

Summary of recommendations



New vaccine introductions

- » Enhance post-introduction monitoring and evaluation of all new vaccines with partner countries, and consider performance of all vaccines as part of the approval process for new vaccine support.
- » Strengthen Expanded Programme on Immunization (EPI) data use culture and capacity.
- » Develop and provide countries with clear guidance on best practices in phased vaccine introduction as part of the Human papillomavirus 2.0 policy.



Health system strengthening

- » Ensure that Health System Strengthening (HSS) grant decisions, reforms, and other processes are communicated in a timely, easily accessible manner.
- » Invest in creating bottleneck assessment tools that can harmonize across HSS, health system and immunization strengthening (HSIS), Country Engagement Framework (CEF), Programme Capacity Assessment (PCA), and Joint Appraisal (JA) processes.



Technical assistance

- » Gavi should support a menu of technical assistance options from which national programmes may choose, developed through an open solicitation process.
- » Require country technical assistance providers to explicitly plan and measure capacity-building progress.



Programmatic and financial sustainability

- » Scrutinize financial sustainability considerations in decision-making with countries and partners, particularly in Phase I (preparatory) transition countries. Further checks and balances can be established as a part of existing entities (e.g. ICCs, NITAGS).
- » Expand the fragile state policy by considering the application of the country-tailored approach and/or other emergency resources for countries experiencing severe macroeconomic crises.



Leadership and management

- » Work with partners to reduce project siloes within the countries with which they work, and establish or reinforce communication lines between implementation partners.
- » Update Interagency Coordination Committee roles and responsibilities to reflect new strategic goals and the changing landscape of immunization programmes.

- » Work to improve country ownership of PCA recommendations through joint agenda-setting and consistent knowledge management.
- » Align the PCA timing and design with other Gavi activities so that programmes such as HSIS, JA, and others can inform each other's work.



Alliance processes and requirements

- » Continue to include country participation in Secretariat-, global-, and regional-level policy design process.
- » Ensure that SCMs and other relevant teams and partners have the appropriate technical capabilities, contextual knowledge, resources, and support they need to implement CEFs, ensuring that Gavi systems, processes, and requirements are well translated from the global level to the local level.
- » Align incentives in ways that enable a culture of learning and adaptive management in countries, while still ensuring accountability for outcomes.



Constraints analysis

- » Demand generation interventions in Zambia should use reduced dropout as a key metric of success.
- » New vaccine introduction programmes should focus on facility readiness to achieve success.

Introduction

The Gavi Full Country Evaluations (FCE) was a prospective study from 2013 to 2016 in four countries: Bangladesh, Mozambique, Uganda, and Zambia. The study aimed to understand and quantify the barriers and drivers of immunization programme improvements, with a focus on the contributions made by Gavi, the Vaccine Alliance. This brief summarizes the key cross-country findings and recommendations from the 2013-2016 evaluation period, with an emphasis on the 2016 recommendations that are most timely, relevant, and actionable.

New Vaccine Introductions

The FCE countries introduced a range of new vaccines into their systems during the evaluation period, including: pneumococcal conjugate vaccine (PCV) (all), rotavirus vaccine (Mozambique, Zambia), measles second dose (MSD) vaccine (Mozambique, Zambia), inactivated poliovirus vaccine (IPV) (Bangladesh, Mozambique, Uganda), and measles-rubella vaccine campaign (Bangladesh, Zambia) (see Table 1). Selected findings include:

- PCV introduction quickly scaled in Mozambique; however, uptake has been slower in Uganda and Zambia.
- In subnational studies in Mozambique and Bangladesh the introduction of PCV was effective in reducing the vaccine-type pneumococcal nasopharyngeal carriage in children.
- Reporting differences between PCV and pentavalent vaccine at the facility level could account for reported gaps in vaccine delivery in Uganda and Zambia.

TABLE 1: IMPLEMENTATION STATUS OF NEW VACCINE INTRODUCTIONS IN GAVI FCE COUNTRIES (2013-2016)

	BANGLADESH	MOZAMBIQUE	UGANDA	ZAMBIA
2013	None.	PCV introduction.	PCV introduction in one district.	PCV, MSD vaccine, and rotavirus vaccine introduction.
2014	Measles-rubella vaccine campaign.	PCV routinization.	PCV national rollout and routinization.	PCV, MSD vaccine, and rotavirus vaccine routinization.
2015	PCV and IPV introduction.	IPV, MSD vaccine, and rotavirus vaccine introduction.	PCV routinization.	PCV, MSD vaccine, and rotavirus vaccine routinization.
2016	PCV and IPV routinization.	PCV, IPV, MSD vaccine, and rotavirus vaccine routinization.	PCV routinization. IPV introduction and routinization.	Measles-rubella vaccine campaign.

