

Cross-Country 2017-2018













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## **Evaluation team**

This report presents findings from year 1 of the Gavi Full Country Evaluations phase 2 (FCE2), prepared by PATH (United States) in collaboration with the Universidade Eduardo Mondlane (Mozambique), Health Alliance International (Mozambique) the Infectious Disease Research Collaboration (Uganda), and the University of Zambia (Zambia).

This work is intended to inform evidence-based improvements for immunization programs in FCE countries and, more broadly, in low-income countries, with a focus on contributions from Gavi. The contents of this publication may not be reproduced in whole or in part without permission from the Gavi FCF team at PATH.

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## **Executive summary**

Despite improvements in access to and coverage of childhood vaccines in Mozambique, Uganda, and Zambia, progress is not equitable, nor is it inevitable. This first report of the second phase of the Full Country Evaluations (FCE2) by Gavi, the Vaccine Alliance highlights the multiple, complex, interrelated drivers of equitable coverage of vaccines and the fragility of programmatic gains.

The most recent administrative data from Uganda suggests backsliding, and Zambia's many programmatic successes are at risk without adequate and sustainable financing. While Mozambique has been notably successful at reducing the geographic equity gap in coverage and has strong community commitment to vaccination, systemic management challenges to result in ongoing stockouts and implementation delays. Yet, learning and improvement is happening, highlighted through examples of: effective management in districts and facilities in Uganda, efforts to improve health systems strengthening (HSS) implementation in Mozambique, and leadership to improve immunization financing in Zambia. At the household and community levels we report emerging evidence on the cumulative burden of multiple barriers to vaccination and the need to refine equity indicators to measure all potential causes: behavioral intent, community access, and facility readiness and health system quality.

What can be done? Our findings and recommendations suggest the need for greater emphasis on strengthening performance management in every facility, district, and national team and for increased political will to improve the coverage, quality, responsiveness, and financing of health systems to achieve universal immunization coverage. This call to action involves all stakeholders, not only Gavi and Alliance partners.

#### **OVERVIEW OF THE GAVI FCE2**

The Gavi Full Country Evaluations (FCE) are prospective, mixed-method evaluations of Gavi support and immunization programs in Mozambique, Uganda, and Zambia.

The first phase of the Gavi Full Country Evaluations (FCE1) aimed to identify the drivers of immunization-program improvement and was implemented from 2012 to 2016. The second phase (FCE2) runs from 2017 to 2019 and evaluates the new policies, programs, and processes implemented by the Gavi's 2016-2020 strategy with a focus on identifying the drivers of equitable coverage and Gavi's contribution to observed changes.

FCE2 aims to answer 22 evaluation questions (EQs) prioritized by country and global stakeholders. This first FCE2 report is based on three months of primary data collection due to time required for securing ethical and administrative approvals in this new phase of the FCE. In spite of the shortened data collection period, this report highlights important issues to investigate through the prospective evaluation platform in Year 2 of FCE2.

#### EXECUTIVE SUMMARY

Findings in this report are based on data collected and analyzed using multiple approaches: process tracking based on document review, observation, and fact-checking interviews; key-informant interviews (KIIs); descriptive and statistical analyses of secondary data from health management information systems (HMIS), household and health facility surveys, and budgets and expenditures; and district-level case studies (DCSs).

FCE2 is implemented by a consortium of evaluators in collaboration with the national immunization programs in each country: Health Alliance International and Universidade Eduardo Mondlane (Mozambique); Infectious Diseases Research Collaboration (Uganda); University of Zambia (Zambia); and PATH (United States).

Table 1. Findings and recommendations summary.

#### **FINDINGS**

#### **RECOMMENDATIONS**

#### SECTION 1: Coverage and equity drivers and trends in FCE countries

#### Finding 1.1:

Recent data from DHIS2 are consistent with the trajectory of the small area estimates' trends.

- In Mozambique, the number of DPT1 and DPT3 doses administered continue to increase with lower drop-out between those doses than in the other FCE2 countries. Additional gains in coverage are constrained by ongoing HSS delays.
- In Zambia, the slowing upward trend in the number of doses administered for BCG, DPT1, and DPT3 is in part due to inadequate immunization financing.
- Stakeholders in Uganda attribute coverage declines in 2017 to the gap in HSS funds, more accurate data reporting as a result of the Data Improvement Team (DIT) strategy, and more focus on new vaccine introductions compared to routine vaccines.

#### Finding 1.2:

Gavi HSS is intended to address health systems and access barriers to vaccination, but its potential impact is limited by delays in disbursement and initial implementation, implementation challenges, and channeling funds away from government systems.

- In Uganda, immunization stakeholders attribute the 2017 coverage declines in part to the delays in accessing HSS2 funds, which led to reduced frequency of operational activities.
- Continue doing: Gavi should continue to ensure that PCAs and GMRs are leading to demonstrable and adequately resourced efforts to strengthen country systems, even if the decision is made to channel funds through partners.
- Act now: In line with the Board's request to develop criteria for channeling funds back through country systems, Gavi should propose and monitor indicators that measure the ongoing capabilities of national financial management systems as well as other

#### **FINDINGS**

#### RECOMMENDATIONS

- In Mozambique, persistent HSS implementation challenges due to suboptimal planning and alignment at all levels limit the potential impact of HSS.
- > Across Gavi-eligible countries, Gavi cash support is increasingly being channeled through partners partly as a result of weak national financial management systems. While this may be a necessary risk management and accountability strategy in the short-term, it poses risks to long-term programmatic sustainability and effective transitions from Gavi support.
- consequences related to effectiveness, efficiency, country ownership, and sustainability. These indicators would ensure that even if funds are being channeled through partners, there are measurable improvements in strengthening country systems and outcomes and would identify when countries have met the criteria for self-managing Gavi funds:
- > This builds on the FCE1 recommendation in the 2016 Report that Gavi should formally assess whether it is actually more efficient in the short term to channel funds through partners versus government systems, and the long-term consequences of this trend on country ownership and sustainability. Gavi should also review other best practices in mitigating risk of financial mismanagement of donor funds, while still strengthening country systems.

#### Finding 1.3:

Across FCE2 countries, we observe the influence of leadership, management and coordination at national and subnational levels on immunization system performance. In particular:

- Sub-optimal financial planning and management led to delayed disbursements or inadequate resources in Mozambique. This was exacerbated in Uganda with the creation of new districts.
- > Effective and coordinated partners contributed to improved performance.
- Stronger performing districts in Uganda used data for performance management which led to motivated staff and improved performance.
- Continue doing: Gavi should continue to strengthen national-level LMC and should study where gaps in district-level LMC exist through PEF-TCA and the LMC Strategic Focus Area. These activities should include a focus on financial management and evidence-informed performance management.

#### Finding 1.4:

Current indicators and data sources for measuring vaccine equity do not adequately measure which children are under vaccinated and why. Decision-makers also lack information on how to best address the causes of under vaccination. As a result efforts to improve equitable coverage are not targeting the right problems with the right solutions.

- Continue doing: As part of the Data SFA or HSS funding, Gavi, partners, and country stakeholders should continue to invest in strengthening existing data quality and data systems with a focus on integrating administrative vaccine data with supply chain / logistics and health system performance data.
- Continue doing: Gavi and Alliance partners should consider the costs and benefits of introducing data systems that capture individual-level data on vaccine service delivery (e.g., an electronic immunization registry or electronic medical record) in order to provide

## **FINDINGS RECOMMENDATIONS** granular data on which children to target to close the coverage gap. Study further: As a resource for countries and an input into HSS and JA processes, Gavi and partners should synthesize the evidence on how to most effectively address common, underlying bottlenecks or causes of inequalities. This could lead to the development and use of decision-support tools to inform the design and targeting of the most cost-effective and high-impact interventions to address the root causes of inequitable coverage. Study further: Gavi and partners should expand or modify the current list of equity indicators and data sources to include all potential causes of under vaccination as informed by the FCE2 TOC. Indicators should enable timely, granular, and actionable decision-making, particularly at the lowest levels of the health system.

# SECTION 2. The role of the Gavi Secretariat written guidance and tools in supporting countries to improve coverage and equity

#### Finding 2.1:

The Gavi Secretariat and Alliance's emphasis and approach to coverage and equity has shifted over time to increasingly focus on within-country inequities in utilization of immunization services. Based on a review of Gavi policies, guidance, and grant frameworks the FCE2 found:

- Suidance on the importance of identifying equity bottlenecks and how to identify them has improved in Gavi documents since 2016.
- The Gavi Secretariat does not consider itself a technical agency but has increasingly provided linkages to other resources on how to improve coverage and equity.
- However, Gavi guidance is still not specific and actionable enough to identify the most important underlying causes of poor coverage and inequalities.
- Gavi and partners should expand or modify the current list of equity indicators and data sources to include all potential causes of under vaccination as informed by the FCE2 TOC. Indicators should enable timely, granular, and actionable decision-making, particularly at the lowest levels of the health system, requiring further consideration and weighing the tradeoffs against Gavi's current approach to support the strengthening of country data systems, availability, quality, and use.
- Study further: As recommended in Section 1, as a resource for countries and an input into HSS and JA processes, Gavi and partners should synthesize the evidence on how to most effectively address common underlying bottlenecks or causes of inequalities. This could lead to the development and use of decision support tools to inform the design and targeting of the most cost-effective and highimpact interventions to address the root causes of inequilable coverage:

FINDINGS	RECOMMENDATIONS			
	<ul> <li>As funders, Gavi could play a stronger role in ensuring the activities they fund are technically and operationally sound, engaging in ongoing monitoring and adaptive management, and thereby maximizing the value for money of Gavi's investments.</li> <li>More specifically, Gavi should consistently provide links to this technical guidance in relevant Gavi policies, documents, and frameworks to make it easy for countries to access the appropriate resources.</li> </ul>			
SECTION 3: Sustainability of national immunization programs				
Finding 3.1: Immunization program expenditures are rising in FCE2 countries, and costs are projected to continue rising due to new vaccine introductions. However, operational costs have not increased substantively which may pose a threat to the sustainability of activities needed to increase immunization equity.	Study further: Gavi, partners, and in-country stakeholders should invest in and support microcosting studies to estimate how costs vary across geographic and population subgroups or other drivers of coverage and equity in order to inform resource allocation decisions necessary to improve coverage and equity.			
Finding 3.2: Financing in FCE2 countries has kept pace with rising costs, primarily due to the contributions of external donors. As countries move towards transition, the confluence of rising costs and stagnating external financing presents a risk to each country's ability to adequately finance their immunization program and ensure their future programmatic and financial sustainability. Uganda has shown promise in planning for long-term sustainability; Zambia is facing increasing financing challenges.	Act now: Gavi, partners, and in-country stakeholders should invest in and support microcosting studies to estimate how costs vary across geographic and population subgroups or other drivers of coverage and equity in order to inform resource allocation decisions necessary to improve coverage and equity.			
Finding 3.3: Gavi guidance had been updated to better support countries to take into account the financial sustainability aspects of NVIs during decision-making processes. However, there remains limited guidance on how to plan for long-term financial sustainability or how to maintain programmatic activities and outcomes after the end of Gavi support.	<ul> <li>Continue doing: Gavi's 2018 application guidelines encourage countries to engage with sustainability issues throughout the life of the grant, not just during the application and transition periods.</li> <li>Continue doing: Gavi and partners should continue to invest in NITAG strengthening with a focus on sustainability (and coverage and equity)</li> </ul>			

equity).

#### EXECUTIVE SUMMARY

# FINDINGS RECOMMENDATIONS Study further: Gavi should expand their sustainability guidance beyond New Vaccine Introduction (NVI) to include a focus on the long-term operational and programmatic sustainability of vaccine delivery.

# Next steps for FCE2 year 2



This first report of FCE2 highlights many drivers of equitable coverage, measured using multiple data sources. Year 2 of FCE2 will focus on expanding the measurement of each driver and estimating its relative contribution toward changes in vaccine coverage. Year 2 will add greater visibility into the dynamics of immunization systems, with a focus on how the implementation of new Gavi policies affect system performance in real time. Finally, beyond these reports, FCE2 has a larger goal to inform decision-making through the production of timely and relevant evidence and to transfer real-time and prospective evaluation capabilities into Expanded Programmes on Immunization (EPI).

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# **Abbreviations**

BCG Bacillus Calmette–Guérin

CCEOP Cold Chain Equipment Optimization Platform

CEF Country Engagement Framework

CMYP Comprehensive Multiyear Plan

cso civil society organization

DCS district-level case study

DHIS-2 District Health Information System

DHO district health officer

DHS Demographic and Health Survey

**DIT** Data Improvement Team

**DPT** diphtheria–pertussis–tetanus

**EPI** Expanded Programme on Immunization

**EQ** evaluation question

FCE Full Country Evaluations
FIC fully immunized child
GFF Global Financing Facility

GMR Grant Management Requirements

GPF Grant Performance Framework

**HMIS** health management information systems

HPV human papillomavirus

HSIS Health System and Immunization Strengthening

HSS Health Systems Strengthening

JA Joint Appraisal

JRF Joint Reporting Form

KII key informant interview

#### EXECUTIVE SUMMARY

LMC Leadership, Management,

and Coordination

MOH Ministry of Health

MR measles-rubella

NITAG National Immunization Technical Advisory Group

NVI New Vaccine Introduction

NVS New Vaccine Support

PCA Programme Capacity Assessment

PCV pneumococcal conjugate vaccine

PEF Partner Engagement Framework

penta1 pentavalent first dose

penta3 pentavalent third dose

PHC primary health care

PSR Programme Support Rationale

RED/REC Reaching Every District/Reaching Every Child

RCA root cause analysis

SAE small area estimates

SCM senior country manager

SFA Strategic Focus Area

TA technical assistance

TCA Targeted Country Assistance

TOC theory of change

UNEPI Uganda National Expanded Program

on Immunisation

UNICEF United Nations Children's Fund

WHO World Health Organization

## Introduction

#### WHAT ARE THE GAVI FULL COUNTRY EVALUATIONS?

The Gavi Full Country Evaluations (FCE) are prospective, mixed-method evaluations of Gavi support and immunization programs in Mozambique, Uganda, and Zambia.

The FCE are prospective, mixed-method evaluations of Gavi support and immunization programs in Mozambique, Uganda, and Zambia. The first phase of the Gavi Full Country Evaluations (FCE1) aimed to identify the drivers of immunization program improvement and was implemented from 2012 to 2016. The second phase (FCE2) runs from 2017-2019 and evaluates the new policies, programs, and processes implemented during the Gavi strategic period between 2016 and 2020, with a focus on identifying the drivers of equitable coverage and Gavi's contribution to observed changes.

FCE2 aims to inform program and policy decision-making at national and global levels, in particular:

#### Country aims

- > To generate evidence and learning, with timely feedback loops to help strengthen the Expanded Programme on Immunization (EPI) and, ultimately, to help improve immunization coverage and equity.
- > To inform evidence-based country decisions to apply for new Gavi support and to inform the design of these proposals.
- > To generate evidence and learning to help the country to improve the implementation of Gavi support.
- > To strengthen the capacity of national research and technical institutions within and between countries, as well as to provide capacity strengthening to country stakeholders.

#### Global aims

- > To provide timely evidence to inform the review and improvement of Gavi's application guidelines, strategies, policies, programs, and processes.
- > To generate cross-country learning to track implementation of new Gavi policy programs and processes and inform course corrections and to provide information for the design of the next Gavi strategy for the period 2021 to 2025.

FCE2 aims to answer 22 evaluation questions (EQs), nine of which are cross-country. These questions were identified and prioritized based on discussions with national EPI stakeholders, Gavi and its partners, and the FCE2 evaluation teams.

Table 3 lists the full suite of questions FCE2 will answer during its 2017-2019 implementation period. The legend indicates to what extent EQs are answered in this first report of FCE2.

#### **Building on FCE1**

FCE2 builds on FCE1 in many ways. The consortium is largely the same, building on the skills, capacity, knowledge, and relationships built in FCE1. The overall evaluation design remains prospective and mixed-methods but has shifted from a largely descriptive emphasis in FCE1—when shedding light on Gavi and country processes was needed—to a more targeted hypothesis-testing approach in FCE2. FCE2 uses data collected in FCE1 where possible to ensure value for money; yet FCE2 will collect substantial sub-national qualitative data to fill gaps in the quantitative household-, facility-, and district-level data collected during FCE1. Over the course of this six year endeavor we have made significant progress in developing, testing, and refining hypotheses related to whether, why, and how immunization programs are improving and that is reflected throughout this report.

#### The FCE2 consortium

FCE2 is implemented by a consortium of multidisciplinary evaluators and researchers in collaboration with the national immunization programs in each country: Health Alliance International and Universidade Eduardo Mondlane (Mozambique); Infectious Diseases Research Collaboration (Uganda); University of Zambia (Zambia); and PATH (United States). FCE2 is funded by Gavi, the Vaccine Alliance. The implementation of FCE2 is guided by a number of principles to ensure the usefulness, relevance, and quality of FCE2's findings and of the sustainability and transferability of the platform beyond FCE2. A central principal of FCE2 is to strengthen in-country capacity of evaluation teams and local stakeholders such that country teams can increasingly lead and implement all aspects of the evaluation. Progress towards this goal is impressive.

#### **METHODS**

The Gavi FCE is a mixed-methods prospective evaluation that triangulates information from multiple data sources and methods.

This first report of FCE2 covers varying time periods depending on the EQs and country. FCE2 teams secured ethical and administrative approvals in January 2018, allowing three months of concerted data collection and analysis leading up to this report. EQs which could be answered retrospectively were, but the prospective nature of many EQs means that they will be addressed in greater detail and depth in the 2019 report.

FCE2 country reports include additional details on how specific methods were applied in each country. Evaluation components relevant to this cross-country report include:

- > Process tracking of application for, and ongoing implementation of, Gavi support in FCE countries through observation, document review, and fact-checking interviews.
- Descriptive analysis of routine administrative data and small area estimates (SAEs) to identify trends in vaccine coverage and between-district coverage inequalities.

- > Descriptive analysis of immunization-program financing data, co-financing and cost data, and HSS budget and expenditure data to identify trends in immunization-program costs, expenditures, and financing.
- > Descriptive and statistical analysis of household and health facility survey data collected in FCE1.
- > District-level case study (DCS) to identify drivers of variance in district performance.
- > Key-informant interviews (KIIs) with immunization stakeholders.
- > Document review of Gavi policies, guidelines, reports, and evaluations.

The FCE2 approach emphasizes the importance of theory-based and realistic evaluation; <sup>1</sup> the approach to answering each EQ is informed by social science and program theory. Table 2 describes key strengths and limitations of the methods applied to inform the findings covered in this report. The findings stem from the evaluation questions (

Table 3) that were developed by stakeholders at the global and country levels at the outset of Phase 2. Each key finding in the report is accompanied by a robustness ranking (

Table 4) that assesses the robustness of the evidence underlying the finding based on the level of triangulation, where the finding lies on the continuum between fact and perception, and the quality of the data. A full explanation of the robustness rankings and additional details on the methods for data collection and analysis are included in the methods annex.

#### Table 2. Strengths and limitations of this Gavi FCE2 report.

#### **STRENGTHS**

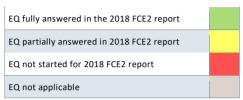
- > Triangulation of multiple secondary data sources (HMIS, household and health facility surveys, small area estimates, budget and expenditure data)
- > A focus on mixed-methods throughout the analytic process
- > Flexibility to prioritize each country's most pressing programmatic questions as well as findings that have the greatest potential for impact
- Evaluation platform was established in FCE countries through Phase 1, allowing FCE2 to build on the existing team capacity, contextual knowledge, and strong relationships with country stakeholders
- > Prospective approach allowed for collection of information in real time so that key issues could be identified as they arose, allowing for the opportunity to inform the implementation process
- > The FCE2 evaluation questions allowed for more in-depth data collection and analysis on specific, targeted topics of interest to stakeholders

#### **LIMITATIONS**

- > Short period of primary data collection and analysis and limited time to systematically synthesize evidence across countries
- > Limited visibility into processes occurring in 2017 prior to FCE2 administrative and ethical approvals
- > Prioritization of timely country-specific evaluation questions has resulted in fewer opportunities to answer cross-country questions
- > While multiple methods are employed, FCE2 does not include resources for household or health facility surveys; instead, FCE2 depends on administrative data, existing survey data, and in-depth qualitative data.

Table 3. FCE2 evaluation questions (EQs) and status in first report.

## Legend



EVALUATION QUESTION	MOZ	UGA	ZAM
1. What are the drivers of vaccine coverage and equity?			
2. Whether, how, and why is Gavi support contributing to <i>changes in</i> vaccination coverage and equity?			
3. What are the major factors influencing the achievement of these results?*			
4. What has been the contribution of HSS funds to vaccine coverage in priority provinces and districts?			
5. What are the advantages and consequences of managing HSS funds through partners, outside of government systems?			
6. What is the effect of an interruption in Gavi HSS funding on routine service delivery, highlighting Government of Uganda and other partner funding?			
7. Whether, why, and how is the introduction of measles, rubella (MR) vaccine in routine immunization being conducted as planned?			
8. Whether, why, and how is the switch from pneumococcal conjugate vaccine (PCV) 10 to PCV13 being implemented as planned?			
9. Whether, why, and how is an analysis of the lessons learned from previous support being taken into consideration?			
10. Whether, why, and how is the human papillomavirus (HPV) national scale-up using the lessons learned from the HPV demonstration projects?			
11. Whether, why, and how is the new HPV 2.0 policy facilitating national scale-up?			
12. What are the demand-side reasons for the low coverage of HPV second dose in Uganda?			
13. To what extent is the national introduction of HPV implemented as planned?			
14. Whether, why, and how are country decisions to apply for new Gavi support taking into account the programmatic and financial sustainability aspects?			

EVALUATION QUESTION	MOZ	UGA	ZAM
15. What are the drivers to increase financial support for immunization?			
16. To what extent can recent programmatic gains of the Expanded Programme on Immunization (EPI) be sustained over time?			
17. What are the positive and negative consequences of the new/updated Gavi processes?			
18. What unintended positive and negative consequences occur as a result of Gavi support?			
19. To what extent are the Gavi-supported activities that are designed to enhance performance management practices of the EPI effective in strengthening the Interagency Coordinating Committee and accountability across the program?			
20. Why and how is the new Immunization Act affecting implementation (e.g., demand generation) and outcomes of Gavi support?			
21. What is the <i>composition</i> of the immunization partnership in the country at national and district levels?			
22. How effective is EPI management at the local level?			

