Newer processes (JA, PEF, grant performance frameworks, HSIS) include explicit principles related to strengthening country ownership and reducing complexity.

At the global level, vaccine **price and supply** influenced countries' access to vaccines, while Gavi's **market-shaping** efforts were an important prerequisite to vaccine availability at points of delivery. From the country-centric lens of the FCE, rarely did global-level market dynamics impede country-level vaccine delivery – with the notable exception of IPV global supply in 2015–2016.

Historically, the **Alliance partnership** has provided the blueprint for both operational and governance structures and functions. Evaluating "the" partnership was an original FCE evaluation question, but teams quickly observed that while there may have been a conceptualization of a single partnership at the global level, the way in which "partnership" as concept, input, and output translated to countries was highly variable. The global Alliance partnership certainly affects coverage by informing Alliance priorities and activities, but the real added value of partnership is likely best observed in countries, where organic networks and alliances shift with changing resources and needs. At the global level, the partnership shifted over time from a looser alliance based on mutual goals and leveraging comparative advantages to a more contractualized model with shifting power among actors. The single largest influencer was the PEF, which forced necessary shifts but also affected trust. As the Alliance partnership continues to change, much can likely be learned from how national-level partnerships have built their legitimacy, resilience, and trust over time.

Box 13: 2016 FCE recommendation

2016 RECOMMENDATION

Echoing our recommendations from 2015, we continue to encourage Gavi, partners, and countries to further invest in concrete and user-friendly tools and processes that support evidence-informed assessments of immunization bottlenecks (e.g., in the way that Spectrum modeling software is used to inform concept notes to the Global Fund to Fight AIDS, Tuberculosis and Malaria). Such tools and processes should be comprehensive and harmonized across HSS, the HSIS/CEF, and PCA and JA processes.

Expanded Program on Immunization program-level drivers and trends

The EPI program is the critical decision-maker, planner, and implementer of all vaccines and the gatekeeper for many other drivers of coverage. That said, the EPI program exists within broader health system, socioeconomic, and behavioral contexts. Over the course of the FCE, we identified program and financial **management** as a necessary condition for an effective program, yet also as one of the most persistent bottlenecks to success. Weak capacity across countries, at various times and for various activities, led to delays or inefficiencies (e.g., HSS planning and implementation in Mozambique, understaffing at subnational levels in all countries, and lack of midlevel managers' training in all countries). Although TA funded through HSS or PEF-TCA was used to fill these gaps, sustainable, long-term solutions are needed. Indeed, in-country leadership, management, and coordination are highlighted by Gavi as "strategic enabler[s]" – i.e., critical elements – necessary to achieve Gavi's strategic goals.

Leadership and management of an EPI program also require a high level of strategic-thinking, priority-setting, and **decision-making** capacity, particularly in the context of many new vaccines and growing program costs. We observed persistent limitations in countries' and partners' abilities to systematically identify and prioritize the most important decision-making bottlenecks, and then to systematically identify and prioritize investments to address them. Part of this inefficiency will always be due to politics, but a significant proportion of the loss in technical and allocative efficiency of investments could be remedied by guidance from Gavi on how to identify problems and what works to fix them. As more of these decisions are delegated to the country level, we expect to see prioritization and decision-making capacity in countries continue to improve over time.

Decision-making functions also depend on strong institutions and processes, whether native to the country or in existence because of Gavi requirements. Over time, we observed an improvement in NITAG functioning and effectiveness. Uganda is a promising example, in which the government has tapped the NITAG to advise on new vaccine introduction decisions in light of financial sustainability concerns. Whether due to the role of the FCE or to other factors, countries seem to be paying increased attention to the effectiveness of their ICCs. Strengthening these bodies will enable sustainable and country-led decision-making in the future.

As noted above, country-level **partnerships** are central in facilitating improved vaccine coverage in FCE countries. Partnerships are highly dynamic. This was observed through partnership network mapping in Uganda, which compared their relatively small and effective HPV vaccine application team in 2014 to their larger HSS-2 application team in

2016. We observed trade-offs across various partnership structures – efficiency sometimes occurred at the cost of legitimacy and country ownership, for example – suggesting that there is no "one size fits all" partnership, but rather a set of principles to guide certain objectives. The underlying source of all partnerships' performance is trust. Subsequent opportunities to work together strengthened the trust among partners. Trust and positive relationships resulted in efficient and effective processes, as well as partners who step up to fill resource gaps (for example, Zambia partners filled gaps to prepare for the MR campaign when HSS funds were delayed). Growing leadership and empowerment of EPI managers to lead the partnership benefitted all members and contributed to strengthening the EPI programs.

The FCE observed large shifts in how **technical assistance** was conceptualized and then funded during our evaluation period. In early years, we were aware that the Business Plan model of funding TA was not transparent or country-owned: It did not include mechanisms for monitoring TA outputs and holding TA providers accountable for their deliverables. The introduction of the PEF changed the process of identifying, funding, and implementing TA. We wrote extensively in 2015, and again this year, that these principles are

pointed in the right direction but that, ultimately, success will be measured through the ability of TA to develop sustainable and long-term skills transfer and capacity building. While TA may always have a role

Box 14: 2016 FCE recommendation

2016 RECOMMENDATION

Gavi should require TCA providers to outline their explicit approach to capacity building and skills transfer, define how to measure progress in capacity building, and hold TA providers accountable for capacity building by having them report on these measures/indicators.

