Gavi Full Country Evaluations

2015 Annual Dissemination Report

Cross-Country Findings

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This report presents findings from the 2015 Gavi Full Country Evaluations (FCE). It was prepared by the Institute for Health Metrics and Evaluation (IHME) at the University of Washington (UW) in collaboration with members of the FCE Team: icddr,b in Bangladesh; University of Eduardo Mondlane (UEM), Mozambique; Manhiça Health Research Centre (CISM), Mozambique; Health Alliance International (HAI), Mozambique; the Infectious Diseases Research Collaboration (IDRC), Uganda; the University of Zambia (UNZA), Zambia; and PATH in the United States.

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Acronyms

Acronym	
AAR	After-Action Review
ABCE	Access, Bottlenecks, Costs, and Equity
APR	Annual Progress Report
BCG	Bacillus Calmette-Guérin
CHAI	Clinton Health Access Initiative
CHU	Child Health Unit
CSO	Central Statistical Office
DBS	Dried blood spots
DFS	Direct financial support
DPI	Department of Planning and Information
DSS	Demographic surveillance site
EA	Enumeration Areas
EPI	Expanded Program on Immunization
FCE	Full Country Evaluations
FCI	Fact-checking interviews
FGD	Focus group discussion
FMA	Financial management assessment
FMR	Financial management requirement
FPHP	Federation for Private Health Professionals
GAMR	Grant Application, Monitoring, and Review
GIS	Geographic Information Systems
GNI	Gross national income
GoB	Government of Bangladesh
HAI	Health Alliance International
HED	Health Engineering Department
HFS	Health Facility Surveys
HLRP	High Level Review Panel
HMIS	Health Management Information System
HPV	Human papillomavirus
HR	Human resource
HSIS	Health Systems Immunization Strengthening
HSS	Health Systems Strengthening
IBD	Invasive bacterial diseases
ICC	Interagency Coordinating Committee
IDRC	Infectious Diseases Research Collaboration
IEC	Information, education, and communication
IFMS	Integrated Financial Management System
IHME	Institute for Health Metrics and Evaluation
IPD	Invasive pneumococcal disease
IPV	Inactivated polio vaccine
IRC	Independent Review Committee
JA	Joint Appraisal
KII	Key informant interviews

KPI	Key Performance Indicators
M&E	Monitoring and Evaluation
MCDMCH	Ministry of Community Development, Mother and Child Health
MCH	Maternal and child health
MoE	Ministry of Education
MoES	Ministry of Education and Sports
MoF	Ministry of Finance
NIP	National Immunization Program
NITAG	National immunization technical advisory groups
NVI	New Vaccine Introduction
NVS	New Vaccine Support
PATH	Program for Appropriate Technology in Health
PBF	Performance-based funding
PCV	Pneumococcal vaccine
PEF	Partner Engagement Framework
PFA	Program Financial Assessment
PHC	Primary health care
PIE	Post Introduction Evaluation
RBF	Results-based financing
RFI	Request for information
RT	Resource tracking
SCM	Senior Country Manager
SEA	Standard Enumeration Areas
SFA	Strategic focus area
SHA	System of Health Accounts
SIA	Supplementary Immunization Activities
SMART	Specific, Measurable, Attainable, Relevant, Trackable
SNA	Social network analysis
TA	Technical assistance
TCA	Technical Capacity Assessment
TOC	Theory of change
UBOS	Uganda Bureau of Statistics
UEM	University of Eduardo Mondlane
UNEPI	Uganda National Expanded Program on Immunisation
UNITAG	Uganda National Immunization Technical Advisory Group
UNZA	University of Zambia
UW	University of Washington
VTS	Vaccine serotypes
WHO	World Health Organization
ZISSP	Zambia Integrated Systems Strengthening Program

Executive summary

Introduction

The Gavi Full Country Evaluations (FCE) are prospective studies covering the period 2013-2016 that aim 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 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. The first annual dissemination report (2013) evaluated the introduction process of pneumococcal vaccine (PCV) in Mozambique, Uganda, and Zambia (available online). The second annual dissemination report (2014) evaluated multiple Gavi support streams in all four countries. This third annual dissemination report complements previous reports by providing key findings and recommendations for the 2015 evaluation period in the four evaluation countries.

The FCE encompasses all phases of Gavi support, from the decisions 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 scope of the evaluation during the 2015 period.

Table 1: Overview of streams evaluated in each country

	Bangladesh	Uganda	Mozambique	Zambia
Health Systems Strengthening (HSS)	Conclusion of HSS-1 grant and application for HSS-2	Implementation of HSS-1	Implementation of HSS-2	Application for HSS-2
Human papillomavirus vaccine (HPV)	Preparation for demonstration project	Preparation for national introduction	Year two of demonstration project	Post-demonstration project
Inactivated polio vaccine (IPV)	Preparation, launch and post-introduction	Preparation for introduction	Preparation for introduction	Preparations for introduction
Measles-rubella vaccine (MR)				Application
Measles second dose (MSD)			Preparation for introduction	Post-introduction
Meningitis A Vaccine (Men A)		Application		

Rotavirus vaccine		Application	Preparation for introduction and launch	Post-introduction
Pneumococcal conjugate vaccine (PCV)	Preparation, launch and post-introduction	Post-introduction	Post-introduction	Post-introduction

In 2015 we identified pertinent cross-country evaluative themes outside of Gavi's streams to guide additional data collection in countries and at the global level. These themes are programmatic and financial management capacity, technical assistance, and Gavi's new approach to funding technical assistance: the Partners' Engagement Framework.

Methods

We used a mixed-methods approach to generate the findings included in the Gavi FCE 2015 report, including process tracking based on document review, observation, and fact-checking interviews; in-depth process of the process using key informant interviews (KII), focus group discussion (FGD), and social network analysis (SNA); resource tracking studies to generate estimates of national-level resource envelopes on immunization; analysis of Health Management Information Systems (HMIS); health facility surveys; household surveys; analysis of secondary data to generate small-area estimates of vaccine coverage and child mortality at subnational levels; causal analysis of small-area estimates of vaccine coverage and child mortality at subnational levels to estimate the relationship between new vaccine introductions and child mortality; and vaccine effectiveness studies in Mozambique, including pre- and post-introduction nasopharyngeal carriage surveys and pre-and-post analyses of surveillance data on invasive pneumococcal disease and X-ray-confirmed pneumonia.

Key findings

Below we summarize the key findings from the 2015 evaluation period. We cover the main cross-country findings which synthesize the findings from each of the four FCE countries and the global level. These are arranged around five main areas: new vaccine introductions (excluding HPV vaccine); HPV vaccine; Health Systems Strengthening; programmatic and financial capacity; and technical assistance including the Partner Engagement Framework. The country reports contain the findings specific to each of the four FCE countries. For each finding, we designated a ranking that reflects the robustness of evidence (both qualitative and quantitative) with the four-point ranking scale (Annex 3) and note our qualitative assessment of generalizability of the finding.

New vaccine introductions

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 stockouts 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. (Robustness ranking: A; Generalizability: Medium)

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 8.9–91.7 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)

HPV vaccine

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 limited mechanisms to transfer evidence and lessons from other countries' experiences when designing HPV vaccine demonstration projects. (Robustness ranking: A; Generalizability: High)

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. (Robustness ranking: A; Generalizability: Medium)

Health systems strengthening

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. (Robustness ranking: B; Generalizability: High)

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. (Robustness ranking: B; Generalizability: Medium)

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. (Robustness ranking: C, Generalizability: Medium)

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. (Robustness ranking: B, Generalizability: Medium)

Programmatic and financial capacity

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. (Robustness ranking: B, Generalizability: High)

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. (Robustness ranking: B, Generalizability: High)

3. Overly optimistic application and implementation timelines – set by Gavi and by countries – result in the limited ability to adaptively manage grants. (Robustness ranking: B, Generalizability: High)

Technical assistance, including the Partners' Engagement Framework

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.
(Robustness ranking: B, Generalizability: N/A)

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 EPI programs. 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 the potential to build country capacity going forward. (Robustness ranking: A, Generalizability: N/A)

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. (Robustness ranking: A, Generalizability: N/A)

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. (Robustness ranking: B, Generalizability: Medium)

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. (Robustness ranking: B, Generalizability: High)

Recommendations

For each cross-country and country-specific finding described above, we developed related recommendation(s). Table 2 summarizes the recommendations for the cross-country findings. In the table we noted the intended audience for the recommendation as well as the FCE team's assessment of generalizability based on other studies and information at hand. For brevity, we have not included the country-specific recommendations in this table but include them at the beginning of each of the country-specific sections.

Table 2: Cross-country findings and recommendations, including intended audience and generalizability

Finding	Recommendation(s)	Audience	Robustness ranking	Generalizability
New vaccine introductions, excluding HPV vaccine				
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.	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. This includes data on vaccine coverage and vaccine supply. 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.	Gavi Secretariat, Alliance partners, Countries Gavi Secretariat, Alliance partners, Countries	A	Medium

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 8.9–91.7 reduction in PCV10 serotype-specific invasive pneumococcal disease) suggest that the scale-up of PCV is reducing pneumococcal disease burden in Mozambique.			B	Medium
HPV vaccine				
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 limited mechanisms to transfer evidence and lessons from other countries' experiences when designing HPV vaccine demonstration projects.	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.	Alliance partners, Gavi Secretariat Alliance partners, Gavi secretariat	A	High

	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.			
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.	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	Gavi Secretariat, Alliance partners	A	Medium

	refine the delivery model prior to the second year of the demonstration project.			
Health systems strengthening				
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.	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	Gavi Secretariat, Alliance partners Gavi Secretariat, Alliance partners, countries	B	High

	HSS team (with increased staffing) at the design phase.			
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.	1. 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 recommend 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.	Gavi Secretariat, Alliance partners	B	Medium

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.	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.	Gavi Secretariat, Alliance partners, countries	C	Medium
	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.	Gavi Secretariat, Alliance partners		

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.	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.	Alliance partners, countries	B	Medium
Programmatic and financial capacity				
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.	1. Gavi and Alliance partners should invest further in strengthening national and subnational 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	Gavi Secretariat, Alliance partners, countries	B	High

	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.	Gavi Secretariat

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.	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.	Gavi Secretariat	B	High
3. Overly optimistic application and implementation timelines – set by Gavi and by countries – result in limited ability to adaptively manage grants.	1. 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.	Countries, Gavi Secretariat, Alliance partners	B	High

*Technical assistance, including the Partners' Engagement Framework**			
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.	B	Not applicable

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.	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.)	Gavi secretariat, Alliance partners and countries	A	Not applicable

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.	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	Gavi Secretariat	A	Not applicable

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.	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.	Gavi secretariat	B	Medium

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.	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.	Gavi secretariat	B	High

* Recommendations for this section are not specific to a particular finding

Contents

Introduction

The Gavi Full Country Evaluations (FCE) is a prospective study covering the period 2013-2016 with the aim of understanding and quantifying the barriers to and drivers of immunization program improvement, with emphasis on the contribution of Gavi, the Vaccine Alliance in four countries: Bangladesh, Mozambique, Uganda, and Zambia. This third annual dissemination report complements previous reports by providing key findings and recommendations for the 2015 evaluation period in the four FCE countries. The FCE encompasses all phases of Gavi support, from decisions to apply, application and approval, preparation, and implementation in each of the relevant streams of support. Table 3 summarizes the scope of the evaluation during the 2015 period. In addition to evaluating the various streams of support active in each of the FCE countries, we have in parallel also included findings related to cross-stream processes, most notably, the Joint Appraisal (JA) and Partner Engagement Framework (PEF).

Table 3: Overview of streams evaluated in each country

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

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:

- Process tracking based on document review, observation, and fact-checking interviews;
- Root-cause analysis to identify underlying causes of identified challenges and successes;
- In-depth analysis of the process using key informant interviews (KII), focus group discussion (FGD), and social network analysis (SNA);
- Resource tracking studies to generate estimates of national-level resource envelopes on immunization, including newly conducted studies in Uganda, Mozambique, and Zambia;
- Analysis of Health Management Information Systems (HMIS) and EPI administrative data to understand the rollout of new vaccine introductions;
- Health facility surveys with observation at facilities, including continuous measurement of cold-chain temperatures and patient exit interviews in Uganda and Bangladesh (Annex 9 and Annex 13). The Zambia health facility survey was reported on in the 2014 FCE report.
- Household surveys (HHS) in Uganda and Zambia on immunization coverage and related key indicators (Annex 11 and Annex 15). Household survey samples were sampled to overlap with health facility survey.
- Analysis of secondary data to generate small-area estimates of vaccine coverage and child mortality at subnational levels (Annex 6);
- Causal analysis of small-area estimates of vaccine coverage and child mortality at subnational levels to estimate the relationship between new vaccine introductions and child mortality (Annex 5); and
- Vaccine effectiveness studies in Mozambique, including pre- and post-introduction nasopharyngeal carriage surveys and pre-and-post analyses of surveillance data on invasive pneumococcal disease and X-ray-confirmed pneumonia.

Strengths and limitations of the Gavi FCE approach are summarized in Table 4.

Table 4: Strengths and limitations of the Gavi FCE

Strengths
• Mixed-method approach allows for triangulation of findings across evaluation components to increase robustness of findings and provide more in-depth understanding. Findings from one data source also inform the design and implementation of other data collection. • Concurrent evaluation of all relevant streams of Gavi support in a country allows for timely understanding of the interactions between streams of support. • Evaluations such as Post-Introduction Evaluations (PIEs), monitoring and evaluation of HPV vaccine demonstration projects, or HSS monitoring and evaluation focus on the implementation phase. The Gavi FCE complements these by examining the full process from decision-making to application, preparation, implementation and routinization, and allows identification and linkage of issues earlier in the process with downstream consequences.

- Data collection designed to build on or complement other surveys and activities to minimize duplication.
  Prospective approach allows for collection of information in real time so that key issues may be identified as they arise, allowing for the opportunity to inform implementation process and implement corrective action.

Limitations

- Due to the wide scope of the FCE, there is a limited ability to examine all issues in detail. However, the broad scope compels selective and more in-depth evaluation of critical issues that are priority areas for Gavi and countries.
- Limited ability to prospectively collect information on larger scale political-economic and social processes (e.g., priority setting at the donor level; social displacement and migration at the country level) that affect immunization activities but fall outside the analytical scope of the process tracking of defined milestones.
- Although there is a better ability to access informal channels of communication and decision-making, there are limits to this which result in an incomplete understanding of the process.
- Absence of a prospective observation mechanism at the regional or global level and at subnational levels.
- In-depth qualitative data collection relies heavily on KIIs that are prone to recall and respondent bias.
- In each country there are a limited number of stakeholders involved across multiple streams, introducing significant potential for respondent fatigue in key informant interviews.
- The timing of surveys means that the evaluation is only able to capture relevant aspects of some, but not all, Gavi support streams.
- Secondary data analyses are subject to the availability and quality of the underlying data source (e.g., HMIS, surveys).

Findings

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

We present findings and recommendations organized around five focus areas that were developed in consultation with the Gavi Secretariat Monitoring & Evaluation team:

1. New vaccine introductions (excluding HPV vaccine)
2. HPV vaccine
3. Health systems strengthening
4. Programmatic and financial capacity
5. Technical assistance, including the Partner Engagement Framework

New Vaccine Introductions

A number of new and underused vaccine introductions with Gavi support have been implemented in Gavi FCE countries over the course of the evaluation period (Table 5). We cover the implementation of HPV vaccine in a separate section of the report.

Table 5: New and underused vaccine introductions in Gavi FCE countries, 2013 to December 2015

	Bangladesh	Mozambique	Uganda	Zambia
Pneumococcal conjugate vaccine	March 2015	April 2013	April 2013	July 2013
Rotavirus vaccine		September 2015		November 2013
Measles second dose		November 2015		July 2013
Inactivated polio Vaccine	March 2015	November 2015		
Measles-rubella campaign	January 2014			

The 2014 Gavi FCE dissemination report covered the evaluation of the measles-rubella campaign in Bangladesh, which showed high post-campaign coverage and corresponding reductions in rubella susceptibility. Given the campaign nature of this support stream, we do not report further on the campaign evaluation. MR continues to be delivered through routine EPI in Bangladesh.

In this 2015 report, we cover early-term findings (10 months post-introduction) for the joint PCV and IPV introduction in Bangladesh. In addition, we report on the ongoing monitoring of PCV routinization in Mozambique, Uganda, and Zambia, and on rotavirus vaccine in Zambia. We present preliminary findings on the impact of PCV introduction on pneumococcal disease burden, based on studies in Mozambique. In Mozambique, the rotavirus vaccine introduction occurred in September 2015, and IPV and MSD occurred in November 2015. We have not reported on these in detail in the 2015 Annual Report, beyond the preparatory activity process (Mozambique country report, p. 20). This will be covered in detail in the 2016 FCE report.

Finding 1

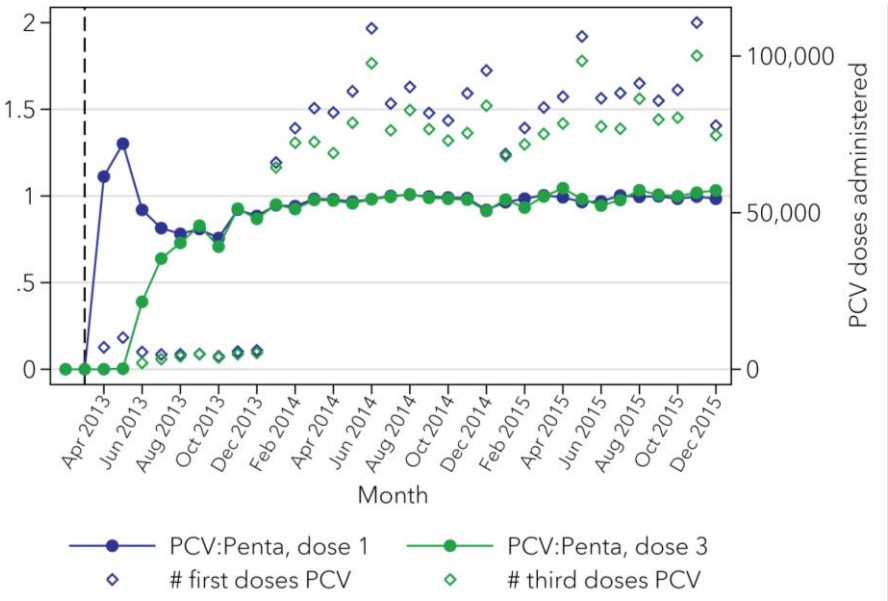
Gavi FCE countries have successfully introduced a range of new vaccines. PCV has been fully routinized in Mozambique, and the first and second dose of PCV were rapidly scaled up in Bangladesh following the joint launch with IPV in March 2015. Challenges, however, persist. In Uganda, PCV delivery remains 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. (Robustness ranking: A; Generalizability: Medium)

Full routinization of PCV in Mozambique

Findings from the 2013 and 2014 FCE reports, which covered the period from the initial PCV launch in April 2013 through December 2014 showed a relatively rapid scale-up of PCV delivery, with the number of delivered PCV doses reported by HMIS approaching the delivery level of existing vaccines (i.e., pentavalent vaccine[1]).

Updated HMIS analysis in the 2015 evaluation period (Figure 1) show that the scale-up of PCV has continued, with delivery stabilizing at levels equivalent to pentavalent vaccine by the beginning of the second quarter of 2014. These findings suggest that PCV has been fully routinized into the Mozambican immunization system.

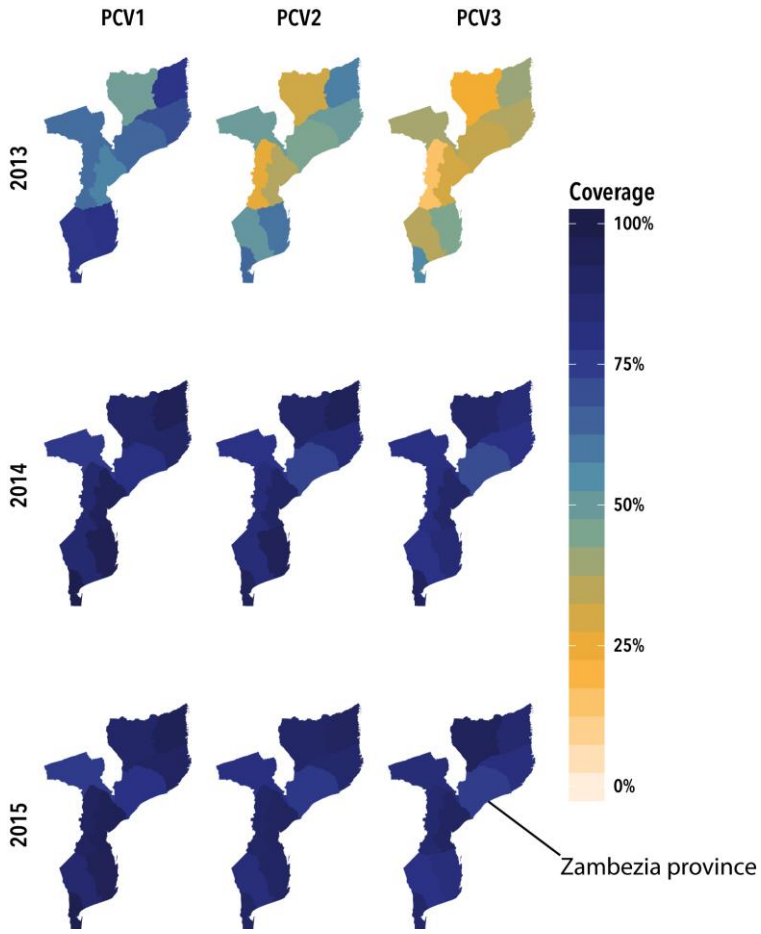
Figure 1: Ratio of PCV to pentavalent doses reported to be delivered from HMIS in Mozambique. A ratio of 1 indicates that PCV has the same number of doses delivered as pentavalent vaccine. *The dashed vertical line indicates when PCV was introduced.*



[1] Three doses of PCV and pentavalent vaccine are delivered to children on a similar schedule. As pentavalent vaccine is already part of routine EPI delivery it provides an appropriate comparator for the routinization of PCV.

We combine HMIS data analysis with Gavi FCE small-area-level estimates of pentavalent vaccine coverage from surveys (Annex 7). The resulting subnational estimates of PCV coverage show generally high coverage across Mozambique in 2014 and 2015 (Figure 2). Coverage is notably lower in Zambezia province, which indicates that even with full routinization of PCV, there is lower coverage of existing vaccines (i.e., pentavalent vaccine). This lower coverage reflects existing immunization system bottlenecks.

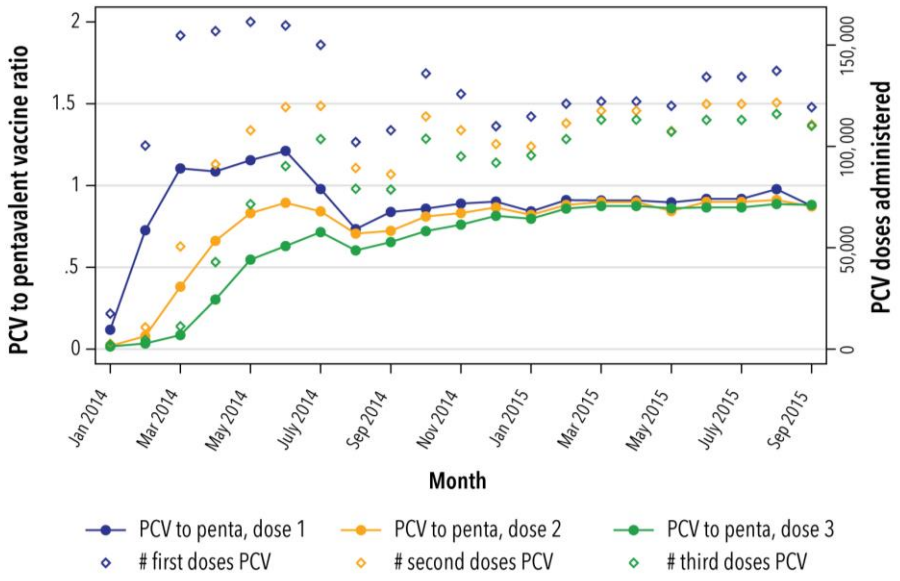
Figure 2: Estimated coverage of PCV by dose and province in Mozambique



Though progress has been made PCV is not fully routinized in Uganda

The 2013 and 2014 FCE report describes the lengthy process of introducing PCV in Uganda. The initial launch in April 2013 was restricted to a single district and an extended time period was required to meet the PCV readiness assessment and introduce the vaccine across all remaining districts. From January 2014, PCV was then gradually rolled out across country; however, delivery declined notably in the last quarter of 2014 (Figure 3). The most recent HMIS data available to the FCE team, which extends through September 2015, indicates that PCV was not fully routinized, with delivery remaining at 11.6% below that of pentavalent vaccine in the third quarter of 2015.

Figure 3: Ratio of PCV to pentavalent doses reported to be delivered from HMIS in Uganda
A ratio of 1 indicates that PCV has the same number of doses delivered as pentavalent vaccine.



Stock-outs in Uganda hindered full routinization of PCV

A root cause of suboptimal routinization in Uganda was the stock-outs of PCV at multiple levels of the health system, as illustrated in Figure 5. The Gavi FCE health facility survey completed in early 2015 noted widespread stock-outs of PCV in the last quarter of 2014 (

Figure **4**). This was also confirmed by the PCV post-introduction evaluation (PIE). The Gavi FCE household survey in Uganda, implemented in the middle of 2015, also indicates that stock-outs were a primary root cause, with 14.1% of mothers of age-eligible children reporting that PCV was unavailable at the time they visited the facility to vaccinate their child.