<sup>\*</sup>Merged with EQs 1 and 2.

**Notes**: Cross-country questions are any that have a color code for each country.

Table 4. Robustness rankings overview.

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

# **SECTION 1. Coverage and equity drivers and trends in FCE countries**

#### **HISTORICAL PERSPECTIVE**

Progress in vaccine coverage occurred in the historical period from 1990 to 2016, but progress has not been equitable, nor is progress inevitable.

#### Progress has been made

Routine immunization currently saves an estimated 2 to 3 million lives per year, <sup>2</sup> and the countries in this report, Mozambique, Uganda, and Zambia, now include nearly all available childhood vaccines in their national immunization programs. Indeed, SAEs from FCE1 show the gains that have been made toward improving diphtheria–pertussis–tetanus (DPT)3 coverage in Uganda, Zambia, and Mozambique (Figure 1). In Mozambique (the lowest performer in 1999) coverage increased 40 percentage points by 2016.

#### **Small Area Estimates (SAEs)**

In FCE1, annual subnational estimates of vaccine coverage were generated at the district level using small area estimation methods and household survey microdata. Using survey data, we estimated historical coverage rates from 1999 to show trends over time that are smoothed, making the SAEs less volatile year over year. These coverage estimates are more accurate than administrative data due to the use of standardized household survey data. The SAE estimates are generally consistent with WUENIC estimates for the most recent year of data available (Table 5). See the methods annex for additional details on the SAE methods and limitations.

Table 5. DPT3 Coverage Estimates from WUENIC and SAE in 2016.

	MOZAMBIQUE	UGANDA	ZAMBIA
DPT3 WUENIC 2016	80%	78%	91%
DPT3 SAE 2016	88%	79%	88%

100%
95%
90%
85%
80%
75%
66%
60%
55%
50%
445%
40%
35%
1990 1992 1994 1996 1998 2000 2002 2004 2006 2008 2010 2012 2014 2016

Figure 1. DPT3 coverage in FCE countries based on small area estimates, 1990-2016.

**Source**: Small area estimates from multiple household surveys; 1990-2016.

Notes: Solid lines represent the national DPT3 coverage estimate; shaded lines represent the 95% confidence interval.

#### Progress is not inevitable

In spite of these impressive initial gains, progress on achieving universal coverage has stalled and many children remain unvaccinated or under vaccinated. If we could reach 100% immunization coverage worldwide, we would save an estimated additional 1.5 million lives a year. From 2016 to 2030 in the context of selected low- and middle-income countries alone, 36 million future deaths could be averted with full immunization.<sup>3</sup>

In Figure 1 we observe that DPT3 coverage improvements have stagnated in the last five years with diminishing marginal gains in coverage. Coverage in Mozambique and Zambia persistently hovers below 90%, and coverage in Uganda has yet to exceed 80%. When examining rates of full immunization of children, a we see even lower rates of coverage, with Uganda below 60% of children fully immunized and Zambia just above 70% (Figure 2). Furthermore, in the last 20 years Uganda and Zambia have not realized any overall gains in coverage of fully immunized children (FIC). The last 20 years has seen a dip in coverage of FIC, from which both countries are still recovering.

<sup>&</sup>lt;sup>a</sup> FIC is defined in the SAE data as the proportion of children aged one year who have received the BCG vaccine, 3 doses of the DPT or pentavalent vaccine, the measles vaccine, and 3 doses of the oral polio vaccine. The definition does not change over time to account for new vaccine introductions in the small area estimates, though DPT3 may be replaced with pentavalent vaccine

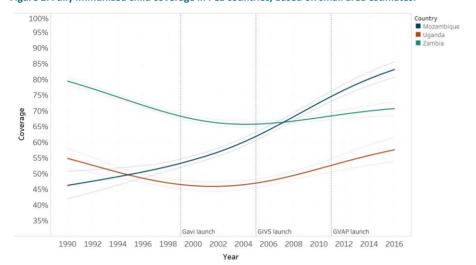


Figure 2. Fully immunized child coverage in FCE countries, based on small area estimates.

**Source**: Small area estimates from multiple household surveys; 1990-2016.

**Notes:** Solid lines represent the national DPT3 coverage estimates; shaded lines represent the 95% confidence interval. Fully immunized child is defined as a child under age 1 who has received all doses of BCG, DPT, OPV (oral polio vaccine), and measles vaccines. The definition does not change over time to account for new vaccine introductions in the small area estimates, though DPT3 may be replaced with pentavalent vaccine.

The notable exception to the trend is Mozambique, which has made significant gains over the past two decades in both DPT3 and FIC coverage and has the smallest difference, or lowest dropout, between DPT3 and FIC coverage across the FCE countries. One reason for Mozambique's initial steep slope of change is the establishment and growth of the country's health system since the signing of a peace agreement in 1992. FCE2 will continue to investigate why dropout occurs at lower rates in Mozambique. Even in Mozambique, however, gains in FIC coverage appear to be slowing now that the 80% threshold of coverage is reached. Broadly, we are still far short of the goal of all children being fully vaccinated.

#### Progress is not equitable

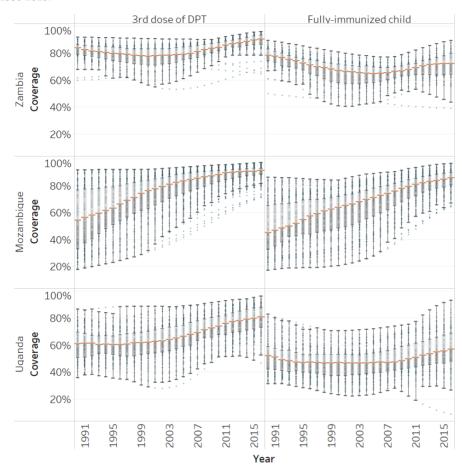
While vaccines have significant distributional impact that benefits those in poverty greatly, many of these same populations are the hardest to reach. Gavi's strategic indicators for equity include "geographic equity," "equity by household wealth," and "equity by maternal education status." While inequalities in coverage between subgroups within these dimensions have decreased over time, 5 absolute inequalities in coverage continue to exist for these and other access- and health systems—related determinants. Geographic inequities are also still widespread, with variation in district-level coverage within countries. 6 This report discusses what we currently know about what is being done, and what more could be done by Gavi (Section 3, page 70) and countries (Section 2, page 59) to address these inequalities.

Examining coverage estimates at the district level using FCE1 SAEs, we observe that between-district differences in coverage have visibly decreased only in Mozambique since 1990. Figure 3 below shows box plots that summarize district-level DPT3 and FIC coverage by country. The box plots show

estimated coverage for each district in each year as a dot; the shaded box indicates the middle 50% of the data (the interquartile range); the median coverage across districts is indicated by the horizontal orange bar. If geographic inequality is improving, we would expect to see the interquartile range shrink as differences in coverage between districts shrink. In Zambia, the median and interquartile range have shifted upwards as DPT3 coverage has improved, but the range spans 7 percentage points in both 1999 and 2016, narrowing only briefly to a span of 6 percentage points (left panel of Figure 3). In Uganda, the DPT3 interquartile range has similarly remained constant, only decreasing by 2 percentage points (from 19 to 17) between 1999 and 2016. There has been movement amongst the lowest performers (seen in the whiskers and outliers), but districts still struggle to reach the 80% performance benchmark. The lack of change in variance of DPT3 coverage suggests that between-district inequality has been virtually unchanged in the last decades.

The portrait of between-district coverage for FIC shows that geographic inequalities have increased since 1999 in Zambia and Uganda (right panel of Figure 3). The increase in variance of district-level FIC coverage suggests that geographic inequality for full vaccination has actually worsened in the last two decades, indicating that countries are struggling to reach all children with all vaccines equally. In contrast, the range of between-district FIC coverage has decreased in Mozambique; as the median FIC coverage level has increased, FIC coverage in the lowest coverage districts has improved more rapidly, thus shrinking the overall district spread.

Figure 3. Between-district DPT3 and FIC coverage in FCE countries based on SAEs, 1990-2016.



**Source**: Small area estimates from multiple household surveys; 1990-2016.

**Notes:** The graphs show box plots of district-level coverage by year. Within a year, coverage for each district is shown as a dot, and the shaded box indicates the middle 50% of the data (the interquartile range, with light gray indicating the upper quartile and dark gray indicating the lower quartile). The median coverage across districts is indicated by the orange line. Fully immunized child is defined as a child under age 1 who has received all doses of BCG, DPT, OPV (oral polio vaccine), and measles vaccines. The definition does not change over time to account for new vaccine introductions in the small area estimates, though DPT3 may be replaced with pentavalent vaccine.

# THE FCE2 THEORY OF CHANGE: EXPLORING THE DRIVERS OF EQUITABLE COVERAGE

EQ1-3: What are the major factors influencing the achievement of the results of Gavi support? Whether, how, and why is Gavi support contributing to increased vaccination coverage and equity? (cross-country)

To assist in exploring the multiple complex drivers of coverage, FCE2 uses the Theory of Change (TOC) in Figure 4.<sup>b</sup> The aim of the FCE2 TOC is to describe all potential drivers of vaccine coverage at all levels of the health system which result in whether or not a given child is vaccinated ("vaccine coverage" in the green level). The global level includes contextual and institutional enabling factors of success in Gavi-supported countries. The national level reflects that the EPI and Ministry of Health (MOH) teams have adequate Leadership, Management, and Coordination (LMC) capacity and skills, access to the necessary data and evidence to inform decision-making, adequate supply and logistics management and infrastructure, financing and policy planning capacity and structures, and mechanisms in place to coordinate and evaluate partner performance. Many of these same drivers are included at the subnational level, as they are also important for regional and district health officers (DHOs). The household-, community- and facility-level drivers include intent to vaccinate, community access, and facility readiness. (A full description of the FCE2 TOC is included in Annex 1. Methods.)

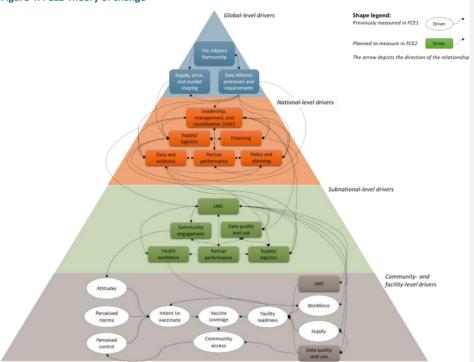
FCE2 defines equitable immunization coverage as the state when all children are vaccinated on time with vaccines that work. We consider any inequalities in immunization<sup>c</sup> coverage to be inequitable and recognize that underlying social inequity—in wealth, power, social status, access to health services, and availability of quality and responsive health services—drive many of the coverage inequalities we observe. While not all of those dimensions are included in our TOC, we note their importance in observed coverage inequalities; the TOC enables the measurement and monitoring of drivers of inequalities that are more immediately addressed by health providers and the health system as a whole.

<sup>&</sup>lt;sup>b</sup> This TOC is based on two previous frameworks: the FCE TOC from phase 1 and a conceptual framework which emerged from a systematic review of the literature on drivers of vaccine coverage and which was used to inform how FCE1 modeled linked-household and health facility survey data.

<sup>&</sup>lt;sup>c</sup>We generally use the term "vaccination" as opposed to "immunization" throughout this report as we are unable to measure whether vaccination has resulted in immunization.

#### FCE2 TOC: Unpacking potential drivers of coverage and equity.

Figure 4. FCE2 Theory of change



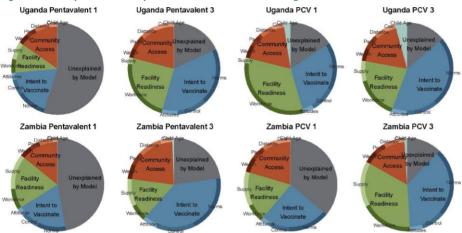
In FCE1 we used linked-household and health facility survey data to estimate the relative contributions of the drivers colored as white in Figure 4 on a given child's vaccination status in Uganda and Zambia. 

The pie charts in Figure 5 show the contribution of each driver—intent to vaccinate, community access, and facility readiness—in explaining coverage. A substantial proportion of coverage is unexplained by the model and points to the importance of FCE2's ongoing data collection on other drivers. Of coverage that is explained by the model, it is clear at a glance that, while some patterns exist, the relative influence of each driver varies by country, antigen, and dose. For example, in the case of Uganda, 18.6% of pentavalent first dose (penta1) coverage is explained by intent to vaccinate, 33.8% by community access, and 11.2% by facility readiness. These values shift for pentavalent third dose (penta3), with a notable increase in the role of intent to vaccinate, or demand-side considerations, in the completion of the pentavalent schedule. Consistent with other literature, we posit that if access barriers are overcome for the first dose, the subsequent doses will depend strongly on the health care experience and the resulting recalculation of costs and benefits of immunization. In other words, ensuring a high-quality experience likely has positive feedback effects on a caregiver's willingness to return.

#### Three principal drivers of coverage explored through FCE1:

- 1. Intent to Vaccinate—Demand for vaccines on the part of the caregiver that would result in vaccination in the absence of other barriers.
- 2. Facility Readiness—Supply (by the health system) of vaccine services to adequately meet demand. Incorporates supplies (vials, syringes, etc.), human resources, and the consistency of their availability.
- 3. Community Access—the ability (or inability) to successfully carry out the transaction of vaccine utilization (i.e., barriers and facilitators between Intent and Readiness).





The sizes of the pie slices change again for pneumococcal conjugate vaccine (PCV), a newer vaccine. Intent to vaccinate continues to explain a large proportion of dropout between PCV1 and PCV3. Unlike pentavalent vaccine, PCV coverage is more strongly explained by facility readiness, suggesting the importance of supply-side inputs in successfully routinizing new vaccines. For example, evaluation teams observed multiple instances of stockouts; lack of clarity on administration, vial, and wastage policies; and suboptimal health worker training during process tracking of new vaccine introductions in FCE1.

These results reveal a complex picture of many drivers interacting to influence whether a child is vaccinated and highlight the added value of FCE1. In FCE2 we continue to build on this measurement approach and link it with mixed-method process evaluation evidence from all levels of the health system. In year 2 of FCE2 (2018 to 2019), we aim to quantify the remaining drivers and their relationships to identify drivers that need to be addressed as a matter of priority to accelerate and optimize progress toward equitable coverage.

## APPLYING THE TOC TO OBSERVED DATA: WHAT IS DRIVING COVERAGE AND **EQUITY TRENDS IN FCE COUNTRIES?**

EQ1-3: What are the major factors influencing the achievement of the results of Gavi support? Whether, how, and why is Gavi support contributing to increased vaccination coverage and equity? (cross-country)

**Finding** 1.1

Recent data from DHIS2 are consistent with the trajectory of the small area estimates' trends.

- In Mozambique, the number of DPT1 and DPT3 doses administered continue to increase with lower drop-out between those doses than in the other FCE2 countries. Additional gains in coverage are constrained by ongoing HSS delays.
- In Zambia, the slowing upward trend in the number of doses administered for BCG, DPT1, and DPT3 is in part due to inadequate immunization financing.
- Stakeholders in Uganda attribute coverage declines in 2017 to the gap in HSS funds, more accurate data reporting as a result of the Data Improvement Team (DIT) strategy, and more focus on new vaccine introductions compared to routine vaccines.

#### Cd **ROBUSTNESS RANKING**

This finding is based on observed trends in DHIS2 data from 2014 to 2017 in the FCE countries, triangulated with SAEs. The robustness is limited by the data quality of DHIS2. In Uganda KIIs, observation, and document review support the explanations for coverage declines in 2017; however, further statistical analysis of secondary data is planned to confirm the hypotheses related to the HSS gap and DIT strategy. More data collection is required to further explain observed trends in Mozambique and Zambia, which will be achieved through DCSs in year 2.

Examination of monthly DHIS2 data show trends consistent with the SAEs: vaccine coverage plateaued from 2014 to 2017 in Zambia and declined in 2017 in Uganda (Figure 6). Due primarily to underestimated denominators, 8 coverage calculations from health management information systems (HMIS) data often exceed 100%, and so we also show absolute number of doses delivered for BCG, DPT1, and DPT3 vaccines (Figure 7; see text box on data quality issues).

<sup>&</sup>lt;sup>d</sup> The robustness of FCE findings are ranked, from best to worst, as A, B, C, and D. Details on the criteria for these rankings are available in the methods annex, Table 18.

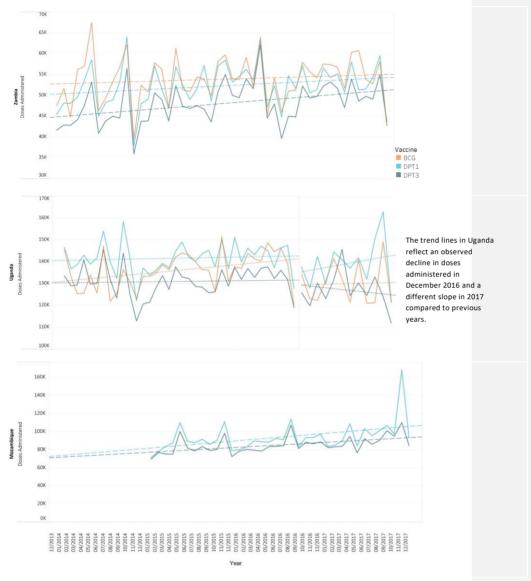
Vaccine
DPT1
DPT3 150% 135% 120% **Zambia** Coverage 105% 90% 75% 150% 135% Mozambique 120% 105% 90% 75% 150% 135% 120% **Uganda** Coverage 105% 90% 75% 2015 Q4 2017 Q2 2017 Q4 2016 Q2 2013 Q4 2014 Q2 2014 Q4 2015 Q2

Figure 6. DPT1 and DPT3 coverage in FCE countries from 2014-2017, based on HMIS.

Source: DHIS-2 data from Uganda, Mozambique, and Zambia; 2014-2017.

**Notes**: To aid interpretation of trends over time, monthly data from DHIS2 were aggregated by quarter.

Figure 7. Number of doses of BCG, DPT1, and DPT3 administered in Uganda, Zambia, and Mozambique (DHIS2).



**Source**: DHIS-2 data: 2014-2017

**Notes**: Solid lines are vaccine doses administered (numerators) from DHIS2; dotted lines are the fitted trend over time (i.e., the slope of change in doses administered over time). Note that the y-axis has a different range by country.

#### Denominator challenges affecting HMIS vaccine coverage

FCE2 countries face challenges with outdated national census results that inform denominators for target populations. Some noise in the coverage trends in DHIS2 is due to updates to census estimates which change denominators used for each administrative area and, thus, coverage estimates. The creation of new districts, which has occurred in all FCE2 countries in recent years, also contributes to changing denominators. Finally, the existing approach to estimating facility and district catchment denominators does not capture population mobility.

Part of the explanation for the observed "noise" in the administrative data is due to external events (e.g., annual seasonal drops in Uganda in December during the holidays and the August 2016 national election in Zambia). In Zambia, the absolute number of doses administered for BCG, DPT1, and DPT3 is still trending upwards; however, the year-over-year trend shows a decline in the rate of increase. Section 3 of this cross-country report and Zambia's country report discuss how inadequate immunization financing, particularly for operational costs, are not keeping pace with program needs and the costs of vaccinating the fifth child.

In Mozambique, the number of DPT1 and DPT3 doses administered continue to increase with lower dropout between those doses than in the other FCE2 countries. The Mozambique FCE2 team continues to follow up on the spike in DPT1 doses administered during their November 2017 national health week.

In Uganda, coverage across the displayed antigens dropped in December 2016 (Figure 6). Unlike most years where this seasonal drop is quickly compensated, in 2017 the annualized median coverage remained lower for all three antigens shown, and the slope of change in DPT3 doses administered declined relative to previous years (Figure 7). The Uganda FCE2 team heard two principal explanations for the decline from national and subnational stakeholders: both attributed the decline to the gap in HSS funding in Uganda (page 34), and national stakeholders also attributed it to more accurate data reporting due to the DIT strategy.

Uganda's DIT strategy was launched in 2014 with the aim to improve the management, collection, analysis, and use of immunization data at district and health facility levels. Round 1 of implementation took place October 2014 through September 2016 and deployed to all districts and 89% of all health centers in Uganda that provide immunization services. Common challenges included a shortage of immunization recording and reporting tools in many health facilities, data that were not well organized, and insufficient number and high turnover of staff. The US Centers for Disease Control and Prevention and the World Health Organization (WHO) are leading round 2 of implementation (2017 to 2019), which was funded by Gavi's Partner Engagement Framework (PEF)—Targeted Country Assistance (TCA) in 2017. Round 2 includes key activities such as trainings, field deployment and supervision of DIT teams, and mentorships at health facilities in 50 districts. These data quality improvements likely contributed to the observed 6.7 percentage point decline in penta3 coverage from 2016 to 2017 in DHIS2 and will be an area for follow-up in FCE2 year 2.

Another hypothesis is that the Uganda EPI team has prioritized applications for Gavi support, introduction of new vaccines, and implementation of campaigns—which has left little time to focus on coverage and equity of routine vaccines. (See the Uganda FCE2 report for additional details.) While the

focus on NVIs can overshadow routine vaccines, NVIs can also strengthen routine administration by improving facility readiness (via health care worker (HCW) refresher trainings embedded in NVI trainings) and raising community awareness of immunization generally (through NVI social mobilization) which influences intent to vaccinate.

## Next steps for FCE2 year 2°



- >>> In Mozambique, continue to investigate causes of the observed spike in DPT1 doses delivered in the 4th quarter of 2017.
- >>> In Uganda, continue to explore the hypothesis of data quality improvements leading to perceived declines in coverage through statistical analysis and triangulation with data quality assessments and the 2016 coverage survey results soon to be released.
- >>> In Uganda, conduct additional KIIs to understand how the Uganda National Expanded Programme on Immunisation's (UNEPI's) focus on Gavi applications and NVIs may have affected coverage of routine vaccines.

<sup>&</sup>lt;sup>e</sup> Country-specific recommendations are included in this year's country reports.

