First Report of the Gavi Full Country Evaluations

Phase 2

Zambia

2017-2018

Acknowledgements

All errors in this report do not represent in any way the views of the aforementioned institutions. The authors remain solely responsible for the content of this report.

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

This year's report focuses on three thematic areas containing five evaluation questions on Gavi, the Vaccine Alliance' support to Zambia. Following the publication and dissemination of the previous report of 2016, a number of evaluation questions were identified through a consultative process at the country level. For example, the 2016 report and other reports in Phase 1 noted major achievements in new vaccine introductions and other programmatic achievements such as partner support and innovations in data. Importantly, the reports also documented significant progress in increased immunisation coverage, particularly from 2011 to 2016. However, the reports also highlighted concerns around sustainability as well as the need to understand drivers of immunisation coverage.

OVERVIEW OF THE GAVI FCE2

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

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

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

METHODS

We apply a combination of qualitative and quantitative methods to address our evaluation questions. Quantitative data analysis used administrative data on immunisation indicators such as immunisation outputs, infant and under-five population figures, health expenditure, and macroeconomic variables. From these we constructed coverage indicators over time and across provinces to assess changes in coverage. We have gathered data on government expenditure on immunisation for the period from 2011 to 2017. Our qualitative methods were based on in-depth interviews with key informants who are familiar with the immunisation programme. Finally, we reviewed several official documents which contain information relevant to new vaccine introduction, programme planning and implementation, and economic outlook for the country.

FINDINGS AND RECOMMENDATIONS

FINDINGS	RECOMMENDATIONS
SECTION 1. Coverage and equity (EQ 1–3)	
Finding 1: Continued data quality issues with the potential to affect monitoring and evaluation of the EPI programme. **Finding 1.2:** Slow catch-up of the second dose of the measles-rubella vaccine (MR2) leading to continued high drop-out between the first dose (MR1) and the second. **Finding 1.3:** Despite a noticeable increase in vaccine coverage, inequalities in coverage remain significantly high.	◎ **Urgent Attention**: The programme needs to strengthen demand-generation activities targeting children in the second year of life to improve coverage beyond the first year. ➡ **Continue doing:** The programme needs to expedite learning from initiatives such as ZEIR aimed at improving overall immunisation data quality and the expansion of the same to provide appropriate information to the programme.
SECTION 2. Sustainability (EQ 14-16)	
Finding 2.1: Financial and programmatic sustainability implications of introducing HPV vaccine nationally have not been thoroughly assessed using local evidence.	◎ **Urgent Attention**: The creation of the ZITAG is a commendable step in enhancing financial sustainability assessment of new vaccine introductions. The Ministry of Health now needs to develop clear policy and guidelines for purposes of economic evaluation of New Vaccine Introductions and other programs. ZITAG membership should also include adequate economic evaluation capacity.
Finding 2.2: The immunisation programme is going to experience increasing financing challenges because of slow revenue growth from both government and partners, and an increasing cost of sustaining high immunisation coverage.	○ **Study further:** The programme should develop a framework for monitoring budgetary allocations and resource flows to the programme at the national and subnational levels on a regular basis. Such information would inform appropriate resource allocation, decision-making, and advocacy for needed investment into the programme.
Finding 2.3: Institutionalisation of new vaccines into the routine immunisation system has provided a platform for secured public resources and has increased prospects that recent gains in coverage can be sustained. **Finding 2.4:** The greatest threat to sustained high immunisation coverage is that core programme activities at national and subnational levels are	◎ Urgent Attention: > The EPI programme should facilitate the development of accurate and reliable estimates of the operational costs of immunisation service delivery. > The MoH/government needs to build capacity in costing, economic assessment, and financial planning to mitigate some of the factors that lead to unpredictable public funding.

FINDINGS	RECOMMENDATIONS
significantly scaled down to match severely inadequate and unstable operational funding. **Finding 2.5:** A separation between planning and budgeting for new vaccine introduction and capital costs, and budgeting for ongoing recurrent costs, leads to an imbalance between operational budgets and operational plans and underfunding of major recurrent activities. **Finding 2.6:** Delays to develop a clear medium- to long-term plan for how the government will take over the recurrent costs associated with activities that are intended to maintain immunisation coverage following Gavi support compromise programme capacity to sustain coverage.	> The government should invest in developing a financial sustainability plan and/or transition plan as soon as possible without waiting for Gavi support to start declining.
Alliance systems/processes (EQ 18)	
Finding 3.1: The cMYP is not being adequately utilised as a tool for bringing about harmonisation, reducing duplication, and aligning national systems.	✎ **Act now:** There is need for WHO, in collaboration with EPI, to review the cMYP costing assumptions to ensure that they are realistic and free from errors. ✎ **Study further:** The cMYP needs to be better aligned to and utilised with other country processes and documents, such as the budgeting process and Yellow Book, to be more useful to the EPI.

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Abbreviations

BCG	Bacillus Calmette–Guérin
CCEOP	Cold Chain Equipment Optimisation Platform
cMYP	comprehensive Multi-Year Plan
CSO	Central Statistical Office
DPT	diphtheria, pertussis, and tetanus
EPI	Expanded Programme on Immunisation
EPIC	Costing and Financing of Routine Immunisation and New Vaccines
FCE	Full Country Evaluations
FIC	fully immunised child
GFF	Global Financing Facility
GHE	government health expenditure
HepB	hepatitis B
Hib	*Haemophilus influenzae* type B
HPV	human papillomavirus
HSS	Health System Strengthening
ICC	Inter-Agency Coordinating Committee
IEC	information, education, and communication
IPV	inactivated poliovirus vaccine
ISS	Immunisation Services Support
MCV	meningococcal vaccine
MOH	Ministry of Health
MR2	measles-rubella second dose
MSD	measles second dose
MTEF	Medium-Term Expenditure Framework
MVacc	mobile Vaccination
NHA	national health accounts
NHSP	National Health Strategic Plan
NVI	New Vaccine Introductions

NVS	New and under-used vaccine support
OPV	oral poliovirus vaccine
PCA	Programme Capacity Assessment
PCV	pneumococcal conjugate vaccine
REC	Reach Every Child (initiative)
SHI	social health insurance
SIA	Supplemental Immunisation Activity
THE	total government expenditure on health
WHO	World Health Organisation
ZDHS	Zambia Demographic and Health Survey
ZEIR	Zambia Electronic Immunisation Registry
ZITAG	Zambia Immunisation Technical Advisory Group

Summary of Gavi support in Zambia

Zambia first received Gavi support in 2001. Over the following 16 years, the country received a total of US$130.6 million in Gavi funds for new vaccine introductions (NVI), immunisation services support (ISS), and health system strengthening (HSS). The country introduced the measles second dose (MSD) vaccine and pneumococcal conjugate vaccine (PCV) jointly in July 2013 and rotavirus vaccine later in November 2013. The measles-rubella (MR) pre-introduction campaign was conducted in September 2016 and the measles-only vaccine was subsequently switched to MR in routine immunisation around August 2017. The country has approval for Gavi support for the introduction of inactivated poliovirus (IPV) and human papillomavirus (HPV) vaccines, the latter targeting girls aged 10 years. Because HPV will be school based and that majority of 10 year girls are in grade 4, the programme will target in-school girls in grade 4 provided they are above 9 years. However, the introduction of IPV and HPV has been delayed due to global shortage of vaccines. Beginning in 2018, Zambia started the implementation of the Gavi-funded Health Systems Strengthening grant of about $10 million. Table 1 below shows the details of the Gavi support from 2001 to date.

Table 1. Gavi Support for Zambia

Type of support	Commitments	Period
Health system strengthening (HSS 1)	$2,552,998	2007-2008
Health system strengthening (HSS 2)	$10,500,000	2017-2019
Immunisation services support (ISS)	$3,864,060	2001-2002, 2004, 2006
Injection Safety Devices (NVS)	$1,023,500	2017-2019
Injection safety support (INS)	$689,237	2002-2004
IPV (NVS)	$705,935	2015-2016, 2018
Measles (NVS)	$936,518	2011-2014, 2017-2018
Measles-Rubella (NVS)	$5,439,180	2016
MR - Operational costs (OPC)	$4,501,608	2016
Penta (NVS)	$68,524,295	2005-2019
Pneumo (NVS)	$66,274,753	2012-2019
Product Switch Grant (PSG)	$204,986	2018
Rotavirus (NVS)	$22,480,032	2016-2019
Tetra DTP-Hib (NVS)	$8,878,028	2004
Vaccine Introduction Grant (VIG)	$2,875,179	2002, 2012-2013, 2015-2016
Total	**$199,450,309**	

Source: Zambia page. Gavi, the Vaccine Alliance website. Available at https://www.gavi.org/country/zambia

Introduction

WHAT ARE THE GAVI FULL COUNTRY EVALUATIONS?

The Gavi Full Country Evaluations (FCE) is a prospective study initiated in 2013 with the aim of understanding and quantifying the barriers and drivers of immunisation programme improvement, with emphasis on the contribution of Gavi, the Vaccine Alliance.

The first phase of the evaluation was conducted in four countries (Bangladesh, Mozambique, Uganda, and Zambia) for a four-year period up to 2016. Phase 1 highlighted the following topic areas:

> Vaccine routinisation
> Partnerships and partner support to the Expanded Programme on Immunisation (EPI)
> Technical assistance
> Administrative adjustments and planning arrangements
> Competing priorities among EPI partners
> Inaccurate population denominator problems
> Gavi processes and requirements

The second phase of the evaluation is looking at Mozambique, Uganda, and Zambia over a two-year period, from August 2017 to July 2019. To ensure continuity, the second phase of the FCE broadly encompasses cross-stream issues including vaccine introduction, vaccine coverage and equity, programme and financial sustainability, and Gavi systems/processes and their consequences on the performance of the EPI programme.

Building on FCE1

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

The FCE2 consortium

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

The implementation of FCE2 is guided by a number of principles to ensure the usefulness, relevance, and quality of FCE2's findings and of the sustainability and transferability of the platform beyond FCE2. A central principal of FCE2 is to strengthen in-country capacity of evaluation teams and local stakeholders such that country teams can increasingly lead and implement all aspects of the evaluation. Progress towards this goal is impressive.

METHODS

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

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

Evaluation questions (see Table 2) were developed after a consultative process with the EPI partners. The FCE2 approach emphasises the importance of theory-based and realistic evaluation; the approach to answering each EQ is informed by social science and programme theory. Additional details on the methods for data collection and analysis are included in the methods annex.

Table 2. Evaluation Questions and Methods

EVALUATION QUESTION	METHODS
EQ 1–3 Coverage and equity 1. What are the drivers of changes in coverage and equity?	> Reviewed reports including census analytical reports, Zambia Demographic and Health Survey (ZDHS), and Zambia's Living Conditions Monitoring Survey (LCMS). > Reviewed District Health Information System (DHIS2) monthly data (2013–2017) to assess district-level coverage and equity performance. > Analysis done using Tableau software.
EQ 14–16 Sustainability 1. Whether, why, and how are country decisions to apply for new Gavi support taking into account the programmatic and financial sustainability aspects, with a specific focus on HPV? 2. What are the drivers of changes in financial support for immunisation? 3. To what extent can recent programmatic gains of the EPI programme be sustained over time?	> Document review: FCE reviewed Ministry of Health (MOH) and EPI planning documents such as the National Health Strategic Plan (NHSP), comprehensive Multi-Year Plan (cMYP), EPI optimisation plan, new and underused vaccine support (NVS) applications and decision letters, etc. In addition, national development plans were also reviewed (SNDP and 7NDP). > Statistical analysis of government health expenditure (GHE) and projections of immunisation expenditure based on past trends in health expenditure. Data on planned and actual expenditure was extracted for 2013–2016. > Key informant interviews: Eight key informants were interviewed from a broad range of EPI stakeholders. In addition, a number of on-the-spot fact check interviews were conducted for verification or confirmation of certain

	information.
EQ 18 Alliance systems/processes 1. What positive and negative unintended consequences occur as a result of Gavi support, with a focus on cMYP?	> Meeting observations: FCE attended and reviewed a number of meetings, including Inter-Agency Coordinating Committee (ICC), technical working group, and planning meetings. > Document review: FCE reviewed MOH and EPI planning documents such as the NHSP, cMYP, EPI optimisation plan, Programme Capacity Assessment (PCA) report, etc. National development plans were also reviewed (SNDP and 7NDP). > Key informant interviews: Eight key informants were interviewed from a broad range of EPI stakeholders. In addition, a number of on-the-spot fact check interviews were conducted for verification or confirmation of certain information.

Table 3. Strengths and limitations of this Gavi FCE2 report.

STRENGTHS
> Triangulation of multiple secondary data sources (HMIS, household and health facility survey, 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
> While multiple methods are employed, FCE2 does not include resources for household or health facility surveys; instead, FCE2 depends on administrative data, existing survey data, and in-depth qualitative data.

Table 4. FCE2 evaluation questions (EQs) and status in first report.

Legend

EQ fully answered in the 2018 FCE2 report	■
EQ partially answered in 2018 FCE2 report	■
EQ not started for 2018 FCE2 report	■
EQ not applicable	■

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

EVALUATION QUESTION	YEAR 1	YEAR 2
15. What are the drivers to increase financial support for immunization?	🟩	🟩
16. To what extent can recent programmatic gains of the Expanded Programme on Immunization (EPI) be sustained over time?	🟨	🟩
17. What are the positive and negative consequences of the new/updated Gavi processes?	🟨	🟩
18. What unintended positive and negative consequences occur as a result of Gavi support?	🟥	🟩
19. To what extent are the Gavi-supported activities that are designed to enhance performance management practices of the EPI effective in strengthening the Interagency Coordinating Committee and accountability across the program?		
20. Why and how is the new Immunization Act affecting implementation (e.g., demand generation) and outcomes of Gavi support?		
21. What is the *composition* of the immunization partnership in the country at national and district levels?		
22. How effective is EPI management at the local level?	🟥	🟩

Merged with EQs 1 and 2.

Coverage and equity

Zambia has continued to broaden the Expanded Programme on Immunisation in line with World Health Organisation (WHO) recommendations for routine immunisation.

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

At the beginning of 2013, the programme included all eight of the WHO-recommended antigens: BCG, DTP-HepB-Hib, OPV, and Measles containing vaccine (Burton et al., 2009). In 2014, two more vaccines were introduced in the routine immunisation schedule: a three-dose PCV and a two-dose rotavirus vaccine. In the same year, the country introduced a second dose of MCV, administered at 18 months of age. To deal with cases of rubella, the country decided to switch from a measles-only vaccine to a combination of measles and rubella (MR). A pre-introduction catch-up campaign was conducted at the end of 2016. The country had fully switched from measles-only vaccine to MR by September 2017. Therefore, reference to MR must be construed as reference to measles or measles containing vaccine if referring to the period before September 2017. A fully immunised child (FIC) is expected to have received all doses of the above antigens.

This section relates to evaluation questions 1–3, which are focused on understanding the drivers of changes in coverage and equity. The evaluation question also seeks to understand the relative contribution of Gavi support to changes in coverage and equity. These questions will be evaluated based on a district case study in the second year of evaluation. To provide background to the district case study, this section gives a situational analysis of vaccine coverage and equity.

The analysis takes a quantitative approach to assess district-level coverage and equity performance. Monthly data covering 2013 to 2017 from the District Health Information System (DHIS) was sourced from the Ministry of Health. The data has number of doses administered monthly for each antigen. In addition, the data has estimated annual district-level population (as well as population of children under one) based on estimations done by the Central Statistical Office (CSO). Other data sources include district-level poverty assessment and infant and under-five mortality rates extracted from the 2010 Census of Population and Housing.

Tableau software (a business application that helps people see and understand their data) was used to generate necessary measure of coverage and equity and to cross-tabulate with other variables to assess the contribution or influence of other factors on vaccine coverage and equity.

> ## Finding 1.1
>
> *Continued data quality issues with the potential to affect monitoring and evaluation of the EPI programme.*

ROBUSTNESS RANKING   A

All findings are based on quantitative DHIS2 data. The finding is also supplemented by previous surveys and past FCE findings.

The importance of timely and quality data for the monitoring and evaluation of programs such as the EPI cannot be overemphasised. Good-quality data is essential in order to give appropriate feedback for the continuous improvement of the programme.

Zambia has been having an unending debate on the accuracy of the population projections done by CSO. Most districts have argued that the numbers often underestimate the true target population in districts, resulting in over 100% coverage. As an alternative to the official population estimate, facilities also do head counts, which come out higher than the official figures. During the PCV and rotavirus vaccine introductions, this disparity was actually cited as the cause for vaccine stockouts, because districts were supplied based on official figures, which were in most cases below the headcounts (Gavi FCE Team, 2016).

This problem continues to affect the accuracy of vaccine coverage, raising concerns about the true performance of the country. While we register more than 100% on paper, some stakeholders have argued that the inaccuracy of the numbers masks the true performance of the country.

> *"[I] don't think the coverage is true because we can't have 103% coverage—more than 100% coverage is a problem. We can't say coverage has improved because we don't know what it is. We don't know how we are performing."* —Key informant interview

Nonetheless, available data on the number of doses administered is expected to be accurate, representing the actual number of doses. Consider Figure 1 below, which gives the coverage categories for Penta 3 vaccine and Fully Immunised Child at one year for 2017.

