

Phase 2

Mozambique

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 FCE team at PATH.

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Executive summary

Gavi, the Vaccine Alliance is a public-private partnership that aims to save children's lives and protect people's health by increasing access to immunization in poor countries. Since its introduction in 2000, the Alliance has funded immunization programs of low-income countries through various types of support, including new vaccine introduction, vaccination campaigns and health systems strengthening (HSS). Gavi is in the implementation stage of its strategic plan 2016-2020, which is focused on improving equitable immunization coverage.

With a view to measuring the effectiveness and impact of its support to countries, the Alliance called for a Full Country Evaluations (FCE) in 2013. In this first stage of the process, all stages of the Gavi support were evaluated, from application, the request and approval, preparation and implementation in each of the relevant streams of support in four countries: Bangladesh, Mozambique, Uganda and Zambia. This phase lasted four years. The results of this evaluation were used locally for decision making and to improve the implementation of activities of Gavi grants, and globally as an important source of information for the review of new policies. To continue the exercise, Gavi launched the FCE2 which is planned for two years (2017-2019). This phase has greater focus on vaccination coverage and equity, sustainability and evaluation of new policies introduced by Gavi.

This report focuses on three main topics in line with the three objectives presented above, namely: drivers of coverage and equity, perceptions of the role and contribution of health systems strengthening support in improving coverage and equity outcomes, and new vaccine introduction. For each topic, we present the main findings followed by evidence to support them, and lastly we propose practical recommendations aiming to improve the program's performance.

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.

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.

METHODS

We applied a combination of qualitative and quantitative methods to address our EQs. A mixed methods approach was used for this evaluation. In the qualitative component, the data collection was based primarily on: document review, observation, fact checking interviews and key informant interviews (KIIs). The quantitative component was based on analysis of administrative data obtained through the Health Management Information System (HMIS) and other administrative data from the Expanded Programme on Immunization (EPI; "PAV" in Portuguese).

FINDINGS AND RECOMMENDATIONS

Here we present the summary of the main findings and recommendations proposed by the evaluation team. The findings are categorized into three levels: act now, for those the team think are possible to be implemented under the current conditions without major difficulties, and which show some potential to significantly improve the process; continue doing, for the initiatives and activities which have demonstrated to have been producing the desired effect or that have great potential to do so; and, study further, for those that have a potential to improve the current situation but which for more consideration, study, or resources are needed before a decision can be taken.

Table 1. Summary of findings and recommendations from 2017, 2019 report

FINDINGS	RECOMMENDATIONS		
Coverage and Equity EQs 1-3: What are the main factors that influence the achievement of coverage and equity outcomes?			
Finding 1.1: Routine data indicate that vaccination coverage of fully immunized children increased by 8 percentage points from 2015 to 2017, while there was a reduction in the between-district inequalities within provinces.	Continue doing: MISAU and partners should maintain focus on community involvement, especially in hard-to-reach areas, including through mapping of hard-to-reach communities, education on the importance of vaccination, and active outreach of under-vaccinated children.		
Finding 1.2: Persistent challenges related to leadership, management, and coordination have the potential to negatively influence vaccine coverage and equity.	 Act now: Improve communication between the central and provincial level to strengthen the coordination and allocation of support to areas in greatest need. Continue doing: Continue with the district managers' capacity building plan to improve thei planning skills and extend the MB Consulting support to the district level for financial management and reporting issues. 		
Finding 1.3: Recurrent failures to maintain vaccine stocks undermine the program's ability to maintain adequate coverage and improve equity.	Continue doing: EPI, MISAU, and partners should continue to advocate to the government for administrative reforms to better facilitate procurement processes in order to avoid the delays in the acquisition of vaccines and other products important for the success of the program. This initiative should be accompanied by the appointment of focal points of the ministries involved in monitoring the progress of the talks.		
	Act now: EPI should explore the possibility of using Gavi funds to sign a contract directly with a gasoline plant to purchase fuel for the		

FINDINGS	RECOMMENDATIONS		
	distribution of vaccines and other related products.		
Finding 1.4: Data quality and capacity to manage and analyze data at the more peripheral levels influence the use of results to address coverage and equity challenges.	 → Continue doing: MISAU and partners, including WHO and others interested in data quality, should improve the coordination of and intensify ongoing data quality improvement activities. ○ Act now: MISAU and its partners involved in data quality improvement should support teams at provincial, and particularly at district levels, in the collection, analysis, and use of data with the aim of improving performance through the following strategies: (i) Strengthen information on the importance of data for performance planning and monitoring processes; (ii) Focus on discussion of the causes and factors that influence vaccination coverage, as well as potential solutions, rather than whether or not targets are achieved, both in the data review meetings and in the supervision sessions; (iii) Periodically choose data from a particular health facility or district for a thorough discussion in the presence of data experts, to strengthen data management in a practical way and with concrete examples. 		
Finding 1.5: Poor access to services may exacerbate inequities in vaccination coverage.	Act now: MISAU and partners should fully implement the REC strategy as soon as possible to ensure coverage of areas currently underserved.		
Health Systems Strengthening EQ 4: What is the contribution of HSS funds to vaccine coverage in the priority provinces and districts? EQ 5: What are the advantages and consequences of managing HSS funds through partners, outside of government systems?			
Finding 2.1: There was a significant improvement in the HSS funds' expenditure, however, to improve the performance towards reducing inequities in coverage, the program should improve the proportion of funds allocated to community actions and to management.	 Continue doing: Gavi, MEF, and MISAU should continue initiatives to ensure the timely availability of funds to enable more budgeted activities to be implemented. Study further: MISAU should reprogram the HSS budget in order to increase the proportion allocated to management activities and those at the community level. 		
Finding 2.2 The management of HSS funds by partners for HSS procurements did not bring significant advantages to the procurement and installation processes for coldchain equipment and vehicles, compromising the plans for supply-chain and consequent provision of services.	 Continue doing: MISAU should continue initiatives to improve administrative processes to allow greater flexibility and fluidity of the procurement and allocation of resources to the more peripheral levels. Study further: MISAU and partners must find mechanisms to coordinate the processes of procuring, distributing and assembling 		

equipment.

FINDINGS RECOMMENDATIONS

New vaccine introduction

EQ8: Whether, why and how the switch from PCV10 to PCV13 was implemented as planned?

Finding 3.1:

The delay in the disbursement of funds from the MEF to MISAU, the late arrival of PCV13 in the country and the delays in its distribution to the provinces were the factors that contributed to the successive adjustments to the plan for the switch from PCV10 to PCV13.

- **Act now:** EPI should realistically plan its activities taking into account the time it takes to transfer funds from MEF to MISAU to avoid constant changes to the plan.
 - Study further: Even with the construction of regional warehouses in progress and the acquisition of refrigerated trucks to assist in the distribution of vaccines by land, EPI should study alternatives to minimize the constant lack of fuel (due to lack of payment), since this has been a frequent cause of delays.

Use of Data, Evidence and Lessons Learned

EQ9: Whether, why, and how is the EPI program considering lessons learned from past implementation of HSS in its current efforts?

Finding 4.1:

The EPI program aligned the HSS planning and registration process with the national planning cycle of the Ministry of Economy and Finance and the Department of Planning and Cooperation of MISAU in 2017 for the 2018 HSS business plan.

- Act now: MISAU and EPI should explore the possibility of requesting the Administrative Court's financial audit of MISAU earlier, in order to be able to respond in a timely manner to funder requirements for this audit.
- Act now: Gavi should start the HSS planning process for the following year during the first months of the third quarter of the current year to allow approvals to occur in time to ensure availability of funds, once the other requirements have been met.
- Act now: MISAU and EPI should request that Gavi allows MISAU to include in its annual HSS plan a contingency plan for the implementation of HSS activities in the first 3 months of each year while the normal process of HSS approval and disbursement is carried out.

The findings on leadership and management challenges resulting in consequent delays in disbursements of funds and allocation of vaccines and other materials to the more peripheral levels is recurrent and have been identified in previous FCE reports. However, a solution has not yet been identified given the complexity of the challenges.

Next steps for FCE2 year 2



The FCE2 team will use additional data collection and analysis methods in year 2 to be able to get a better estimate of the contribution of HSS to observed changes in coverage and equity. The FCE2 team will expand the district case study approach to Mozambique and conduct research in two districts in a priority province, and two districts in a non-priority province to the contribution of factors such as community activities and leadership, management and coordination on vaccine coverage. Moreover, the team will focus efforts to document best practices of districts with good performance and investigate in greater depth the causes of coordination and communication challenges between the central and provincial levels. In partnership with EPI, the FCE2 team will discuss the proposed recommendations and approaches in order to identify initiatives able to respond to the challenges encountered, especially those that appear on a recurring basis, such as those associated with leadership, management and coordination.

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Abbreviations

AT **Technical Assistance**

CHAI Clinton Health Access Initiative

DAF Department of Administration and Finance DPC **Directorate of Planning and Cooperation**

DPT Diphtheria, Pertussis, Tetanus **DSS** Demographic Surveillance System **EPI Expanded Program on Immunization**

FCE Full Country Evaluations GBS **General Budget Support TWG Technical Working Group** HAI Health Alliance International

HMIS Health Management Information System

HSS Health System Strengthening

ICC **Interagency Coordinating Committee IDRC** Infectious Diseases Research Collaboration

ISS **Immunization Support Services**

JA Joint Appraisal

KII Key Informant Interview M&E Monitoring and Evaluation

MFF Ministry of Economy and Finance

MOH Ministry of Health

PAV Portuguese abbreviation for EPI

NITAG National Immunization Technical Advisory Group

New and Underutilized Vaccine Initiatives NUVI

NVI **New Vaccine Introductions** NGO Non-governmental organization

PATH Program for Appropriate Technology in Health

Pneumococcal conjugate vaccine **PCV**

RED/REC Reach Every District/Reach Every Child

SCM Senior Country Manager **TCA Targeted Country Assistance**

TOC Theory of Change

UEM Eduardo Mondlane University

UNZA University of Zambia UW University of Washington **VIG** Vaccine Introduction Grant

VTs Vaccine serotypes

Summary of Gavi support in Mozambique

Gavi financing to Mozambique began in 2001, about 22 years after the establishment of the Expanded Program on Immunization (EPI) in 1979, to expand access to vaccines within the primary health care (PHC) approach adopted across the country. Since the beginning of its support to Mozambique, Gavi has invested over US\$200 million. Of this amount, more than half has been disbursed in the last five years, with greater focus on support for new vaccines. Parallel to the introduction of new vaccines in recent years, Gavi has supported the strengthening of the health system, through a specific project (Health Systems Strengthening; HSS) launched in 2007. Mozambique has submitted three HSS funding proposals and the third was approved in 2013. In addition, Gavi provides support to supplemental immunization activties and campaigns, particularly to support new vaccine introductions. As part of this, the Measles-Rubella (MR) vaccination campaign is currently ongoing. This campaign was launched April 9, 2018 and is in its first phase and is expected to cover more than 12 million children from 0 to 14 years across the country. Table 2 shows the different Gavi financed activities to date.