#### HOW IS HSS CONTRIBUTING TO IMPROVED COVERAGE?

- EQ4: What has been the contribution of HSS funds to vaccine coverage in priority provinces and districts? (Mozambique)
- EQ5: What are the advantages and consequences of managing HSS funds through partners, outside of government systems? (Mozambique)
- EQ6: What is the effect of an interruption in Gavi HSS funding on routine service delivery, highlighting Government of Uganda and other partner funding? (Uganda)
- EQ9: Whether why and how is an analysis of the lessons learned from previous support being taken into consideration? (cross-country)
- EQ17: What are the positive and negative consequences of the new/updated Gavi processes? (cross-country)

Finding 1.2

Gavi HSS is intended to address health systems and access barriers to vaccination, but its potential impact is limited by delays in disbursement and initial implementation, implementation challenges, and channeling funds away from government systems.

- In Uganda, immunization stakeholders attribute the 2017 coverage declines in part to the delays in accessing HSS2 funds, which led to reduced frequency of operational activities.
- In Mozambique, persistent HSS implementation challenges due to suboptimal planning and alignment at all levels limit the potential impact of HSS.
- > Across Gavi-eligible countries, Gavi cash support is increasingly being channeled through partners partly as a result of weak national financial management systems. While this may be a necessary risk management and accountability strategy in the short-term, it poses risks to longterm programmatic sustainability and effective transitions from Gavi support.

## ROBUSTNESS RANKING B

HSS implementation challenges are a persistent theme supported by evidence from FCE1, other Gavi HSS evaluations, and new process-evaluation findings in FCE2. In Uganda, the timing of the end of HSS-1 fund disbursement to districts aligns with observed declines in coverage, and many key informants at the national and subnational levels cited the lack of HSS funds as an explanation for declining coverage. Findings from Mozambique and Zambia are supported by national-level process evaluation methods. We conducted a document review of HSS proposals and implementation plans to analyze activities across the three countries.

HSS is intended to increase equitable coverage by addressing many of the health systems and access drivers in the TOC. A major focus of previous FCE reports has been the alignment (or lack thereof) of Gavi HSS with health system bottlenecks and the suboptimal use of data for targeting. In all countries we have reported on challenges in implementing HSS. Gavi guidance and processes have improved

over time, but many challenges remain that constrain timely and efficient disbursement, implementation, reporting, monitoring, and adaptation of HSS funds. A table of current HSS activities for FCE2 countries can be found on page 54 and Gavi HSS guidance is further addressed in Section 2.

In Uganda, the FCE2 team interviewed district health officers, health workers, and sub-national partners across 18 districts to evaluate the consequences of the HSS funding gap (see DCS methods box). The last tranche of HSS-1 was disbursed to districts in February 2016. Although Uganda has been approved for HSS-2, as of April 2018 the country is still working to clarify and put in place the grant management requirements (GMR) that are a necessary precursor to receiving HSS-2 funds. This process has been prolonged by Gavi's decision to channel HSS-2 funds through UNICEF (based on concerns related to the MOH's financial systems) which requires a tripartite grant agreement between Gavi, UNICEF, and the Government of Uganda. Zambia is facing a similar situation where conducting the PCA and addressing the GMR has delayed implementation of HSS funds.

#### District-level case study (DCS) approach in Uganda

To explain the varying trends in coverage and equity, the Uganda FCE2 team applied a DCS approach to compare multiple districts with varying immunization performance in order to identify the drivers and barriers to coverage and equity. This approach was used to understand the complex social phenomenon surrounding the major drivers of district-level changes in vaccine coverage and equity by allowing the FCE2 to retain the "holistic and meaningful characteristics of real-life events." The generalizability of findings identified through this type of case study depends on the strength of theory underlying it. The Uganda FCE2 team visited 4 districts to understand the drivers of changing coverage and equity, 18 districts to assess consequences of the gap in HSS funding, and 4 districts to evaluate demand-side reasons for low HPV2 coverage. See the Uganda FCE2 report for further details on district selection and findings.

Most subnational respondents attributed the observed 2017 declines in coverage to the gap in HSS funds. While the national level does not issue specific guidelines on how to spend HSS-1 or primary health care (PHC) funds, according to the visited districts, HSS-1 had supported district health team facilitation for microplanning, district health team supervision and logistics, social outreach mobilization by village health teams, and outreach facilitation for health workers. While most visited districts continued to implement these activities without HSS funding, key informants reported that these activities continued at a reduced frequency, or at a limited scale; for example, outreaches may only be offered to the communities closest to the facility in order to reduce costs—leaving the more distant areas unattended to.

In my opinion, all factors that have previously hindered immunization coverage have remained the same—the only thing that has changed is the reduction in HSS. In fact, in 2016, there were a number of campaigns that were conducted routinely and also during new vaccine introductions (IPV [inactivated polio vaccine], MenA, etc.) which overall increased awareness on immunization. There were no new vaccine introductions in 2017 and additionally, with the drop in HSS, routine campaigns ceased. (National KII, Uganda MOH)

In other words, *Gavi Alliance processes and requirements* related to HSS at the global level have influenced *financing* at the national level, and this lack of HSS funds has had consequences related to *LMC*, *facility readiness*, and *community access* at lower levels of the health system.

FCE1 reported extensively on Mozambique's HSS grant and its numerous delays, which have impeded the grant's ability to achieve its intended outcomes. Some improvements were made for 2017, including the hiring of key HSS management personnel who have contributed to improved planning and financial management (see EQ9 in Mozambique's report). However, critical steps in each of these processes, and particularly in the disbursement process, remain outside the control of those staff. For instance, delays in the national audit process in 2017 resulted in delayed 2018 disbursement from Gavi. By April 2018 provinces had still not received their HSS funds for the 2018 calendar year and were using measles—rubella (MR) campaign funds to initiate activities. Delays and management challenges related to key HSS procurements have also continued in Mozambique. The UNICEF-led procurement of HSS equipment (temperature monitors, motorcycles, vehicles, etc.) faced numerous challenges, including miscommunication with the MOH regarding who should register the imported equipment with customs. MOH finalized the customs registration to import these essential inputs in February 2018, nearly halfway through the HSS grant's life cycle.

In part as a result of these delays, the country has struggled to finalize its planned improvements of the cold chain and logistics systems which has led to ongoing<sup>9</sup> stockouts in the central and northern regions where no central cold stores exist. Inactivated polio vaccine coverage declined to 49% in the 3<sup>rd</sup> quarter of 2017 and was 35% in Zambezia province, where a polio outbreak occurred in late 2016.

As it stands, persistent delays in HSS disbursement and implementation due to *Gavi processes and* requirements, national policy and planning, and inadequate LMC constrain its potential impact. Gavi must continue to focus on strengthening countries' capacity for effective planning, financial management, and implementation of HSS funds.

# Who spends the money? A continued trend toward channeling Gavi funds through partners

As reported in FCE1, Gavi is channeling an increasing share and total amount of non-vaccine cash funds through partners. Across Gavi-eligible countries, over US\$658 million in cash support was disbursed to partners from 2010 to 2016, equivalent to 46% of all cash support during this period and 67% of cash support for the year 2016. This issue is of concern to the Gavi Board, who requested that Gavi should aim to channel funding through governments.<sup>10</sup>

The root causes underlying decisions to channel funds through governments or partners are complex. Gavi's decision criteria reflect the Alliance's low appetite for risk and are highly influenced by the strength of national financial management and audit systems. However, decisions to channel funds through partners are also sometimes made by country governments as a means of accelerating procurement processes (e.g. HSS in Mozambique through UNICEF) or potentially to reduce the perceived challenges associated with managing cash support. It should also be noted that when cash support does flow from Gavi to country systems, it may flow directly to the EPI program, a sector-wide approach or common funding basket, or "project management units" (e.g. HSS1 in Uganda) or a mix. The issue of funds channeling and its effect on national capacity is easily oversimplified: channeling through the government does not necessarily result in increased financial management capacity. For instance in Mozambique the improvements observed in the ability to plan, budget, and report on HSS funds has been largely attributed to the role of MB Consulting, an external consulting group seconded to the health ministry.

Global and national stakeholders recognize the importance of strengthening national financial management systems to ensure long-term programmatic sustainability and effective transitions from Gavi support but operationalizing this vision requires additional work.

### In Year 2 we will further explore the consequences of channeling funds through partners or governments on:

- > Expenditure rates
- > Implementation timeliness
- > Implementation efficiency
- > Implementation outcomes
- > Strength of country financial management systems and financial managers
- > Country ownership of activities and outcomes
- > Sustainability or potential sustainability of improvements in processes or outcomes after the funding ends

Gavi's decision to channel Uganda's HSS-2 funds through UNICEF has already resulted in negative, unintended consequences due to the required time to agree to terms and operationalize a tripartite agreement between Gavi, UNICEF, and the Government of Uganda, which is contributing to the ongoing delay of HSS-2 implementation. The Uganda FCE2 team will continue to track the consequences of this decision, which may include: reduced country ownership for the grant, as was observed in Bangladesh in 2016;<sup>11</sup> reduced ability to strengthen country systems and processes and then sustain HSS inputs upon the end of HSS; and implementation delays due to additional layers of institutional processes.<sup>12</sup>

Gavi is perceived by many national decision-makers as more flexible than other donors, but the anxiety surrounding the consequences around perceived misuse of funds and related transaction costs, particularly for large procurements of capital equipment, continues to influence government decision-making around the management of non-vaccine support. A more operational concern for governments is that of how to receive, disburse, and account for large sums of money with suboptimal financial management systems. For these reasons Mozambique supported the decision to channel HSS funds for equipment procurement directly from Gavi to UNICEF.

Many operational and management challenges are yet to be resolved with regards to spending and implementing cash grants, and they must be if these grants are to have their intended impact.

#### **Recommendations**

- Continue doing: Gavi should continue to ensure that PCAs and GMRs are leading to demonstrable and adequately resourced efforts to strengthen country systems, even if the decision is made to channel funds through partners.
- Act now: In line with the Board's request to develop criteria for channeling funds back through country systems, Gavi should propose and monitor indicators that measure the ongoing capabilities of national financial management systems as well as other consequences related to effectiveness, efficiency, country ownership, and sustainability. These indicators would ensure that, even if funds are being channeled through partners, there are measurable improvements in strengthening country systems and identify when countries have met the criteria for self-managing Gavi funds:
  - > This builds on the FCE1 recommendation in the 2016 report that Gavi should formally assess whether it is actually more efficient in the short term to channel funds through partners versus government systems and what are the long-term consequences of this trend on country ownership and sustainability. Gavi should also review other best practices in mitigating risk of financial mismanagement of donor funds, while still strengthening country systems.

#### Next steps for FCE2 year 2



- Continue to analyze Uganda coverage and HSS expenditure data using interrupted time series methods to further quantify the association between the end of HSS funding and coverage declines (EQ6).
- >>> Continue to track HSS implementation in Mozambique with a focus on whether learning and adaptive management is occurring (EQ4, 9).
- Coordinate or partner with Zambia's EPI, which will be implementing an HSS baseline-coverage survey in mid-2018. This affords an opportunity to triangulate across FCE data, including surveys from FCE1 and planned DCSs, as well as costing studies from FCE2.
- >>> Continue to track unintended consequences due to PCA and funds channeling on HSS implementation and outcomes (Uganda and Zambia; EQ17; Mozambique EQ5).

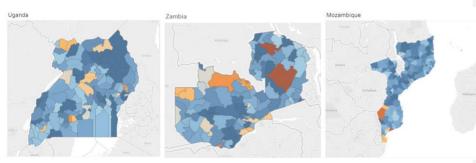
## SUBNATIONAL TRENDS: WHY DO SOME DISTRICTS PERFORM BETTER THAN OTHERS?

The FCE's historic focus on national processes has resulted in a wealth of evidence establishing the influence of drivers at the national level on the implementation and outcomes of those processes. In FCE2 we place a greater emphasis on the subnational level in an effort to explain why some districts perform better than others and which district-level drivers from our TOC ought to be prioritized to improve equitable coverage.

The FCE2 focus on the subnational level is aligned with the immunization field's increasing emphasis on subnational data, for example through the WHO/UNICEF Joint Reporting Form's (JRF) shift to collecting, analyzing, and disseminating subnational immunization coverage data. <sup>13</sup> In FCE2, we hypothesize that, in countries with functioning EPIs and performing health systems, districts are the administrative unit with the greatest influence over immunization outcomes.

District-level maps of DPT3 coverage show stark differences, even between neighboring districts. The blue districts in Figure 8 have reached Gavi's benchmark of 80% coverage for DPT3, but pockets of underperformance exist. Figure 9 shows box plots of DPT3 coverage in 2017 to give a sense of the scope of inequality. Each district is represented as a blue dot; the shaded box indicates the middle 50% of the data (the interquartile range); the median across districts is indicated by the orange line. Mozambique has the least inequality of the FCE countries in 2017 as measured by an interquartile range of 17 percentage points, though there are many districts with particularly poor performance that lie outside the whiskers of the box plot. Zambia has the most inequality with an interquartile range of 22 percentage points.

Figure 8. 2017 DPT3 coverage by district in FCE countries, based on HMIS.

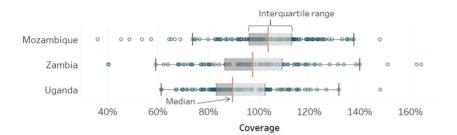




Source: DHIS-2 data from Uganda, Mozambique, and Zambia: 2017.

**Notes**: Districts shaded in blue have reached or exceeded Gavi's benchmark of 80% coverage for DPT3; districts shaded in orange are below 80% coverage.

Figure 9. Between-district inequality in DPT3 coverage in 2017, based on HMIS.



Source: DHIS-2 data from Uganda, Mozambique, and Zambia: 2017

**Notes:** The graphs show box plots of district-level coverage by country. Each district is represented as a blue dot; the shaded box indicates the middle 50% of the data (the interquartile range); the median coverage across districts is indicated by the orange line.

To explain between-district differences, the Uganda FCE2 team implemented the DCS approach in 2018 (see DCS approach text box on page 35). We found that higher-performing districts tended to have stronger DHOs and stronger overall LMC as manifested through (1) coordination of partner activities, (2) close monitoring of immunization coverage performance, and (3) recognition of the health workforce. Further, districts with stronger LMC capabilities were able to more effectively respond to shocks, including the gap in HSS funding. These subnational findings are triangulated with evidence from all FCE countries on the importance of LMC at the national level. Year 2 will focus extensively on sub-national drivers of coverage.

#### LMC IS A KEY DRIVER OF PERFORMANCE

- EQ1-3: What are the major factors influencing the achievement of the results of Gavi support? Whether, how, and why is Gavi support contributing to increased vaccination coverage and equity? (cross-country)
- EQ4: What has been the contribution of HSS funds to vaccine coverage in priority provinces and districts? (Mozambique)
- EQ5: What are the advantages and consequences of managing HSS funds through partners, outside of government systems? (Mozambique)
- EQ21: What is the structure of the immunization partnership in the country at national and district level? (Uganda)

Finding 1.3

Across FCE2 countries, we observe the influence of leadership, management and coordination at national and subnational levels on immunization system performance. In particular:

- > Sub-optimal financial planning and management led to delayed disbursements or inadequate resources in Mozambique. This was exacerbated in Uganda with the creation of new districts.
- > Effective and coordinated partners contributed to improved performance.
- Stronger performing districts in Uganda used data for performance management which led to motivated staff and improved performance.

#### ROBUSTNESS RANKING

В

The important role of LMC was cited by health care workers across different facility types in two high-performing districts in Uganda. The Uganda DCS approach to understanding drivers related to increasing or decreasing DPT3 coverage in 2017 was limited by a small sample size (two districts with increasing and two with decreasing coverage), but the role of LMC came out strongly. Mozambique's management challenges in implementing HSS are based on observed trends in the DHIS2 data, triangulated with meeting observations and KIIs, and are consistent with findings in FCE1.

Improving or sustaining high vaccine coverage requires strong LMC at all levels. favi's approach to strengthening LMC is based on three elements: (1) strengthening EPI teams at the national or subnational level; (2) boosting national coordination forums; and (3) enhancing the ability of national immunization technical advisory groups (NITAGs). In this section we present findings related to LMC

<sup>&</sup>lt;sup>f</sup>The FCE2 uses the WHO list of management functions as a starting place to consider the types of LMC skills and capacities that health workers should have: http://www.who.int/management/functions/en/.

of EPI teams (national and subnational) regarding financial management, coordination with partners, and managing performance through information.

#### Financial management and coordination

As mentioned in the HSS section above, persistent financial management and planning challenges at national and subnational levels in FCE countries have constrained immunization-program performance. We have reported extensively on the consequences of suboptimal financial management coupled with misalignment of management processes across stakeholders and levels in Mozambique. For HSS planning and disbursement, some adaptive management has occurred. In 2017 both PCV switch and MR campaigns were delayed in Mozambique due to inadequate planning for the length of time required to get the funds from the Ministry of Economy and Finance to the MOH.

In Uganda, challenges with disbursement and receipt of PHC funds were a principal explanation for coverage declines cited by underperforming districts. Both underperforming districts visited as part of the case study approach reported insufficient PHC funds to support routine immunization activities like facilitating health workers to conduct outreaches. Financial management challenges in Manafwa district were complicated by the administrative change when the district was split to create Namisindwa district in July 2017; this resulted in a decrease in PHC funds, which coincided with a drop in vaccine coverage. This is part of a decentralization movement in Uganda that created four new districts in 2016 and six new districts (including Namisindwa) that took effect in July 2017, with plans for an additional six districts to become effective in July 2018 and seven districts to become effective in July 2019. PHC allocations are based on the total population served under that administrative unit so when a district is split, its PHC allocation reduces. The other five parent districts that split in 2017 show similar subsequent declines in DPT3 coverage, which we hypothesize could be due to similar financial management challenges as those cited by Manafwa district or inaccurate denominators following the split.

#### Coordination of partner activities

In Uganda, the two high-performing districts included in the DCS cited the importance of leveraging partner activities (even partners outside of immunization) to support district immunization activities. For example, in Kibaale district the district health team has coordinated with the Infectious Diseases Institute to encourage their TB–HIV facility mentors to also push the immunization agenda and share their vehicles to facilitate outreaches.

In my view, the reason why our coverage is high is because of the several activities that we have been able to conduct because of the presence of IDI [Infectious Diseases Institute] in the district; these include support supervision, outreaches, and mentorship. (Uganda subnational level KII, MOH)

The benefits of partners can be diluted if their activities are not relevant or if the partners are not effective or well-coordinated. The Uganda FCE2 team found through their partner mapping survey that each district in Uganda had at least one partner present working on immunization and that partners tended to add the most value when the DHO was effective at coordinating, or even requesting, partner activities, and the activities of those partners were, in turn, relevant and effective.

At the national level, FCE1 reported many instances where the partnership model improved the effectiveness of national processes—for instance, applications for Gavi support—and where partners filled gaps in either funding or technical assistance (TA). In FCE2 in Zambia, we observe that where the EPI faces a critical shortage of operational funds, partners have contributed funds to close this gap (although this has implications for the sustainability of the program, as discussed later in Section 3). However, there have been challenges with coordination and integration of partners at the national level in Zambia as each partner budgets and plans his or her own activities; the EPI Optimisation Plan is one solution that has been put in place to better integrate activities and budgets across partners, but there remains room for strengthening partner coordination at all levels. <sup>16</sup>

#### **Partner Performance**

The FCE2 TOC includes partner performance as a driver of coverage and equity to note the importance of the roles, actions, and effectiveness of partner organizations outside of the MOH who support immunization activities. FCE2 will not evaluate partner performance in detail, as Deloitte is in the process of conducting a Gavi-funded evaluation of the TCA provided through the PEF.

#### Managing performance through information

The two stronger districts in Uganda's DCS used HMIS data to closely monitor vaccine coverage indicators, potentially driving coverage improvements, as compared to the other two districts visited. Particularly in Mpigi district, the DHO pays close attention to DPT3 coverage as a key performance indicator, which ensures health workers track their performance and achieve high coverage. This is operationalized through reviewing performance at quarterly meetings, emphasizing immunization performance during supportive supervision visits, and using data to target activities to poorer performing subcounties and facilities.

Key informants in Mpigi district pointed out an added benefit of the DHO's evidence-informed performance management: during the quarterly performance review meetings, recognition from the DHO for strong immunization performance motivates the health workforce at the facility level. Key informants said the gratitude and recognition received from the DHO on good performance has motivated them to improve or increase their efforts. The importance of strong leadership that recognizes health workers was also observed in Bangladesh during FCE1. 11

#### Recommendation

Continue doing: Gavi should continue to strengthen national-level LMC and should study where gaps in district-level LMC exist through PEF-TCA and the LMC Strategic Focus Area. These activities should include a focus on financial management and evidence-informed performance management.

#### Next steps for FCE2 year 2



- Implement DCSs (Mozambique and Zambia), with an emphasis on measuring the influence of LMC and data use / performance management on district and facility performance and on best practices for coordinating partners (EQ1-3; EQ22).
- >>> Evaluate the design, progress, and outcomes of Mozambique's TCA-funded activity to coordinate partners and address whether it could be a helpful approach for other countries.
- >>> In Mozambique, continue to explore why it is so difficult to overcome these persistent financial-management challenges (EQ9).
- >>> In Uganda and Zambia, continue to explore the unintended consequences of the creation of new districts, especially on coverage and equity. (EQ1-3)
- >>> In Zambia, plan to implement a subnational resource-tracking survey. Data collected through this survey will illuminate between-district inequalities in resources, particularly those coming from or implemented by partners. (EQ1-3; EQ16)

## DRIVERS OF COVERAGE INEQUALITIES AND PROGRESS TOWARDS VACCINE EQUITY

EQ1-3: What are the major factors influencing the achievement of the results of Gavi support? Whether, how, and why is Gavi support contributing to increased vaccination coverage and equity? (cross-country)

Finding 1.4

Current indicators and data sources for measuring vaccine equity do not adequately measure which children are under vaccinated and why. Decision-makers also lack information on how to best address the causes of under vaccination. As a result efforts to improve equitable coverage are not targeting the right problems with the right solutions.

