

# CROSS-COUNTRY

Findings from the 2015 Gavi Full Country Evaluations

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This report presents cross-country findings from the 2015 Gavi Full Country Evaluations (FCE), led by the Institute for Health Metrics and Evaluation (IHME) at the University of Washington (UW), in partnership with PATH in the United States; icddr,b in Bangladesh; University of Eduardo Mondlane (UEM), Health Alliance International (HAI), and Manhica Health Research Centre, Mozambique (CISM) in Mozambique; Infectious Diseases Research Collaboration (IDRC) in Uganda; and the University of Zambia (UNZA) in Zambia.

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.

This brief provides an overview of cross-country findings from the 2015 evaluation year; for full details, please refer to the Full Country Evaluations 2015 Annual Report, available on Gavi's website.

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# ABOUT the FCE

The Gavi Full Country Evaluation (FCE) is a prospective evaluation covering the period 2013-2016 that aims to understand and quantify the barriers to and drivers of immunization program improvement, with emphasis on the contribution of Gavi, the Vaccine Alliance in Bangladesh, Mozambique, Uganda, and Zambia. The mixed-methods evaluation is carried out by a consortium of institutional partners led by the Institute for Health Metrics and Evaluation (IHME) at the University of Washington (UW), in partnership with PATH in the United States; icddr,b in Bangladesh; University of Eduardo Mondlane (UEM), Health Alliance International (HAI), and Manhiça Health Research Centre, Mozambique (CISM) in Mozambique; Infectious Diseases Research Collaboration (IDRC) in Uganda; and the University of Zambia (UNZA) in Zambia.

## SCOPE OF EVALUATION

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 in the Gavi FCE countries. Table 1 summarizes the evaluation's scope during the 2015 period.

**Table 1:** Overview of funding streams evaluated in each country

	Bangladesh	Uganda	Mozambique	Zambia
<b>Health systems strengthening (HSS)</b>	Conclusion of HSS-1 grant and application for HSS-2	Implementation of HSS-1	Implementation of HSS-2	Application for HSS-2
<b>Human papillomavirus vaccine (HPV)</b>	Preparation for demonstration project	Preparation for national introduction	Year two of demonstration project	Post-demonstration project
<b>Inactivated polio vaccine (IPV)</b>	Preparation, launch, and post-introduction	Preparation for introduction	Preparation for introduction	Preparation for introduction
<b>Measles-rubella vaccine (MR)</b>				Application
<b>Measles second dose (MSD)</b>			Preparation for introduction	Post-introduction
<b>Meningitis A vaccine (Men A)</b>		Application		
<b>Rotavirus vaccine</b>		Application	Preparation for introduction and launch	Post-introduction
<b>Pneumococcal conjugate vaccine (PCV)</b>	Preparation, launch, and post-introduction	Post-introduction	Post-introduction	Post-introduction

# KEY findings

Each finding is accompanied by a ranking that reflects the robustness of evidence. The four-point ranking scale is summarized below. Each finding also has a generalizability ranking, denoted as High (\*\*), Medium (\*\*), or Low (\*).

Symbol	Ranking	Rationale
●	A	The finding is supported by multiple data sources (good triangulation) which are generally of good quality. Where fewer data sources exist, the supporting evidence is more factual than subjective.
●	B	The finding is supported by multiple data sources (good triangulation) of lesser quality, or the finding is supported by fewer data sources (limited triangulation) of good quality but is perhaps more perception-based than factual.
●	C	The finding is supported by few data sources (limited triangulation) and is perception-based, or generally based on data that are viewed as being of lesser quality.
●	D	The finding is supported by very limited evidence (single source) or by incomplete or unreliable evidence. In the context of this prospective evaluation, findings with this ranking may be preliminary or emerging, with active and ongoing data collection to follow up.

# NEW VACCINE introductions from 2013 to 2015\*

\*Implementation of HPV vaccine covered separately

**Figure 1:** Overview of new vaccine introduction in FCE countries, excluding HPV vaccine

## VACCINE INTRODUCED

- Pneumococcal conjugate vaccine
- Rotavirus vaccine
- Measles second dose
- Inactivated polio vaccine
- Measles-rubella campaign

\* We have not reported beyond preparatory activity. These will be detailed in the 2016 FCE report.

\*\* The 2014 Gavi FCE report covered the evaluation of the measles-rubella campaign in Bangladesh. Though we do not report further on the campaign evaluation, MR continues to be delivered through routine EPI.



## FINDING 1

Gavi FCE countries have successfully introduced a range of new vaccines. PCV has been fully routinized in Mozambique, and the first and second dose of PCV were rapidly scaled up in Bangladesh following the joint launch with IPV in March 2015. Challenges, however, persist. In Uganda, PCV delivery remains 11.6% below that of pentavalent vaccine, and in Zambia PCV and rotavirus vaccine remain 6.1% and 15.8% below that of pentavalent vaccine, respectively. Suboptimal routinization in both countries has been driven in part by vaccine stock-outs. In Bangladesh, third-dose PCV at the end of 2015 was not fully routinized, in part due to the use of an additional visit at 18 weeks for third-dose PCV rather than at 14 weeks when third dose pentavalent is given. IPV in Bangladesh also experienced suboptimal delivery due to stock-outs driven by higher than estimated wastage from multi-dose vials and inaccurate subnational target population estimates when forecasting of initial vaccine supply. This was addressed by the use of a multi-dose vial policy. ♦♦

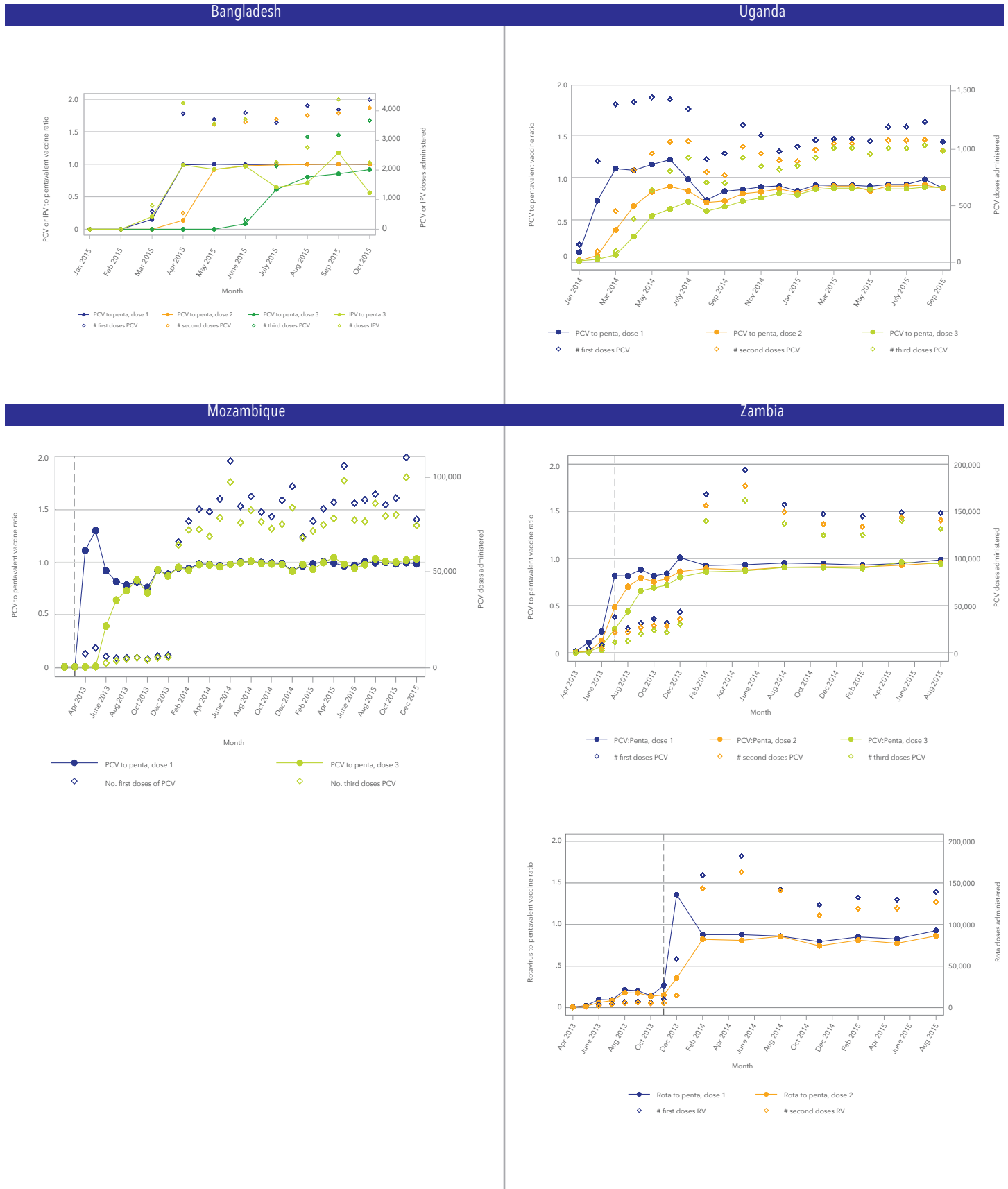
**Table 2:** Overview of country progress toward routinization of new vaccine launches

Summary of new vaccine routinization	
<b>Bangladesh</b>	<p>PCV and IPV were jointly launched in March 2015 in Bangladesh. FCE Health Facility Survey results and routine HMIS data (Panel A) suggest that PCV was rapidly scaled up to levels equivalent to pentavalent vaccine. However, third dose PCV delivery at the end of 2015 was still not fully routinized. A likely cause of this was the addition of a separate visit for the third dose of PCV at 18 weeks, rather than providing third-dose PCV at the same time of the pentavalent third dose at 14 weeks.</p> <p>The decline in IPV delivery (Panel A) was driven by widespread IPV stock-outs, with the Gavi FCE health facility survey showing that 57% of facilities reported stock-outs in the last quarter (Figure 2).</p> <p>IPV stock-outs were driven by higher than projected wastage for the five-dose vaccine presentation, estimated at 41%, compared to the projected wastage rate of 30% and inaccurate forecasting of vaccine supply at the subnational level.</p>
<b>Mozambique</b>	<p>PCV launched in April 2013, with delivery stabilizing at levels equivalent to pentavalent vaccine by the beginning of the second quarter of 2014 and has continued to be delivered at the same level as pentavalent vaccine.</p>
<b>Uganda</b>	<p>PCV launched in April 2013. By the end of 2015 PCV was not fully routinized. The PCV post-introduction evaluation (PIE) and the Gavi FCE health facility survey indicated that suboptimal PCV routinization in Uganda was initially the result of widespread stock-outs of PCV in the last quarter of 2014 (Figure 3). Later routinization challenges are tentatively linked to vaccine supply challenges and discrepancies between forecasted and supplied doses.</p>
<b>Zambia</b>	<p>Since their launch in April 2013, routinization of PCV and rotavirus vaccine in Zambia has stabilized, but that delivery remains lower than existing vaccines in the system, particularly for rotavirus vaccine. The less-than-full routinization is presently attributed to supply challenges between national and district/facility levels and challenges in forecasting vaccine supply needs.</p>

*i Three doses of both PCV and pentavalent vaccine are delivered to children on the same schedule, and pentavalent is already part of routine EPI delivery. Therefore, the ratio of PCV to pentavalent vaccine can describe routinization.*

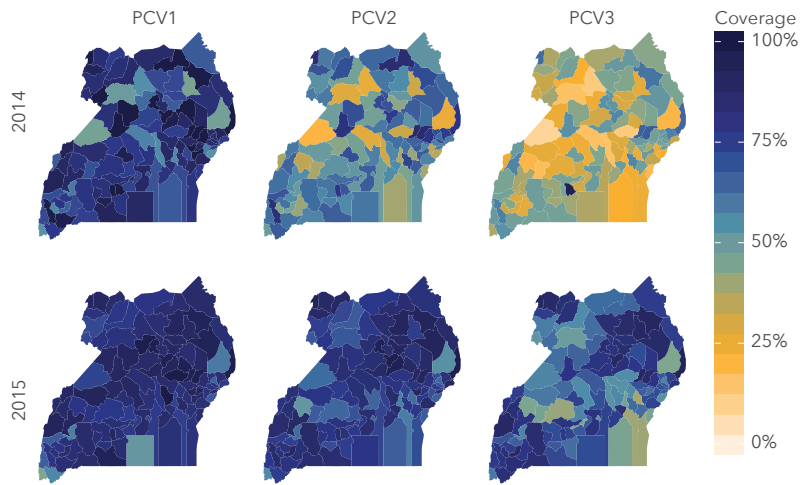
**Panel A:** Ratio of PCV and/or IPV to pentavalent doses reported to be delivered from HMIS

A ratio of 1 indicates that a new vaccine has the same number of doses delivered as pentavalent vaccine. The vertical dashed line indicates the month the new vaccine was introduced.