TABLE 2: IMPLEMENTATION STATUS OF HPV VACCINE IN GAVI FCE COUNTRIES, 2013-2016

	BANGLADESH	MOZAMBIQUE	UGANDA	ZAMBIA
2013	None.	Demonstration project application.	Demonstration project in several districts (not Gavi-supported); application for national rollout.	Demonstration project in Lusaka Province (not Gavi-supported).
2014	Demonstration project application; site selection.	Demonstration project in three districts (one Gavi-supported), Year 1.	Demonstration project and national rollout preparations.	Demonstration project in Lusaka Province, continued (not Gavi-supported).
2015	Preparation for demonstration project.	Demonstration project, Year 2.	Ongoing national rollout preparations.	Demonstration project in Lusaka Province, continued (not Gavi-supported).
2016	Demonstration project.	Review meeting in March; developing application for national rollout.	National rollout and routinization.	Demonstration project completed; developing application for national rollout.

- The global IPV stockouts affected routinization in Bangladesh, Mozambique and Uganda, and delayed introduction in Zambia.
- Uptake and national rollout of the HPV vaccine in Mozambique and Zambia has been delayed and varied due to financial concerns and limited Expanded Programme on Immunization (EPI) ownership.
- Less priority has been given to identifying root causes and solutions to suboptimal routinization by programmes and partners.

The FCE has evaluated the implementation of HPV vaccine in various stages of implementation (see Table 2). HPV vaccine demonstration projects have shown a tension between the objectives of demonstrating sustainability of a delivery model and achieving coverage criteria for national introduction, and could therefore be better designed to balance these objectives and maximize learning. Mozambique and Zambia have delayed applying to Gavi for support to introduce HPV vaccine nationally due to concerns about financial sustainability and limited ownership by the EPI team. Uganda introduced HPV vaccine nationally, but rollout has been slow and varied (see Table 2).

Despite the successful introduction of new vaccines into immunization programmes noted in each country, common persistent challenges related to the routinization of new vaccines constrain their potential impact on child health remain, including:

- Stockouts due to multiple underlying causes.
- Inadequate attention paid to social mobilization.
- External macroeconomic shocks.
- Delayed implementation of complementary HSS activities.

New vaccine introduction recommendations



Enhance post-introduction monitoring and evaluation of all new vaccine lines with partner countries, and consider performance of all vaccines as part of the approval process for new vaccine support.



Strengthen EPI data use culture and capacity.



Develop and provide countries with clear guidance on best practices in phased vaccine introduction as part of the HPV 2.0 policy.

MOZAMBIQUE PCV EFFECTIVENESS

Findings from FCE PCV vaccine effectiveness studies, conducted by Centro de Investigação em Saúde de Manhiça (CISM) with support from the United States Agency for International Development (USAID) and the United States Centers for Disease Control and Prevention (CDC), have shown that the scale-up of PCV is reducing pneumococcal disease burden in Mozambique. There was an estimated 44% reduction (95% confidence interval: 33 to 59%) within 18 months in vaccine serotype pneumococcal nasopharyngeal carriage among human immunodeficiency virus (HIV)-uninfected children who received three doses of PCV; after 30 months, there was an observed 70% reduction (95% confidence interval: 57 to 78%).

A 60% reduction (95% confidence interval: 25 to 95%) was observed in HIV-infected children who received three doses of PCV after 18 months with no additional decline at 30 months. There was an early signal of an indirect effect of PCV introduction among HIV-infected children who did not receive PCV doses. As expected, there was also an increase in non-vaccine serotype pneumococcal carriage.

The reduction in carriage in Mozambique was accompanied by a reduction in vaccine-type invasive pneumococcal disease (IPD). We estimated a significant reduction in vaccine-type IPD of 94% (95% Uncertainty Interval: 65.8 to 99%) and a significant reduction in X-ray-confirmed pneumonia of 85% (95% uncertainty interval: 64.3 to 93.7%). There was a nonsignificant change in nonvaccine-type IPD.