In the coming months, the country is expected to submit proposals for two more grants, one for the introduction of HPV vaccine and the other for cold chain strengthening (Cold Chain Equipment Optimisation Platform, CCEOP).

Table 2. Gavi Funding to Mozambique.

GAVI SUPPORT	FUNDING PERIOD	TOTAL FUNDING (US \$)
Immunization services support (ISS)	2001-2003, 2011	1,665,500
Injection safety support (INS)	2003-2005	835,881
Cash support (CASHSUPP)	2014	170,000
Injection safety devices (NVS)	2017 - 2019	1,902,000
Measles/Rubella Campaign	2017	16,875,112
HPV Demo (NVS)	2014	56,503
New vaccine introduction (NVS)	2002, 2008, 2012, 2015, 2018	4,709,499
First Measles/Rubella dose	2018-2019	731,016
Health Systems Strengthening (HSS)	2015-2019	7,528,323
Second Measles dose (NVS)	2015-2018	1,688,000

EXECUTIVE SUMMARY

GAVI SUPPORT	FUNDING PERIOD	TOTAL FUNDING (US \$)
Product Switch Grant (PSG)	2017	271,286
Tetra DPT-Hep B (NVS)	2001-2007	16,897,320
Pentavalent vaccine (NVS)	2009-2019	45,877,693
Pneumococcal conjugate vaccine (NVS)	2013-2019	96,177,344
Rotavirus vaccine (NVS)	2015-2018	14,441,210,426,652
Inactivated Polio Vaccine (NSV)	2015 - 2018	4,420,927

Source: http://www.gavi.org/country/all-countries-commitments-and-disbursements, accessed on May 31, 2018.

Introduction

In 2013, Gavi commissioned the Full Country Evaluations (FCE) in order to measure the effectiveness and impact of the support it provides for immunization. This evaluation was designed to understand and quantify the barriers and conductors to improve the immunization program. The first phase of this evaluation took place in four countries: Bangladesh, Mozambique, Uganda and Zambia and focused on all phases of support from Gavi, from the decision to apply to Gavi for support, the application itself, approval, preparation and implementation in each of the relevant support streams. The results of this evaluation were used locally for decision-making and improve the implementation of Gavisupported activities and globally as a significant source of information for the review of new policies and guidance which in the meantime where under development, update of guides and development of Gavi's new programs and initiatives.

Based on the first phase of the evaluation findings, Gavi launched an extension (FCE2) to run from 2017-2019, including Mozambique, Uganda, and Zambia. In this second phase of the FCE, the selected countries will continue the work began in the first phase but will also focus on the new Gavi strategy to improve vaccine coverage and equity. The new policies and new programs and processes implemented by Gavi should also be evaluated for the five-year period 2016-2020.

The results and recommendations of phase 1 were instrumental in the preparation of proposals for issues to be evaluated in the second phase. These have been suggested for each country, considering the flow of ongoing support. Thus, a set of evaluation questions (EQs) suggested by the global team have been combined with others suggested by local stakeholders, totaling 13 EQs for Mozambique. These were discussed and agreed between the stakeholders involved in Mozambique's EPI program.

This prospective evaluation of Gavi support provides a means of obtaining timely information to inform relevant changes, not only for the evaluation countries, but also for Gavi's processes and policies. In this context, one of the objectives of this evaluation is to generate evidence and lessons to support the improvement of immunization coverage and equity.

METHODS

For this first report of FCE2, 7 out of 13 questions are answered. These were selected based on two main criteria: availability of sufficient and concise information for a clear response and properly detailed and current state of implementation of activity to be assessed, i.e., if they have started or not, and if they have initiated the time elapsed since the start is sufficient for it to be evaluated.

The FCE2 approach emphasizes the importance of theory-based and realistic evaluation; the approach to answering each EQ is informed by social science and program theory.

Table 3 describes key strengths and limitations of the methods applied to inform the findings covered in this report.

Table 3. 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.

The following process evaluation components were employed for this report: (i) discussion of topics and main approaches with global and local teams to orient the evaluation; (ii) process tracking, mainly through document review, observation and fact-checking interviews (FCIs); (iii) in-depth analysis of the processes through key informants interviews (KII); and (iv) analysis of administrative data obtained through the Health Information Management System (HMIS) and administrative data from EPI to assess issues related to coverage. The team used analytic tools such as root cause analysis (RCA) to synthesize data and developing findings. Table 3 shows in summary form the relationship between the methods employed, information sources and issues addressed by each method. More details can be found in Annex I on the methods used in the evaluation.

Each key finding in the report is accompanied by a robustness ranking (Error! Reference source not found.) 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 4. Methods used in the evaluation.

METHODS	INFORMATION SOURCES	ISSUES INVESTIGATED
Process tracking	Document review - the following documents were reviewed: > Phase 1 FCE reports > EPI programmatic reports, provincial and national > EPI monthly reports > HSS annual plans, provincial and national > HSS budget execution reports > 2017 Joint Appraisal Report (JA) > Communication between the National Public Health Directorate (including EPI) and Directorate of Planning and Cooperation > New Gavi policies and other strategic documents. Team representatives participated in the following events for observation: > COPI meeting in 2017 > Discussion meeting on the next phase of PCV switch > Discussion meeting on the current stage of preparation for the vaccination campaign against Measles/Rubella. 7 fact-checking interviews were also carried out with managers, 5 with EPI managers (general and HSS) and with two partner representatives (UNICEF and WHO)	This method supported in the evaluation of the following FCE2 issues: > What are the main factors influencing the achievement of coverage and equity results? > What is the relative contribution of Gavi support for the changes in the results of coverage and equity? > What is the contribution of HSS funds to vaccination coverage in the priority provinces and districts? > Is the change from PCV10 to PCV13 being implemented as planned? > Is EPI making use of the lessons learned from the execution of funds and the implementation of the HSS activities in the past in their current efforts? Why and how? > Are the national decisions (including the role of COPI/NITAG) to apply for a new support from Gavi made considering the aspects of programmatic and financial sustainability (e.g., the country's eligibility status, the requirements for co-financing, impact analysis in the budget)?
Key informants interviews	10 key informant interviews were made - 6 with the MOH (EPI and HSS), 1 with the UNICEF, 1 with the WHO, 1 with a representative of CoPI and 1 with the Gavi's SCM.	 What is the contribution of the HSS funds in vaccination coverage in the priority provinces and districts? What are the advantages and consequences of the management of HSS funds through partners outside the government system? Is the switch of PCV10 to PCV13 being implemented as planned? Is EPI making use of the lessons learned from the execution of funds and the implementation of the HSS activities in the past in their current efforts? Why and how? Are the national decisions (including the role of COPI) to apply for a new support from Gavi made considering the aspects of programmatic and financial sustainability

INTRODUCTION

METHODS	INFORMATION SOURCES	ISSUES INVESTIGATED
		(e.g., the country's eligibility status, the requirements for co-financing, impact analysis in the budget)?
Routine data analysis	HMIS database was queried for extracting data on vaccination and the data obtained through the EPI data manager.	 What is the relative contribution of the support from Gavi for the changes in the results of coverage and equity? What is the contribution of the HSS funds in vaccination coverage in the priority provinces and districts?

Table 5. 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.

Coverage and equity

EQ 1-3: What are the drivers of changes in coverage and equity?

Gavi's strategy was revised in its latest strategic plan 2016-2020, moving from a focus on the introduction of new vaccines toward a focus on improved coverage and equity of vaccines². To achieve this goal, Gavi aims to: remove barriers to vaccination such as wealth, geographic location and gender; promote the use of modern technologies and approaches, not only to improve the effectiveness and efficiency of immunization services, but also to support countries to make their health systems more responsive to the other problems they face; share critical information to assist countries to make informed decisions on the programmatic and financial point of view, thinking of the long-term sustainability once Alliance support ends, and; continue to shape the global vaccine market in order to keep costs affordable for countries in most need.

Finding 1.1

Routine data indicates that vaccination coverage of fully immunized children increased by 8 percentage points from 2015 to 2017, while there was a reduction in the between-district inequalities within provinces.

ROBUSTNESS RANKING

Α

This finding is based on HMIS data, which has known data quality issues. However similar trends are reflected in the FCE1 small area estimates.

NATIONAL COVERAGE TRENDS

The team performed a routine analysis of coverage of DTP3 vaccine and coverage of all major antigens (fully immunized child - FIC) offered by Mozambique's National Health Service over the last three years (2015-2017), based on routine HMIS data. In the case of Mozambique, FIC refers to those children who have received all required doses of vaccines for all major vaccine preventable diseases, namely: polio, measles, tuberculosis, diphtheria, pertussis and tetanus. The findings of the DTP3 coverage analysis were later compared to those reported from WHO-UNICEF (WUENIC) joint estimates for triangulation. The results of this analysis indicate that the coverage of DTP3 at the national level registered a growing trend over the three years, although it was small, see Figure 1.

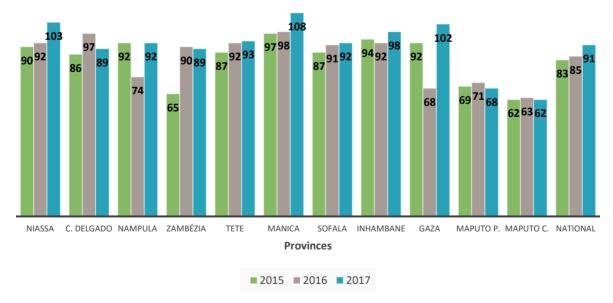
110 100 90 DTP3 cpverage (%) 80 70 60 50 40 30 20 2015 2016 2017

Figure 1. National DTP3 coverage trends, 2015-2017.