#### ROBUSTNESS RANKING B

The findings describing limitations of current indicators, data sources, and evidence on addressing inequalities are based on document review, a limited number of KIIs, and content analysis. The linked household and health facility data from Uganda clearly show the influence of multiple constraints to vaccine coverage. While the specific results from Uganda cannot be generalized to other countries, the finding that inequalities are driven by a range of behavioral, access-related, and facility-readiness determinants is generalizable. This finding could be strengthened by a more systematic review of the real-world effectiveness of interventions and strategies to reduce coverage inequalities.

#### Defining and measuring coverage inequalities

While there is broad agreement on the meaning and intention of Gavi's 2016–2020 strategic goal of ensuring equitable coverage of vaccines and a consensus that equitable vaccine coverage means universal, on-time coverage of effective vaccines, there is much less agreement, at all levels, on the drivers and dimensions of equitable coverage, how to target action, and what this action should look

Conceptualizing vaccine equity is surprisingly fraught, but it need not be. Vaccines are considered a global good and we aim for universal immunization. As such, any missed opportunity for vaccination is unjust. Addressing inequitable coverage means vaccinating children who are currently un- or undervaccinated. Determining how to do so is the more challenging step and requires information on why these children are under-vaccinated and which operationally feasible intervention strategies would most effectively target these children. However, decision-makers currently lack appropriate, relevant, timely information on which children are under-vaccinated, why they are under-vaccinated, and how those causes can be most effectively addressed (Figure 10).

Figure 10. Principal limitations with current state of vaccine equity conceptualization and measurement.

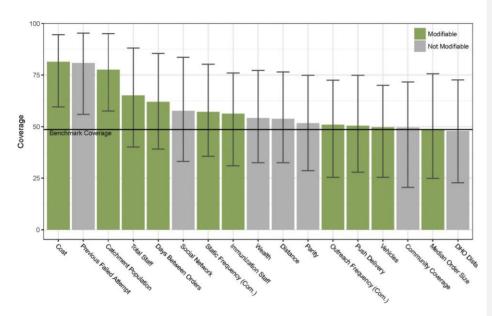


#### "If you can measure it you can manage it"

Identifying which children are under vaccinated and why have both been historically shaped by the reliance on household survey data to measure inequalities according to individual- and householdlevel characteristics typically measured through those surveys: household wealth, maternal education, place of residence. 17,18,19 Discourse related to vaccine inequity tends to elevate those indicators, which are frequently associated with coverage inequalities, to the level of causation or even a misunderstanding that because they are the most often measured and discussed, they bear the strongest association with coverage. Instead, when we have data on all the potential drivers, we observe the significant association of demand, access, and supply-side drivers (e.g., "intent to vaccinate," "community access," and "facility readiness") on unequal access to and utilization of vaccines at the community and facility levels. For example, 2014 DHS data indicate that poor children in Zambia are much more likely to experience missed opportunities for vaccination than non-poor children; however, when we control for other intent, community access, and facility readiness variables in the structural equation model<sup>g</sup> we observe that removing the wealth constraint would have a lower impact than removing other constraints (Figure 11). While these supply-side and health systems constraints are not typically considered dimensions of equity, we argue that because they are inherently remediable, their presence and contribution to differences in coverage is unjust. 5 Efforts to address the underlying social determinants of health disparities are also crucial and an area for advocacy by Gavi and Alliance partners, but perhaps outside the focus of Gavi's investments.

<sup>&</sup>lt;sup>g</sup> See FCE1 2016 report for a full description of the 'constraints analysis' structural equation modeling of linked household and health facility survey data.

Figure 11. Estimated penta3 coverage if various intent, community access, and facility readiness constraints were removed (Zambia).



**Source**: Based on linked household survey and health facility survey data from FCE1. See methods box for more information. From Phillips (2017).

Through the lens of the FCE, this phase seeks to identify the drivers of coverage and equity, how progress is being made to address them, and the contribution of Gavi towards improvements. As noted elsewhere, the condensed reporting period reflected in this report limited the FCE2 teams' ability to answer these questions. However, year 2 of FCE2 will contribute additional data and analyses to answer what is driving differences in coverage and how they are being addressed. One hypothesis teams will explore at district, facility, and community levels is how the accumulation of multiple constraints or bottlenecks affects coverage or missed opportunities for vaccination. Considered more positively, how are high-performing districts able to remove many of the most significant constraints to vaccination? We test the hypothesis that the accumulation of constraints drives missed opportunities for vaccination below.

Reanalysis of the linked data from household and health facility surveys from Uganda illustrates that as intent, access, and facility-readiness constraints accumulate, they are associated with declining levels of coverage. Addressing only one of these bottlenecks will help, but targeting communities with multiple bottlenecks related to intent, access, and facility-readiness will optimize impact. For instance, the first row of Figure 12 shows children at two ends of the spectrum on "previous failure to obtain vaccine," a facility-readiness constraint which also impacts future intention. While children who experienced a previous failed attempt have lower penta3 coverage than those who did not, the difference between them is small. On the other hand, when we compare children who have multiple constraints versus those who have none, we observe a stark difference in coverage between those subgroups. The last row shows the example of knowledge, distance, and community coverage

constraints. Coverage of penta3 is 64% among children whose caregiver had low knowledge of vaccine purpose (intent to vaccinate), who live furthest from a facility (access), and who live in a community with low coverage (intent, access, and facility readiness). This is compared to 81% penta3 coverage among children with none of those constraints. These findings suggest that the inequitable distribution of accessible, high-quality and responsive health systems is driving a significant proportion of inequalities in vaccine coverage in Uganda. As discussed in Section 3, "Sustainability of national immunization programs" (Finding 3.1), this finding has resource considerations which, if not addressed, will further entrench this inequity.

#### Methods

Figure 12 is a descriptive analysis using data from household and health facility surveys linked on the individual child. We compared children at opposite ends of the spectrum for a set of covariates we knew to be statistically significant in explaining penta3 coverage in Uganda. The original data and the structural equation model used to identify which covariates are most significant are described in the methods annex.

Unfortunately, very few of the indicators commonly used to measure and monitor vaccine coverage inequalities are capable of identifying *which* children are under vaccinated and *why*. Table 6 summarizes equity indicators recommended by Gavi and currently in use in FCE2 countries; the vast majority still depend on household survey data and overlook access and supply-side drivers. Uganda's 2016 equity assessment focused on social and/or economic characteristics associated with under vaccination to inform their Reach Every Child strategy and did not include supply-side or health systems barriers despite having access to FCE1 data and evidence. Zambia is in the process of planning an equity assessment to identify the underlying factors of unequal immunization coverage but also plan to focus on those that are structural, cultural, and socioeconomic. To overcome some of the conceptual barriers around *why* inequalities occur, we recommend Gavi explore updates to its Grant Performance Framework (GPF) indicators and Joint Appraisal (JA) analysis guidance based on a more holistic theory of the drivers of inequitable coverage.

Category Previous failure to obtain\*\*\* ■ Greatest barriers Knows vaccine purpose\*\* ■ Fewest barriers Distance to facility\* Coverage in community Perceived cost\* Coverage is compared between population subgroups with barriers to immunization. Groups are defined by all selected characteristics (see checkboxes) as having the fewest or greatest barriers. Coverage is then computed for the selected groups. One (1) barrier to immunization V  $\checkmark$ **V** with low coverage Interaction between two (2) barriers to immunization **V** ๔ **♂** and perceives the cost of vaccination to be high Interaction between three (3) barriers to immunization V. বেরে ব low coverage, is far from a facility, and knows one or

Figure 12. Drivers of inequalities in penta3 coverage in Uganda.

Source: Linked household survey data and health facility survey data from Full Country Evaluation phase 1: 2016. **Notes**: Individuals in the "fewest" barriers subgroup are in the low barrier group for all selected variables; conversely, "greatest" barrier subgroup members have high barriers for all selected variables. Variables are categorized into "high" or "low" barrier by the following subgroups:
\* continuous—top quintile vs. bottom quintile.

Penta3 Coverage

75%

80%

85%

60%

70%

65%

<sup>\*\*</sup> categorical—knows one or less purposes of vaccines vs. knows more than one purpose of vaccines.

<sup>\*\*\*</sup> categorical—has had a failed attempt vs. has not had a failed attempt.

Table 6. Vaccine equity indicators currently reported by Gavi and FCE2 countries.

INDICATOR (SOURCE)	MOZ	UGA	ZAM			
Indicators to help identify where children are under vaccinated						
% districts <u>&gt;</u> 80% penta3 (GPF indicator, cMYP)	х	х	х			
Coverage trends in identified / suspected vulnerable groups including ethnic, religious, slums, refugees, internally displaced, etc. (JA analysis guidance)		х				
"Priority" provinces or districts with low coverage (HSS application; GPF indicator)	х		х			
High-risk communities associated with immunization inequities: tribe, urban/rural, and proximity to the facility (Uganda Equity Assessment, 2016)		х				
Indicators to help identify why children are under v	accinated	j				
Inequality difference and/or ratio. Disaggregated per: Household economic status (quintile 5–quintile 1), mother's education (secondary school or higher–no education), place of residence (urban–rural), sex (male–female) (JA analysis guidance)		х	х			
In addition to above, place of delivery for the child, religion, mother's age (Uganda Equity Assessment, 2016)		х				
Vulnerable groups: Coverage trends in identified / suspected vulnerable groups (ethnic, religious, slums, refugees, internally displaced, etc.) (JA analysis guidance)		x				
Gender-related barriers: Qualitative analysis of gender related barriers for immunization from available gender related studies and KAP surveys; trend analysis of sex disaggregated data on coverage from surveys or electronic immunization registry when available; subnational disaggregation highly desirable (JA analysis guidance)						
Percentage gap in penta3 coverage between the highest and lowest socioeconomic quintiles (cMYP)			х			
Number of high-risk communities identified for accelerated routine immunization program (cMYP)			х			
Use of <i>material deprivation index</i> to guide the allocation of health grants to districts (Zambia's National Health Strategic Plan)			х			

Indicators must be measurable, hence the historical reliance on indicators from household surveys which have high internal validity and are consistent across countries. With improvements in administrative data, particularly individual-level data systems, increasing possibilities exist to measure

and monitor which children are under vaccinated and associations with drivers (why) in near real-time and at increased geographic granularity. More timely, relevant, and geographically granular data improve health care workers', managers', and decision-makers' ability to act to address under vaccination. Table 7 summarizes issues with existing measurement approaches and data sources.

Table 7. Comparison of household survey, HMIS, and individual-level data for identifying and monitoring vaccine coverage inequalities.

ISSUE	SURVEYS	AGGREGATE ADMINISTRATIVE DATA (HMIS)	INDIVIDUAL-LEVEL ADMINISTRATIVE DATA
Sample	Usually limited, around 1,000 children aged 12–23 months	Potentially includes all children who are vaccinated	Potentially includes all children who are vaccinated or registered at birth
Representativeness	Representative, probability sample (if population- / community-based)	Depends on the coverage of HMIS, on completeness of reporting, and on availability of accurate denominators	Depends on the coverage of registry and on completeness of reporting
Periodicity	Typically, every 4–5 years for DHS and MICS; may be more frequent for smaller immunization surveys	Ongoing, although there are lag times in reporting cycles	Ongoing, may be as frequent as daily in a fully digital system
Data on drivers of coverage inequalities (why inequalities exist)	Usually includes information on wealth, maternal education, sex of child, ethnic group, residence (large geographical areas); does not typically include information on access or health systems performance	Information for small geographical units, age and possibly sex of the child; information for facility performance indicators (depending on system) and supply and cold chain indicators if integrated with LMIS; no information on wealth, education, or ethnicity	Information for individuals, including age, sex, place of residence, maternal characteristics, other health status and careseeking indicators; can include facility, operations, cold chain and supply chain indicators if integrated with other systems
Data quality	Usually highly controlled, but when vaccine cards are not available may depend on maternal recall (the validity of	Routine data entry, often poorly standardized; accurate denominators can be difficult to obtain	Routine standardized data entry; user/system error, data cleaning, and de- duplication of records can be challenging

SECTION 1. COVERAGE AND EQUITY DRIVERS AND TRENDS IN FCE COUNTRIES

ISSUE	SURVEYS	AGGREGATE ADMINISTRATIVE DATA (HMIS)	INDIVIDUAL-LEVEL ADMINISTRATIVE DATA
	which can be questioned)		
Ease of analysis	Databases are standardized and easy to analyze; few missing data	Databases are often complex, often with many missing data due to incomplete reporting; embedded dashboards (e.g., DHIS2) have improved access to data and ease of analysis	Databases are complex and require developer assistance to extract data; trained staff needed to analyze data; missing data are limited; embedded reports have improved access to aggregate data
Potential for ecological analyses	Limited because of the small number of children aged 12–23 months in each cluster/geographic unit	Strong, given the large number of children in each unit and the possibility of linking coverage with data on poverty, ethnicity, etc.	Strong, given the individual-level nature of the data and potential for including individual-level characteristics in the record
Potential for feedback to managers and health workers	Limited because results only available every few years, but have the potential to help validate administrative data	Real-time feedback is possible, although there is often lag time before a record is finalized; feedback is aggregated to the district or facility level	Real-time feedback is possible; feedback can help identify individual children to target

 $\textbf{Source:} \ A dapted \ from \ Victora \ and \ Ryman \ (draft) \ paper \ to \ UNICEF \ Equity \ Reference \ Group.^{20}$   $\textbf{Notes:} \ Individual - level \ or \ administrative \ data \ obtained \ from \ immunization \ registries \ or \ electronic \ medical \ records.$ 

Improved measurement and monitoring is not out of reach. In Zambia, for example, the government has requested HSS and TCA funds to support national scale-up of their electronic immunization registry, which includes patient-level demographic and health characteristics and access-related variables and is linked to supply data at the facility level.

#### Current efforts to address coverage inequalities

Section 2 of this report describes Gavi guidance provided to countries to support them in addressing coverage inequalities. In this current report, we provide an overview of FCE2 countries' activities but will require the full data collection in Year 2 to answer how activities contribute to improved coverage and equity.

FCE2 countries employ a range of intervention strategies funded through HSS, TCA, domestic programs and other external assistance to improve coverage in low-performing areas or in the absence of geographic targeting: community outreach (all countries), mobile brigades (Mozambique),

Supplementary Immunization Activities and campaigns (all countries), and child health weeks (Mozambique, Uganda). Limited evidence exists on the effectiveness of these strategies in real-world settings, and particularly under conditions of unpredictable resources or suboptimal implementation fidelity.<sup>21</sup> Further, design and implementation of these strategies typically occurs with minimal consideration of how they fit into a theory of change to address specific causes of under vaccination. While HSS applications require a results framework, content analysis of HSS grants during FCE1 suggested limitations in the design of HSS grants in part due to suboptimal bottleneck assessments and inadequate technical capacity.<sup>6</sup>

#### PROPOSED HSS ACTIVITIES TO ADDRESS COVERAGE AND EQUITY

We reviewed HSS grant proposals, awards, budgets, and workplans from FCE2 countries and found that roughly half of all proposed activities have the potential to affect vaccine coverage and equity in FCE countries directly. The other half may have an indirect impact on improving coverage and equity through capacity building, streamlining of processes, procuring required resources, and improving the overall functionality of the health system.

- > Of the 36 activities proposed in the HSS2 proposal for Uganda, 13 have a more immediate and direct impact on improving coverage and equity through increased and equitable access to immunization services through EPI and civil society organizations (CSOs).
- Of the 71 activities proposed in the HSS2 proposal for Zambia, 47 have a more immediate and direct impact on building capacity of EPI staff and CSOs, improving service delivery through vehicle procurement, training EPI managers and health workers in the Reach Every District/Reach Every Child (RED/REC) strategy to improve coverage and equity.
- > Of the 15 items listed in the 2017 Mozambique HSS workplan and budget, 8 have a more immediate and direct impact improving coverage and equity through strengthening the quality and accountability of the health workforce, supporting social mobilization of CSOs, and investing in service delivery at all levels of the health system.

The table below includes a sample of the types of activities included in HSS proposals and budgets that have the potential to directly affect coverage and equity. However, this assessment does not account for the resources allocated toward each of those activities or the effectiveness of their implementation.

Table 8. Sample of coverage and equity activities in HSS proposals and budgets across FCE countries

	SERVICE DELIVERY	CAPACITY BUILDING AND HEALTH WORKFORCE	STRENGTHENING CSO CAPACITY AND ENGAGEMENT
Mozambique	Implement outreach  Scale up community engagement and participation mechanisms  Management capacity building and strengthening of central-level EPI	Training for vaccine delivery Improve and expand supportive supervision	EPI communication strategy Advocacy and social mobilization
Uganda	Strengthen outreach through micro- planning, vehicle procurement, and data collection to inform EPI performance	Train health workers on RED/REC strategy  Improve and updated health training institutions on EPI curriculum  Strengthen supportive supervision of DHOs and health workers by EPI Programme	Fund CSOs and CHWs to conduct community mobilization and registration  Map private health facilities to include in EPI communication and HMIS system  Establish Community Based Health Information System (CBHIS) and train users
Zambia	Improve and increase outreach through vehicle procurement and fuel to reach disparate and remote areas	Train trainers and health works in RED/REC strategy and implementation	Support CSOs to conduct community mobilization and sensitization on immunization

The potential equity impact (and value for money) of these activities could be increased through geographic or population-based targeting, which is encouraged in Gavi HSS guidance. Mozambique and Zambia targeted their HSS funds to priority districts (Zambia) and provinces (Mozambique). As reported in FCE1, the Government of Zambia's decision to target HSS to five neighboring districts in northern Zambia (with average DPT3 coverage of 74.6% in 2017; DHIS2) was driven by a combination of coverage data and other factors, including coverage of other partners or resources and clustering of districts in one region for implementation purposes. Despite using data to identify four "priority" (low coverage) provinces of HSS funds in Mozambique, the MOH disbursed HSS funds to all provinces in

2016 and 2017, with the priority provinces receiving smaller shares based on need (Figure 12; priority provinces are indicated with a star). One illuminating explanation for this is that, in Mozambique's bottom-up planning and budgeting system, lower-performing provinces have less capacity to adequately plan and budget for the use of HSS funds, in turn reinforcing their low performance and inequities.

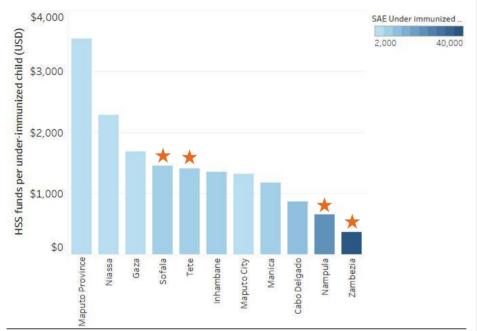


Figure 13. Provincial HSS budget per under vaccinated child in target population, Mozambique 2017.

**Source**: DHIS-2 data from Mozambique: 2017, HSS disbursed funds data from Mozambique: 2017, small area estimates of coverage from Mozambique.

**Notes:** The graphs show the amount of HSS funding per under vaccinated child. "Under vaccinated child" is calculated using provincial population estimates for the infant cohort and small area estimates of vaccine coverage. The percentage of under vaccinated children is multiplied against the total age cohort to get an estimate of the total number of under vaccinated children. Per capita expenditures are calculated accordingly. The shading on the bar chart indicates the total estimate of under vaccinated children in a province. Provinces prioritized for HSS funding are indicated with stars: Sofala, Tete, Nampula, and Zambezia.

#### **BOTTLENECKS TO COVERAGE AND EQUITY AND RELATED TCA ACTIVITIES**

A review of the 2017 TCA plans for FCE2 countries indicates that TCA is becoming increasingly effective at filling resource gaps to address bottlenecks to coverage and equity. As a Tier 1 country Uganda receives more TCA support than Mozambique, with Zambia receiving the least. The extent to which these activities reduce inequalities will depend in large part on how they are designed and targeted to context-specific drivers of under vaccination.

Table 9. Highlighted coverage and equity-related TCA activities across FCE countries (2017).

	DEMAND GENERATION	SERVICE DELIVERY	LMC
Mozambique	UNICEF: communication for immunization strategy development and advocacy, RED/REC support (capacity building) and implementation	JSI/VillageReach: TA for supply chain planning and coordination, implement routine monitoring and reporting, and expand use of logistics management software	UNICEF: provide technical support on immunization outreaches and campaigns
Uganda	UNICEF: develop HPV communications plan, update UNEPI communication strategy and district-level communications plans, create and distribute communications materials on routine immunization	UNICEF: strengthening the immunization supply chain, cold chain maintenance and repair, and development logistics management system.	UNICEF: support the update of the cMYP, train district health team members and EPI managers for immunization and supportive supervision, bi-annual review meetings with immunization officers at district levels, support RED/REC implementation (equity assessment)  WHO: support districts in development of annual workplan, support development of 2016 JA, support RED/REC implementation (microplanning training and support, update RED/REC guidelines, skills-building)
Zambia		UNICEF: support in the use of Stock Management Tools at national and subnational level, and support the effective use of logistics data	WHO: support NITAG meetings, Data Quality Self- Assessment, TA for outreaching and campaigns

#### Recommendations

Addressing coverage inequalities requires a staged approach to first identify which children are under vaccinated, then understand why they are under vaccinated (what are the drivers and bottlenecks), and finally design and implement solutions that address the root causes of under vaccination. Some steps of this process can be acted on now, while others require further study:

- Study further: Gavi and partners should expand or modify the current list of equity indicators and data sources to include all potential causes of under vaccination as informed by the FCE2 TOC. Indicators should enable timely, granular, and actionable decision-making, particularly at the lowest levels of the health system.
- Continue doing: As part of the Data SFA or HSS funding, Gavi, partners, and country stakeholders should continue to invest in strengthening existing data quality and data systems with a focus on integrating administrative vaccine data with supply chain / logistics and health system performance data.
- Continue doing: Gavi and Alliance partners should consider the costs and benefits of introducing data systems that capture individual-level data on vaccine service delivery (e.g., an electronic immunization registry or electronic medical record) in order to provide granular data on which children to target to close the coverage gap.
- Study further: As a resource for countries and an input into HSS and JA processes, Gavi and partners should synthesize the evidence on how to most effectively address common, underlying bottlenecks or causes of inequalities. This could lead to the development and use of decision-support tools to inform the design and targeting of the most cost-effective and high-impact interventions to address the root causes of inequitable coverage.