Figure 4: Stock-outs reported by facilities for the approximate period of Q4, 2014, for all antigens. This includes any stock-out lasting at least one day *(source: Uganda Gavi FCE Health Facility Survey)*

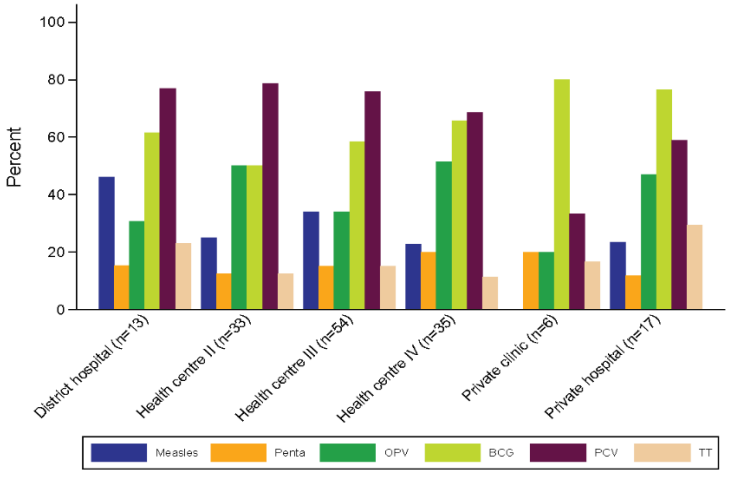
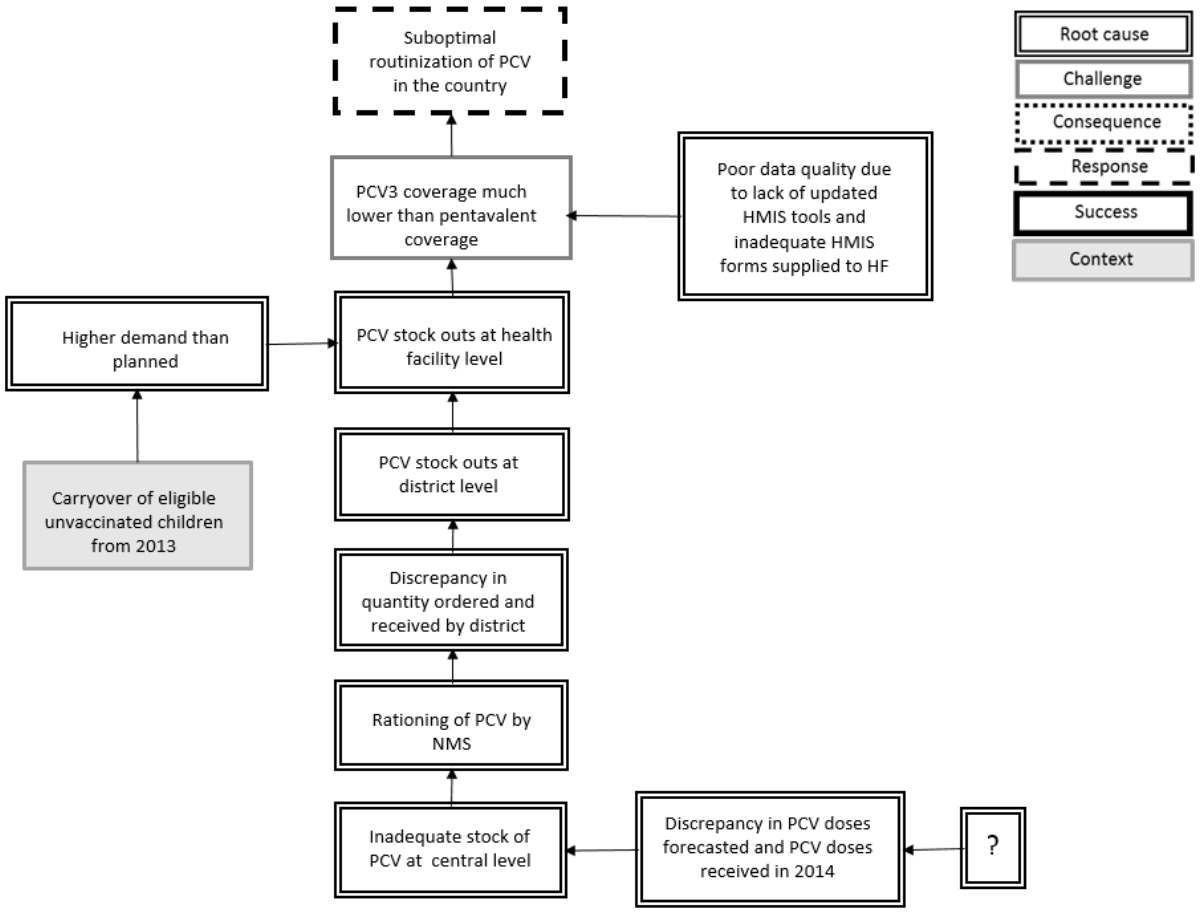


Figure 5: Root cause analysis for a lower PCV coverage as compared to pentavalent in Uganda in 2014



Inadequate supply of PCV at the national level may have contributed to the suboptimal routinization. There are inconsistencies in the vaccine needs forecasted by the country in the Annual Progress Reports, the amount committed by Gavi in the annual decision letters, and the amounts shipped to the country by UNICEF in 2014.

In the past, Uganda submitted an Annual Progress Report (APR) to Gavi that includes the target number of children to be immunized for each vaccine. In the 2013 APR, submitted in May 2014, Uganda forecasted the same number of target children to be vaccinated for both Pentavalent and PCV vaccines in 2014 and 2015. The number of doses of each vaccine to be provided by Gavi is outlined in the annual Gavi decision letter and is based on key parameters that the country provides in the APR, including the target number of children, number of doses for fully immunized child (3 for Penta; 3 for PCV), the calculated wastage rate, and the desired level of buffer stock. The target number of children and number of doses for fully immunized child are the same for PCV and Penta, while the wastage rate differs between the two vaccines.

Uganda forecasted a total of 4,691,200 PCV doses were needed in 2014, however the 2013 Gavi decision letter committed only 2,736,700 PCV doses (including the Gavi and country co-financed vaccines). According to UNICEF shipping records, only 3,830,000 PCV doses were shipped to the country in 2014, and the National Medical Stores (NMS) stock status reports indicated only receiving 3,205,000 PCV

doses. Thus, there is a shortfall between what the country forecasted for PCV doses needed in 2014 and what was actually reported as received at the national level in 2014. NMS confirmed that there were insufficient quantities of PCV at the national level in 2014 and they resorted to rationing PCV doses dispersed to lower levels of the health system, which could have led to stock-outs at district and facility levels.

These large inconsistencies are not seen in 2015, where the amount of PCV doses forecasted in the 2014 APR is consistent with the amount of PCV doses committed in the Gavi decision letter (both show 4,861,600 PCV doses). According to the UNICEF shipping records, 4,843,200 PCV doses were shipped to Uganda in 2015 which is consistent with the NMS stock status reports on the amount of PCV doses received.

At this time, the FCE team is unsure of the reason for this discrepancy in PCV doses forecasted compared to those received in 2014. There is confusion among national stakeholders about the reason for receiving inadequate doses at the national level. Key informants from NMS attributed the insufficient doses to inaccurate quantification, whereas most key informants from the MoH thought that less PCV doses had been shipped to the country due to delayed co-financing.

> *We received less doses of PCV than we anticipated. We were made to understand that we only got the doses paid for by Gavi since the country had not honored the co-financing obligations. But this did not last long.* (MoH KII)

> *We had not paid all co-financing, this could have affected the quantities (PCV) shipped.* (MoH KII)

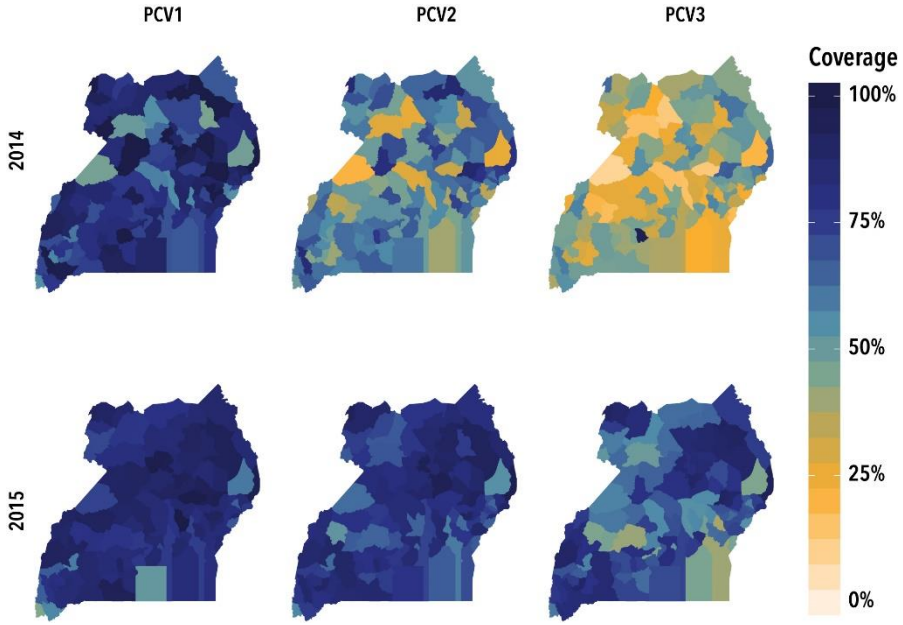
Gavi co-financing is actually co-procurement; the country co-finances a new vaccine by directly procuring a fraction of the required doses. According to UNICEF shipping records, the total of 262,000 PCV doses to be co-financed by the country in 2013-2014 were not actually shipped until the 3rd quarter of 2015. Despite this delay in Uganda's co-financing commitment, this only represents a small fraction of the total number of PCV doses and should not have resulted in major stock-outs.

> *The part they need to procure is very small, so at the end of the day if they don't procure they are not going to have stock-outs; it's not that they're not going to vaccinate children because Gavi provides a 25% buffer in the system and their co-financing is around 5 to 7, 7 to 10%. So they don't feel it.* (Global-level KII, Gavi Secretariat)

Given the inconsistencies between the PCV doses forecasted and received in 2014, and the conflicting reasons for stock-outs cited by national-level stakeholders in Uganda, the FCE team is not able to come up with a conclusive explanation for the suboptimal PCV routinization. The FCE team continues to gather evidence to fully understand the primary causes for both the national level PCV stock-outs in 2014 and continued lack of complete routinization in 2015.

At the subnational level, even after accounting for improved routinization of PCV as measured by the PCV: pentavalent ratio, remaining geographic inequities reflect existing bottlenecks in Uganda's immunization system. There was both less-than-full routinization of PCV in Uganda and existing inequities in pentavalent vaccine coverage, with three-dose coverage of PCV being less than 75% across more than half of the districts and less than 40% in Mubende, Namutumba, and Kyenjojo districts (Figure 6).

Figure 6: Estimated coverage of PCV by dose and district in Uganda



Routinization of PCV and rotavirus vaccine in Zambia also remains incomplete

In Zambia, PCV and rotavirus vaccine were launched in July and November of 2013, respectively. These new vaccine introductions did not suffer a protracted rollout as was experienced in Uganda. Gavi FCE Health Facility data reported in the 2014 Gavi FCE report suggested that the scale-up of these two new vaccines was approaching that of existing vaccines, i.e., pentavalent vaccine. The 2015 FCE report updates this coverage analysis using HMIS data up to quarter three of 2015. These data indicate that while delivery of PCV and rotavirus vaccine stabilized over 2014 and the first half of 2015, it remained lower than existing vaccines in the system (Figure 7 and Figure 8), particularly for rotavirus vaccine. Data indicate some improvement in the last quarter of 2015 for both new vaccines.

Figure 7: Ratio of PCV to pentavalent doses reported to be delivered from HMIS in Zambia
A ratio of 1 indicates that PCV has the same number of doses delivered as pentavalent vaccine. The vertical dashed line indicates the month PCV was introduced.

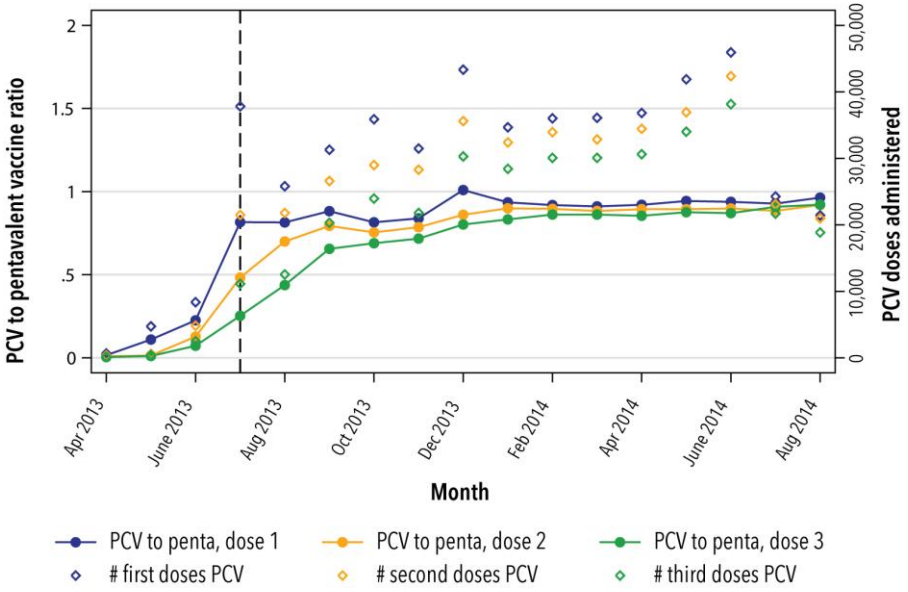
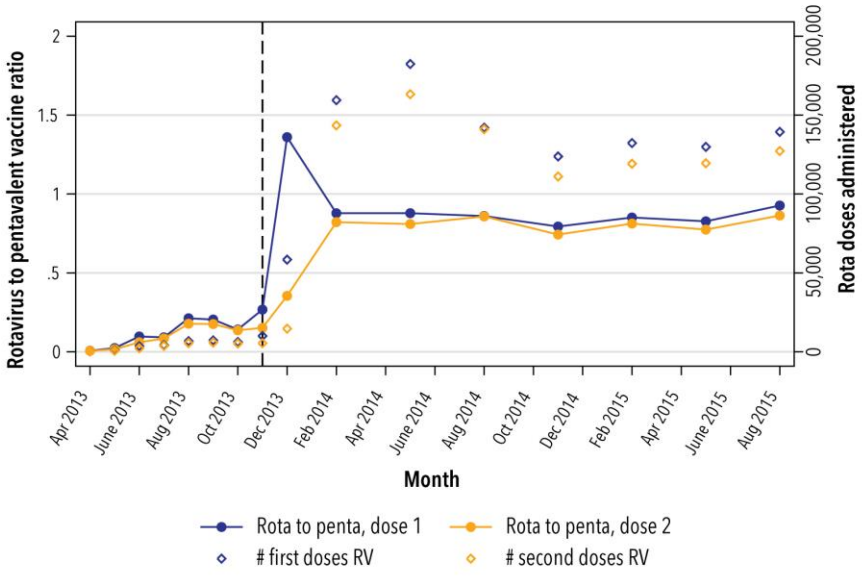


Figure 8: Ratio of rotavirus vaccine to pentavalent doses reported to be delivered from HMIS in Zambia. *A ratio of 1 indicates that rotavirus vaccine has the same number of doses delivered as pentavalent vaccine. The vertical dashed line indicates the month rotavirus vaccine was introduced*.



Less-than-complete routinization of PCV and rotavirus vaccine driven by stock-outs in Zambia

Low routinization is attributable to several factors. There have been reports of stock-outs in several districts that the FCE team has conducted fact checking interviews in. At the national level, while the national logistician indicated that there have been no national level stock-outs, it was confirmed that

logistical challenges in getting vaccines from national to district level have caused stock-outs of PCV and Rota in some districts. It was also pointed out that PCV and Rota supplies by UNICEF are based on an anticipated 60% coverage in year 1 and about 80-90% in year 2, which has not since been updated and could also contribute to stock-outs at district level. Another factor contributing to this has been challenges with getting accurate target population figures – whilst government supplies of pentavalent vaccine are given according to requested demand, supplies of PCV and rotavirus vaccine from UNICEF are according to CSO official figures, which are often underestimated. The government has since communicated to UNICEF to request for more PCV and rotavirus stocks to meet the shortfall.
Similar to Uganda, the combination of less-than-full routinization of the new vaccines and existing geographic inequalities in vaccine coverage are represented in the estimates of PCV and rotavirus vaccine coverage (Figure 9 and Figure 10). A large number of districts have PCV coverage of less than 75%, with Mumbwa, Shang'ombo, Kapiri-Mposhi, Kalomo, and Mkushi districts having less than 50% coverage. A similar pattern emerges for two-dose rotavirus vaccination coverage, with Sinazongwe and Kapiri-Mposhi districts having two-dose rotavirus vaccine coverage of less than one-third.

Figure 9: Estimated coverage of PCV by dose and district in Zambia

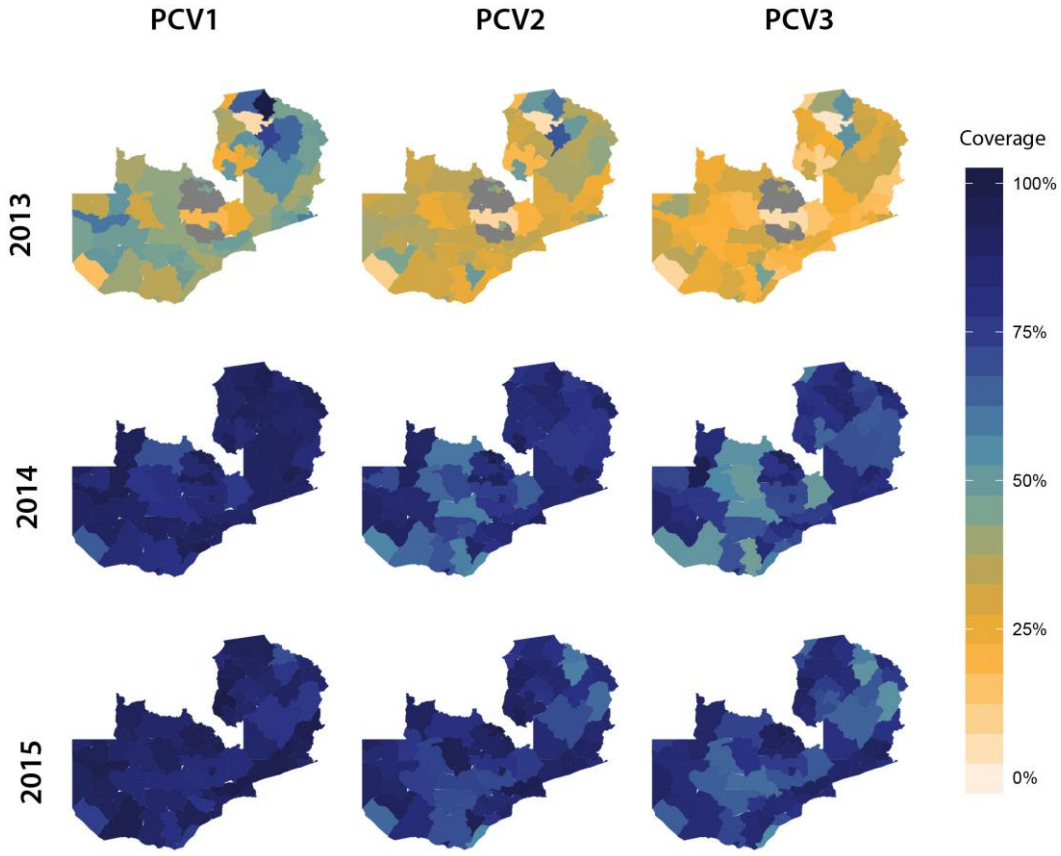
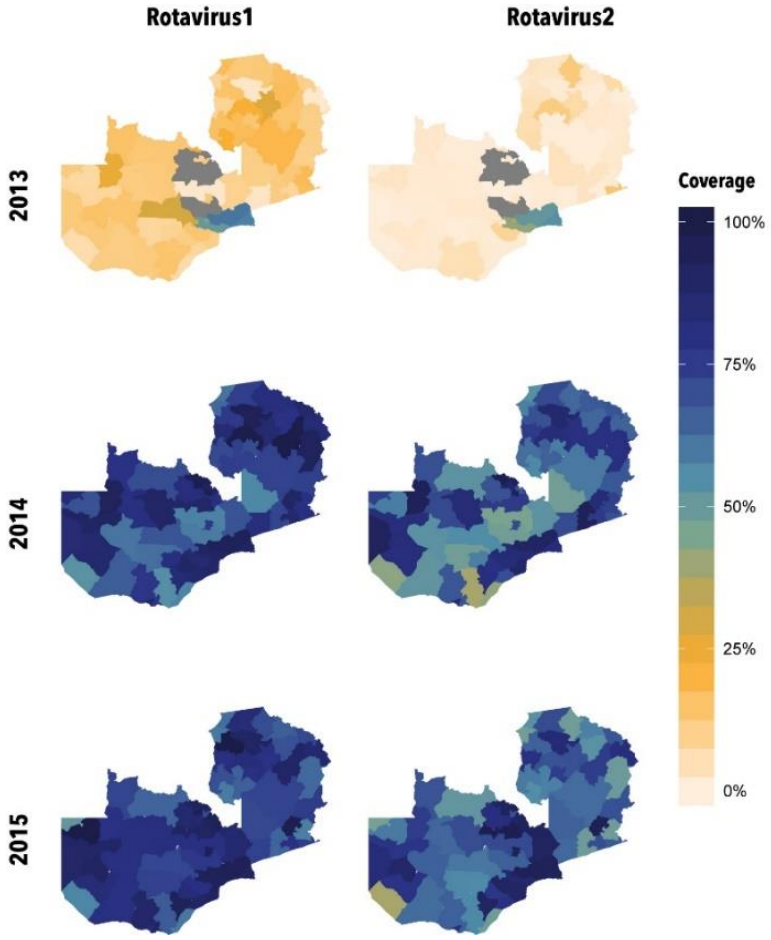


Figure 10: Estimated coverage of rotavirus vaccine by dose and district in Zambia



Ongoing monitoring of new vaccine delivery beyond the post-introduction evaluation (PIE) period of six to 12 months is critical

The two case studies of Uganda and Zambia, both with less-than-full routinization of new vaccine delivery one to two years post-introduction highlight the importance of ongoing monitoring of new vaccine introductions. While the Post-Introduction Evaluations (PIE) conducted six to 12 months post-introduction are a valuable tool to understand the preparation phase (training, social mobilization, etc.) and the initial rollout, timely and continued monitoring of new vaccine delivery and following through on findings and recommendations from the PIE is critical to ensure that these vaccines are fully routinized into the system. The ability to monitor ongoing delivery is significantly hampered by the timely availability of administrative data for this purpose. For example, in Zambia, HMIS data were not complete for a number of districts in the Copperbelt region (Figure 10).

First- and second-dose PCV has been rapidly scaled up, however, third-dose PCV delivery is not yet fully routinized in Bangladesh

PCV and IPV were jointly launched in March of 2015 in Bangladesh. The early findings show how the EPI and partners worked together to launch both vaccines in March 2015; this is described in further detail in the Bangladesh country report (p. 20). An aspect of this was implementation of the PCV readiness

assessment. The PCV readiness assessment was better communicated and executed in Bangladesh compared to the other three FCE countries, as detailed in the 2013 FCE report. The challenges experienced in other countries encouraged the Gavi Secretariat to send reminders to Bangladesh and other countries slated to launch PCV10. Bangladesh received a reminder six months prior to the scheduled launch in Q4 2014, and the UNICEF country office also reminded GoB about the completion of the readiness assessment as a pre-condition to vaccine shipment.

The results from the FCE Health Facility Survey (Figure 11) and HMIS (Figure 12) show the scale-up of PCV and IPV. Once introduced, coverage of first- and second-dose PCV rapidly increased to the same level as pentavalent vaccine. However, third-dose PCV remains less than fully routinized when compared to third-dose pentavalent vaccine (Figure 12).

Figure 11: Ratio of PCV to pentavalent doses reported to be delivered from the Health Facility Survey in Bangladesh. *A ratio of 1 indicates that PCV has the same number of doses delivered as pentavalent vaccine.*

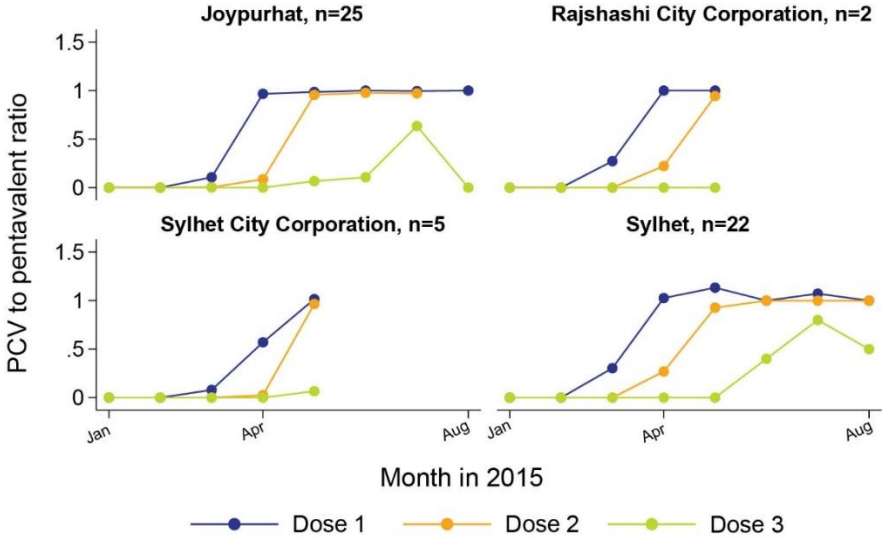
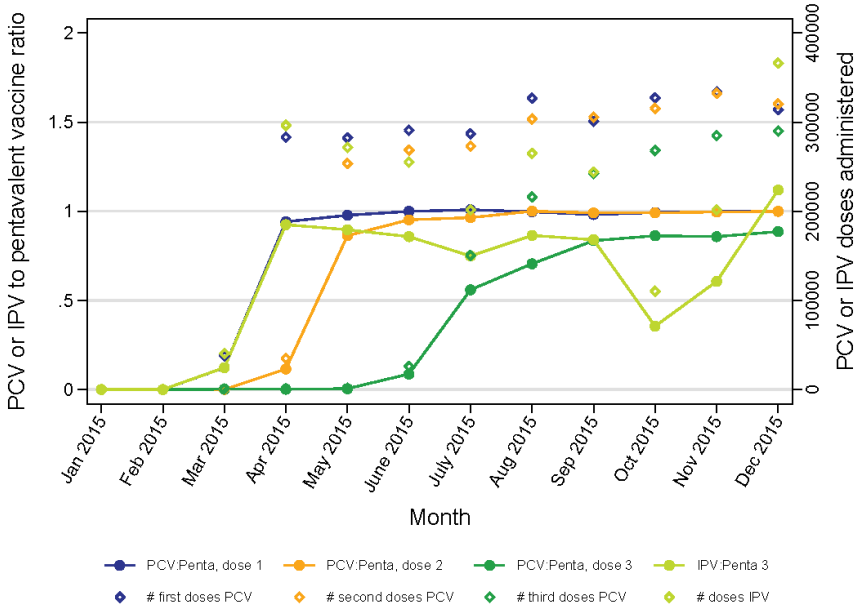


Figure 12: Ratio of PCV/IPV to pentavalent doses reported to be delivered from HMIS in Bangladesh. *A ratio of 1 indicates that PCV/IPV has the same number of doses delivered as pentavalent vaccine.*

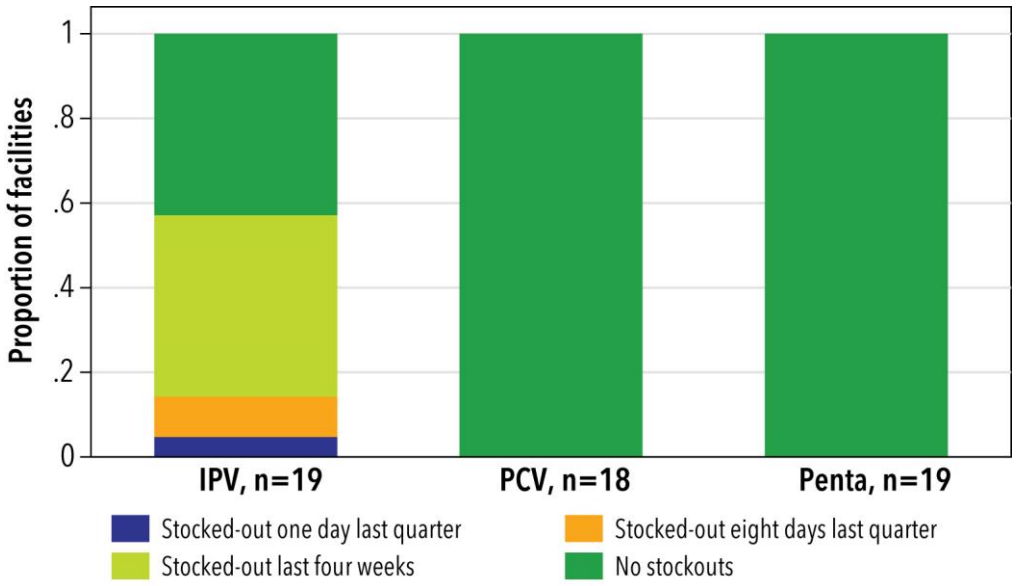


One likely root cause is the introduction of a separate visit for third-dose PCV (at 18 weeks) rather than delivery of third-dose PCV at the same visit as third-dose pentavalent (at 14 weeks). The separate visit was based on evidence suggesting that mothers preferred a separate visit for third-dose PCV. However, the need for caregivers and children to return on a separate occasion for third-dose PCV may contribute to higher dropout for PCV compared to pentavalent vaccine.