Figure 1. Fully Immunised Child at One Year (FIC 1) and Penta 3 Vaccine Coverage Categories in 2017[a]
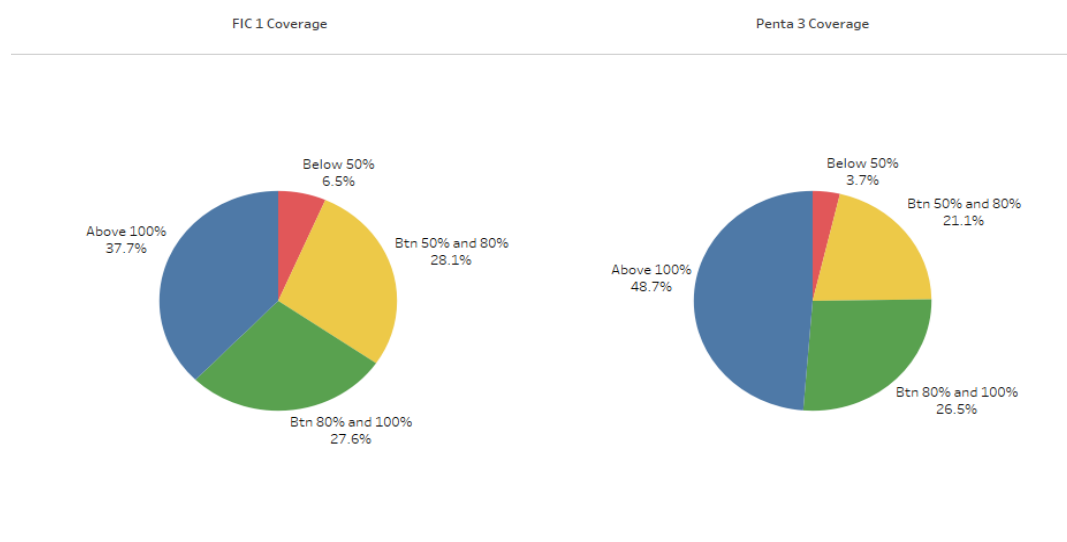
As discussed above, more than a third of districts are reporting FIC coverage of more than 100% and close to half of the districts are reporting Penta 3 coverage above 100%. This is evidence of weak data, mostly due to the disputed accuracy of the CSO population denominator, often said to underestimate the target population. Therefore, the coverage rates discussed below must be understood with that caveat.

INITIATIVES TO IMPROVE DATA QUALITY

The problem of data quality has been acknowledged by stakeholders and remains an impediment to knowing the true performance of the country on immunisation coverage. A number of initiatives have been introduced to improve the quality and timeliness of data. These include PATH's BID Initiative, which is contributing to the development of the Zambia Electronic Immunisation Registry (ZEIR). The electronic registry provides timely data and reporting on immunisation at facility levels. The initiative is being piloted in Southern Province and is in the process of rolling out to Western Province. Alongside ZEIR is the UNICEF-supported mobile Vaccination (mVacc), a community-based tool to register birth data and aid follow-up on defaulting children, still being piloted in Southern Province. The FCE has observed that these initiatives are yet to be formally evaluated.

On logistics management, the programme has rolled out an electronic supply chain software programme, Logistimo, to help districts and health facilities to better manage vaccine logistics and provide an early signal on stock levels to the national level. Logistimo is currently used at all district health offices and at most health facilities in Lusaka District.

The programme also recognises that some data-quality problems are a result of a poor data culture among health workers. Health workers are unable to detect data-entry errors at the point of entry. For

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[a] This is derived from the number of districts in each coverage band as a percentage of the total number of districts, using 2017 annual coverage rates.

instance, during the 2016 MR Supplemental Immunisation Activity (SIA) campaign, some facilities were reporting having immunised children in excess of the available doses. In response, the programme is also working on building a data-use culture among frontline health workers. As proposed in the draft EPI Optimisation strategy, "teaching basic data analysis skills, such as calculating percentages, enables facility staff quickly spot errors or inconsistencies in the data and identify potential solutions to address them". The combination of these initiatives will improve the overall quality of data around the EPI programme, albeit in the long run. The initiatives are yet to be scaled up countrywide or to the point of service delivery.

Exploring the use of BCG as an alternative denominator

The official target population, as generated by CSO, is alleged to either underestimate or overestimate the true target populations. There has been an ongoing debate on the unsuitability of the official target population, with no agreement on what could be the best alternative. In the pursuit of a good denominator, we propose to try the use of the BCG (Bacillus Calmette–Guérin) vaccine as an alternative denominator amidst data quality concerns. We must be clear here that the use of BCG is neither supported by past literature nor is it an attempt to solve the problem. Rather, the aim is to present a slightly different picture where both the numerator and denominator are locally (health facility and district) generated.

BCG is the earliest vaccine a child receives (between 0 and 14 days) and its number of doses administered are often highest compared to other antigens. The doses of BCG can therefore be considered as an alternative measure of the number of births and, accordingly, the number of children eligible for other vaccines later in life. In Figure 2 below we show line graphs tracking the number of BCG doses and the official populations as projected by CSO.

Figure 2. Line Graph of BCG Vaccine Doses and Official Population

Measure Names
- CSO Projected Under 1 Population
- Doses of BCG Administered
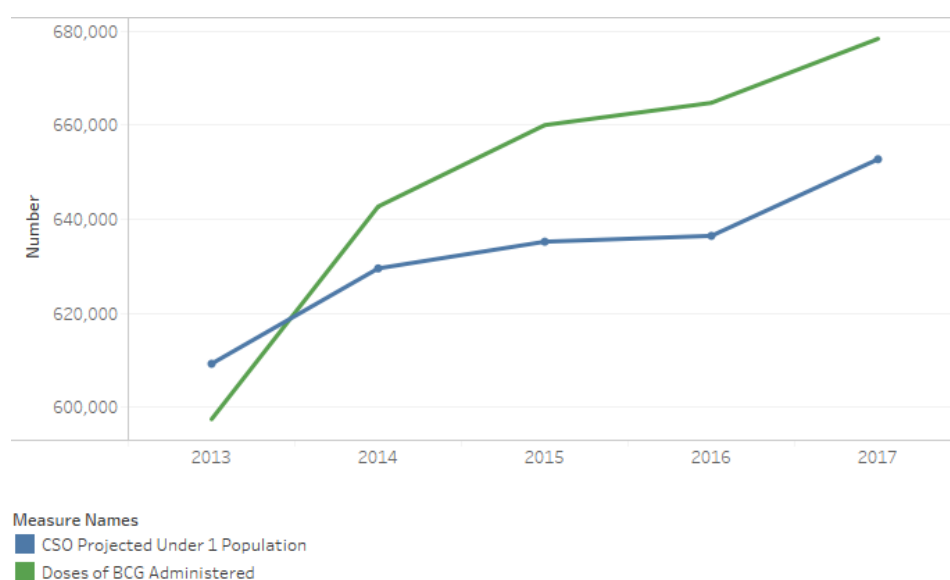
A clear upward trend is visible in both the population and number of doses over the entire period. We note from the figure that the number of BCG doses reported as administered was below the official population in 2013 but shot up to above the latter in the rest of the years. There are two possible explanations for the variance. First, CSO assumes that children under 1 constitute 4% of the population. As such, the eligible population is calculated based on this ratio, itself derived from past

censuses;[b] the actual population structure may differ across regions or districts or between rural and urban (CSO, 2012, p. 12). Second, there may be some imperfections in the number of BCG doses being reported, as may be true for other vaccines. While neither estimate is a perfect portrait of the number of births, we present a comparison of both denominators to explore coverage trends, as the number of BCG doses suggests a much higher target population for successive vaccines. The main weakness of using BCG arises if there is a greater portion of children that miss their BCG, but this does not make it worse than the official population. BCG doses remain higher than the latter.

In Figure 3 below, we compare geo-maps of Penta 3 vaccine coverage in 2017 using either (a) CSO data as the denominator or (b) BCG vaccine doses as the denominator.

Figure 3. Comparison of Coverage of Penta 3 Vaccine Using CSO Data and BCG Doses as Denominators, by District for 2017
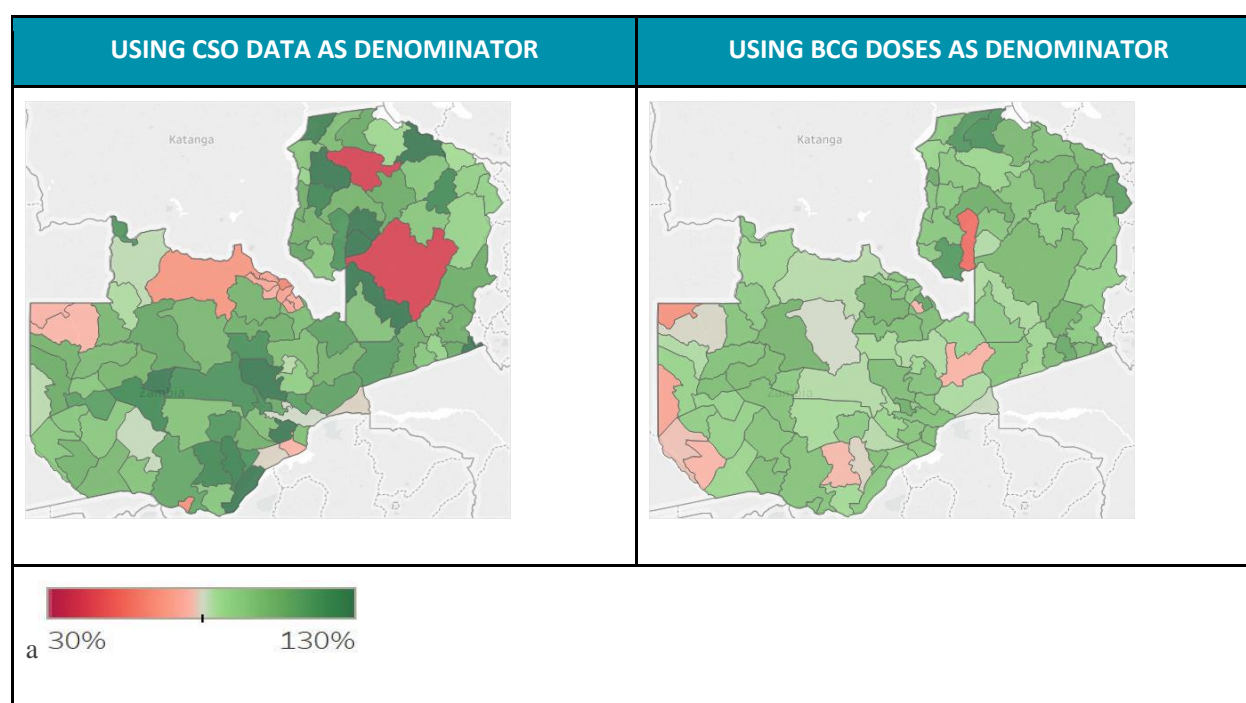
The map using the official population for the denominator seems to have a lot of extreme values, both on the lower and higher side, compared to the map using BCG doses. This reinforces concerns about the CSO figures being at variance with actual target populations. The map using BCG doses on the other hand does not show extreme cases. This indicates that the use of BCG as a denominator may have a "smoothing" effect which accounts for the CSO estimates that are the greatest outliers from the actual population.

With this smoothing effect, the BCG map seems to show some regional patterns in coverage, with similarities among regional clusters of districts. In particular, it shows poor coverage rates on the far west portion of the country and isolated instances of poor coverage in west-central regions. Poor performance in the far west highlights broader regional low performance; this may be linked to the

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[b] The census of population in Zambia is conducted every 10 years; the last was conducted in 2010.

Zambezi River basin, which logistically cuts off the region from the rest of the country. This same region also has higher incidences of poverty.

VACCINE COVERAGE

The 2015 and 2016 FCE reports (Gavi FCE Team, 2016) documented improvements in the vaccine coverage rates. There was quite good improvement both at the national and district level. The latest data on 2017 also confirms this steady upward change in country-level coverage rates. This subsection discusses vaccine coverage using CSO population estimates as the denominator. The box plot in Figure 4 shows Fully Immunised Child under 1 coverage rates.

Figure 4. Fully Immunised Child (FIC) Under 1 National-Level Coverages
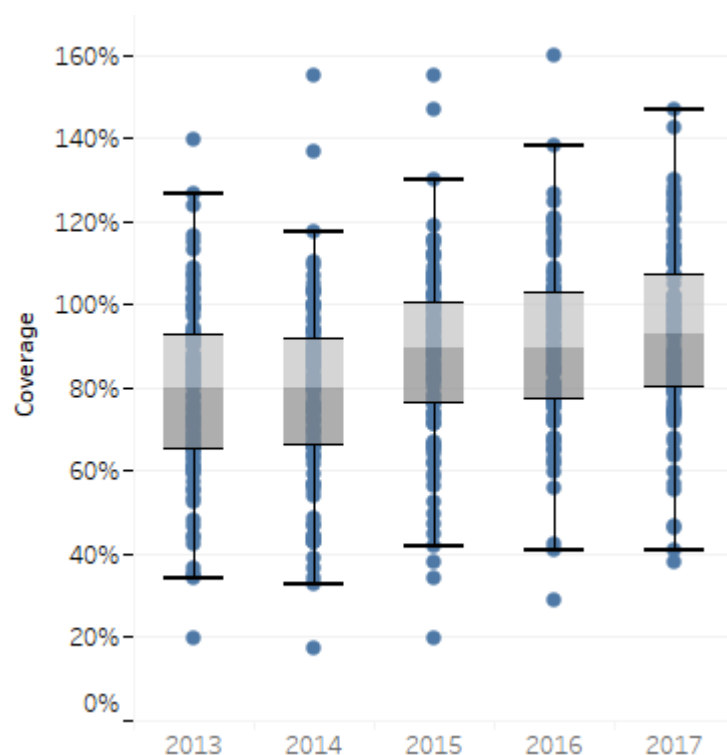
Figure 4 shows that coverage rates have increased overall, from a district median of 80% in 2013 to a median of 93% in 2017. Further, the number of districts performing well has also increased. The lower quartile shows that 75% of districts had 65% or more coverage in 2013. In 2017, we have 75% of districts hitting the 80% coverage mark. This is contrary to the 2013–2014 Zambia Demographic and Health Survey (ZDHS), which found that the percentage of FIC had not changed between 2007 and 2014 (CSO 2015, p. 142). This supports the view that recent improvements may be a product of the recent vaccine introduction activities, which were noted to have 'strengthened EPI delivery by provision of more logistics, capacity building, good acceptance by the community and overall, high demand for vaccines' (WHO, 2014, p. 5). An analysis of this trend and specific drivers will be discussed in the upcoming district case studies in selected districts.

One of the key indicators used by Gavi to assess progress towards immunisation targets is the number of countries reaching 80% coverage; at a national level, we consider the number of districts that are

reaching 80% coverage. Overall, there is marked improvement in the vaccine coverage rates based on administrative data. This was also reported in the latter works of the FCE. In Figure 5 below, we show district-level performance for 2013, 2016, and 2017. The general trend is that the maps are moving from more yellow (mid performance) to more green, an indication that more districts are now achieving the set target of 80% or more than before. Figure 5 shows district-level performance on Penta 3 vaccine coverage in the first row and FIC 1 in the second row for 2013, 2016, and 2017.

Figure 5. Penta 3 Vaccine and Fully Immunised Child (FIC) Under 1 Coverage
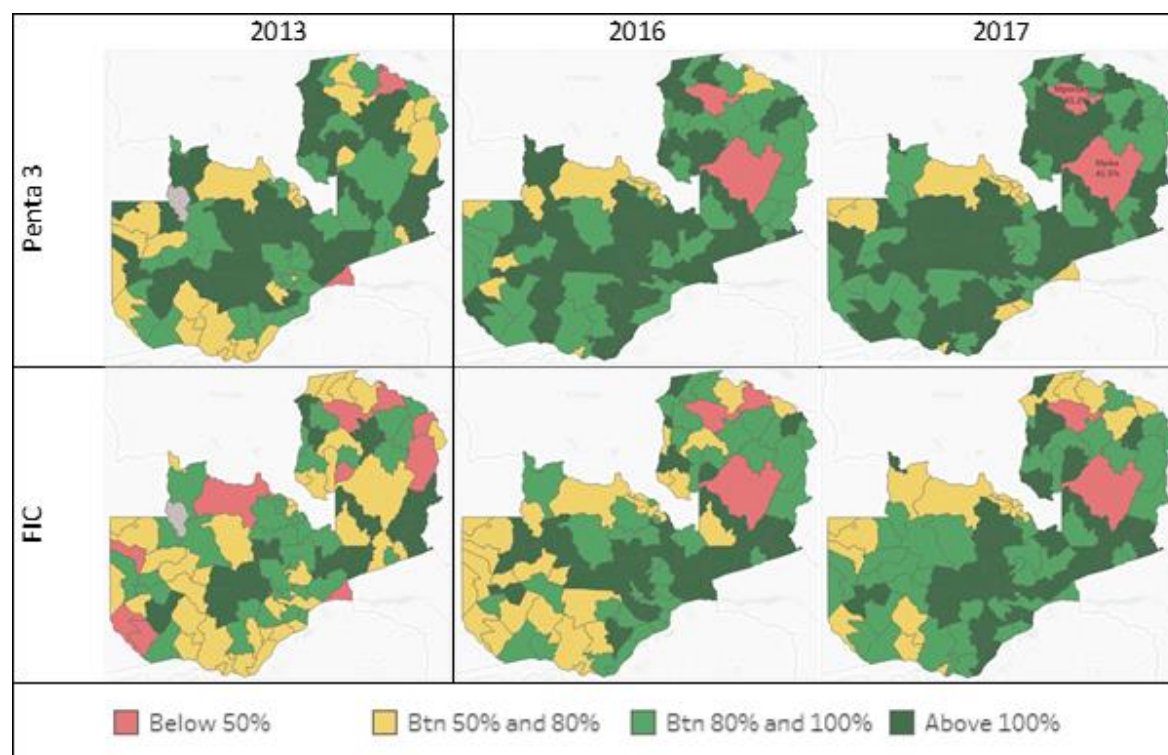
When the last two years are compared to 2013, there is a remarkable improvement in the overall picture. We see a number of districts transitioning from mid-level performance to above 80%. This is particularly visible for FIC coverage. Most district that were in the 'yellow region' have changed to green. Table 3 shows the proportion of districts below 50%, those between 50% and 80%, and those hitting the target of 80% or more.