Source: HMIS

The result of this analysis indicates that there was an increase in FIC coverage of about 8 percentage points at the national level during the period. As illustrated in Figure 2, this FIC coverage increase was higher from 2016 to 2017, an increase of 6 percentage points, whereas from 2015 to 2016 there was only a 2-percentage point increase. The increase in 2016 to 2017 reflects significant improvements of Gaza, Nampula, Niassa and Manica with 34, 18, 11 and 10 percentage point increments, respectively.

Figure 2. FIC coverage (%) by province, 2015-2017.

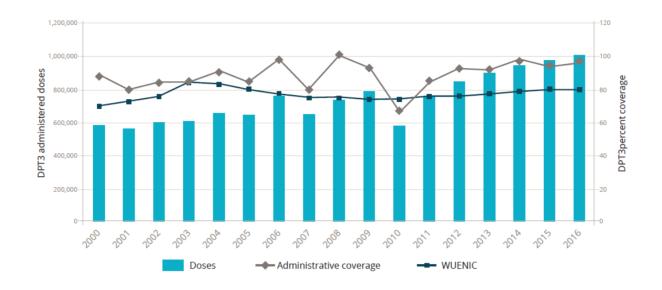


Source: HMIS and EPI Annual Reports

As noted earlier, for triangulation issues, the team made use of WHO-UNICEF national coverage estimates to compare them with country administrative data (HMIS). As can be seen in Figure 3, which presents DTP3 coverage from 2000 to 2016, for the period of our analysis there is a convergence in terms of trend, which is similarly and consistently increasing from 2012 to 2016, although in terms of

percentages those presented by WUENIC estimates are noticeably lower. Thus, even if data quality inconsistencies persist, there is a real possibility of coverage improvements, even if they are slight.

Figure 3. Estimates of WUENIC national coverage trends for DTP3 in Mozambique, 2000-2016.



Source:

WHO/IVB database, data reported to WHO by Member States as of 15 July 2017.

WHO-UNICEF estimates of immunization coverage (WUENIC) as of 15 July 2017

http://www.who.int/immunization/monitoring_surveillance/data/administrative_coverage.xls

http://who.int/entity/immunization/monitoring_surveillance/data/coverage_estimates_series.xls

Source:

http://apps.who.int/immunization_monitoring/globalsummary/countries?countrycriteria%5Bcountry%5D%5B%5D=MO Z&commit=OK#, accessed June 2, 2018.

In the same period from 2015 to 2017, improvements were reported in the inequalities observed between districts within provinces. Per the 2017 Joint Appraisal report and HMIS data, the number of districts with DTP3 coverage exceeding 80% increased from 127 of 148 districts (86%) in 2015 to 144 of 159 districts (91%) in 2016 and subsequently to 147 of 159 districts (92.5%) in 2017.

Community building activities contributed significantly to the observed outcomes as indicated by a number of documents and strategic initiatives, including: (i) revitalization of the community health worker (CHW or APE in Portuguese) program in 2010 by the Ministry of Health (MISAU), where child health was one of the main topics, including the importance of promotion of vaccination at the community level; (ii) the strategic health sector plan (PESS 2014-2019, which has defined community involvement in improving community services (including improving coverage and equity of vaccination) as a priority; (iii) ongoing actions under the leadership of the National Directorate of Public Health that have resulted in a significant increase in community health agents, including CHWs (APEs), traditional midwives and health committees. Together they have supported all components of health promotion within primary health care including active outreaches and community mobilization; (iv) additional investments to intensify the training of the agents listed in the previous point, as well as practitioners of traditional medicine in actively seeking and mobilizing the community to utilize various services, including immunization.

Figure 4. Trend of the number of CHWs (APEs), 2010-2017.

"... under the activities funded by the HSS, the EPAs program is supported to intensify active search in areas of difficult access and which cannot be easily reached even using mobile brigades..." (KII Manager, central level EPI)

The active outreach and community mobilization activities mentioned above are complemented by health promotion activities such as dissemination of key information through media, including community and national radio and television.

Despite these gains, there is still evidence of inequalities between provinces and between districts within provinces. Figure 5, which presents data from the year 2017, we observe FIC coverage ranging from 62% in Maputo City just over 100% in Manica. Figure 5 shows inequalities between districts of the same province, as illustrated by deviations from the average coverage of the respective districts. This figure highlights considerable variations in the provinces of Maputo City and Gaza, as there are longer intervals between the districts' coverage in these provinces.

NIASSA CABO DELGADO NAMPULA ZAMBEZIA TETE 0 MANICA SOFALA INHAMBANE GAZA MAPUTO PROVINCIA MAPUTO CIDADE 50 100 150 200

Figure 5. Variation of district FIC coverage from the provincial average coverage.

Source: HMIS

Data available from the country's periodic household surveys, such as IDS 2011, IMASIDA 2015, and synthesized data from the 2017 Joint Appraisal indicate that factors such as living in rural areas, maternal education, and belonging to the lowest wealth quintile are associated with the observed inequalities. However, there are other factors such as the perceived quality of services by the main beneficiaries, and access to their services, which also contribute to equitable access to vaccines and other health services. To further examine these factors, in the second year of the evaluation the team intends to conduct district level case studies to be able to assess the contribution of such factors on coverage and equity, as well as to investigate potential opportunities to improve the coverage and equity results presented above.

FIC coverage (%)

Recommendations

Continue doing: MISAU and partners should maintain focus on community involvement, especially in hard-to-reach areas, including through mapping of hard-to-reach communities, education on the importance of vaccination, and active outreach of under-vaccinated children.

USING THE FCE2 TOC TO EXPLAIN COVERAGE AND EQUITY

EQ 1: What are the main factors influencing the achievement of coverage and equity results?

To answer this evaluation question, the FCE adapted a theory of change (ToC) for immunization coverage (see FCE2 Cross-Country report for more information). The team added two dimensions to a ToC used in FCE1: leadership, management and coordination (LMC), and data quality and use. According to the ToC, vaccine coverage is influenced by factors related to the provision of services, access by beneficiaries and demand for such services. The TOC can be found in the 2018 cross-country report at: http://www.gavi.org/results/evaluations/full-country-evaluations.

Finding 1.2

Persistent challenges related to leadership, management and coordination have the potential to negatively influence vaccine coverage and equity.

ROBUSTNESS RANKING

B

This finding is based partly on KII and document data, but would be strengthened through primary data collection and observation of the effects of LMC at provincial, district, and community levels. This is planned for Year 2 of FCE2.

The EPI program consists of three levels of management and leadership -- central, provincial and district - each with its own challenges. In general, all suffer from the chronic problem of availability of human and financial resources. For example, the 2017 Joint Appraisal Report notes that between June 2016 and June 2017, the program lost eight senior staff at the central and provincial levels, leaving a significant deficit in terms of management capacity and supervision of the program at the more peripheral levels.

At the provincial level, and associated with the ongoing system decentralization, there are challenges with the alignment and coordination of activities between different actors. Under decentralization, provinces are eligible to receive support directly from partners without coordination with the central level. While this has benefits in terms of raising support locally, from the planning point of view, it can contribute to duplication of effort and reduction in program efficiency. For example, UNICEF reported that during the time it was distributing refrigerators to the provinces they detected the existence of other refrigerators purchased by other partners which were in disrepair/disuse and there has been no communication with the central level.

"... one of the major constraints is the lack of alignment between the MOH and provinces ... in a supervisory visit I carried out in 2015/2016 it was noted that the equipment distribution plan that came from the central level to reach the province has been completely changed, i.e., the province is autonomous and can say: the situation has changed and no longer want this equipment because that location already have a FUNAE refrigerator, so now we should send it to another location ... i.e. there have been changes at the provincial level that were not properly communicated at the central level ... there are situations where we think that certain

COVERAGE AND EQUITY

aspects are already solved, but when we go to the field we see that is not so ... there are many situations like this ..." –KII, Partner central level

Similarly, an EPI senior manager reported difficulty in acquiring accurate information on provinciallevel initiatives, since they do not receive timely and comprehensive information of the initiators of such initiatives. EPI often learns of activities only after they have been implemented without ever having had the possibility to align with the current procedures for similar activities approved at the central level. This negatively influences the coordination of activities and limits the possibility of harmonization of procedures as well as diverting support from where it is needed most, further reducing the efficiency and cost-effectiveness of activities implemented.

"... we do not always know everything that happens in the provinces nor the approaches, since partners involved in other activities, such as women's health, also implement aspects related to vaccination without consulting us, or send us the reports in order ... because their primary activity is not in the field of vaccination." -KII, Manager central level

At the district level, challenges related to human resource shortages are reported, for example 1,620 providers for 1,536 fixed vaccination posts, and inadequate technical capacity for fund management and planning. At this level of care, the activities of management of the EPI program are carried out by the preventative medicine technicians, who in addition to this responsibility are responsible for other programs as part of integrated services. This is associated with the observed gaps in capacity for critical and thorough program evaluation, with consequent deficiencies in the planning process at this level. These deficiencies lead to delays in the planning process, with a consequent delay in the availability of funds.

"... the planning process starts at the district level, where the health facilities needs are prioritized, to go up to the central level ... what we notice is that the districts still lack capacity and need a lot of support from the provinces ... this process sometimes takes a long time and delays all subsequent processes." –KII, Manager central level

Recommendations

- Act now: Improve communication between the central and provincial level to strengthen the coordination and allocation of support to areas in greatest need.
- --> Continue doing: Continue with the district managers' capacity building plan to improve their planning skills and extend the MB Consulting support to the district level for financial management and reporting issues.

HOW VACCINE STOCK INFLUENCES COVERAGE AND EQUITY

Finding 1.3

Recurrent failures to maintain vaccine stocks undermine the program's ability to maintain adequate coverage and improve equity.