Box 15: 2016 FCE recommendation

2016 RECOMMENDATION

Gavi should update suggested roles and functions of ICCs to capture new strategic goals and the changing landscape of immunization programs. Country ICC TORs should be updated to reflect these. Moreover, ICCs themselves should be strengthened to include the right people and skills, as well as to ensure that these people are at the right level of authority and have the appropriate level of resources, including perhaps a dedicated secretariat for a country's ICC. These reforms will ensure that these bodies serve as more than a rubber stamp on Gavi applications. In November 2016, Gavi provided new guidance and tools on ICC membership, mandate, and governance.

in filling specific gaps in the EPI program, Gavi-funded TA should not become a substitute for a strong national program. We applaud the efforts of countries such as Mozambique and Uganda, which are developing frameworks for TA and partner involvement. Thereby, these countries acknowledge that if roles that historically were played by the public sector were to shift elsewhere, the government should be in the driving seat of these shifts.

Health system drivers and trends

The EPI program works within a broader health system with **processes and operations** that impact the effectiveness and efficiency of EPI activities. These include financial systems to receive Gavi funds and distribute them subnationally, procurement systems often required for HSS, and human resources rules and regulations. The FCE identified challenges with the bureaucratic, protracted processes in these systems that were not taken into account in operational plans and delayed the use of HSS funds in Uganda and Mozambique. In extreme cases, Gavi required diverting funds away from government systems to mitigate risk (e.g., in Uganda for HSS-1, meningitis A, and HSS-2).

The timely use of high-quality, relevant **data** can inform programmatic decision-making, ultimately leading to improved immunization coverage. Systems to capture and report data are expanding and improving, but use remains weak in most FCE countries, largely due to root causes related to technical capacity at lower levels and the lack of a data-use culture. Data quality is also a persistent challenge, particularly in relation to routine HMIS data, the validity of which suffers due to challenges in estimating true population catchments or denominators. Across the FCE, incorrect denominators affected supply and stock processes, leading to stockouts (e.g., in the Zambia MR campaign, described in Box 2). Even when data or evidence were available in time to inform decisions (as was the case for the small-area estimates produced by the FCE), they were not always used.

In order to achieve coverage and equity and sustain population demand, the health system must deliver the sufficient vaccine **supply** to the right place at the right time throughout the country. The FCE identified challenges in forecasting, in-country distribution, stock management, and cold chain capacity. These challenges had multiple root causes, many of which overlapped with other drivers in the theory of change and were often exacerbated by the rapid increase of new vaccine introductions – and, thus, supply and cold chain requirements. Of note, many HSS grants address supply, but it is not always clear whether HSS-funded cold chain and supply activities happen in time (see the experiences of Uganda, Mozambique, and Zambia) to support progress toward increased coverage, or whether they are designed to target the most pressing needs (as in Mozambique, for example). For certain vaccines, a readiness assessment was added as a global-level response, but this also led to delays in getting sufficient supply to the country. The new Gavi-funded Cold Chain Equipment Optimization Platform, which commits an initial \$US 50 million, underscores the importance of a functioning cold chain to sustaining vaccine supply.

Programmatic and financial sustainability are necessary to ensure long-term maintenance of equitable coverage. While sustainability is one of Gavi's strategic goals, and represented in our theory of change as part of the desired impact of Gavi support, the ongoing processes related to ensuring sustainability are health system functions that must be owned by country governments. During the FCE, we observed many instances of unsustainable decision-making (e.g., HSS activities that cannot be sustained past the

HSS grant; new vaccine introductions that are unlikely to be sustained; HPV vaccine delivery models that may not be financially sustainable, etc.).

Broader macroeconomic declines further threaten the financial sustainability of the EPI in countries such as Mozambique and Zambia.

While we observed growing attention paid to the cost-effectiveness of specific vaccines, governments still

demonstrate minimal awareness regarding the comparative cost-effectiveness of interventions across their health programs or their EPI program's long-term costs. We caution that the limited attention paid to planning should be addressed sooner rather than later. Promising steps were made in Uganda, for example, with their immunization financing bill and the NITAG's careful attention to financial sustainability issues.

Box 16: 2016 FCE recommendation

2016 RECOMMENDATION

Building on recommendations from 2015, Gavi, countries, and partners should ensure more scrutiny of financial sustainability considerations in decision-making, particularly in Phase I (preparatory) transition countries. Further checks and balances can be established as part of existing entities, e.g., NITAG and ICC.

Box 17: Dried blood spot analysis results

DRIED BLOOD SPOT ANALYSIS RESULTS

During the Gavi FCE household surveys, a subset of children (2,117 in Mozambique; 1,138 in Uganda; and 970 in Zambia) were randomly selected for dried blood spot (DBS) sampling. Trained health workers absorbed five drops of blood from consenting participants onto specially designed filter paper following a finger prick. Blood spots were dried and sent to a laboratory for antibody testing. Antibodies examined were those related to hepatitis B (three separate antibodies) and tetanus (IgG). (Laboratory methods and data processing methods are described in Annex 4.) The DBS results allowed us to assess which vaccinated children actually gained immunity and which did not.