#### Next steps for FCE2 year 2



- Implement DCSs and other subnational data collection (Mozambique and Zambia) and ongoing analysis of existing data (all countries) to continue to estimate the drivers of coverage and the root causes of coverage inequalities to help those countries design and target HSS and other investments and to identify improved equity indicators.
- >>> In Zambia, request access to Zambia's patient-level electronic registry data to assess whether a routine patient-level data source could help in identifying which children are under vaccinated and why.
- >>> In Mozambique, focus on evaluating the implementation of HSS and the contribution of HSS to coverage (EQ4).

#### **Summary**

Despite tremendous global progress in improving access to and coverage of vaccines, progress in Mozambique, Uganda, and Zambia is not equitable, nor is it inevitable. In Mozambique, coverage of many antigens increased in recent years, but coverage declined in Uganda in 2017 and is stagnating for most antigens in Zambia. This is a "wicked problem" with a set of complex, interrelated drivers described in the FCE2 TOC. The underlying causes of inequalities are driven by a range of behavioral, access-related, and facility-readiness determinants that are not currently integrated into a single timely measurement approach. While there is a general awareness and political commitment to equity in FCE countries, measurement challenges have constrained effective action to address vaccine inequalities and their underlying causes. This can lead to inexact targeting strategies for addressing health system bottlenecks to address inequalities.

The experience in FCE countries also presents potential solutions to reach the unimmunized children. We observe the important role of strong LMC, particularly at the district level, to support activities to increase the efficiency and effectiveness of the immunization program. We observe that effective and well-coordinated partners have accelerated, and can continue to accelerate, progress toward equitable coverage and that political will exists to do so. In year 2 of FCE2 we will continue to measure the contribution of the drivers in the FCE2 TOC with a focus on the application of mixed methods at the subnational level; this can identify barriers to address, as well as opportunities to advance.

# SECTION 2. The role of the Gavi Secretariat written guidance and tools in supporting countries to improve coverage and equity

EQ2: Whether, how, and why is Gavi support contributing to increased vaccination coverage and equity? (cross-country)

Finding 2.1

The Gavi Secretariat and Alliance's emphasis and approach to coverage and equity has shifted over time to increasingly focus on within-country inequities in utilization of immunization services. Based on a review of Gavi policies, guidance, and grant frameworks the FCE2 found:

- > Guidance on the importance of identifying equity bottlenecks and how to identify them has improved in Gavi documents since 2016.
- > The Gavi Secretariat does not consider itself a technical agency but has increasingly provided linkages to other resources on how to improve coverage and equity.
- > However, Gavi Secretariat guidance is still not specific and actionable enough to identify the most important underlying causes of poor coverage and inequalities.

ROBUSTNESS RANKING

This finding is from the FCE2's review of select Gavi policy and guidance documents from 2016 to the presenth, based on a predefined set of evaluation criteria. It could be strengthened by observing guidance provided by senior country managers (SCMs) and other Gavi program staff directly to national EPI stakeholders. This finding could have also been strengthened through reviewing Alliance partner guidance and technical support documents to provide a holistic view of the Gavi Alliance's approach to coverage and equity.

<sup>&</sup>lt;sup>h</sup> The FCE team reviewed Partner Engagement Framework, Country Engagement Framework, HSIS Framework, Grant Performance Framework, Fragility Policy, Joint Appraisal suite of guidance (including analysis guidance and reporting templates), the CCEOP suite of guidance (application materials, technical and target requirements, and technology guides), and the 2018 Application guidelines for all types of Gavi support.

#### SECTION 2. THE ROLE OF GAVI GUIDANCE IN SUPPORTING COUNTRIES TO IMPROVE COVERAGE AND EQUITY

Gavi-eligible countries routinely use and rely on Gavi policy, frameworks, and tools to design and implement HSS, NVI, and other programs aimed at increasing equitable coverage, which in turn, has a direct impact on implementation and meeting country's and Gavi's coverage and equity objectives.

Gavi has made significant reforms to its business model during the current strategic period (2016 to 2020), many of which have been effective at raising the issue of coverage and equity on global and national policy agendas. This section describes those successes but notes that, as seen in Section 1, actual progress in FCE2 countries remains suboptimal. Previous year's FCE reports have noted the delayed implementation of HSS programs, resulting in suboptimal impact on coverage and equity indicators. The result is that some of Gavi's largest non-vaccine investments—particularly HSS—seem to be yielding suboptimal impact.

While Gavi recognized that reaching the last mile would require significant adjustments to how it does business, implementation of change has not always occurred smoothly or quickly. The following section identifies the lack of clear and easily accessible written guidance as a bottleneck to improving coverage and equity in FCE countries. Additionally, the lack of alignment across Gavi guidance and guidance that does not sufficiently provide technical assistance in identifying bottlenecks to coverage and equity, access to Gavi and Alliance partner technical resources, and establishes a monitoring and learning framework as a challenge to improving coverage and equity in FCE and Gavi eligible countries.

Our analysis was conducted during the FCE2 data collection period ending in April 2018. Our analysis of Gavi Phase 4 documents centers on their alignment with the coverage and equity goals outlined in the 2016-2020 strategy. Knowing where to access the right Gavi tools and resources has been a challenge in FCE countries, with countries often using outdated Gavi materials and guidance in their applications or reviews (as stated in previous FCE reports). In some cases, SCMs often serve as the main source of Gavi guidance for countries applying for and renewing support, which can create bottlenecks and inefficiencies in providing technical feedback and grant support. In year 2, the FCE team will continue to monitor and analyze the impact of SCMs and Gavi's strategic focus areas on coverage and equity.

GAVI'S CHANGING APPROACH TO COVERAGE AND EQUITY (PHASES 1 THROUGH 3, 2000-2015)

Gavi has responded to shifts in the global development discourse, which has moved from a comparison between "developed" and "developing" countries and a geographic approach to encompass a more people-centric approach, focusing on the marginalized and underserved wherever they live. Over time, Gavi has increasingly sought to address within-country inequities in utilization of immunization services in Gavi countries. Improvements in data systems and data quality have allowed for Gavi to take a more targeted approach in addressing coverage and equity at a subnational level in phases 3 and 4.

For much of Gavi's first two phases of operations, within-country equity considerations were implicit in discussions on raising national coverage levels and equity improvements were seen as an added benefit of raising national coverage (100% coverage implies zero inequities within countries). In phase 1, equity was not explicitly discussed in formal policies, application guidance, or Board meetings. Gavi continued to focus on between-country inequities in its phase 2 strategy, focusing on increasing access to new vaccines and immunization services. The phase 3 strategy was explicit and consistent in

**Commented [GN1]:** Revisit – I tried to rewrite this but wasn't sure of exactly what we were trying to convey here.

articulating the focus on within-country equity in operating principles, strategic objectives, and strategic goal target indicators. As part of Gavi's phase 3 strategy, Gavi supported WHO to lead TA efforts to improve equity in access to immunization services in Gavi countries with DPT3 coverage below 70% and to develop improvement plans.

#### Key takeaways to consider are:

- Access to new and underutilized vaccines. Phases 1 through 3 of Gavi operations have been characterized by a drive to address the inequities in access to vaccines/antigens between higherincome (ineligible) countries and lower-income (Gavi-eligible) countries.
- Access to and allocation of Gavi resources. In terms of resource allocation mechanics and program policies, Gavi has focused almost exclusively on between-country equity concerns. In most instances, policies dealing with access to Gavi resources have been driven by vertical equity concerns: they sought to apportion greater resourcing to greater needs. However, the measures of need have often differed from policy to policy.

#### **COVERAGE AND EQUITY ALIGNMENT IN PHASE 4 (2016-2020)**

In 2015, Gavi released the 2016–2020 strategy outlining four strategic goals: vaccines, health systems, sustainability, and market shaping. The language around vaccines and health systems shifted to include more language related to equity and its dimensions: "We support developing countries to accelerate vaccine coverage and make it more equitable [...] We work to remove barriers to immunization, particularly those related to wealth, geography and gender, to make sure we reach all children, even in the most fragile countries and communities." While there is no explicit focus in the strategy on between- or within-country equity, there is specific mention of achieving equity of coverage and barriers as distributed by geography, wealth quintile, education status of mothers, and fragile-state status. To measure progress toward equity, Gavi proposed at the June 2015 Board Meeting that indicators capturing geographic distribution, wealth quintile distribution, and distribution by education status of mother be used. While these definitions include language that might help to address within-country equity concerns, the use of these indicators will be to compare equity across Gavi countries.

As noted in Section 1 above, when we consider data on both demand- and supply-side drivers, household income, per se, does not drive coverage inequalities. Access- and facility-related variables seem more important than the socioeconomic characteristics normally measured in household surveys. While we recognize that not all Gavi countries have data on the supply- and demand-side drivers, frameworks and other tools to inform identification of bottlenecks and targeting strategies should consider a holistic range of drivers. Year 2 aims to further distill timely and available indicators for monitoring inequalities.

Gavi's policies, guidance, and grant frameworks have made significant progress toward focusing more explicitly on coverage and equity as strategic outcomes. Nearly all policies and frameworks developed during the current strategic period clarify improving coverage and equity as an objective of the policy, aligning various frameworks and policies with the overall 2016–2020 strategy. The updated

language also encourages countries to demonstrate *how* they will use Gavi funds to achieve coverage and equity targets.

Based on the evaluation rubric (Table 10), the FCE team systematically identified and evaluated Gavi policies that either cover or are closely related to coverage and equity. The policies were then assigned to a category based on their performance against the evaluation criteria as seen in Table 11. Based on the evaluation rubric, the FCE team systematically identified and evaluated Gavi policies that either cover or are closely related to coverage and equity. The policies were then assigned to a category based on their performance against the evaluation criteria as seen in Table 10.

Table 10. Coverage and equity rubric for Gavi policy documents.

CRITERIA	EXCELLENT	MODERATE	POOR
Has strategic focus on coverage and equity	Coverage and equity identified as strategic objective, provides additional explanation and resources	Identifies the importance of coverage and equity, but not a strategic objective of document	No specific mention of equity or its role as an objective, focus, or policy goal
Identifies challenges or bottlenecks	Clearly describes and identifies challenges or bottlenecks to coverage and equity; includes additional resources	Identifies challenges or bottlenecks to coverage and equity but does not provide additional explanation or resources	Does not identify challenges or bottlenecks to coverage and equity
Implements or achieves a solution	Provides documentation on implementing a solution to improve coverage and equity and additional guidance	Provides documentation on implementing a solution to improve coverage and equity with no additional guidance	Does not provide guidance on implementing a solution to improve coverage and equity
Accesses additional technical resources	Provides access or directly links to additional technical resources or guidance from Alliance partners	Mentions additional technical resources but does not provide additional guidance or resources	Does not provide or mention access to additional guidance or resources
Includes monitoring and learning components	Document provides details on monitoring progress toward coverage and equity (C&E) objectives/goals and routine learning/adapting based on results	Document provides little detail on monitoring progress toward C&E objectives and routine learning/adapting based on results, or provides details on monitoring, learning, and adapting but is not specific to C&E	Document does not cover monitoring of C&E objectives (or general ones) or routine learning opportunities

Table 11. Performance of Gavi policies, guidance, and tools based on the coverage and equity rubric

	<b>PEF</b> (2016)	CEF (2016)	HSIS (2016)	<b>GPF</b> (2016)	Fragility Policy (2017)	JA Guidance (2017)	CCEOP (2017)	Appli- cation Guidelines (2018)
Strategic focus on equity								
Identified challenges, constraints or bottlenecks								
Provides guidance on implementing or achieving solution								
Provides access or links to further technical resources								
Includes monitoring and learning components								

#### Identification of equity bottlenecks and solutions

Guidance on the importance of identifying equity bottlenecks and how to identify them has improved in Gavi documents since 2016. In the Country Engagement Framework (CEF), countries must indicate how they plan to address bottlenecks using Gavi funds. The JA allows countries an opportunity to identify coverage and equity bottlenecks, presenting it to Gavi as a check on grant implementation and progress toward coverage and equity goals. The goal of Gavi's Health System and Immunization Strengthening (HSIS) grants is to improve coverage and equity, which is identified in the framework as a main health system bottleneck that can be overcome through Gavi support.

The 2017 JA template requires countries to provide an overview of the coverage and equity situation in their country since the last JA update or full appraisal. Included in this overview, countries must provide an analysis of the coverage and equity situation across geographical areas, populations, and communities, aligning with Gavi indicators including maternal education, gender, household income, and place of residence. Countries are also asked to highlight the key drivers of low levels of coverage and equity from the previous section.

#### Access to technical resources

Gavi does not consider itself a technical agency but has increasingly provided linkages to other technical resources on how to improve coverage and equity. However, reference to these technical resources in documents and guidance remains inconsistent and lacks specificity. Guidance encourages countries to seek out technical partners or SCMs but provides little detail or transparency on the external engagement process. Beyond policy creation and program, application, and eligibility guidelines, Gavi does not provide much additional TA on carrying out their guidance related to equity, instead relying heavily on their Alliance partners (WHO, UNICEF). While providing TA directly to countries is the mission of SCMs, previous FCE reports have found that there is variable in the capacity of SCMs to help design investments to attain coverage and equity objectives.

Within the CEF, the Programme Support Rationale (PSR) provides a country-specific rationale for requesting Gavi support and requires countries to address systems-related bottlenecks to sustainably improve coverage and equity, drawing information from a number of sources. Through an iterative process, Gavi and Alliance partners provide feedback on drafts. The CEF itself provides access to additional information available in the PSR template and guidance on targeting investments.

The JA is the main venue for countries to identify their coverage and equity-related challenges to be addressed by the TCA component of the PEF. The PEF management team then approves TCA country-specific requests identified through the JA. Effective implementation of this process could increase countries' access to high-impact and innovative solutions; however, it is not clear that TCA is improving the effectiveness or sustainability of efforts to address coverage and equity. An important finding related to coverage and equity from the Deloitte TCA evaluation 16 was concerns around TCA quality and sustainability at subnational levels—where coverage and equity bottlenecks exist.

Gavi identifies itself as a global policy- and market-shaping alliance that creates policies, frameworks, and guidance, rather than an agency with deep technical capacity. As a result, Gavi leans heavily on Alliance partners like WHO and UNICEF to provide most of the direct TA based on Gavi guidance. The onus on coverage and equity therefore falls to the national government and the TA partners to ensure equitable distribution of Gavi resources within countries. Gavi's current structure limits the organization from providing a full suite of financial and technical support to countries who are or have applied for funding.

#### Monitoring, learning, and adapting

Gavi documents should either provide details on monitoring progress toward coverage and equity objectives or goals and routine learning and adapting based on results or direct users to a single guideline or tool around monitoring progress toward coverage and equity goals (much like the GPF). The HSIS, New Vaccine Support (NVS), and Cold Chain Equipment Optimization Platform (CCEOP) frameworks all mention monitoring, learning, and adapting the frameworks or grant implementations through the GPF. The GPF monitors grant performance during implementation based on a previously agreed upon set of core and tailored indicators. Several of the core outcome indicators are focused specifically on coverage and equity but, as noted in Section 1, are often not fit-for-purpose for assessing whether progress is being made toward addressing the causes of inequalities or changes in equitable coverage at a granular, operational level. Tailored outcome indicators may be included to reflect country-specific circumstances or grant objectives, but FCE2 countries do not currently include any in their GPFs.

The PEF, as part of a new accountability structure for partners, created a new set of strategy indicators, deliverables for each partner funded under the PEF, and Alliance key performance indicators that are country-specific in the hopes of regularly monitoring the outcomes and impacts of Gavi support in the respective country. The CEF uses differentiating review mechanisms with flexible timelines to monitor progress while increasing the engagement of Alliance partners in supporting country-level grant implementation and routine monitoring to better deliver results and enhance accountability. The CEF also includes an annual review to monitor and report progress. It is unclear at this point if these frameworks intend to monitor overall financial and programmatic progress toward grant objectives, or if coverage and equity are a main focal point.

#### **Recommendations**

As introduced in Section 1, the following recommendations, if reflected in Gavi's guidance documents, would address the gaps identified in the above policy analysis:

- Study further: As recommended in Section 1, Gavi and partners should expand or modify the current list of equity indicators and data sources to include all potential causes of under vaccination as informed by the FCE2 TOC. Indicators should enable timely, granular, and actionable decision-making, particularly at the lowest levels of the health system, requiring further consideration and weighing the trade-offs against Gavi's current approach to support the strengthening of country data systems, availability, quality, and use.
- Study further: As recommended in Section 1, as a resource for countries and an input into HSS and JA processes, Gavi and partners should synthesize the evidence on how to most effectively address common, underlying bottlenecks or causes of inequalities. This could lead to the development and use of decision-support tools to inform the design and targeting of the most cost-effective and high-impact interventions to address the root causes of inequitable coverage:
  - > As funders, Gavi could play a stronger role in ensuring the activities they fund are technically and operationally sound, engaging in ongoing monitoring and adaptive management, and thereby maximizing the value for money of Gavi's investments.
  - > More specifically, Gavi should consistently provide links to this technical guidance in relevant Gavi policies, documents, and frameworks to make it easy for countries to access the appropriate resources.

#### Next steps for FCE2 year 2



>>> Evaluate the implementation of JA processes in 2018, with a focus on how the tools and guidance provided by Gavi, including the GPF, influence discussion and decisions related to identifying which children remain underimmunized and why, and how best to address the identified bottlenecks (EQ17). Continue to monitor and analyze the implementation and effectiveness of strategies in place in FCE countries to improve coverage and equity. In year 2, the FCE team will continue to monitor and analyze the impact of SCMs and Gavi's strategic focus areas on coverage and equity.

#### **CASE STUDY:**

## Applying the FCE2 TOC to observed data: The case of human papillomavirus (HPV) vaccine

The introduction and routinization of HPV vaccine in FCE countries has faced unique challenges due to a combination of drivers in the TOC. We present HPV vaccine as a case study to illustrate how the influence of drivers in the TOC can apply at different levels by country.

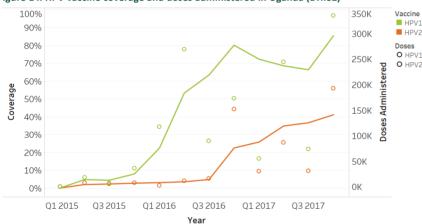


Figure 14. HPV vaccine coverage and doses administered in Uganda (DHIS2)

Source: DHIS-2 data from Uganda: 2014-2017

**Notes**: HPV is primarily administered in Uganda during twice-yearly child health weeks. In order to smooth out these two dramatic spikes for a more annualized portrait, we use a moving average that averages the prior two quarters with the current quarter to estimate coverage and doses administered. Seasonal trends are still observed.

#### Facility- and community-level drivers

In Uganda, low HPV vaccine coverage and high dropout between first and second dose (Figure 14) are mainly due to facility- and community-level drivers. In response to these coverage trends, the Uganda FCE2 team interviewed district and facility staff, teachers, and parents/guardians of girls eligible to receive HPV vaccine in four districts in Uganda (see "District-level case study (DCS) approach in Uganda" text box on page 35. The team found evidence of weaknesses across all three of the principal drivers:

- Related to intent to vaccinate, there was a lack of knowledge and awareness about HPV vaccine
  among girls in the target population and their parents/guardians in the visited districts. Some girls
  did not understand why they needed a second dose of the vaccine, in other cases parents or girls
  believed myths that circulated in the community, and some girls faced peer pressure or bullying
  from boys in school—all of which negatively affected their intent to vaccinate.
- There were also challenges related to community access; in low coverage districts visited, parents/guardians did not know where their children could access the vaccine.

Barriers related to facility readiness included low level of knowledge among health workers on the vaccine (in part due to inadequate training), difficulty tracing girls who received HPV1 (exacerbated by stockouts of HPV cards), and lack of clarity among health workers and teachers on the target age group for HPV (again, likely due to inadequate training). There were also challenges with communication between health workers and teachers and vaccine stockouts.

#### Global-level drivers

In Mozambique and Zambia, HPV vaccine has not been scaled up nationally, in part due to *global supply shortages*. Gavi's vaccine market shaping at the global level aims to increase Gavi-eligible countries' access to new vaccines such as HPV vaccine. The HPV vaccine market-shaping strategy hit a roadblock in June 2017 when "Merck informed Gavi that it had not planned for the level of production required to support the revised HPV strategy in the short term." <sup>22</sup> One potential root cause for the supply shortage was initial low volume of orders for HPV vaccine; as of 2016 the pace of national introductions was slower than expected and may have led Merck to reallocate manufacturing space to other vaccines or markets. Yet, with the opening of Gavi's new HPV 2.0 policy in January 2017, which allows countries to apply to vaccinate multiage cohorts, 12 countries applied by the September application deadline; and now demand outstrips supply. Zambia and Mozambique are both affected by this supply shortage. Zambia submitted an application in September 2017 after approximately two years of discussion following their demonstration project. National EPI stakeholders now anticipate waiting until 2020 for HPV vaccine to be introduced. Mozambique has yet to apply, and while many competing priorities have led to delays in their application, the perception of supply shortages has contributed to a lowered sense of urgency.

#### **Recommendations**

- Conduct intensified social mobilization for HPV vaccine to raise awareness, specifically targeting adolescent girls and boys, all teachers in schools where HPV vaccine is administered, religious leaders, and parents.
- > Strengthen the communication between schools and health workers to facilitate planning and implementation of HPV administration in schools.
- > Involve the Ministry of Education in planning for implementation of HPV vaccine at both national and district levels. 12

 $<sup>^{\</sup>mathrm{i}}$  FCE1 reported that training quality suffered when HPV training was merged with training for measles campaign and supplementary immunization activities to conserve resources.

## **SECTION 3. Sustainability of national immunization programs**

- EQ14. Whether, why, and how are country decisions to apply for new Gavi support taking into account the programmatic and financial sustainability aspects? (cross-country)
- EQ15. What are the drivers to increase financial support for immunization? (cross-country)
- EQ16. To what extent can recent programmatic gains of EPI programs be sustained over time? (cross-country)

Gavi's 2016–2020 strategy emphasizes sustainability as one of four strategic goals. The sustainability goal aims to improve the sustainability of national immunization programs with three objectives:

- 1. Enhance national and subnational political commitment to immunization.
- 2. Ensure appropriate allocation and management of national human and financial resources to immunization through legislative and budgetary means.
- 3. Prepare for sustained performance in immunization after graduation. 25

Through the FCE lens, we focus on two broad categories of sustainability that are essential to achieving overall sustainability of immunization programs and which intersect with Gavi's sustainability objectives: financial and programmatic sustainability.