IPV was initially scaled up rapidly in Bangladesh but coverage suffered from stock-outs driven by higher than expected wastage of multi-dose vials and inaccurate forecasting of supply

IPV has suffered from successful integration into routine immunization program in the first six to eight months following introduction (Figure 11) and Figure 12). This was driven by widespread IPV stock-outs, as noted in the Gavi FCE survey (Figure 12), with 57% of facilities reporting stock-outs in the last quarter and many of these facilities experiencing continuous stock-outs over the previous four weeks (duration varied from March to August 2015, based on time of data collection).

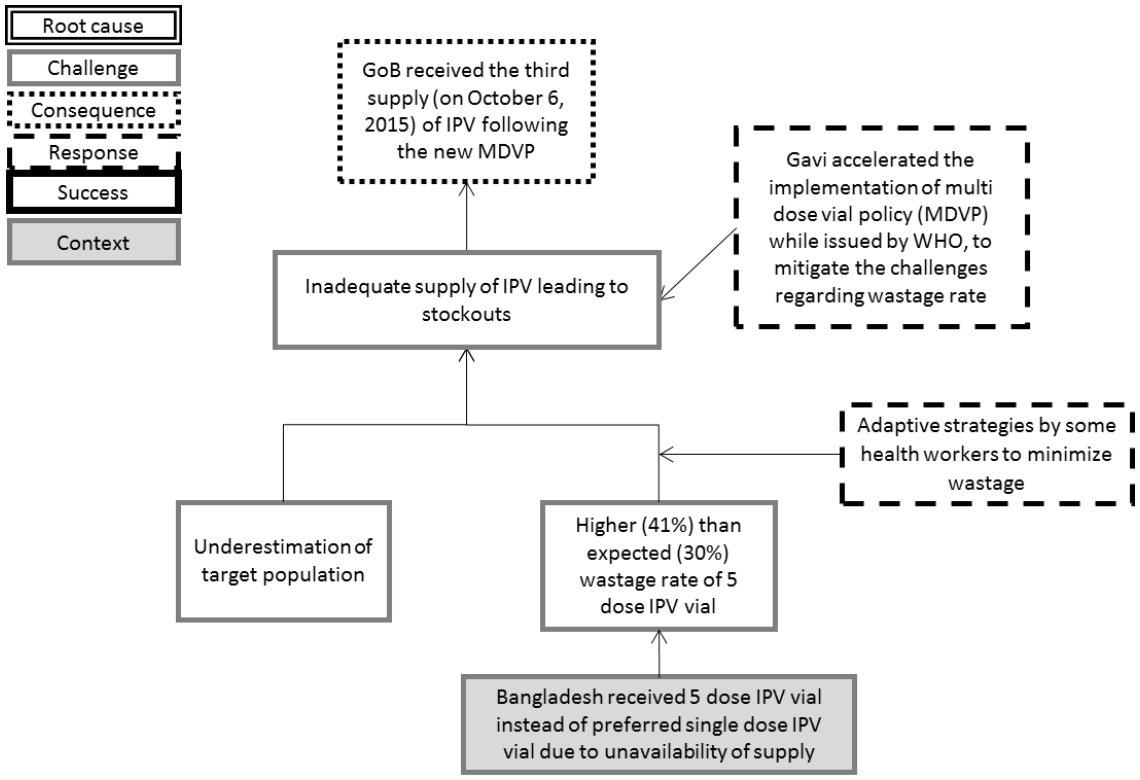
Figure 13: Health facility survey reports of vaccine stock-outs for IPV, PCV, and pentavalent vaccine, Bangladesh, Q2 2015



Our process evaluation describes the root causes of these stock-outs (Figure 14). Administrative data indicated that the wastage rate was 41% (up to end of October 2015) while according to one key informant the PCV/IPV PIE found a 38% wastage rate of IPV; this is in comparison to the projected wastage rate of 30% that was used to determine vaccine supply, which is a root cause of the stock-outs in addition to the unavailability of the one-dose presentation as earlier described:

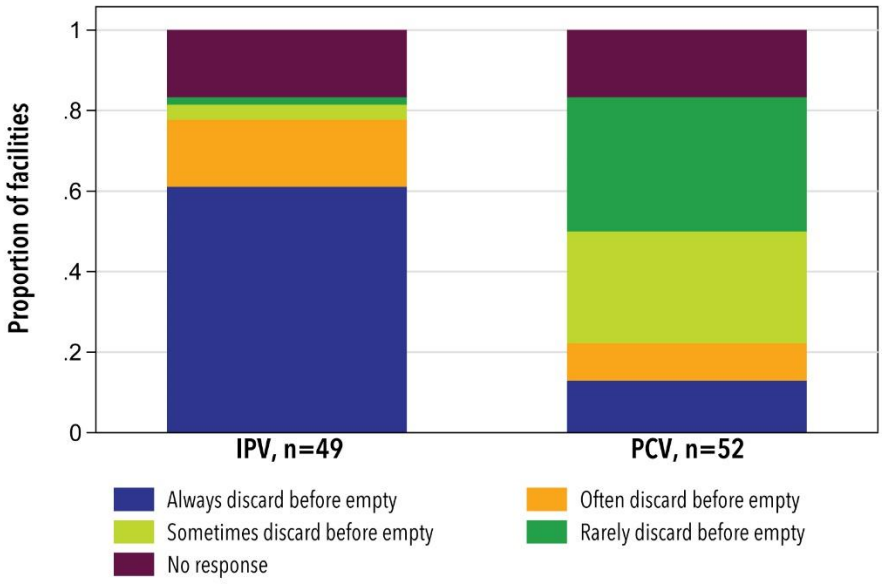
> *Bangladesh has 120,000 outreach centers, so at least one vial needs to be distributed for each center, regardless of the targeted number. However, the country had to apply for IPV based on population, and Gavi estimated the wastage rate based on the targeted population and vaccine doses, not on vaccine vial, which resulted in high shortage of IPV.* (Bangladesh KII)

Figure 14: Root causes analysis of IPV stock-outs in Bangladesh



In some areas in Bangladesh, adaptive strategies have been used. For example, some subdistrict-level supervisors directed health workers to merge children of two or more nearby EPI sessions and vaccinate accordingly. The Gavi FCE health facility survey confirms the high wastage of IPV in comparison to, for example, PCV (Figure 15).

Figure 15: Health facility survey reports of vaccine discard for IPV and PCV, Bangladesh, Q2 2015



IPV stock-outs were mitigated by introducing a multi-dose vial policy at the end of 2015 These challenges were addressed in the third supply of IPV (October, 2015) that allows use up to 28 days after opening the vial cap (with accompanying guidelines on storage procedure). In addition, from the second year of IPV introduction, supply will be estimated based on coverage for the previous year. These actions led to a rebound in delivery of IPV in December 2015 (Figure 12).

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. This includes data on vaccine coverage and vaccine supply. 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.

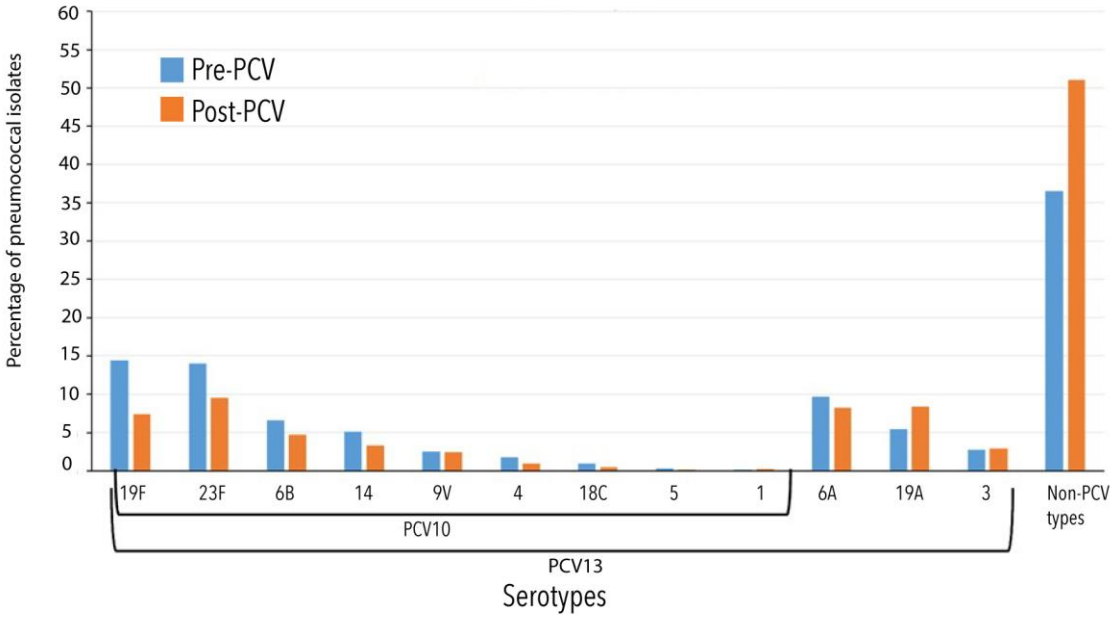
Finding 2

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 8.9–91.7 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 FCE partner CISM with support also from other partners (USAID and CDC). The first study aims to estimate the direct and indirect effect of PCV10 introduction on pneumococcal nasopharyngeal carriage among HIV-infected and HIV-uninfected children. The study involves cross-sectional carriage surveys pre- (October 2012 –March 2013) and post- (October 2014 –April 2015) PCV introduction. Carriage surveys were conducted among HIV-infected children < 5 years old enrolled from HIV clinics in Nampula, Maputo and Manhiça. Carriage surveys were also conducted among HIV-uninfected children < 5 years old from Manhiça community, sampled at random from the demographic surveillance site (DSS). Sample size was 1001 children in the post-PCV period and 700 in the pre-PCV period.

Based on this study, a direct effect of the vaccine on PCV10 serotype-specific (VTS) pneumococcal carriage was observed within 18 months after PCV introduction. A 41% (95% CI 6–69) reduction in VTS pneumococcal carriage was observed in HIV-uninfected children receiving three doses. A 61% (95% CI 9–82) reduction was observed in HIV-infected children receiving three doses. 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). Figure 16 summarizes the serotype distribution for the pre-and-post-PCV periods.

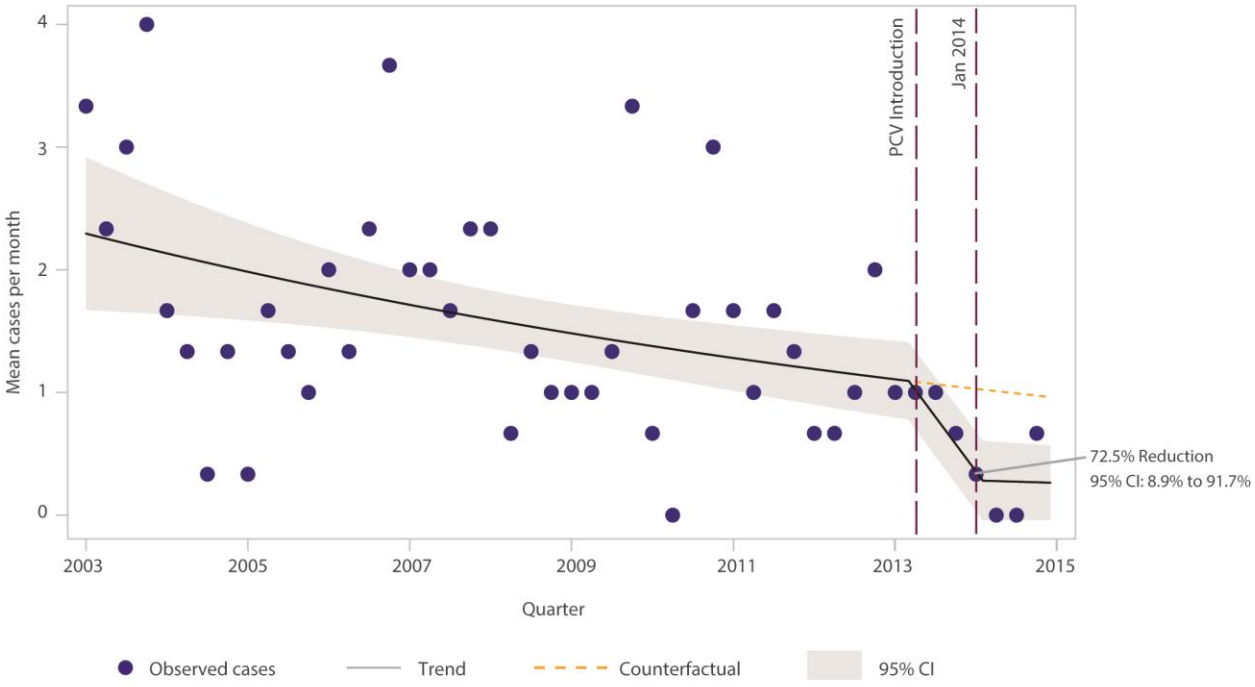
Figure 16: Serotype distribution pre- and post-PCV10 introduction among children <5 years old in Mozambique



In addition to the carriage study, we also report on preliminary results from before-and-after surveillance conducted in the Manhica DSS. Based on a regression discontinuity design with the post-PCV period defined as January, 2014 onwards, we estimated a significant reduction in vaccine type IPD of 72.5% (95% CI 8.9–91.7; Figure 17). There was a non-significant reduction in x-ray confirmed pneumonia (20.8%, 95% CI -43.2–56.3) and overall IPD (25.8%, 95% CI -39–60.4). There was also a non-significant increase in nonvaccine type IPD (49.9%, 95% CI -30 to 221.3). We caution that these are preliminary results on vaccine effectiveness and represent changes only 18 months post-introduction and are based on observational studies. In the 2016 annual report, we will report on results for the case-control study in addition to updating the studies presented here.

In addition to the vaccine effectiveness studies conducted, the FCE has conducted causal analyses using the small-area estimates of vaccine coverage and child mortality previously produced by the Gavi FCE. To estimate the relationship between new vaccine introductions of PCV and rotavirus vaccine and child mortality, the FCE uses mixed-effects multivariate regression models that adjust for other important drivers of child mortality.

Figure 17: Trends in PCV10 serotype-specific invasive pneumococcal disease in Manhica DSS



These other drivers or covariates were separately estimated at the corresponding geographic level (province, district, or subdistrict), and include household wealth, maternal age and education, other vaccination (BCG, pentavalent, measles, polio), breastfeeding, childhood malnutrition (stunting, wasting, underweight), and maternal health care (antenatal care, in-facility delivery/skilled birth attendance). Our analysis indicates non-significant changes in child mortality associated with the new vaccine introductions (PCV in Mozambique, Uganda, and Zambia; rotavirus vaccine in Zambia; full results available in Annex 4). It is important that these results are not translated as an absence of an effect, given the short time period post-introduction, a likely lag period between coverage scale-up and full impact, and a less specific health outcome than for the vaccine effectiveness studies.

HPV vaccine

The 2014 Annual Report presented findings on the implementation of HPV vaccine support in Gavi FCE countries. True to the prospective nature of the Gavi FCE, we have continued to evaluate the implementation of HPV vaccine during 2015. Various stages of implementation of HPV vaccine support covered in the reports are summarized in Table 6.

Table 6: HPV vaccine implementation covered in the 2014 and 2015 FCE reports

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

The 2014 report highlighted three overall findings in relation to HPV vaccine support:

(i) Lack of clarity around the primary purpose and implementation of the HPV vaccine demonstration projects as a mechanism for learning and guiding national HPV vaccine introduction;

(ii) Insufficient and underutilized technical guidance for countries implementing HPV vaccine demonstration projects; and

(iii) Failure of the application process to account for the feasibility, sustainability, and ongoing financial resources required for the chosen and tested HPV vaccine delivery model for national introduction.

The London School of Hygiene and Tropical Medicine (LSHTM) and PATH recently released an HPV Vaccine Lessons Learned[2] report that provides a comprehensive synthesis of country experiences in implementing HPV demonstration projects and national introductions. The report includes a detailed set of findings and recommendations in seven domains: preparation, communication, delivery achievements, sustainability, pitfalls, and value. To avoid duplication of findings in this report, we highlight the specific areas where our findings overlap with the HPV Vaccine Lessons Learned report (Table 7).London School of Hygiene & Tropical Medicine,, and PATH, “HPV Vaccine Lessons Learnt.” In addition, we provide two findings regarding missed opportunities for countries to learn from

[2] London School of Hygiene & Tropical Medicine,, and PATH, “HPV Vaccine Lessons Learnt.”

demonstration projects for designing HPV vaccine delivery at scale, which we believe warrant particular emphasis.

Table 7: Overlapping findings of LSHTM/PATH report and FCE reports on HPV vaccine implementation

HPV Lessons Learned (LSHTM/PATH) **Scope:** 37 Countries; eight national introductions, 55 demonstration projects (six Gavi-supported)	**FCE Reports** **Scope:** Four countries; one national introduction (UGA), one Gavi-funded demonstration project underway (MOZ), one planned (BGD), one non-Gavi demonstration project (ZMB)
PREPARATION	
• Ensure political will during preparation critical for gaining support at all levels. Ensure that national immunization program feels ownership and is involved in each phase.	• Political will plays an important role in creating the momentum for HPV introduction in FCE countries. However, unclear ownership of HPV vaccine between EPI stakeholders and partners and departure of key champions (e.g., First Lady) were factors that hampered the transition from demonstration to national introduction.
• Timely inter-sectoral planning and collaboration between health and education ministries (national level) is critical for implementation and sustainability of school-based initiatives. Involvement of finance ministry important for national programs.	• Lack of effective collaboration between health and education ministries in all FCE countries negatively impacted planning and implementation (e.g., alignment of demonstration with school calendar).
• Cooperation between local representatives from health and education sectors facilitated effective microplanning. Ineffective coordination associated with low coverage.	• Poor coordination by district-level health and educational sectors in Zambia, as well as underestimation of target school-based population led to suboptimal coverage in demonstration project.
• Several countries reported HPV vaccination required more “intense” resource mobilization and preparation.	• Preparation for school-based delivery for demonstrations, including coordination with expanded partners, presented challenges to countries.
DELIVERY	
• Delivery strategies including a school component effectively captured most 9- to 13-year-old girls but were resource intensive.	• Countries testing school-based implementation observed the delivery strategy to be resource intensive and not sustainable for national introduction
• Countries should consider a range of factors, such as cost and sustainability, when selecting a delivery strategy.	• FCE Countries have generally targeted coverage requirement over cost and

	sustainability in design of demonstration projects.
• District selection criteria: conditions constituting "typical" district, convenience/practicality, variable conditions, challenges requiring additional testing.	• District selection for demonstration tended toward favorable districts. • In Mozambique, additional learning was possible due to inclusion of two additional districts funded by the government
ACHIEVEMENT	
• Projects/program with strategies using schools resulted in higher uptake, lower dropouts, and higher coverage than those using only health facilities. • Use schools as vaccination sites to maximize coverage.	• FCE countries who have implemented demonstrations have not been able to compare delivery strategies along these indicators because they have not tested different delivery models.
SUSTAINABILITY	
• When implementing a demonstration project, test different delivery strategies, compare implementation costs, and identify a sustainable option. • Share operational costs with the national immunization program to reduce costs of implementation. • Explore sustainable funding options and expand the funding base beyond Gavi. • Call for and facilitate additional research on scale-up experiences.	• FCE countries have tested only single delivery strategies and have limited ability to refine or test alternatives over the course of demonstration projects • Insufficient technical assistance and evidence sharing contributes to lack of country learning about designing demonstrations to test sustainability. • For FCE countries that have implemented HPV demonstrations, coverage appears to be a more important goal (related to the demonstrated ability criteria) than sustainability when designing demonstrations.
VALUE	
• Countries report benefits from "learning by doing" during demonstration projects. Experience gained in planning and budgeting, population enumeration, consent procedures, working with the Ministry of Education (MoE), developing community education materials.	• Missed opportunities for learning in multiple areas have been widely observed in FCE countries in 2014 and 2015.
• Demonstration projects using resource-intensive strategies generated concerns about sustainability.	• As noted above, countries testing school-based implementation observed the delivery

	strategy to be resource-intensive and not sustainable for national introduction.
• Demonstration projects may have influenced momentum of, or intention by, some countries to introduce HPV vaccine nationally. Some countries reported "loss of momentum" after demonstration projects completed.	• Implementation and learning challenges experienced in Mozambique and Zambia have led to uncertainty about national introductions.
Value could be increased by: • Testing different delivery strategies to identify sustainable approaches. • Testing the delivery of combined interventions with HPV vaccine–tetanus toxoid vaccine, deworming, or vitamin A supplementation. • Countries have not yet fully taken advantage of opportunities to test different combinations of vaccination venues, timing, eligibility criteria in different populations, and co-delivery with other health interventions.	• There is limited evidence that FCE countries are actively working to integrate HPV delivery with other adolescent health interventions.
• Some countries could consider a stepwise national rollout in place of demonstration projects due to increasing vaccine availability and access to lessons learned.	The 2014 FCE Annual Report recommended that countries, in selecting demonstration districts, should maximize potential for representativeness by comparing multiple sites in simultaneous or phase manner. This notion aligns with the LSHTM/PATH recommendation for stepwise national rollout.

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 limited mechanisms to transfer evidence and lessons from other countries' experiences when designing HPV vaccine demonstration projects. (Robustness ranking: A; Generalizability: High)

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. For example, in Mozambique, coverage of HPV vaccine in two of the three demonstration districts was below 50% (the threshold for the demonstrated ability criteria) as a results of challenges related to demand generation and community mobilization. This experience provided valuable learning and an opportunity for correction for national introduction of HPV vaccine.

Supporting Evidence from the Gavi FCE

- **Uganda**. The country tested a school-based model but later shifted to implement an untested facility-based strategy for national introduction after determining post-approval that the former was not financially or programmatically feasible at a national scale (2014 Uganda Country Report).
- **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 (Mozambique HPV finding 1).
- **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 (Zambia HPV finding 2).
- **Bangladesh**. The country is yet to commence its demonstration project but plans to test a single school-based delivery model. (Bangladesh HPV finding 1)

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

Despite this, demonstration projects could be better designed to maximize learning for national introduction. FCE countries have tested or are planning to test school-based delivery in demonstration projects with countries subsequently experiencing financial or programmatic barriers towards proceeding with the tested delivery model for national introduction (see supporting evidence at right). These findings mirror those in non-FCE countries; for example, Bhutan shifted from a school-based delivery model to a health facility-based model for national introduction. While this move may result in improved financial sustainability, it has had a more immediate negative consequence on vaccine coverage. For example, the shift to the latter model in Bhutan was associated with a "decline in HPV vaccine coverage from 90% to 65%" (global-level KII, Alliance partner) and consequently the country shifted back to school-based delivery following the drop in coverage. An important focus for the

FCE in 2016 is to monitor the potential consequence on coverage related to the delivery strategy shift in Uganda.

> *… the shift from school-based to facility-based approach, we support that move – it's more sustainable and will eventually raise the coverage as well. This needs to be implemented, followed, monitored, and improved. If a strategy is not sustainable it will fail. This was the idea of the [HPV] demo project from the beginning, if the country embarks on one and sees it's not sustainable with the conditions […], if there are conditions that cannot easily be changed, in short you choose and take the most balanced approach*. (Global-level KII, Alliance partner)

> *The demonstration project as it is currently designed determines technical feasibility and areas for improvement. If they had tested different delivery models it would have been more interesting for countries, they would have learned by having health service delivery in one district and school-based delivery in another. They would have learned something useful, but I don't think any country has proposed that. … The guidelines were a bit too open at the beginning. (Global-level KII, Alliance partner)*

Although school-based delivery models are not financially or programmatically infeasible in all settings, the decision by many 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, as highlighted in the 2014 FCE report. This year we noted a recognition at the global level 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.

> *If you ask them to reach very high coverage, and that's the objective you're judging them on, they all choose the school model. So in a way you are pushing them to select this strategy so in some ways don't be surprised that they do it. (Global-level KII, Alliance partner)*

> *Because we made coverage the bar, it becomes the dominant metric at the expense of thinking about anything else, planning, communications, alternate delivery approaches. There is not much experimentation going on. Part of it is school-based programs work to achieve coverage. If we assume coverage is goal, we're not off. But we don't need more demo programs to tell us that. Need better budgeting, costing tool.* (Global-level KII, Alliance partner)

> *I am not sure they [countries] understand the intent of the demo for HPV – which is a slightly different target group. They apply their understanding of childhood vaccinations to this – apply same standards to HPV … they're chasing coverage at whatever cost. For immunization, coverage is key. That is the barometer of success that Gavi has, or has not quite articulated. It's like Pavlov's dog – if you have given them a grant to do immunization, they automatically think coverage. The challenge is for HPV is it's a different target audience, which may necessitate different stakeholders to achieve not just coverage but coverage with sustainability over time, at a sustainable cost. (*Global-level KII, Alliance partner)

These findings highlight the importance of clearly communicating the primary rationale for the demonstration projects and encouraging countries to test and compare delivery models (school-, facility-, community-based), including combination models along a continuum of options, with varying resource requirements to target both coverage and sustainability goals (as noted in the 2014 FCE

report). It also highlights the importance of earlier assessment of financial feasibility to potentially avoid testing a delivery model that is ultimately not going to be sustainable for national introduction. An earlier assessment of financial sustainability at the design phase of the demonstration project may have steered countries toward testing a delivery strategy that was more financially feasible than the oft-chosen school-based delivery model. This may avoid countries implementing a two-year demonstration project to conclude that a delivery model is not financial sustainable.