Based on the DBS results, in Uganda 49.1% of children were immune to hepatitis B and 95.6% were immune to tetanus. In Mozambique, 92.1% of children were immune to tetanus (hepatitis B results were not procured in time for this report). In Zambia, 56.8% of children were immune to hepatitis B and 86.8% were immune to tetanus. According to control samples, sensitivity and specificity were to be higher for tetanus than hepatitis B.

We then compared the DBS results to children's pentavalent vaccine status ("vaccinated" being defined as receiving three doses, according to either maternal recall or vaccine card). The table below shows the percentage of vaccinated children who successfully gained immunity in each country. We caution against interpreting these as estimates of vaccine effectiveness, as the study was designed to measure seroprevalence, not effectiveness.

Percentage of vaccinated children successfully immunized, by country and antigen

	HBsAb	Tetanus IgG
Uganda	50.5	96.2
Zambia	59.5	87.9

We report for the first time in 2016 on the growing proportion of Gavi cash support disbursed directly to partners instead of country governments. We suggest that this trend, and its potential consequences on long-term sustainable coverage and equity, be thoroughly debated at all levels.

The **delivery strategies** employed by countries' health systems, including fixed, outreach, and supplementary components, contribute to *how many* and *which* children receive their essential vaccines. Over the course of the FCE, we observed a mix of routine immunization delivery, supplemental campaigns (e.g., MR, polio), and school-based models (for HPV vaccine). The choice of delivery strategy was most notable in the HPV vaccine demonstration projects in FCE countries, for which we observed trade-offs between delivery strategies that achieved high coverage but were not financially sustainable.

In order to have a functioning health system that is able to achieve high vaccine coverage and equity, an adequate **health workforce**, in terms of quantity and skills, is needed at all levels, from the national MOH and EPI program that manage the immunization program down to the frontline health workers delivering vaccines to children. At the national level, the FCE observed that EPI teams were often overburdened by the processes and requirements of Gavi and other donors, which limited their time for strategic planning and adaptive management. Although TA was put in place to support the EPI teams, TA partners did not consistently build capacity and transfer skills. At subnational levels, the Uganda FCE team observed that health care workers' workloads increased as multiple new vaccines were introduced into the system. Although adding vaccines may increase workloads, in some cases, countries leveraged new vaccine introductions as an opportunity to provide refresher trainings to health care workers – not only for new vaccines but also for existing vaccines in the delivery system.

Population and context drivers and trends

Population demand is a necessary condition for coverage and was identified as the most significant driver of vaccine coverage, as measured through the constraints analysis in a subset of FCE countries (Uganda, Zambia; see Box 3). Demand-side variables are not independent of supply; a strong and predictable supply will strengthen beneficiaries' trust in and utilization of the health system. Demand is an important driver of equity, with intergroup variations in vaccine confidence, attitudes, and beliefs driving inequity in many countries. We observed some very positive examples of demand (e.g., high demand and enthusiasm for HPV vaccine in Uganda) and effective demand-side interventions (e.g., effective IPC in Bangladesh and an overall high level of trust for the health system there drove high coverage). We also observed that suboptimal awareness led to low demand and, thus, low coverage (e.g., MSD in Mozambique, HPV vaccine demonstration in Zambia). While it is difficult to tell if overall demand is increasing or not, Gavi's strategic focus on equitable coverage necessitates renewed attention to the types of issues, and corresponding interventions, that address demand. As highlighted by our small-area estimates of vaccine coverage, geographic pockets of low vaccine coverage exist across all four FCE countries (see Figure 29 through Figure 32). This suboptimal coverage seems to be driven primarily by low demand (see Box 3).