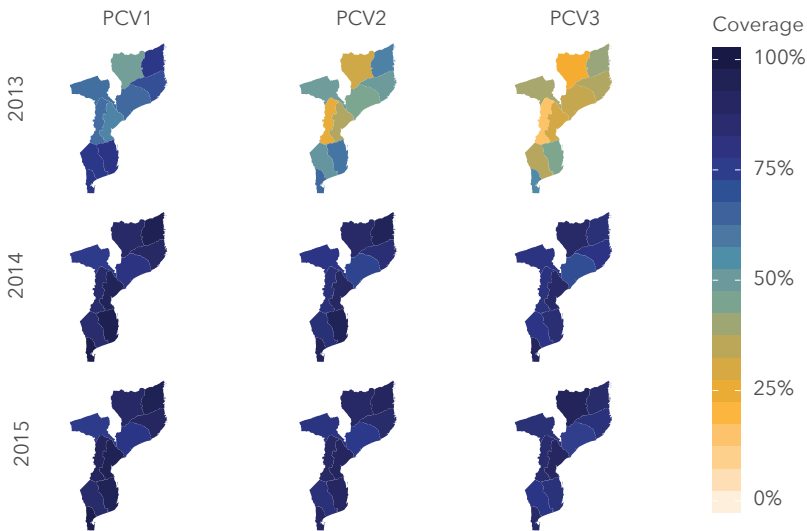


Panel B: PCV coverage estimates for all countries

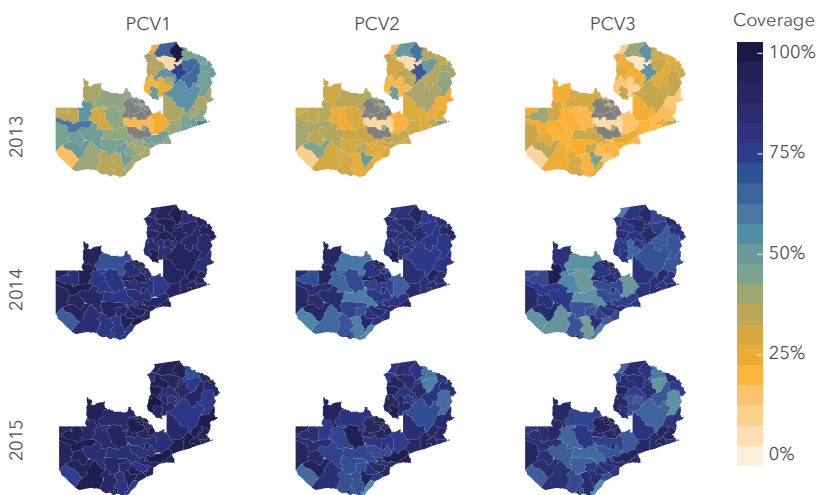
Uganda



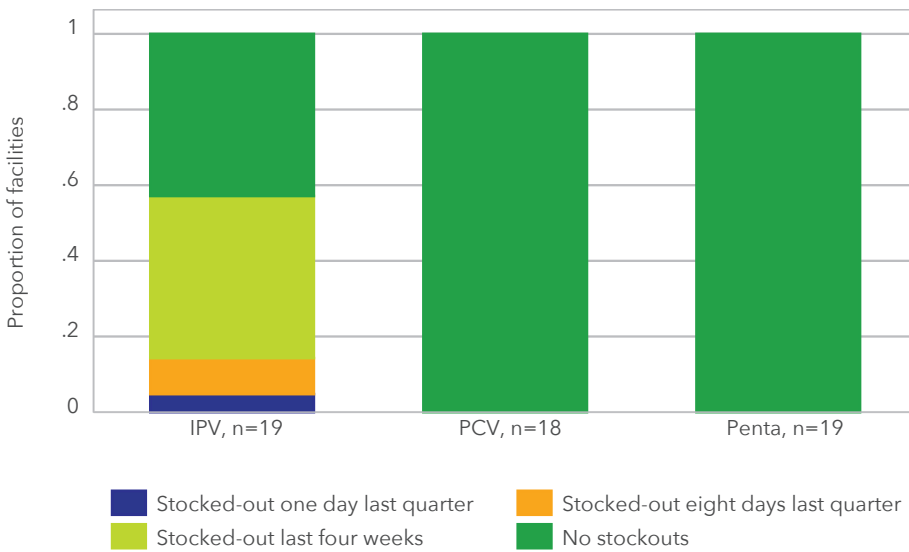
Mozambique



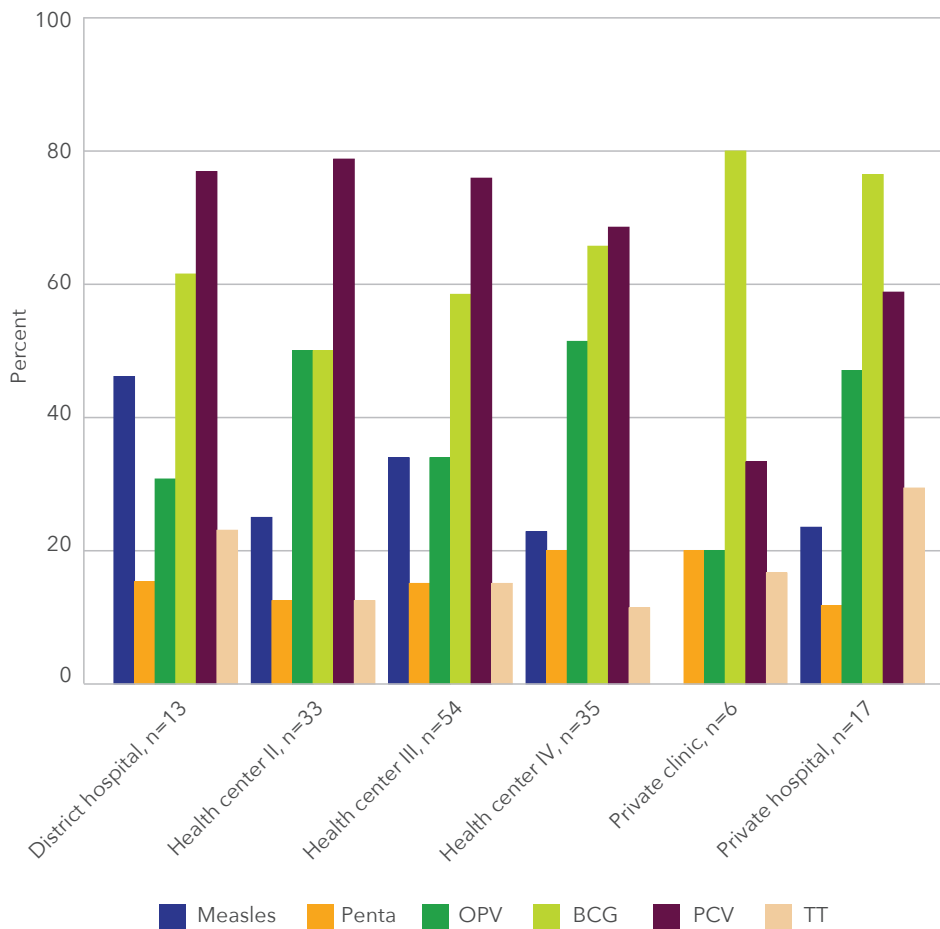
Zambia



**Figure 2:** Health facility survey reports of vaccine stock-outs for IPV, PCV, and pentavalent vaccine, Bangladesh, Q2 2015



**Figure 3:** Stock-outs reported by facilities for the approximate period of Q4, 2014, for all antigens (source: Uganda Gavi FCE Health Facility Survey)



**New vaccine introductions in Uganda and Zambia highlight the importance of ongoing monitoring of new vaccine introductions.**

- EPIs in Zambia and Uganda were generally unaware of less-than-full routinization of new vaccines.

## RECOMMENDATIONS

1. We recommend enhanced investments in the quality, timeliness, and use of data to facilitate ongoing monitoring and evaluation of new vaccine introductions beyond the PIE by Gavi, partners, and countries. Investments in EPI capacity to analyze and use data, broadly, are part of Gavi's Strategic Focus Area on Data but could further emphasize the importance of post-introduction monitoring.
2. Greater investments in denominator and target population estimation and better forecasting of vaccine supply, including wastage rates, at the subnational level are necessary to support smooth introduction of new vaccines. Investments in denominator and target population estimation are included as part of Gavi's Strategic Focus Area on Data.



## FINDING 2

Early-term findings from vaccine effectiveness studies, including nasopharyngeal carriage surveys pre- and post-PCV introduction (41%, 95% CI 6-69, reduction on PCV10 serotype-specific pneumococcal carriage among HIV-uninfected children receiving three doses of PCV; 61%, 95% CI 9-82, reduction on PCV10 serotype-specific pneumococcal carriage among HIV-infected children receiving three doses of PCV) and pre-and-post surveillance of invasive pneumococcal disease (72.5%, 95% CI 8 to 91.7, reduction in PCV10 serotype-specific invasive pneumococcal disease) suggest that the scale-up of PCV is reducing pneumococcal disease burden in Mozambique. (Robustness ranking: B; Generalizability: Medium). ♦♦

As part of the Gavi FCE, vaccine effectiveness studies of PCV are being conducted in Mozambique by CISM with support also from USAID and CDC.

### Pneumococcal nasopharyngeal carriage study

- **Direct effect of vaccine on burden among HIV-uninfected children and HIV infected children <5 years old**

A 41% (95% confidence interval [CI] 6, 69) reduction in pneumococcal carriage of vaccine serotypes (VTS) was observed among HIV-uninfected children receiving three doses. A 61% (95% CI 9, 82) reduction was observed in HIV-infected children receiving three doses.