Limited mechanisms to share lessons learned from other countries' experience with HPV vaccine

An additional barrier for countries when designing demonstration projects is relatively limited effective mechanisms for sharing knowledge and evidence about different countries' experiences with HPV vaccine. We noted in Bangladesh, and described further in the Bangladesh country report, the limited ability of the program to draw on other countries' experience when choosing the school-based delivery model (Bangladesh country section, HPV Finding 2, p. 33).

> *The two-year [demonstration] program, way it is structured, doesn't lend itself to giving people opportunity to think outside the box because it's fairly quick the movement…It's acknowledged in Gavi, but EPI managers only do childhood immunization. We need to reach out to them before the design of the program to say here's what works in other countries, here's what you should consider if you don't already have ways of reaching girls. That dialogue is not taking place. That discussion could lead to countries wanting to test different models. There's either no time for that discussion or people don't necessarily think about it*. (Global-level KII, Alliance partner)

> *We need to continue with demos, they need to be better designed, more south to south learning so that countries don't engage in HPV demo before they have visited and seen all the trouble in another country. (Global-level KII, Alliance partner)*

Perhaps with better sharing of experiences from other countries and earlier technical guidance at the design phase, Bangladesh may have been able to make a more informed decision regarding the model to be tested in the demonstration project – one that is potentially better suited for national introduction of HPV vaccine in the Bangladesh context.

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. (Robustness ranking A; Generalizability Medium)

Mozambique pursued a school-based delivery model as part of its HPV vaccine demonstration project in year one (refer to 2014 FCE report for further detail). 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 (to be conducted at the time of final dose);
ii) Community-based coverage survey (to be conducted within six weeks of the final dose); and
iii) Micro-costing analysis of program implementation costs (to begin at the time of the first dose).

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. Our findings, as further described in the Mozambique report, indicate that 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 program (Mozambique country report, Finding 1).

The unavailability of evaluation products in a timely fashion is also a common finding across other Gavi-supported demonstration projects. While not Gavi-supported and therefore not bound by the requirements for the availability of learning products at the end of year one, the demonstration project in Zambia was also an example of the limited ability to refine the delivery model and/or test an alternative delivery model during the demonstration project period. The costing analysis only became available at the end of year two of the demonstration project, and as a result, it was only at the end of the demonstration project that Zambia concluded that the school-based delivery model was not financially feasible.

The challenges experienced in Mozambique and Zambia reflect what a global key informant referred to as an "underestimation" of the technical complexity of HPV demonstration projects and, for many countries, the lack of appropriate technical knowledge among government and partners to implement them in a timely fashion according to the Gavi guidelines.

The consequence of the limited ability to refine delivery models is that both Mozambique and Zambia face uncertainty regarding design of national introduction of HPV vaccine, in particular, what delivery model to use. In Mozambique, interest in considering other delivery modalities has been expressed in

NIP TWG meetings during the course of 2015 due to the acknowledgement that the school-based delivery model is likely to be unaffordable.

The recently revised 2016 guidelines for HPV vaccine support have been amended, following the findings from the 2014 FCE report, to note the possibility that countries may apply for a second demonstration program if they wish to further explore feasibility, acceptability, and cost of different, untested strategies for HPV vaccination prior to national introduction. Guidelines also indicate a possibility for countries to ask for a bridge year between the end of the demo program and national roll-out. At this stage, our evaluation notes that country stakeholders are not yet aware of this option, although we acknowledge that the 2016 guidelines have only recently been amended. Strong technical assistance will be necessary along the course of the extended phases of demonstration to ensure that learning toward sustainable design can be achieved.

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 Systems Strengthening

In the 2014 FCE report we reported that all Gavi FCE countries experienced slowed implementation of HSS support due to multiple barriers. Barriers noted in the 2014 report included difficulties in coordinating across multiple stakeholders and with other health systems strengthening efforts, the complex and diverse range of activities, and difficulty navigating complicated bureaucratic systems for fund disbursement and procurement. This slow progress of HSS implementation undermined the potential of HSS investments to catalyze increases in vaccine coverage and reduce inequities.

Table 8: HSS implementation stages evaluated in the 2014 and 2015 reports

	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

Our findings in 2015 are based on continued evaluation of the HSS funding stream in FCE countries as summarized in Table 8. FCE countries are in varying stages with regard to HSS; however, the overall finding is one of continued slow preparation for and implementation of HSS support (see supporting evidence text box).

Supporting evidence from the Gavi FCE

- **Mozambique:** Continued delays toward implementation due to complex processes for fund disbursement (first from Gavi to country, then within the country). The first tranche of funds was disbursed in July 2015, two years after approval. (Mozambique HSS finding 1, page 34).
- **Uganda.** No civil works has been implemented under the HSS within the two-year grant implementation period, which expired in June 2015. Also, implementation of HSS supported activities to strengthen private sector involvement in immunization in Kampala district faced numerous challenges including resulting in several delays. (Uganda HSS finding 1 & 2, page 29 and 32)
- **Bangladesh.** Disbursement delays (three years from approval to disbursement to the country) in implementing first HSS grant led to misalignments with national plans, slow human resource recruitment, infrastructure development, and lack of familiarity with Gavi financial audit requirements. Submitted application for a second HSS grant in January. The January submission was not approved, and in September 2015 the government of Bangladesh resubmitted. The resubmission included only a subset of activities included in the original application; the remainder will be developed into a second proposal for submission in 2016 to ensure alignment with pooled funds in the next SWAp. (Bangladesh HSS findings 1, 3, 4, 5, 6 and 8, page 35)
- **Zambia.** The HSS application process strained existing capacity and led to limited country ownership, an over-reliance 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. (Zambia finding 1 and 2, page 31, 35)

The root causes of this are unpacked in the rest of this section of the report. These delays in preparation for and implementation of HSS support, particularly in the case of Mozambique, Uganda, and HSS-1 in Bangladesh, are widely acknowledged to be problematic, a situation one global level key informant described as “disastrous, absurd.” We note consequences on new vaccine introductions – most commonly reflected by delays in cold-chain expansion – but slow progress also limits the potential for the window of support to affect coverage and equity targets, key measures of success for Gavi under its new five-year strategy. In the following section we elaborate on a range of root causes that are related to slow progress with HSS in FCE countries.

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. (Robustness ranking: B; Generalizability: High)

Health systems strengthening to improve immunization coverage is necessarily more complex than typical EPI functions

Health systems strengthening is widely acknowledged to be necessarily more complex than typical EPI functions such as vaccine introductions. In this context, Gavi HSS activities encompass a diverse set of activities relative to what EPIs are typically tasked with (e.g., procurement, infrastructure development, training, etc.) and as a result requires a wider set of stakeholders (bringing together government agencies and other stakeholders often unaccustomed to working together).

Gavi's HSS design, application and implementation processes and complicated, time-consuming and not always well understood at the country level

The challenges of operating HSS with a wide network of actors is increasingly accompanied by a complicated administrative process for Gavi's HSS window of support. New processes and approaches linked to Gavi HSS is not a new phenomenon. Gavi's overall HSS strategy has experienced multiple, radical changes over the last decade. While initially a broad, no-strings attached approach, it has recently evolved to a narrower focus on immunization outcomes with a performance-based financing component. According to one global-level key informant, "Gavi has used the same vaccine model for 15 years so we're really good at it, but with HSS every three to five years we've done a sharp right turn."

As the HSS strategy has undergone shifts, the Alliance's current approach to grant and policy revision for HSS is to first obtain clarity and alignment at the level of the Gavi board, and "to have that filter down" and be operationalized at the Secretariat. However, by the time these changes, including the resulting rationale and requirements of the HSS support window, reach the country level, they are not well understood.

> *The form and guidelines are okay. In the case of the HSS at the time of the application we were not aware of the recent changes to the guidelines… Gavi should simplify the form so as to simplify the process. The current form is tedious. They also change the guidelines. This is confusing. Sometimes you are told, 'you have the wrong form or guidelines have changed.' Let Gavi simplify this and make life easier. Some countries are desperate for these funds.* (Zambia KII)

These complicated procedures with limited understanding are exemplified by the process of obtaining approved HSS-2 funds in Mozambique. Mozambique had not previously negotiated a financial management requirement (FMR), a prerequisite for Gavi HSS disbursements to beneficiary countries, with Gavi. Establishing the FMR was a protracted process involving multiple levels of negotiation between not only Gavi and the NIP, but also with many directorates within the Ministry of Health and across government sectors, including the Ministry of Finance, National Bank, and provincial health offices, in order to revise and agree upon financial rules and reporting and auditing requirements (Mozambique country report, p. 35). A long waiting period from approval to disbursement and implementation predates the current iteration of Gavi HSS;[3] the 2016 guidelines, in part stimulated by the 2014 FCE report, now include the average timeline for grant procedures such as the FMR. The importance of countries and partners adequately planning for these Gavi and in-country processes is particularly important given the recent policy change of limiting no-cost extensions for HSS to one year.

[3] Plowman, B.A and Abramson, W.B, "Health Systems Strengthening Tracking Study."

Key principles of Gavi HSS are that it should be country-driven, aligned with national plans, and harmonized with existing efforts to strengthen the health system. However, alignment was a noted area of weakness in both Bangladesh's and Zambia's January submissions, suggesting incomplete understanding of how to achieve these goals.

Another example of weakness in alignment of Gavi HSS with country processes is the performance-based financing component of the new HSS-2 design. Although no FCE countries are advanced enough with HSS-2 implementation to receive performance-based funds, we have noted a lack of discussion about the potential receipt of performance-based funds as part of HSS applications. This suggests that the performance-based component of HSS is not well understood by countries and is thus not incentivizing performance as intended. Indeed, one global-level informant noted that this is a broader issue beyond FCE countries and that countries are often surprised to learn that they will receive a performance-based payment for HSS (as a reward for achieving outcomes). This indicates that the Gavi HSS performance-based payment is not incentivizing performance. At this stage, it is not clear whether this is merely a lack of awareness, or related to the actual size of the performance payment. As FCE countries move forward with the implementation of HSS-2 grants, we will continue to monitor and evaluate understanding and planning for performance payments.

Notably, although the HSS grant has evolved toward a narrower focus on immunization outcomes, HSS grants are not solely owned by EPIs. Rather, the HSS application guidelines stipulate the active involvement of a wide set of stakeholders in the design and management of HSS grants. This includes, but is not limited to, departments of maternal and child health, departments of planning, departments of human resources, ministries of finance, and ministries of local government/administration.[4] This reflects feedback from previous evaluations of Gavi HSS, which noted insufficient coordination around HSS beyond EPI.[5]

One global-level key informant noted concerns that the funds might exert a destabilizing effect if they were owned by EPI alone and voiced a need for greater accountability and oversight. However, coordinating across this more diverse range of stakeholders has proven challenging in FCE countries, at all stages of the process, leading some key informants to ponder why immunization programs alone cannot own HSS grants, as they do vaccine introduction grants and other Gavi support, especially with the shift toward immunization systems strengthening. 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. Aligning the implementation process with the underlying objective of improving immunization outcomes may simplify what is at present a complicated process for countries to implement.

Ongoing changes to Gavi's HSS and associated processes aim to reduce complexity and transaction costs

Efforts are currently underway at the Secretariat to address the complexity and transaction costs associated with HSS. These changes include:

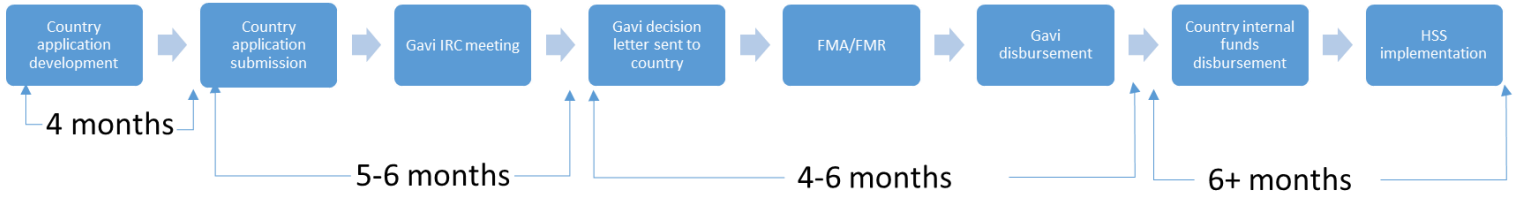
[4] Gavi, the Vaccine Alliance, "Apply for Support."
[5] HLSP, "GAVI Health Systems Strengthening Support Evaluation 2009."

- Recent changes to the approval process whereby the Independent Review Committee (IRC) no longer grants conditional approvals, only approvals or requests for revision and resubmission, which it hopes will reduce the time lag between application and implementation.
- Increased flexibility for SCMs to work with countries to *reallocate*, rather than formally *reprogram*, funds when budget implications are less than $1 million or 25% of the overall budget.
- Establishment of more realistic expectations around how long various stages in the application and implementation process will take so that countries can plan accordingly (Figure 18).

Further changes are also anticipated as part of the broader review of direct financial support, including not just HSS but all direct financial support provided by Gavi (Figure 18). While many of the changes (in particular the attempt to increase clarity around the time associated with various steps in the process) may indeed increase predictability and accelerate the process, they do not address all the complexities of HSS or the lack of country-level understanding about changes to Gavi's HSS strategy, which are the key challenges that have emerged in FCE countries. Concerted efforts must be undertaken to ensure that countries are aware of and plan according to these timelines.

Figure 18: HSS application and implementation process, timing, and involved stakeholders

HSS process steps



Stakeholders involved

Global / Gavi			X	X	X	X		
National EPI	X	X					X	X
National MoF	X	X			X	X	X	
MOH, non-EPI	X	X			X		X	
ICC, HSCC	X							X
Partners	X							
Expanded partners	X							
Subnational	?						X	X

Table 9: Proposed changes to HSS under the review of direct financial support (based on December pre-workshop paper[6])

Proposed change	Relevant insights from the FCE
Allocation of support across countries. Current allocation for HSS based on gross national income (GNI) per capita and population size. Considering revisiting formula to include indicators such as rolling three-year average GNI per capita, birth cohort size, strength of the health system, and potentially political will**.**	While ensuring appropriate allocation of HSS funds across countries is an important consideration for Gavi, this has not emerged as a significant process issue in FCE countries; therefore we are unable to evaluate the implications of this proposed change based on FCE findings. However, from our perspective this is not among the most pressing HSS challenges. The most pressing challenges in FCE countries relate to the complexity of HSS, particularly considering the size of HSS grants. This is something the FCE will track in 2016.
Grant programming direct financial support (DFS). While all DFS investments must be linked to immunization outcomes, Gavi does not prescribe which investments a country should prioritize but recommends linking investments to the Strategic Focus Areas and providing greater guidance on how to invest in these areas**.**	FCE countries have found HSS grants to be challenging to design and manage, particularly in the context of all of the changes to Gavi HSS. Indeed, Bangladesh, Mozambique, and Zambia have all been unsuccessful with their initial HSS proposals. While better guidance around evidence-based priority investments to achieve immunization outcomes could simplify the design and application process for countries, it may also compromise the extent to which HSS grants are country-driven, a key principle of Gavi's HSS window. Furthermore, we question whether Gavi has sufficient data and contextual knowledge of each country to effectively prioritize and prescribe investments.
Grant architecture. Gavi provides a variety of DFS grants to countries, including HSS, vaccine introduction grants, operational support for campaigns, etc. Considering pooling DFS grants to ensure integration and reduce administrative burden. This could also include efforts to improve transparency by moving grant administration to a higher managerial level in the health system.	To the extent that pooling DFS grants reduces the administrative burden and increases predictability, pooling of grants is likely to improve the efficiency of implementation and the related transaction costs. However, it is important to ensure that delays related to achieving milestones related to one component of DFS (e.g., procurement in Uganda) does not stall other needed investments, for instance investments that might be part of a vaccine introduction grant. Therefore, within a pooled structure, we would advocate for retaining separate budgets and work plans for different grants.

[6] Gavi, the Vaccine Alliance, "Gavi Alliance Programme and Policy Committee Meeting Minutes."

Furthermore, coordinating across the expanded partnership for HSS has been a challenge in FCE countries. Were this move to bring grant administration closer to EPI (for instance, away from Departments of Planning toward Directorates of Public Health, or other relevant departments within which EPIs are housed), this holds potential to increase the efficiency of implementation while maintaining transparency and accountability. The trade-offs associated with these different models is something the FCE will investigate in 2016.

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. (Robustness ranking: B; Generalizability: Medium)

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, we noted identified a heavy reliance on technical assistance, often in the form of consultant support, to assist with the application process.

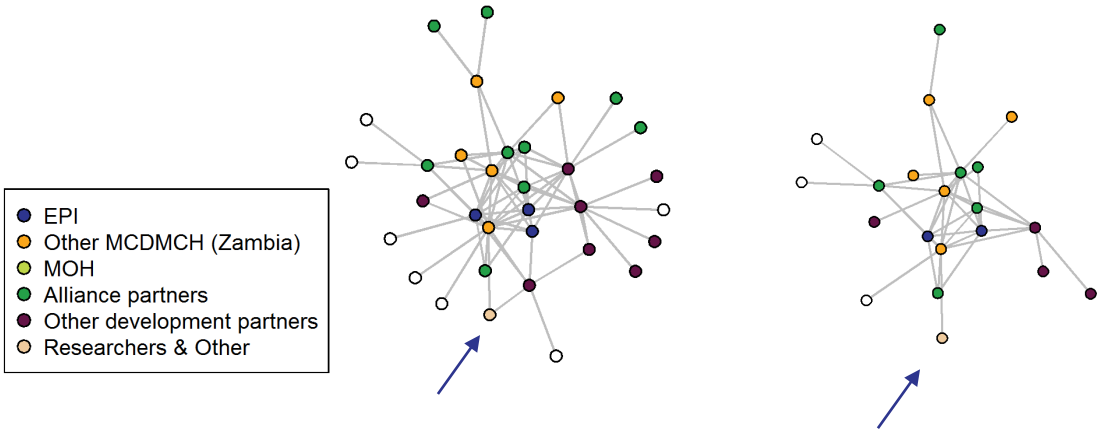
> *We opted for a consultant to handle the Gavi HSS process. We saw the process that we went through and it was nerve-wrecking, and besides, we have a lot of programs we were running so we wanted a dedicated person to handle the process.* (Zambia KII)

See the TA section, Finding 2, for an in-depth analysis of TA networks in Bangladesh, Mozambique, and Zambia.

TA facilitates 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. Our evaluation notes that the consultant hired to help develop Zambia's HSS application process was engaged late in the process, possessed limited familiarity with the country context, and had insufficient time to consult extensively with country stakeholders. The limited interaction with the external consultant is reflected by the network maps shown in Figure 19. The peripheral location of the consultant in the network could be interpreted as a positive finding, indicating a high degree of country ownership of the HSS proposal. However, in the case of Zambia, the consultant was tasked with a significant amount of responsibility for compiling the proposal and therefore should occupy a more central position in the network.

Figure 19: Network of working together relationships during Zambia HSS application (left) and resubmission (right). Arrow points to consultant.



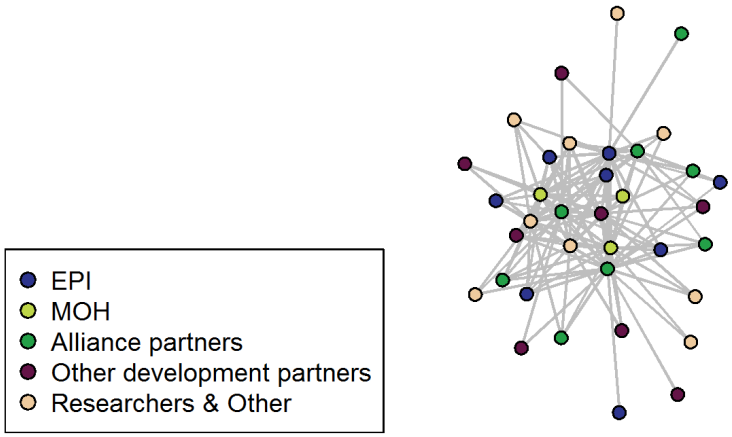
Key informants reported that during the proposal writing process there was also a lack of involvement from individuals with experience in key areas such as monitoring and evaluation and results-based financing, and noted areas of weakness in both the January submission and the September resubmission. This indicates that the TA available was not well aligned with all of the areas where support was required and points to a degree of rigidity in the supply of TA as the TA network for the resubmission of the HSS proposal in Zambia was not substantially different from the initial submission.

Bangladesh also engaged a consultant for an initial submission in January (see Figure 20 for the January application network) and again for resubmission in September. As in Zambia, support was reported to arrive late, resulting in an application process that was described as rushed, and consultants were reported to possess limited knowledge of the country context. Key informants also questioned the selection process for consultant support in Bangladesh. Furthermore, some informants pointed to splitting apart Bangladesh's HSS into two separate proposals (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) as evidence of maintaining the status quo by providing ongoing reliance on technical partners to implement, rather than building capacity of the ministry to provide these functions. In this way the TA actually requested through the HSS proposal was perceived by some key informants as being

misdirected. The consultants in Bangladesh were for the most part more centrally located in the network than in Zambia, suggesting a greater deal of engagement with country stakeholders. However, they were not the most central nodes in the network, which indicates country ownership of the proposal.

According to one global-level key informant, shortcomings with TA for HSS are in part attributable to Gavi's aforementioned shift toward a narrower focus on immunization. Despite this change in approach, much of the available TA at the country level for HSS is oriented toward what the informant described as "the real HSS" (a reference to much broader, systems-wide approaches to HSS, as opposed to Gavi's immunization systems focus), emphasizing that "there is a dichotomy between EPI and HSS. A tough war is happening in many countries."

Figure 20: Network of working together during the Bangladesh HSS application



This suggests that the expertise possessed by those providing TA for HSS is misaligned with Gavi's much narrower approach to HSS. While previous iterations of the Gavi HSS window may have truly required this expanded partnership for HSS, the current focus on immunization outcomes is perhaps more suitable to the expertise of traditional EPI partners. The FCE will continue to track this in 2016 with Uganda applying for a new HSS grant, and Bangladesh potentially applying for a second HSS grant.

Ineffective or misdirected TA has several potential consequences including reduced country ownership

The consequences of ineffective or misdirected TA for the HSS proposal process are many. We highlight three important ones here. First, the TA provided, often short-term in nature, is not being accompanied by capacity strengthening to effectively design and apply for Gavi support. Second, the resulting failure to increase understanding of Gavi processes in relation to HSS may have the knock-on effect of slowing implementation as countries navigate complex requirements surrounding Program Financial Assessment (PFA), FMA, and FMR and other administrative processes post-approval. This scenario is well highlighted by the case of Mozambique as described above. Finally, reliance on external technical assistance with limited engagement with country stakeholders can lead to reduced country ownership of the resulting

grant with knock-on effects during implementation. As noted by one global-level key informant, "the application is developed by partners, then the country is at a loss at how to implement it."

Recommendation

Gavi is in the process of implementing a new model of technical assistance provision – the Partner Engagement Framework – which is covered in a later section. A number of related recommendations are contained in that section. Based on FCE findings for HSS specifically, we recommend:

1. 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 recommend 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

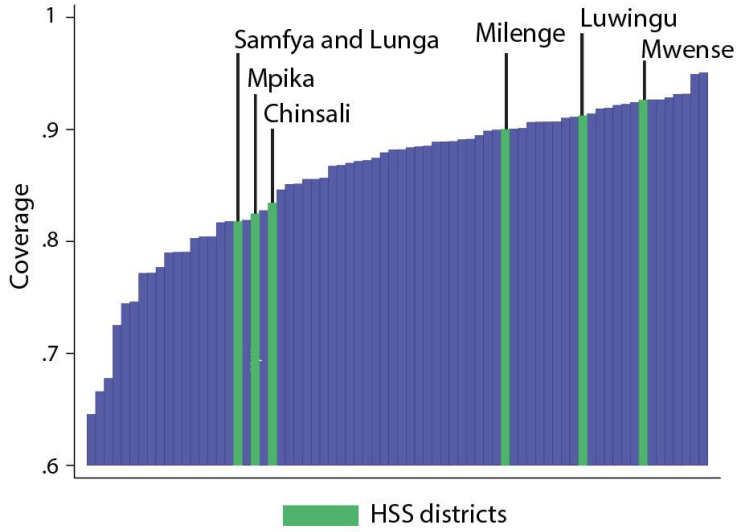
Even with technical assistance, we note a number of deficiencies (insufficient data or evidence to support investments, failure to harness catalytic nature of Gavi HSS investments, and limited consideration of sustainability) in the design of Gavi HSS grants that limit the potential of the window of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

Robust high-quality data and evidence to inform the design of investments are central to the success of Gavi's HSS window of support. The potential for HSS investments to achieve impact is heavily reliant on identification of the key bottlenecks to immunization coverage. However, evidence from FCE countries suggests that the bottleneck analyses and design of HSS grants are not always based on comprehensive information on immunization systems factors. In Bangladesh and Zambia, bottlenecks were identified (and in the case of Bangladesh, weighted) in stakeholder workshops; however it is unclear to what extent these processes were based upon any robust analysis of strong evidence. This is in part attributable to a lack of tools, guidelines and technical support to aid countries in conducting the bottleneck analysis and in prioritizing identified bottlenecks. Weak bottleneck analyses also have implications for targeting HSS funds.

Targeting implementation of HSS grants to specific administrative or geographic areas is not always done in a way that will maximize impact. Many countries have prioritized implementation of HSS activities to address bottlenecks in targeted subnational areas, in part because of the relatively small size of Gavi HSS grant amounts. For example, Zambia has applied for a $9 million HSS grant over three years from Gavi, whereas the USAID-funded Zambia Integrated Systems Strengthening Program (ZISSP) grant was for US$97 million over 4.5 years. As a result, Zambia chose to target HSS to seven districts, but the selection of those areas to achieve impact could have been improved. For instance, in Zambia's September resubmission, FCE small-area estimates that incorporate the latest 2013/14 DHS and Gavi

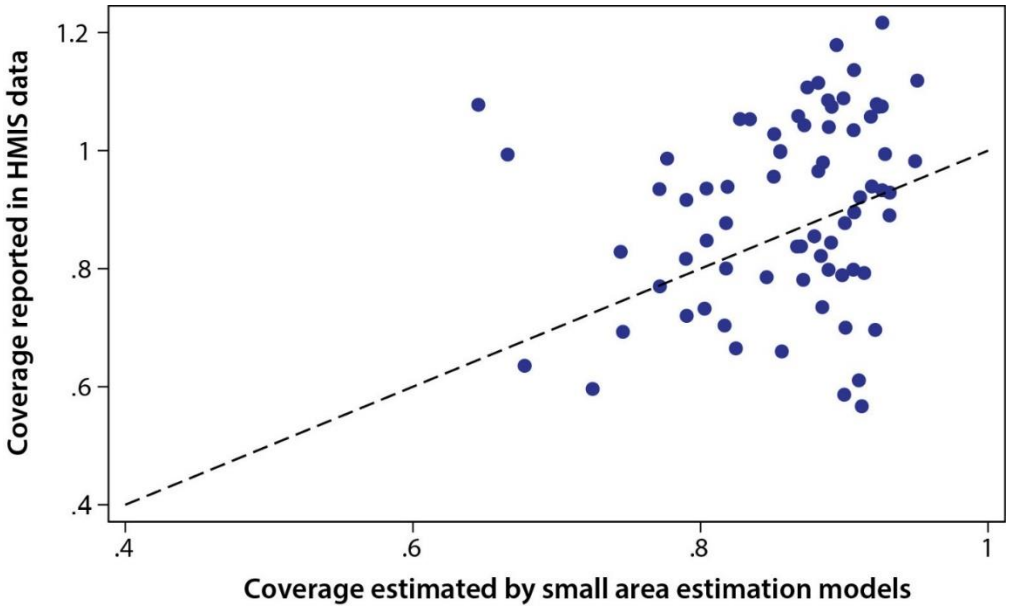
FCE household survey indicate the selected districts do not represent those districts with the lowest vaccine coverage (Figure 21).