Figure 29: Full vaccination coverage by *upazila* in Bangladesh, 2016

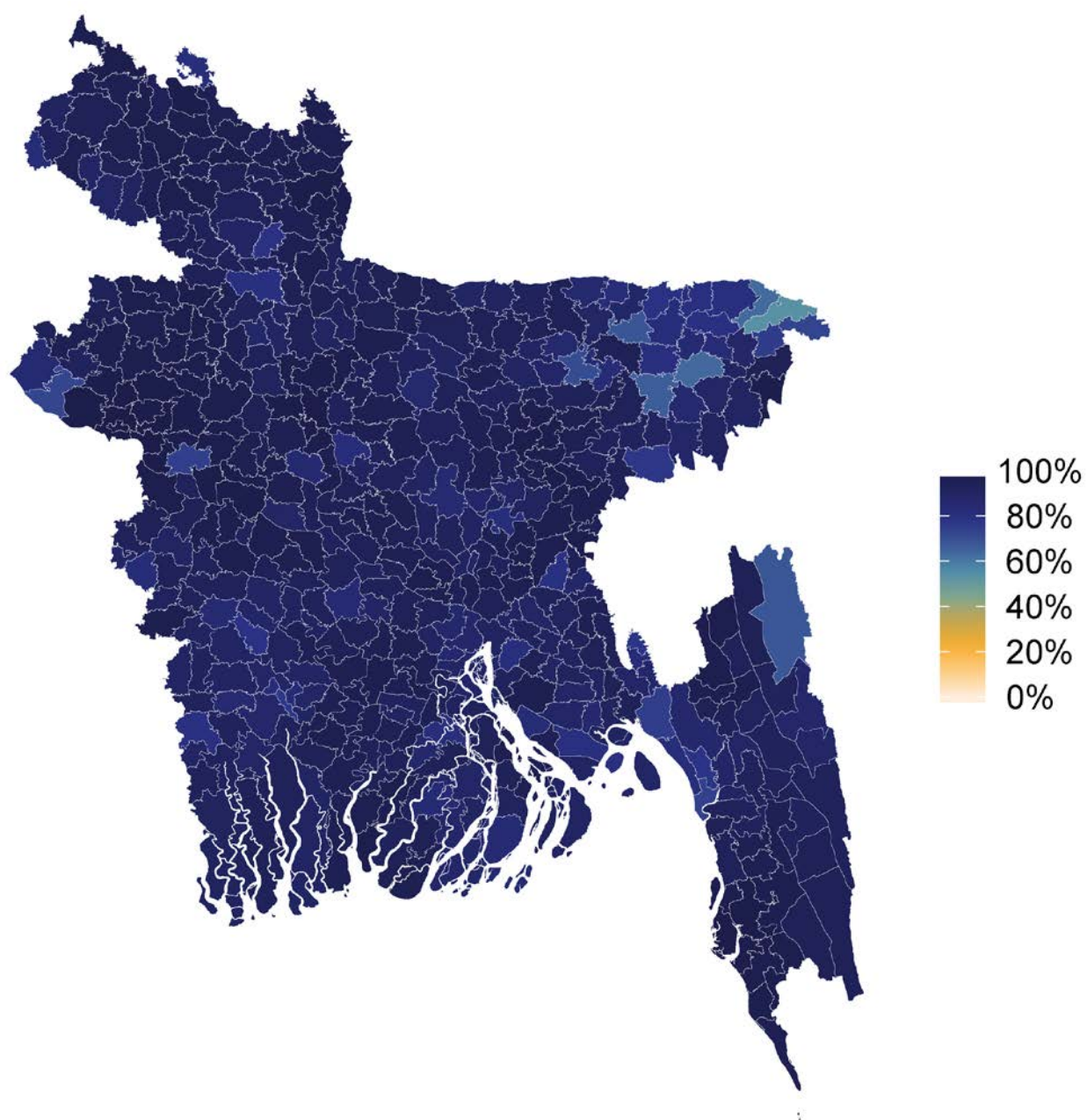


Figure 30: Full vaccination coverage by district in Mozambique, 2016