Table 5. Proportion of Districts Achieving 80% of Penta 3 Vaccine Coverage

	2013	2014	2015	2016	2017
Below 50%	2.0	2.9	2.9	1.9	1.9
Between 50% and 80%	24.5	22.3	16.5	11.7	13.5
Above 80%	73.5	74.8	80.6	86.4	84.7

The table shows that over the past five years, an increasing number of districts are achieving the target of 80%. There is a remarkable increase from about 73.5% of districts achieving 80% coverage in 2013 to 84% based on the latest 2017 data. At the same time, the proportion of districts in the 50% to 80% category decreased from 24.5% in 2013 to 13.5% in 2017. These improvements could be linked to improving service delivery and overall acceptance of immunisation by caregivers, due to vaccine introduction activities (WHO, 2014, p. 5).

However, there still remain a few districts with very low coverage rates. Available evidence, as discussed earlier, shows that it is almost always the same districts that are persistently below 50%. For instance, Mpika and Mporokoso districts in northern Zambia (see Figure 5 above) have remained at below 50% for both Penta 3 vaccine and FIC 1 coverage in the last two years. For some districts, this may be due to data-quality issues as a result of disproportionate division of population between new and old districts when new districts are created. The district case studies in Year 2 will examine some high- and low-performing districts to understand systematic barriers.

While coverage has improved broadly, by examining Small Area Estimates (SAE) of immunisation coverage data from Phase 1 on historical Penta 3 national coverage we see that the trend in improvements may be slowing. From 1999 to 2016, Zambia has realised a 5% gain in Penta 3 national coverage. An initial decline in coverage is observed, but the trend is reversed in 2000, around the same time as the renewed global focus on vaccine delivery. Since then, improvements have sharply accelerated from a low of 79% in national coverage, to just shy of 90%, reflecting the rapid improvement observed in DHIS data.

Figure 6. Penta 3 Coverage According to Small Area Estimates Data, 1990 to 2016
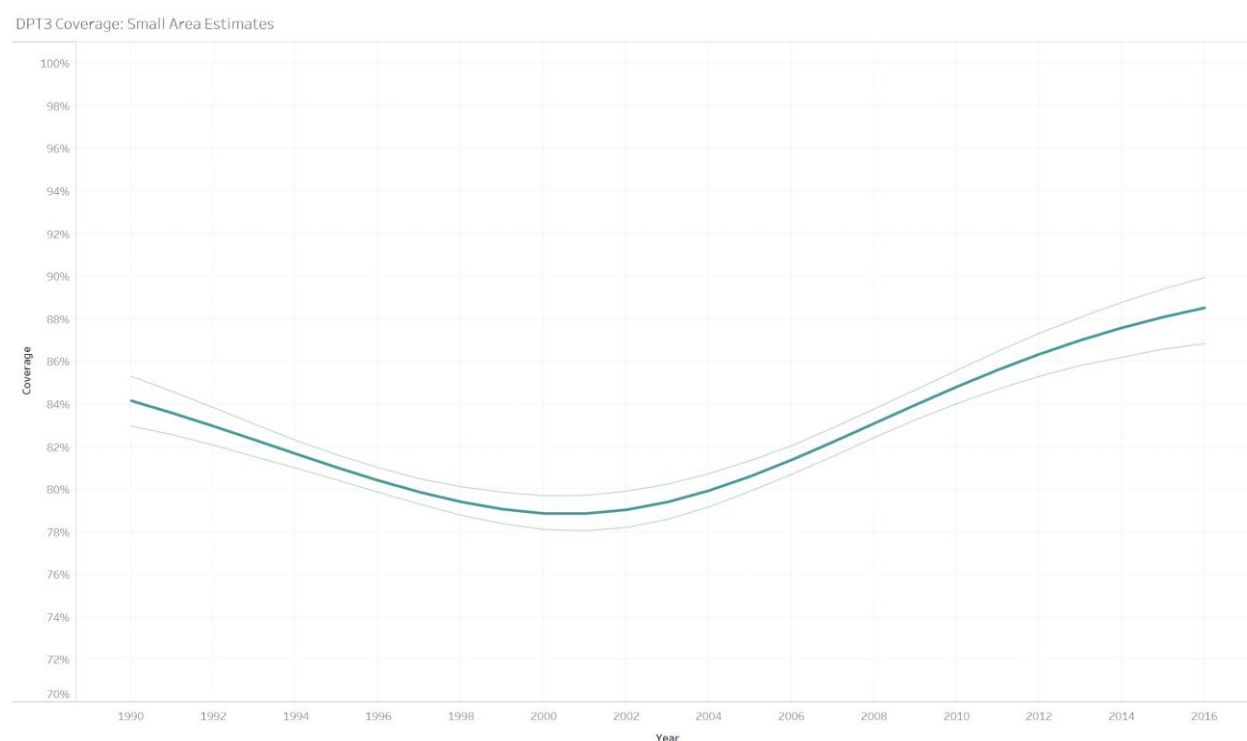
However, the rate of growth has slowed as coverage nears the 90% mark; in the last five years, the slope of the change in coverage is seen to be diminishing as gains marginally increase. This was also seen in Table 3, where the number of districts obtaining 80% coverage has slightly decreased from 2016 to 2017. The slowing improvements in coverage may pose a threat to reaching the remaining unvaccinated children.

Finding 1.2

Slow catch-up of the second dose of the measles-rubella vaccine (MR2) leading to continued high drop-out between the first dose (MR1) and the second.

ROBUSTNESS RANKING A

All findings are based on quantitative DHIS2 data. The finding is also supplemented by previous surveys and past FCE findings.

Most of the vaccines are administered in the first year of life. However, Zambia introduced the second dose of measles containing vaccine in July 2013 (switched to measles-rubella in 2017), administered at 18 months. Though coverages rates for all other vaccines are overall high, the second dose of measles-rubella (MR2) has struggled to register good coverage rates. Dropout rates between dose 1 and 2 are often high due to the age of administration of the second dose.[c] Figure 7 below shows the doses of MR2 as a ratio of doses of MR1 from the preceding year. The time shift is important to ensure that the numbers refer to the same cohort. Children that receive MR1 are only eligible for MR2 in the following year. The figure therefore shows the proportion of children that, having received MR1, go on to receive MR2. For comparison, MR1 coverage for the period increased from 90% in 2013 to about 100% in 2016.

Figure 7. Countrywide Coverage of the Second Dose of Measles-Rubella Vaccine (MR2) as a Percentage of the First Dose (MR1)

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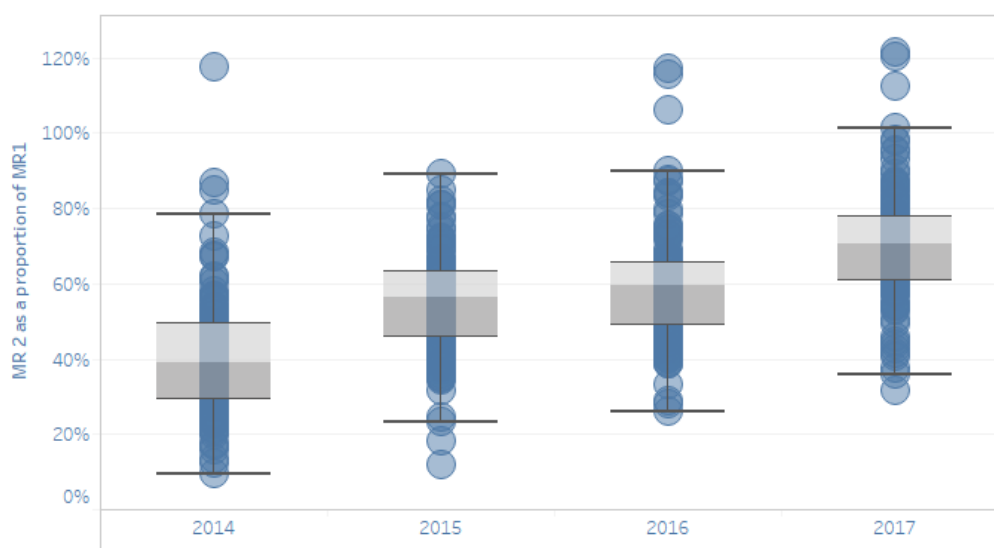
[c] Comparison of the catch-up of PCV/rotavirus vaccine introduced in the same period discussed in the previous reports.

The figure shows a general upward trend in the percentage of children who receive the second dose of MR after receiving the first dose. Beginning in 2014 with a median of just below 40% of children receiving MR2, the median rises to more than 70% in 2017 (indicating a 30% dropout). This means the second dose of MR is slowly moving towards 100% coverage and no dropout. However, the slow rate means it may take several more years for MR2 to fully catch up with MR1.

The geographical map in Figure 8 compares the MR2 to MR1 scenario in 2014 and 2017. The 2014 map shows 2014 MR2 as a percentage of 2013 MR1 and the 2017 map shows 2017 MR2 as a percentage of 2016 MR1. This highlights the geography of improvement and makes easy to see how different regions are faring.

Figure 8. Regional Coverage of the Second Dose of Measles-Rubella Vaccine (MR2) as a Percentage of the First Dose (MR1)
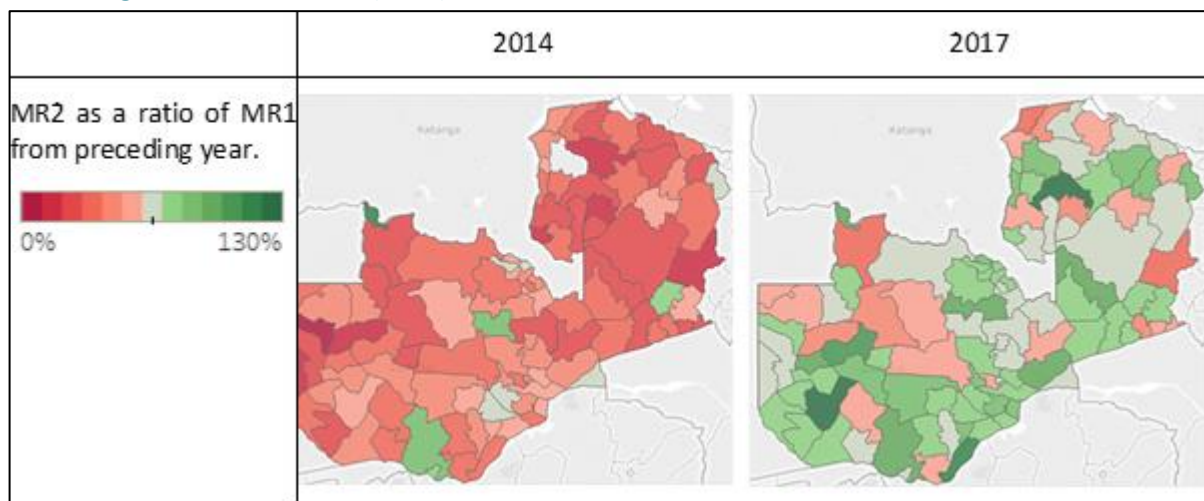
We note the remarkable change from more red to more green, an indication of improvement across the country. However, there seem to be some disparities on the levels and improvements registered. The southern and central parts of the country seem to have progressed more than the upper and mostly border parts of the country.

VACCINE COVERAGE EQUITY

Gavi support is increasingly focused on addressing within-country inequalities related to vaccine coverage. This is reflected in Gavi's 2016–2020 strategic mission, which includes the "increase of equitable use of vaccines in lower income countries" (Gavi Strategic Plan, 2016–2020). Existing literature suggests that certain dimensions of inequity are of particular importance, including household economic status, mother's education level, and urban/rural population (WHO State of Inequality, 2015). Gavi's 2016–2020 strategic plan is similarly aligned on the importance of these equity dimensions, highlighting geography, wealth quintiles, education of female caretakers, and fragile state status as areas of interest (Gavi Strategic Plan, 2016–2020).

| *Finding*	*1.3*
Despite a noticeable increase in vaccine coverage, inequalities in coverage remain significantly high.	

ROBUSTNESS RANKING	A
All findings are based on quantitative DHIS2 data. The finding is also supplemented by previous surveys and past FCE findings.	

An analysis of coverage equity for geography, household economic status, and mother's education status was conducted to provide a portrait of the current state of vaccine coverage equity in Zambia.

Geographic equity

For geographic equity, Figure 5 and Figure 8 above show that coverage varies by geography, with not much change on the coverage spread across districts from 2013 to 2017. The box plot in Figure 10 shows that geographic variations have consistently stayed the same, with an interquartile range of about 25 percentage points. This is consistent with the findings from the 2016 Gavi FCE Annual Report, which showed that geographic equity ratios have hovered just below 2 for the last decade. Further, we did a year-on-year pairwise correlation to assess how district ranking changed from one year to another. This was computed in two stages: first we assigned ranks for each district in each year using FIC 1, with 1 for the highest coverage, 2 for the second coverage, and so on. Then a pairwise correlation was carried out on the rank values; the rank matrix is presented in Figure 9.

Figure 9. Pairwise Rank Correlation

2013-2014	2014-2015	2015-2016	2016-2017
0.83	0.58	0.74	0.58

The figure shows higher levels of correlation between successive years. This loosely means there is consistency in the district ranking from one year to another. This could point to fundamental barriers to immunisation so that poor performing districts are not able to make drastic improvement. The box plot below (Figure 10) shows the geographic variety in coverage rates for Penta 3 vaccine in 2017.

Figure 10. Box Plot Showing Geographic Variations by Province for Penta 3 Vaccine Coverage
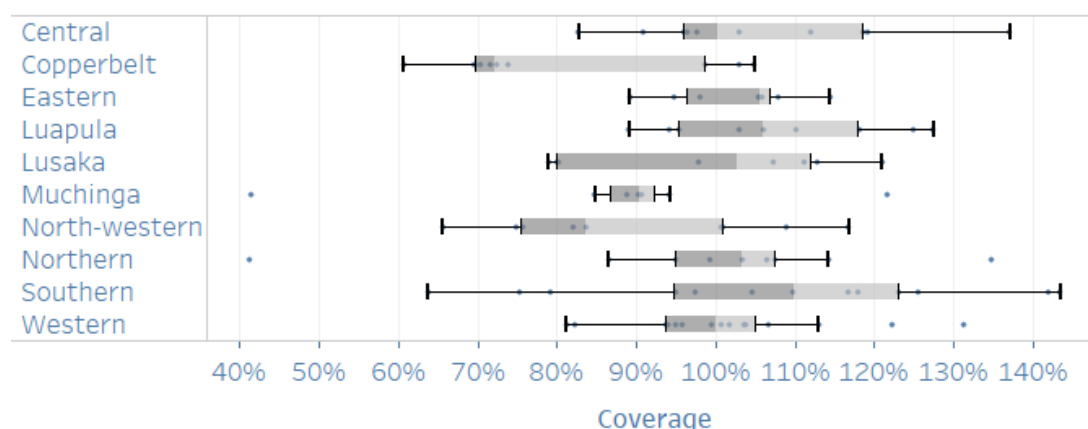
As is visible from the box plot, there are huge variations both among provinces as well as within provinces. Differences in within-province variations may be influenced by varying number of districts per province. On average, however, there does not seem to be much variation in the provincial averages. An analysis of variance employing the F-test shows a statistic of $F = 1.878$, which fails the significant test at 5% level of significance ($F_{9,94,0.05} = 1.981$). The test does confirm that there is no significant difference in the geographical performance if geography is defined by provincial groupings. There is the possibility that urban/rural groupings may exhibit differences in geography; however, this report is not able to analyse differences between rural and urban populations due to unavailability of appropriate classification mode.

Mother's education status and household economic status

The level of education of mothers or caregivers can play a critical role in the decision or intent to have the child immunised. The recent Demographic and Health Surveys (CSO, 2009; CSO, 2015) report that the percentage of fully immunised children rises with mother's education. The same trend is observed with coverage levels for individual antigens. Mothers with higher levels of education are more likely to understand the value of immunisation and therefore respond positively to information, education, and communication (IEC) material. There may be a need to tailor the IEC material to suit mothers of varying education levels.

The economic status of a household may have an effect on the household's ability to seek health care, including immunisation for infants. When caregivers must travel long distances to access immunisation, the command of economic resources has the potential to pose a hindrance to access of immunisation services. As with mother's education level, DHS reports (CSO, 2009; CSO, 2015) show declining coverage with lower wealth quintiles. These equity issues are also acknowledged by the 2017–2021 National Health Strategic Plan (MOH, 2017).

The FCE, however, does not have up-to-date data that would allow our own analysis of the association of education and coverage performance.

Strategies for addressing equity

In line with the current Gavi emphasis on equity, Zambia has recently increased its focus on achieving health equity. To that end, the 2012–2016 comprehensive Multi-Year Plan (cMYP) for Zambia included ensuring that the benefits of immunisation are equitably extended to all people as a key objective. To address equity, the cMYP focused on wealth quintiles and gender as key equity indicators. In

particular, the cMYP suggested three indicators of equity: 1) percentage gap in Penta 3 coverage between the highest and lowest socioeconomic quintiles; 2) number of districts with Penta 3 coverage of more than 80%; and 3) number of high-risk communities identified for an accelerated routine immunisation programme. Further, the country is in the process of conducting an Equity for Immunisation assessment with support from UNICEF. The assessment is tailored to conduct an in-depth equity analysis focusing on the underlying factors (structural, cultural, and socioeconomic) of uneven immunisation coverage and will inform on the extent as well as the drivers of coverage variations.