This section presents preliminary answers and additional hypotheses related to each of the FCE2 sustainability evaluation questions (EQs 14-16). We acknowledge the catalytic role of Gavi and its business model in ensuring that low-income countries can access vaccines. Similar to the shifting agendas around coverage and equity, Gavi's sustainability agenda is increasingly driven by considerations of country needs. Sustainability – like so many issues for complex immunization programs – is fraught with many unknowns. While data and evidence on the costs of vaccination have improved significantly in recent years, we still have a gap pertaining to the children who are never touched by immunization programs. While non-FCE countries are starting to successfully graduate from Gavi support and FCE2 countries are showing interest in early planning for that transition, it remains to be seen whether and how governments will be able to finance their immunization programs.

The economic situation in all three FCE2 countries differs greatly (Table 12). Reflective of this, countries have different Gavi transition statuses, determined by gross national income per capita. Mozambique and Uganda will remain in the "initial self-financing" category for at least the next five years. Zambia is projected to remain in the preparatory transition phase for at least five years when it will move into Gavi's accelerated transition phase. After five years in that phase, Zambia should self-finance 100% of their new vaccines.<sup>23</sup>

#### SECTION 3. SUSTAINABILITY OF NATIONAL IMMUNIZATION PROGRAMS

Table 12. Economic situation for FCE2 countries.

	MOZAMBIQUE	UGANDA	ZAMBIA
Gross National Income per capita, USD, 2016	480	630	1360
Gross Domestic Product per capita growth (annual %) 2016	0.9	1.3	0.5

Source: World Bank. GNI per capita growth not available for all countries.

Despite the different transition stages, there are shared lessons we draw from all three countries. This section of the report highlights common constraints to achieving both programmatic and financial sustainability in FCE2 countries.

#### **IMMUNIZATION PROGRAM COSTS ARE RISING**

- EQ15. What are the drivers to increase financial support for immunization? (cross-country)
- EQ16. To what extent can recent programmatic gains of EPI programs be sustained over time? (cross-country)

#### Finding 3.1

Immunization program expenditures are rising in FCE2 countries, and costs are projected to continue rising due to new vaccine introductions. However, operational costs have not increased substantively which may pose a threat to the sustainability of activities needed to increase immunization equity.

#### ROBUSTNESS RANKING B

This finding is based on comprehensive multiyear plan (cMYP) resource estimates, which are detailed, evidence-based estimates but do not necessarily reflect the actual expenditures for a country. This finding is triangulated with factual data on program expenditures from the JRF, as well as process evaluation data from Uganda and Zambia on challenges with underfunding operational costs. One data gap is the lack of studies that estimate costs for reaching the "fifth child," although we assume it will be more cost intensive based on existing cost data.

#### SECTION 3. SUSTAINABILITY OF NATIONAL IMMUNIZATION PROGRAMS

#### **Definitions**

**Cost**: The value of resources used to produce a good or service. Economists differentiate between financial costs (actual monetary flows on goods and services purchased) and economic costs (the economic value; not what has actually been paid). We use 'cost' where appropriate to denote the economic value of goods and services related to immunization but specify when other definitions supersede ours.

**Vaccine and injection supplies cost**: Total costs include delivery to the country, fees associated with clearing customs, import taxes, and procurement fees, if relevant.<sup>25</sup>

Operational or immunization delivery cost: These costs are extensive and include the cost of health worker time to administer vaccines and costs related to training, planning, management and supervision, social mobilization, surveillance, and monitoring and evaluation. They also include supply chain and logistics costs, including for cold chain equipment and overhead, vehicles, transportation, and personnel time involved in the storage and delivery of vaccines to point-of-care settings. The supply chain has both recurrent and capital costs. Recurrent costs include transportation fuel, use of refrigeration units, salaries, and the maintenance of cold chain equipment (which is frequently underbudgeted in immunization planning). Capital expenditures include the purchase of new trucks, motorcycles, and refrigeration units.<sup>31</sup>

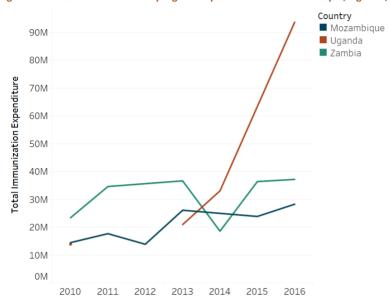
Expenditure: What has been spent or will actually be spent.

**Financing**: A process that includes mobilizing, pooling, and allocating financial resources. As a noun it refers to the financial resources that have been mobilized.

Vaccine program costs have risen dramatically over the last five years in FCE2 countries, due in large part to the introduction of new vaccines. According to country-reported data in JRFs, total expenditures in US dollar on vaccine programs, including vaccine and immunization supplies and operational costs, have risen from 2010 to 2016: from 14 million to 28 million in Mozambique; 13 million to 93 million in Uganda; and from 23 million to 37 million in Zambia (

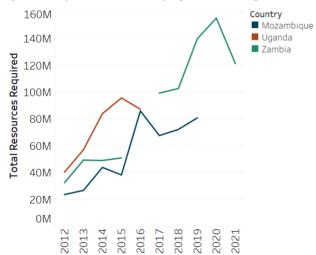
Figure 15). Projected resource requirements outlined in the cMYPs envision a continued increase in immunization program costs: to 121 million by 2021 for Zambia and 80 million by 2019 for Mozambique (Figure 16). Uganda's recently released Financial Sustainability Plan projects required costs ranging from 115 million to 185 million by 2021, depending on the vaccines introduced.<sup>30</sup> Current financing of these program costs is derived from both domestic governments and external development assistance (see Finding 3.2).

Figure 15. Historic immunization program expenditures for Mozambique, Uganda, and Zambia.



Source: Joint-Reporting Framework from Mozambique, Uganda, Zambia: 2010–2016.

Figure 16. Projected immunization-program costs for Uganda, Zambia, and Mozambique.



Source: cMYP's from Uganda, Zambia, and Mozambique: 2012–2021.

**Notes:** Total resources required are based upon cMYP resource estimates which are evidence-based but do not reflect actual expenditures.

The main driver of increases in the required resource envelope is the cost of vaccines and injection supplies, given multiple NVIs (see Figure 17 and Figure 18 for magnitude and relative difference

#### SECTION 3. SUSTAINABILITY OF NATIONAL IMMUNIZATION PROGRAMS

between vaccine costs versus operational/immunization delivery costs). Since 2013, each FCE2 country has introduced four or more new vaccines with more NVIs currently planned. During accelerated transition countries will take on an increasing share of the vaccine costs and upon graduation from Gavi support countries will be responsible for financing 100% of all costs with domestic resources (Finding 3.2).

Cost Category (group) 80M Cold chain
Infrastructure
Labor
Per diems 70M ■ Transport 60M 50M \$ USD 40M 30M 20M 10M OM 2011 2012 2013 2014 2015 2016 Year

Figure 17. Budget categories for projected EPI resource requirements in Uganda.

Source: cMYP from Uganda: 2011-2016.

**Notes**: Budget categories are defined in keeping with the methods outlined in Geng et al.'s Cost Structure of Routine Infant Immunization Services.<sup>26</sup>

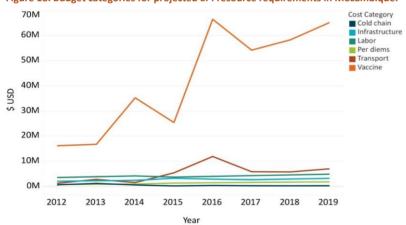


Figure 18. Budget categories for projected EPI resource requirements in Mozambique.

Source: cMYP from Mozambique: 2012-2019.

**Notes:** Budget categories are defined in keeping with the methods outlined in Geng et al.'s Cost Structure of Routine Infant Immunization Services.  $^{26}$ 

#### The value and costs of vaccinating the fifth child: Scaling the U-shaped curve

Focusing now on the costs of delivering immunization services, we hypothesize that not only are many program costs currently under-financed, the incremental cost of immunizing the fifth child is greater than current estimates of the cost of fully vaccinating a child and is currently underestimated in projections and not reflected in expenditures. Recent analyses have shown that vaccination is more cost-effective among the poorest children in a country, owing to the disproportionate health impact that accrues among these children—if vaccinated.<sup>27</sup> Yet at the same time a growing body of microcosting data on the drivers of the variance in immunization costs provides strong theoretical and empirical evidence that the operational activities for targeting hard-to-reach populations—outreach-based delivery, more open days per week at facilities, social mobilization efforts, and higher fraction of costs for management—are all associated with higher costs.<sup>28</sup> Few costing studies have measured the costs of supplementary immunization activities which are another key delivery strategy for reaching un- and under vaccinated children. As we recommend below, additional evidence is needed to build a case for increased and more targeted spending to improve coverage and equity.

Cuts to immunization budgets or challenges in disbursing allocated funds may disproportionately affect children in the hardest-to-reach communities; this demonstrates the interconnections between *financing*, *planning*, *LMC*, and *facility readiness* in the FCE2 TOC and their effects on coverage and equity. In Zambia, comparing actual expenditures to allocated (approved) funds shows that in 2017, all districts received less than 50 percent of their allocated funds (Figure 19). In Uganda during the FCE1, funds were delayed on average 1-2 months, leading to disbursement in the second or last month of the quarter (FCE1, resource tracking study).

Figure 19. Percentage of actual expenditures compared to allocated funds, by district in Zambia.



Notes: Each dot represents one district in Zambia.

While costs for vaccine supplies have dramatically risen, operational and recurrent costs have not commensurately increased. Other operational costs (such as labor, cold chain, or outreaches) have seen relatively moderate budgetary increases. The one notable exception to this trend is transport costs (for outreach, mobile brigades, and vaccine distribution) in Mozambique, which are projected to grow 450 percent from 2012 to 2019, for an absolute increase of \$5.5 million. Stakeholders in Zambia indicate that the limited increase in operational costs is in part due to poor alignment between the EPI and broader national stakeholders on the implications of NVIs and support:

"Sometimes our colleagues in the Ministry of Finance seem to think that funding for operations such as supervision, training, social mobilization, M&E [monitoring and evaluation], which are key functions of the programme are not very important for the survival of the immunization programme. They see immunization budgeting as only about vaccines and cold chain." KII, Zambia.

Considered from another angle, core immunization system functions and activities are underresourced in most FCE2 countries but are necessary for the success of EPI and other vertical health programs.

The Zambia case study box illustrates how budgeting and planning processes in Zambia compound this differentiation between funding for operational costs versus capital vaccine costs.

#### Zambia case study on operational and capital budgeting processes

In Zambia, one of the challenges in securing immunization funds is the lack of integration in planning for recurrent expenditures versus capital expenditures. The Directorate of Public Health develops the budget primarily for vaccine supplies and capital costs, while the Directorate of Public Policy budgets ongoing services funded through the recurrent budget. As a result, the budgeting process does not adequately account for the fact that capital investments initiated with Gavi funding may incur associated operational and recurrent costs. Accordingly, operational and recurrent costs from the Directorate of Public Policy often use an incremental costing approach to increase immunization budgets annually, regardless of projected EPI budgetary needs. The result is that budgetary planning is viewed as being primarily about new vaccine introduction instead of about recurrent operational costs. This process risks leaving districts and facilities short of needed operational funds. To help redress gaps in the current budgeting process, Zambia has been developing the EPI Optimisation Plan to help secure funds from partners for operational projects to address strategic areas for improving immunization program performance.

Through the FCE2, we have observed consequences of the insufficient resources for immunization programs. In Zambia, program expenditures at the lowest levels of the health system are being scaled back in response to funding gaps or disbursement delays. Chronic underfunding of key operational areas has limited the ability of districts to meaningfully microplan, conduct consistent outreach, provide supportive supervision, or print child health cards as detailed in the Zambia FCE2 report.

"In 2017, we received about 10 percent of the operational budget. Activities like supervision, training, mentorship, outreach, printing child health cards, and data forms are not done, especially at province and district levels, because of funds." KII, Zambia.

"Outreach in rural areas is worst affected by lack of funding or erratic disbursement of funds. In rural areas, which rely heavily on outreach, this does have serious consequences for coverage." KII, Zambia.

In Uganda, the gap in HSS funding negatively affected implementation of outreach, microplanning, and supportive supervision. These weakened program operations make it more difficult to reach the fifth child. In Mozambique, MOH budget cuts affected outreach campaigns during the country's national health weeks; however, HSS funds were used to fill budgets gaps for those weeks and ensured that outreach and vaccination campaigns occurred as planned. Ongoing challenges in disbursing HSS funds have undercut the grant's potential to achieve impact in Mozambique. Ensuring quality and performance of the immunization program and its activities is essential for preventing missed opportunities for vaccination – which occur as a result of multiple constraints or barriers (Section 1).

Of course EPI is not uniquely under-resourced compared to other MOH programs and depends on cross-program operational budgets to function. Gavi and global stakeholders are very aware of the need to build political will at all levels to increase immunization financing. There are many fiscal constraints associated with increasing immunization funding, for example, the poor alignment between the EPI and other national stakeholders in Zambia, as mentioned above. We explore additional fiscal constraints further in Finding 3.2.

### Recommendation

Study further: Gavi, partners, and in-country stakeholders should invest in and support microcosting studies to estimate how costs vary across geographic and population subgroups or other drivers of coverage and equity in order to inform resource allocation decisions necessary to improve coverage and equity.

# Next steps for FCE2 year 2



- The Zambia FCE2 team will implement a subnational expenditure-tracking survey and, if possible, will partner with the MOH on the HSS baseline survey to measure how costs vary by subgroups and how this aligns with district-level expenditures and coverage.
- >>> The Zambia FCE2 team will further investigate the root causes of sub-optimal disbursement of immunization operational funds from national to sub-national levels.

# DOMESTIC IMMUNIZATION FINANCING IS NOT KEEPING PACE WITH RISING COSTS

- EQ14. Whether, why, and how are country decisions to apply for new Gavi support taking into account the programmatic and financial sustainability aspects? (cross-country)
- EQ15. What are the drivers to increase financial support for immunization? (cross-country)
- EQ16. To what extent can recent programmatic gains of EPI programs be sustained over time? (cross-country)

Finding 3.2

Financing in FCE2 countries has kept pace with rising costs, primarily due to the contributions of external donors. As countries move towards transition, the confluence of rising costs and stagnating external financing presents a risk to each country's ability to adequately finance their immunization program and ensure their future programmatic and financial sustainability. Uganda has shown promise in planning for long-term sustainability; Zambia is facing increasing financing challenges.

ROBUSTNESS RANKING A

This finding is supported by many data sources, including secondary financing data (all countries), document review (all countries), KIIs (Uganda, Zambia), and published literature (e.g., the EPIC study). Key documents reviewed include cMYPs, JRF indicators, Uganda's financial sustainability plan, and Gavi documents on country co-financing commitments and sustainability and transition. A limitation is that cMYP resource estimates, which are detailed, evidence-based projection estimates, do not reflect the actual expenditures for a country.

In FCE2 countries, the quantity and availability of financial resources for immunization is driven largely by the role of Gavi in financing vaccines as part of its business model. As countries take on an increasing share of financing obligations, their ability to meet overall financing needs, particularly for vaccines, will become questionable. This is illustrated in Figure 20 where Zambia faces the greatest challenges in mobilizing sufficient financial resources, with a stagnation in secured funds. As Zambia is in the preparatory transition phase, they are receiving fewer Gavi funds than Mozambique or Uganda, requiring securement of funds from other sources. It has also been documented in Zambia qualitatively (detailed further below) that the number of other external immunization partners is declining. This exemplifies how as countries move closer to transition and Gavi support declines, they will be expected to secure the bulk of immunization financing domestically; the Zambia experience suggests that this may pose difficulties. While a growing number of Gavi countries have made this transition successfully, Ghana stands out as one example of a country who defaulted on its growing cofinancing obligations. Being in earlier stages of self-financing, cMYP projections show that Uganda and Mozambique expect to be able to meet nearly all of their resource requirements, primarily through Gavi financing and other external development assistance.

In order to fund increasing immunization program resource needs, countries leverage external donor support and domestic health financing with varying degrees of success. Uganda's and Mozambique's immunization programs have been able to mobilize funds to meet the majority of their projected resource requirements. However, the bulk of fund commitment has been from external partners, which sustains the program in the short term but does not ensure long-term sustainability. On the other hand, Zambia's immunization program has struggled to meet resource requirements even in the short term, mobilizing only half of the required funds and operating with a funding gap in excess of 40 percent annually. Among FCE countries, Zambia is particularly at risk of facing both rising expenditures and decreasing resources. This is a risk for long-term programmatic and financial sustainability.

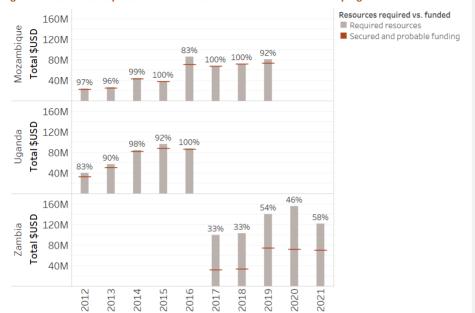


Figure 20. Resources required and secured to fund national immunization programs.

Source: cMYP's from Uganda, Zambia, and Mozambique: 2012–2021.

**Notes**: The gray bars indicate the total amount of resources required, as projected in the cMYP. The red marks indicate the total amount of resources that have been identified as secured or probable funding from all sources; this represents the relative share of the required funds that have been committed to date.

## External development assistance and partner support

Financial resources for immunization programs include external donor funds and domestic resources. However, countries' access to donor funds is determined fairly subjectively by real and perceived need, political and technical priorities of donors, and countries' ability to advocate for and/or use funds

Gavi's resource allocation formula allocates additional resources to Uganda, a Gavi Tier 1 country, based on its gross national income per capita and number of underimmunized children. Emerging from their financial crisis and decades of internal conflict, Mozambique recently received \$105 million from the World Bank and Global Financing Facility (GFF) for primary health care strengthening (including child health). Zambia, on the other hand, has experienced a decline in development assistance for the immunization program in recent years, as well as a decline in the number of partners working on immunization. Reductions in external assistance to Zambia likely reflect both real reductions in need—particularly compared to other sub-Saharan African countries—as well as declining incentives for partners who are aware that external assistance will continue to decline. Country stakeholders have noted this decline in external partners, and the impact on immunization program:

"I would say that the number of partners supporting immunization is not the same in the last three years or so. For example, I don't see Care, GSK, Child Fund, etc., anymore. Some of these smaller donors were crucial in providing support in a flexible and easier way than the bigger

donors. In many instances, we relied on them to come to our aid when we had shortfalls at short notice. So, their absence will be felt." KII, Zambia.

Zambia is investigating whether the country could access GFF funds to meet its financing obligations to support some programs under child health. The GFF's potential to provide financing on a long-term basis for a country such as Zambia remains to be assessed. However, apart from it being a loan financing, the GFF option is indicative of the dwindling options of raising grant funding from traditional donors and from domestic resources, which is further detailed in the Zambia FCE2 report.

While Uganda and Mozambique have mobilized external development assistance to meet the projected resource requirements for their immunization programs, domestic (government) financing has remained a small share of the overall envelope and, in Uganda, has not increased at the same rate as external expenditures from 2013 to 2016 (Figure 21). As many of these external increases have been driven by Gavi financing of vaccines, Gavi funds have come to represent the majority of country immunization financing. These historic trends in government's contribution declining as a relative share of funding (even when the absolute value of contributions has increased) due to the outsized contribution of increased commodity support from Gavi have been further documented in FCE1 and EPIC analyses. While FCE2 countries are not expected to be self-financing at this juncture, this highlights the heavy reliance of country governments on external donor support to continue funding immunization programs.

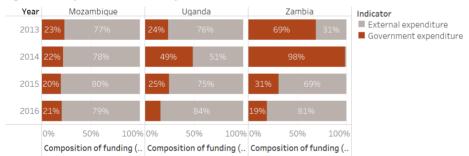


Figure 21. Composition of EPI costs by donor.

Source: cMYP's from Uganda and Mozambique: 2012–2019.

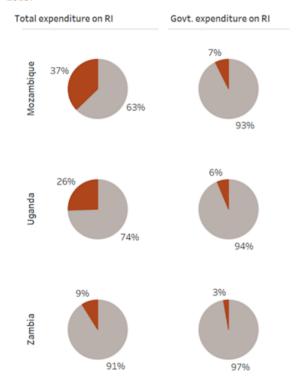
**Notes:** "Co-financing of Gavi" indicates funds that are allocated by the national government for payment of co-financing commitments. "Common fund" indicates funds that are allocated by the national government but may be financed through a basket of different donors.

#### Domestic financing of immunization programs

Interpreting the current portrait of domestic health financing for immunization activities is complex owing to the fact that FCE2 countries are not yet required to inject additional domestic resources. Allocating additional financial resources to immunization is an inherently political decision and one that is difficult to predict the likelihood of. However, feasibility of increased domestic financing for immunization can be inferred based on the projected resource needs as a share of the total government health expenditure (

Figure 22). If countries were to have self-financed all routine immunization expenditures in 2015, it would have required from 9% (in Zambia) to 37% (in Mozambique) of total government health expenditure; in actuality, countries self-financing only required from 3% (in Zambia) to 7% (in Mozambique) of total government health expenditure.

Figure 22. Immunization expenditure as a share of total government expenditure on health in 2015.



Source: Joint Reporting Framework and National Health Accounts from Uganda, Zambia, and Mozambique: 2015
Notes: Govt. health expenditure (represented as the entire circle) captures the total domestic health expenditure in a
given country. The highlighted share of the pie represents the relative share of domestic health expenditure that would
be required for national immunization programs. Govt. expenditure on RI represents how much domestic financing is
currently allocated to immunization programs; total expenditure represents how much domestic financing would need
to be allocated to immunization programs to maintain current expenditure levels.