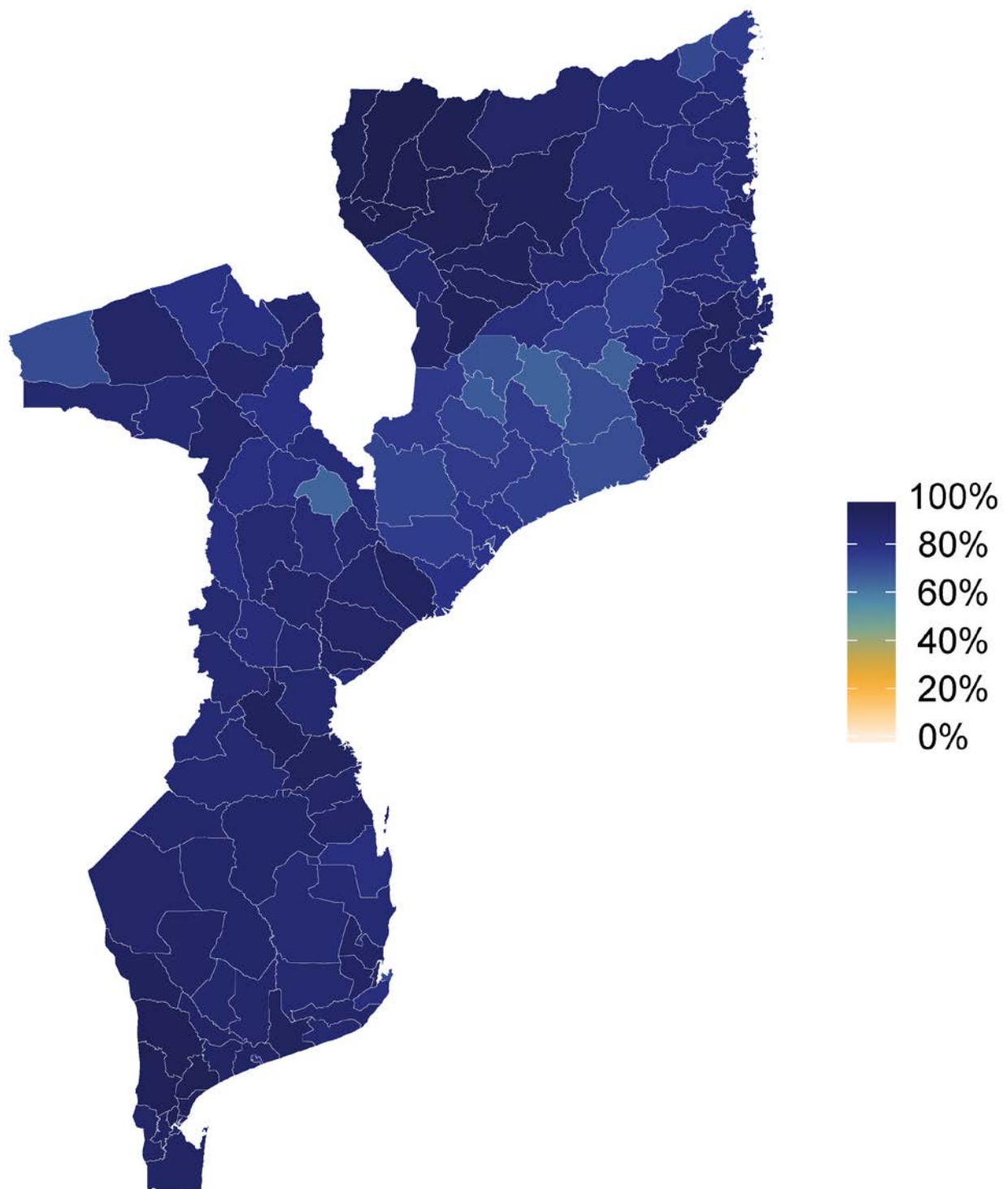


Figure 31: Full vaccination coverage by district in Uganda, 2016

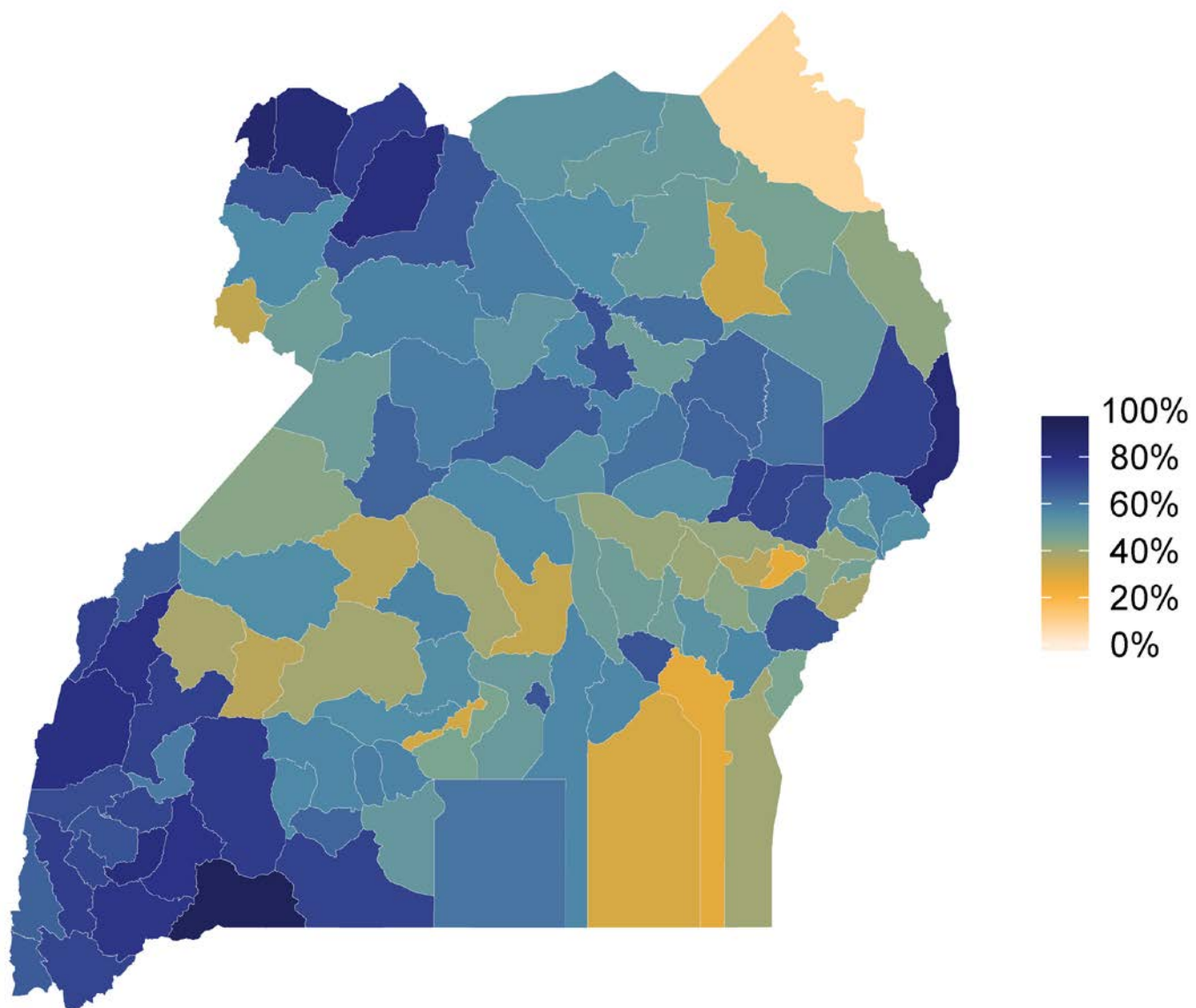
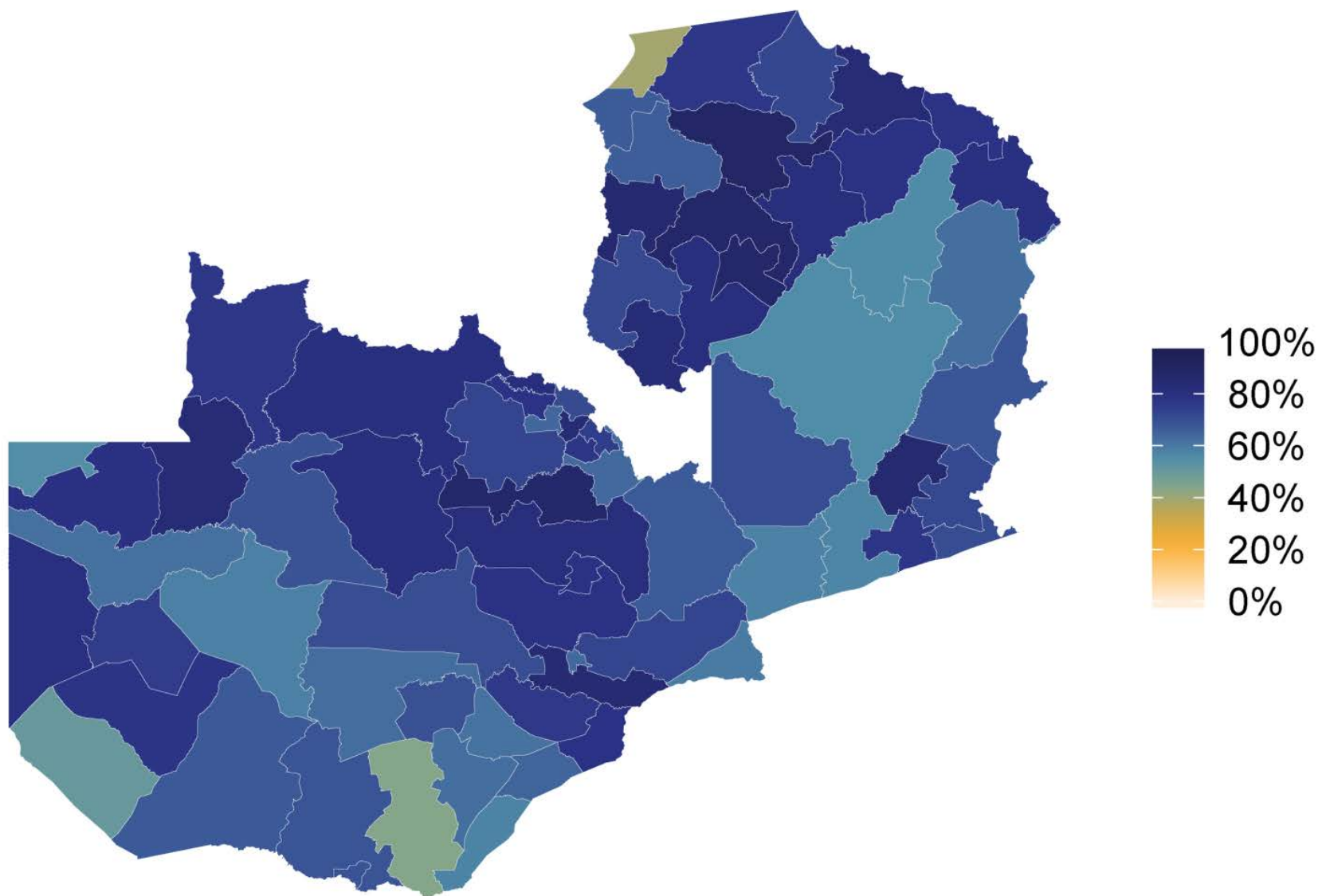