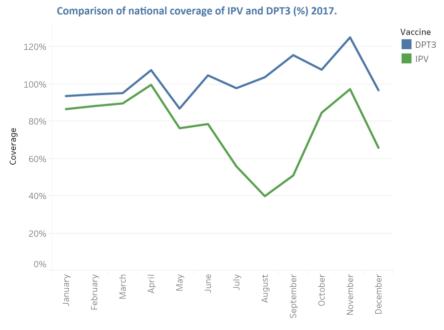
ROBUSTNESS RANKING

Δ

This finding is considered an "A" because it is support by triangulation across multiple data sources (HMIS, program documents, meeting observation, KIIs).

In 2017, vaccine stock shortages were reported on a regular basis. For example, coverage of IPV vaccine, which is administered simultaneously with DTP3, fell to 40% in August, more than 60 percentage points lower than DPT3 coverage (see Figure 6, below). IPV coverage fluctuated considerably throughout the year, most notably between July and October and December. According to data from the EPI annual report, the vaccine showed the longest period without availability of stocks. The most likely cause was the global unavailability of vaccine, due to insufficient production.⁷

Figure 6. Comparison of DPT3 and IPV coverage, by month, 2017.



Source: HMIS

In parallel with this vaccine, shortages of three other vaccines were reported at the national level, namely BCG, OPV3 and tetanus toxoid vaccine. For these vaccines, mostly financed by the government, logistical problems, such as delays in procurement and arrival in country, are reported for their unavailability. This is persistently observed reported to be recurring for these vaccines funded by the state, as can be inferred from KIIs.

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"... there are usually frequent stock-outs, especially vaccines funded by the state ... the bureaucratic process does not facilitate the timely availability of funds for activities and the scenario is now aggravated by the crisis, the state has no money ..." -KII, Manager central level

Manica, Nampula, Zambézia and Cabo Delgado provinces were most affected by shortages in these vaccines, and in IPV. Vaccine shortages for long periods can have a negative impact on coverage and therefore on equity, since the provinces most affected are also those which are also classified as priority, either because of their large populations and/or the existence of more hard to reach communities.

On the other hand, other new vaccines showed improvements compared to previous years. This is the case, for example, of the rotavirus vaccine, which, unlike the slow routinization reported in the annual evaluation report in 2016, for 2017 showed 100% coverage in the first dose and about 94% in the second dose and there were no cases of stockouts during 2017. The same was recorded for PCV, with reported coverage of about 100% for both the first and third doses.

Regarding the delays in procurement, the FCE 2016 evaluation report recommended that MISAU/EPI identify and solve the problems that led to delays in the availability of vaccines in 2016 and to sign memoranda of understanding with customs authorities and entities to ease import procedures. In order to respond, there were changes such as timely registration and requisition of internal codes, such as the Moz Number for example, so that the import and clearance process would be faster, as described later in this report. However, the delays continued to be observed for unexplained reasons and that some informants suspect they have to do with difficulty in perceiving the importance of the procedures by a certain type of staff, usually the executors.

"... whenever there are these kinds of difficulties, we ask for meetings with the responsible ministries, for example the Ministry of Economy and Finance, and we have even achieved good results and commitments at the leadership level, but I have the feeling that the problem is at the level of people ... whichever technician deals with the daily activities -- he/she has difficulties in responding adequately to our requests ... " -KII, Senior Manager of MISAU

One of the most reported reasons for the observed failures in relation to the internal distribution of vaccines has to do with the availability of fuel to transport the vaccines. The reason reported for this is that the fuel requisition process is centralized and under a rigid control system, which in case of delay in the justification of consumption from any level of the system blocks new requests. To unlock the process is slow and not flexible.

Recommendations

- administrative reforms to better facilitate procurement processes in order to avoid the delays in the acquisition of vaccines and other products important for the success of the program. This initiative should be accompanied by the appointment of focal points of the ministries involved in monitoring the progress of the talks.
- Act now: EPI should explore the possibility of using Gavi funds to sign a contract directly with a gasoline plant to purchase fuel for the distribution of vaccines and other related products.

DATA QUALITY AND CAPACITY

Finding 1.4

Data quality and capacity to manage and analyze data at the more peripheral levels influences the use of data to address coverage and equity challenges.

ROBUSTNESS RANKING B

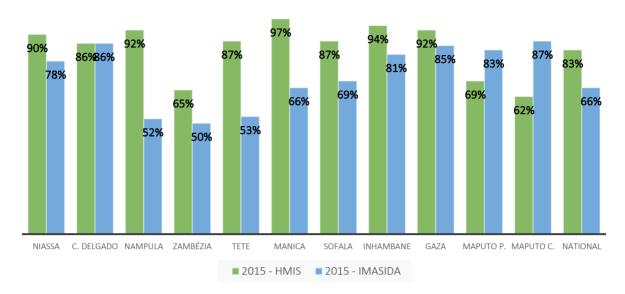
This finding is considered a "B" because it is consistent with existing theory and empirical evidence from low-income countries. While the finding that data quality is sub-optimal is supported by multiple evidence sources, the team was not able to observe the impact of poor-quality data or other barriers and facilitators of data use at more periphery levels.

Data quality has been consistently reported as one of the main EPI program challenges. Although the evaluation team has not carried out an exhaustive assessment of data quality, there is evidence from previous reports and findings in other fora of disparities observed in data collected in different ways, such as between administrative EPI data (HMIS) and population-based surveys.

COVERAGE AND EQUITY

Figure 7 below, presents FIC coverage data for 2015 taken from two sources, HMIS data and the last population survey conducted in the country. As can be seen, HMIS data reports consistently higher FIC coverage in most provinces, except for Maputo City and Maputo Province, which have the reverse scenario. Often, HMIS data even show coverage higher than 100%, which may be due to factors such as denominator problems, the poor quality of records, provider work overload, among other factors.

Figure 7. FIC coverage by province with two different data sources, in 2015.



Source: IMASIDA (Demographic and Health Survey) and administrative (HMIS) data.

On the other hand, some informants report there is weak capacity to process and analyze data at the district and provincial levels. Indeed we know from other sources and observations in other forums within the public health system that most of the data discussion meetings are used to discuss issues of reaching or not achieving goals superficially and without in-depth analysis of causes and associated factors.

"... in our discussions there is great emphasis on goals set and we often forget to allocate time to the deepening of basic questions for failure that is sometimes observed ... but this is partly because, in the more peripheral levels, colleagues are concerned in targets outreach and do not carry out deep analysis on performance problems ... "-KII, Health Manager

These aspects contribute to the limited use of existing data for planning and monitoring and evaluation issues, as expected.

Data quality improvement interventions

There are ongoing initiatives to address the issue of data quality. In 2016, a workshop was held on data quality improvement using technical assistance provided by WHO (a second workshop was scheduled for 2017, but it had to be postponed and the team is not aware of the current situation). Another initiative consists of placing a Village Reach staff person in the EPI program to support access, data visualization and analysis by creating Excel "dashboards" to facilitate improved management practices by compiling various data sources to allow managers to access it in an integrated way.

Since 2016, MISAU through the Directorate of Planning and Cooperation (DPC), introduced a new electronic health management information system, DHIS2. During the implementation process more than 5,000 health workers were trained to use the tool based on a 'data cycle' framework approach, from registration and data collection to methods to validate the consistency, completeness, and timeliness of data. Other trainings were held for DHIS2 including in-service training with an emphasis

COVERAGE AND EQUITY

on data quality improvement. Currently, there are electronic system validation rules being implemented, however action on data quality improvement should be intensified and coordinated by districts and provinces at regular periods.

Recommendations

- Continue doing: MISAU and partners, including WHO and others interested in data quality, should improve the coordination of and intensify ongoing data quality improvement activities.
- Act now: MISAU and its partners involved in data quality improvement should support teams at provincial, and particularly at district levels, in the collection, analysis, and use of data with the aim of improving performance through the following strategies:
 - Strengthen information on the importance of data for performance planning and monitoring processes;
 - Focus on discussion of the causes and factors that influence vaccination coverage, as well as potential solutions, rather than whether or not targets are achieved, both in the data review meetings and in the supervision sessions;
 - Periodically choose data from a particular health facility or district for a thorough discussion in the presence of data experts, to strengthen data management in a practical way and with concrete examples.

ACCESS TO SERVICES

Finding 1.5

Poor access to services may exacerbate inequities in vaccination coverage.

ROBUSTNESS RANKING

B

This finding is considered a "B" because it is based on triangulated data from HMIS and document review; however, it could be strengthened through a more systematic evaluation of the contribution of mobile brigades and REC to vaccination coverage.

Regarding access factors, there are two aspects to highlight, one is related to the coverage of the health system, which clearly is below what are the population needs. Per the health sector review report, in 2011 less than 60% of the population had access to the health system and more than 40% of the population had to travel more than 10 km to the nearest health facility. It is expected that most of these 40%, which are not covered by fixed vaccination posts, will be covered by the mobile brigades and other service extension activities. However, for the year 2017, the contribution of mobile brigades for the observed coverage was about 10%, as presented in Figure 8.

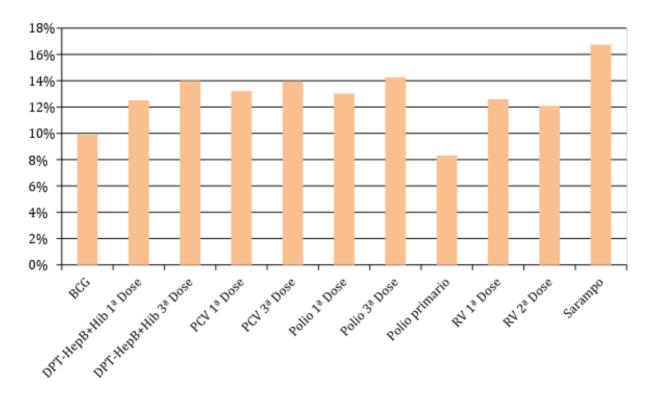


Figure 8. Contribution of mobile brigades to vaccine coverage, by vaccine, 2017.

Source: HMIS (2017). "Sarampo" = measles

COVERAGE AND EQUITY

Information available from sources consulted, as well as informants interviewed by the team, indicate that the number of doses administered through the mobile brigades has been far below what was planned. This low proportion of mobile units is influenced by several factors, especially availability of vehicles, fuel and funds for allowance payments.^{5,3} Previous reports have identified these as being the biggest challenges to the success of mobile brigades' activities and despite several recommendations to minimize its effect as described in health system strengthening section below.