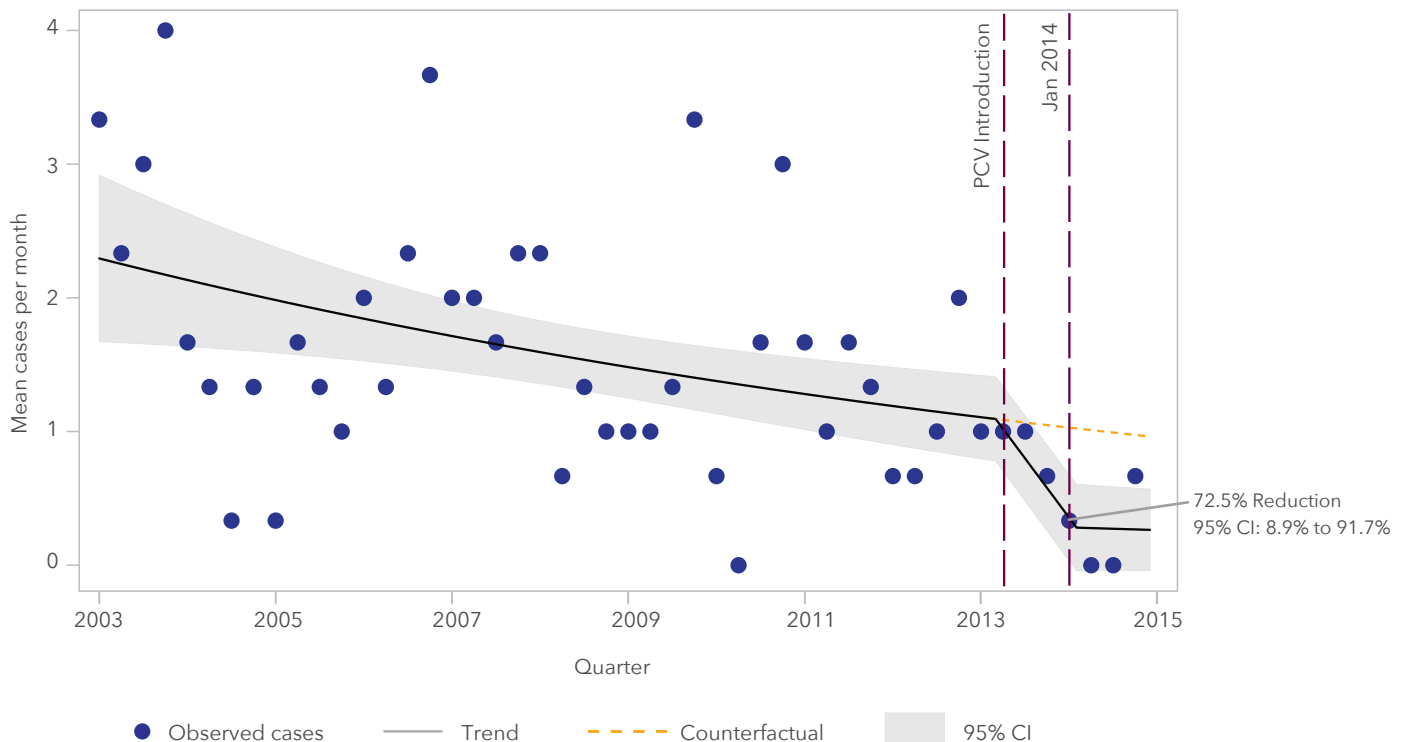
- **Early indications of indirect effect of vaccine on burden among HIV-infected children**

There was a 61% reduction (95% CI 9-82) among HIV-infected children receiving no PCV doses. There was an increase in pneumococcal carriage of non-PCV10 VTS, including serotypes in PCV13.

### Pre-and-post surveillance of invasive pneumococcal disease (IPD) in Manhica (Figure 4)<sup>ii</sup>

- **Reduction in vaccine type IPD.** There was a significant reduction of vaccine type invasive IPD (72.5%, 95% CI 8.0, 91.7).
- **There was a non-significant increase in non-vaccine type IPD (49.9%, 95% CI -30.1, 221.3).**
- **There was a non-significant reduction in x-ray-confirmed pneumonia (20.8%, 95% CI -43.1, 56.3) and overall IPD (25.8%, 95% CI -39.0, 60.4).**
- As expected, there was also an increase in pneumococcal carriage of non-PCV10 VTS, including serotypes in PCV13.

Figure 4: Trends in vaccine-type invasive pneumococcal disease in Manhica DSS



<sup>ii</sup>These preliminary results on vaccine effectiveness represent changes 18 months post-introduction and are based on observational studies.

# HUMAN PAPILLOMAVIRUS

## vaccine

The FCE continues to evaluate the implementation of HPV vaccine in various stages of implementation (Table 3).

**Table 3:** HPV vaccine implementation covered in the 2014 and 2015 FCE reports

	Bangladesh	Uganda	Mozambique	Zambia
2014	Application for demonstration project in September 2014, including demonstration site selection	Previously conducted demonstration and preparations to introduce HPV vaccine nationally in 2015	Completion of first year of demonstration project in three districts (one Gavi-supported)	Not covered
2015	Preparation for demonstration project	Ongoing preparation for and launch of national introduction on November 24, 2015	Implementation of second year of demonstration project	Implementation and completion of HPV demonstration project in Lusaka province (not Gavi-supported)

**Table 4:** Overview of supporting evidence from the FCE

Testing, refining, and comparing HPV vaccine delivery strategies with a view toward national introduction is a key goal of the demonstration project. In practice, this goal has been difficult for countries to achieve.		
	FCE evidence	Citation
Bangladesh	The country has yet to commence its demonstration project but plans to test a single school-based delivery model.	2015 FCE Bangladesh report, HPV finding 1
Mozambique	The country tested a single school-based approach in years one and two, but stakeholders recognize that the model is unlikely to be affordable for national introduction.	2015 FCE Mozambique report, HPV finding 1
Uganda	The country tested a school-based model but later shifted to implement an untested facility-based strategy for national introduction after the post-approval determination that the former was not financially or programmatically feasible at a national scale.	2014 FCE report, Uganda country section
Zambia	The country tested a school-based delivery model for two years in their HPV vaccine demonstration and concluded that it is not financially feasible.	2015 FCE Zambia report, HPV finding 2

## FINDING 1

HPV vaccine demonstration projects have provided opportunities for FCE countries to learn about various aspects of HPV vaccine delivery. Demonstration projects, however, could be better designed to maximize learning for national introduction. All FCE countries have or are testing single delivery models based on school-based campaigns, with the majority concluding that this approach is not financially feasible. This may have been avoided by an earlier assessment of financial feasibility, i.e., at the demonstration project design stage. This problem is exacerbated by an limited mechanisms to transfer evidence and lessons from other countries' experiences when designing HPV vaccine demonstration projects. ♦♦♦

### **HPV vaccine demonstration projects are important learning opportunities to inform national introduction.**

- Testing, refining, and comparing HPV vaccine delivery strategies with a view toward national introduction is a key underlying goal of the demonstration project.
- FCE countries have acquired valuable experience in implementing HPV vaccine demonstration projects.

### **Demonstration projects could be better designed to maximize learning by choosing delivery models that better balance coverage goals with programmatic and financial feasibility for national introduction.**

- FCE countries tested or are planning to test school-based delivery in demonstration projects and are experiencing financial or programmatic barriers towards proceeding with the tested delivery model for national introduction.

### **There is tension between the objectives of demonstrating sustainability of a delivery model and achieving coverage criteria for national introduction.**

- Although school-based delivery models are not financially or programmatically infeasible in all settings, the decision by FCE countries to test a school-based model reflects a tension between the objectives of demonstrating sustainability of a delivery model and achieving coverage criteria for national introduction
- In 2015, the FCE identified a global-level recognition that countries have a strong incentive to demonstrate their ability to meet coverage criteria in the demonstration program at the expense of learning about sustainability.

### **It is critical to clearly communicate and encourage countries to test and compare delivery models with varying resource requirements to address both coverage and sustainability goals.**

- Additionally, earlier assessments of financial feasibility, i.e. at the design phase may help to guide delivery models to test and potentially avoid testing delivery models that are not sustainable for national introduction.

### **Countries lack an effective mechanism to exchange knowledge and evidence on HPV vaccination.**

- In Bangladesh, the FCE identified limited opportunity to draw on other countries' experience when selecting a school-based delivery model (Bangladesh country section, HPV Finding 2).
- With improved sharing of experiences from other countries, Bangladesh may have been equipped to test a model through the demonstration project that was better suited for national introduction.

## RECOMMENDATIONS

1. The recent LSHTM/PATH report summarizing a range of country experiences with HPV vaccine is an important resource for designing and implementing HPV vaccine programs. An HPV vaccine implementation booklet is also under development by WHO. We recommend that the Alliance develop a communication plan, including roles and responsibilities of Secretariat and partners, to ensure the timely transfer of learnings from these and other reports, particular for those countries yet to implement HPV demonstration projects.
2. Comprehensive and early technical guidance to countries, beyond guidelines, is recommended at the design stage of HPV demonstration projects (both Gavi- and non-Gavi-supported) to ensure clear understanding of the rationale for demonstration projects and trade-offs regarding the delivery strategies to test. This should include advising countries to test multiple delivery models, where feasible, and to undertake an initial financial feasibility assessment when choosing delivery models. This reiterates and builds on our 2014 FCE recommendation.

## FINDING 2

A design element of Gavi's HPV vaccine demonstration projects is to facilitate testing alternative delivery models or adjust previously tested models in the second year of implementation. In Mozambique, this was difficult to achieve in practice, in part, as a result of learning products (coverage, costing, post-introduction evaluation) not being available in a timely manner. When demonstration projects have concluded that the tested delivery model is not feasible, the pathway to national introduction remains unclear to country stakeholders. ♦♦

### **A design element of Gavi's HPV vaccine demonstration projects is to facilitate testing alternative delivery models or adjust previously tested models in the second year of implementation**

- Following the first year of Gavi-supported demonstration projects, three products are required: (i) post-introduction evaluation (PIE) to assess the feasibility of the tested delivery model; (ii) community-based coverage survey; and (iii) micro-costing analysis of program implementation costs.
- These three products are intended to guide a review of year one of the demonstration project to adjust the tested delivery model or to design a new strategy to be used in year two.

### **In Mozambique there was inadequate review of the tested delivery model and no consideration of an alternative delivery model due in part to the unavailability of the required evaluation products**

- As a result, the country continued with the initial school-based delivery model and missed the opportunity to adjust the delivery model or test an alternative.

- The lack of appropriate review in Mozambique was driven by unrealistic timelines for the evaluation products, late disbursement of funds, insufficient technical assistance and guidance, unclear roles and responsibilities, and untimely communication between Gavi and the EPI.

## RECOMMENDATIONS

1. Comprehensive and sustained technical guidance to countries, beyond guidelines, is recommended at the implementation and evaluation stage of HPV demonstration projects (both Gavi- and non-Gavi-supported) to facilitate the completion of the required evaluation components (costing analysis, coverage survey, PIE) in time to guide the year one review and maintain countries' momentum transitioning from demo to national introduction.
2. The Alliance should review the feasibility of requiring countries to delivery evaluation products and refine the delivery model prior to the second year of the demonstration project.

# HEALTH SYSTEM Strengthening

## IMPLEMENTATION

The FCE continues to evaluate the implementation of HSS in various stages of implementation (Table 5).