Further, initiatives especially targeting needy communities have been introduced in response to equity needs of the programs. For example, the implementation of the Reach Every Child (REC) initiative in all districts is another country effort to narrow gaps in district-level coverage performance. The initiative's focus is on every hard-to-reach child in all the districts. The initiative requires a strong outreach programme at facility level as well as supportive supervision. Evidence, however, suggests that inadequate funding especially at the lower level has inhibited the implementation of outreach activities. Supervisory visits also tend to be irregular due to unavailability of necessary resources. As such, the gloomy funding situation, discussed in the latter sections, is likely to have a bearing on the success of the REC strategy.

Despite all these steps towards equity, there are still challenges in integrating equity considerations into all aspects of immunisation planning. For instance, as noted in the 2015 Gavi FCE Annual Report, the HSS selected districts were not necessarily the lowest in vaccine coverage. Coverage was considered, but there were other selection criteria such as absence of key immunisation support from other donors and being in hard-to-reach regions.

POTENTIAL DRIVERS OF IMMUNISATION COVERAGE

There are various drivers of immunisation coverage, both on the demand side and the supply side. The FCE team (GAVI FCE Team, 2017) used the Phillips framework (Phillips et al., 2017) to analyse the interplay of some of these factors and their effect on immunisation coverage. The root cause analysis (RCA) chart in Figure 11 shows the causal links of various factors based on the Phillips framework and expanded based upon LaFond et al., (2012).

Figure 11. Root Cause Analysis (RCA) Links of Factors Driving Immunisation Coverage
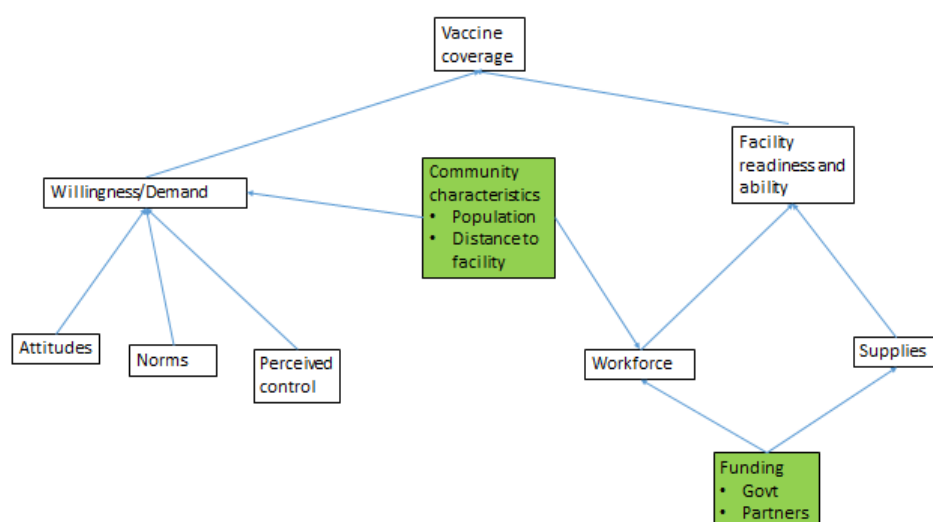
The demand side factors affect a caregiver's willingness to seek immunisation. Major factors behind a caregiver's willingness and demand for vaccination include attitude, norms, and perceived barriers which can loosely be referred as KAP (knowledge, attitude, and practices). These will influence the caregiver's willingness to invest resources, including time, in the immunisation of a child. They are the main target in immunisation demand-generation activities.

The supply side looks at the service provider's (or health facility's) readiness and ability to provide the service, in this case, the immunisation service. It looks at what goes into the provider's ability to provide immunisation service. There are two main drivers on the supply side: funding and community characteristics. Funding affects a facility's ability to mobilise supplies such as transport and fuel and other consumables that are critical in the service delivery. The 2016 report (Gavi FCE team, 2017, pp. 43-45) recognised the role of resource mobilisation in the success of the MR campaign. Further, funding may also interplay with community characteristics to influence the mobilisation of the human resources necessary for an appropriate level of immunisation service delivery. The mobilisation of community health workers (CHWs) and volunteers depends on both the availability of funding and the community characteristics.

Community characteristics can affect both the demand and supply. For instance, the levels of education, poverty, and the geography (distances to health facilities) in a community will shape caregiver's attitudes and norms and community access to vaccination services. At the same time, the availability of other resources including human resources such as CHWs will also depend on the community characteristics.

Due to limited availability of data, however, this section only highlights some of the potential drivers, which include government funding, population size, and distance to a health facility. We will explore these drivers of immunisation coverage further in the district case studies in Year 2.

Government funding

Government funding to subnational levels play an important role in incentivising service delivery. Health workers may be highly motivated to provide the services with increasing funding. In addition, funding may also affect the logistical capacity of service providers to deliver a service. Thus we see

funding having two potential links to the performance of immunisation at the subnational level. The first link is through the motivation of health workers, including community participants. Second, funding affects the availability of supplies such as transport and fuel for outreach activities and non-vaccine supplies which are essential in the provision of immunisation services. This section is therefore devoted to examining the impact of government funding to districts on the performance of the district.

The analysis notes differences in district size, especially in terms of population. Per-capita funding is derived by dividing the total funding per district by the respective population size. The available data also includes a lump sum of the actual government health expenditure per district. Although we are unable to isolate components directly going to EPI, we nonetheless rely on an assumption that the proportion of EPI funding to total district funding will not have significant variation. A detailed discussion of the funding situation and the implications for immunisation activities is discussed later under the Sustainability theme.

Figure 12. Scatter Chart of Per Capita Health Expenditure and Fully Immunised Child Under 1 (FIC 1) Coverage
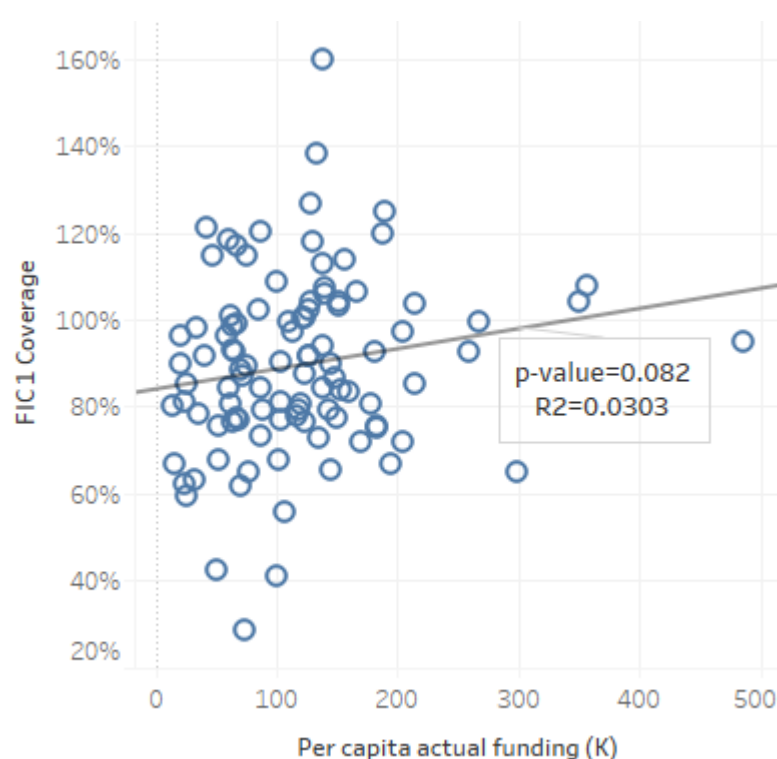
The scatter plot in Figure 12 shows some positive relationship between government per-capita funding (excluding partner funding) and the FIC 1 coverage rate. This positive relationship still holds with other vaccines. This suggests that increasing government funding to districts can help improve vaccine coverage rates. The trend, however, fails the test of significance (p-value = 0.082).

Population per facility

The size of the target population may also serve as an impediment to immunisation coverage. In particular, districts or facilities with higher populations may not reach out to all the families as easily as counterparts with lower populations. In this section, we assess the influence of population on coverage rates at district level. Figure 13 below shows the scatter plot between the average

population per facility in a district and the district-level coverage rate for BCG vaccine. The former is calculated by dividing the district total population by the number of health facilities in a district. This is a valuable indicator of the burden on the health facilities.

Figure 13. Scatter Chart of Population Per Facility at District Level and BCG Vaccine Coverage
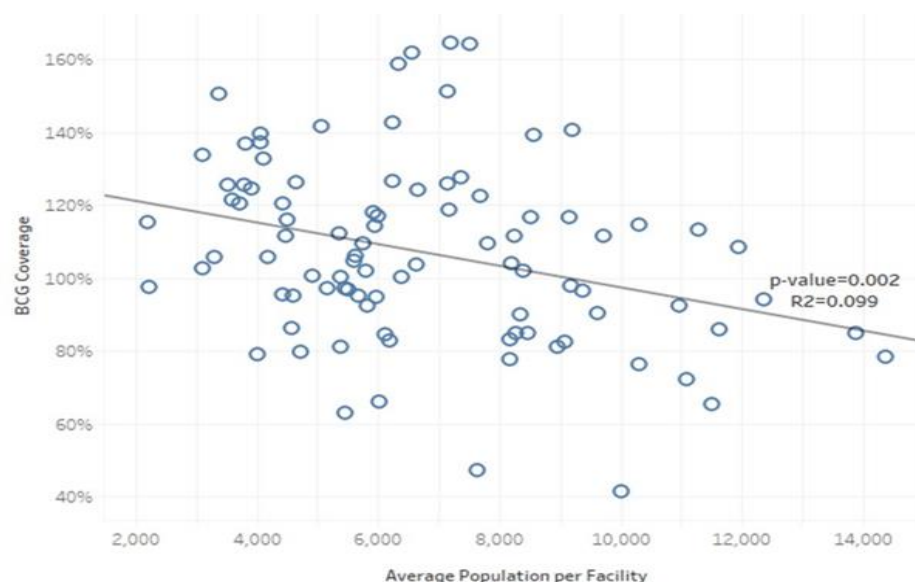
The target population per facility ranges from 2,000 to about 14,000 persons per facility. Using the 4% proportion of Under1 children, this gives a range of about 80 to just below 600 Under 1 children per facility. The scatter plot also reveals a negative relationship between the two variables. That is, coverage rates are generally lower for districts with high population per facility. This trend is highly significant with p-value = 0.002. We conclude that a high population does impair a health facility's ability to reach out to all families, resulting in lower coverage rates. We nonetheless acknowledge the lower explanatory power as shown by a lower coefficient of determination.

Average distance between facilities

In addition to population burden, long distances to health facilities may also hinder caregivers from accessing immunisation from health facilities. Coupled with inadequate or absent transport means and limited outreach activities, distance has the potential to undermine efforts to increase access to immunisation services. This evaluation is however limited by the lack of household-level data on distances to health facilities. What is available, instead, is the total distances to all health facilities in a district (from the district health office). Reducing this to an average distance will provide a proxy for the sparseness of health facilities in a district, which in itself is an indicator of the distance caregivers have to travel to reach health facilities. Average distance between facilities is an indicator of the vastness of a district and the long distances caregivers have to trek to access vaccines. Figure 14 is a scatter plot of average distance to health facility compared to BCG vaccine coverage.

Figure 14. BCG Vaccine Coverage Plotted Against Average Distance from Health Facility
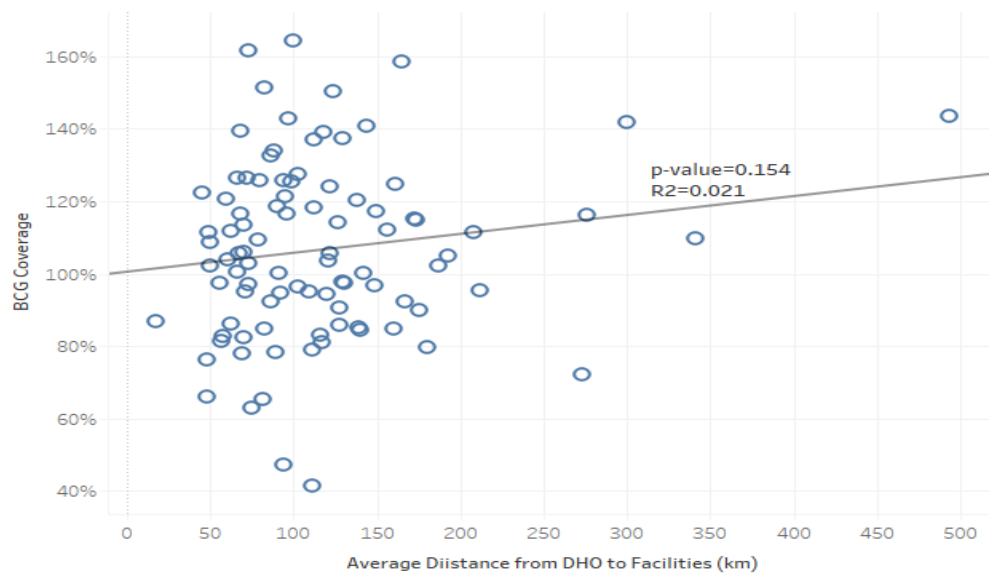
As shown in Figure 14, average distances range from about 50 to 200 km for most of the districts. Lusaka District is only 20 km, and a handful of other outliers show higher distances of up to 500 km. The distance seems to be positively related with coverage. That is, districts with long distances tend to have high levels of vaccine coverage, though insignificant.

A plausible explanation for this positive relationship may lie in the occurrence and effect of outreach programs. It is possible that districts with longer distance may compensate by having more outreach posts which have an effect of shortening the effective distance to an immunisation centre. However, there is no available data on number of outreach centres in districts and therefore we are unable to probe this further. In addition, the selected proxy may have its own limitations. Due to the low p-value of the observed trend above, we conclude that there is no empirical relationship between distance to the DHO office and coverage as is evident from the above figure. The district case studies in Year 2 may be more informative on this question of the role of distance.

Recommendations

➡ **Continue doing:** The programme needs to expedite learning from initiatives such as ZEIR aimed at improving overall immunisation data quality and the expansion of the same to provide appropriate information to the programme.

◎ **Urgent Attention:** The programme needs to strengthen demand-generation activities targeting children in the second year of life to improve coverage beyond the first year.

Next steps for FCE2 year 2

≫ In Year 2, subnational district case studies will be conducted to further investigate district-level coverage trends, challenges and barriers, such as financial management, LMC, and data quality.

Sustainability

The Zambian EPI has scored many successes in recent years with several new life-saving vaccines having been introduced and, importantly, coverage of all vaccines having increased in most districts as highlighted earlier in this report. There have also been some improvements in terms of programme management. However, there have been concerns about sustainability of these gains among stakeholders. In this section, we assess sustainability from the perspective of decision-making around NVI, capacity to mobilise sufficient resources to meet the growing demand, and planning for sustainability.

> **EQ 14: Whether, why, and how are country decisions to apply for new Gavi support taking into account the programmatic and financial sustainability aspects, with a specific focus on HPV?**

Zambia applied to Gavi in 2017 for HPV vaccine national introduction following a successful HPV demonstration project from 2013 to 2017. The budget for the process of HPV vaccine national introduction is US$2,663,394, with Gavi support amounting to about 43% of this at US$1,138,490.

The national introduction was initially planned for 2018 but has been delayed due to a global vaccine shortage. So far there is no indication of when the global HPV vaccine shortage will be resolved and thus when HPV introduction will be done. The country expects it to take a while owing to the experience with shortage of IPV, which was due for introduction in 2015 but is only being done now in 2018. Thus, estimates for introduction so far are for 2020.

Finding   *2.1*

Financial and programmatic sustainability implications of introducing HPV vaccine nationally have not been thoroughly assessed using local evidence.

ROBUSTNESS RANKING   B

Finding based on evidence from key informant interviews, document review, and meeting observations. However, due to the timing of the HPV application, this evaluation question requires some retrospective data which may thus introduce some limitations.

The main consideration for moving towards introducing HPV vaccine in Zambia was the high burden of cervical cancer cases in the country, which is said to be one of the highest in Africa. It is estimated that annually 2,330 women in Zambia are diagnosed with cervical cancer and 1,380 die from it, and it is the most frequent cancer among women of childbearing age (HPV Centre, 2017). The annual mortality rate per 100,000 people from cervical cancer in Zambia has increased by 19.7% since 1990, an average of 0.9% a year (IHME, 2017). There was thus consensus that the burden of disease is high and that there has to be more effort to tackle it in addition to current measures such as the cervical cancer screening

programme, setting up of the gynaecological oncology unit, and setting up of the chemoradiation centre (ZITAG, 2017). While the motivation for introducing HPV vaccine broadly was the burden of disease, the motivations to launch an HPV demonstration versus introducing HPV nationally were shaped by differing influences and interests.

MOTIVATIONS FOR HPV DEMONSTRATION

The decision to introduce HPV immunisation in a demonstration phase was driven by commitments to global agendas and key political stakeholders. Global agendas also drive vaccine introduction decisions, such as global-level agreements and declarations signed by ministers on behalf of the country, sometimes without consideration of funding or budget implication at the time of signing. Global considerations were therefore an important factor to introduce HPV vaccine in Zambia and were key in the HPV demonstration phase as illustrated in previous HPV reports, though not as important a consideration for the application itself once the HPV agenda had gathered momentum.

Another important driver for HPV vaccination during the demo phase was active involvement of the First Lady at the time as a champion of the move, but this was not the case during the last stages of the demo project, as noted in the 2015 FCE report, and not significant during the HPV application process itself. Related to leadership of HPV vaccination was the fact that initially HPV vaccine work was under the Adolescent Health Unit and then the Cancer Unit at the Ministry of Health, rather than under the Child Health Unit (CHU), and thus it had leadership and coordination challenges. But in the last stages of the demo project and during the application process, CHU took up the task and this has aided in making the process smoother. Thus, it seems that current buy-in for HPV vaccination within EPI is high.