Figure 21: Districts selected for HSS funds in Zambia as part of the September 2015 resubmission represent a range of estimated third-dose pentavalent vaccine coverage levels in 2014 – not only those districts with the lowest coverage



For the first January HSS submission, district selection was reported to be politically motivated, with pressure to include newly created districts so that political leadership could show activity and investment in those districts, even though they did not represent the lowest coverage districts. Part of the targeting is a function of low-quality administrative data, a well-known problem in Zambia, which is often used for programmatic and work-planning purposes. Figure 22 shows that many districts in Zambia report administrative data-based vaccine coverage greater than 100% and that there is a poor correlation with the Gavi FCE small-area estimates, which are based on household surveys.

Figure 22: Third-dose pentavalent vaccine coverage estimation in Zambia, comparing HMIS data to small-area estimation models, 2014



Sustainability considerations are a priority for Gavi, evidenced by the sustainability Strategic Focus Area. Even though the SFAs will not be accompanied by dedicated funding, because Gavi's approach to the SFAs is still in relatively nascent stages (the sustainability SFA will go to the Gavi Board for approval in 2016), FCE countries have not benefited from the availability of additional guidance or tools to improve planning for sustainability, and to integrate these considerations into their HSS designs in a meaningful way. This is a missed opportunity in a country like Zambia, which will begin transition planning next year and has just submitted a new HSS proposal. Because the SFAs (with the exception of the data and supply chain SFAs), and the sustainability SFA in particular, will not be reviewed by the Gavi Board until 2016, implementation is unlikely to commence until later in the year. As HSS grants are at least three years in duration, it is important to consider how countries with already active grants will benefit from these new mechanisms.

The other challenge that we note in the design of HSS grants relates to the principle that Gavi HSS investments are intended to be catalytic and sustainable in nature. Given the relatively small size of available funds in relation to larger HSS investments from other donors, Gavi HSS is not meant to stand alone but to attract and complement other funds for systems strengthening activities. At the same time, HSS investments must demonstrate financial and programmatic sustainability, beyond the period of Gavi support. These principles should be considered at the program design stage and inform decisions surrounding the design of activities to address identified bottlenecks. However, in FCE countries we do not see serious consideration of sustainability or the catalytic nature of HSS at the design stage (see supporting evidence text box).

Supporting evidence from the Gavi FCE

- **Zambia**. The country's September HSS application resubmission indicates that CSOs will contribute additional funds and interventions, but does not provide details. The proposal does not describe plans for training staff on the maintenance of purchased transport equipment to ensure sustainability, or plans to continue financing fuel for vehicles at the end of the HSS support period. These sustainability concerns were raised by the IRC but not the ICC. (Zambia HSS finding 1, page 31)

- **Bangladesh**. The country's September HSS submission included funding for WHO and UNICEF to continue implementation of ongoing activities related to surveillance and effective vaccine management. This poses serious questions about the programmatic sustainability of HSS investments when Gavi's support ends. (Bangladesh HSS finding 8, page 46)

Recommendations

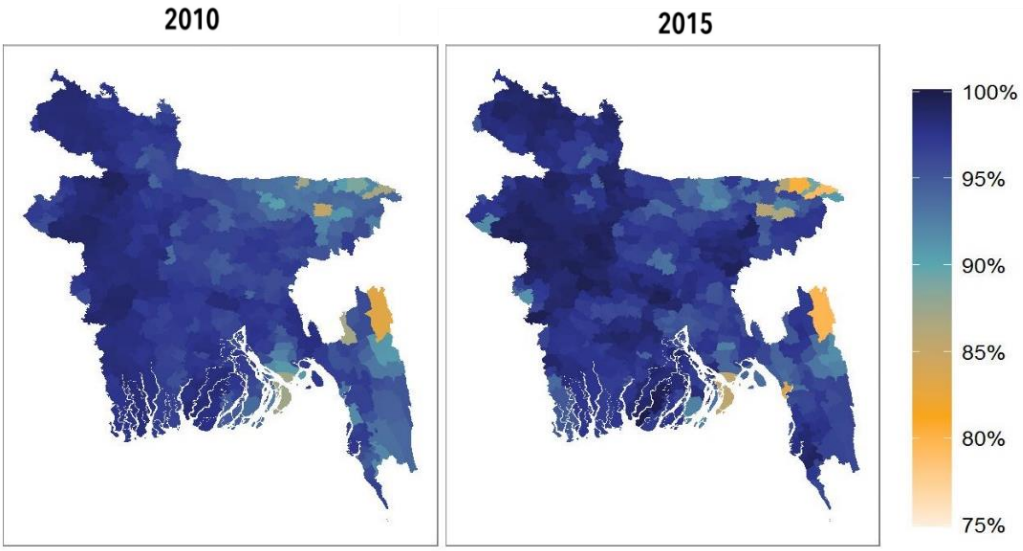
1. Enhanced investments in data, tools, and analysis to support countries' bottleneck assessments and overall HSS grant design are recommended to maximize the potential impact of HSS grants. This is particularly important given the relatively small size of HSS grants. This should be part of Gavi's Strategic 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.

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. (Robustness ranking B, Generalizability Medium)

While we note a number of challenges and related recommendations for potential improvements for Gavi's HSS above, the positive story is that FCE countries, supported by recent household survey results including those conducted by the Gavi FCE, have shown marked improvement in immunization coverage over the last five years. In Bangladesh, our 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 time period (Figure 23).

Figure 23: Bangladesh has experienced improvements in third-dose pentavalent coverage in nearly all districts from 2010 to 2015



An important objective of the Gavi FCE is to assess the contribution of Gavi's HSS support to vaccine coverage improvements and downstream health outcomes. The small-area estimates generated by the Gavi FCE provide an innovative approach for assessing this in settings where the HSS support window has been implemented, such as Bangladesh (Bangladesh country report, HSS finding 7, p. 44). The Gavi FCE small-area estimates show that improvements in third-dose pentavalent coverage and coverage of the fully immunized child (Penta3, Polio3, Measles, BCG) are larger in those districts, particularly Phase I HSS districts that were targets of Bangladesh's recently completed HSS-1 grant (Figure 24 and Figure 25). We estimated statistically the changes in vaccine coverage associated with HSS using a difference-in-difference model, controlling for changes over the same time period in maternal education at the district-level. For third-dose pentavalent coverage, we estimate a non-significant increases ($p>0.05$) compared to non-HSS districts of 0.3% (95% CI -0.1 to 0.8) and 0.1% (95% CI -0.2 to 0.4) for HSS Phase I

districts and HSS Phase II districts, respectively. For the coverage of the fully immunized child, we estimated significant increases ($p<0.05$) compared to non-HSS districts of 1.9% (95% CI 0.8 to 3.1) and 0.9% (95% CI 0.0 to 1.8) for HSS Phase I districts and HSS Phase II districts, respectively. We caution, however, that this analysis is based on observational data and does not control for other potential confounders, for example, implementation of other health system efforts in Bangladesh.

Although less strongly correlated with HSS, we also noted greater improvements in child mortality in HSS districts (Figure 26). While the overall improvements and potential contribution of HSS to those improvements is a positive sign, the Gavi FCE small-area estimates also highlight areas of lower (<90%) pentavalent third-dose coverage in 2015, several of which have not shown improvements in the recent time period. Some of these areas are well known as poorer-performing areas; for example, our Gavi FCE evaluation of the MR campaign coverage in 2014 noted the lower campaign coverage in Sylhet division. These lower-coverage areas such as Sylhet, Habiganj, Rangmati, and Noakhali districts should be targets of future health systems strengthening efforts, for example, as part of the next Gavi HSS application.

Figure 24: Change in third-dose pentavalent vaccine coverage from 2011-2015 by HSS-1 status in Bangladesh

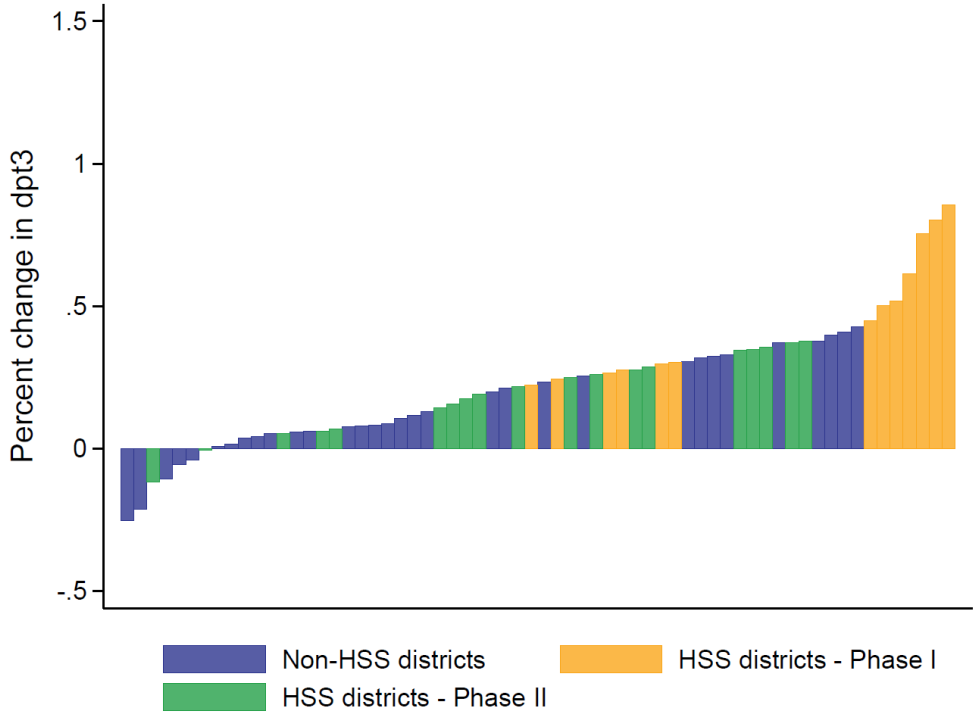


Figure 25: Change in coverage of the fully immunized child (Penta3, Polio3, Measles, BCG) from 2011-2015 by HSS-1 status in Bangladesh

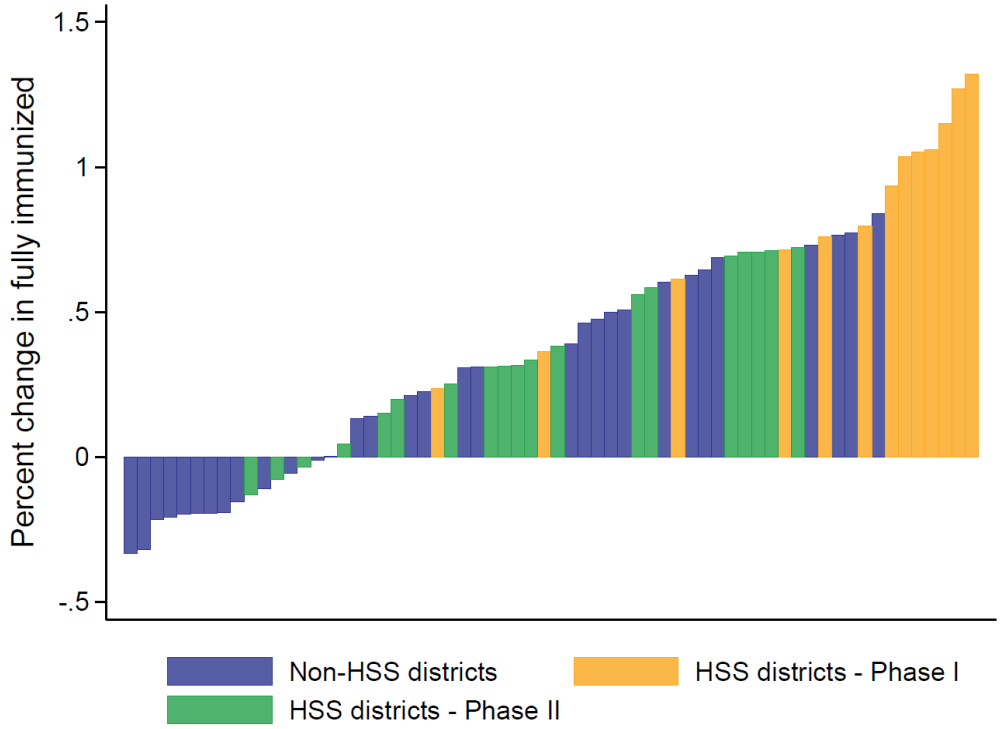
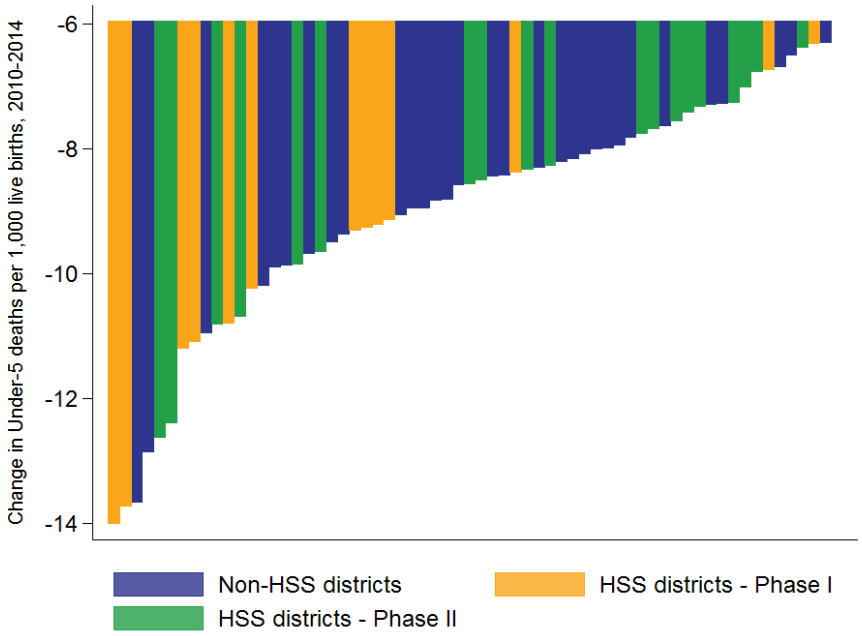


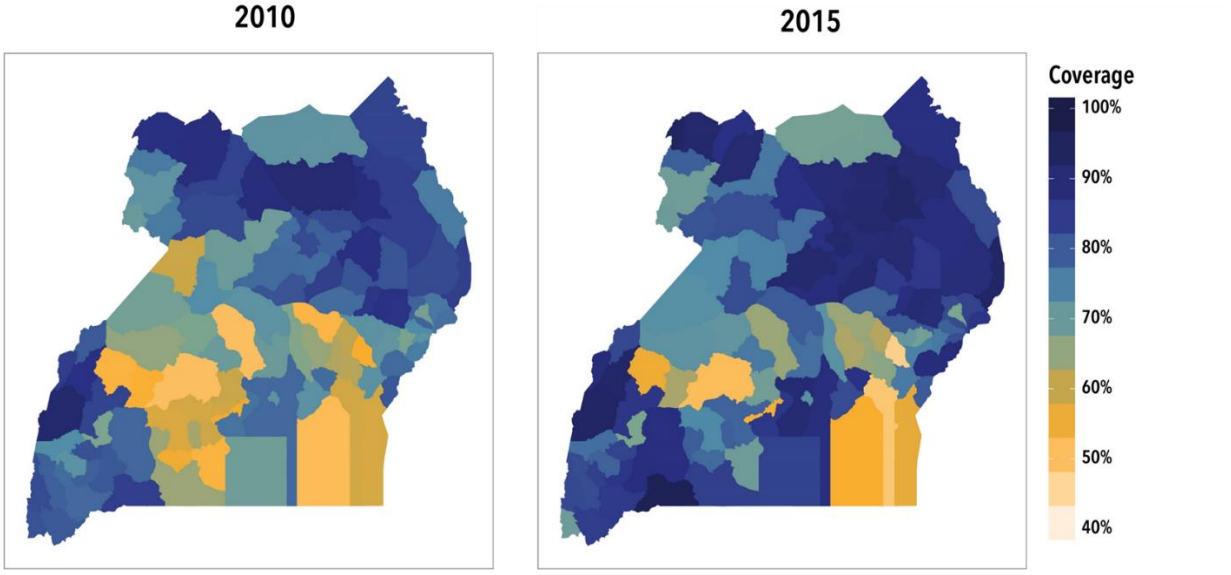
Figure 26: Change in child mortality from 2010-2014 by HSS-1 status in Bangladesh



Uganda has also experienced improvements in vaccine coverage, as shown by the Gavi FCE small-area estimates which incorporate the Gavi FCE household survey conducted in 19 districts in 2015 (Figure

27). Increases are particularly notable among districts in the Western and Central, and to a less consistent extent, Eastern regions.

Figure 27: Uganda has experienced improvements in third-dose pentavalent vaccine coverage in nearly all districts from 2010 to 2015

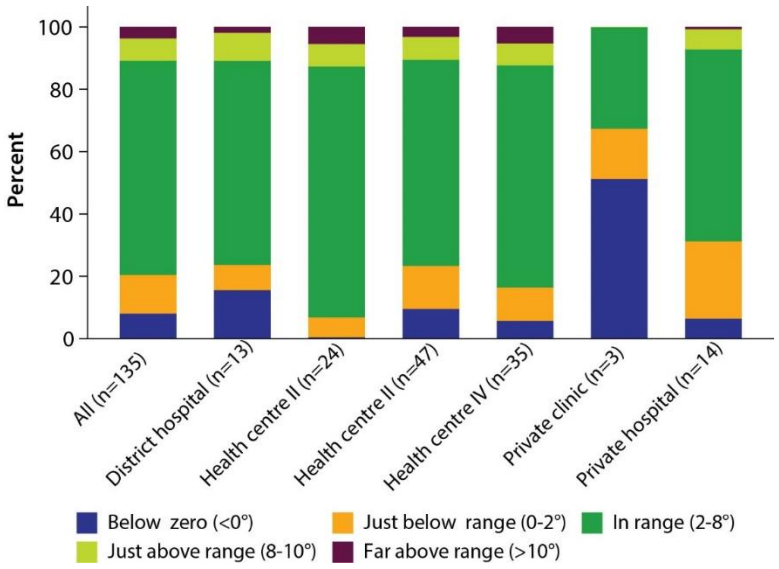


There has been limited implementation of the Gavi HSS-1 grant over this time period, as noted in further detail in the Uganda country report (Uganda country report, HSS finding 3, p. 35), and as a result we do not present an analysis analogous to Bangladesh above. Our initial investigation of these improvements show that they coincide with concerted efforts to revamp the immunization program through the Uganda EPI revitalization plan and the immunization multiyear plan 2012-2016. Prompted by declining coverage in the early-mid 2000s, the re-emergence of wild polio virus, and numerous measles outbreaks, the MoH and partners conducted a number of assessments to establish the root causes for the low immunization performance. The EPI revitalization plan and the EPI multiyear plan drew on this evidence to create strategies, including (i) strengthening community-level mechanisms through community health workers to reach the most vulnerable, underserved and un/under-immunized groups to ensure service delivery and sustained demand for immunization services; (ii) improve and streamline vaccine delivery mechanisms to minimize vaccine stock-outs at service delivery points; and (iii) strengthen advocacy efforts especially to establish a Parliamentary forum on immunization to influence higher budget allocation for EPI and enactment of favorable immunization laws. We are in the process of understanding more fully the drivers of these improvements in vaccine coverage, which will help to inform Uganda's next Gavi HSS support application, expected to be submitted in 2016.

Although the improvements noted are positive, the Gavi FCE small-area estimates also highlight a number of districts where third-dose pentavalent vaccine coverage in 2015 remains low (< 60%). To reduce geographical inequity, these could be the focus of investments through Gavi HSS and other system strengthening efforts. As detailed in the Uganda country report (Uganda country report, p. 35), the Gavi FCE health facility survey has identified a number of system gaps that could be the focus of the next Gavi HSS. These include broken primary vaccine storage equipment with limited regular

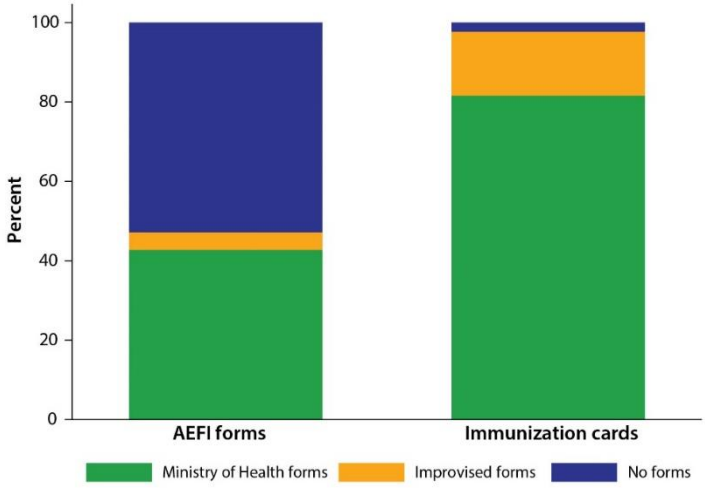
maintenance, which is reflected by cold chain temperatures being out of the recommended range (<2°C and >8°C) approximately 31% of the time, averaged across platforms (Figure 28).

Figure 28: Percent of temperature recordings in various temperature ranges by platform (source: Uganda Health Facility Survey)



Another notable limitation was the absence of M&E tools such as AEFI forms and immunization cards (Figure 29). Further details from the Gavi FCE Health Facility survey can be found in the Uganda country report (Uganda country report, p. 37).

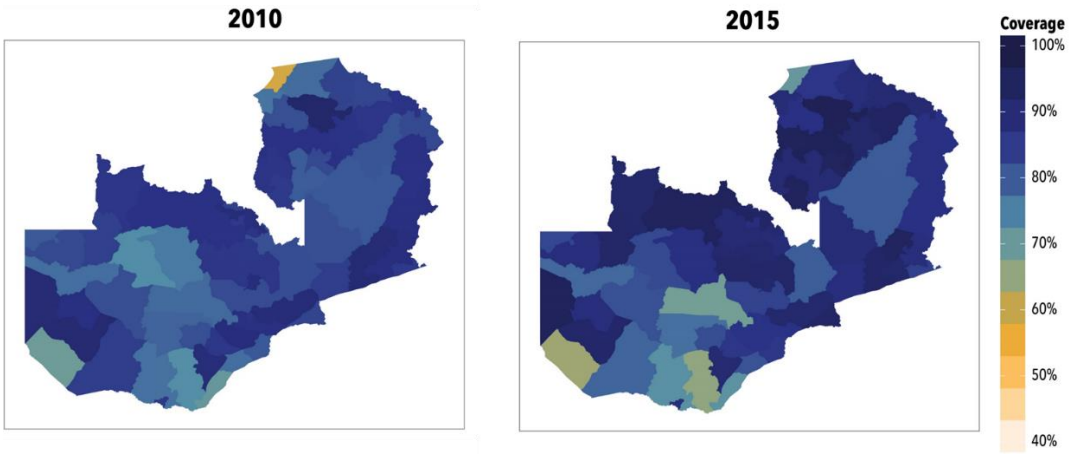
Figure 29: Percent of facilities with AEFI forms and immunization cards, Uganda Health Facility Survey



In Zambia, we have also incorporated into the latest round of Gavi FCE small-area estimates, data from the Gavi FCE survey conducted in 2015, and the recently available data from the 2013–2014 Demographic and Health Survey. This latest set of estimates also suggests significant improvements in vaccine coverage over the past five years, particularly in provinces such as Northwestern and Luapula.

Similar to Uganda, this is over a time period where Gavi HSS has not been active and also followed a period of declines in vaccine coverage in many areas that begun in the mid-to-late 1990s. We are in the process of investigating the factors behind these changes; at this point we highlight a number of possible underlying causes that could explain progress. First, significant investments have been made in the cold chain to support the delivery of immunization with support from partners such as JICA, CIDRZ, CIDA, and WHO. Specifically, the provincial and district cold-chain capacity was expanded, and new national logistician posts were created in 2013 and 2014. Second, with support from the World Bank, Zambia implemented a pilot results-based financing project that incentivized improved immunization coverage in 10 districts between 2011 and 2014. A partial intervention (excluding the cash incentive) was implemented in 10 other districts. Third, heightened policy focus on EPI is likely to have resulted through a ministerial realignment of maternal and child health programs.

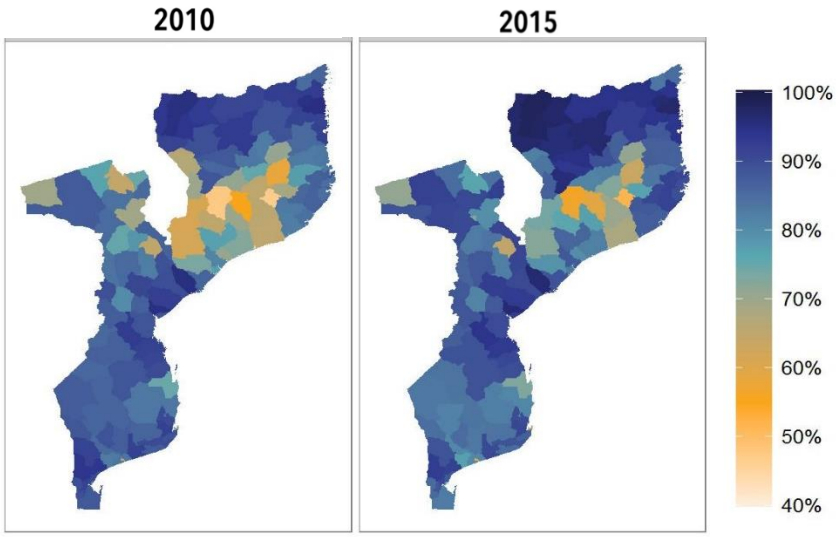
Figure 30: Zambia has experienced improvements in third-dose pentavalent vaccine coverage in nearly all districts from 2010 to 2015



Finally, although there is a positive story to be highlighted in the coverage improvements in a number of provinces, as noted in Figure 30 geographic inequality in vaccine coverage persists in 2015, with a number of districts having coverage below 70%, particularly in the Southern province. These areas should be the target of increased investments to reduce geographic inequity in vaccine coverage, for example through the Gavi HSS window of support. As noted earlier, in Zambia's recent HSS application resubmission in September 2015, the Gavi FCE small-area estimates indicated the selected districts do not represent those districts with the lowest vaccine coverage.