Figure 32: Full vaccination coverage by district in Zambia, 2016



At the population level, vaccine coverage is largely influenced by the broader **social, political and economic contexts**. Throughout the FCE, we observed the influence of changing leadership and election cycles, political instability, and macroeconomic shifts, among other contextual shifts. These contextual factors play out through the global- and country-level drivers outlined above, and ultimately influence vaccine coverage and equity in countries. An added value of the FCE platform – not one to be underestimated – is the ability to contextualize the coverage and equity changes (or lack thereof) that we observe over time.

Learning

The theme of learning cuts across all levels and has emerged as an important condition for improving equitable coverage. We applaud Gavi's efforts, as a "learning organization" over the course of the FCE, to learn from FCE findings and adapt accordingly. We report on many positive developments (for example, the HPV 2.0 policy, HSIS and CEF, and the refinement of PEF over time) related to strategic and operational shifts, and a growing culture of measurement in the Secretariat. The Gavi Board and Alliance donors must create an environment that encourages learning (and occasional failure) to occur at the Secretariat, among partners, and in countries. This is in line with Gavi's original principle of encouraging catalytic innovation, but it has perhaps been diluted in recent years by the growing interest of donors and other stakeholders in Gavi's outcomes and in how donors' investments are managed. This shift in approach can be felt in countries, as in, for example, the case of the PCA. The FCE recommends that Gavi align incentives in ways that enable a culture of learning and adaptive management in countries, while still ensuring accountability for outcomes.

Summary of findings and recommendations

The table below summarizes the findings and recommendations of the 2016 Gavi FCE.