MOTIVATIONS FOR HPV NATIONAL INTRODUCTION

Availability of donor funding, especially from Gavi, was a major driver for decisions on new national vaccine introductions in Zambia and this was also the case for HPV. Key informants indicate that without funding from Gavi, HPV would likely not be introduced in Zambia as it would simply not be a priority given everything else that is competing for EPI funds. This is especially the case given the different age group that the vaccine targets compared to other vaccines within the EPI programme.

> *"Of course, the country wouldn't have applied for HPV support if Gavi did not support part of it."* —*Key informant interview*

It is worth noting in this regard that Zambia postponed its HPV application to Gavi from 2016 to 2017 due to competing priorities and later consideration of possibly getting more funding during the 2017 window once the new HPV 2.0 guidelines were implemented. The new guidelines allowed countries to apply for national introduction, with the option of implementing a phased introduction, and they could apply for support for multi-age cohort HPV vaccinations (9–14 years of age) in Year 1 of introduction of the vaccine, including support for 100% of vaccine costs for the additional cohorts, and operational support of up to US$0.65 per targeted girl of those cohorts. Thus, although the decision to postpone the application was due to competing activities, the increased funding availability in 2017 was a

welcome benefit of applying later, possibly pointing to a realisation that more support was critical and could not be obtained from government budgets.

Assessment of financial and programmatic sustainability

In spite of the interest in introducing the HPV vaccine nationally, the financial and programmatic sustainability implications have not been thoroughly assessed using local evidence. There does not seem to have been detailed analysis of the long-term implications of introducing HPV vaccine. Inter-Agency Coordinating Committee (ICC) minutes (17th September 2015; 11th May 2016) indicate that sustainability of HPV national introduction has been a concern of both government and partners since the demo project and that HPV national introduction had been a standing item on the meeting agenda for over two years. The major concern was that HPV targets a different age group than other vaccines in EPI and therefore requires special effort to deliver through schools and not the usual health facilities. These factors could potentially contribute to higher costs than other vaccines within EPI that mainly target under-5 children through health facilities and outreach. However, these concerns are still outweighed by the availability of funds from Gavi, as noted by stakeholders:

> *"Of course Gavi support plays a role in decision-making. We always look at fund availability when planning and when Gavi offers funding, it makes easier to put those activities. Personally I don't know of any analysis to look at epidemiological evidence as well as cost-effectiveness. But the decision to introduce HPV is not political, it's backed by the problem." —Key informant interview*

From ICC proceedings, government has no specific plans to address HPV vaccine sustainability concerns or mobilise additional resources other than general plans aimed at increasing the health budget, such as social health insurance (SHI), which has been planned for introduction for some years now and seems to be at the point of commencing implementation soon. The general perception is that once HPV vaccination is introduced, government would find the money to sustain it, as it has done for other vaccines in the past. As one key informant said:

> *"All programmes start the same. Once we start we will fill the gaps."- Key informant interview*

However, driven by HPV concerns, it has been a point of discussion in both the 2016 and 2017 Joint Appraisal, and the plans are to utilise PEF funding and WHO support to assist the government in developing an EPI resource mobilisation framework.

Other than financial sustainability, programmatic sustainability considerations are also important, and national stakeholders said this was considered. For example, what are the human resource implications of HPV vaccine introduction and the implications of health workers being deployed to schools during child health week? During the application, it was thought that administering HPV during child health week would lower the costs of delivering the vaccine, but there was no data generated to this effect to support the decision other than initial budget calculations.

Cold chain capacity and vaccine transportation to handle additional vaccines in the required quantities is another important consideration. It has recently come up that Zambia will be applying to Gavi for support using the Cold Chain Equipment Optimisation Platform (CCEOP). The general assessment is that there is better cold chain capacity at provincial and district levels than at national level. Vaccine orders would thus need to be staggered or vaccines stored at provincial level to cater for the

additional capacity needed for HPV vaccines. However, generally cold chain capacity needs to be improved at all levels to adequately handle it.

Prior to the submission of the HPV application to Gavi, Zambia launched the Immunisation Technical Advisory Group (ZITAG), whose mandate includes focusing on immunisation financing to strengthen financial sustainability of immunisation programs, as enshrined in the ZITAG Terms of Reference. However, the ZITAG had only one opportunity to deliberate on the introduction of HPV vaccine. This was in part due to the fact that ZITAG was established on 17th March 2016 to provide evidence-based recommendations on vaccine policy and this was during the advanced stages of the demonstration project.

Thus, ZITAG did not give any input during the HPV demo as it was not operational then, but held an ad-hoc meeting to discuss the HPV national introduction application on 4th September 2017 as it was a requirement of Gavi for the application that ZITAG should have deliberated and approved it. Among the evidence considered during this meeting were efficacy, impact on the health system, cost, cost-effectiveness, disease burden, and alternative measures. The cost and cost-effectiveness evidence utilised was mainly from Brazil, Canada, and the United Kingdom, with one paper from Tanzania (ZITAG, 2017). The transferability of such findings from these countries to the Zambian context is arguable.

Additional evidence was considered by the EPI programme in the national introduction of HPV vaccine. A cost study that was done by PATH to address the cost per FIC based on the first phase of the HPV demo in Zambia was referenced. Based on this, the national scale-up was projected to cost (financially) between US$9.98 and US$10.40 per fully immunised girl depending on whether the national rollout follows a phased approach or not. Such evidence was used to convince EPI members, many of whom had doubts about introducing HPV, with such anecdotes as "a fully vaccinated child is equivalent to 5 litres of cooking oil cost-wise, which is much lower than the cost of hospitalisation for a patient with cervical cancer." Another argument was used that reducing cervical cancer cases would also decrease the amount of blood required for transfusions and thus overall costs to the health system, as it had been noted that cervical cancer cases were one of the major drivers of the increased need for blood transfusions in recent years.

There were however some doubts raised around whether demo conditions would be a true reflection of what would happen during national introduction, further complicated by the fact that the national introduction plan varies slightly from the demo project in giving only two doses of HPV vaccine per child and in using child health weeks as the time to administer the vaccine to the target age group, although the second phase of the demo also utilised two doses. Generally, demo conditions are perceived as being more expensive, so the hope is that national rollout will be less costly. It should be noted, however, that budget lines such as social mobilisation are usually what is missing or markedly less during national rollout and that social mobilisation would be critical for a vaccine such as HPV. Thus, no cost-benefit analysis was done to examine HPV national introduction in the Zambian context, to examine the implications for sustainability, or to compare HPV vaccine administration versus other cervical cancer prevention methods, such as cervical screening.

There were also some concerns about ZITAG and ICC not having enough time to deliberate on matters of this nature, as documents were sent late before meetings for review and it is doubtful they were scrutinised in detail before meetings. Such meetings are also packed agenda-wise, leaving little time to focus on one matter. There was a suggestion by key informants that other meetings and fora at which ICC members are present could have been utilised to discuss the matter more in depth.

"ZITAG did not have enough time on HPV but ICC did as this was on the agenda for two years and the discussion was exhausted. Government commitment was the biggest question. The ZITAG also does not have much economic evaluation capacity." —Key informant interview

"There are very few people that can critique the HPV proposal (200 pages) in the ICC because they haven't read it and don't have the time. With the model to use, it is hard to know the best way when you haven't done it. I think the NITAG [ZITAG] could give a better critique. I don't think the majority of the ICC members can review the proposal." —Key informant interview

More broadly, Zambia has no established standardised method or policy in place for economic appraisal of new vaccine introductions or other EPI interventions. This speaks to a lack of capacity, guidelines, and expertise to address sustainability at EPI. Some partners, however, feel economic appraisal should be a Ministry of Health (MOH) function and not necessarily restricted to EPI, as such considerations are relevant for other programs within the MOH and it would be a good idea to look at funding at MOH holistically rather than in a fragmented manner. Entrenching economic evaluation into the Policy and Planning Department would probably be the most prudent way to go, as suggested by some key informants, as such matters go beyond EPI and are important for other economic decisions.

All these factors are said to have been considered and planned for, but the level of attention to detail may not have been adequate in planning for programmatic and financial sustainability. While there was no analysis of the programmatic and financial sustainability of HPV, it should be noted that the need for such analysis was well recognised by the EPI and several requests were made for support to do this, including to the World Bank, WHO, and the Costing and Financing of Routine Immunisation and New Vaccines (EPIC) study team. Unfortunately, no support has materialised in this regard. The national introduction of the HPV vaccine will be an interesting case of how sustainability planning is undertaken once the introduction commences.

"EPI asked World Bank for help with [economic evaluation] evidence but nothing came up. MOH approved for this to be done but it was not possible. The EPIC study team was also approached to assist. WHO was also asked to model as in application." —Key informant interview

Root cause analysis of programmatic and financial sustainability

Figure 15 below presents a summary of the root cause analysis around financial and programmatic considerations for sustainability. Overall, assessment of these elements of sustainability is not well institutionalised due to a lack of policy direction around economic evaluation for such decisions. This in turn means that there is a general lack of capacity within technical working groups (TWGS), ICC, and ZITAG to fully evaluate economic implications of new vaccine introductions, despite the need for them to carry out this function. As a result, there is inadequate time and effort dedicated to sustainability considerations. In the absence of such assessment, other considerations such as availability of external funding, global commitments, competing priority areas within EPI, and political considerations become the drivers of such decisions.

Figure 15. Root Cause Analysis (RCA) of Programmatic and Financial Sustainability Consideration in Applying for New Gavi Support

RCA - Programmatic and financial sustainability considerations in applying for new Gavi Support
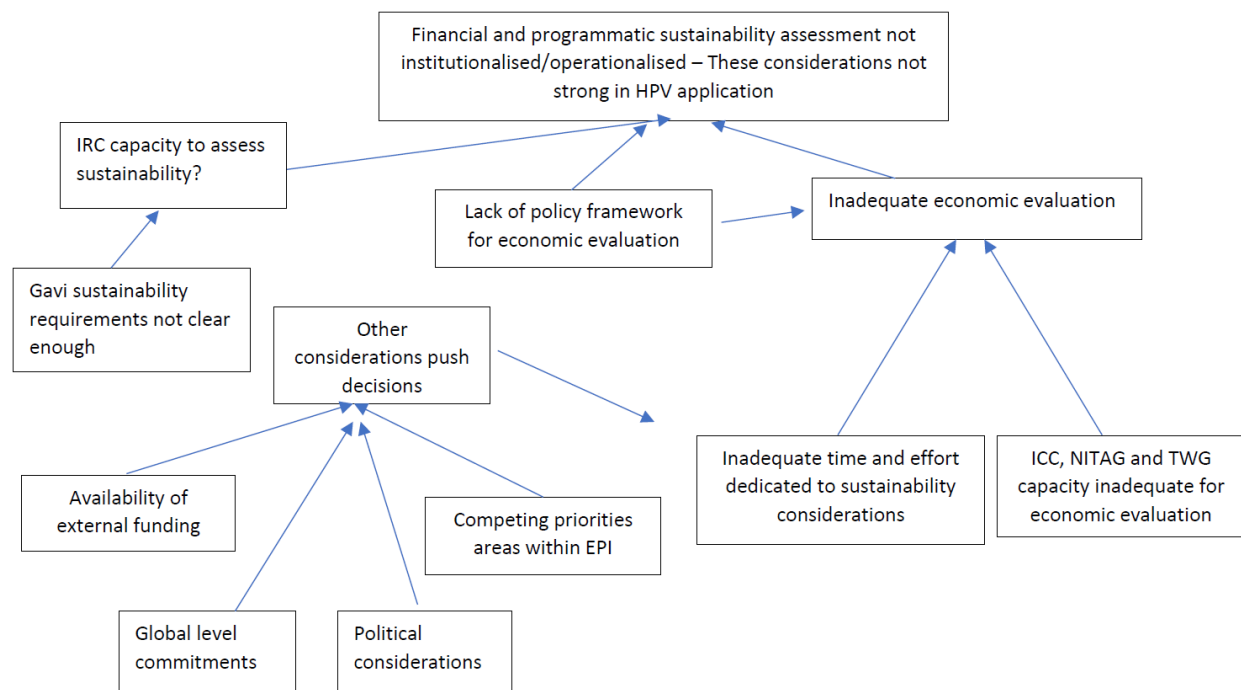
Recommendations

◎ **Urgent Attention:** The creation of the ZITAG is a commendable step in enhancing financial sustainability assessment of new vaccine introductions. The Ministry of Health now needs to develop clear policy and guidelines for purposes of economic evaluation of New Vaccine Introductions and other programs. ZITAG membership should also include adequate economic evaluation capacity.

EQ 15: What are the drivers of changes in financial support for immunisation?

In the recent past, notably 2011–2017, the Zambian immunisation programme has expanded its portfolio of services into the routine system. There has been an increase in funding to immunisation both from the government and from partners, notably Gavi, for new vaccine introduction and for immunisation system support. Importantly, immunisation has increased in most districts, reassuring policymakers and partners that investments are saving lives. However, there are concerns among immunisation partners that to ensure sustainability of gains, the country needs to assess its fiscal space for increasing or sustaining financing to the programme, partly given the trajectory of costs.

We have adopted a fiscal space analysis approach to assess drivers of immunisation financing for Zambia. The main purpose of this section is to assess the revenue potential of all five revenue drivers—also called fiscal space pillars. The five options we consider are: (i) economic growth, (ii) increasing the share of health in total public spending, (iii) introducing new financing mechanisms,

(iv) increasing donor funding, and (v) increasing efficiency of current immunisation spending. Ultimately, we provide an evidence-based expert opinion about the financing options that we believe have potential to increase fiscal space for immunisation in the short to medium term. We believe that the national immunisation programme can benefit from the evidence, data, and expert opinion on financing options. Such evidence can then be used to lobby the national treasury for more resources into the programme.

What is the value addition of this section? We see three specific contributions. First, this report provides a full diagnosis of immunisation financing and the country's economic context. The second contribution is that we have taken a prospective perspective by examining the economic outlook and the extent to which current investments are likely to contribute to sustained gains in immunisation coverage and equity for the coming years. Finally, as Zambia is earmarked for accelerated transition out of Gavi support, we consider the country's readiness for transitioning and its capacity to mobilise sufficient resources to meet demand, and we propose a set of indicators for prospectively monitoring sustainability of the programme.

OVERVIEW OF THE CURRENT IMMUNISATION FINANCING SITUATION

Over the period 2011 to 2017, resource tracking and national health accounts (NHA) data show that there has been an increased investment into the immunisation programme by both the government and EPI partners. Gavi has been the largest donor, providing over US$86 million in cash and non-cash support to the programme in the same period. As can be seen from Table 4 below, most of these funds have gone into supporting new vaccine introduction, notably PCV, rotavirus, and pentavalent vaccines. Other notable investments include support by local partners to cold chain expansion.

Table 6. Distribution of Gavi Disbursement to Zambia, 2011–2017 (US$)

Programme	2011	2012	2013	2014	2015	2016	2017	Total
HSS			-194,847		-169,655			-364,502
Measles		316,063	316,490	-17,534				615,018
Measles-Rubella						5,704,977	-265,797	5,439,180
Penta	7,861,820	1,383,530	6,468,901	-839,830	6,313,554	1,587,160	2,196,960	24,972,095
PCV		10,658,950	8,436,180	2,602,421	8,212,692	4,730,958	6,651,663	41,292,863
Rotavirus			2,451,594	3,010,010	2,410,247	2,662,362	2,980,690	13,514,902
IPV					494,223	-436,149	-19,639	38,435
Injection Safety Devices							265,531	265,531
MR - Operational costs						4,501,608		4,501,608
Vaccine Introduction Grant		1,103,000	567,000		526,500	-29,239	607,918	2,775,179
Total	**7,861,820**	**13,461,543**	**18,045,317**	**4,755,067**	**17,787,562**	**18,721,678**	**12,417,325**	**93,050,310**

Source: Gavi, https://www.gavi.org/results/disbursements/

Despite these investments, Zambia's immunisation programme currently operates with a large funding gap, which may increase by 2025 because the country's anticipated graduation into accelerated transition (Table 5). Under accelerated transition, it is expected that the co-financing for vaccines will increase substantially after 2025. Hence, the financing picture in the table will look even more dire. Apart from personnel and vaccines, the third biggest part of the funding gap is for recurrent operational cost items. These include transportation, cold chain, per diem for outreach, and other delivery costs. This trend clearly suggests that unless the government develops a new strategy for financing immunisation (and health more generally) which generates significantly new resources into the health sector, this funding gap is unlikely to be met.

Table 7. Projected Resource Needs and Funding, for Comprehensive Multi-Year Plan 2017–2021

Year	2017	2018	2019	2020	2021
Total resources needed	$99, 196, 192	$102,614,229	$139,764,914	$155,172,865	$121,287,552
Secured funding	$29,237,280	$29,738,937	$59,992,835	$25,753,857	$29,357,571
Probably funding	$3,022,900	$3,847,967	$14,796,242	$45,998,997	$41,336,020
Probable funding gap	67.5%	67.3%	46.5%	53.8%	41.7%

Source: Comprehensive Multi-Year Plan (cMYP) 2017–2021

Finding   *2.2*

The immunisation programme is going to experience increasing financing challenges because of slow revenue growth from both government and partners, and an increasing cost of sustaining high immunisation coverage.

ROBUSTNESS RANKING **A**

Assessment of tight fiscal space is defined by well-controlled data on expenditure on health and immunisation and macroeconomic variables that describe the underlying economic context. Government and Gavi data accurately define the fiscal envelope for the current and recent past. One possible limitation is that our projections are based on an assumption of a simple linear trajectory of GDP and GHE. This assumption could be belied if GDP growth rate were to be much higher than 4% or if some exogenous increase in GHE were to prevail in the next five years. Key informants are virtually unanimous in their assessment of limitations of all key sources of financing.