In Mozambique, although we do not see the same rate of improvement in vaccine coverage (Figure 31) over this time period, with the exception of Niassa Province, our estimates for Mozambique are not as robust due to limited contemporary household survey data. This will be addressed in the 2016 FCE study period following completion of the IMASIDA/Gavi FCE survey in early 2016. This will be accompanied by an investigation of drivers of coverage changes.

Figure 31: Changes in third-dose pentavalent vaccine coverage in Mozambique from 2010 to 2015



The improvements noted in Zambia and Uganda in particular highlight the opportunity for countries to reflect in HSS grant designs the factors that have historically driven these improvements. From the Gavi perspective, HSS-1 end-of-grant evaluations provide an important source of information for designing HSS-2 grants, but HSS design should also leverage the positive or negative experiences from other non-Gavi investments to improve vaccine coverage, such as those seen in Uganda and Zambia. As part of the 2016 FCE we will continue to explore the potential drivers of these changes. These improvements also highlight the potential for Gavi HSS grants to more explicitly leverage successful strategies that are in place. This could be achieved through pooled funding mechanisms.

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.

Programmatic and financial capacity

In 2013 and 2014 we reported on the limited capacity of EPI programs to effectively plan and manage Gavi support. In the 2015 evaluation period, we have further elaborated, as detailed in the country report sections, a number of instances where FCE countries face programmatic and financial constraints that limits the realization of their programs' full potential. This section describes these constraints as observed in FCE countries and analyzes their determinants and root causes. In bringing out positive examples, we hope to identify actionable lessons, with particular attention to how Gavi's SFA on Leadership, Management, and Coordination could be informed.

In 2015, for example, Mozambique continued implementation of an HPV demonstration project, engaged in planning and preparation for a HSS grant, and introduced rotavirus vaccine, IPV, and measles second dose at the national level. This is on top of the program's work to routinize pentavalent vaccine and PCV. The introduction of new vaccines, which is a success story in terms of increasing access to health improving technologies, requires significant time for grant writing, financial administration and management, and budgeting and work-planning outside of the normal cycle. The burden of these activities on countries is compounded by the fact that the EPI program does not always include the appropriate management capabilities and support systems. The Mozambique FCE reports that this "cumulative effect" of New Vaccine Introduction (NVI) and cash grants has stretched the immunization system, compromising the program's ability to effectively perform its routine work. Although the consequences of this heavy workload are yet to be fully evaluated by the FCE team, with rotavirus vaccine only recently introduced in September 2015, and IPV and measles second dose introduced in November, our evaluation of the implementation process highlights a number of areas where overstretched capacity has contributed to suboptimal implementation in Mozambique. This includes the fact that Mozambique's HSS grant took two years to arrive in country due to planning and coordination challenges between multiple stakeholders, including the EPI program, health ministry, Alliance partners, and the Secretariat, as well as limited expertise in the NIP to manage financial processes. The FCE will carefully track the reporting of VIG and HSS spending in 2016, as this will likely pose another challenge to the program.

In addition to stretching and being stretched by programmatic capacity, the cumulative effect of multiple vaccine introductions calls into question immunization programs' financial sustainability – both in the short term as new vaccines are added that must be co-financed and in the longer term as countries transition away from Gavi support. The evaluation of Gavi's co-financing policy calls out this problem of "vaccine stacking" as an emerging root cause of countries' defaulting on co-financing requirements.[7] In Mozambique, the Gavi FCE resource tracking study (Mozambique report, p. 50) shows that 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 32; excluding the system delivery cost, which was not quantified). 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.

Evidence of mismatched programmatic and financial capacity to optimally manage the implementation of Gavi support streams is also present in Uganda. As noted earlier, despite improvements in the delivery of PCV in Uganda, coverage remains lower than that seen for traditional vaccines in the system

[7] Gavi, the Vaccine Alliance, "Co-Financing Policy Evaluation."

and is not yet fully routinized. Inadequate funds for preparatory activities for national HPV vaccine introduction and planned measles SIAs led to a decision to merge preparatory activities. This led to impacts on the quality and extent of HPV vaccine training and social mobilization and possible downstream effects on HPV vaccine coverage. A recent decision to apply for Gavi support to introduce rotavirus vaccine also raises questions about financial sustainability, particularly in light of Uganda's recent co-financing default, which was driven by procedural issues in-country but also the PCV introduction, which increased the co-financing requirement considerably, evidence of "vaccine stacking" (Figure 33).

Figure 32: Gavi funding accounted for the large majority (71%) of the overall funding envelope for immunization in Mozambique in 2014, raising concerns about financial sustainability of the immunization program

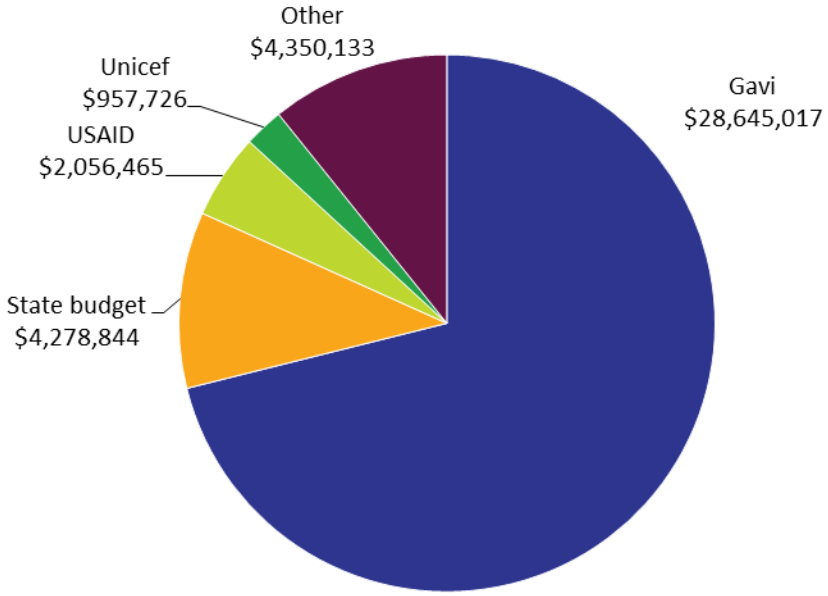
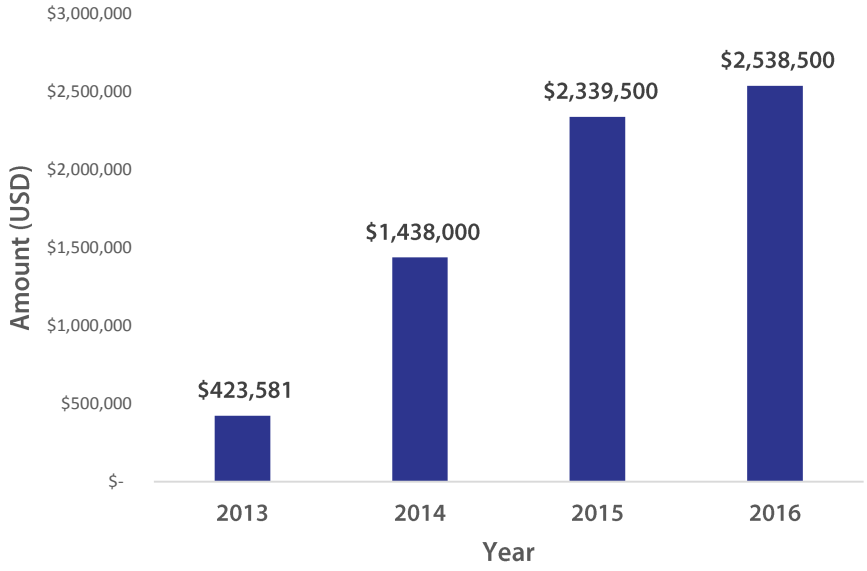


Figure 33: Uganda's annual co-financing obligation based on decision letters (USD)



In Zambia, we also document similar evidence. We noted in the HSS section a heavy reliance on external TA to write the HSS application, leading to reduced country ownership and a lower-quality application. The HPV demonstration project, although not Gavi-funded, suffered from suboptimal planning and implementation, and plans for national introduction are faced with financial sustainability questions regarding the tested delivery strategy. Most important, Zambia is a Phase 1 or Preparatory transition country, which raises questions about the financial sustainability of the program given the associated increases (15% annually) in the co-financing requirements linked to pentavalent vaccine, PCV, rotavirus vaccine, and – if it proceeds with national introduction – HPV vaccine. This in the context of heavy reliance on external donor financing for immunization as shown by the Gavi FCE resource tracking study (Zambia country report, p. 43).

Bangladesh has been notably different than the three other FCE countries in its capacity to manage multiple Gavi support streams. The MR campaign evaluation reported in the FCE 2014 report showed strong evidence of an ability for national and subnational managers and health workers to adaptively manage a large-scale campaign. 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. In several ways, Bangladesh is a positive deviant in its ability to manage multiple support streams. Bangladesh, however, did utilize consultant support in its HSS application submission in January 2015 and resubmission in September of 2015. As noted in the country section, EPI stakeholders in Bangladesh described being dependent upon traditional partners for application technical assistance, given the greater complexity of the HSS grant, the need for involving non-immunization partners, and the short time for preparation of the application.

In the remainder of this section we describe underlying root causes that lead to ineffective decision-making around, and then management of, cumulative streams of Gavi support. We adopt a case study

approach to identify the variables that have led to more effective responses in Bangladesh as compared to the other FCE countries.[8]

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. (Robustness ranking: B, Generalizability: High)

Political pressure from global and national-level stakeholders to adopt new vaccines is well-known, and indeed part of Gavi's advocacy strategy.[9] Most notably and as documented in the FCE 2014 report, global advocacy efforts to accelerate progress toward achieving the Polio Endgame Strategy's goals has led to the planned adoption of IPV Gavi-eligible countries. The push toward eradication, while justified, has, as noted in FCE countries, added to the workload associated with implementing multiple Gavi support streams. There is also evidence of reduced country ownership for IPV, for example, as noted in Zambia.

Another important global pressure stems from how Gavi's "success" has been conceptualized and measured historically. Since Gavi's inception, a key measure has been the number of new and underused vaccines introduced in Gavi countries. Though their strategy has changed to move away from simply the number of introductions to emphasize sustainable introductions along with equitable uptake and coverage of new vaccines, the number of vaccines introduced remains a key metric. This "global push" for new vaccine introduction has not historically been matched with a push for building the required capacity to manage and implement all of these vaccines and cash grants.

> *[There is a] disconnect between level of capacity actually present at the country level and what needs to be delivered on. Especially within this context of this large increased overall volume and complexity of work.* (Global-level KII, Gavi Secretariat)

National political pressure, is also notable in Gavi FCE countries. Early political pressure for HPV vaccine adoption by first ladies was instrumental in driving the applications for HPV vaccine support in Zambia and Mozambique. Like IPV, while justified, the push for HPV vaccine introduction affected other support streams; for example, the HPV demonstration project was identified as a contributing root cause of the PCV launch postponement in Zambia. Yet short-term political pressure is not always sustainable, whether due to a changing political landscape or changing agendas. We have observed declines in political attention in Zambia and Mozambique, which, without underlying support and leadership from EPI program for HPV vaccine, pose a threat to the HPV vaccine efforts in those countries.

A core root cause of this is the fact that investments in generating political will and priority have not been paired with investments to strengthen prioritization and decision-making processes within the MOH but also in bodies such as NITAGs and ICCs.

> *The problem is that every time you provide a support grant to a country to do anything… a lot of countries they don't have strong decision-making capacity so they take up the opportunity like they have done for all the new vaccines in the past years without really thinking about, actually,*

[8] Yin et al., "Prevalence of COPD and Its Association with Socioeconomic Status in China."
[9] Gavi, the Vaccine Alliance, "Gavi's Strategy."

do I really want to introduce HPV? Can I introduce HPV? So I think the decision-making phase doesn't exist so I think this is a critical issue. (Global-level KII, Alliance partner*)*

There is evidence from FCE countries that country-level priority-setting institutions are suboptimal in execution. For example, the intended role of ICCs during planning and implementation – to guide and support the MOH, to coordinate all EPI partners – is infrequently observed. In Zambia, ICCs are used primarily as a "rubber stamp" required on Gavi applications. In Mozambique the ICC is not being leveraged as it could be, for example, to improve the timely coordination of partners during HSS planning for implementation and the delays associated with the HPV vaccine demonstration project evaluations. The counterexample is in Bangladesh, where the ICC and GoB reacted effectively to the postponement of PCV introduction, deciding on a joint launch of PCV and IPV. The ICC also made the decision to defer the HPV demonstration program to 2016 so as not to conflict with the joint PCV and IPV introductions and to ensure alignment with the new school year for delivery of HPV vaccines. Moreover, the ICC in Bangladesh generally reviews and monitors EPI-related activities, approves budget and expenditure statements of the Annual Progress Report (APR) before sending to Gavi, and shares information and feedback between different implementing levels and partners within and outside the country to facilitate success of the activity.

The other advisory bodies at the country level are national immunization technical advisory groups (NITAG) that "can guide country policies and strategies based on local epidemiology and cost-effectiveness."[10] In Mozambique, although a NITAG was established a number of years ago, it was inactive between 2013 and 2014 and was only recently revitalized. In Uganda, the NITAG was formed in December 2014, but has already demonstrated the potential to guide prioritization and decision-making processes around applications for Gavi support. Uganda's NITAG queried the financial sustainability of applications to Gavi for supporting the introduction of rotavirus and meningitis A vaccines. Given that Uganda is already facing co-financing challenges for pentavalent and PCV vaccines and has experienced financial sustainability issues with the HPV vaccine introduction, the NITAG raised legitimate concerns about the country's ability to sustain new additional vaccines without compromising routine immunization activities. The guidance provided by the NITAG was ultimately not taken up by the government, and the applications for rotavirus and meningitis A vaccines were submitted in September 2015. We note that as an advisory committee, it is essential that NITAGs maintain their independence and are not perceived to threaten the decision-making authority of policymakers, in line with WHO recommendations.[11] However, Alliance partners must explore how to strengthen the remit of NITAGs while maintaining the authority of ministries of health and particularly their elected representatives. In all countries, efforts must continue to strengthen NITAGs.[12]

At the global level, there is likewise not an effective prioritization process to assess the financial and programmatic capacity of a country to introduce new streams of support or to manage its existing streams. The IRC and High Level Review Panel (HLRP) (the monitoring IRC has been replaced by the High-Level Review Panel as part of the Grant Application, Monitoring and Review [GAMR] process changes) do not have the mandate to question how vaccine introduction decisions are made, nor do they often have sufficient information to assess country capacity to understand whether countries can achieve

[10] "WHO | Global Vaccine Action Plan 2011 - 2020."

[11] Duclos, "National Immunization Technical Advisory Groups (NITAGs): Guidance for Their Establishment and Strengthening."

[12] Adjagba et al., "Supporting Countries in Establishing and Strengthening NITAGs: Lessons Learned from 5 Years of the SIVAC Initiative."

their stated plans. According to global level key informants, members of the HLRP are very "high-level" and cannot possibly understand every country context; as a result they generally defer to the SCM, cover note, and JA report. Although the HLRP is designed to be "a secondary check of a primary process" (the Joint Appraisal) which occurs in country, if there is insufficient prioritization or unrealistic consideration of capacity at the country level, the HLRP is not well prepared to assess this.

Even when concerns are raised at the global level about a country's ability to manage additional or existing streams of support, there is not a mechanism to ensure that countries, the Secretariat, or others address the concerns. For example, the IRC (under the previous IRC process of conditional approval) questioned Uganda on the financial sustainability of their planned national HPV vaccine introduction, but those concerns were not systematically addressed. There are divergent opinions from key informants on whether the new Joint Appraisal and HLRP process will create more country-level accountability. On one hand, there may be more country ownership as countries produce their own recommendations through the JA process, but if countries do not recognize the need to improve management capacity or strengthen the support structures for guiding prioritization, the HLRP is "just rubber stamping." The "feedback loop [from the HLRP] to country hasn't really been formalized particularly well" to communicate any recommendations back to the country.

> *There's a lot of meat there [in the HLRP] and where's the accountability... It would be great to use that panel more effectively as an accountability mechanism because it's great – it is the Alliance. That is the Alliance speaking and holding countries and partners accountable for "you said you were going to do this and haven't" or "where are you with this, we need to know more" and I think it's underutilized for that.* (Global-level KII, Gavi Secretariat)

Recommendations

1. Gavi and Alliance partners should invest further in strengthening national and subnational 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. (Robustness ranking: B, Generalizability: High)

There is a high administrative and management burden of cash grants

Whereas familiarity with new vaccine applications and associated procedures such as the PCV readiness assessment have increased in FCE countries, cash grants, as covered in detail in the HSS section, remain fraught by confusion and delays due to new and unfamiliar or complex processes. This administrative and management burden is not in the spirit of the Paris Declaration on Aid Effectiveness.[13] In addition to HSS, we have also noted other examples of increased management and administrative burden and poor alignment with country cycles. For example, the new GAMR mechanisms were timed according to global-level submission deadlines rather than country planning cycles and had in some cases an unintended consequence of creating additional work for countries and EPI managers. In Mozambique, the joint appraisal process took three weeks to prepare and implement, even with significant consultant support. The counter-example is Bangladesh, where EPI program staff were relatively uninvolved in the JA process that occurred there in August because of other competing priorities they had, most notably with the HSS-2 application. The JA process in Bangladesh was coordinated by the Gavi SCM, who recognized the competing deadline for the HSS application and did not pressure the government and partners (WHO, UNICEF) to engage in the JA process.

Where there is an objective to align with national processes to reduce transaction costs, we also observe cases where "alignment" leads to additional, unplanned work on the part of the government. This has been the case for HSS grants, but also new vaccine introductions. For example, in Uganda, the cMYP was completed at the same time as the applications for rotavirus and meningitis A vaccine introductions. This indicates that the cMYP process is also not fulfilling its objective as a strategic planning tool, the consequence being a program that is under-resourced for an increasingly large volume of work.

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 implementation of new processes at the country level. Such an example was given for the case of the performance-based financing component of HSS:

> *One of Gavi's issues I think fundamentally is that we make policies and don't think through the operationalization and implementation thoroughly enough. So again what you had was a paper which… a lot of work went into it…but it was done at this [high] level and there was none of this "how is this actually going to work in practice?" or there was, but it was limited. And then what you had was, at Gavi at the time, you have a group developing a policy and then potentially a different group who are then responsible for implementing a policy.* (Global-level KII, Gavi Secretariat)

Moreover, country-level stakeholders may struggle to understand Gavi policies and guidelines when they are not written for an implementing audience. But what country stakeholders find most challenging

is the lack of communication of the revision or introduction of existing or new guidelines. Stakeholders have trouble keeping track of which guidelines to use, further adding delays to the process:

> *Our guidelines are not clear... Our guidelines are pretty appalling and I think what's so shortsighted is that we produce guidelines with no communication strategy. Which is such a shame because I think if you put more investment there, the dividends it would pay would probably be large. – Global-level KII, Gavi Secretariat*

In Zambia, for example, unclear HPV vaccine application guidelines led to drawn-out debates in country as to whether an HPV vaccine coverage survey was an application requirement, with real consequences; one partner suggested that the frustrating experience was the final straw for the government, possibly leading to their ambivalence, or lack of support, for the country's HPV vaccine program.

Ongoing and planned changes at the Secretariat and Alliance levels may reduce administrative and management burden of Gavi support

There are a number of planned or potential changes at the Secretariat and Alliance levels that could reduce the administrative and management burden of Gavi support on countries. In addition to the ones noted in the HSS section, these include revised application guidelines; a single performance framework per country that consolidates metrics for all streams of support; and a streamlined IRC process with NVS and HSS together, new decision categories, and more frequent and predictable review windows. We commend the intention of these changes, as the number and frequency of Gavi processes and rules have become burdensome. Also commendable is the assignment of fewer countries to each SCM, which we hope will help to solve turnover problems and lead to improved communication and engagement. However, even when individual guidelines, policies, or procedures are streamlined or improved, we also acknowledge that the sheer number of changes, especially when not well coordinated, aligned, or communicated, can put additional burden on countries. We elaborate on this further using the example of PEF in a later section.

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. (Robustness ranking: B, Generalizability: High)

Overly optimistic timelines create artificial delays

Once support is approved, countries often face unrealistic implementation timelines first proposed during applications. Countries often do not rely on past experience to inform a realistic timeline for new vaccine planning and introduction, and timelines included as part of applications are almost universally considered to be optimistic. Thus, on paper, countries seem to be "delayed" – at least in relation to the

proposed timelines. In reality, these "delays" may lead stakeholders at the global or country level to reprogram or reallocate the grant and its implementation plan. This has been particularly problematic for HSS grants, with many downstream effects, as noted in the HSS section.

Countries may propose unrealistic guidelines for a variety of reasons. First, as a potential grantee they hope to attract investment from Gavi by demonstrating their motivation to implement quickly. As is recommended in the HPV section of this report, Gavi should ensure that incentives are aligned with long-term goals related to programmatic sustainability instead of merely incentivizing behaviors to accelerate short-term gains. Second, countries may propose unrealistic timelines without past experience of how long it will or should take.

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. We hope that the new 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.

Under the new application guidelines, Gavi has put forth clear timelines for a number of operational processes related to application and disbursement. This adds to existing efforts to communicate specific calendar dates of IRC and HLRP meetings and decisions. The FCE team expects that having set, predictable dates outlined for the application process will improve countries' planning as they will know when to expect funds and when they can be incorporated into the country's existing planning cycle. We urge Gavi to ensure that SCMs have the country knowledge to engage in a discussion around these timelines with country stakeholders, given the variability observed in these processes across countries. We plan to track this in 2016 and assess whether new application timelines developed by countries are consistent with the forecast timelines in the revised application guidelines.

Recommendation

1. 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

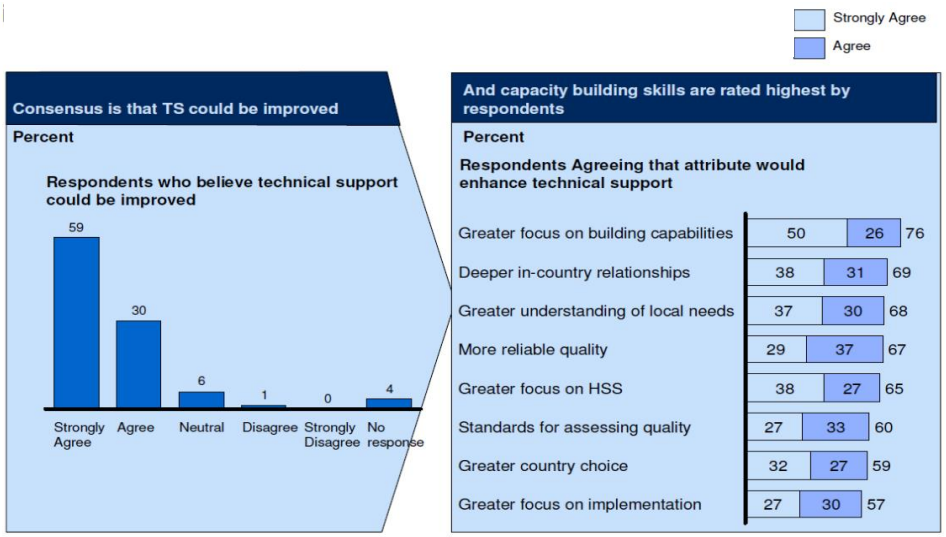
2015 represented an important year for Gavi TA. In July, the Gavi Board approved the new principles and structure of funding TA, the Partners' Engagement Framework (PEF). PEF replaces the Gavi Business Plan to improve transparency, coordination, and country alignment of TA funded by Gavi. This section provides evidence supporting the reform of Gavi's TA system as well as in-depth analysis of the process of developing the PEF architecture and the transition year between the Gavi Business plan and PEF in FCE countries.

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. (Robustness ranking: B, Generalizability: N/A)

Beginning in 2011, the Gavi business plan was developed every two years by global-level stakeholders and approved by the Gavi Board. The business plan was introduced following a McKinsey study commissioned by the Secretariat that highlighted four main challenges related to Gavi's provision of technical support, which remain largely the same today: (i) unclear and inflexible funding making it difficult for countries to spend money on what they need; (ii) poor visibility into availability of providers or their quality; (iii) poor transparency in the procurement process leading to lack of accountability of technical support providers to countries; and (iv) no systematic requirements or incentives or providers to build local capacity and transfer skills.[12] The latter "greater focus on building capabilities" was the most highly rated by 450 survey respondents (Figure 34).

Figure 34: **Appendix Exhibit C, technical support could have great impact if it focused more on capacity-building**



Source: 2008 GAVI Technical Support Survey; McKinsey analysis

As noted in previous reports, country-level stakeholders have been generally unaware of the contents of the business plan since its introduction in 2011, including which partners are being funded to provide TA and which activities are funded. This was observed in the FCE analysis of Uganda's HPV application partnership in 2014,[13] where in-country Alliance partners themselves reported being unaware of the contents of the Business Plan. This was in part due to the design of the Business Plan process, where annual planning and budgeting occurred at the global level, with the expectation that headquarter-level staff would communicate the business plan activities to regional and country offices. Effective communication did not always occur. Much of the funded TA went to Alliance partner staff in regional offices, further limiting transparency and coordination with in-country needs and partnerships. In the case of Mozambique for the HPV vaccine demonstration project, as we reported in 2014, suboptimal in-country coordination between partners led to disagreements as to who was responsible for given TA activities. This challenge was compounded by the fact that Mozambique, until recently, had limited engagement from Gavi SCMs to assist in interpreting which partners were responsible for which activities in the business plan. In 2015 we observed a much more positive engagement of SCMs, with the potential to resolve TA coordination issues in a more timely manner.

An additional consequence of business planning at the global-level was the lack of concordance between business plan-funded TA activities and local needs. TA activities were presented very broadly (e.g., "support for rotavirus application") without consideration of specific gaps that would require attention. Finally, the business plan model had limited mechanisms for monitoring whether the funded TA activities were delivered in a high-quality manner. There were few if any mechanisms to hold TA providers accountable, either to Gavi or to the countries who they support.

With the development of the 2016-2020 Alliance strategy, and the new focus on coverage and equity, there was an increased realization that the existing types of and approaches to TA were insufficient. In many countries, attaining coverage and equity goals will require a clear sense of the system challenges and how to prioritize interventions to achieve the greatest potential impact. For example, and as noted throughout this report, the management of the increasingly complex EPI program is a significant challenge that will require a new way of thinking. This focus was also identified in the 2008 McKinsey report,[14] in each of the FCE reports, and by the Alliance, which is investing in leadership, management, and coordination through the SFA and raising the issue on the agenda through the 2016-2020 Strategic Goal Three for increasing programmatic and financial sustainability.