The REC (Reach Every Community) strategy is another approach to meet the challenges for serving hard to reach populations. REC implementation had been scheduled for 2016, but so far its start is not yet in full and it is only expected to be effective later this year, 2018. The strategy is intended to facilitate better coordination of activities to reach the communities that are not included by different immunization activities for various reasons, including their very remote location. The main factors involved in the successive delays of the effective start of the REC strategy were the switch of PCV10 to PCV13; polio vaccine campaigns required to respond to the case of flaccid paralysis registered in the new district of Derre, as shown below, and; the ongoing MR campaign.

Demand for services

The demand for services factors requires an approach, which for purposes of this report it was not possible to implement due to the requirements for its materialization. The team will conduct a site visit as soon as appropriate, to perform a study at the community level for clarification on the level of knowledge and the factors that influence the demand for immunization services by the community.

Recommendations

Act now: MISAU and partners should fully implement the REC strategy as soon as possible to ensure coverage of areas currently underserved.

Health systems strengthening

EQ4: What has been the contribution of HSS funds to vaccine coverage in priority provinces and districts? (Mozambique, proposed by country stakeholders)

EQ5: What are the advantages and consequences of managing HSS funds through partners, outside of government systems? (Mozambique, proposed by country stakeholders)

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.

Gavi introduced the Health Systems Strengthening Grant in 2007 to address structural issues in health systems that influence the reach of the most disadvantaged populations and are less likely to be covered by immunization activities in the context of countries with weak systems. Mozambique submitted three HSS proposals, and the third was approved in 2013. The first disbursement occurred in 2015. Since then, funds have been implemented for two consecutive years, 2016 and 2017, although with several challenges reported by previous evaluations, including difficulties in the execution of important proportions of the funds due to questions of various kinds, duly reported in previous years.

The country applied for HSS funds to strengthen the EPI program and optimize the vaccine distribution system. When these objectives have been achieved, we expect to see a reduction in under-5 mortality through improved access to and use of immunization services, as well as the health of mothers, newborns and children, especially in hard-to-reach areas.

By supporting the system, MISAU, through the EPI program, hopes to be able to expand services to the hardest-to-reach populations, which contribute to the inequities observed in the provision of care.

Finding 2.1

There was a significant improvement in the HSS funds' expenditure, however, to improve the performance towards reducing inequities in coverage, the program should improve the proportion of funds allocated to community actions and to management.

B ROBUSTNESS RANKING

This finding is considered a "B" because while it is based on triangulated data from HMIS, document review, and meeting observation, it would be strengthened through primary data collection evaluating the contribution of HSS to community activities and management activities.

2017 was the second year of budget execution of the HSS funds by the EPI program. Due to the challenges faced in the previous year, namely weak budget execution capacity and challenges to

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report expenditures, the following reforms were made, as part of Gavi recommendations, FCE1 and results of the Joint Appraisal:

- Procurement of technical assistance from MB Consulting to support the planning and financial management at the provincial level. With this hiring there was the objective of improving financial planning, execution and reporting.
- Holding meetings with provincial and other representatives within the ministry for dissemination and clarification of HSS-eligible activities. The purpose of this activity was to increase flexibility in the selection of activities and thus to improve the implementation of the available funds.
- > Implementation of the bottom-up planning process and without consideration of any financial ceiling. The purpose of this was to enable districts to select all activities considered critical to improving program performance, looking specifically at local needs and challenges.
- > Development of orientation guides for the provinces and other units to facilitate the planning process.
- > Reviewing the plans of the priority provinces for guidance on possible additional activities to accelerate the improvement of their coverage.

As a result of the reforms made to the project in the year 2017, the execution of funds was around 100%, as can be seen in Table 6, below:

Table 6. HSS Financial Implementation, 2017.

IMPLEMENTER	ANNUAL BUDGET	AMOUNT SPENT	EXECUTION
мон	63,278,890.59	60,992,535.11	96%
Niassa	9,531,224.54	9,531,224.54	100%
Cabo Delgado	8,819,783.17	8,812,283.17	100%
Nampula	15,865,103.00	15,770,894.00	99%
Zambézia	14,416,872.25	14,362,797.25	100%
Tete	9,687,332.92	9,682,832.92	100%
Manica	9,686,942.62	9,686,942.62	100%
Sofala	10,218,102.11	10,190,464.11	100%
Inhambane	8,252,988.00	8,252,988.00	100%
Gaza	8,087,755.00	8,052,555.00	100%
Maputo Province	9,066,334.53	9,063,534.53	100%
Maputo City	3,758,516.08	3,758,516.08	100%

Source: HSS Financial report, 2017; amounts in Mozambican meticals

In the evaluation of the annual budget for 2017 by category, according to

Figure 9, most of the year's budget was allocated to the provision of services, supply chain, and workforce. Aspects such as program management and demand-generation activities and active community-level outreach accounted for less than 10% of the total budget.

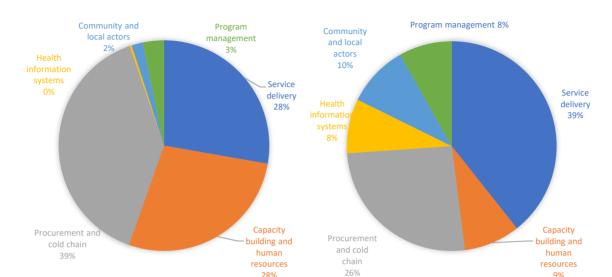


Figure 9. Annual budget by budget category, 2016 (left) and 2017 (right).

Information from sources such as the joint appraisal and the analysis in the previous section of this report indicate the importance of persistent challenges in terms of EPI management capacity and also the importance of community-level interventions to improve coverage and reduction of inequities. The evaluation team is of the opinion that while other activities are also of key importance for program performance, a reorientation of investment into the areas described here would have the potential to further improve the results achieved. The reason for this is that an investment in improving management would include an improvement in the collection, processing and interpretation of data, improved communication and coordination, among other constraints listed above, which would support more informed decisions about the locations with the greatest needs, as well as the type of need at the district level and health area of health facilities. Similarly, given the limited coverage of fixed vaccination posts (60%), coupled with the fact that service extension activities (mobile brigades, for example) only contribute about 10% of needs, more community activities would benefits in terms of improving the reach of hard-to-reach populations.

The change in the level of execution of the procurement and cold chain heading from about 20% to almost 100% despite a reduction of about one-third of its amount is a clear illustration of the outcome of the reforms made in the HSS project, such as anticipation of obtaining approvals, in order to reduce the burden of delay resulting from MISAU's internal administrative requirements.

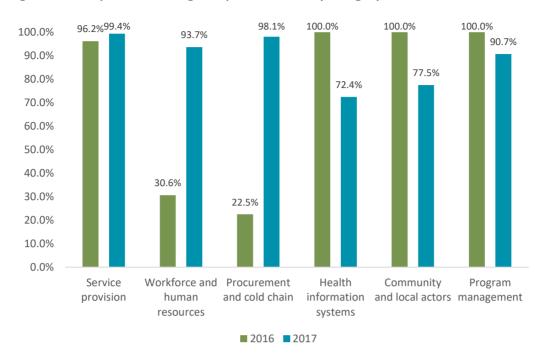


Figure 10. Comparison of budget implementation by category, 2016 and 2017.

Recommendations

- Continue doing: Gavi, MEF, and MISAU should continue initiatives to ensure the timely availability of funds to enable more budgeted activities to be implemented.
- Study further: MISAU should reprogram the HSS budget in order to increase the proportion allocated to management activities and those at the community level.

HSS MANAGEMENT AND FUNDS DISBURSEMENTS

Finding 2.2

The management of HSS funds by partners for HSS procurements did not bring significant advantages to the procurement and installation processes for cold-chain equipment and vehicles, compromising the plans for supply-chain and consequent provision of services.

ROBUSTNESS RANKING

C

This finding is considered a "C" because the evaluation team did not have access to all supporting documents requested. Interview data from MISAU and partners often diverged, resulting in low confidence of evidence for this finding.

Context

Despite significant advances, one of the aspects that has been considered as a constraint for the effective functioning of the EPI program in Mozambique is the cold chain and supply chain that has been highlighted in the Effective Vaccination Management (EVM) and EVM improvement plan. Given the importance of these components and in order to overcome the already known problems in the availability of vaccines, Gavi and MISAU, as part of systems strengthening, listed as a priority the acquisition of cold stores for the provinces, refrigerators, and motor vehicles for the distribution of vaccines. Moreover, due to the constant lack of motorized means to support the mobile brigades, Gavi and MISAU also prioritized the acquisition of motorized vehicles, thus contributing to the objectives of the HSS proposal, namely:

- (1) To achieve equitable access to the provision of services to the community level, including the expansion of the ability to conduct mobile brigades by providing employees with the means to do so, such as vehicles for distribution;
- (2) To increase the availability and efficiency of immunization services through the improvement of the immunization and logistic system in order to improve the logistics system of the EPI program.

As part of the Transparency and Accountability Policy requirements in December 2013, a financial management assessment (FMA) was carried out which took into account the current state of affairs and ongoing reforms in financial management in Mozambique. The FMA has identified several aspects among which the time from approval of acquisition to receipt of goods and services is long due to the slow approval of processes and the lack of an effective monitoring system. Based on the FMA Gavi developed the financial management requirements that was signed by MISAU where procurement was dealt with, for instance, cold chain equipment to be via UNICEF.

UNICEF Supply Division (SD) has a well-established global procurement system through its Copenhagen-based unit. The role of UNICEF's offices in Mozambique consisted in providing technical support and acting as an intermediary between the procurement unit in Copenhagen and MISAU. Payments were made directly from Gavi to UNICEF SD in July 2015. However, not everything went as

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expected. As most of the respondents said, the procurement process by the UNICEF unit took longer than expected.

What happened?

The first delay had to do with the discussions of the technical specifications of the materials prior to the preparation and sending of the purchase order, as well as the beginning of the procurement process itself due to the difficulties of the technical teams in reaching a consensus on the materials to be acquired mainly in relation to the vehicles. During the process of defining the technical specifications, MISAU identified a certain type of vehicle compatible and sustainable with the rough roads in rural areas. However, the UNICEF technical team, as a means of securing more resources, suggested vehicles that responded to technical specifications but were not seen as viable in the specified areas by MISAU. MISAU ordered the vehicles they thought best suited to the road conditions.