Zambia's immunisation programme has expanded its portfolio with support from Gavi and local partners. As these new vaccines are now fully integrated into the routine, the costs of vaccines and delivery will need to be met by increasingly regular, sustainable financing. It is anticipated that government will be required to increase the level of domestic resource mobilisation to meet the projected increase in the funding gap over the next one to five years as external support is not expected to increase significantly. As a number of programmes and activities have been initiated with partner support, there is still an assumed expectation that the government would provide ongoing recurrent budgetary support to sustain the associated delivery costs.

Modest economic growth and tight fiscal conditions

The data in Table 6 seems to make a definitive case that the Zambian EPI programme is operating under a severely constricted fiscal space, mainly on account of a weak macroeconomic situation. The Zambian economy has taken a slow turn since 2015 with real economic growth growing at 3.2%, 3.4%, and 4% in 2015, 2016, and 2017, respectively. GDP growth for the next five years is forecast to remain moderate at around 3.5% to 5% per annum. Considering a population growth rate of 2.3%, this rate of growth is too low to support a significant increase in domestic revenue generation for public spending on immunisation.

Apart from slow growth, the country's fiscal situation is expected to remain generally tight and unable to generate significantly new revenues to support expansionary public spending. First, as seen in Table 5, tax revenue to GDP ratio in Zambia has declined in the last five years to below 18%, which is significantly low relative to the average in Southern Africa Development Community (SADC) countries at 23.7% (IMF World Economic Outlook database). Furthermore, the tax code is littered with generous tax incentives, differentiated tax rates (mainly on a sector basis), and exemptions from regional free trade, areas which limits the ability to generate revenue from domestic taxes. According to WHO (McIntyre and Kutzin, 2014), this level of tax revenue potential is indicative of low fiscal space and is too low to support increased spending. This situation means that the country's potential to raise additional health financing from tax revenue is limited as the share of the government income from the overall economy is small. As a result of these low domestic tax collections, tax revenues are projected to remain low and insufficient to fund increasing EPI funding obligations.

Table 8. Macroeconomic and Fiscal Indicators, 2011–2016

	2011	2012	2013	2014	2015	2016
Real gross domestic product (GDP) growth rate	6.3	6.7	6.7	5	3.2	3.4
GDP per capita ($)	1,644.62	1,734.93	1,850.79	1,738.09	1,313.89	1,269.57
Inflation	7.2	7.3	7.1	7.9	21.1	7.5
Fiscal deficit as percentage of GDP	3.6	4.8	6.5	5.2	9.39	5.8
Tax revenue as percentage of GDP	20.2	18.6	19.1	18.5	14.4	12.9

Second, Zambia's public debt has increased to a very high level. In the period 2012–2016, the country's external debt stock has accumulated rapidly and now stands at around 60% of GDP (IMF World Economic Outlook 2018), driving an increase in debt interest payments (Figure 16). The International Monetary Fund (IMF) debt sustainability assessment classifies Zambia as being in a high risk of debt distress. It is anticipated that the level of interest payments on debt will increase further over the next two to ten years. The government in its fiscal outlook for 2018–2020 states that priority will be on reducing deficit levels and directing resources to productive programs (MTEF, 2018–2020). The implication is that social sector spending is expected to grow at a slower rate than in the past five years. In this context, the capacity of the country to increase public funding for EPI can be expected to decline even further.

Figure 16. Declining Share of Resources for Public Services and Operations, by Year

Source: Ministry of Finance
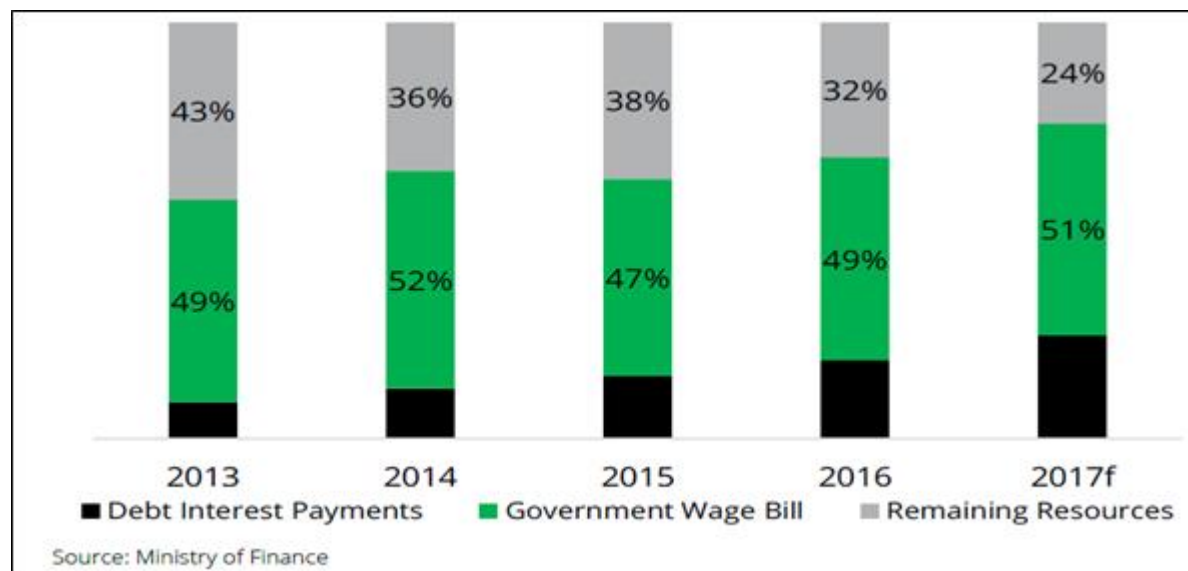
Third, the recent recruitment of health workers is laudable in addressing the major constraint to immunisation service delivery. However, the commitment to fund their wages will leave fewer resources for the government to meet funding needs for the immunisation programme. Within the health sector, we observe that an increasing share of total government health expenditure (GHE) is now going to wages of health workers. In the last four years, the proportion of personal emoluments

in health to GHE has increased to a high of 62% (Figure 17). As more resources of a shrinking share of total public resources are committed to human resource wages, fewer resources are available to support operations of programs such as immunisation. A key stakeholder describes the confluence of these factors in the following way:

> *"With less growth in overall public health spending, there is less capacity to increase spending for discretionary spending for immunisation operations. However, it should also be noted that in the last five years, the government has invested heavily in constructing new health facility infrastructure, and recruiting new human resources, and increased salaries. [...] As a consequence, the amount of funding that can be extended to other components of the programme budget. Most of these resources have come from external borrowing rather than re-allocation of domestic fiscal resources. These developments have left very limited scope for significantly increasing the share of the public budget that can go to health."* —Key informant interview

Figure 17. Personal Emoluments in Health as a Share of Government Health Expenditure
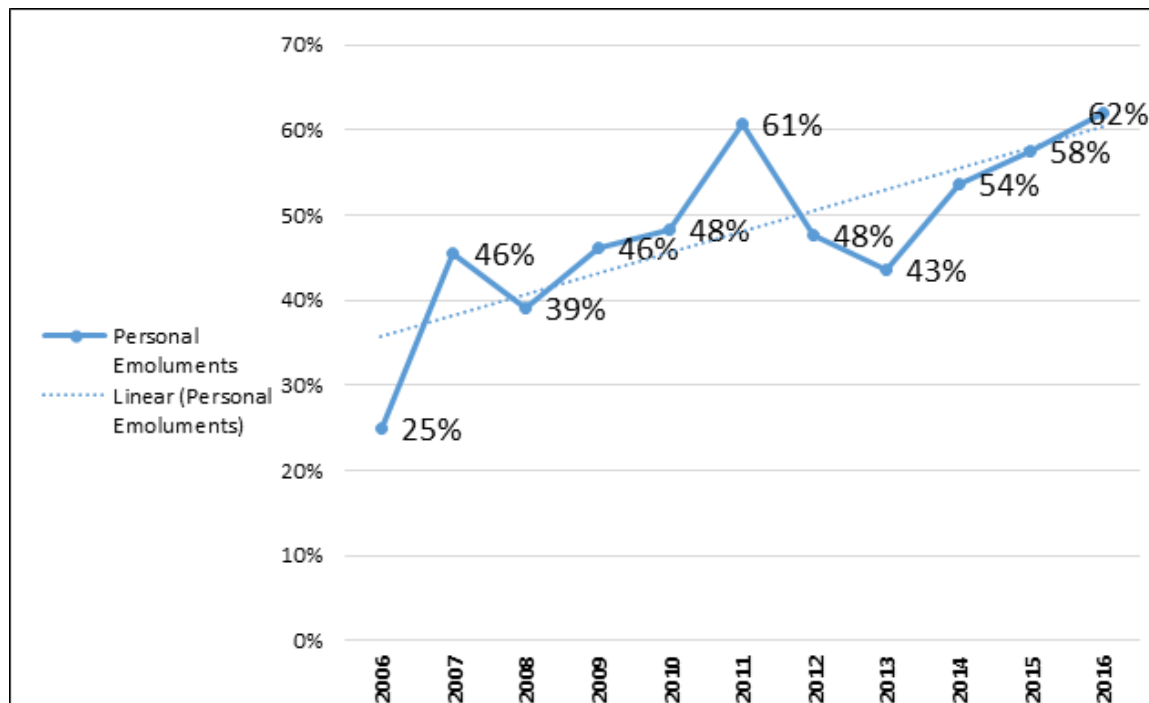
Finally, our analysis shows that the modest macroeconomic conditions are likely to constrain the country's potential to significantly increase immunisation financing over the next five years (Table 7). In this analysis we have assumed that the estimated long-term relationship between economic growth and government health spending remains constant. Of course, any exogenous increase in spending may change this scenario. However, the overall macroeconomic framework is projected to be characterised by a tightening fiscal space. If GDP growth rate remains at 3% to 5%, and GDP elasticity of government health expenditure remains constant at 1.05, immunisation expenditure per surviving infant by the government will increase from US$64 in 2016 to US$87 in 2022. This increase falls short of generating significantly additional resources and will fall short of meeting the projected increase in EPI resource needs according to the cMYP in the period. Thus, at the rate government health

expenditure is projected to increase over the next years, the country is expected to continue to depend on donor support, including Gavi.

Table 9. Key National Health Accounting Indicators, 2011–2016

	2011	2012	2013	2014	2015	2016
Total health expenditure (THE) (K million)	4,469	5,310	7,276	6,853	7,681	10,075
Real THE (K million)	4,046	4,446	5,578	4,982	5,236	6,007
THE as % GDP	4.6	4	4.8	4.1	4.2	4.7
Government health expenditure (GHE) as % GPD	1.8	1.5	1.4	2.1	1.9	1.9
GHE as % of general government expenditure	8	7.7	6.8	9.3	6.8	7.9
External funding for health as % of THE	46.6	47.3	55.3	31.0	37.1	40.7
THE per capita (US$)	67.4	73.0	92.6	74.2	57.5	61.3
GHE per capita (US$)	26.9	27.8	27.9	38.7	26.3	25.0

Source: NHA estimates (preliminary)

Allocations of public spending to health

The share of total public spending dedicated to health and immunisation has declined in recent year, indicating prospects for significantly increasing the share of domestic resources for health and immunisation are limited in the short term. One of the options to increase fiscal space is by increasing the share of total public spending that is dedicated to immunisation. In the past three years, government allocation to the health sector as a proportion of total public spending has declined, which might reflect worsening fiscal constraints and/or increasing competition for public resources. For example, in 2016, the Zambian government allocated 8% of its budget to health. Further, Zambia allocates a smaller share of its GDP and total budget compared with countries in the region with similar or worse level of economic performance (Table 8). If we also consider that less than 40% of all health expenditure is borne by the government (MOH-NHA, 2015), a case could be made that the level of priority to health can be improved upon through reallocation within public funding towards health.

Table 10. Government Health Expenditure (GHE) as a Percentage of Gross Domestic Product (GDP) and Total Government Expenditure (TGE) in Selected Sub-Saharan African Countries

Country	GHE as share of GDP	GHE as share of TGE
Guinea	0.5	3.4
Central African Republic	1	8.8
Niger	1.4	7.1
Angola	1.5	5.6
Kenya	1.8	6.5
Zambia	2.1	8
Tanzania	2.2	8.5
Malawi	3	9
Lesotho	8.1	13.1

Source: Compiled from World Health Organisation (WHO) and International Monetary Fund (IMF) World Economic Outlook (WEO) databases

However, we recognise that re-prioritisation is not just an accounting exercise but a more complex political process. Public expenditure has made numerous capital-intensive commitments on infrastructure, roads, agriculture, and other social projects, which leaves very limited scope for significantly increasing health's share in the overall budget, at least in the medium term. Nonetheless, the best option for increasing sustainable financing lies in increasing the immunisation share of the total public budget. As shown in Figure 18 below, the share of public fiscal resources dedicated to health has fluctuated over time, giving the impression that a higher proportion is feasible. Nonetheless, it would appear that re-prioritising public spending towards health still provides the greatest potential for increasing fiscal space for immunisation. Recent trends in the share of government health expenditure (GHE) in total government expenditure (TGE) shows that an improvement can be feasible by the government committing to at least 15% of total fiscal envelope to go to health (Figure 19).

Figure 18. Share of Government Expenditure on Health, by Year
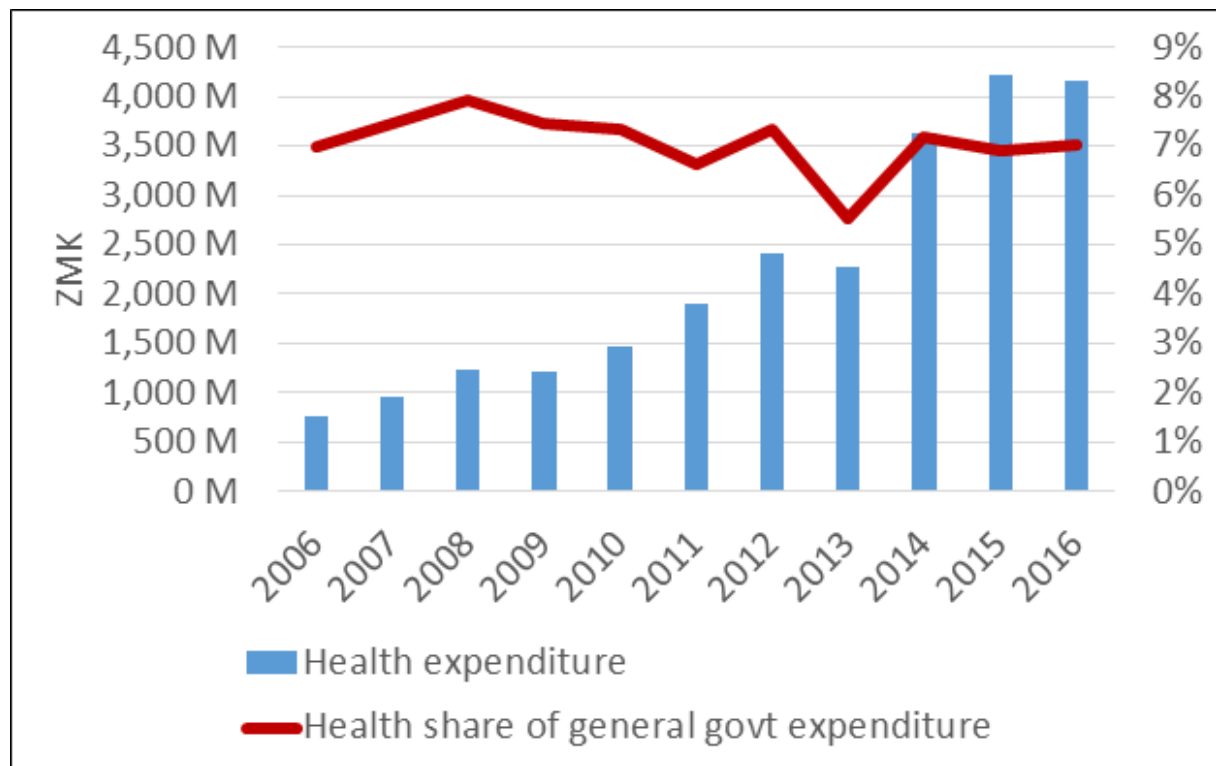
Figures 19. Trajectory of Government Health Expenditure to Meet Gavi Financing
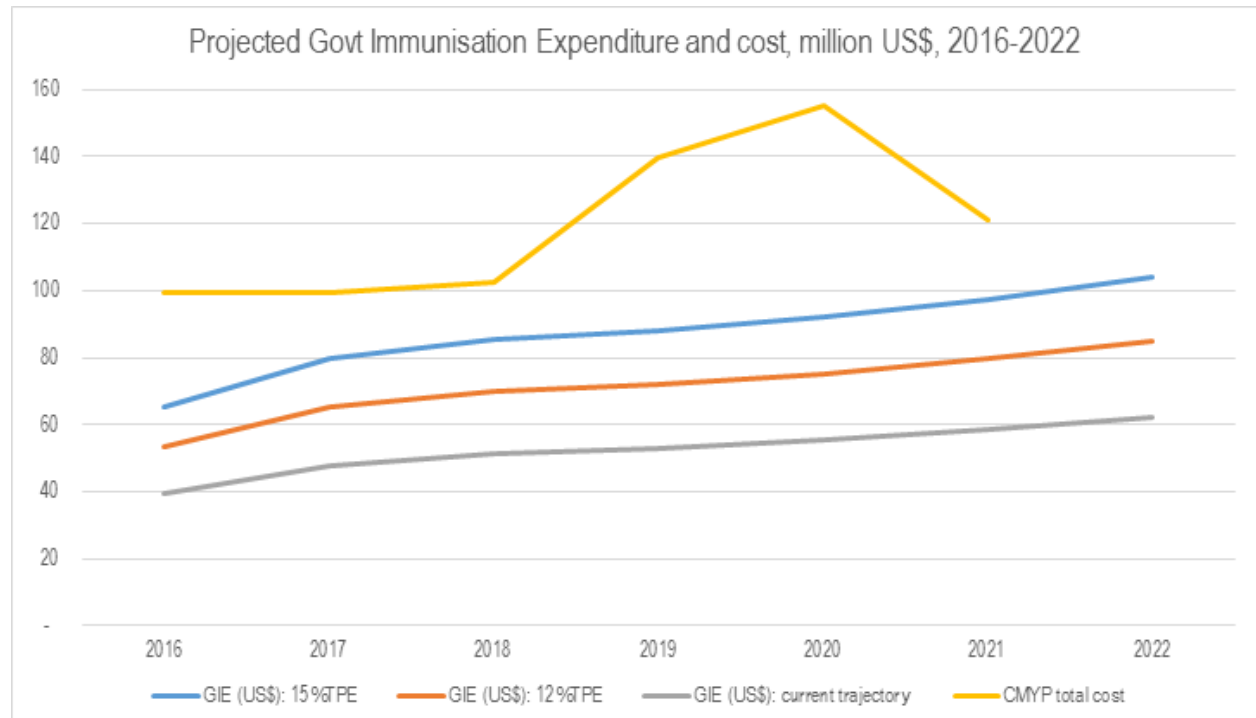
Decline in number of donor partners

The donor landscape is showing a declining number of partners supporting immunisation and a declining volume of support, implying that donor funding will remain low and unpredictable in the short term. Already we observe that the number of donors that provide financial, material, and technical support has decreased significantly since 2013. For immunisation specifically, the number of partners has declined even as the costs of running the programme are increasing. Putting aside the decline in the level of donor funding to the health sector, there is also increased volatility in donor flows in the last three years. The health sector generally is going through a period where donor funding is highly unpredictable and also more short-term making it difficult to plan on increased donor funding. Mobilising resources or securing commitments from domestic partners is also proving to be a challenge. Prospects of increasing resources through donor funding are low in the next five years.