**Table 5:** HSS implementation stages evaluated in the 2014 and 2015 reports

	Bangladesh	Uganda	Mozambique	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

While countries are in varied stages of implementation, the evaluation identified continued slow preparation for and implementation of HSS support (Table 6).

**Table 6:** Overview of supporting evidence from the FCE vaccine

While countries are in varied stages of implementation, the evaluation identified continued slow preparation for and implementation of HSS support.		
	FCE evidence	Citation
Bangladesh	Disbursement delays in implementing first HSS grant led to misalignments with national plans, slow human resource recruitment and infrastructure development, and lack of familiarity with Gavi financial audit requirements.  Progress toward approval of HSS-2 has been slow.	2015 FCE Bangladesh report, HSS findings 1-6 and 8
Mozambique	There are continued delays toward implementation due to complex processes for fund disbursement. The first tranche of funds was disbursed in July 2015, two years after approval.	2015 FCE Uganda report, HSS finding 1 and 2
Uganda	No civil works have been implemented under the HSS within the two-year grant implementation period, which expired in June 2015. Implementation of HSS-supported activities to strengthen private sector involvement in immunization in Kampala district faced numerous challenges and delays.	2014 FCE report, Uganda country section
Zambia	The HSS application process strained existing capacity and led to limited country ownership, an overreliance on a consultant team that did not include sufficient technical skills, and contributed to weaknesses in the M&E and PBF framework of the proposal.	2015 FCE Zambia report, HSS finding 1 and 2

## FINDING 1

A major root cause of slow implementation of Gavi's HSS in FCE countries is the complex nature of health systems strengthening coupled with a time-consuming, unfamiliar, and difficult design, application, and implementation process including disbursements from Gavi to country and to the final implementation level, which are not taken into account in operational plans. This complexity is compounded by multiple changes to the design of Gavi's HSS window of support over time and limited understanding of these changes at the country level due to insufficient communication and guidance. ◆◆◆

**Table 7:** Root causes of slow implementation of Gavi's HSS support in FCE countries

Health systems strengthening is complex.	The design, application, and implementation process of HSS support is time-consuming, unfamiliar, and difficult. This is not taken into account in operational plans.	There have been multiple changes to the design of Gavi's HSS window of support over time. There is limited understanding of these changes at the country level due to insufficient communication and guidance.
<p>Health systems strengthening encompasses activities that extend beyond the typical role of EPIs (e.g., procurement, infrastructure development, training).</p> <p>HSS activities involve an expanded set of stakeholders who are often unaccustomed to collaboration. FCE evidence and previous evaluations of Gavi HSS noted insufficient coordination around HSS beyond EPI.<sup>4</sup> In both Mozambique and Zambia, we have observed coordination challenges between EPI and directorates of planning, in part because there are no lines of accountability between the two.</p>	<p>HSS application guidelines stipulate the active involvement of a wider set of stakeholders in the design and management of HSS grants than for vaccine introductions. Coordinating across this more diverse range of stakeholders has proven challenging in FCE countries at all stages of the process.</p> <p>Complicated HSS procedures with limited understanding are exemplified by the protracted process of obtaining approval for HSS-2 funds in Mozambique, which was delayed by the requirement to negotiate a financial management requirement (FMR) between Gavi and the NIP, as well as directorates within the Ministry of Health and across government sectors to revise and agree upon financial rules and reporting and auditing requirements.</p> <p>Alignment of Gavi HSS with national plans was a noted area of weakness in both Bangladesh's and Zambia's January submissions, suggesting incomplete understanding of how to achieve these goals.</p>	<p>A decade ago, Gavi's overall HSS strategy used a broad, no-strings-attached approach; it has experienced multiple, radical changes over the last decade.</p> <p>It recently adopted a narrower focus on immunization outcomes with a performance-based financing component. Although no FCE countries are advanced enough with HSS-2 implementation to receive performance-based funds, the FCE notes a lack of discussion or active planning for the potential receipt of performance-based funds as part of HSS applications. This suggests that the performance-based component of HSS is not fully understood by countries.</p> <p>Clarity and alignment for grant and policy revisions flow from the Gavi Board to the Secretariat, where it is operationalized. By the time these changes, including the rationale and requirements of the HSS support window, reach the country level, they are not well understood. This is confirmed by FCE key informant interviews.</p>

## RECOMMENDATIONS

1. The Alliance is in the process of implementing changes to reduce the complexity of HSS grant processes, and we commend these efforts. Following a full assessment of advantages and disadvantages, we support Gavi's considering channeling the HSS grant through EPI or its parent department. The most appropriate set-up should be considered on a country-specific basis, and should be discussed between Gavi and the country.
2. Beyond the 2016 guidelines, there is a clear need for the Alliance to proactively enhance country understanding of the HSS grant design, requirements, and procedures. This should be accompanied by enhanced dialogue between country governments, partners, and the Gavi Secretariat to ensure HSS grants are aligned with country planning cycles and accurately reflect the time required for Gavi and in-country processes. This could take the form of greater involvement of the SCM or the Gavi HSS team (with increased staffing) at the design phase.

## FINDING 2

The combination of a complex support window and limited capacity at country level has resulted in a heavy reliance on external technical assistance for HSS in FCE countries, particularly at the design and proposal phase. While this technical assistance facilitates submission of applications for Gavi HSS support, it may be misdirected, ineffective, and/or not provided in a timely fashion. ♦♦

### There is heavy reliance on technical assistance for HSS in FCE countries, particularly at the application phase.

- With the complexity of HSS and the Gavi HSS process among FCE countries, the FCE identified a heavy reliance on technical assistance, often in the form of consultant support, to assist with the application process.

### TA facilitates the submission of HSS application, but may be misdirected and provided in an appropriate or timely manner.

- The FCE experience indicates that the TA that is provided is often insufficient, misdirected, or not provided in a timely way. It may lead to reduced country ownership for the HSS grant. It may lead to reduced country ownership for the HSS grant.

**Table 8:** Overview of findings for HSS TA

Country	Characteristics of consultant	Characteristics of network
Zambia	The external consultant was engaged late in the process, had limited familiarity of the country context, and had insufficient time to consult extensively with country stakeholders.	The external consultant not very connected to other actors (Figure 10 in TA section).  Key informants report there was a lack of involvement from key individuals experienced in monitoring and evaluation and results-based financing during the proposal writing process.  Weaknesses in both the January submission and September resubmission indicate that the TA provided was not well aligned with the needs.
Bangladesh	Bangladesh engaged a consultant for an initial submission in January and for resubmission in September.  Key informant interviews suggest assistance arrived late, which resulted in a rushed application process, and that the consultants were reported to have limited knowledge of the country context.  Key informants questioned the selection process for consultant support in Bangladesh.	The consultants in Bangladesh were more connected than in Zambia, suggesting a greater deal of engagement with country stakeholders (Figure 10 in TA section). However, EPI and MOH stakeholders remained the most connected in the network, indicating country ownership of the proposal.  The structure of the Bangladesh HSS proposal may promote ongoing reliance on technical partners to implement, rather than building capacity of the ministry to provide implementation functions.  Some informants noted that dividing the Bangladesh HSS proposal into two separate parts (the first, submitted in September, to provide funding for WHO and UNICEF, and the second, to be submitted in 2016, to align with the SWAp) reduced opportunity to build country implementation capacity.

## RECOMMENDATION

The Alliance should prioritize opportunities to channel resources for technical assistance (whether for HSS design or implementation) to positions within the government system and then from within the country, with accompanying orientation of local TA providers to Gavi HSS. Where this is not possible, Gavi could explore models of embedded TA (the FCE will examine the strengths and weaknesses of this model in 2016). This may strengthen country ownership of HSS grants. Where external technical assistance is required, we recom-

mend earlier and better coordination, including orientation of external TA providers around country context. External TA consultants could be paired with a local TA provider to build country capacity in designing HSS applications. (See Recommendations 1, 2, and 3 of Finding 3 of TA section for further detail on these issues.

## FINDING 3

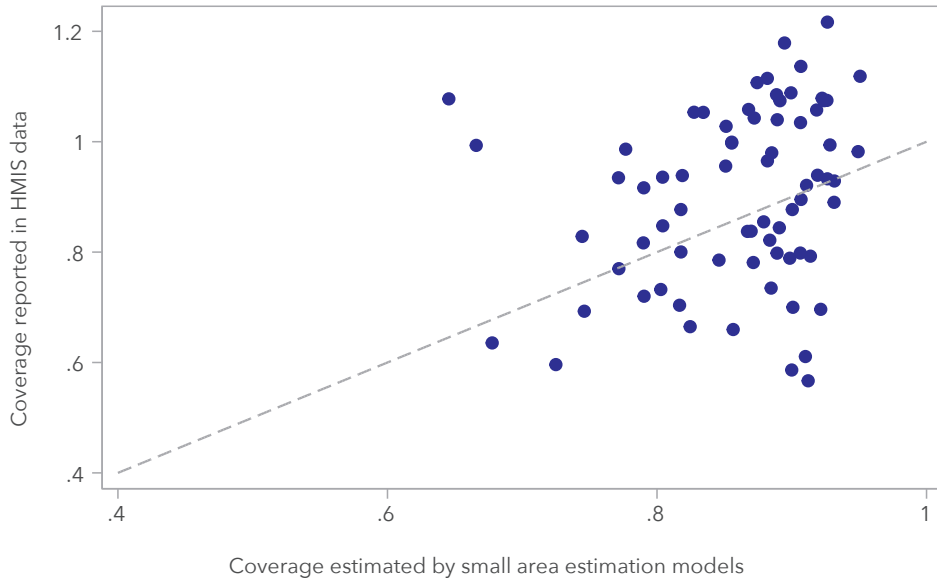
Even with technical assistance, we note a number of deficiencies (insufficient data or evidence to support investments, failure to harness catalytic nature of Gavi HSS investments, and limited consideration of sustainability) in the design of Gavi HSS grants that limit the potential of the window of support to meet its objectives of improving immunization coverage and equity. (Table 9). ♦♦