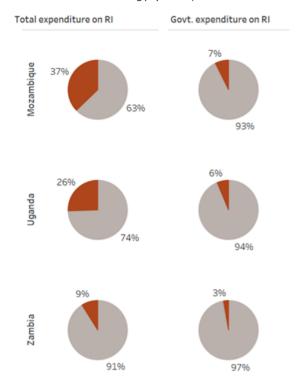
4.0M Country ■ Mozambique Uganda 3.5M 7ambia 3.0M Co-financing payments (\$US) 2.5M 2.0M 1.0M 0.5M 0.0M 2010 2015 2016 2017 2014 2018 [projecte.. 2019 [projecte.. 2020 [projecte.. 2021 [projecte.. 2022 [projecte.. 2023 [projecte..

Figure 23. Actual and projected co-financing payments in Mozambique, Uganda, and Zambia, 2010–2022.

**Source**: Gavi co-financing information sheets: Uganda, Zambia, and Mozambique. **Notes**: Co-financing payments are determined by the number of Gavi-supported vaccines in a given country and transition status. See Gavi country co-financing information sheets for further information on the breakdown of co-financing payments.<sup>29</sup>

While countries have made strides to increase domestic financing of immunization programs, countries will need to accelerate government financing to absorb increases in co-financing, as well as to sustain increased program costs. In 2019, Uganda is projected to contribute \$15M to immunization programs, representing a 59% increase in funding since 2016; Mozambique is projected to contribute \$5M in 2019, representing 17% increase in funding since 2016. In Uganda, co-financing commitments are expected to rise 38% in the same period, indicating that the planning may in fact be adequate to keep up with projected co-financing needs. However in Mozambique co-financing commitments are expected to rise 75% in the same period, thus co-financing commitments are growing at a faster rate than projected government spending.

In the case of Zambia, it is perceived that domestic financing is not increasing at the rate needed to absorb additional co-financing payments (



Source: Joint Reporting Framework and National Health Accounts from Uganda, Zambia, and Mozambique: 2015

**Notes:** Govt. health expenditure (represented as the entire circle) captures the total domestic health expenditure in a given country. The highlighted share of the pie represents the relative share of domestic health expenditure that would be required for national immunization programs. Govt. expenditure on RI represents how much domestic financing is currently allocated to immunization programs; total expenditure represents how much domestic financing would need to be allocated to immunization programs to maintain current expenditure levels.

Figure 23), posing a risk to program sustainability:

"Realistically, coverage cannot be sustained using domestic resources alone in the short term. Domestic resource mobilization has not kept pace with the pace of immunization programme investments in the last five years. There is no evidence that the function of coordination of various grants initiated with donor support is taking place. This is increasing government's vulnerability to failing to meet the cost of sustaining these programme." KII

Zambia is operating under a severely constricted fiscal space due to weak macroeconomic growth (projected to average 4.4% over the next five years) and low tax revenue potential. There is also a concern that increasing public debt will require more resources to be allocated toward debt servicing

in the coming years. As a result, there are limited opportunities for expanding the domestic fiscal space. The Government of Uganda has more promising macroeconomic growth (projected to average 6.9% over the next five years) and has demonstrated considerable strategic attention to immunization financing and sustainability issues in recent years, particularly considering that transition is not within Uganda's immediate future. However, Uganda also faces low levels of domestic resource mobilization (and health sector prioritization) and increasing public debt. There are also continuing concerns about inefficient resource usage.

Both countries have also identified opportunities for increasing immunization financing. In consideration of how to sustain immunization financing after the country graduates from Gavi support, the Government of Uganda signed the Immunization Act (2016), which provides for compulsory immunization against vaccine-preventable diseases and establishes an immunization fund. The immunization fund is an instrument meant to "provide legal commitment for public funding of immunization to secure adequate and sustainable financing for immunizations"30 for funding vaccines and related supplies, cold chain equipment, and immunization outreach activities. Key to the operationalization of this fund is the development of a financial sustainability plan, recommended by the Uganda NITAG in 2016. The plan<sup>36</sup>, released in April 2018 and funded through TCA, presents a range of cost and expenditure scenarios and options to mobilize additional resources and strengthen financial sustainability. In Zambia, the most promising opportunity for increasing public spending on health and immunization is to increase the share of total public spending that is allocated to health programs. Both Uganda and Zambia have also identified National Health Insurance (NHI) programs as being potentially opportunities for further revenue. In Zambia, the Social Health Insurance policy is currently being taken up for discussion in parliament. In Uganda, a NHI program has been proposed but has yet to be implemented. The 2017-2018 FCE2 Zambia report and the 2018 Uganda Sustainability report detail these opportunities and constraints in further depth

The question that remains is whether governments will be able to overcome the challenges in the fiscal space to mobilize immunization resources as external donor financing declines. The rising costs of EPIs, coupled with increasing co-financing commitments and limited government investment is a risk for long-term programmatic and financial sustainability. EPI resource requirements have increased—and are likely to continue to—due to NVIs and the high cost of reaching the fifth child. Country governments are facing increased burden due to increased EPI costs and increased co-financing commitments. In Zambia, the government is facing further constraints from declining external financing. These trends present a risk to sustainable financing of immunization program gains in the absence of Gavi funding if domestic financing is not able to adequately replace the removal of external funds.

# Recommendation

Act now: Gavi, partners, and EPI stakeholders should invest in developing and implementing a financial sustainability plan to increase domestic financing for immunization. These efforts should include the highest levels of political and bureaucratic representation and should align where possible with broader health-sector financing reforms.

# Next steps for FCE2 year 2



- Continue evaluation of the consequences of channeling funds through partners (all countries; EQ5&18).
- >>> Continue ongoing evaluation of the drivers of changes in immunization financing (EQ15), with emphasis on the influence of Uganda's Immunization Act on securing additional resources for immunization (EQ20).
- >>> Assess political will to overcome challenges in the fiscal space and allocate more financial resources to immunization.

#### GAVI'S RESPONSE AND APPROACH TO ENSURING FINANCIAL SUSTAINABILITY

# Finding 3.3

Gavi guidance had been updated to better support countries to take into account the financial sustainability aspects of NVIs during decision-making processes. However, there remains limited guidance on how to plan for long-term financial sustainability or how to maintain programmatic activities and outcomes after the end of Gavi support.

### ROBUSTNESS RANKING

This finding is from the FCE2's review of select Gavi policy and guidance documents from 2015 to present, based on a predefined set of evaluation criteria. It could be strengthened by observing guidance provided by SCMs and other Gavi program staff directly to national EPI stakeholders and KIIs.

В

As reported in previous reports, decisions to apply for Gavi support are not always undertaken with a full assessment of the implications on financial sustainability. Country decision-making processes are influenced by many competing factors, including interests, misaligned incentives, institutional constraints, and external events. Considerations of programmatic and financial sustainability rarely rise to the surface. In this section we describe a recommendation made in the 2016 FCE report and the Alliance management response (Table 13) and analyze the key actions Gavi states in their management response to assess progress and learning.

Table 13. FCE finding and Alliance management response related to financial sustainability (2016).

FCE FINDING	FCE	ALLIANCE	KEY ACTIONS
	RECOMMEND-	MANAGEMENT	PROPOSED BY
	ATION	RESPONSE	ALLIANCE
Decisions to apply for Gavi support are not always undertaken with a full assessment of the implications on financial sustainability. In 2016, Gavi FCE observed that countries had challenges in meeting co-financing requirements, as	Gavi Secretariat, partners, and country governments: Should ensure more scrutiny of financial sustainability considerations in decision-making, particularly in phase 1 (preparatory) transition countries. Further checks and balances can be established as part of	As part of the 2015 review of Gavi's transition policies, the Board recognized the importance of engaging countries on discussions around the sustainability of Gavi's investments from an early stage.	Relevant templates, forms and guidance (e.g., CEF guidance, Joint Appraisal templates) have been or are currently being updated to better capture financing-related aspects regarding the decision-making process for new vaccine introductions.

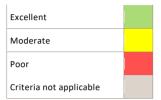
To assess Gavi's learning on this issue, we evaluated Gavi's progress toward their "key actions proposed" by assessing updates to CEF, JA, and application guidance during the FCE2 reporting period ending March 30, 2018. Using the rubric criteria in Table 14, we took a narrow focus to assess Gavi on the exact details laid out on their management response in relation to "financing-related aspects" as they inform decision-making for NVI (Table 15). Using the criteria, we evaluated policies called out in the above management response to track changes and updates as they relate to financial sustainability. During the FCE2 reporting period, only the HSS application guidelines and JA template have been updated, but we acknowledge that additional updates will be released in May 2018.

Table 14. Management Response evaluation rubric criteria.

CRITERIA	EXCELLENT	MODERATE	POOR
Emphasis on financial sustainability during decision-making for NVI	Document provides introduction and detailed financing-related components for decision-making for NVI	Document provides introduction to financing-related components for decision-making for NVI	Document does not provide any information on financing-related components for decision-making for NVI
Emphasis on financial sustainability considerations prior to or during preparatory transition	Document emphasizes importance of, and provides overview of how to, incorporate financial sustainability in decision-making during transition periods (esp. phase 1)	Document introduces the idea of incorporating financial sustainability in decision-making, but does not explain importance or how	Document does not introduce or provide overview of how to incorporate financial sustainability in decision-making during transition periods
Technical support or guidance to NITAGs on financial sustainability	Document provides technical support or resources for NITAGs on financial sustainability for decision-making	Document does not provide technical support, but provides resources for support	Document does not provide technical support or resources for NITAGs on financial sustainability

Table 15. Management response matrix

#### Legend



	HSS APPLICATION GUIDELINES (2015)	JOINT APPRAISAL TEMPLATE/ GUIDANCE (2016)	JOINT APPRAISAL TEMPLATE (2017)	COUNTRY ENGAGEMENT FRAMEWORK (2017)	GAVI SUPPORT APPLICATION GUIDELINES (2018)
Emphasis on financial sustainability during decision-making for NVI					
Emphasis on financial sustainability considerations prior to or during preparatory transition					
Technical support or guidance to NITAGs on financial sustainability					

## Application guidelines for all Gavi support

The 2018 update to the Application Guidelines has a stronger emphasis on financial sustainability than previous iterations, namely the 2015 version. The 2015 guidelines introduced financial sustainability in relation to decision-making but framed sustainability in the context of transition from Gavi support as opposed to the timelier decisions that could be made to support sustainable decision-making at all steps of the process.

In the 2018 Application Guidelines, programmatic and financial sustainability of the country's immunization program is a core principle of Gavi HSS, NVS, and CCEOP grantmaking. The 2018 guidelines highlight the need for countries to target investments in ways that build local capacity and ensure timely distribution and execution of resources. The guidance explicitly references NITAGs as being forums for conversations on NVI decisions. The application guidelines walk through all types of Gavi support and include language on sustainability throughout the life of the grant, not just during the application and transition periods. There is no additional mention of NITAGs' role in providing evidence or informing decisions on whether and how countries will be able to secure immediate or longer-term financing for NVIs.

#### Joint Appraisal guidance

By design, the annual JA is an early opportunity, pre-application or renewal, to discuss programmatic and financial sustainability issues in the context of the entire immunization program among a diverse group of stakeholders. As the mechanism for identifying gaps in investment and TA, the JA ought to be used to focus on barriers to improving financial sustainability. The report template prepared by Gavi is a critical determinant of what is discussed, and how.

The 2016 JA suite of guidance (JA template, guidance on conducting a JA, and guidance on developing the JA report) references financial sustainability in a several ways—through prioritizing country needs, immunization financing, and transition planning in developing the JA report—as well as provides tips on how to hold discussions on sustainability when conducting the JA:

- > The purpose of the transition planning section is to monitor the implementation of those transition plans to ensure the financial and programmatic sustainability of the program (not relevant for FCE2 countries).
- > The section on immunization planning includes overall expenditure and financing information for immunization from all sources and an overview of the country's financial contribution to the immunization program. This information is intended to inform a focused discussion on financial sustainability issues within the immunization program, particularly in light of any expected increases in funding needs.

As of March 2018, Gavi has not updated the 2017 JA report template or the additional guidance on drafting and planning a JA from 2016. However, the 2017 JA template includes significant changes from the 2016 version in language around TA in ensuring financial sustainability. Countries can now specify TA needs through TCA. A new section in the 2017 JA template provides guidance on assessing and strengthening financial and programmatic sustainability (through transition planning) with the following instructions (Section 4.3, Sustainability and Transition Planning):<sup>31</sup>

Provide a brief overview of key aspects and actions concerning the sustainability of Gavi support to your country. Please specify the following:

- > Financing of the immunisation programme: key challenges related to the financing of the immunisation programme, including co-financing requirements.
- Savi transition planning: if your country is transitioning out of Gavi support, specify whether the country has a transition plan in place. If no transition plan exists, please describe plans to develop one and other actions to prepare for transition.

JA templates from both 2016 and 2017 make no specific mention of NITAGs and do not address technical support or guidance to NITAGs on financial sustainability during decision-making.

To evaluate the application of JA guidance in motivating countries to examine the financial sustainability of their immunization programs, we reviewed Mozambique and Uganda's JA reports from 2017 and found that sustainability is typically addressed as it relates to financial management and capacity. Financial management is identified as a bottleneck to ensuring the sustainability of Gavi program outcomes throughout the life of the grant, during transitionary phases, and as countries transition out of Gavi support. It is unclear from the reports themselves if sustainability is discussed in reference to NVI and how countries take financial sustainability of current Gavi-funded programs into account in decision-making around the introduction of new vaccines.

### Country engagement framework

The CEF was introduced late in 2016 and was not implemented until 2017, so no comparisons on financial sustainability can be made in response to this case. Currently, CEF does not affect FCE2 countries who applied for HSS funding under the previous grant architecture.

Programmatic and financial sustainability are listed as principles of Gavi's CEF. As part of the CEF, countries must submit a PSR as their request for new Gavi support, contributing to the national immunization program for the upcoming three- to five-year period. It highlights past performance, implementation challenges, and lessons learned from existing Gavi support as well as the high-level objectives and key activities for all types of requested future Gavi support (i.e., NVS, HSS, CCEOP). The PSR discusses the priority areas of need and strategic actions that could improve financial sustainability. TA can be made available to countries to reduce barriers to sustainability but does not indicate at which point countries should be thinking about programmatic and financial sustainability.

## **Recommendations**

- Continue doing: Gavi's 2018 application guidelines encourage countries to engage with sustainability issues throughout the life of the grant, not just during the application and transition periods.
- Continue doing: Gavi and partners should continue to invest in NITAG strengthening with a focus on sustainability (and coverage and equity).
- Study further: Gavi should expand their sustainability guidance beyond NVI to include a focus on operational and programmatic sustainability of vaccine delivery.

#### **SUMMARY**

As immunization programs have introduced multiple new life-saving vaccines, costs have also increased. Rising costs have been heavily driven by the capital costs of new vaccines. Operational expenditures have not risen as rapidly, threatening program implementation components that are crucial to reaching underimmunized populations. Gavi has increasingly focused on the financial sustainability of country immunization programs, with particular emphasis on NVI decision-making and transition planning, which has encouraged country discussion of long-term financing. However, there is still limited guidance on how—or to what level—countries should plan for programmatic and operational sustainability. Increased study of the actual operational costs of reaching unimmunized children, and subsequent guidance on planning for financial sustainability of all program components, is needed. These planning conversations for long-term financial sustainability of capital vaccine costs and operational costs should include the highest levels of political and bureaucratic representation to ensure alignment with broader health-sector financing reforms.

These conversations on financial and programmatic sustainability are set against a backdrop of constrained fiscal space. Countries are still heavily reliant on donor financing to absorb the increased cost of EPIs; and government investment, while increasing, has not kept up with the rising cost of immunization programs. Limited domestic investment, coupled with the high costs of immunization programs and increasing co-financing commitments, presents a risk to the long-term financial sustainability of immunization programs. In countries where donor financing is beginning to decline, such as Zambia, this risk is particularly acute. These trends present a risk to sustainable financing of immunization-program gains in the absence of Gavi funding and to sustainable program gains in coverage and equity. Further attention is needed to the fiscal environment and to how countries can be supported in increasing the available resources for health spending.

# **Conclusion**

Despite tremendous global progress in improving access to and coverage of vaccines, progress in Mozambique, Uganda, and Zambia is not equitable, nor is it inevitable. Reaching the "fifth child" and achieving universal coverage requires new ways of doing business and new levels of resources and commitment. The underlying drivers of equitable coverage are complex and interdependent and require multi-stakeholder and multi-level action. We observe that current data systems and measurement approaches are insufficient for measuring and monitoring granular trends in inequalities. Decision-makers have inadequate information and tools to inform intervention design and resource-allocation decisions. While this has been a perennial FCE finding across our reports, we also observe (and have played a role in) success stories related to the production, exchange, and use of information to make better decisions.

As a resource for countries and an input into CEF (and the design of the program support rationale) and JA processes, Gavi and Alliance partners should synthesize the evidence on how to most effectively address common, underlying bottlenecks or causes of inequalities. This could lead to the development and use of decision-support tools to inform the design and targeting of the most cost-effective and high-impact interventions to address the root causes of inequitable coverage. As part of the Data SFA or HSS funding, Gavi, Alliance partners, and country stakeholders should continue to invest in strengthening existing data quality and data systems with a focus on integrating administrative vaccine data with supply chain, logistics, and health system performance data. Gavi and partners should expand or modify the current list of equity indicators and data sources to include all potential causes of under vaccination as informed by the FCE2 TOC.

The FCE also explored LMC, including policy, planning and financing, as a main driver, or barrier, to equitable coverage. Across FCE countries, the influence of LMC on immunization system performance was observed through suboptimal financial planning and management leading to delayed disbursements or inadequate resources (seen through the various HSS implementation challenges and delays) and the effective coordination of partner activities. Gavi should continue to strengthen national-level LMC and should study where gaps in district-level LMC exist through PEF TCA and the LMC Strategic Focus Area, with a focus on financial management and evidence-driven performance management. While Gavi has shifted the focus of its guidance, policies, tools, and frameworks toward improving within-country inequities in coverage and utilization of immunization services, there is still room for improvement in specifying and operationalizing the tools and approaches to help countries identify the underlying causes of inequalities and appropriate, evidence-based solutions.

This report also explored financial and programmatic sustainability of Gavi vaccine and cash-based support. The FCE2 team found that immunization program costs are rising as more vaccines are incorporated into national vaccine schedules, but domestic and external financing for operational costs are not keeping pace, presenting risks to the ability of FCE countries to adequately and sustainably finance immunization programs. Gavi guidance has been updated to better support country consideration of financing in the decision-making process for NVIs. However, there remains limited guidance on how to plan for long-term financial sustainability or how to maintain programmatic activities and outcomes.

#### CONCLUSION

Gavi, partners, and EPI stakeholders should invest in developing and implementing a financial sustainability plan with the aim of increasing domestic financing for immunization. These efforts should include the highest levels of political and bureaucratic representation and should align where possible with broader health-sector financing reforms. As funders, the Gavi Alliance could play a stronger role in ensuring the activities they fund are technically and operationally sound, engaging in ongoing monitoring and adaptive management, and thereby maximizing the value for money of Gavi's investments. Gavi should expand their sustainability guidance beyond NVI to include a focus on the long-term operational and programmatic sustainability of vaccine delivery.

#### **NEXT STEPS FOR FCE2 YEAR 2 REPORT**

In this report, the FCE2 team has outline several next steps that will be further investigated in year 2. In year 2, the FCE2 Consortium will:

- Use multiple data sources across FCE countries to test the hypothesis that district-controlled drivers explain the largest proportion of the variance in coverage.
- Expand the DCS to Mozambique and Zambia, further investigating district-level coverage trends and financial management as well as LMC challenges and barriers (EQ4).
- Continue to explore and quantify as many of the drivers of coverage and equity in the FCE2 TOC as
  possible in the data-collection period.
- Further investigate hypothesized variance in coverage estimates due to changes in data quality.
- Continue to analyze Uganda coverage and HSS expenditure data using interrupted time series
  methods to further quantify the association between the end of HSS funding and coverage
  declines (EQ6).
- Continue to track HSS implementation in Mozambique with a focus on whether learning and adaptive management is occurring (EQ4 and 9).
- Continue to track unintended consequences due to PCA on HSS implementation and outcomes (Uganda and Zambia; EQ17).
- Continue ongoing evaluation of the consequences of channeling funds through partners (all countries; EQ5 and 18)
- Continue ongoing evaluation of the drivers of changes in immunization financing (EQ15), with emphasis on the influence of Uganda's Immunization Act on securing additional resources for immunization (EQ20).

The FCE2 team will continue to explore Gavi's approach to financial and programmatic sustainability, monitoring funds funneled to TCA partners and the overall costs of vaccines (including program costs of new vaccines and operational costs funded by Alliance partners). The FCE team will also evaluate the implementation of Joint Appraisal processes in 2018, with a focus on how the tools and guidance provided by Gavi, including the Grant Performance Framework, influence discussion and decisions related to identifying which children remain under immunized and why, and how best to address the identified bottlenecks (EQ17). In year 2, the FCE team will also continue to monitor and analyze the implementation and effectiveness of Gavi coverage and equity strategies and the impact of SCMs and Gavi's strategic focus areas on improving coverage and equity.

# **Methods Annex**

This section describes the methods utilized in generating the findings covered in this report of the Gavi, the Vaccine Alliance Full Country Evaluations (FCE). Table 16 provides a high-level overview of the various methods, data sources, and topics investigated. We provide additional details on the FCE theory of change (TOC), mixed-method analysis, process evaluation, secondary analysis, qualitative methods, and robustness rankings. The FCE country reports and accompany appendices also provide further details on the application of methods within each country context.

Table 16. Methods overview.