> *"I would say that the number of partners supporting immunisation is not the same in the last three years or so. For example, I don't see Care, GSK, Child Fund, etc., anymore. Some of these smaller donors were crucial in providing support in a flexible and easier way than the bigger donors. In many instances, we relied on them to come to our aid when we had shortfalls at short notice. So, their absence will be felt." —Key informant interview*

> *"We need to change the way we ask for funding from donors. We can't go to donors with a just a PowerPoint presentation and expect to receive financial support, even for those who have committed to supporting health programmes. We need to increase the number of partners. But it will take a lot of time and effort into producing documents that describe what we deliver as an immunisation programme. And the immunisation programme is effective in reducing child mortality, decongesting health facilities, and saving a lot of lives. We need to document the economics of what we do." —Key informant interview*

> *"Furthermore, as the number of EPI stakeholders decline, the Ministry of Health is losing a coalition of partners that has been helpful in supporting recent programmatic improvements. Their involvement in helping to develop a sustainability plan for sustaining EPI gains is required." —Key informant interview*

Finally, it is worth noting that at one of the recent ICC meetings, the country has mentioned that it is seriously considering looking to the Global Financing Facility (GFF), a new financing arrangement, to meet its financing obligations to support some programs under child health. These discussions have not yet reached any advanced stages at policy level. The country's middle-income status is hurting its ability to mobilise financing through grants. The potential for GFF to provide financing on a long-term basis for a country such as Zambia remains to be assessed. However, as it is a loan financing, consideration of the GFF option is indicative of the dwindling options of raising grant funding from traditional donors and from domestic resources.

Mobilising new revenue stream for immunisation from new taxes

Sin taxes are considered to be already very high in Zambia. For example, taxes on tobacco and tobacco substitutes are at 145%. Excise duty on all types of wines is 60%, and clear beer is taxed at 40%. Furthermore, stakeholders in the Ministry of Finance (MOF) indicated that there is little appetite for

increasing these taxes at the moment (MOF Green Paper, 2018–2020), and the tax base from these products is also limited. Additional fiscal space from earmarked taxes on luxury commodities also appears small due to a limited tax base. The tax policy framework does not favour new taxes for specific programs. One other option is the social health insurance (SHI) which has been introduced and is currently under debate in parliament (expected to be passed into law in 2018), but we assess the revenue potential of this option to be low. If the bill passes as currently designed, all formal sector employees in both public and private sectors will be captured as contributors. SHI is expected to generate a new revenue stream for the health sector, including immunisation. However, no estimates on revenue (and costs) are available yet. As a result, its potential to generate fiscal space for immunisation remains limited.

Revenue potential from increasing allocative and operational efficiency of current spending on EPI is low

According to the government financial report, almost 80% of total public expenditure on immunisation is on human resources and vaccines and supplies. This implies that any efficiency gains would have limited potential to generate significant fiscal space. Health human resources are effectively a fixed cost, while vaccines are procured through UNICEF at internationally competitive unit prices. Therefore, the only options for improving efficiency may lie in reducing vaccine wastage, or other operational costs. The amount of savings from these options is modest at best, but most likely very low. There are efficiency gains from more integrated service-delivery options. Although there is a paucity of data on operational efficiency of the immunisation programme at district and facility levels, our assessment is based on the low level of resources currently allocated to recurrent operational costs. Hence our assessment of fiscal space from this option is low.

FISCAL SPACE PROJECTIONS

As mentioned earlier, to assess the financial sustainability of recent immunisation programme gains, we have considered the five pillars of fiscal space analysis—economic growth, increasing the share of health in total public spending, introducing new financing mechanisms, increasing donor funding, and increasing efficiency of spending. We note considerable limitations in virtually all fiscal space analysis pillars. In Table 9, we present projections of the fiscal space for health and immunisation for the period 2017–2022 based on an analysis of trends in the share of the economy that is dedicated to immunisation financing.

Table 11. Fiscal Space for Health and Immunisation Projections

	2016 [est]	2017 [est]	2018 [proj]	2019 [proj]	2020 [proj]	2021 [proj]	2022 [proj]
Real annual GDP growth (%)	3.4	4	3.5	4	5	5.5	5.5
GDP (in current US$ billion)	21.010	25.576	27.328	28.242	29.521	31.267	33.345
Population (million)	15.9	16.4	16.9	17.38	17.9	18.4	18.8

	2016 [est]	2017 [est]	2018 [proj]	2019 [proj]	2020 [proj]	2021 [proj]	2022 [proj]
GHE (US$ million)	487.6	593.5	634.2	655.4	685	725.6	773.8
GHE (US$) per capita	30.6	36.18	37.55	37.7	38.3	39.43	42.05
GIE (US$) per capita	2.75	3.26	3.38	3.39	3.45	3.55	3.78

Notes: Estimated GDP elasticity of GHE 1.046; GHE as a percentage of TGE 2000–2010 is 8.6%; GHE as a percentage of GDP 2000–2010 is 2.21%.

Despite falling short of meeting all financing requirements, and even with the constraints imposed by modest economic outlook and the politics of the budgetary process, Zambia's potential to increase the health share in total public spending would generate the greatest financing space for immunisation:

1. **Conducive macroeconomic and fiscal conditions:** Getting more real revenues from growth in the economy is limited because the economy is projected to grow at only a modest annual rate of 5% over the next few years. If we assume that the share of public funding that goes to health remains constant, and the GDP elasticity of GHE also remains constant at 1.05, we can project that growth in immunisation resources would only grow by 3% to 4% per annum, which is not sufficient to change the financing situation. Overall score: Low

2. **Reallocating existing public expenditure towards immunisation:** Zambia's GHE is low in comparison to similar countries; health share in total public expenditure is 8.6%. Hence, despite the constraint imposed on revenue potential by slow growth, increasing the share of total public spending that should go to health presents the best and most sustainable way among all the five options we have considered to increase fiscal space for immunisation. The only major threat is the country's public debt situation, which is likely to result in a reduction in social spending as more resources go towards debt servicing over the next five years. Overall score: Low/Moderate

3. **Introduction of new earmarked taxes towards immunisation:** Sin taxes are already considered very high in Zambia. Revenue potential from sin taxes is low. One other option is the SHI, which is currently under debate in parliament. Revenue potential of SHI net of administrative and other institutional costs is still low. Overall score: Low

4. **Increased donor funding for immunisation:** The donor landscape has changed adversely in the past few years. Donor funding is erratic and likely to be so for the future. The possibility of creating new donor money for immunisation is slim. What donor funding does, though, is provide resources more efficiently and in targeted areas in times of great need. Overall score: Low

5. **Efficiency gains:** The scope of new resources that could be realised from efficiency gains by re-allocation of existing resources and reducing wastage of major inputs (vaccines and human resources) remains low as well. The vaccine share in total costs is fairly small and even a major reduction in wastage would not lead to significantly high new funds into the immunisation programme. In theory, improving productivity of human resources would generate significant savings, but this is unlikely to be practicable because of weak governance over deployment and performance. Overall score: Low

INDICATORS FOR PROSPECTIVELY MONITORING IMMUNISATION FINANCING AND PROGRAMME SUSTAINABILITY

It is our belief that the foregoing analysis can be used in a prospective manner to contribute to securing sustainable financing by providing evidence-based data and synthesis of financing options to policy makers. It is well documented in this report and other past FCE reports that mobilising increased domestic financing for immunisation is hampered by a lack of usable data and synthesised policy options that can inform the country's domestic budgeting processes at various levels. We further argue that such data and evidence can be monitored over time to ensure progress is achieved. For Zambia, such data and process tracking can be useful for assessing how the country is readying up for eventual transition out of full Gavi support. That is, we can examine how the level and types of investments into the immunisation programme are improving capacity and readiness for the country to maintain high and equitable immunisation coverage.

Our foregoing analysis guided our development of a set of core indicators that can point decision-makers towards policies that promote sustainability of immunisation gains, as well as monitor the impact of such policies. We do not attach any normative values or thresholds to these indicators. Rather, we would propose that the country EPI programme would within their context define its own measure of sustainability and use these indicators to monitor progress over time.

Having said all the above, the institutional framework under which this prospective monitoring should be organised is key. What we learned from Zambia's experience with the aborted move into accelerated transition out of Gavi support tells us that countries are not empowered to initiate these important policy processes at country level. As such, working together with Gavi, countries can start early on and also lead this process and tap into other key stakeholders beyond EPI partners.

What would be key in prospectively assessing immunisation programme sustainability is regular tracking of immunisation financing and investments. We propose that a framework for prospective monitoring could include the indicators shown in Table 10.

Table 12. Proposed Indicators for Prospective Monitoring of Immunisation Financing and Programme Sustainability

INDICATOR	HOW WILL THE INDICATOR BE USED TO ASSESS SUSTAINABILITY
Change in EPI expenditure per infant	Extent to which total resource envelope has increased
Change in share of public health resources going to immunisation programme	Level of priority but also capacity to increase allocation
	Distribution of total resources for immunisation
Annual incremental cost for EPI	Assess annual budgetary gap (are allocations are matching with incremental costs?)
Cost per child fully immunised as percentage of total health expenditure per capita	Efficiency of delivery or production cost per unit of output
Change in expenditure per child immunised in urban areas as a ratio of expenditure in rural areas	Equity of resource allocation

INDICATOR	HOW WILL THE INDICATOR BE USED TO ASSESS SUSTAINABILITY
Change in GHE and percentage of TGE	Level of priority of health and immunisation
	Health spending is protected from economic shocks
Actual expenditure as a proportion of Budget	Budget execution bottlenecks and fiscal weakness

Recommendations

- 🔎 **Study further:** The programme should develop a framework for monitoring budgetary allocations and resource flows to the programme at the national and subnational levels on a regular basis. Such information would inform appropriate resource allocation, decision-making, and advocacy for needed investment into the programme.

Next steps for FCE2 year 2

» In year 2, national resource tracking surveys will be implemented to further understand expenditures and costs at the national level.

EQ 16: To what extent can recent programmatic gains of the EPI programme be sustained over time?

Zambia has received about US$86 million in various forms of support from Gavi between 2011 and 2017 to support both new vaccine introduction and existing vaccines. Government financing has also increased. However, although capacity to deliver immunisation has been strengthened through added availability of staff and improved supply of vaccines in most facilities, overall capacity is undermined by inadequate funding to support critical operational functions. Sustainability of achievements in coverage remains a concern. In this section, our analytical approach examines how both the economic and financing context for the immunisation programme and the quality of programmatic activities contribute to sustainable immunisation outputs. We identify a number of threats to sustainability of high coverage as well as their underlying causes, following our Theory of Change (TOC), as seen in Figure 20.

Figure 20. Theory of Change on Sustainability
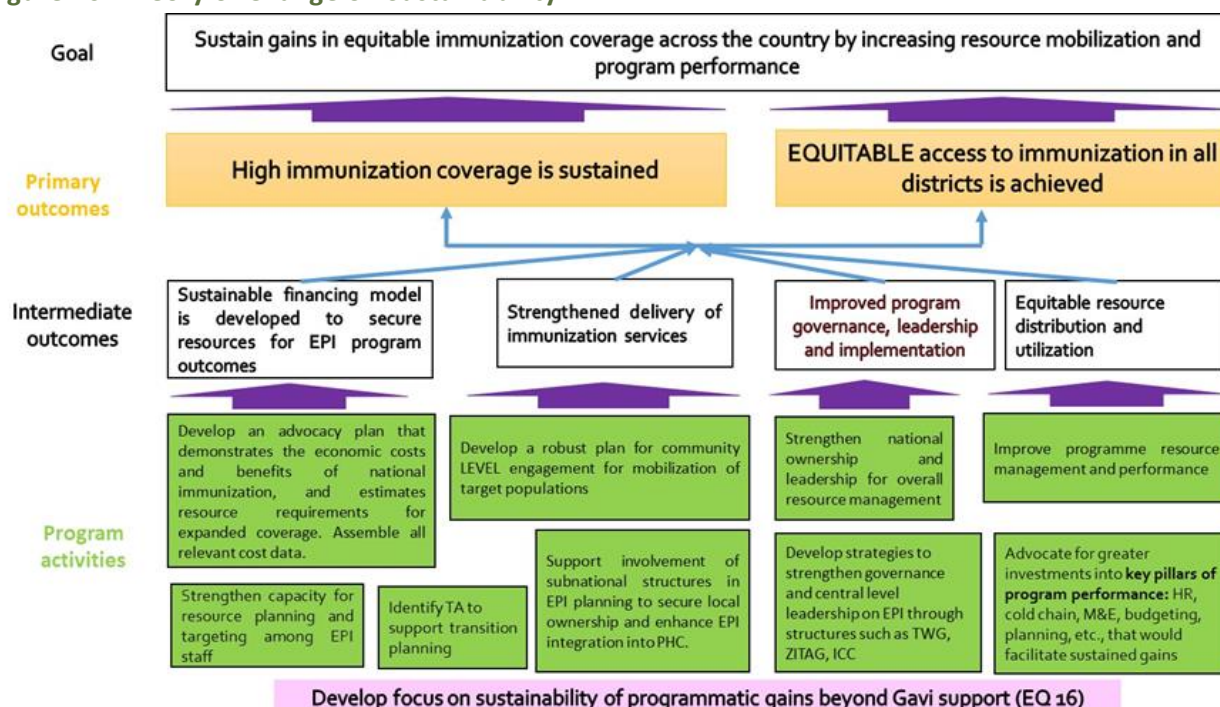
Abbreviations: EPI, Expanded Programme on Immunisation; HR, human resources; ICC, Inter-Agency Coordinating Committee; M&E, monitoring and evaluation; PHC, primary health care; TA, technical assistance; TWG, technical working group; ZITAG, Zambia Immunisation Technical Advisory Group

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Finding   *2.3*

Institutionalisation of new vaccines into the routine immunisation system has provided a platform for secured public resources and has increased prospects that recent gains in coverage can be sustained.

ROBUSTNESS RANKING   **B**

Findings are based on widely triangulated data gathered from key staff closely connected with the programme over many years. Findings are also backed by quantitative data on budgets and cost.

Getting all new vaccines to scale within the institutional system of primary health care has been a hallmark of Zambia's new vaccine introduction. Over the past five years, the EPI programme has gained new prominence within the health sector as a programme with relatively good success. The justification for sustaining the immunisation programme lies in demonstrating the health benefits of immunisation programs. The ability to sustain financing and general support to the programme from the government and partners and community lies largely in the ability of immunisation to demonstrate clear health benefits to a population that is well defined. Thus, there is no question that immunisation will continue to attract support and resources and continue to be a core part of the national health

plan. In this evaluation, we determine that in the context of recently introduced vaccines and other initiatives in the immunisation programme, the health benefits of all are highly valued and therefore likely to received sustained support.

> *"For us, immunisation is a high-profile health programme and a household name. Our strategy has been to take every intervention to scale from the start, rather than start piloting or phased approach—partly because we know that vaccines work. But, also because we know that we cannot wait until we have evidence that the government will have found the capacity take over the financing before we can launch a new health programme. So, sometimes you start something, demonstrate how good it is, then lobby for government financing, and government support will definitely come through to support its continued provision should the original donors move on. Sometimes things can happen like that and I think there are examples of this from other health programmes." —Key informant interview*

> *"Even at community level, immunisation is a popular programme in which local structures want to participate. Community interest is important to ensure that community are interested in immunisation, they bring resources to support implementation of immunisation activities." —Key informant interview*

To ensure that all costs associated with new vaccines are taken up by the government as soon as possible, the idea of rolling new vaccines into the routine was utilised. To some extent, this has happened as funding for old and new vaccines has been secured through incorporating budget lines into the government budget. Further, the staff that deliver these vaccines are employed by the government. Thus, integration of immunisation into routine care and delivery within the primary health care (PHC) framework was seen as a vehicle for ensuring sustainability. The involvement of all MOH structures from the top of the Ministry of Health to the provinces, districts, facilities, and communities form the basis for implementing sustained immunisation programs. Overall, the progress achieved in scaling up routine immunisation and reaching high coverage of all key antigens, and the demonstrable reduction in vaccine-preventable diseases in Zambia in recent years, underscores progress towards programme sustainability.