**Table 9:** Overview of identified deficiencies in the design of Gavi HSS grants

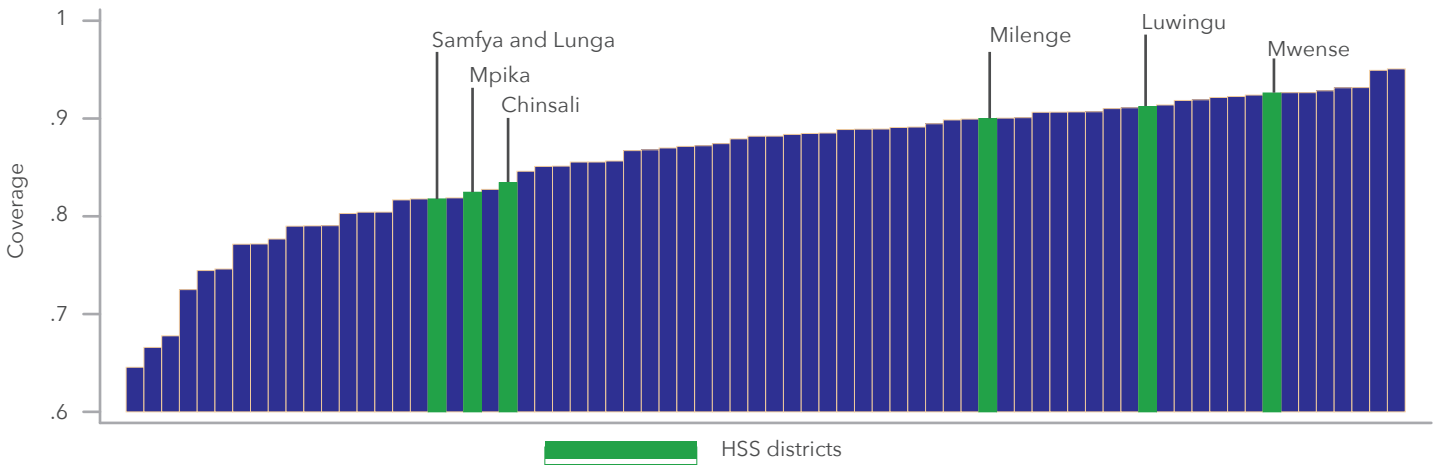
Insufficient data or evidence to support investments	
<p><b>Identification of key bottlenecks for immunization coverage and design of HSS grants is not always based on comprehensive information.</b></p>	<ul style="list-style-type: none"> <li>In Bangladesh and Zambia, bottlenecks were identified in stakeholder workshops, but it is unclear that informed, robust analyses of strong evidence were used.</li> <li>This is partially attributable to the dearth of tools to aid countries in conducting the bottleneck analysis and in prioritizing identified bottlenecks.</li> </ul>
<p><b>Administrative data affects HSS targeting.</b></p>	<ul style="list-style-type: none"> <li>HSS targeting in Zambia is affected by low-quality administrative data, which is used for programmatic and work-planning purposes. Many Zambian districts report administrative data-based vaccine coverage greater than 100%. These data have poor correlation with the Gavi FCE small-area estimates, which are based on household surveys (Figure 5).</li> </ul>
<p><b>Political considerations affect targeting of HSS funds.</b></p>	<ul style="list-style-type: none"> <li>Evidence indicates that newly created districts in Zambia did not represent the lowest-coverage districts</li> </ul>
Limited ability to harness catalytic nature of Gavi HSS investments	
<p><b>Targeting implementation of HSS grants to specific administrative or geographic areas is not always done in a way that will maximize impact.</b></p>	<ul style="list-style-type: none"> <li>Countries are required to demonstrate national-level impact of HSS; however, countries target relatively limited HSS funds to subnational areas, which does not necessarily result in national-level impact.</li> <li>Zambia applied for a US \$9 million HSS grant over three years from Gavi, compared to a 4.5-year, US \$97 million USAID-funded Zambia Integrated Systems Strengthening Program (ZISSP) grant. Zambia selected seven districts for HSS support, but the selected districts do not represent districts with the lowest vaccine coverage (Figure 6).</li> </ul>
Limited consideration of sustainability	
<p><b>The FCE has not observed country consideration of HSS sustainability at the design stage.</b></p>	<ul style="list-style-type: none"> <li>HSS investments must demonstrate financial and programmatic sustainability, beyond the period of Gavi support.</li> <li>In Zambia, the September HSS resubmission lacked details on how the Central Statistical Office would contribute additional resources and did not describe plans to train staff on purchased transport equipment maintenance, or indicate plans to continue financing fuel for vehicles at the end of the HSS support period. The Interagency Coordinating Committee (ICC) review and endorsement did not flag these areas of weakness.</li> <li>In Bangladesh, the September submission included funding for WHO and UNICEF to continue implementation of ongoing activities for surveillance and effective vaccine management. This raises questions of sustainability of HSS investments when Gavi's support for HSS ends in Bangladesh.</li> </ul>
<p><b>FCE countries have not benefited from the availability of additional Gavi guidance or tools to improve planning for sustainability.</b></p>	<ul style="list-style-type: none"> <li>Gavi's sustainability Strategic Focus Areas (SFA) will go to the Gavi Board for approval in 2016. This is a missed opportunity in a country like Zambia, where the new HSS proposal was submitted prior to the approval and implementation of Gavi's sustainability SFA.</li> </ul>



**Figure 5:** Third-dose pentavalent vaccine coverage estimation in Zambia, comparing HMIS data to small-area estimation models, 2014



**Figure 6:** Districts selected for HSS funds in Zambia as part of the September 2015 resubmission<sup>iii</sup>



## RECOMMENDATIONS

1. Enhanced investments in data, tools, and analysis to support countries’ bottleneck assessments and overall HSS grant design are recommended to maximize the potential impact of HSS grants. This is particularly important given the relatively small size of HSS grants. This should be part of Gavi’s Strategic Focus Area on Data and Health Systems Immunization Strengthening (HSIS) reforms.
2. We recommend earlier guidance and technical support from Gavi and partners to ensure that the design of HSS

grants is sustainable. While the provisions included in the guidelines represent an important first step, guidelines alone are insufficient without active and in-depth engagement to orient countries. This would take into account how close a country is to transitioning out of Gavi eligibility. For those countries that have, or have already applied for, HSS grants, we recommend that Gavi identify opportunities to work with countries to improve the sustainability aspects of active HSS grants. This should be part of Gavi’s Strategic Focus Area on Sustainability.

<sup>iii</sup>Coverage estimates based on FCE small-area estimates that incorporate the latest 2013/14 DHS and Gavi FCE household survey.

## FINDING 4

Despite the challenges of implementing Gavi HSS, our findings suggest that improvements in immunization coverage have been realized in FCE countries over the past five years. In Bangladesh, districts receiving Gavi HSS-1 support have experienced the largest improvements in immunization coverage. Although improvements in FCE countries have been realized, subnational estimates of vaccine coverage highlight in some cases considerable geographical inequity in vaccine coverage. This supports the new Gavi strategic focus on coverage and equity (Table 10). ♦♦

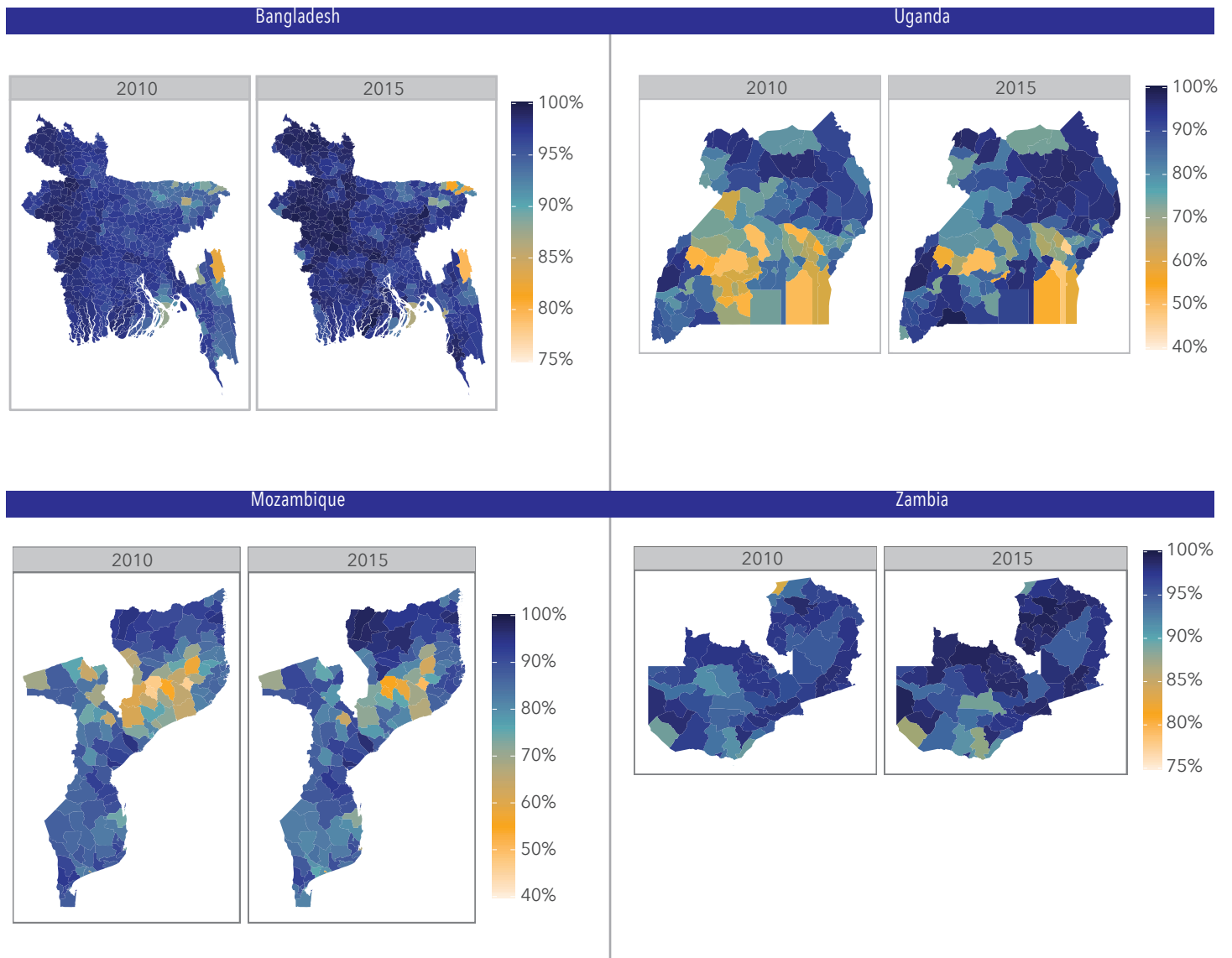
**Table 10:** Overview of trends in immunization coverage

Landscape of immunization coverage	
<b>Bangladesh</b>	<p>Small-area estimates, which incorporate the country's most recent 2014 Coverage Evaluation Survey (CES), show widespread improvements in third-dose pentavalent vaccine coverage over this period (Panel C).</p> <p>The Gavi FCE small-area estimates show that improvements in third-dose pentavalent coverage are larger in Phase I HSS districts that were targets of Bangladesh's recently completed HSS-1 grant (Figure 7). However, statistical estimation of the difference in third dose DPT3 coverage between HSS and non-HSS districts indicates a non-significant difference. We caution that this analysis is based on observational data and does not control for influences like other health system efforts.</p>
<b>Mozambique</b>	<p>Estimates for Mozambique are not as robust due to limited contemporary household survey data, with improvements to follow in 2016.</p> <p>Based on these estimates, we do not see the same rate of improvement in vaccine coverage as in other FCE countries, with the exception of Niassa Province (Panel C).</p>
<b>Uganda</b>	<p>Increases are particularly notable among districts in the Western and Central, and to a less consistent extent, Eastern regions (Panel C) There are a number of districts where third-dose pentavalent vaccine coverage in 2015 remains low (&lt; 60%).</p> <p>The Gavi FCE health facility survey identified contributing system gaps that include broken primary vaccine storage equipment with limited regular maintenance, which could be the focus of future Gavi HSS and other system strengthening efforts.</p>
<b>Zambia</b>	<p>Estimates suggest significant improvements in vaccine coverage over the past five years, particularly in provinces such as Northwestern and Luapula (Panel C).</p> <p>Like Uganda, estimates cover a period when Gavi HSS had not been active and follow a period of declines in vaccine coverage in many areas that began in the mid-to-late 1990s. A number of districts have coverage below 70%, particularly in the Southern province (Panel C).</p> <p>These areas should be the target of increased investments to reduce geographic inequity in vaccine coverage.</p>