Health System Strengthening

HSS grants have enormous potential to increase coverage and equity, but problems with the complexity and implementation procedures for the grants have routinely reduced their predictability, relevance, and effectiveness (see Table 3).

- All FCE countries experienced substantial HSS grant delays related to application, post-approval, and implementation processes.
- FCE has been unable to fully evaluate the implementation of HSS grants because compounding delays have pushed HSS grant implementation beyond the FCE end date.

Root causes of HSS grant delays include:

- Insufficient coordination around HSS grant among the wider set of stakeholders required beyond the EPI team.
- Lack of alignment of Gavi HSS grant timelines with country national plans.
- Limited understanding at the country level of changes to Gavi's HSS window of support over time.
- Lack of clarity on the HSS grant post-approval process.

TABLE 3: STATUS OF HSS GRANTS IN FCE COUNTRIES, 2014-2016.

	BANGLADESH	MOZAMBIQUE	UGANDA	ZAMBIA
2014	Implementation of HSS-1 grant (preliminary findings).	Preparations for implementation of HSS-2 grant.	Implementation of reprogrammed HSS-1 grant.	Preparations for submission of HSS-2 grant application.
2015	Implementation of HSS-1 grant. Submission of HSS-2 grant application (January); resubmission of revised application (September).	Preparations for implementation of HSS-2 grant, continued.	Implementation of reprogrammed HSS-1 grant, continued.	Submission of HSS-2 grant application (January); resubmission of revised application (September).
2016	Implementation of first of bifurcated HSS-2 grants. Second bifurcated grant will be aligned with the new Sector-Wide Approach; application expected in 2017 as part of country engagement framework (CEF).	First year of HSS-2 implementation; decision to reprogramme (November).	Final stages of implementing the HSS-1 grant. Applied and approved for a second HSS grant; requirements process to enable disbursement of funds.	Approved for new HSS grant (November); requirements process to enable disbursement of funds.

COUNTRY ENGAGEMENT FRAMEWORK

In 2015 and 2016, Gavi implemented a series of process reforms aimed at addressing issues identified through the FCE and other evaluations. One of the major outputs of this effort was the introduction of the country engagement framework (CEF). The goal of the CEF is to align timelines and planning with country needs, in order to boost immunization coverage. CEF represents an important positive shift in Gavi's model of country engagement, however, it is too early to evaluate its affect, and there has been no application in FCE countries.

Health system strengthening recommendations



Ensure that HSS grant decisions, reforms, and other processes are communicated in a timely, easily accessible manner.



Invest in creating bottleneck assessment tools that can harmonize across HSS activities, HSIS, CEF, PCA, and JA processes.



Monitor SCMs to ensure that they have the resources and skills they need to implement CEF.

Constraints analysis



In addition to systemic and global challenges, vaccine coverage can often be constrained by supply-side demand challenges. The related Gavi Full Country Evaluations surveys provided a unique opportunity to examine constraints to vaccine coverage. The data and model indicate that there are different drivers of vaccination initiation and dropout, and different drivers for new and routine vaccines.

Recommendations

- Demand generation interventions in Zambia should use reduced dropout as a key metric of success.
- New vaccine introduction programmes should focus on facility readiness to achieve success.

Drivers Affecting Gavi Support

TECHNICAL ASSISTANCE

Relevant, effective, and efficient technical assistance is one way to strengthen the capacity of the EPI to implement increasingly complex immunization programmes to ultimately improve coverage and equity. The FCE identified weaknesses of the top-down Business Plan model and saw that the growing complexity and scope of immunization program needs could not be addressed solely by core Alliance partners. 2016 saw a shift from the Business Plan model to the Partners' Engagement Framework (PEF).

PEF, particularly targeted country technical assistance, is an improvement over the Business Plan in its aim to achieve country ownership, transparency, and accountability.

PEF is designed to shift accountability of technical assistance partners from the Secretariat to countries, although this will take time to achieve in practice.

Technical assistance recommendations

- Support a menu of technical assistance options from which national programmes may choose, developed through an open solicitation process.
- Require country technical assistance providers to explicitly plan and measure capacity-building progress.