The second delay had to do with the arrival of the equipment to Mozambique and its customs clearance. The process of importing cars and motorcycles has some peculiarities that differentiate it from importing other equipment. MISAU/EPI is required to provide an import plan to the Supply Center well in advance to initiate procedures with the MEF in order to facilitate the customs registration process. In addition, the timely shipment of original documents facilitates the customs clearance process. According to KIIs, the import plan was not sent in advance to the supply center and consequently made the customs clearance process subject to alternative mechanisms aggravated by the late arrival of the original documents to Mozambique due to mail problems. Even so, MISAU sought alternative means to facilitate the exit and distribution of goods. This includes signing a contract with a dispatcher so that the dispatcher can make monetary advances to the taxing authority. MISAU also signed a Memorandum of Understanding (MoU) with MEF allowing vehicles to leave customs warehouses and avoid additional fees.

The third delay as reported by the interviewees, was that the vehicles required license plates. This required a local agent to do the pre-delivery inspection (PDI), guaranteeing that the vehicles are in working condition and with the respective guarantees. The availability of the local agent to receive the vehicles and to carry out the pre-delivery inspection was limited since it did not have the capacity to receive the vehicles in a timely manner and to continue the process of registration and delivery due to the overlap of schedules. For the motorcycles, they were not expected to be dismantled and consequently the need to search for a local agent for assembly resulting in alternative contracting and payment mechanisms.

The vehicles should have been used to support the activities of mobile brigades for outreach. However, about two years after the purchase of motorcycles, these were still found in MISAU's central warehouse, allegedly because the warehouse was not aware of the destination of the motorized vehicles. With this factor, the EPI program missed opportunities to carry out various outreach activities.

.... we paid a visit to the central warehouse and found motorcycles acquired two years ago still packed, because we did not know who would assemble them and what their destination would be ..." -KII, Senior Manager, MISAU

Since the disbursement in July 2015 until the date of this report (see

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Table 7), the process of procuring and distributing the equipment has not yet been completed, which

PERIOD	EVENT
April 2013	Mozambique submits the Gavi HSS proposal (third submission attempt).
December 2013	Gavi communicates requirement for Financial Management Assessment (FMA).
July 7, 2015	Gavi sends HSS funds to the country/MEF (including funds for MISAU, UNICEF and WHO)
January 14, 2016	UNICEF procurement: Purchase Voltage Regulators for Electrical Fridges. Purchased 50 regulators. Delivered to the beneficiary.
April 5, 2016	 UNICEF procurement of motorcycles for districts in the 4 lowest performing provinces of Nampula, Zambezia, Tete and Manica): purchased 100 motorcycles. UNICEF procurement: Purchase Electrical Fridges for the Health Facilities - Purchased 100 electric refrigerators. Delivered to the beneficiary.
April 11, 2016	 UNICEF procurement: Purchase portable generators for mobile maintenance units @ \$ 2,000/unit (South, Central & North Regions) - Three generators have been purchased for the three regions; delivered to the beneficiary. UNICEF procurement: purchase hot zone SDD fridges for health facilities Purchase temperate zone SDD fridges for health facilities - purchased 14 and delivered locally
April 14, 2016	UNICEF procurement: Five (5) 4x4 multi-purpose vehicles (2 for central level supervisory visits & 4 for 4 lowest performing provinces of Nampula, Zambézia, Tete and Manica) - a total of 9 vehicles were purchased, 5 Hilux for Central Level and 4 for the respective provinces). The cars were bought locally at Toyota.
April 20, 2016	 UNICEF procurement and delivery: Maintenance Kits for Mobile Maintenance Units @ \$ 230 / kit (South, Center & North Regions) Procurement of Vacuum Pump for Mobile Maintenance Units @ \$ 1,500 / unit (South, Center & North Regions) - 14 basic toolkits have been purchased, delivered locally to the beneficiary at regional warehouses
July 1, 2016	UNICEF procurement: Two (2) refrigerated trucks
Subsequent stages of HSS	The search process started in 2017 but was not completed because customs duties were not anticipated or entered in the Ministry of Finance. MISAU requested the re-registration (February 22, 2018) of funds for the acquisition of cold chain equipment, temperature monitors, 9 vehicles and 300 motorized vehicles through UNICEF.

presupposes that the procurement process carried out by UNICEF was not able to respond in a timely manner.

Table 7. Events of the HSS procurement process.

HEALTH SYSTEMS STRENGTHENING

Recommendations

- **Continue doing:** MISAU should continue initiatives to improve administrative processes to allow greater flexibility and fluidity of the procurement and allocation of resources to the more peripheral levels.
- Study further: MISAU and partners must find mechanisms to coordinate the processes of procuring, distributing and assembling equipment.

New vaccine introductions

From 2001 to the present, Gavi has supported the introduction of six vaccines in Mozambique: tetravalent DPT-HepB (2001), pentavalent (2008), pneumococcal conjugate vaccine (2013), rotavirus vaccine, measles booster and injectable polio in 2015. With further support from Gavi, the country is preparing for the introduction of MR in April-May 2018 and submission of the proposal to introduce HPV vaccine in September 2018.

The application for measles-rubella (MR) vaccine was submitted in September 2016 and approved in May 2017. The introduction of MR through a campaign was scheduled for September 2017, which was postponed to November 2017, but due to the delay in the disbursement of Gavi funds (which were only available in August 2017), this had to be postponed to April-May 2018 to allow the pre-campaign activities to take place.

The proposal for the introduction of HPV vaccine will only be submitted in September 2018, even though the decision to introduce was made the previous year. The reason for the lag is that MISAU decided to wait for the release of the new Gavi HPV vaccine application guidelines (HPV 2.0), which occurred at the end of 2017. Then, the vaccine became unavailable due to global supply shortages.

This section of the report aims to understand the process of implementing the switch from PCV10 to PCV13, with focus on compliance with the approved plan. Thus, the following question was answered: Whether, why and how was the switch from PCV10 to PCV13 implemented as planned?

Finding 3.1

The delay in the disbursement of funds from the MEF to MISAU, the late arrival of PCV13 in the country and the delays in its distribution to the provinces were the factors that contributed to the successive adjustments to the plan for the switch from PCV10 to PCV13.

ROBUSTNESS RANKING

A

The robustness of the results for the evidence surrounding this conclusion is A as it is supported by strong triangulation of data from document review, meeting observation and KIIs.

Context

Mozambique took the decision to introduce PCV in 2010. The decision-making process was led by MISAU and involved the following partners: WHO, UNICEF, VillageReach, Community Development Fund (FDC), Committee of Experts on Immunization (CoPI; Mozambique's NITAG) and the Interagency Coordination Committee (ICC), including consultation with Gavi. In the decision-making phase, the country chose the 13-valent pneumococcal conjugate vaccine (PCV13), based on scientific evidence of its efficacy, associated with the burden of the disease, and in the surveillance studies carried out by

the CISM, in coordination with the ICC and CoPI. Surveillance studies indicated that the serotype coverage of the 13-valent conjugate vaccine would be 83%.

The initial date chosen for the PCV launch under the Comprehensive Multi Year Plan (cMYP, 2011) was January 2012, however, the proposal for submission of the application to Gavi had not yet been developed. The PCV application was approved in July 2011, but two factors contributed to the fact that its introduction was not possible on the date previously proposed: the first was that the EVM evaluation had been postponed to May 2012 and the second was that PCV13 would not be available on the open market in 2012 and 2013. Thus, Gavi granted two options to the country: to start the introduction with existing PCV10 or to wait for PCV13, for introduction on an indefinite date. Mozambique chose to start with PCV10 and set March 2013 as the month of introduction, which was changed to April of that year due to the overlap of the agenda of MISAU (CISM and PCV10 Introduction, Phase I of FCE).

After the introduction of PCV10, 3 sentinel sites were installed in the central hospitals of Maputo, Beira and Nampula to monitor pneumonia cases, taking into account the coverage spectrum of PCV10. The results obtained through the sentinel sites demonstrated a significant reduction of cases of pneumonia covered by the vaccine, however, new pneumococcal strains not covered by PCV10 were emerging, so PCV10 switch to PCV13 became imperative (INS, 2015).

For the beginning of the switch a series of preparatory activities were planned:

- Training of trainers (central level)
- Training of EPI managers (provincial, district and health units)
- Distribution of vaccines to the provinces-districts-health units
- Withdrawal of the circulation PCV10 to the provincial deposits of the provinces concerned.

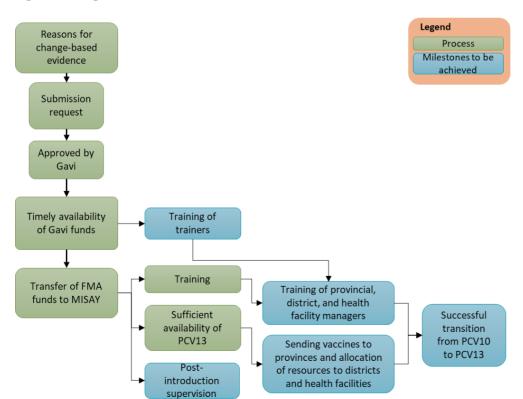


Figure 11. Logic model for the transition from PCV10 to PCV13.

NEW VACCINE INTRODUCTIONS

The PCV switch plan was initially targeted for July 2017 in the northern and central provinces. However, this was not implemented as planned due to the following factors: delay in the disbursement of funds, late arrival of PCV13 to the country and delays in the distribution of the same to the provinces. Another aspect that also contributed to the delay was the outbreak of polio that occurred in Zambezia province (central region), which dispersed resources and attention in the last months of 2016 and early 2017 (KII Manager of the EPI at the level central).

What happened?

There was a delay in the transfer of funds from MEF. Funds were only available in August 2017 due to bureaucratic and time-consuming processes of transferring external funds from MEF to MISAU.