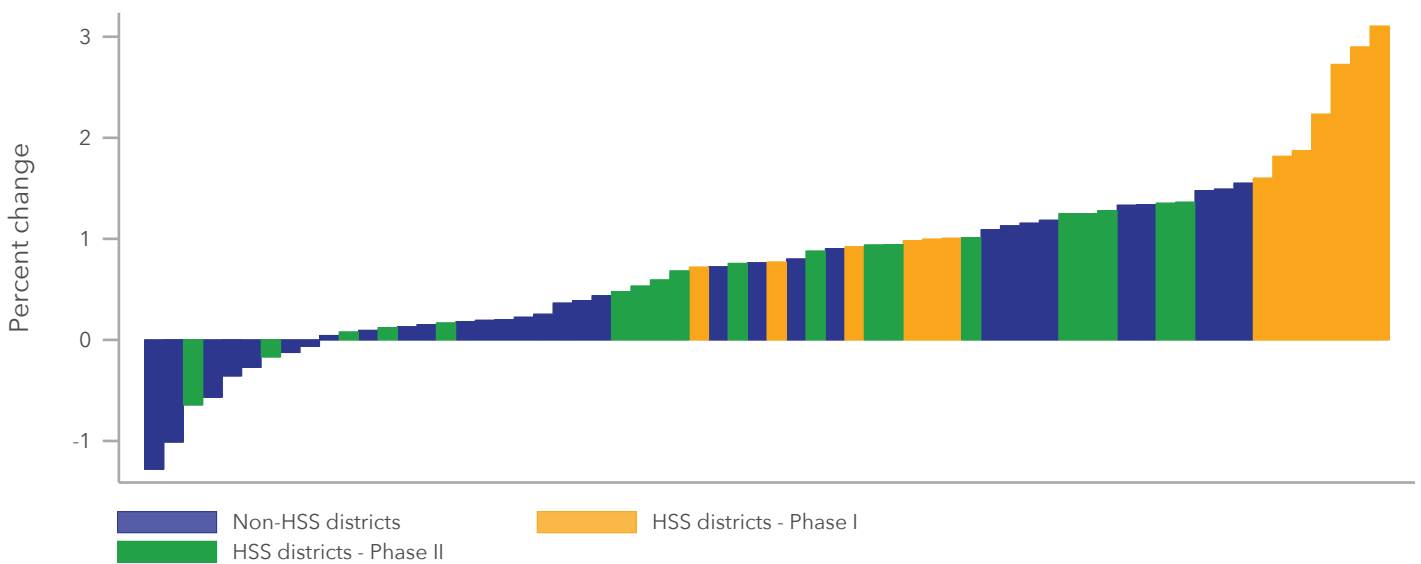
## RECOMMENDATION

1. Countries and partners should maximize opportunities to build on the success of past strategies to improve vaccine coverage when designing HSS grants. This could include stronger integration of Gavi HSS grants with those efforts, for example through pooled funding mechanisms where they already exist and are found to be effective.

**Panel C:** Third-dose pentavalent coverage estimates for all countries



**Figure 7:** Change in third-dose pentavalent vaccine coverage from 2010 to 2014 by HSS-1 status in Bangladesh



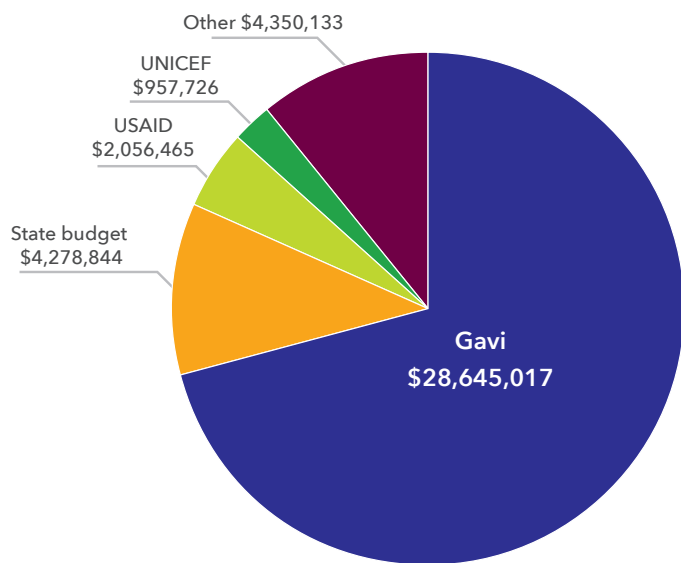
## PROGRAMMATIC AND FINANCIAL capacity

The FCE indicated limited capacity of EPI programs to effectively plan and manage Gavi support in 2013 and 2014. In the 2015 evaluation period, we observe a number of instances where FCE countries face programmatic and financial constraints that limits the realization of their programs' full potential (Table 11).

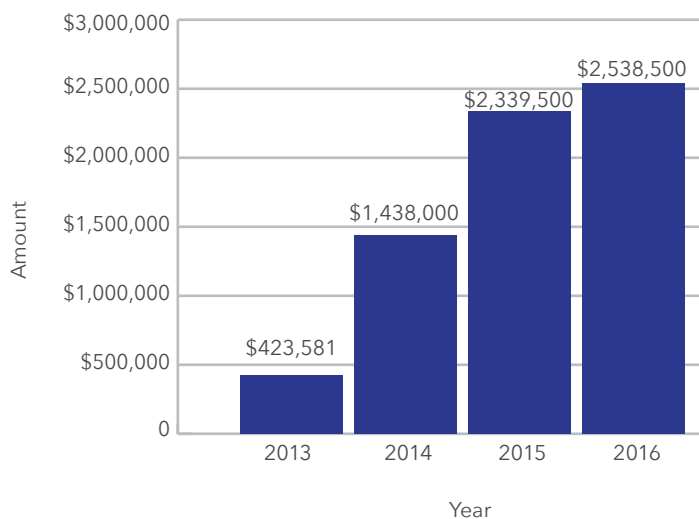
**Table 11:** Overview of multiple vaccine introductions in FCE countries

	Gavi funding streams implemented	Country experience with new vaccine introductions (NVI) and cash grants	Financial sustainability considerations
<b>Mozambique</b>	<ul style="list-style-type: none"> <li>Second year of HPV demonstration project implemented in 2015</li> <li>Preparations for implementation of approved HSS-2 grant in 2015</li> <li>National-level introductions for rotavirus vaccine (introduced in September 2015), IPV, and measles second dose (both introduced in November 2015)</li> </ul>	<ul style="list-style-type: none"> <li>HSS implementation was de-prioritized.</li> <li>There was a missed opportunity for learning through redesigning delivery strategies for HPV vaccine in the second year of the demonstration project.</li> </ul>	Gavi funding already accounts for more than two-thirds of the overall funding envelope for immunization as compared to the approximately 10% that direct government funding contributes (Figure 8). This is before accounting for the increase in the potential co-financing associated with the recent introduction of rotavirus vaccine, as well as the potential co-financing and delivery cost of national HPV vaccine introduction in the future.
<b>Uganda</b>	<ul style="list-style-type: none"> <li>PCV introduction in 2013</li> <li>HSS-1 grant implementation ongoing in 2015</li> <li>Ongoing preparation for and launch of national introduction in November 2015</li> </ul>	<ul style="list-style-type: none"> <li>Overstretched financial and programmatic capacity led to a decision to merge HPV vaccine preparatory activities with measles supplemental immunization activities, with potential negative consequences on the quality of HPV activities such as training and social mobilization.</li> </ul>	A recent decision to apply for Gavi support to introduce rotavirus vaccine raises questions about financial sustainability, particularly in light of Uganda's recent co-financing default, which was driven by procedural issues in-country and the PCV introduction, which increased the co-financing requirement considerably, evidence of "vaccine stacking" (Figure 9).
<b>Zambia</b>	<ul style="list-style-type: none"> <li>PCV and measles second dose jointly introduced in 2013</li> <li>Rotavirus vaccine launched in 2013</li> <li>Submission of HSS-2 grant in 2015</li> </ul>	<ul style="list-style-type: none"> <li>The HPV demonstration project, although not Gavi-funded, suffered from suboptimal planning and implementation, and plans for national introduction faced financial sustainability questions regarding the tested delivery strategy.</li> </ul>	Zambia is a Phase 1 or Preparatory transition country, which raises questions about the program's financial sustainability, given the associated increases (15% annually) in the co-financing requirements linked to pentavalent vaccine, PCV, rotavirus vaccine, and possibly the national introduction of HPV vaccine. This is in the context of heavy reliance on external donor financing for immunization as shown by the Gavi FCE resource tracking study (see 2015 FCE Annual Report for Zambia).
<b>Bangladesh</b>	<ul style="list-style-type: none"> <li>Measles-rubella campaign in 2014</li> <li>HSS-1 grant with an HSS-2 grant submitted in 2015</li> <li>PCV introduction in 2015</li> </ul>	<ul style="list-style-type: none"> <li>The FCE's 2014 evaluation of the MR campaign showed strong evidence of an ability for national and subnational leaders and health workers to adaptively manage a large-scale campaign.</li> <li>In 2015, we observed effective planning and coordination at multiple levels of the system in the joint launch of PCV and IPV. Their effective management was also evidenced by the decision to postpone the HPV demonstration project launch to a later date to avoid three vaccine introductions within a short time period.</li> </ul>	

**Figure 8:** Funding envelope for immunization in Mozambique, 2014 (source: Gavi resource tracking study)



**Figure 9:** Uganda's annual co-financing obligation based on decision letters



## FINDING 1

National decision-makers must balance the public health impact of new vaccine introductions and global and country-level political pressure with programmatic and financial sustainability. Strengthening national decision-making and prioritization capabilities and processes could assist in achieving this balance. (Table 12). ♦♦♦

**Table 12:** Overview of contributing factors for country decisions to apply for multiple Gavi support streams.

	Global level	National level
<b>Political pressure from global and national-level stakeholders affects country's decision to implement multiple Gavi support streams.</b>	<p>New vaccine use and adoption remains major benchmark for Gavi success, though there is new emphasis on sustainable introductions and equitable uptake and coverage of new vaccines.</p> <p>Global advocacy efforts for vaccine adoption, like the Polio Endgame Strategy, also creates political momentum for vaccine introduction.</p>	<p>Political pressure from global and national-level stakeholders to adopt new vaccines is well-known and part of Gavi's advocacy strategy.<sup>7</sup></p> <p>National advocacy campaigns and high-level national support for vaccine adoption (i.e., HPV vaccine), affect decisions to adopt. For example, early political pressure for HPV vaccine adoption by first ladies was instrumental in driving the applications for HPV vaccine support in Zambia and Mozambique.</p>
<b>FCE evidence suggests that country-level priority-setting institutions are suboptimal</b>	<p><b>Independent Review Committee (IRC) and High-Level Review Panel (HLRP)</b></p> <p>The IRC is responsible for review and approval of new proposals while the HLRP is designed to serve as a secondary check of the in-country Joint Appraisal process.</p> <p>The IRC and HLRP<sup>iv</sup> do not have the mandate to question how vaccine introductions are made and lack the ability to assess stated plans with an understanding of country context.</p>	<p><b>Interagency Coordinating Committees (ICC)</b></p> <p>In Zambia and Mozambique the ICC does not fully match its intended role to guide and support the MOH and coordinate EPI partners.</p> <p>By contrast, in Bangladesh, the ICC has operated effectively with the government to manage streams of support and support decision-making.</p> <p><b>National immunization technical advisory groups (NITAG)</b></p> <p>In addition to the ICCs, national immunization technical advisory groups (NITAG) "can guide country policies and strategies based on local epidemiology and cost-effectiveness"<sup>8</sup> as an independent advisory committee.</p> <p>Alliance partners must explore how to strengthen the sphere of activity of NITAGs while maintaining the authority of ministries of health and particularly their elected representatives.</p>

<sup>iv</sup>As part of the Grant Application, Monitoring and Review [GAMR] process changes, the monitoring IRC has been replaced by the High-Level Review Panel.