PROGRAMMATIC AND FINANCIAL SUSTAINABILITY

In the FCE countries we observed the following sustainability challenges:

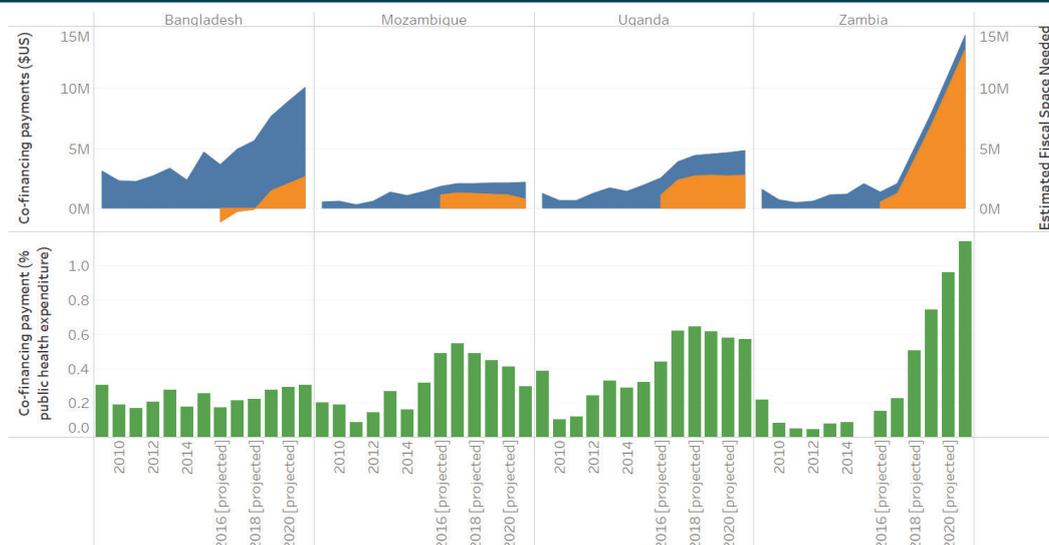
- Difficulty meeting co-financing requirements.
- Unstable fiscal health of immunization programmes.
- An increasing trend to direct funds through partners instead of country systems, which may have consequences for country ownership and programmatic and financial sustainability.
- Limited evidence that countries are planning or preparing for entering into the accelerated transition phase and subsequent graduation from Gavi support.
- Little guidance from Gavi on what countries should be doing in the pre-transition phase to ensure a smooth transition.