The funds disbursement process was observed and covered in 2015 FCE Annual Report (focusing specifically on HSS disbursements) during the FCE phase 1. Summarizing this complex process, the external funds enter the country into a Central Bank account that later transfers the money to the Single Treasury Account in the MEF where it has several sub accounts including Gavi HSS. The MEF transfers money quarterly to MISAU through its account at the Bank of Mozambique in accordance with activities planned and approved by the Department of Planning and Cooperation. Within MISAU there is also a lengthy process until the activities to be carried out are approved and paid (Source: FCE report 2015). This fund transfer process, which may take up to 12 weeks if there are no delays in any of the steps, has contributed to changing the start dates of the PCV10 to PCV13 swap.

Delay of PCV13 to the country and delay in the distribution to the provinces.

PCV13 should have arrived in the country in June 2017 but only arrived in October of the same year. This delay delayed the training of EPI managers at all levels (provincial-district-health facility) and consequently postponement twice of the initially proposed dates for the exchange of the vaccine.

There were also constraints on the distribution of the vaccine to the north and center of the country, a recurrent problem that was mentioned in the FCE 2016. For the central and northern regions that are about 1,000-2,500 km apart, the vaccine is transported from Maputo (capital) where the only national depot is located. The only aviation service in the country (LinhasAéreas de Moçambique-LAM) has encountered space problems to carry large quantities of vaccine. During the distribution of PCV13 in the 1st phase, the amount sent was not sufficient to cover the whole quarter in some provinces (noting that Nampula and Zambézia have a large proportion of the country's population) due to lack of space in the airplane, however there was no stock-out because several trips were made by LAM to send more vaccines (Source: FCI with national vaccine deposit manager).

To overcome this problem, the construction of regional warehouses in the northern and central zones is under way and refrigerated trucks have also been acquired to assist in the distribution of vaccines.²

Polio in Derre in the province of Zambézia.

Located in the center of the country, Zambézia is the second most populated province with many remote communities and hard-to-reach children who have never been vaccinated (Joint appraisal Report, 2017).

In 2016 Zambezia province reported a case of Acute Flaccid Paralysis (AFP) in the district of Derre in the center of Zambézia province. As a result, there was a need to carry out a vaccination campaign covering 14 surrounding districts, 11 from Zambézia province, two from Sofala and one from Tete. The vaccination campaign took place in February 2017 for the 1st round and in May for the 2nd round. In that year, the national IPV coverage rate was 88%, which was partly due to the stock-outs of OPV and

NEW VACCINE INTRODUCTIONS

IPV in most provinces. Stock-outs were reported by 7 provinces, 44% of districts and 31% of health units, lasting 26 days on average (range: 4-60 days) (source: EPI report, 2016 and EPI Review, 2016).

The first IPV stockout in the north and center of the country in the first half of 2016 and the second stockout reported in the 4th quarter of the same year was caused by low production of the vaccine worldwide.2

In 2017, the problem of the lack of some vaccines persisted and the IPV was the one that remained the most time in stock disruption, affecting mainly the provinces of Manica, Zambézia, Nampula, Cabo Delgado and Niassa. The annual national coverage was 73% and the months of July (49%), August (30%), September (47%) and December (62%) were the worst, see Figure 4 above.²

Polio in the district of Derre required intensive engagement from EPI, WHO and UNICEF staff making them otherwise unavailable for the PCV switch during 6 months. This deviation of attention postponed the PCV10 to PCV13 switch initially scheduled for July 2017 to December of the same year.

How was the switch made?

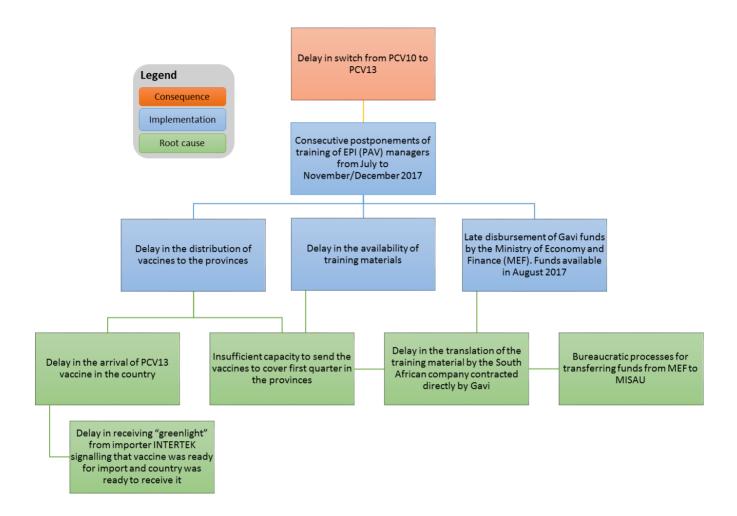
Initially, it had been planned to switch in three phases: the first in the three provinces of the northern zone and Zambézia, the second in the remaining three provinces of the central zone and Inhambane and the third in the other provinces of the southern zone.

The first stage of the switch took place in the provinces of Niassa, Cabo Delgado, Nampula and Zambézia, where the training planned for July at the provincial level and beginning of August at the district level was only carried out at the beginning of October and beginning of November respectively. Between November 13 and 17, the district trainers were trained. The following week the district trainers trained 1 preventive medicine technician from each health unit. PCV13 was introduced on December 4 for these provinces (initially scheduled for 10 August and then for 21 November).

The second phase took place in the central zone and Inhambane, where the training was scheduled for the 1st and 2nd week of September for the provincial and district levels, which only happened in the 2nd week of October (provincial level) and the 1st of December (district level) of 2017. From December 4 to 8, district trainers were trained and the technicians in the health units the following week. The use of PCV13 in these provinces began on December 18 (initially scheduled for September 21).

The 3rd phase for the southern zone (Gaza, Maputo Province and Maputo City) was scheduled to take place on February 26, 2018, but was postponed to March 21, which did not happen since the activities that should take place before the switch, including distribution of the new vaccine and the training, had not occurred on time. These provinces still had a large amount of PCV10 that should be used until that stock is depleted. As there was no contraindication to its use, its wastage was not justified. The 3rd phase will only take place when the existing PCV10 in the country is finished.

Figure 12. Root cause analysis for the delay of PCV10/PCV13 switch.



Recommendations

- Act now: EPI should realistically plan its activities taking into account the time it takes to transfer funds from MEF to MISAU to avoid constant changes to the plan.
- Study further: Even with the construction of regional warehouses in progress and the acquisition of refrigerated trucks to assist in the distribution of vaccines by land, EPI should study alternatives to minimize the constant lack of fuel (due to lack of payment), since this has been a frequent cause of delays.

Use of data, evidence and program learning

FCE2 was tasked with tracking the extent to which Mozambique is learning from the experience of implementing Gavi HSS support. HSS implementation began in 2016 after years of delays. The delays were caused in part by the process of registering HSS funds in the financial management system, the fact the grant timeline did not align with the normal planning cycle of the government, and the resulting late registration and consequent delays in the disbursement of the funds to the implementing levels. To address the problem of delays in the disbursement of HSS funds at the beginning of each year, the FCE team in 2016, recommended to the EPI program that: "The EPI must adhere to the deadlines of the budget planning cycle of the DPC and the MEF and submit necessary business plans and required documents according to the deadlines. 1"

Finding 4.1

The EPI program aligned the HSS planning and registration process with the national planning cycle of the Ministry of Economy and Finance (MEF) and the Department of Planning and Cooperation (DPC) of MISAU in 2017 for the 2018 HSS business plan.

ROBUSTNESS RANKING A

This finding is considered highly robust because it is based on triangulation of multiple data sources, including documents, meeting observation, and KIIs.

Following successive delays in the start-up of HSS activities in the years 2015 and 2016 due to the problems associated with the HSS funds planning and enrollment process, MISAU finally succeeded in aligning the HSS planning and enrollment process with the national planning cycle of the MEF and DPC in 2017 for the HSS 2018 implementation plan.

The planning process for HSS activities for the year 2018 took place between April and May 2017 in the provinces with the guidance and support of MB Consulting and the regional HSS adviser of the southern zone, with the support of the central HSS management team to ensure that the provinces had workplans until May 2017.

The individual planning of the provinces was followed by a national meeting on HSS activities in 2017 and joint planning of the HSS activities of 2018. This meeting aimed to harmonize the HSS plans of the provincial health directorate (DPS) with the original HSS workplan submitted to Gavi, in order to guarantee that the provincial workplans were ready for submission and subsequent registration. The meeting was held from June 28 to 30, 2017. The HSS plan enrollment for the year 2018 ran between August 4-8, 2017.

The successful alignment of HSS planning and budget registration to the MEF and DPC planning cycles in 2017 to 2018 was associated with several factors, including:

USE OF DATA, EVIDENCE AND PROGRAM LEARNING

- Gavi hiring a consultant to advise the EPI program on the process of planning, managing and disbursing HSS funds at various levels, from central to district level. In this context, with the support of MB Consulting, HSS planning tools and activity reports have been developed to assist EPI managers at various levels in the HSS planning and management process;
- All central and provincial fund managers have been trained to use these tools, including the Gavi workplan tool.
- Hiring HSS regional advisers to support the provinces in the management of HSS, and the coordination between HSS and MB Consulting, together with the support of the EPI managers, helped accelerate the planning process at the provincial level so that these could take with them the plan for aligning the outstanding balance and planning as described above.

Although the EPI program was able to register the 2018 HSS funds in August 2017, as of early April 2018, the EPI program still did not have access to HSS funds to implement the 2018 workplan. Three reasons for this were identified:

- The delay in carrying out the financial audit of Gavi's support to the EPI program for the year 2016.
- The delay was due to the fact that the administrative court had a full agenda to carry out an audit last year, only succeeding in doing so in December 2017 and making the report available to MISAU only in the first week of March 2018. (FCI, Key Informant MISAU Central Level).
- The delay in the preparation of the financial report for HSS year 2017, which was only available on March 23, 2018. This was sent to Gavi only in the week of March 26 to 30, 2018 (FCI, Key Informant of the Central Level of MISAU).
- It takes time to discuss the workplans between Gavi and MISAU. According to one of our key informants, the negotiations for the approval of the 2018 workplan began in December 2017, which meant that until February 2018, a consensus had not yet been reached on the workplan.
 - "... Gavi only started the process of discussing the plan in December and it does not help us because we know that there are always comings and goings of adjustments plans, and often they (Gavi) take about 2 weeks to respond to our corrections ... " - KII Central Level Manager

Figure 13. Schedule of the application process of HSS 2017 funds for Fiscal Year 2017 and 2018.