## RECOMMENDATIONS

1. Gavi and Alliance partners should invest further in strengthening national and sub-national EPI programmatic and financial management, including ensuring EPI programs have the appropriate number of people, with the appropriate skills and capabilities, supported by a well-coordinated partnership (support systems). Gavi's new Strategic Focus Area (SFA) on Leadership, Management, and Coordination should ensure that their efforts are linked to the Direct Financial Support reforms that aim to reduce the complexity of Gavi's grant processes.
2. Gavi and Alliance partners should invest further in strengthening evidence-informed country-level decision-making in Ministries of Health, including the EPI program, and its advisory bodies (e.g., ICCS, NITAGS), while ministries of health should carefully consider recommendations from ICCS, NITAGS, and the IRC and address them where feasible. Gavi's new Strategic Focus Area (SFA) on Leadership, Management, and Coordination should address lessons learned through existing investments in immunization decision-making.
3. The Gavi Secretariat should articulate how country and global-level monitoring processes (JA, HLRP, IRCS) will recognize and flag when countries are at risk of becoming overwhelmed, programmatically or financially, by the cumulative effect of immunization program activities and implementation of Gavi grants. This should be followed by an engagement process to determine appropriate responses and support needed.

## FINDING 2

The oversized administrative and management burden of Gavi grants and processes, both for specific windows of support such as HSS and across streams, further strains limited EPI program capacity. ♦♦♦

### There is a high administrative and management burden of cash grants.

- Cash grants, remain fraught by confusion and delays due to new and unfamiliar or complex processes.
- In addition to HSS, there are examples of increased management and administrative burden and poor alignment with country cycles:
  - New GAMR mechanisms were timed according to global-level submission deadlines rather than country planning cycles, which created additional work for countries and EPI managers.
  - In Mozambique, the Joint Appraisal process took three weeks, even with significant consultant support.
  - By contrast, the JA process in Bangladesh was coordinated by the Gavi SCM, who recognized the competing HSS-2 application deadline faced by EPI staff and did not pressure the government and partners (WHO, UNICEF) to engage in the JA process.

### Limited anticipation at the global level of grants' operational implications contributes to administrative and management burden.

- The administrative and management burden of Gavi grants is in part due to insufficient consideration during policy

development at the global level of the time, capabilities, and coordination necessary for country-level implementation of new processes.

- Moreover, country-level stakeholders may struggle to understand Gavi policies and guidelines when they are not written for an implementing audience.
- What country stakeholders find most challenging is the lack of communication of the revision or introduction of existing or new guidelines. In Zambia, unclear HPV vaccine application guidelines led to drawn-out debates about whether an HPV vaccine coverage survey was an application requirement. The country's negative experience impacted government support of the country's HPV vaccine program.

## RECOMMENDATIONS

1. We recommend developing a process map that describes how all the concurrent policy and operational changes will be integrated. Communicate this within the Alliance and down to the country level.
2. Continue strengthening the representation and participation of implementers or their representatives on global-level policy and program review and development committees. For each new or revised policy, procedure, or guideline, include an assessment of potential impact on country program capacity.

## FINDING 3

Overly optimistic application and implementation timelines – set by Gavi and by countries — result in limited ability to adaptively manage grants. ♦♦♦

### Countries often struggle to adhere to the unrealistic timelines that were set in applications.

- Countries often do not rely on past experience to inform a realistic timeline for new vaccine planning and introduction or set timelines that demonstrate their motivation as potential grantees to implement quickly.
- Countries appear “delayed” relative to proposed timelines, which, especially in the case of HSS, may lead stakeholders at the global or country level to reprogram or reformulate the grant and its implementation plan.

### Increased transparency around timelines and strengthened engagement may lead to more accurate operational plans

- Unrealistic timelines have been accepted by the IRC or other global-level decision-making bodies in the past.

- New efforts for transparency around estimated timelines, strengthened engagement of SCMs in global-level processes, and ongoing efforts to understand and align with country processes will improve this issue.
- In 2016, The FCE will assess whether new application timelines developed by countries are consistent with the forecast timelines in the revised application guidelines.

## RECOMMENDATION

Reiterating a 2014 FCE recommendation, countries should include realistic timelines in their applications and implementation plans – paying particular attention to their administrative and financial processes. Country-level and global-level decision-making bodies and processes such as ICCS, as well as SCMs and the IRC should provide the necessary checks and balances to vet proposed timelines to avoid unnecessary reprogramming of grants.

## TECHNICAL ASSISTANCE: the present and the future

The Gavi Board approved the new principles and structure of funding TA, the Partners’ Engagement Framework (PEF). PEF replaces the Gavi Business Plan to address weak transparency, coordination, and country alignment of TA funded by Gavi.

## FINDING 1

As noted in previous FCE reports, in other evaluations, and by the Alliance, the Gavi Business Plan model of identifying and funding TA needs, gaps, and approaches had multiple weaknesses. As we noted in 2014, the content and amount of TA funded through the Business Plan were decided at the global level and were often unknown in countries. The growing complexity and scope of immunization program needs were no longer addressable solely by the traditional capabilities of core Alliance partners in the Business Plan. ♦ Generalizability not applicable

### Country-level stakeholders have been generally unaware of the contents of the business plan since its introduction in 2011 (i.e., what TA is provided, by whom).

- This was observed in the FCE analysis of Uganda’s HPV application partnership in 2014.<sup>15</sup> In-country Alliance partners reported being unaware of the Business Plan, due in part to the design of the Business Plan Process, which operated annual planning and budgeting at the global level, with the expectation that headquarter staff would communicate the Business Plan activities to regional and country offices. Much of the TA went to Alliance partner staff in regional offices, further limiting transparency and coordination with in-country needs.
- In Mozambique, sub-optimal in-country coordination during the 2014 HPV vaccine demonstration led to disagreements about who was responsible for TA; this was compounded by the then limited engagement of Gavi SCMs to assist in interpreting which partners were responsible for TA. SCMs were more positively engaged with TA coordination resolution in 2015.

### **Business planning at the global level resulted in lack of concordance between Gavi-funded TA activities and local needs.**

- TA activities were presented broadly (i.e., “support for rotavirus vaccine application) without consideration of specific gaps.

### **The business plan model had limited mechanisms for monitoring whether funded TA activities were delivered in a high-quality manner.**

- There are few mechanisms to hold TA providers accountable, both to Gavi and to the countries.

### **TA needs and gaps are increasingly operational, systemic, and complex in nature and require a new set of TA providers, models, and approaches**

- During the development of the 2016–2020 Gavi Strategy, there was broad awareness that TA should increasingly

address specific, complex bottlenecks related to the implementation of a growing portfolio of Gavi support in order to attain coverage and equity goals.

- This focus was identified in the 2008 McKinsey report<sup>14</sup>, in each of the FCE reports, and by the Secretariat, which set a Strategic Focus Area (SFA) for leadership, management, and coordination and the Strategic Goal 3 for increasing programmatic and financial sustainability.
- There is recognition that the traditional network of Gavi TA providers may need to expand to include providers with expertise more aligned with operational and management needs.

## **FINDING 2**

The relevance, effectiveness, and efficiency of technical assistance to address coverage and equity goals, as well as to build sustained country capacity, could be improved. The relevance and effectiveness of technical assistance seem to be maximized when TA targets the most significant gaps (which are often operational or systemic rather than technical in nature), when it comes from in-country providers, and is provided through models that emphasize the transfer of skills. TA is most efficient when coordination is strong. Ultimately, short-term gains from TA will only be sustained if Gavi explicitly invests in building the programmatic and financial capacity of EPIS. Early signs in Mozambique’s HSS implementation point to a focus on capacity strengthening in this area and more broadly, the new Gavi strategic focus areas on Leadership, Management and Coordination, and Sustainability have potential to build country capacity going forward. ♦ Generalizability not applicable.

### **In-country TA ecosystems are more diverse and connected than the business plan suggests.**

- In 2015, FCE used a network analysis approach to identify who provides TA in Bangladesh, Mozambique, and Zambia, enabling a bottom-up description of the TA ecosystem.
- The network figure (Figure 10) show many individuals who provide or receive TA in immunization programs (39 for HSS application in Bangladesh; 33 for HSS application in Zambia; 60 for all streams in Mozambique). The overall picture is one of relative connectedness (density) within the networks. We observe relatively few actors with a high number of TA relationships (centralization), who are grouped in the center or core of the network. The most connected individuals tend to be EPI program staff and core Alliance partners suggesting these individuals and their relationships should be leveraged.
- Knowledge and skills appear equally distributed throughout the network, without hubs of expertise. Hubs

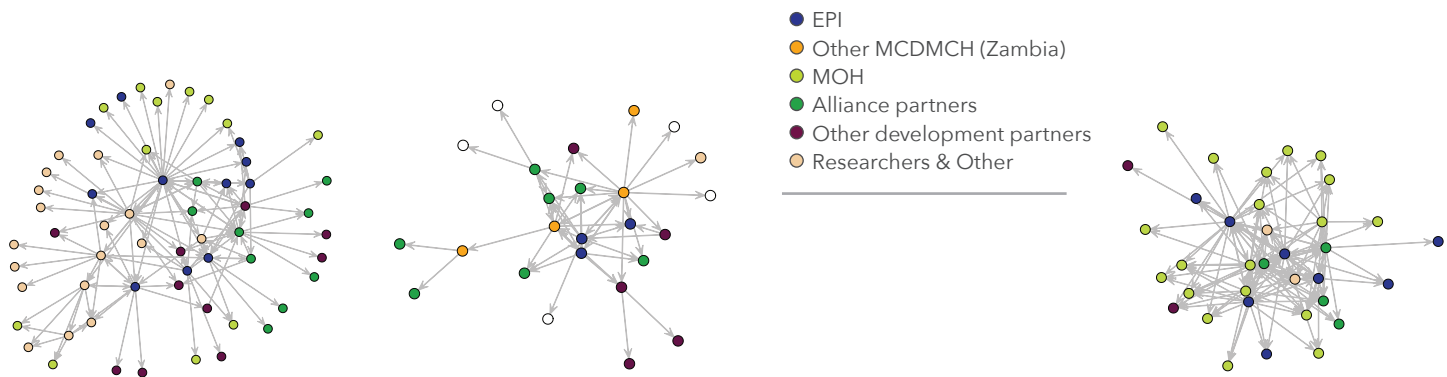
of expertise could improve the partnerships’ ability to respond to complex technical needs, a gap that was observed during the HSS applications in Bangladesh and Zambia.

### **TA is most effective and relevant if targeted the most significant gaps, which are often systematic or operational rather than technical.**

- Alignment of Gavi TA with TA needs of countries requires a systematic and evidence-informed process to identify the major bottlenecks to achieving coverage and equity.
- TA gaps should be identified based on a comprehensive understanding of which gaps can be addressed by the existing skills and resources of the EPI program, which require TA intervention, and which of those are or could be filled by other partners.
- The FCE observed that the bottlenecks identified through the HSS bottleneck assessments do not seem to align with either the Gavi SFAs or the FCE evaluation findings.