Table 10: Summary of 2016 FCE findings and recommendations

Report Section	Finding	Recommendation(s)
New Vaccine Introductions	Finding 1: FCE countries have improved the routinization of new vaccines over time, although there has been variable success across countries in the medium to long term. The underlying root causes are highly variable and emphasize the importance of post-introduction monitoring and evaluation. Robustness of finding: B	1. We reiterate our 2015 recommendation for countries, Gavi, and partners to enhance post-PIE monitoring and evaluation of new vaccines, particularly if routinization at the time of the PIE is noted to be suboptimal. This could include activities such as placing greater scrutiny on HMIS data, conducting supervision visits to districts and facilities, as well as leveraging existing performance frameworks and the JA process with explicit linkages to Targeted Country Assistance (TCA) as a mechanism for investigating and identifying solutions. In parallel, strengthening the data-use culture and capacity in EPI programs is needed to make enhanced monitoring and evaluation of new vaccines sustainable. 2. Gavi should consider countries' past performance in introducing new vaccines and how countries intend to address previous bottlenecks as part of the approval process for new vaccine support.
	Finding 2: In Mozambique, evidence from multiple vaccine-effectiveness studies suggests that the introduction of PCV in 2013, which was rapidly routinized in the country, has reduced nasopharyngeal carriage of vaccine-type pneumococcus and reduced the incidence of vaccine-type IPD and pneumonia. In Bangladesh, we also observed reductions in vaccine-type pneumococcal carriage among children who were age-eligible for PCV, but not among age-ineligible children. Our analysis of child mortality changes at	

	the subnational level also suggests that new vaccine introductions have impacts on child mortality. Robustness of finding: A	
	Finding 3. Mozambique and Zambia have been delayed in introducing human papillomavirus (HPV) vaccine nationally. Moreover, there was an interruption in vaccine delivery in demonstration sites. The main root causes were concerns about financial feasibility and limited ownership by the EPI program. The Bangladesh demonstration program highlighted some of the challenges previously experienced, including financial feasibility and the timeliness of evaluation products to inform year two delivery. In Uganda, where HPV vaccine was introduced nationally in November 2015, the rollout was slow and varied, with 83.37% of eligible girls reported to have received one dose and 22.75% of eligible girls reported to have received two doses of HPV vaccine by December 2016. Gavi is revising the HPV vaccine window of support, which has the potential to address some of these challenges. Robustness of finding: B	In developing the HPV 2.0 policy and process further, we recommend that Gavi and partners provide clear guidance coupled with strong TA to facilitate implementation of phased introductions. This should include aspects ranging from introduction planning, monitoring and evaluation, and systematic processes for capturing learnings from phased introductions as well as from other countries.
Health System Strengthening	If designed appropriately to target the most critical bottlenecks, HSS investments have the potential to add immense value. However, in FCE countries, we have found that regardless of design, the many complexities associated with implementation of these grants (for example, responding to Independent Review Committee [IRC] feedback, the PCA, and Grant Management Requirement [GMR] during the post-approval process) undermine this potential at all phases of the grant life cycle. These challenges diminish the predictability of Gavi HSS	1. The Secretariat should ensure that HSS decision letters include next steps, timing of those next steps, and responsibilities of various actors, as well as the PCA process and any conditions. Gavi should make decision letters available in a timely and accessible manner by putting them on the country portals and Gavi website so that all relevant stakeholders have access. 2. Echoing our recommendations from 2015, we continue to encourage Gavi, partners, and countries to further invest in concrete and user-friendly tools and processes that support evidence-informed assessments of immunization bottlenecks (e.g., in the way that Spectrum modeling software is used to

	funds and, in some cases, the relevance of the design of the grant. Robustness of finding: B	inform concept notes to the Global Fund to Fight AIDS, Tuberculosis and Malaria). Such tools and processes should be comprehensive and harmonized across HSS, the HSIS/CEF, and PCA and JA processes. 3. The Secretariat must ensure that SCMs, and other relevant teams and partners, have the appropriate technical capabilities, contextual knowledge, resources, and support that they need to implement the CEF, as they will be required to increase their level and complexity of engagement as compared to their current role. 4. Many countries (including the FCE countries) with existing HSS grants will not benefit from the full suite of HSIS/CEF reforms in the short term, although some elements will apply to all countries. Gavi should clarify this situation and how to access certain elements, as there is limited understanding at the country level about these reforms and the potential implications.
Leadership and management	In 2016, we observed multiple, overlapping root causes of suboptimal program management. The most actionable short-term root cause was the cumulative burden of Gavi and other partners' processes and requirements. While no individual process itself represented an undue burden on EPI programs, the combined effect of those processes constrained EPI programs' ability to stay on top of day-to-day program needs. Robustness of finding: B	1. Gavi and other partners should coordinate and align their country missions to avoid burdening EPI programs and in-country partners. The Gavi Secretariat should explore potential synergies between JA, PCA, audit, and other similar processes. Secretariat and Alliance partners should communicate planned activities and missions, with general time lines, at the start of each year to country stakeholders. 2. Gavi should update suggested roles and functions of ICCs to capture new strategic goals and the changing landscape of immunization programs. Country ICC TORs should be updated to reflect these. Moreover, ICCs themselves should be strengthened to include the right people and skills, as well as to ensure that these people are at the right level of authority and have the appropriate level of resources, including perhaps a dedicated secretariat for a country's ICC. These reforms will ensure that these bodies serve as more than a rubber stamp on Gavi

applications. In November 2016, Gavi provided new guidance and tools on ICC membership, mandate, and governance.

3. See HSS recommendations three and four (page 45, above):

- The Secretariat must ensure that SCMs have the appropriate technical capabilities, contextual knowledge, resources, and support that they need to implement the CEF, as they will be required to increase their level and complexity of engagement as compared to their current role.
- Many countries (including the FCE countries) with existing HSS grants will not benefit from the full suite of HSIS/CEF reforms in the short term, although some elements will apply to all countries. Gavi should clarify this situation and how to access certain elements, as there is limited understanding at the country level about these reforms and the potential implications.