Programmatic and financial sustainability recommendations

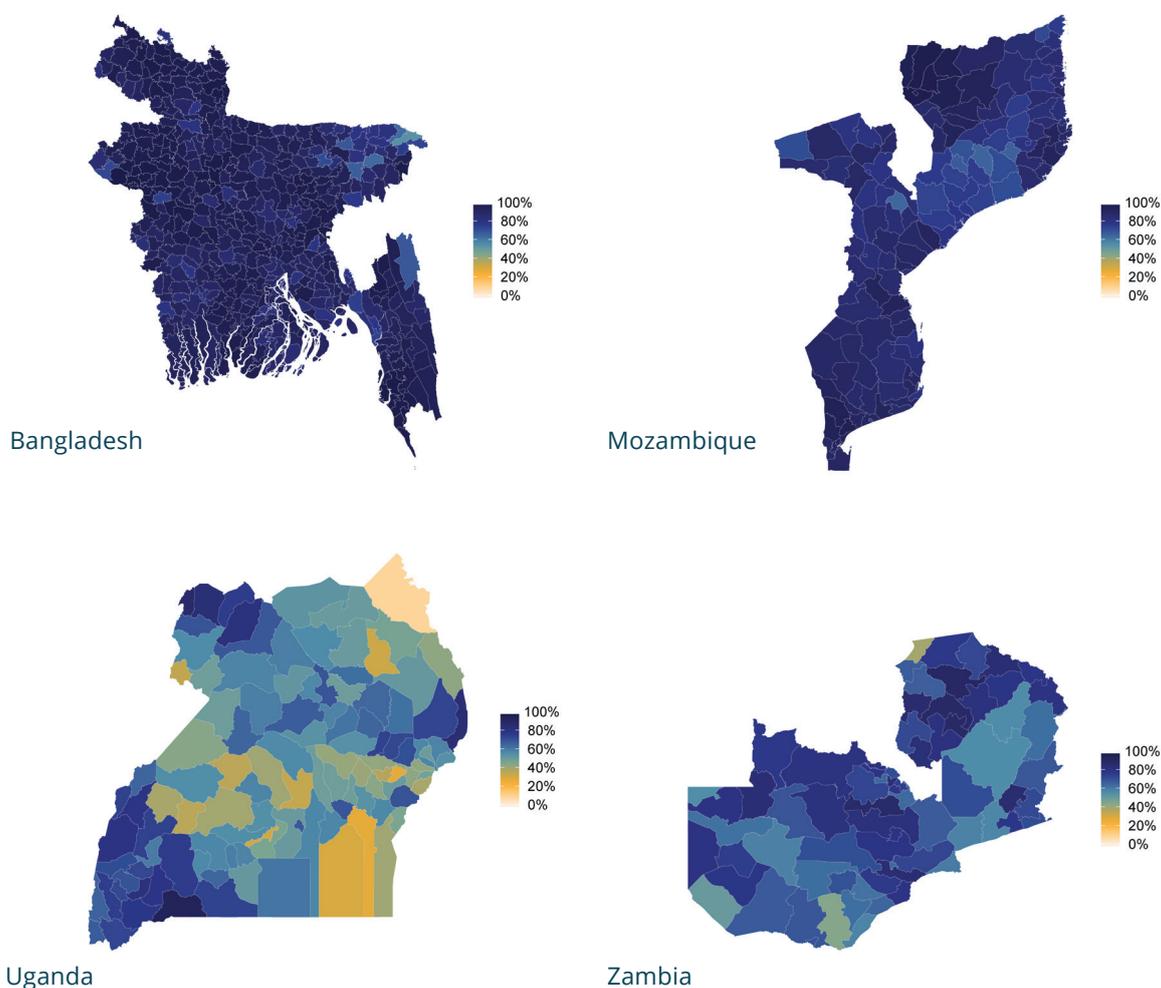
- Scrutinize financial sustainability considerations in decision-making with countries and partners, particularly in Phase I (preparatory) transition countries. Further checks and balances can be established for existing agreements.
- Expand the fragile state policy by considering the application of the country-tailored approach and/or other emergency resources for countries experiencing severe macroeconomic crises.

Figure 1 illustrates the projected variability in co-financing payments by countries.

FIGURE 1: CO-FINANCING IN FCE COUNTRIES, 2009-2021 (PROJECTED)



FULL VACCINATION COVERAGE BY ADMINISTRATIVE UNIT IN MOZAMBIQUE, ZAMBIA, BANGLADESH, AND UGANDA, 2016



Leadership and management



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

Recommendations

- Work with partners to reduce project siloes within the countries with which they work, and establish or reinforce communication lines between implementation partners.
- Update Interagency Coordination Committee roles and responsibilities to reflect new strategic goals and the changing landscape of immunization programmes.
- Work to improve country ownership of PCA recommendations through joint agenda-setting and consistent knowledge management.
- Align the PCA timing and design with other Gavi activities so that programmes such as HSIS, JA, and others can inform each other's work.

Alliance processes and requirements



Donor processes and requirements have the potential to add value—for both countries and Gavi—when they are designed and implemented to balance their administrative and management burden with their potential benefits. However, the FCE found that these processes happen at a pace and frequency that national programmes cannot readily absorb. We are seeing an effort at aligning the suite of Gavi processes and requirements, but flag the potential short-term complexity and country-level management burden of these changes.

Recommendations

- Continue to include country participation in Secretariat-, global-, and regional-level policy design process.
- Ensure that SCMs and other relevant teams and partners have the appropriate technical capabilities, contextual knowledge, resources, and support they need to implement CEFs, ensuring that Gavi systems, processes, and requirements are well translated from the global level to the local level.
- Align incentives in ways that enable a culture of learning and adaptive management in countries, while still ensuring accountability for outcomes.

Conclusion

Behavioral, organizational, and institutional factors can act as significant brakes on Gavi's—and countries'—success. These processes can be changed; and over the course of the Gavi FCE, we have observed changes, such as the Health Systems and Immunization Strengthening Support Framework. Gavi is indeed listening to partner and end-user feedback, and we encourage the Gavi Secretariat and Alliance partners to continue to foster an environment that encourages learning and growth.

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