METHODS	SOURCES	TOPICS INVESTIGATED
Document review	<ul> <li>&gt; Gavi policies and guidance documents</li> <li>&gt; Gavi Board, PPC, and IRC meeting minutes</li> <li>&gt; Country funding applications (HSS, NVI, etc.)</li> <li>&gt; Joint Appraisal Reports</li> <li>&gt; PCA findings and recommendations</li> <li>&gt; EPI reviews</li> <li>&gt; Gavi grant performance frameworks</li> <li>&gt; FCE phase 1 (FCE1) reports</li> <li>&gt; Post-Introduction Evaluation reports</li> <li>&gt; Effective Vaccine Management assessments</li> <li>&gt; Sustainability Strategic Focus Area</li> </ul>	Coverage and equity (EQ1–3); HSS (EQ4–6); Use of data, evidence, and program learning (EQ9); HPV vaccine (EQ10, 12); Sustainability (EQ14–16); Alliance systems and processes (EQ17–18)
Data analysis	Health Management Information     Systems (HMIS) data      DHIS-2 data      HHS and HFS data from FCE1      Small area estimates from FCE1	Coverage and equity (EQ1–3); HSS (EQ4–6); HPV vaccine (EQ12); Sustainability (EQ14– 16)
District-level case study (DCS)	> KIIs > Subnational immunization data (HMIS/DHIS-2)	Coverage and equity (EQ1–3); HSS (EQ6); HPV vaccine (EQ12)
Key informant interviews (KIIs)	> Relevant stakeholders at global and country levels	Coverage and equity (EQ1-3); HSS (EQ4-6); Use of data, evidence, and program learning (EQ9); HPV vaccine (EQ10, 12); Sustainability

METHODS	SOURCES	TOPICS INVESTIGATED	
		(EQ14–16); Alliance systems and processes (EQ17–18)	
Policy analysis	<ul> <li>&gt; Gavi immunization financing policy and guidelines (and other relevant documents)</li> <li>&gt; Resource gap analysis</li> <li>&gt; Resource-tracking data from phase 1</li> <li>&gt; Program costing data from EPIC</li> <li>&gt; Root cause analysis</li> <li>&gt; KIIs</li> </ul>	Coverage and equity (EQ1–3); Sustainability (EQ14–16)	
Process tracking	> Observation > Document review > EPI reviews > Performance frameworks > Root cause analysis > Ripple-effect mapping > KIIs	Coverage and equity (EQ1–3); HSS (EQ4–6); Use of data, evidence, and program learning (EQ9); HPV vaccine (EQ10, 12); Sustainability (EQ14–16); Alliance systems and processes (EQ17–18)	

#### Theory of Change

For the purposes of this evaluation, the Gavi FCE team developed a Theory of Change (TOC) for each of the relevant Gavi support streams active in the FCE countries. During FCE1, we developed a high-level TOC (Figure 24) based on FCE evidence regarding the most important drivers of sustainable coverage and equity. The FCE2 TOC builds off the FCE1 TOC by examining subnational-, national-, and global-level drivers of immunization coverage and equity. The expanded FCE2 TOC (Figure 25) includes more granular demand-side drivers that were not a focus of the phase 1 process evaluation. The key thematic categories of the expanded TOC, corresponding vaccine coverage determinants, indicators, and proposed data sources are outlined below. The thematic categories include those identified in the phase 1 TOC, while the determinants and indicators draw additional nuance from new research on immunization coverage, equity monitoring, and country-level determinants of inequality in vaccination and are informed by the frameworks referenced in the systematic review describing the determinants of vaccine coverage. Within these categories, we aim to better understand the causal pathways between coverage and determinants that are more proximate (e.g., adequate stock), versus others that are more systemic. By ensuring that these distinctions are clear, we are able to develop actionable recommendations that are directed to the appropriate stakeholders.

Figure 24. FCE1 Theory of Change

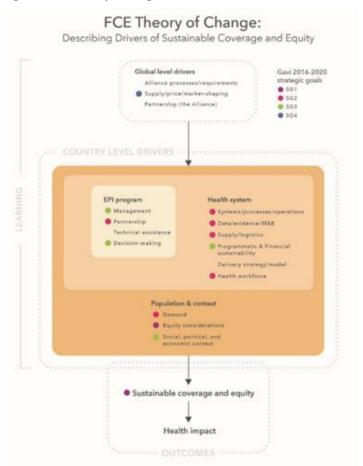
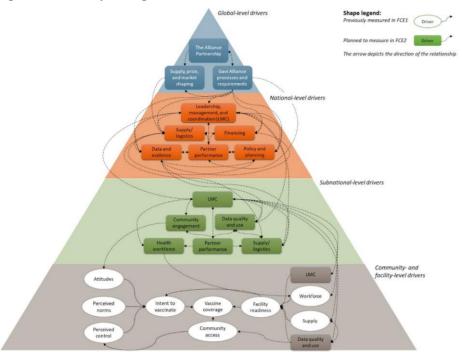


Figure 25. FCE2 Theory of Change.



The levels depicted in the FCE2 TOC include:

- > Global-level drivers. This relates to the contextual and institutional enabling factors of success in Gavi-supported countries. Drivers include Alliance processes and requirements that have the potential to add value—both to countries and to Gavi—when they are designed and implemented to balance their administrative and management burden with their potential benefits. Supply, price, and market-shaping factors are part of the contextual enabling factors that are outside of countries' control. The Alliance partnership contributes to the global-level drivers through its technical expertise, financial resources, and coordination support.
- National-level drivers. This predominately includes ensuring that the EPI and MOH teams have adequate LMC capacity and skills, access to the necessary data and evidence to inform decisionmaking, adequate supply and logistics management and infrastructure, financing and policy planning capacity and structures, and mechanisms in place to coordinate and evaluate partner performance. Relevant, effective, and efficient technical assistance (TA) is a related driver within this category for its role in strengthening the capacity of national teams to implement increasingly complex immunization programs.
- Subnational-level drivers. This includes the supply-side barriers to coverage as they relate to health facility readiness to administer vaccines. It draws on WHO's Health Systems Framework, describing the supply of essential medicines and the health workforce as the most proximal components of a successful health system. This includes determinants related to data and evidence; vaccine supply and logistics; and delivery strategy. We include performance

- management in this category, recognizing management as a systems-level driver of immunization coverage due to its role in strategic decision-making, particularly at the subnational level.<sup>32</sup>
- Community- and facility-level drivers. This includes the demand-side, patient-centric barriers to coverage as they relate to a caretaker's intention to vaccinate his or her child. It draws on behavioral models of health service utilization, such as the Theory of Planned Behavior, the Health Belief Model, and the Vaccine Perceptions, Accountability and Adherence Model. 33,34,35 Pulling from these models, this category describes the cultural and economic factors that influence choice, as well as perception-related factors that drive the individual-level decision to vaccinate. Contextual drivers take into account the community-level access barriers to coverage that fall in between supply- and demand-side barriers. Factors related to access include physical access and resource capacity, as well as ability. Distance and affordability are examples of access-related barriers that exist between the child's caretaker and the child's contact with health workers. Within this category, we also include factors that are recognized determinants of inequities in child health, such as maternal education, place of residence (urban versus rural), gender, and wealth.<sup>36</sup>

#### Mixed-method analysis

An important aim of the Gavi FCE is to maximize linkages between the different evaluation components and strengthen confidence in findings through triangulation of evidence. The prospective design lends itself to various opportunities for integrating evidence from the different data sources. The evaluation questions (EQs) provided an overarching analytical framework within which to analyze and synthesize quantitative and qualitative evidence.

Comprehensive cross-country analyses have been recently conducted to measure determinants of immunization coverage and equity, including the contribution of Gavi, across Gavi-eligible countries. <sup>37,18</sup> These existing analyses focus on national-level indicators of coverage and equity. FCE1 was also largely focused on national-level data collection. To complement and avoid duplicating this important work, we use the TOC as a guiding framework for analysis of the drivers of coverage and equity at national and subnational levels. Understanding the role of the drivers and relationships between drivers was achieved through monitoring TOC drivers and conducting district-level cast studies.

1. Monitoring TOC drivers of coverage and equity and descriptive analysis

We used the TOC to establish indicators to measure and monitor the potential drivers of sustainable coverage and equity over the data-collection period. Within each FCE country, health management information systems (HMIS) dashboards were created to track changes in vaccination coverage and equity in real time at the national and subnational levels. Leveraging the work completed in FCE1, we compared coverage and equity results from the SAE with the trends in coverage and equity observed in the HMIS data. For additional information on the data analysis using SAE and HMIS data and comparisons of data quality, please see the "Secondary data analysis" section below.

2. District-level case study (DCS) of inequities in vaccination coverage

The objective of the DCS is to compare multiple districts (or "cases") with varying success in increasing coverage and equity in order to identify the drivers of their success. The FCE team employed a district-level mixed-methods comparative case study approach to qualitatively explore through KIIs with district-level stakeholders how the TOC drivers are influencing the achievement of results in those districts. This approach primarily answers EQs 1 through 3 but can incorporate data-collection tools to

help answer other EQs. The DCS investigated the major drivers of district-level changes in vaccine coverage and equity.

For this report, Uganda implemented the district case study approach to answer EQs 1 through 3, as well as EQ6 (HSS) and EQ12 (HPV vaccine). For each EQ the Uganda FCE team selected a sample of districts in collaboration with the EPI team. For HSS, 18 districts were selected purposively based on their vaccine-coverage statistics and other, relevant characteristics. To measure vaccine coverage, districts were chosen based on changes in diphtheria–pertussis–tetanus (DPT)3 vaccine coverage in 2017, geographical distribution of districts using the Uganda DHS subregions, and the presence of immunization inequities according to the Uganda Immunization Equity Assessment <sup>38</sup> conducted in 2016. Health facilities within districts were randomly selected. A subset of four districts from the 18 selected were asked additional questions specifically related to EQs 1 through 3.

For HPV, the Uganda FCE team purposively selected 4 districts using DHIS-2 data for 2017 (2 with high HPV vaccine coverage and 2 with low HPV vaccine coverage). KIIs were conducted with the district health officers (DHOs), EPI focal persons, health unit in-charges, health workers responsible for immunization, teachers, caretakers of girls aged 9 to 13 years found at the health facility, and the district education officer. In each of the districts, three health centers representing all the levels of care were also randomly selected and visited. (HCIV, HCIII, HCII). Additionally, three schools were visited in each of the districts.

#### **Process** evaluation

The process evaluation is an important component of the evaluation that examines the interface between Gavi and countries as Gavi inputs (including financial and TA) are applied for, received, and implemented. A process evaluation examines the quality of the process, with the underlying assumption that improving the process will improve the outputs and outcomes. The prospective process evaluation employs a developmental approach, with various stakeholders of the evaluation engaged in the design, collection, synthesis, and use of findings throughout the study. Two important methods for data collection and analysis include root cause analysis and key informant interviews.

### Root cause analysis (RCA)

RCA is a procedure for identifying underlying causes of identified challenges and successes. A "root cause" is a key factor in a causal chain of events that, if removed from the sequence, would prevent the final undesirable or desirable event from occurring or recurring. A,5 RCA were applied to all countries and in the cross-country analysis, using it to prioritize process-tracking findings along with selected survey findings, and then to construct diagrams of causal chains to visually illustrate the dynamic links between observed challenges or successes to possible root causes. This process was iterative because RCA diagrams were continually refined through testing assumptions against multiple data sources and through collective deliberation. In this way, RCA enabled both intermediate-stage development of hypotheses and key questions for in-depth investigation, as well as end-stage confirmation of assumptions and development of recommendations.

#### **Key Informant Interviews**

Semi-structured key informant interviews (KIIs) were conducted at the global, national, and subnational levels. Key informants were identified purposively based on relative authority or responsibility as it pertains to the topics investigated. Topic guides and questions were generated based on the evaluation questions, existing evidence, and notable gaps or outstanding questions from

our analysis. Interviews are particularly important to understand complex phenomena that are not measurable through other qualitative or quantitative methods. Interviews are an important component of any mixed methods approach in order to understand and interpret why data collected through other methods say what they say.

#### Rubric-based policy analysis

The FCE team used a policy analysis rubric and matrix to track changes in Gavi policy over time as they relate to coverage and equity and sustainability EQs. The FCE evaluation rubrics provide an explicit way of defining what different levels of quality, value, or performance look like in practice. Rubrics are made up of evaluative criteria – the aspects of performance the evaluation focuses on – and merit determination – the definitions of what performance looks like at each level. In this way, rubrics are useful for synthesizing multiple data sources from multiple methods, especially when there is no clear empirical threshold or target for an indicator. They allow us to take evidence and turn it into clear evaluative conclusions that are straightforward to communicate and visualize.

#### Coverage and equity

As Gavi's operations are currently divided into four stages, with the previous three stages' documents not being available, we relied on other analyses of Gavi's approach to coverage and equity to guide our analysis of Gavi policies from 1999 to 2015.

Using the analysis and conclusions from Gavi's approach to equity from 1999 to 2015, using the TOC, the FCE team brainstormed what key concepts and approaches Gavi guidance could explain in order for Gavi-eligible countries to understand the importance of coverage and equity, identify barriers to achieving coverage and equity targets, and learn which solutions would make the most impact. We then defined what excellent, moderate, and poor adherence to the criteria is (see Table 10 on page 62).

For the current operational phase (phase 4, 2016 to 2020), we collected all publicly available Gavi documents, policies, and frameworks that are relevant to Gavi's strategy toward coverage and equity. Conventional steps of a literature review were followed: searching the literature and extracting the relevant information. The literature review involved extracting information from documents written and published by Gavi: Gavi Board papers, Gavi Committee papers, Gavi policies/strategies/program documents/frameworks), or independent evaluations of Gavi's policies and programs. We restricted the search to documents published during 2015 (to be enacted during 2016) up until March 2018, when we conducted our analysis. Since our analysis, Gavi has published and updated a number of policies included in our analysis that will be examined in future FCE2 reports.

Information was extracted from all identified documents meeting the inclusion criteria and based on assessment of relevance to the policy analysis objectives and scope. Information from these documents were then categorized based on the criteria the FCE team identified for the coverage and equity policy analysis and placed into a coded matrix so that the FCE team could easily draw conclusions and findings, synthesizing the different documents over time and across themes.

### Sustainability

The sustainability policy analysis used many of the same methods and documents as the coverage and equity analysis but differed in a couple of significant ways:

- > The analysis was based on a single Management Response<sup>39</sup> from the 2016 FCE1 Annual Report<sup>6</sup> that was identified as significant and actionable by Gavi in the Management Response itself and through FCE team consensus.
- > The policy analysis rubric was generated from the management response and the actions Gavi had planned to take to address the finding.
- > The policies and documents analyzed to answer EQ9 at the global level were taken directly from the management response (see Table 13), as well as from policies that are used to inform the identified documents (e.g., the HSIS framework and guidelines inform parts of the JA, which is a document Gavi said that they would update to reflect the findings in the management response).
- > The publication dates of the documents reviewed were limited to documents published before the release of the 2016 FCE1 Annual Report and before March 2018, when the analysis was conducted.

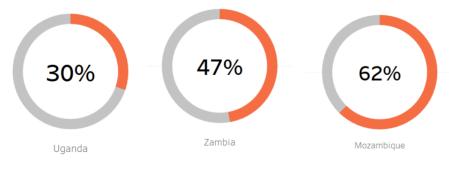
### Secondary data analysis

In Mozambique, Uganda, and Zambia, we analyzed administrative data on immunization coverage at the national level and between-district inequalities in coverage. In Mozambique, this included data from the HMIS system, called *Módulo Básico*, as well as a parallel reporting system implemented by the National Immunization Program. In Uganda and Zambia we relied on the HMIS data captured in DHIS-2.

#### **DHIS-2** methods

Country DHIS-2 systems capture subnational estimates of vaccine coverage on a monthly basis. Routine administrative data contains doses of vaccines administered monthly for each antigen at the facility level, and these data are then aggregated to the district, region/province, and national levels. In order to calculate immunization coverage, annual population estimates from the Central Statistical Office are used as the denominator. These annual population estimates are derived from historical census data, projected birth rates, and assumptions of the population structure (percentage of population under 1 year). Coverage rates calculated from DHIS-2 frequently exceed 100% coverage, presumably because population estimates from the civil society organization often underestimate the true target population in districts. Without accurate denominator data, it is difficult to assess the true immunization performance. For example, 2017 DPT3 coverage rates from DHIS2 show that between a third and two-thirds of districts in each country have coverage rates in excess of 100% (Figure 26).

Figure 26. DHIS2 DPT3 coverage rates in 2017.



In addition to the issue of the population denominator, there are concerns that data quality may be affected by the completion and accuracy of forms at the district level. 40 In spite of the poor validity of coverage calculations of DHIS data, we expect that trends observed in the DHIS data are reliable, as the inaccuracies in the denominator are not expected to change greatly over time.

#### Small area estimate methods

### SAE estimates include survey data from:

- Demographic and Health Surveys
- Living Conditions Monitoring Surveys [Zambia]
- Multiple Indicator Cluster Surveys

In FCE phase 1, annual subnational estimates of vaccine coverage were generated at the district level using small area estimate (SAE) methods and household survey microdata. All available survey data were fit to hierarchical linear models, which were adjusted for survey stratification and weighting, to produce annual estimates for select antigens. Due to the inclusion of multiple data sources and the model specifications, this results in longitudinal data that are smoothed over space and time. Multicountry household survey data (e.g., Multiple Indicator Cluster Survey, DHS) is typically considered the gold standard of coverage data, due to the standardized nature of the survey and the rigorous survey design and implementation. 41 The reliance on household survey data also ensures that coverage estimates are always less than 100 %, as the population denominator is known from the survey. However, the accuracy of the estimates is limited by the quality of the inputted survey data, where child-specific vaccination information is based on the child's health card record and/or maternal recall.<sup>40</sup> The input survey data are particularly limited in terms of survey data coverage at the subnational level. There are certain subnational areas where there is little area-specific information available, and many surveys are not designed to be representative at the subnational level. This is compounded by the issue of changing subnational boundaries. For instance, the SAE estimates for Zambia contain 72 consistent districts from 1999 to 2016, in spite of the fact that new-district creation since 1999 has raised the total number of districts to 10,312 in 2016.

# Usage of secondary data

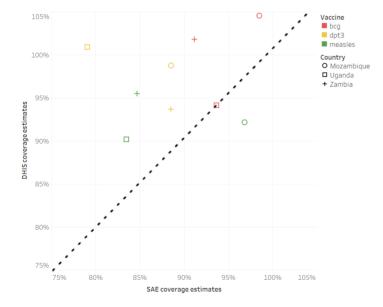
The FCE2 annual report utilizes data from both DHIS and SAE, acknowledging that there are tradeoffs in using both. Table 17 summarizes the strengths and weaknesses of both data sources.

Table 17. Strengths and weakness of SAE and DHIS data sources.

	STRENGTHS	WEAKNESSES
SAE	> Due to the use of multiple data sources and smoothing, the estimates are less volatile year over year	> Coverage accuracy is dependent on the availability and quality of survey inputs, particularly at the subnational level

	Coverage estimates are more accurate due to use of standardized household surveys      Using survey data, we are able to estimate historical coverage rates from 1999	> There is lack of country ownership in creating and understanding SAE estimates
DHIS	Country ownership is greater as administrative systems are maintained by country stakeholders      Data is accessible and usable by country stakeholders; most actionable      More responsive to country changes, such as new subnational boundaries      Data is more frequent and granular than SAE data (monthly and facility level)	> Validity is poor, with indicators often exceeding 100%  > There are other reporting-accuracy challenges, such as recording and entering data  > Due to its being a single, unsmoothed data source, estimates vary more dramatically over time  > Data are not available prior to the introduction of DHIS2 (2008) for historical trends

Figure 27. Coverage estimate comparisons, SAE and DHIS.



When comparing the data from the SAE estimates and DHIS, they show similar patterns over time, though the relative volatility of the DHIS data makes the comparison imprecise. Absolute estimates of coverage do not align precisely between DHIS data and SAE; DHS estimates are about 10 percentage points higher across all FCE countries. Figure 27 shows the comparison between annual SAE estimates and DHIS estimates for 2016 (the most recent year where both data sources are available); DHIS is

higher, due to the challenges of data validity, with the exception of measles coverage estimates in Mozambique.

In this report we primarily use SAE data to present the historical trends in vaccine coverage. To present current coverage and emerging trends, we primarily utilize DHIS data. This is in part due to lessons learned from the FCE phase 1, where there was limited uptake of SAE results among country stakeholders who did not feel ownership of the modeled data. Given the importance of HMIS data as a country-owned resource to manage immunization performance, and to further encourage the use of these data, we use HMIS data to present the current portrait of coverage in countries.<sup>40</sup>

#### Robustness rankina

Considering the prospective design of the evaluation and the flexible, adaptive nature of data-collection activities, the depth and breadth of the evidence base varies across findings. This variation signals the need to gauge the evaluation team's confidence in each finding. We, therefore, developed a robustness ranking scale to subjectively, but systematically, assess robustness of findings with respect to three dimensions:

- > Triangulation refers to the breadth of qualitative and quantitative data sources (e.g., surveys, documents, key informants, etc.) that inform the same finding, where greater triangulation equates to more robust findings.
- Where the finding lies on the continuum between fact and perception, this dimension complements triangulation in that factual information generally requires less triangulation in order to be considered robust. However, it is important to note that some of the EQs are largely perception-based (e.g., the added value of partnership, or caregiver knowledge of disease) and rely on inferences based on more subjective than objective evidence. As long as these findings are supported by well-triangulated data, they could be considered robust even though they are based on more subjective evidence.
- > The quality of the data from each source is the third dimension, where high-quality data clearly contribute to greater robustness. Indicators of quality in qualitative data include, but are not limited to:
  - > Recentness (e.g., timing of interview or group discussion relative to topics discussed to minimize recall bias).
  - Conditions of an interview or group discussion (e.g., rapport with respondent, interruptions, appropriate pacing, appropriate level of privacy for interview, balanced as opposed to one-sided group discussions).
  - > Degree of proximity to the topic or event in question (e.g., first-hand observation by the evaluation team's or respondent's first-hand experience as opposed to second-hand information).

Indicators of quality in quantitative data include but are not limited to reliability, timing, sample size, potential for selection or measurement bias, and potential for confounding in causal analysis.

Our robustness ranking does not systematically distinguish between qualitative and quantitative findings. Rather, each finding is assessed in terms of all relevant and appropriate data sources that inform the conclusion, whether the sources be exclusively qualitative or quantitative in nature, or a combination of both.

Using the dimensions above, we developed the following four-point scale (Table 18) as a general guide for ranking findings and for describing the rationale behind the ranking. A ranking is provided for each key finding in both the cross-country and country-specific sections of the report.

Table 18. Robustness of rankings overview.

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

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