**Figure 10:** . Networks of TA exchanges in Mozambique (left), Zambia (middle) and Bangladesh (right)



**TA effectiveness is maximized if it comes from in-country providers and through models that emphasize the transfer of skills, which lead to long-term sustainability.**

- External TA providers are less likely to be familiar with local programmatic, policy-relevant, and contextual factors.
- This was the case for the HSS application in Zambia and Bangladesh and for the HPV demonstration project in Mozambique.
- The FCE has observed over-reliance on short-term and often external TA, which does not build EPI capacity or sustainability, but some promising models are being implemented:
  - In Uganda, a TA from a consultant embedded with the EPI program led the writing of meningitis A and rotavirus vaccine applications. This facilitated engagement of stakeholders and a positive country experience with TA.
  - In Bangladesh, a partnership of actors has worked successfully together to launch new vaccines, though the TA network for HSS faces a broader set of limitations.

**Varied levels of country satisfaction with TA indicates room for improvement**

- In the case of HSS applications in Zambia and Bangladesh we note that HSS consultants were not always able to achieve successful outcomes, particularly related to the M&E sections of the applications.

- Consultants’ limited knowledge of the country context, processes, and strategic documents has also been a barrier.
- Our observation that core partners tend to rely on external short-term consultants, particularly for HSS applications indicates that the network of TA providers will need to be expanded to include new organizations and individuals with the appropriate skills, ideally in countries.

**RECOMMENDATIONS**

1. Gavi should support mapping of existing TA providers, users, and skill sets in as many countries as possible.
2. Gavi should ensure that TA providers selected have not only the skills and expertise related to substantive gaps and needs, but also familiarity with the most effective approaches to providing TA.
3. Identification of TA needs and potential solutions should be based on a comprehensive, systematic, evidence-informed approach. This process should be country-led and integrated with broader assessments of health system capacities and bottlenecks to ensure that TA is coordinated and complements capacity building goals of other Gavi and non-Gavi supported investments (e.g., HSS, SFAS, other systems strengthening initiatives, etc.)

## FINDING 3

The Partners' Engagement Framework will replace the Gavi business plan beginning in 2016. As part of the PEF principles and structure there is a need for a clearer specification of how capacity-building will be achieved and how it relates to other mechanisms such as HSS. A clear theory of change will help to properly articulate capacity-building goals and objectives as well as the overall design and vision of PEF. ♦ Generalizability not applicable.

### Capacity-building is of central importance to PEF and should be included more explicitly as part of PEF.

- Capacity building is mentioned in the June 2015 board meeting notes for Gavi's Targeted Country Assistance (TCA) stream, is focused on in the Request for Information (RFI) document prepared for potential TCA partners states, and is a key aspect of Gavi's Leadership, Management, and Coordination Strategic Focus Area.
- The Alliance identified country leadership, management, and coordination as a strategic enabler necessary to achieve the 2016-2020 strategic goals. Gavi, the Vaccine Alliance, "Gavi's Strategy."
- When core and expanded partners were asked about capacity-building goals in interviews, they agreed that they should be of central importance. Some respondents expressed surprise that capacity-building was not a principle or explicitly written goal of PEF, whereas others knew this to be the case but agreed that capacity-building was an implicit – if not explicit – objective of PEF.

### It is unclear how capacity-building efforts will be aligned with and leverage other Gavi mechanisms such as HSS.

- HSS entails investments to build capabilities, and it is unclear how and to what extent they are connected to PEF, leading to questions about possible redundancies or gaps.
- There is evidence for this in this transition year where TA requests in JA reports in Bangladesh duplicate what has been requested through HSS.

It is important Gavi develop a strong vision and articulation of capacity building across PEF, HSS, and other mechanisms; this should be informed by multiple analyses. Hyde et al., "The Impact of New Vaccine Introduction on Immunization and Health Systems: A Review of the Published Literature"; McKinsey and Company, "Strengthening Technical Support, GAVI Alliance."

### A clear theory of change for Gavi's partner engagement strategy making explicit the outcomes and goals of PEF will facilitate communication across the Alliance.

## What is PEF?

**PEF replaces the Gavi business plan as the new mechanism for funding technical assistance.<sup>11</sup> It consists of three streams:**

- (i) Foundational support to core partners (WHO, UNICEF, the World Bank, CDC, and the CSO Constituency);
- (ii) Targeted technical assistance for countries, focusing on core partners and with gaps filled by partners based on TA identification from the JA process; and
- (iii) Investments in strategic focus areas identified in the 2016-2020 Gavi Strategy.

PEF activities and outcomes will be monitored and evaluated based on Gavi's existing strategy indicators, the new Alliance Key Performance Indicators (KPI), activity-based indicators of each partner, and regular evaluations of TA.

- If developed in participation with other change initiatives, it could bring additional clarity to the variety of new policies, procedures, and operations occurring in the Secretariat and across the Alliance – particularly as they relate to technical assistance and capacity-building.
- This is perhaps most pertinent for transitioning and non-focus countries, who still have capacity needs that must be met before a successful transition can take place.

## RECOMMENDATIONS

1. The Alliance should include an explicit goal of PEF to build EPI program capabilities and capacity. This goal should be supported by a theory of change (which is presently under development) and be reflected through PEF's design and implementation, in order to ensure the sustainability and impact of Gavi's investments.
2. Build trust by ensuring transparency of and alignment on vision, goals, and objectives of PEF across the Alliance. Ensure that PEF is implemented with clear communication and transparency at all stages.
3. Gavi should consider how to integrate various mechanisms of providing TA and capacity-building (HSS, PEF, SFAS), and how it maps onto an ideal end-to-end process in countries. This is important for all countries, including for graduating and non-focus countries who will receive fewer TCA-specific resources.

## FINDING 4

PEF leverages existing instruments such as the Joint Appraisal (JA) to identify TA needs to reduce the burden of additional change. Our findings in the transition year suggest that the JA has worked relatively well for this purpose in one of the FCE countries (Mozambique) but could be strengthened in the other three. The JA process, as presently designed and implemented, may be limited in its ability to produce unbiased, country-led, and comprehensive assessments of TA needs. ♦♦

### The JA process was leveraged to include country-centric process of identifying TA and avoid the burden of additional change.

- PEF architects relied on the newly developed JA and HLRP processes to identify TA needs based on an inclusive and country-led assessment of immunization bottlenecks.
- Country-led analyses of program and system constraints conducted through the JA could be leveraged to identify TA and take advantage of the local partners.
- If JAs are implemented according to Gavi's principle of alignment with existing country processes (e.g., alongside an EPI review), they could be an effective mechanism for reviewing the EPI program. Ideally, this process will lead to the systematic identification of TA needs while mitigating potential biases of all partners and stakeholders.

### Identifying TA through the JA has worked relatively well in Mozambique, but perhaps not as well in the other three FCE countries.

- In Mozambique, stakeholders generally perceived the JA process to be an appropriate and effective venue for identifying TA needs, and the process benefitted from a dedicated, experienced consultant.
- Other FCE countries' TA sections varied in the level of detail provided, with a tendency to identify a narrow range of types of TA needs and providers. It is important to note that there is a narrow base of TA partners, despite the PEF objective to expand the base of technical assistance providers. In FCE countries, core partners (WHO and UNICEF) accounted for the vast majority of TA provision named during JA.
- Continuous learning on the part of the Secretariat led to SCMS revisiting some of the requests with countries; this demonstrates the flexibility of the Alliance to learn and improve, and to put the focus on countries.

### Norms of practice and cognitive biases entrenching the status quo may explain the nature of the TA section of the JA.

- Underlying biases were compounded by JA guidelines directing readers to start review with the 2015 business plan, further

entrenching “business as usual” instead of providing tools to encourage systematic identification of immunization bottlenecks and TA needs.

### The JA process by itself may not be sufficiently neutral to comprehensively identify the most pressing TA needs

- FCE countries expressed concern that the design and implementation of the JA process encouraged potential conflicts of interest from core partners was mirrored at the global level and from core partners themselves.

Though this conflict of interest is not novel, the contribution of PEF funding might exacerbate conflicts at all stages of the PEF process, not just the JA. Efforts by the Secretariat to work with them to revise TA requests are a positive step.

## RECOMMENDATIONS

1. Echoing other recommendations in this report, we recommend that Gavi develop or provide more systematic, user-friendly tools and approaches to identifying bottlenecks and evidence-informed solutions. Ensure the time/resources to undertake this process, and alignment with country cycles and processes.
2. Repeating an earlier recommendation, the Alliance should ensure that there is a comprehensive mapping of local TA providers and expanded partners to reduce informational asymmetries between the supply and demand of TA. This mapping would complement the Request for Information (RFI) for PEF.
3. Provide time, for example, to be present in-country at the JA, and training to enable SCMS – as a relatively neutral party - to play a stronger coordinating and mediation role in the JA process of identifying TA needs and providers to mitigate potential conflicts of interest.

## FINDING 5

While 2015 represented a transition year from the business plan to PEF, and PEF will inevitably experience growing pains, evidence from the transition year suggests a need for stronger communication, change management, standardization, and guidance on key processes. ♦♦♦

### **Clear communication of change process and purpose of PEF may mitigate growing pains.**

- FCE evidence suggests that stakeholders do not have a complete understanding of the PEF process and perceive insufficient communication on how PEF fits into the scope of Gavi policies.
- A more concerted change management strategy across and within Alliance partners is necessary. Inadequate communication around the need for change and how it will be executed can compromise the engagement and buy-in of those affected by the change.
- To avoid both confusion among stakeholders regarding TA and potential impact on partnership, the transition to PEF must be implemented with clarity of vision, strong coordination and communication, and change management.

### **At the country level it is particularly important that new global-level monitoring processes, including HLRP and the global-level PEF process, incorporate clear feedback loops to countries.**

- Global and country interviews revealed concern that an onerous process, followed by minimal feedback, would lead to ambivalence.
- Partnership trust was affected by a larger perception that the locus of decision-making authority had shifted during the design process. While partners were involved in early workshops, important decisions were made without their buy-in.

### **The shift in staff positions from regional to country offices will likely have positive consequences for transparency, timeliness, and appropriateness of TA delivered by those staff, leading to greater relevance, effectiveness, and efficiency of Gavi-funded TA.**

- If carefully and intentionally implemented, this model may build the capacity of EPI programs, taking advantage of more opportunities for face-to-face contact with TA providers with a broader range of skills.

## RECOMMENDATIONS

1. Efforts should be made to make the global-level policy-making processes more inclusive and transparent of all Alliance partners, particularly countries, reflective of shared goals and mission of partners in the Alliance. This has already occurred in 2016 related to Gavi's new grant architecture.
2. Increase the transparency of all Gavi processes, including PEF, via clear communication from SCMs. Ensure that countries receive actionable feedback and appropriate support to implement that feedback at each stage of the process.
3. Ensure that new partners – whether from regional offices or from expanded partners – have the tools to succeed in the first year of implementing PEF-derived TA, including awareness of the other partners, access to coordinating fora and terms of reference that may exist, and Gavi-specific training and capacity-building as needed. This will require planning, coordination, and trust-building among all partners.

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