As part of this shifting recognition of the persistent and underlying needs, there has also been recognition that the traditional network of Gavi TA providers may need to be expanded to include organizations and individuals with expertise more closely aligned with these operational and management-related needs.

> *This [McKinsey] evaluation, combined with the fact that Gavi now is much more in a place where most countries have introduced vaccine, have an HSS grant approved, etc., – and it's much less*

[13] Gavi Full Country Evaluations, "Uganda Partnership Analysis."
[14] McKinsey and Company, "Strengthening Technical Support, GAVI Alliance."

> *about the decision-making and planning, and much more about the implementation – that's one aspect that led us to say we need to focus much more on the implementation side.* (Global-level KII, Gavi Secretariat)

These conversations in the Alliance also included discussions around the overall goals of TA engagements, including whether they should lead to capacity building and skills transfer instead of the existing focus on meeting short-term 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. (Robustness ranking: A, Generalizability: N/A)

FCE's network analysis shows relative connectedness of TA networks

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. We hypothesize, based on our findings of limited awareness of the business plan, that the TA ecosystem is much more complex and dynamic than assumed. Figure 35 shows network plots in the three countries. Circles represent individuals who were named by survey respondents as having exchanged TA (either providing or receiving it) for the HSS applications in Bangladesh and Zambia and for all Gavi support streams in Mozambique. Lines between the circles represent a reported TA relationship between individuals.

Figure 35: Networks of TA exchanges in Bangladesh (right), Zambia (middle center) and Mozambique (left)

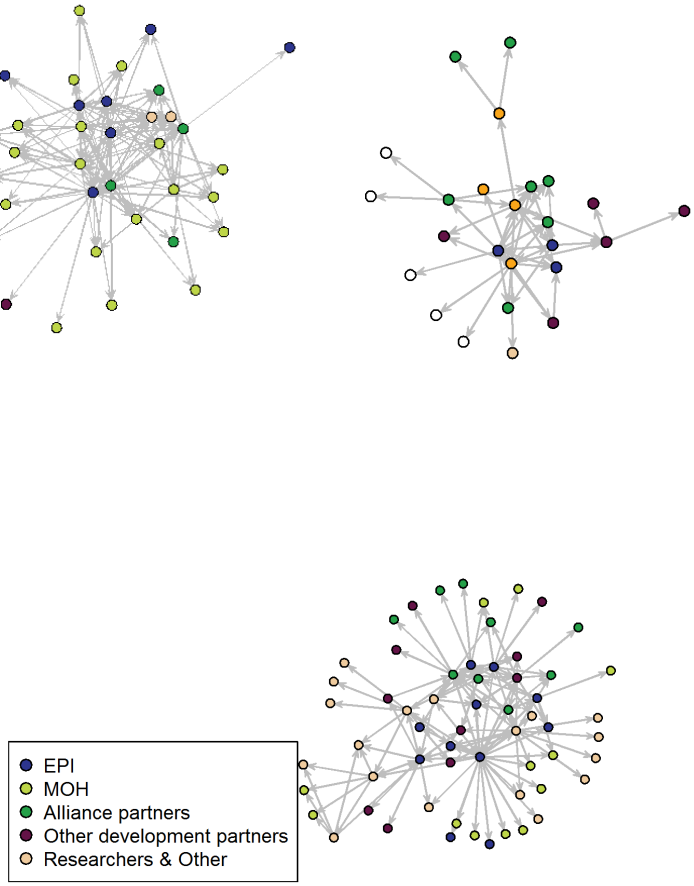


Table 10: Network indicators*

	Bangladesh HSS TA (right)	Zambia HSS TA (center)	Mozambique all streams TA (left)
Number of nodes identified (individuals)	39	33	60
Number of TA ties identified (relationships)	147	51	128
Density of TA network	0.10	0.05	0.04
Centralization of network	0.30	0.24	0.25

Mean number of ties per node	7.53	3.10	4.27
Proportion of ties that span organizational boundaries	72%	80%	75%
Median reported satisfaction with TA (out of 5)	4	5	4
Interpretation	The TA network for the Bangladesh HSS application had the most individuals, had the greatest density of connections, and was the most centralized around a few individuals.	The TA network for the Zambia HSS application had many fewer individuals than in Bangladesh. Even correcting for its smaller size, it had a much lower density of connections. These connections were more likely to connect individuals in different types of organizations. The median reported satisfaction with TA was 5/5 in this network.	In Mozambique we measured the TA network for all Gavi activities. This network had the lowest density of the three countries, meaning that TA is not being exchanged between as many people.

** These indicators are based on different response rates in each country, and thus interpretation of the values should be performed with caution*

The network graphs identify the substantial number of individuals considered to be involved in TA in immunization programs. 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. We recommend Gavi uses these maps or other approaches to understanding who provides TA at PEF's baseline; they could be improved by identifying specific skills embedded in individuals or parts of the network.

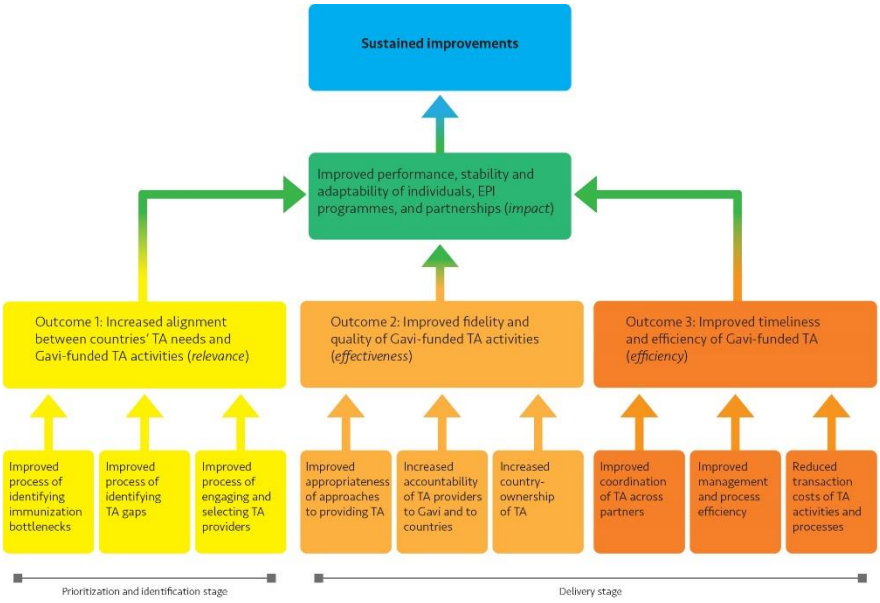
Knowledge and skills appear equally distributed throughout the network without hubs of expertise
Interestingly, we observe no "hubs" or small clusters of individuals in the network, suggesting that knowledge and skills are relatively equally distributed throughout the network. The equal distribution of knowledge and information is appropriate when the knowledge and information can and should be used by all individuals in the network. But when decision-making requires the synthesis and use of complex knowledge or information, as in the case of an HSS application, an ideal network structure should have hubs of expertise. Individuals in these hubs would share similar expertise (for example, expertise in health economics and costing) in order to facilitate the creation, synthesis and use of complex knowledge. The fact that none of these hubs exist, particularly around the consultants, suggests a general distribution of TA, and thus expertise. This is reflected in some of the IRC comments related to

suggested improvements in some of the more complex HSS tasks (e.g., performance based financing, monitoring and evaluation, costing, data use).

TA consultants occupied more peripheral roles in Zambia compared to Bangladesh
Finally, the HSS networks identify the consultants' positions in the TA network. In Bangladesh the consultants are between the network core and periphery, suggesting they played an active role but did not lead the process or "hold the pen." In Zambia, the consultant is on the very edge of the network, and named by only one person, suggesting that despite a heavy reliance on them to write the application, they were not perceived as having provided TA.

In addition to measuring who is involved in TA, FCE analyzed findings related to TA according to its relevance, effectiveness, and efficiency, and how these outcomes lead to sustained improvements in coverage and equity (Figure 36).

Figure 36: FCE Monitoring and evaluation Framework describing relevance, effectiveness, and efficiency of Gavi TA

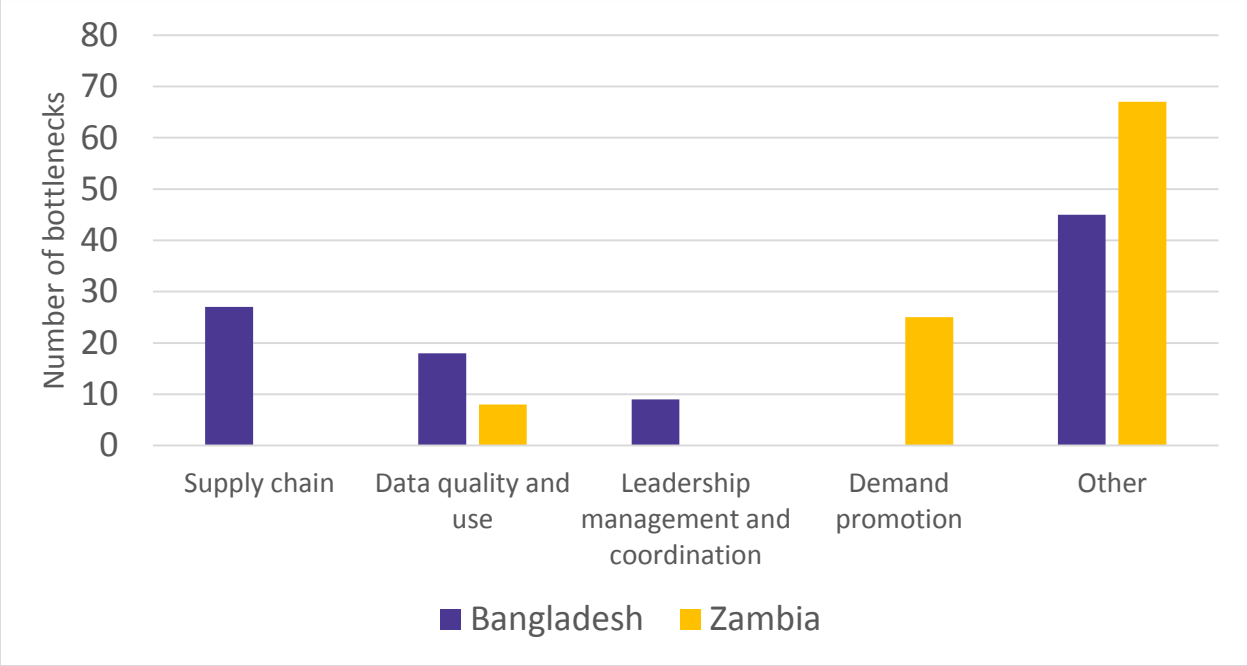


Identification of TA needs requires a more systematic and evidence informed process
As we have reported previously, and as has risen on the global agenda, Gavi TA is not always relevant or well-matched to the TA needs in countries. Relevance, or alignment, requires a systematic and evidence-informed process to identify the major bottlenecks to achieving coverage and equity, and then identification of TA gaps 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. These core competencies are necessary for the program as a whole, not only for the identification of TA needs, and relate to many of our other findings, including those around policy decision-making (Programmatic and financial capacity, Finding 1, Recommendation 2) and to strengthening management capacity overall (Programmatic and financial capacity, Finding 1, Recommendation 1). As one key informant at the Secretariat said:

> *For their own program management and planning and resource allocation purposes, they need to be able to review progress regularly, identify needs and challenges, and figure out what they're going to do about them. Both in terms of budget allocation as well as in terms of prioritizing their own time and mobilizing and leveraging partners and other assets and resources they have. Countries need to be able to do that… It's absolutely essential from a long-term development perspective that countries either have that capacity or are on some kind of track to increase their capacity.* (Global-level KII, Gavi Secretariat)

To date, this process is most easily observed in the context of HSS applications, where countries undertake a bottleneck assessment and then propose activities, some of which constitute or require TA. We also report below a similar process under the new PEF and joint appraisal architecture. In the case of HSS, we analyzed the bottleneck assessments from Zambia and Bangladesh and categorized the identified bottlenecks according to Gavi's SFAs (Figure 37). If we assume that Gavi's SFAs reflect the most significant immunization bottlenecks, then we would hope to see countries' identifying immunization bottlenecks that relate to the Gavi SFAs. We 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. For example, while FCE observed insufficient staff and capacity in Zambia's EPI program, management or EPI team capacity issues were not identified as bottlenecks in their application.

Figure 37: Bottlenecks identified through bottleneck assessment for HSS applications according to programmatic/SFA areas



While HSS applications are one specific example, this analysis raises concerns of whether the culture and skills exist to support systematic, evidence-informed and data-driven, processes needed to ensure not only the relevance of TA, but of immunization investments more broadly.

Mozambique is a case where both the HSS bottleneck assessment as well as the JA process to identify bottlenecks identified program capacity as a gap. Mozambique requested funding through PEF for a HSS technical advisor/grant manager who was hired through UNICEF, and a senior EPI staff person returning from study leave was appointed the NIP HSS focal point, both pointing toward efforts to strengthen management capacity. Their JA process, as we report below, identified a range of management and coordination needs to be funded through PEF. In 2016 we will track which were funded and whether they have any effect on EPI program management and outcomes.

Over-reliance on short-term TA but some promising models are being implemented

To define effective TA depends on the intended outcome. FCE has observed an over-reliance on short-term TA, often external, that does not succeed in building EPI program capacity or sustainability. We note in Uganda an alternative model, where a Ugandan staff member of the Clinton Health Access Initiative (CHAI) was seconded to the EPI at the request of the health minister and led the writing of meningitis A and rotavirus vaccine applications there. In this case, the potential for skills transfer and capacity building is potentially greater than short-term TA, as this person works closely with EPI staff on a daily basis. However, it will be important to track CHAI's phase-out strategy, including whether this will require additional HR investment by the EPI (to hire an additional permanent person) or whether the transfer of skills to existing staff will be adequate. Another positive example of strong TA, as detailed further in the Bangladesh report, is where the partnership of actors has worked successfully together to

launch new vaccines. TA for HSS in Bangladesh was characterized, however, by a broader set of limitations, including those again related to consultants from outside the county being unfamiliar with local strategies and context.

As Figure 38 notes, the short-term effectiveness of TA can be measured in terms of the alignment of the TA approach with the TA need; the quality of individual TA providers and their accountability to Gavi and countries, including their timeliness; and the extent to which TA leads to or enables country ownership. As described earlier in this section, TA models have to date mainly consisted of external consultants with short-term perspectives and the longer-term, typically in-country, engagement of Alliance partners.

When considering how these individuals provide TA, the approaches do not reflect the best evidence of what works for skills transfer, learning and capacity building (e.g., interactive, practice-based approaches that involve direct feedback).[15,16,17,18] With the introduction of PEF, Gavi should ensure that TA providers have not only the skills and expertise related to substantive gaps and needs, but also familiarity with the most effective approaches to providing TA. Gavi has funded an evaluation of TA to be initiated in 2016, which will shed light on the relative effectiveness of various TA approaches and providers.

Varied levels of country satisfaction with TA indicates room for improvement

The individual quality of TA providers is difficult to measure, but Table 10 reports the average reported TA satisfaction collected through the network surveys. 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. Looking forward, FCE will track with interest whether the skills of TA providers funded through PEF are increasingly aligned with the TA gaps. Our observation that core partner 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.

Gavi TA is not always timely and efficient in FCE countries. TA delays have led to larger delays across streams, including the delays in identifying consultants for HSS applications (Zambia, Bangladesh) and delays in completing PIE reports which limit the ability of the PIE to inform program improvements (Bangladesh, Mozambique). One root cause for these delays is poor coordination across partners, and as we noted above, limited transparency in the business plan.

Recommendations

1. Gavi should support mapping of existing TA providers, users, and skill sets in as many countries as possible.

[15] West et al., "Defining and Assessing Evidence for the Effectiveness of Technical Assistance in Furthering Global Health."

[16] Ambrose et al., *How Learning Works: Seven Research-Based Principles for Smart Teaching*.

[17] Potter and Brough, "Systemic Capacity Building: A Hierarchy of Needs."

[18] Rowe, "Health Care Provider Performance Review. Teach to Reach: Innovative Methods for Immunization Training (BMGF)."

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. (Robustness ranking: A, Generalizability: N/A)

What is PEF?

PEF replaces the Gavi business plan as the new mechanism for funding technical assistance.[19] It consists of three streams: (i) foundational support to core partners; (ii) targeted technical assistance for countries; and (iii) investments in strategic focus areas identified in the 2016-2020 Gavi Strategy. The foundational support stream will provide $36.4 million in long-term, predictable funding to WHO, UNICEF, the World Bank, CDC, and the CSO Constituency. The targeted country assistance stream will be allocated mainly to core partners – with expanded partners filling gaps – based on Technical Assistance (TA) needs identified through the JA process. This funding envelope was estimated at $65 million and will be allocated according to Gavi's league table of priority countries based on recommendations from a PEF management team to the Gavi CEO. PEF activities and outcomes will be monitored and evaluated based on Gavi's existing strategy indicators, the new Alliance Key Performance Indicators (KPI), semiannual milestone reporting (TCA and SFAs) and annual milestone reporting (Foundational Support) for each partner, and regular independent evaluations of TA relevance, effectiveness, and efficiency with a focus on Tier-1 countries.

Because PEF is to be formally implemented in 2016, there is a window of opportunity following the 2015 transition year to reflect on the development of PEF's architecture and the design of its investments, to learn from this year's experiences, and refine the process moving forward. We cover below these early-term findings and corresponding recommendations to help guide the design and implementation of PEF. While these findings are particularly relevant to global-level stakeholders who can act on them immediately, they are informed by the FCE's knowledge of country processes and context.

Evaluation approach

The FCE team adopted a realist approach[20] to evaluating the development of the PEF architecture in 2015 in order to answer the following questions:

[19] Gavi, the Vaccine Alliance, "Partner's Engagement Framework, Report to the Programme and Policy Committee, October 7 to 8."

[20] Ray Pawson and Nicholas Tilley, *Realistic Evaluation*.

1. Does the PEF architecture and theory of change facilitate the achievement of PEF's stated objectives?
2. What can we learn from the process of PEF's development in 2015, and from the preliminary design of PEF's investments through JA, HLRP, and PEF management team processes, to inform future communication, design and implementation?

Notably, the 2015 evaluation period ended on 1st December, and so we do not present observations related to the meetings of the PEF management team and particularly the processes to allocate TA budgets and specific activities to PEF countries.

Evaluating the effect of PEF on TA requires defining TA and what it should achieve. We adapted an existing definition[21] of TA for this analysis: the transfer or input of additional expertise, skills, or information necessary for the successful completion of Gavi-related activities. Our definition of TA assumes that TA leads to capacity-building – an assumption that we, as evaluators, feel is a necessary condition to meet Gavi's long-term goals related to sustainability and impact.

History of business plan reforms

The lead-up to the 2016-2020 Gavi strategic period presented a policy window for a number of reforms, including the business plan. The direction and explicit goals in the new strategy provided further direction for the scope of changes to the business plan. 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 also identified in the 2008 McKinsey report[22] and has been identified in each of the FCE reports, which find that programmatic and financial management weaknesses of EPI programs are the key process-related bottlenecks. This concern is shared by the Secretariat as well, as seen in their Strategic Focus Area (SFA) for leadership, management, and coordination, as well as Strategic Goal 3 for increasing programmatic and financial sustainability. However, despite consistent evidence describing this problem, its causes have been framed differently across stakeholder groups in written documentation as well as FCE interviews. WHO and UNICEF have framed it as a misalignment of TA activities with the needs of countries, using language such as "country-tailored" and "needs-based," arguing that a country-tailored approach is what is needed, and what they were beginning to achieve even in previous years' business planning processes. The problem was framed by most interview respondents in the Secretariat as a misalignment between the supply and demand sides: core partners are adept at their core business (e.g., supporting applications, routine monitoring/evaluations, policies and guidelines) but less experienced in providing support to strengthen management and implementation, thus leading to the proposed solution to expand the base of TA providers. Whether the wrong type or wrong provider of TA, the framing rarely questions TA itself.

[21] West et al., "Defining and Assessing Evidence for the Effectiveness of Technical Assistance in Furthering Global Health."

[22] McKinsey and Company, "Strengthening Technical Support, GAVI Alliance."

However, our interviews suggest that at the Board level, the greatest concern and thus rationale for reform was the lack of accountability for outcomes, thus focusing many TA- or business-plan-related conversations on transparency and accountability. These conversations were linked with a larger Board agenda to improve accountability to donors and demonstrate "value for money" of Gavi's investments.[23]

In October 2014, Seth Berkley told the Program and Policy Committee members to expect a "radically changed business plan for the 2016-2020 period."[24] Consultations with core partners occurred in November 2014 and February 2015, and were perceived as fruitful and consultative by those involved. Core partners believed that all were aligned on the principles of making the business plan increasingly country-tailored to address complex implementation needs.

The first explicit mention of principles occurs in the June 2015 Board minutes and related pre-board reading, where the principles of the new "engagement strategy" are called out as:

(a) Ensuring a country-centric process;
(b) Adopting a zero-based budgeting approach; and
(c) Seeking ways to enhance accountability for outcomes at the country level.[25]

To note, these same principles continue to be used in written communication, yet during 2015 we did not observe an accompanying theory of change for PEF which would necessitate making explicit the intended outcomes and goals of PEF. We see capacity-building of EPIs among the most important of these potential outcomes and goals of PEF, which is shared by the Alliance through their identification of country leadership, management, and coordination as a strategic enabler necessary to achieve the 2016-2020 strategic goals.[26] However, we observed limited mention of capacity-building written documentation related specifically to PEF. The two PEF streams explicitly referencing capacity-building are the TCA stream and the Leadership, Management, and Coordination (LMC) SFA (which supports the strategic enabler mentioned above). In the TCA stream, the PEF-related report to the June 2015 board meeting notes that under TCA, "all partners would be expected to provide support to countries in ways that ensure transfer of skills to in-country staff…."[27]

In parallel, the Request for Information (RFI) document prepared for potential TCA partners states that TA provided "must include deliberate approaches to capacity-building of in-country stakeholders and transfer of knowledge and know-how."[28] 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:

[23] Gavi, the Vaccine Alliance, "Gavi Alliance Board Meeting Minutes."
[24] Gavi, the Vaccine Alliance, "Partner's Engagement Framework, Report to the Programme and Policy Committee, October 7 to 8."
[25] Gavi, the Vaccine Alliance, "A New Gavi Engagement Framework for Implementing the 2016-2020 Strategy."
[26] Gavi, the Vaccine Alliance, "Gavi's Strategy."
[27] Ibid.
[28] Gavi, the Vaccine Alliance, "Request for Information. Country Assistance for Accelerated Implementation of Gavi Strategy 2016-2020."

> *TA is for me is all about building capacity. So it's not referred to, you're correct. But … we are very focused on building capacity of national level, when we do workshops to discuss NVI, cMYP, it's all about building capacity of nationals…* to carry out by themselves. *Perhaps there is not enough emphasis in how it is described… but to me TA without this objective is absolutely wasted. Perhaps it will come through more clearly with the SFA on Leadership, Management [and coordination] because this is all about how we put more emphasis on building capacity of EPI team to manage and direct their program. But you're right, perhaps it needs to be made more explicit. (KII, Alliance partner)*

> *The shift in emphasis is clear, where we are constantly saying "please work with EPI, embed yourself, focus on transfer of skills and capacity to EPI management"… In… initial presentations it was very powerfully brought out but I think in some of the subsequent documents it wasn't highlighted.* (Global-level KII, Gavi Secretariat)

The SFA on LMC will be an extremely important mechanism for planning, allocating, and funding capacity-building activities, although there was some concern from interview respondents that delays in this SFA's design would further delay the creation of a common vision and approach to building capacity. What is also not clear at this early stage of implementation is how capacity-building efforts will be aligned with and leverage other Gavi mechanisms such as HSS. Investments to build capabilities are ongoing or planned through HSS grants; however, 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. With multiple analyses[29] including this report identifying strained capacity and capabilities of EPI as a key bottleneck, a strong vision and articulation of capacity-building that describes how this will be achieved across PEF, HSS, and other mechanisms is of central importance.

Beyond capacity-building, a formal theory of change for PEF would be helpful in elucidating and communicating what PEF will change, and how.

> *They are now building a new business plan called the TCA [Targeted Country Assistance] plus SFA [Strategic Focus Area] plus Foundational Support that is missing a rigorous framework, whether it's a logical one or a theory of change one that allows you to connect the dots between activities, outputs, outcomes, objectives, and ultimately Gavi objectives. So the TA being requested might be nice and needed by country but is not necessarily logically connected to what need to be the outcomes at country level in order to achieve the global goals. (KII, Alliance partner)*

A clear theory of change could help in cementing the vision of PEF and would ideally lead toward clearer communication across the Alliance. This theory of change, developed in participation with other change initiatives, could help bring additional meaning and 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-

[29] Hyde et al., "The Impact of New Vaccine Introduction on Immunization and Health Systems: A Review of the Published Literature."

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. (Robustness ranking: B, Generalizability: Medium)

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

Developing the PEF architecture necessitated negotiation across many stakeholder interests and sought to ease the burden of additional change, a worthy goal, by using existing policy instruments.[30] PEF's core instrument is funding (to partners), but PEF needed a mechanism to ensure the funding was "country-centric." PEF architects made the decision to use the newly developed JA and HLRP processes, which were developed as country-centric monitoring mechanisms as part of GAMR. The idea was that TA could be identified at the end of the JA process, thus leveraging the country-led analyses conducted as part of the JA regarding program and system constraints and taking advantage of the local partners at the table.

The JA process is designed, in principle, to encourage an inclusive and country-centric process. If it is implemented according to Gavi's principle of alignment with existing country processes (e.g., alongside an EPI review), it could be an effective mechanism for reviewing the EPI program. Further, if this process then led to the systematic identification of TA needs while mitigating potential biases of those at the table, it would, in principle, be an ideal process.

> *But if it is an artificial process that is dumped on country at a suitable time only for the global level, then it is not fit for purpose. And that's the difficulty. We needed to have all JAs conducted by HLRP, at a time that was convenient to us, rather than a time that was convenient for country*

[30] Policy instruments are the practical tools used to achieve policy objectives or induce behavior changes among individuals or groups targeted by the policy.

cycles. Principle and philosophy of JA is great, with national leading this. A perfect philosophy, but the implementation has not worked in 80-90% of cases I'd say. (KII, Alliance partner)

Our findings from this transition year in FCE countries reflect this quote, with JAs in Mozambique, Zambia, and Bangladesh implemented in August, presumably to meet the mid-September submission deadline for HLRP rather than based on alignment with country processes (where annual review and planning meetings typically occur in the first quarter of the calendar year for the following year).

We also found based on our observations of the JA process variability in the way that the JA was conducted (see supporting evidence text box).