• Registration of the HSS funds by Provincial Health Directorates (DPS) during the 2017 planning and budgeting process • Ministry of Economy and Finance (MEF) confirms the registration of HSS funds from the 2017 fiscal year for DPS Development of HSS planning and reporting tools by MB Consulting and later dissemination to HSS regional, provincial and district officials with guidance on arch – . 2017 on how to use them. • MISAU/EPI requests additional HSS funds from MEF for the EPI Central and Sofala for the 2017 fiscal year. • Development of 2018 HSS workplans at the district, provincial and central levels and later submission to the central-level HSS managers. • National HSS meeting: 2017 reporting and 2018 planning, involving EPI and HSS June 28-30, 2017 officials (provincial and national levels). • Registration of HSS activities workplan for the year 2018 in the MEF system, through the Planning and Cooperation Directorate of MISAU. • Completion of the financial audit of 2016 Gavi funds by the Administrative Court. • Development of the HSS 2017 financial report by EPI/HSS managers. • EPI/HSS manager requests to use MR funds to fill gaps in available HSS funds.

Recommendations

- Act now: MISAU and EPI should explore the possibility of requesting the Administrative Court's financial audit of MISAU earlier, in order to be able to respond in a timely manner to funder requirements for this audit.
- Act now: Gavi should start the HSS planning process for the following year during the first months of the third quarter of the current year to allow approvals to occur in time to ensure availability of funds, once the other requirements have been met.
- Act now: MISAU and EPI should request that Gavi allows MISAU to include in its annual HSS plan a contingency plan for the implementation of HSS activities in the first 3 months of each year while the normal process of HSS approval and disbursement is carried out.

Conclusion

Findings from this report indicate that there has been a slight but steady improvement in vaccine coverage over the past few years, coupled with a reduction in between-districts inequities within provinces. A set of community level initiatives that culminate in increased community involvement may be behind these results. However, challenges persist that may interfere with the system's ability to sustain these gains, especially management and leadership challenges, which have been associated with delays in the disbursement of funds and the allocation of vaccines and other materials to the more peripheral levels on a recurring basis.

HSS showed improvements in the implementation of the financing component allocated directly to the country, and was very close to 100% expenditure for 2017. Root causes of this success include improved support from HSS advisors at all levels, alignment with the national planning cycle, but also the availability of unspent funds from 2016. Typical delays in disbursements from Gavi to Mozambique for the 2018 fiscal year, without carryover funds, has resulted in more than three months of 2018 without available HSS funds. To improve these processes in the future, we recommend that Gavi continue to be more flexible and aligned with existing country processes.

Consequences of channeling HSS funds to partners remain mixed: there were challenges associated with the funds allocated to UNICEF for HSS procurements but without a counterfactual to compare against, it is difficult to know whether UNICEF procurement processes are ultimately more or less efficient than government ones. For FCE2 year 2, the team will continue to investigate the channeling of funds to partners.

Progress towards the introduction of new vaccines was the most challenged component, mostly due to the challenges of fragile systems, characterized by constant emergencies, often lacking the capacity for a prompt response. As a consequence, every time these setbacks occur, all existing resources and personnel are diverted to their response, leading to successive delays.

NEXT STEPS

- >>> The FCE team will apply additional methods of data collection and analysis in year 2 so as to obtain a better estimate of the contribution of HSS to observed changes in coverage and equity.
- >>> The team will conduct district case studies to, among other things, seek evidence on the contribution of factors such as community activities and leadership, management, and coordination aspects on vaccine coverage. Through these case studies the team will focus efforts to document good practices in well-performing districts and to investigate in greater depth the causes of coordination and communication challenges between the central and provincial levels.
- In partnership with the EPI program, the FCE2 team will discuss proposals for recommendations and approaches with a view to identifying appropriate initiatives and responding to the challenges encountered, especially those that appear recurrently, such as those associated with leadership, management and coordination.

CONCLUSION

- In addition, year 2 of the evaluation will focus on responses to the following unanswered questions in this report:
 - > **EQ 10:** Does the national introduction of HPV vaccine use the lessons learned from the demonstration projects?
 - **EQ 11:** Does the new HPV 2.0 policy facilitate nationwide introduction?
 - EQ 14: Will national decisions (including the role of COPI) to apply for new support from Gavi be made taking into account the aspects of programmatic and financial sustainability?
 - > EQ 15: What are the determinants of changes in funding for immunization (total budget as well as sources of funding) and their consequences?
 - > EQ 17: What are the positive and negative consequences of the new updated Gavi processes?
 - EQ 18: What unintended positive and negative consequences occur as a result of Gavi's support?

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 8 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 8. Methods overview.

METHODS	SOURCES	TOPICS INVESTIGATED
Document review	 Gavi policies and guidance documents Gavi Board, PPC, and IRC meeting minutes Country funding applications (HSS, NVI, etc.) Joint Appraisal Reports PCA findings and recommendations EPI reviews Gavi grant performance frameworks FCE phase 1 (FCE1) reports Post-Introduction Evaluation reports Effective Vaccine Management assessments Sustainability Strategic Focus Area 	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

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METHODS	SOURCES	TOPICS INVESTIGATED
		(EQ14–16); Alliance systems and processes (EQ17–18)
Policy analysis	 Gavi immunization financing policy and guidelines (and other relevant documents) Resource gap analysis Resource-tracking data from phase 1 Program costing data from EPIC Root cause analysis KIIs 	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 14) 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 globallevel drivers of immunization coverage and equity. The expanded FCE2 TOC (Figure 15) 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. Error! Bookmark not defined. Within these categories, we aim to better understand the c ausal 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 14. FCE1 Theory of Change

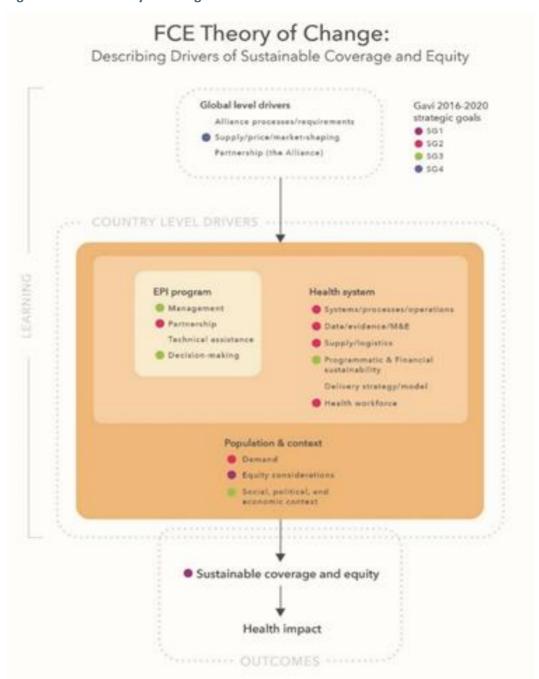
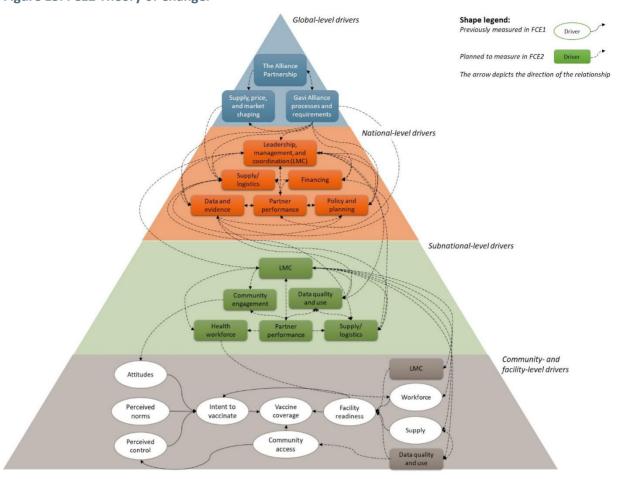


Figure 15. FCE2 Theory of Change.



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 Expanded Programme on Immunization (EPI) and Ministry of Health 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. 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

METHODS ANNEX

- 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.³
- 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. 4,5,6 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.⁷

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.^{8,Error! Bookmark not defined.} These existing analyses focus on national-level indicators of coverage a nd 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 districtlevel 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

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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 (health systems strengthening [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 sub regions, and the presence of immunization inequities according to the Uganda Immunization Equity Assessment⁹ 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.^{4, 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.

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 16).

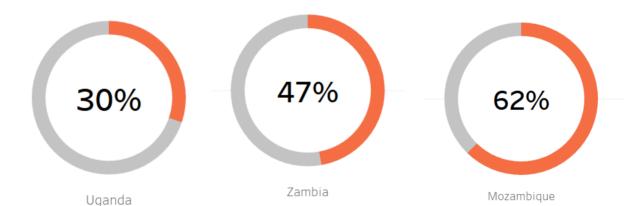


Figure 16. DHIS2 DPT3 coverage rates in 2017.

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. 10 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. 11 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.¹⁰ 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

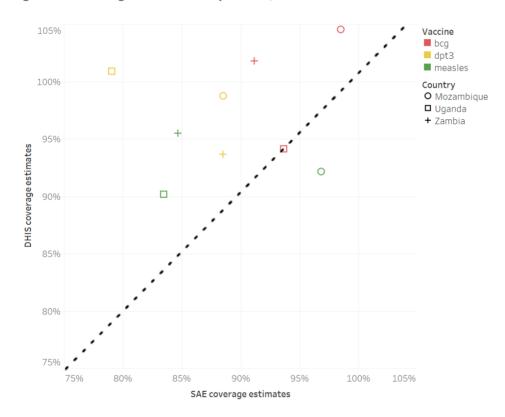
The FCE2 annual report utilizes data from both DHIS and SAE, acknowledging that there are tradeoffs in using both. Table 9 summarizes the strengths and weaknesses of both data sources.

Table 9. 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 	> There is lack of country ownership in creating and understanding SAE estimates
	> Using survey data, we are able to estimate historical coverage rates from 1999	

	STRENGTHS	WEAKNESSES
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 17. 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 17 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

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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. 10

Robustness ranking

Considering the prospective design of the evaluation and the flexible, adaptive nature of datacollection 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 onesided 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 10) 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.

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Table 10. 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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