Finding 2: Implementation of the PCA in Uganda and Zambia, early pilot countries in 2016, suggested that the process of implementing the PCA did not overburden countries, but it was a top-down approach that was perceived by country stakeholders to contribute to delays, particularly in obtaining funds from Gavi for HSS implementation. Robustness of finding: C

1. Gavi should improve the country ownership of PCA recommendations. This could be facilitated by:

- Selecting PCA consultants that are familiar with both country and Gavi contexts so recommendations are contextually appropriate;
- Using the PCA debrief (and/or other discussion venues such as the JA) as an opportunity to present PCA findings and to jointly develop recommendations with country stakeholders; and
- Sharing the PCA report with country stakeholders in a timely manner.

2. Gavi should ensure that the timing and design of the PCA is aligned with other Gavi activities in country so the PCA findings can inform HSIS proposals, JA discussions, and PEF-TCA requests. The PCA report should be made available to country stakeholders

		in a timely manner so that the findings and recommendations can be referenced to inform these discussions. • This is closely related to Recommendation 2 in the HSS section above, which highlights the need for tools and processes to support evidence-informed assessments of immunization bottlenecks – tools and processes that are harmonized across HSS, HSIS/CEF, and PCA and JA processes.
Technical assistance	PEF, particularly TCA, is an improvement over the Business Plan in its aim to achieve country ownership, transparency, and accountability. However, some phases of the process, particularly the PEF Management Team prioritization and funding of TCA activities, suffer from limited country ownership and transparency. PEF is designed to shift accountability of TA partners from the Secretariat to countries, although we acknowledge that this will take time to achieve in practice. The process for implementing PEF is ongoing, and certain lessons learned from 2016 should be considered moving forward. Robustness of finding: B	1. The Gavi Secretariat should use the theory of change developed for the ongoing Gavi TA to guide a discussion during the JA on the intended outputs, outcomes, and impacts of TA, including TA funded through the PEF-TCA. 2. Gavi should require TCA providers to outline their explicit approach to capacity building and skills transfer, define how to measure progress in capacity building, and hold TA providers accountable for capacity building by having them report on these measures/indicators. 3. We reiterate our 2015 recommendations to provide country stakeholders with a menu of TA approaches and systematically compiled map of TA providers. Recognizing that Gavi may not have exposure to all national or subnational TA providers, this activity should be done together with a range of country stakeholders or through an open solicitation process.
Programmatic and financial sustainability	Finding 1: Decisions to apply for Gavi support are not always undertaken with a full assessment of the implications on financial sustainability. In 2016, we observed that Gavi FCE countries had challenges in meeting cofinancing requirements, as well as concerns regarding the overall fiscal health of immunization programs. Robustness of finding: B	1. Building on recommendations from 2015, Gavi, countries, and partners should ensure more scrutiny of financial sustainability considerations in decision-making, particularly in Phase I (preparatory) transition countries. Further checks and balances can be established as part of existing entities, e.g., NITAG and ICC. 2. As covered in the section on HSS, Gavi should expand its fragile state policy by considering the application of the country-tailored

		approach and/or other emergency flexibilities to countries experiencing severe macroeconomic crises (e.g., Mozambique).
	Finding 2: An increasing amount and proportion of Gavi funds are flowing through partners and non-governmental sources, and there is increased reliance on non-governmental systems. The rationale for this trend includes risk mitigation and increased efficiency. We have noted short-term consequences for country ownership and flag potential consequences for long-term programmatic and financial sustainability should this trend continue. Robustness of finding: C	Gavi should formally assess whether it is actually more efficient in the short term to channel funds through partners versus government systems, and the long-term consequences of this trend on country ownership and sustainability. Gavi should also review other best practices in mitigating risk of financial mismanagement of donor funds, while still strengthening country systems.
	Finding 3: There is limited evidence that countries are planning or preparing for entering into the accelerated transition phase and subsequently graduating from Gavi support. There is limited guidance from Gavi on what countries should be doing in the pre-transition phase to ensure a smooth transition. Robustness of finding: B	We recommended earlier dialogue between countries, Gavi, and partners, including clearer guidance and processes for Phase I transition countries that could be implemented as part of the CEF. This ideally would include tools and local resources for assessing and planning for sustainability that should include lessons learned from other countries. This could be part of the sustainability SFA.
Alliance processes and requirements	Gavi changes are numerous and frequent. The Secretariat and partners must be aware of how these changes appear at the country level. We are seeing an effort to bring them together and to simplify, which may lead to increased short-term complexity. Robustness of finding: C	1. Gavi should continue to include country participation in Gavi-/global-/regional-level policy development and design processes. 2. Gavi should slow changes to policies and guidelines and ensure new policies/guidelines are monitored and evaluated so that Gavi and countries can learn from one year to the next. 3. See also the HSS section recommendations, above, regarding CEF.

The Alliance partnership

The global-level Alliance partnership has evolved over time based on changing Alliance and country goals. The single largest driver of change has been the process of designing and implementing the PEF, which has improved transparency and accountability but has also affected perceptions of the partnership's function, level of trust, and performance in countries. Based on global-level KIIs, the health of the Alliance partnership at the global level can currently be described as stable but with room for improvement. Robustness of finding: C

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