Supporting evidence from the Gavi FCE

- **Mozambique**. In Mozambique – one of Gavi's identified high-priority countries – there was a high level of stakeholder engagement in the JA process with a strong preparation phase, facilitated by consultant support. (Mozambique cross stream point 3, page 44)
- **Uganda**. In Uganda – also a high-priority country – the JA occurred in February 2015 with remote engagement of the SCM. This was before PEF had been finalized and thus did not include discussions around TA. (Uganda cross stream point 3, page 44)
- **Zambia**. In Zambia the JA occurred with limited engagement and without an SCM in country. (See Zambia TA finding 1, page 41)
- **Bangladesh**. In Bangladesh the JA was completed by the SCM through a series of smaller group meetings. (Bangladesh cross stream point 2, page 52)

Implementation of JA process to identify TA needs has been variable across FCE countries

This diversity of implementation in countries is partly attributable to the guidance but also a function of individual SCMs.

The other thing it comes down to is how well things are communicated and what the SCM's vision of JA is. It is hard to make it into something more than what it is for the SCM managing it. (KII, Gavi Secretariat)

Variability in the implementation process was accompanied by corresponding variability in the identification of TA needs. In Mozambique, stakeholders generally perceived the JA process to be an appropriate and effective venue for identifying TA needs, which is reflected in their JA report identifying the greatest range of TA needs across the SFAs, as compared to other FCE countries (Figure 38). In Mozambique, the process benefitted from a dedicated, experienced consultant who worked in Maputo for three weeks leading up to the JA. (See Mozambique section for more examples of why it worked, or how it could be improved.) On the other hand, 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 (Figure 38 and Figure 39).

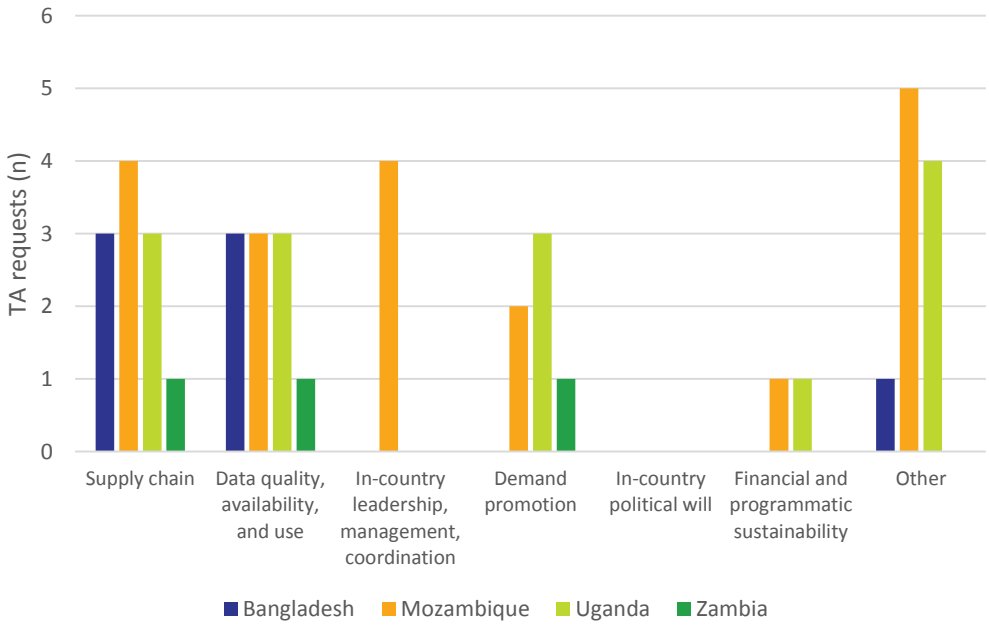
Norms of practice and cognitive biases may affect TA identification

Contents of TA section might also be explained in part by cognitive biases that entrench the status quo:

> *If you put 10 EPI managers in a room and asked them about the most pressing needs facing their programs they would respond with technical needs, e.g., supply chain, etc. Management capacity is not a priority. Will it come from a bottom-up process?* (KII, Gavi Secretariat)

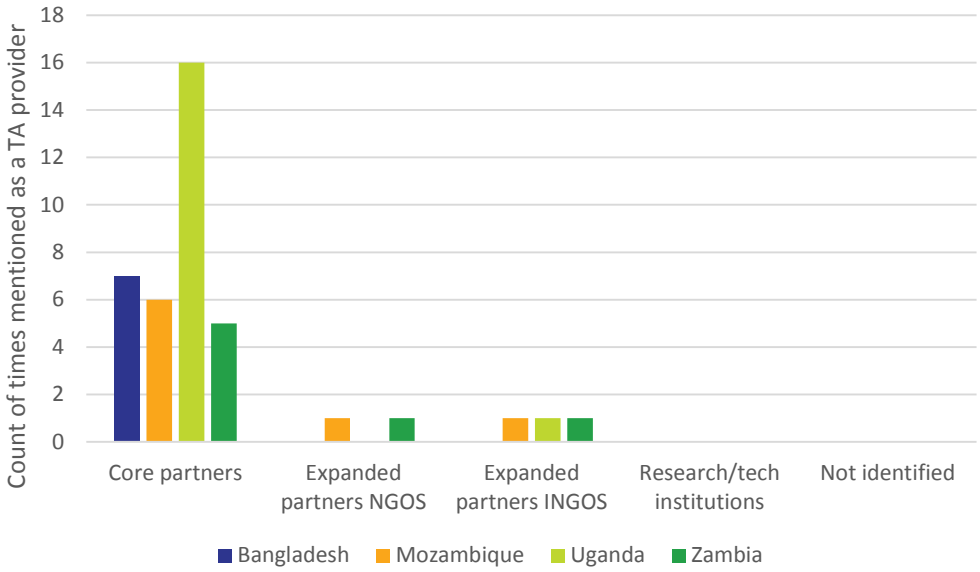
These underlying biases were compounded by JA guidelines that directed readers to start with the 2015 business plan, further entrenching "business as usual" instead of providing tools to encourage systematic identification of immunization bottlenecks and TA needs. Many respondents commented on unrealistically long lists of TA needs provided by some countries, a consequence of little guidance, and multiple respondents across stakeholder groups requested more detailed tools or guidance for the JA.

Figure 38: Technical Assistance requests by Strategic Focus Area categories. *Note: TA requests categorized according to SFA by FCE team*



One of the objectives of PEF is to expand the base of technical assistance providers. In FCE countries, however, core partners (WHO and UNICEF) accounted for the vast majority of TA provision named during JA (Figure 39).

Figure 39: Partners requested in JA TA tables



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

While this is largely a reflection of those agencies' historical and current roles in providing TA and guidance to EPI programs, it may also reflect limitations of the JA process as a tool for unbiased, comprehensive assessment of TA needs. FCE countries expressed confusion over how to have an open conversation about TA when the providers themselves are at the table. Many were worried that such a conversation would weaken trust and goodwill among partners. 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.

> *[Risk of capture] is definitely a risk. TA proposals depend on who is in the room and pushing for them to support the country in some aspects.… It is definitely an unfair process.* (KII, Gavi Secretariat)

> *Pages and pages of TA needs for some countries. My guess is they were probably driven, or written by, partners. Hard to see ownership of government in TA needs. (KII, Alliance partner)*

Others emphasized that the potential for conflict of interest is nothing new; indeed, it has been a persistent tension since Gavi's inception, but that "PEF is like injecting steroids in that [conflict of interest]." (KII, Gavi Secretariat). Most stakeholders also acknowledged that the potential for conflict of interest affected all stages of the PEF process, not just the JA. For example, WHO and UNICEF have a seat at the table during HLRP, the PEF management team, and the Gavi Board. Each of these processes has terms of reference to mitigate potential conflicts of interest, but all respondents acknowledged the tension that persists. Reducing informational asymmetries of all partners might help to level the playing field, as was also recommended by McKinsey and Company in 2008. Interventions might include tools to support evidence-informed identification and prioritization of TA needs (demand-side), as well as mapping of TA providers and skill sets to catalogue TA supply.

Moving to the global-level processes, many respondents expressed confusion over HLRP's purpose in relation to the JA process, particularly as it was presented as country-centric. Country stakeholders wondered how their TA tables in the JA report would be used, or "what happens next?" Secretariat staff, including but not limited to SCMs, were generally unclear about what the process entailed, or how to communicate it, saying "it is a black box for everyone." (KII, Gavi Secretariat)

Respondents raised concerns about whether HLRP and PEF-MT members would have the information and time to assess the relevance and appropriateness of TA needs identified through a country process:

> *A process that was created to be a local conversation is going to be the data source for global planning. That's a big ask of the JA process. (KII, Alliance Partner)*

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. (Robustness ranking: B, Generalizability: High)

2015 was a transition year between the business plan and PEF. PEF affects multiple stakeholders across many agencies and geographies who hold varying interests and preferences on the issue of technical assistance, including financial interests, and like any large reform, PEF will necessarily lead to dissatisfaction among some stakeholders.

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

As such, it is particularly important that the change process is implemented with clarity of vision, strong coordination and communication, and change management; these are essential to avoid confusion among stakeholders and potential downstream consequences on partnership trust. Our findings, including our observations of the JA process at country level, suggest that stakeholders do not have a complete understanding of the PEF architecture and related processes for implementation. Respondents cited insufficient communication on how the parts of the PEF process fit together and relate to other Gavi policies:

> *I don't think they connected all the dots. I don't think they were seeing how all these different things rolling out were confusing to people. At board talking about key performance indicators, at PEF level they were talking about deliverables and accountability for deliverables, at country, performance frameworks. Tell people how all these things fit together! And I'm talking global-regional level, I'm not even trying to imagine how this feels to a country, which I imagine is total gobbledygook.* (KII, Alliance Funder/Board Member)

Change management was also an oft-cited problem not limited to PEF, with decisions being taken too quickly, or occurring alongside implementation without sufficient effort to manage those changes.

> *Is it too much change? I don't know. Is it too much change for the way it's being managed, yes. A lot of change can happen in a well-managed context... it seems there is, overall, an under-management of operational details that need to happen given this amount of change.* (KII, Alliance Funder/Board Member)

That PEF may not lead to a "major shift" – either in process or outcome – was expressed as a concern by country-level stakeholders at this early stage: *[it is] "business as usual." (KII, Mozambique MOH)*

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. Interview respondents in global and country interviews expressed concern that an onerous process, followed by minimal feedback, would lead to ambivalence.

Partnership trust was also affected by a perception that the locus of decision-making authority had shifted during the process of developing the PEF architecture, so that while partners were involved in early workshops, important decisions were made without their buy-in. Partners felt their role had become primarily reactive instead of participatory. While some attributed this shift in locus of authority to PEF, others traced it back as an evolution that has been ongoing for at least two years, with the size and influence of the Secretariat a necessary reaction to the growing scope and size of work to be done.

What seems to be the most significant change for Alliance partners – 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. If carefully and intentionally implemented, such a model could also help to 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. These are the types of outcomes that could be articulated through a clear theory of change and communicated effectively.

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.

Use of FCE findings

At the country level and global level, findings from the Gavi FCE have been used to inform decisions to improve immunization programs. The intention of this section is not to comprehensively catalog or evaluate all the uses of Gavi FCE findings but rather to highlight specific cases where the evaluation has influenced planning or implementation of Gavi support or broader immunization or health system activities.

We define "use" according to definitions used by Landry[31] and Weiss[32] which recognize that research findings can be used in many different ways and to different extents. Some FCE findings may be at earlier stages (e.g., reception or cognition), whereas others have moved along to adoption and influence on decision-making, likely because of factors related to the issue and context. In this report, we define "use of findings" as individual-level use of FCE findings to inform decision-making, whether the individual operates at the level of the Gavi Secretariat, an Alliance partner, a Ministry of Health, or a district health office.[33]

Similarly, one does not expect findings to always be used instrumentally, or in a problem-solving mode. Findings may "enlighten" or be used conceptually. They may also be used symbolically or politically to justify a predetermined policy position. The prospective nature of the Full Country Evaluations lends itself to the timely utilization of findings in planning and implementation of Gavi support.

At the global level, Gavi FCE findings have contributed to a range of policy and procedural changes as highlighted in the management response to the 2014 Annual Report. For example, FCE findings were used in the revision of 2016 guidelines for multiple support streams. This included an increased emphasis on financial sustainability and cost analysis for the HPV vaccine window of support. For HSS, guidelines were revised to emphasize the importance of alignment of HSS with national health plans and budgets to reduce delays. The 2016 HSS Guidelines also contain additional information on the average time between application and disbursement to assist countries in work planning. The FCE findings have also contributed to or provide additional support for some of Gavi's new strategies. The health facility findings on suboptimal temperature maintenance of cold chains in Zambia and Uganda support Gavi's new cold chain support window (Figure *40*).

FCE has also partly contributed to the establishment of Gavi's strategic focus area on Leadership, Management, and Coordination:

[31] Landry, Lamari, and Nabil Amara, "The Extent and Determinants of the Utilition of University Research in Government Agencies."

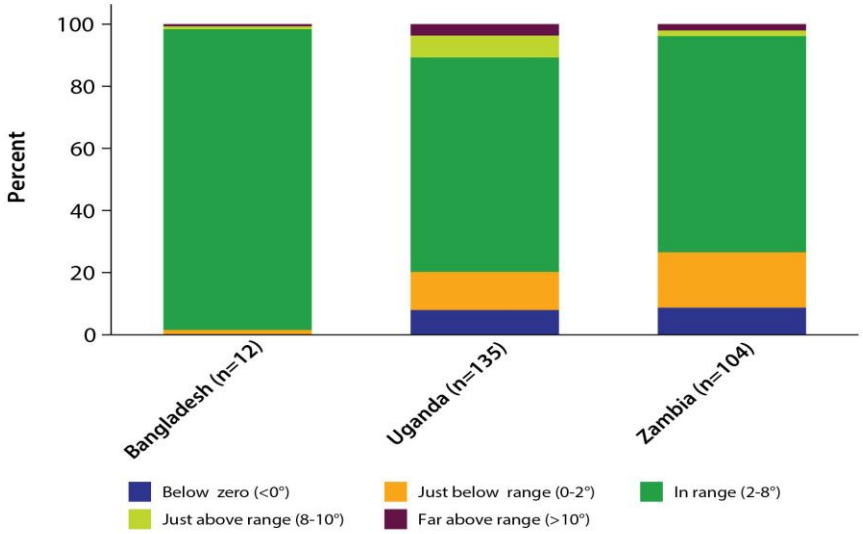
[32] Carol, "The Many Meanings of Research Utilization."

[33] Landry, Lamari, and Nabil Amara, "The Extent and Determinants of the Utilition of University Research in Government Agencies."

> *The single biggest takeaway from the last report was the disconnect between level of capacity at country level and what needs to be done, within this context of increased volume and complexity. It wasn't the FCE alone, but the FCE contributed to motivating the focus on leadership, management, and coordination in the new strategy.* (Global KII, Gavi secretariat)

FCE findings have also been used in various ways at the country level as we detail further below. We highlight processes like the JA and institutions like NITAGs as important mechanisms for participatory, systematic, country-led use of evidence to inform national immunization programs.

Figure 40: Comparison of cold chain temperatures based on continuous monitoring in Bangladesh, Uganda and Zambia



Bangladesh

FCE findings have been used in a number of ways in Bangladesh. These include, but are not limited to, the MR campaign evaluation findings being included in the Bangladesh Internal Appraisal 2014, various FCE findings being used in preparation of the 2014 Annual Progress Report and the 2015 Joint Appraisal Report. In this report we highlight the use of FCE findings in the development of the HSS-2 application that was initially submitted in January 2015. At the request of the Ministry of Health and Family Welfare, the Bangladesh FCE team participated as members of a working group tasked with preparing the application for Gavi's new Health Systems Strengthening (HSS) funding platform (2015-2019). Other members included the Ministry of Health and Family Welfare policy-level officials, the director, Primary Health Care (PHC), the EPI Program Manager, WHO and UNICEF, and external consultants.

The Bangladesh team's role in the working group was to provide information to the working group designing the HSS grant based on findings from the FCE evaluation of the HSS-1 grant. The findings (covered in detail in the Bangladesh report section) identified a range of bottlenecks in the first phase of the HSS grant, including the absence of a Monitoring and Evaluation (M&E) framework and unspecified implementation plan; delays in fund disbursement due to the late completion of the newly introduced Financial Management Assessment and transition between the second and third SWAp; delayed recruitment of key staff; and challenges in coordination between implementers.

The Gavi HSS-1 grant is evaluated as a part of the Gavi FCE team in Bangladesh in collaboration with external institutions. These findings informed the HSS proposal, which took measures to avoid similar challenges under the new grant. The FCE team has shared their findings and reports through meetings (e.g., technical and advisory committee meetings, meetings with Joint Chief, Planning, MoHFW, etc.) and mails to the respective stakeholders of government and partners. As a result of the evaluation findings, included in the Gavi HSS-2 application is a table that provides information related to major issues identified in the FCE and corresponding risk-mitigation measures.

Mozambique

The use of FCE findings in Mozambique includes the use of FCE as evidence to support recruitment of technical assistance at the central NIP and as a key source for the Joint Appraisal process held in June 2015, including a range of stakeholders: the National Immunization Program, WHO, UNICEF, Village Reach, John Snow, Inc. [JSI], Clinton Health Access Initiative [CHAI], Foundation for Community Development [FDC], and the Gavi Secretariat.

In preparation for the JA, a desk review was conducted which drew on findings from the 2013 and 2014 FCE reports. The FCE team were also ask to present the past evaluation findings as part of the JA. FCE findings informed a range of JA discussions. These included discussions around the HPV vaccine demonstration project where the NIP manager noted that the FCE annual dissemination meeting held in March 2014 clarified the importance of refining and testing alternative delivery models as part of the demonstration program. PCV-relevant findings were used in a presentation by Gavi's Senior Country Manager for Mozambique to inform discussions about NIP data quality issues. The FCE findings on PCV demand generation (as part of the After-Action Review (AAR) conducted by FCE) was requested for review by the social mobilization technical working subgroup. This report was used a support document to support weaknesses cited for the information, education, and communication (IEC) section TA needs.

Uganda

FCE findings have also been utilized in various ways in Uganda. For example, the 2014 FCE report findings on partnership, which revealed the exclusion of the Ministry of Education and Sports (MoES) from the HPV vaccine application, informed country efforts to better involve the MoES in planning for HPV vaccine rollout. Lessons learned from the FCE evaluation of PCV introduction have informed planning for HPV rollout.

A particularly notable use of FCE findings has been the use of the FCE resource tracking findings, detailed in the Uganda country section of this report, which build on past work funded by the Bill & Melinda Gates Foundation. These resource tracking findings contributed to the Joint EPI review undertaken in March 2014 and the Joint Appraisal report. They were also used by the Uganda NITAG to inform its guidance on the financial sustainability of decisions to introduce rotavirus and meningitis A vaccines. The resource tracking findings were also used by the Ministry of Health to inform an immunization bill, which was presented to Parliament in 2014 to justify increased government spending for immunization.

Zambia

Similar to other countries, FCE findings have been used, for example, as an input to the 2015 Joint Appraisal Report and to support the switch to solar-powered fridges rather than kerosene or mains powered electric fridges as part of cold-chain improvements. A key example of the use of FCE findings

has been the development of the HSS application initially submitted in January 2015 and resubmitted in September 2015. As part of the HSS application process an HSS coordinator was established under the DPI; this was a specific recommendation from the 2014 FCE Annual Report. Child Health Unit (CHU) also indicated that the small-area estimates would be used as a baseline for HSS indicators and were used to inform the selection of districts for HSS (although as we note in the HSS section, other factors played into the selection of the districts).

Summary

Since the beginning of the Gavi FCE in 2013, the four FCE countries (Bangladesh, Mozambique, Uganda, and Zambia) with support from Gavi's new and underused vaccines support window – which represents the majority of Gavi's support in financial terms – have introduced a range of vaccines into their systems. PCV, introduced in Mozambique in 2013, was successfully routinized (as measured by the ratio of PCV doses to pentavalent doses) from early 2014. Early-term findings suggest that PCV in Bangladesh has also been rapidly scaled up since its launch in March 2015, and the earlier FCE 2014 report showed the successful implementation of the Measles-Rubella (MR) campaign in Bangladesh, which led to high (90%) campaign coverage. Early evidence from the FCE also shows the impact of new vaccine introduction on the corresponding disease burden. In Mozambique, we found significant reductions in vaccine-type nasopharyngeal carriage and invasive vaccine-type pneumococcal disease incidence associated with the introduction of PCV. As reported last year, the high campaign coverage achieved by MR campaign in Bangladesh was associated with a corresponding large reduction in rubella susceptibility.

These success stories are tempered by other less positive findings. Delivery of PCV and rotavirus in Zambia and PCV in Uganda, which were all launched in 2013, remain at less than 90% of the level of pentavalent vaccine, and the scale-up of IPV as part of the joint PCV-IPV launch in 2015 in Bangladesh has also been suboptimal. FCE findings also suggest a range of challenges experienced in introducing HPV vaccine, particularly in terms of maximizing the opportunity that demonstration projects present to learn and inform national introduction. This has led to subsequent delays in national introduction of HPV in Mozambique and Zambia, as well as uncertainty about the ability of the national HPV vaccine introduction in Uganda to achieve high coverage with changed delivery model. We also raise in this report concerns regarding the sustainability of multiple vaccine introductions. The addition of PCV partly contributed to the co-financing default in Uganda, and multiple vaccine introductions are also acknowledged as an increasingly common reason for default by another evaluation study.[34] The Gavi FCE in 2016 will continue to monitor and evaluate these vaccine introductions as well as several vaccines recently introduced (rotavirus vaccine, measles second dose, and IPV in Mozambique, HPV vaccine national introduction in Uganda) and scheduled for the near future (IPV in Zambia).

While support from Gavi's new and underused vaccines window has been positive overall, implementation of Gavi's cash support through the Health Systems Strengthening (HSS) window remains fraught with challenges and resulting slow implementation. In Mozambique, the first tranche of HSS funds was finally disbursed in July 2015, two years after grant approval in 2013, and this has been accompanied by additional time required for subnational disbursement for implementation. In Uganda, there have been ongoing delays in limited implementation of HSS activities, particularly around civil works. These findings on delayed disbursement of funds and slow resulting implementation were

[34] Gavi, the Vaccine Alliance, "Co-Financing Policy Evaluation."

mirrored with Bangladesh's first HSS grant. Both Zambia and Bangladesh were unsuccessful in their first applications for a second HSS grant in January 2015, which led to resubmissions in the later window in September 2015. The importance of addressing constraints to HSS implementation is particularly important in light of Gavi's new 2016-2020 strategy, where there is an enhanced focus on improving coverage and equity, of which HSS will be a primary mechanism.

We have investigated and documented the root causes of these successes and challenges of Gavi support implementation that are presented throughout the report, in both the cross-country section and the accompanying country reports. In this summary, we highlight the key root causes from the Gavi FCE perspective. First and foremost, as we highlight throughout the report (HSS section, Finding 1 and Programmatic Capacity, Finding 2) and in previous FCE reports, is the programmatic capacity of immunization programs to meet an increasing workload, particularly at the central level. EPI programs remain small and underfunded and have in general not grown in line with a broadening scope and accompanying workload. This represents a failure to build capacity; Gavi's new Strategic Focus Area on Leadership, Management, and Coordination represents one initial step toward this, but will need to be accompanied by other investments. The positive consequences of investments in human resources for EPI and the subsequent programmatic successes are exemplified in Bangladesh, where routine EPI coverage is high and new introductions have proceeded smoothly.

> *Let any new vaccine arrive, let rotavirus vaccine come along with PCV and IPV, we can handle them all and no problems will be faced. This is because we conducted the MR campaign, which is a model for the world. Has anyone else provided as many vaccines anywhere else? It was successful, so what can we not achieve?*

Second, as noted in more detail in the *Programmatic and financial capacity* section, are the prioritization processes, both at country and global levels, which lead to a workload that is mismatched to programmatic as well as financial capacity – the "misalignment of aspiration and reality" (Global KII, Alliance Partner). Strengthening decision-making at the country level, including advisory bodies such as ICCs and NITAGs, is an important action item, as is ensuring a robust system of checks and balances at the global level.

Third is the additional strain placed on that limited capacity from resource-intensive, unclear policies and procedures associated with Gavi grants. This is most notable with the HSS support window as detailed in the *Programmatic and financial capacity* section, but also includes the HPV vaccine support window and cross-stream procedures such as the JA and PEF. On a positive note, in 2013 we noted the lack of clarity in the PCV readiness assessment process, which was found to be better implemented with clearer understanding in the recent PCV launch in Bangladesh due to enhanced communication around the requirements. In general, more attention needs to be paid to anticipating the impact of new or unfamiliar policies and procedures on country-level implementers and ensuring that guidelines are accompanied by robust communication strategies, beyond the guideline mechanism, to ensure that country-level programs and partners have a clear understanding. There are a number of changes underway or planned at Gavi that could reduce the present administrative burden on countries.

Fourth is the design and provision of technical assistance. As noted throughout the report, limited capacity has led to a reliance on technical assistance, mostly by providers that are external to country-level immunization partnerships. Across the FCE countries there have been examples of ineffective technical assistance that was sourced late, was misdirected, and has not been accompanied by capacity-

building efforts. This is best exemplified by the provision of technical assistance for HSS applications in Zambia and Bangladesh. Positive examples, however, were also found, including the role of technical assistance embedded with the Uganda EPI program and technical assistance and the accompanying partnership leading to largely successful vaccine introductions in Bangladesh. In our early-term evaluation of the new Partners' Engagement Framework as the new model of technical assistance, we note a number of deficiencies of the new approach, most importantly a need for a clearer objective and plan around capacity-building. We provide a number of recommendations for improving the implementation of PEF at this early stage.

A fifth root cause we noted was limitations in data and evidence to support the implementation of Gavi support, most notably in the area of HSS, where limited evidence has constrained the design of HSS grants. This, however, is relevant to new vaccine introductions, where challenges in accurately forecasting vaccine supply have led to stock-outs for IPV in Bangladesh and PCV in Uganda and Zambia. Untimely data on routinization also limits the ability of EPI programs to detect and address routinization challenges with new vaccines. Better data would also strengthen the allocative efficiency of TA needs and providers identified through the JA process. These needs align with Gavi's new strategic focus area on data.

Finally, across multiple support windows and new policies is the issue of change management. Change can be positive but must be accompanied by strong management and communication of the rationale, design, and implementation, particularly in the context of a broad Alliance with diverse stakeholders. The importance of change management is exemplified by the evolving design of the HSS window which, based on our findings, is not yet fully understood at the country level. It is also an early symptom of the new PEF implementation with potential consequences on stakeholder trust and the Alliance as a partnership.

As we have noted in the report, these findings and those from previous FCE reports have been used by a variety of stakeholders to better guide and improve implementation of Gavi support and related activities. We hope the FCE is increasingly used in this way. True to the prospective nature of the FCE we will continue to monitor and evaluate the implementation of Gavi support in FCE countries in 2016 to produce findings and recommendations that can be used to guide implementation at country and global levels.

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