The case for increasing funding is made by recent programmatic successes. Immunisation saves in the most cost-effective way of all health programs. The country has significant experience and expertise in running an effective national immunisation programme. The support from Gavi has catalysed new innovations in programmatic performance (e.g., HSS, CCEOP) which have resulted in improved service delivery and performance. However, to sustain these gains, the government needs to invest more resources into the programme. Reaching every child and every district in the country requires resources. There are no feasible substitutes to the long-established tradition in the immunisation programme of investing in reaching target populations at community level. For most consumers, immunisation is not naturally attractive compared with curative services. Similarly, immunisation cannot be delivered like education. Hence, unless services are delivered closest to them, most children will go un- or under-immunised. Therefore, securing stable and adequate financing for the operational costs of the immunisation programme especially at the district and facility levels is key to safeguarding these gains. Below we highlight some of the critical issues to support our case.

Finding 2.4

The greatest threat to sustained high immunisation coverage is that core programme activities at national and subnational levels are significantly scaled down to match severely inadequate and unstable operational funding.

ROBUSTNESS RANKING A

Findings are based on widely triangulated data gathered from key staff closely connected with the programme over many years. Findings are also backed by quantitative data on budgets and cost.

While routinisation of vaccines is a necessary and critical step towards sustainability, it is not sufficient. In Zambia, the concern for sustainability is that immunisation coverage (which has increased to over 80%) may decline if adequate resources are not secured to fund ongoing operations associated with vaccine introduction. The TOC identified a number of critical inputs for programme performance including human resources (HR), cold chain, monitoring and evaluation (M&E), budgeting, planning, etc. Since 2012, the Zambian government has invested significantly in recruitment of health workers and construction of health facilities. While these two inputs had been seen as major constraints to improved and sustained health delivery including immunisation, the increased share of public health resources going to HR and capital projects needs to be balanced with adequate operational budget allocations to ensure that immunisation service delivery capacity can meet service expansion and sustained coverage. Key areas of operations including cold chain maintenance, cold chain fuel, outreach logistics, staff training, supervision, etc., are all underfunded. Currently, recurrent allocations are lagging behind the demands generated from these new investments, as illustrated below. Increasingly, districts and the national EPI programme are under pressure to cut back on key programme activities and functions to match available operational resources. The shortage of programme operating funds is a widely shared concern among stakeholders:

> *"In 2017, we received about 10% of the operational budget. Activities like supervision, training, mentorship, outreach, printing child health cards, and data forms are not done especially at province and district levels because of lack of funds." —Key informant interview*

> *"The World Bank presentation I attended showed that 70% of the budget for the health sector is in salaries, which could create a problem. The district level budget is very minimal; this is evident in the coverage rates." —Key informant interview*

Further, disbursement of government funds from the Ministry of Finance has continued to be a challenge, undermining important functions of the programme. Usually disbursements are made late, which leads to low budget execution and cancellation on important programmatic functions. Stakeholders cited this concern, saying;

"Even when we plan, districts do not receive the money they need because the final approved budget has no semblance to what districts planned on. Disbursement is another problem which make planning hard." —Key informant interview

For example, the Joint Appraisal (JA) noted that at "the district and provincial level 10 out of the 12 expected grants from the Ministry of Finance have been disbursed while at the central level only 2 out of the expected 12 grants have been disbursed. By the time of the JA the EPI programme was operating on only a 10% disbursement vs. commitment. This impacts the ability of the programme to operate at a fully optimal level and key activities aimed at strengthening the programme like supportive supervision and outreach services are compromised because of the lack of realised funds" (JA 2016 report). As we show in the data compiled in Figure 21, most districts received less than 50% of their total recurrent budgetary allocations.

Figure 21. Proportion of Actual vs. Budgeted Recurrent (Non-salary, Non-capital) Expenditure
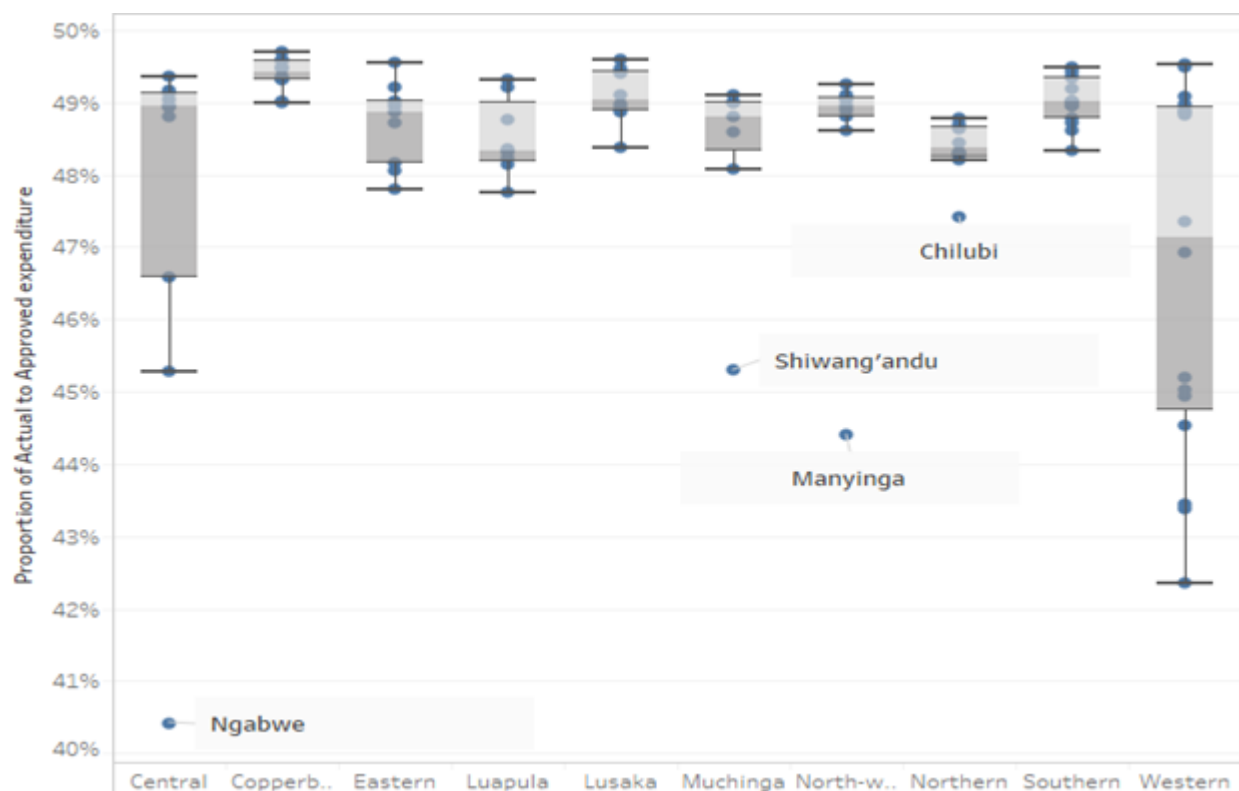
Our TOC informs us that to sustain recent high coverage, the programme needs to secure sustainable financing to sustain core functions of the programme. As government struggles to maintain an adequate level of recurrent funding to the immunisation programme, effectiveness and sustainability of critical functions of the programme are threatened. Eventually, compromised programme input will undermine the availability and accessibility of immunisation services, which would lead to a decline in coverage. This is because the level of funding to districts and facilities is far below the estimated cost of delivering immunisation services (Brenzel et al., 2015).

To illustrate the problem of inadequate funding we take an example, Mafinga District, which received an operational grant (i.e., for non-capital, non-labour expenses) of $82,620 in 2016 for all primary health care programs including routine immunisation and outreach. If we assume that expenditure is apportioned equally across all programs, this translates to a per capita spending of US$0.91. Now, the

EPIC study showed that the operational cost per child is about US$33.00 in 2011 US$. This implies that the cost of maintaining 90% full immunisation coverage in Zambia would be US$1.27 (33.00x90%x41/1000). Hence, if Zambia intends to sustain 90% coverage without further external assistance, the government should increase current recurrent spending by at least 34% (obviously much more if we assume that only 10% of the total recurrent budget is committed to immunisation activities). It remains unclear if districts and facilities would allocate more funds against a decreasing national budget to sustain effective immunisation service delivery. Planned work in this phase on expenditure tracking and resource allocation at the subnational level will be used to address this important question.

We cite a few cases which can undermine coverage due to low levels of operational funding at the subnational level. First, service delivery mechanisms—particularly outreach—are not consistently implemented. The EPIC study showed that routine immunisation including outreach accounts for over 30% of total national level immunisation costs, emphasising the challenges of sustaining coverage with inadequate recurrent funding (Brenzel et al., 2015).

In addition, funding to printing child health cards has remained low for a number of years. For example, the budgetary allocation for printing of cards has remained at K1 million from 2010 when the price per card was K0.50, up to 2017 when the price per card is K9.00. This means that an increasing number of children, especially in rural areas, do not carry a card. Their vaccination details (including dates for next vaccinations) are often written on a piece of paper which is kept at the health facility. The likelihood of such children missing a vaccination is high. In FCE Phase 1, we documented a high proportion of children not having health cards and facilities not having tally sheets (Gavi FCE Team, 2016). This factor could partly contribute to lower immunisation coverage in rural areas.

Furthermore, delays in disbursement of operational grants to districts and health facilities adversely affect execution of micro-plans. Information gathered through key informants suggest that core activities on micro-plans are not implemented as planned:

> *"Micro-plans have become somewhat a hollow shell of activities perpetuated for their own sake, whether or not the activities are implemented or benefits for clients are achieved."* —Key informant interview

> *"You find that what is planned is not done by the end of the year. Then you begin another planning cycle which takes you back to the same situation the following year. So you can't review what went wrong and what works best, because the activities planned were not carried out."* —Key informant interview

The persistent lack of finances to implement micro-plans has resulted in demotivation of EPI staff which has undermined the quality of planning at district and facility levels. Many plans are weak and do not contain strategies that are clear and effective to deliver sustained results.

One of the successes of operational spending has been communities in Zambia responding enthusiastically to recent activity in launching new vaccines in the last several years, leading to increased coverage. A major factor associated with this response is community mobilisation. Hence, under-investment into community empowerment and routine social mobilisation will erode recent successes in reaching hard-to-reach target populations. This has particularly adverse consequences for coverage and equity of rural facilities which depend more on outreach to reach children, as these

facilities receive less and less funding for operations. As is well known, immunisation coverage is sensitive to outreach, especially in rural areas.

> *"Outreach in rural areas is worst affected by lack of funding or erratic disbursement of funds. In rural areas which rely heavily on outreach, this does have serious consequences for coverage"* —Key informant interview

> *"We have a challenge sustaining community behaviour change in the HSS. Sustaining the momentum we are creating is questionable. We will see the coverage levels going down and equity too. We say the hard to reach will suffer more. [...] We are doing mobilisation and creating demand but government could have a challenge with the time, the budget and money taken to have these activities done."* —Key informant interview

Beyond outreach, community engagement is also crucial in mobilising communities to engage with immunisation delivery. Although most community support groups provide labour on a voluntary basis, usually facilities are expected to give volunteers some small allowances for transport and/or lunch. It is these small things that can make a difference between strong and weak community partnerships and ultimately strong or weak immunisation programs. Currently, social mobilisation has only been done with Gavi Vaccine Introduction Grants and not budgeted for afterwards; ideally, social mobilisation should be an ongoing activity in the micro-plan.

Another major consequence of inadequate recurrent finances is the reduction in the frequency and quality of supportive supervision (ideally supervision should be oriented to problem-solving rather than routinely checking items off a list, and supervision should achieve effective programme implementation). In addition, after initial training which was conducted around recent new vaccine introductions, there has been no new funding for training of new health workers and community health workers.

Some of these gaps in operational funding have been filled with current support from civil society organisations such as the Church Health Association of Zambia (CHAZ), which are working with facilities to reach target populations. However, these supplementary funds, while filling operational needs, are being implemented in a manner that does not guarantee sustainability beyond Gavi support as there is no plan to ensure that the costs are integrated into the MOH budget. It can be expected that once the Gavi HSS grant ends, those activities will most likely not be sustained. Acknowledging the full scope of recurrent costs associated with new vaccine introductions and making plans to integrate those costs into the MOH system appears to be a high-priority task for the EPI. It is clear from the HPV case as well as with new vaccines that have been launched that the country is now left with an urgent need to secure new financing arrangements for new costs arising from these new vaccines. In the short term, the immunisation programme is still expected to depend heavily on donor funding to cover certain recurrent costs, such as the supply of essential drugs, and operations even as the government has directed more of its investments into human resource recruitment and infrastructure development as was shown in the previous section.

> *"Although policy pronouncements include other priority sectors such as health and education, key interventions in these sectors only relate to recruitment of frontline staff. And actual budgetary spending has also been overshadowed by policy shifts."* —Key informant interview

The lesson of the past few years might be that the willingness and ability of the government to take over recurrent costs associated with new programs does not happen automatically, but requires planning and lobbying. Investing recurrent funding into strengthening immunisation service capacity will be key to sustaining coverage gains in the short to medium term. These areas include human resource training, costing and budgeting, logistics systems, supervision, etc. It will be key for the MOH planning process to address the problem of recurrent costs in the budget negotiations. As much as the shortage of resources is a real problem, a clear examination of what are true delivery costs and how to integrate those into the MOH budget requires much policy attention. Finding 3 of EQ 16 and EQ 18 will further explore some of the challenges in the EPI budgeting process and how they can be remedied to foster integration of recurrent costs into MOH budgeting.

Finding   *2.5*

A separation between planning and budgeting for new vaccine introduction and capital costs, and budgeting for ongoing recurrent costs, leads to an imbalance between operational budgets and operational plans and underfunding of major recurrent activities.

ROBUSTNESS RANKING   **B**

Findings are based on widely triangulated data gathered from key staff closely connected with the programme over many years. Findings are also backed by quantitative data on budgets and cost.

Within the established planning processes, there seems to be a dichotomy when it comes to planning for vaccines and capital costs on one hand and planning for recurrent budgets for ongoing immunisation programme activities on the other. EPI sits in the Child Health Unit, which is under the Directorate of Public Health. Under this directorate, the budget process at the national level develops a budget for vaccines and capital budgets such as new cold chain and buildings. In addition, two recurrent items, namely costs for printing of cards and national-level programme administration, are added. However, the Directorate of Policy and Planning is ultimately responsible for budgeting for ongoing services funded through the recurrent budget, subject to budget ceilings and guidelines from the Ministry of Finance.

The budgeting process does not address the fact that most new capital investments initiated with Gavi funding will require recurrent funding to effectively provide ongoing services. Individual programs like EPI or Reproductive Health or Malaria, etc., develop their programme budgets often using sophisticated costing tools. Despite that, experience has shown that the Directorate of Policy and Planning, which is responsible for consolidating the overall budget of the Ministry of Health, uses incremental costing to increase allocations to immunisation by a small percentage each year. As a result, programs such as immunisation depend on government calculations of incremental financing increases for recurrent costs, in spite of their more sophisticated cost needs. We were informed that operational expenditures to districts were based on a needs-based formula which was developed around 2003 and is now outdated and redundant. This lack of attention to recurrent costs of the EPI programme is described as being a result of a lack of understanding of the need for recurrent operational costs:

"Sometimes our colleagues in the Ministry of Finance seem to think that funding for operations such as supervision, training, social mobilisation, M&E which are key functions of the programme are not very important for the survival of the immunisation programme. They see immunisation budgeting as only about vaccines and cold chain. The amount of money we get for operations even at the national level is too little. Districts don't generate any money they can use for immunisation activities." —Key informant interview

As a consequence of a critical shortage of operational funds, the immunisation programme has tended to repeatedly fall back on partners to meet some of the budget proposals to cover recurrent costs which are not taken up by the government. This structural separation of capital and recurrent budgeting leads to a failure of coordination and integration as each programme budgets and plans to do their own activities, resulting in immunisation services deprived of running costs and other essential resources.

"On paper, the budget process is one. But we know that the EPI as is the case with other donor supported programmes also have another budget which in practice is considered a separate budget process. Some of the key support for key activities which are not funded in the main budget come from donors. Some of the donors even support districts directly." —Key informant interview

Further, planning for mobilising additional financing for activities to sustain or even increase immunisation coverage is currently not well served by absence of accurate cost data to inform the planning and budgeting process. As a result, there is no clear coordination of partners to fill operational gaps, which jeopardises the sustainability of the programme:

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

This is partly a limitation of the planning and budgeting tools available. As mentioned earlier, the main planning tool that is used to generate resource needs, costs, and funding commitments for the immunisation programme is the cMYP. While the cMYP is used to project programme costs of increasing coverage to programme targets in all districts, its use is very limited for estimating the financial requirements for reaching the national immunisation coverage goals. This is mainly because not many people understand the calculation basis on which total costs are based. Furthermore, the costs estimated based on the cMYP need to be validated as they are considered to be implausibly high by some EPI partners. EQ 18 further explores the challenges of using the cMYP for budgeting.

"We don't know how the cMYP tool calculates total costs. Once we input the primary data, total costs are calculated by the tool. There are problems with the calculated costs in the

Zambian cMYP because our resource gap is too high. Each time you show the resource gap to planners in the Ministry of Health, everyone looks away." —Key informant interview

"Because no one believes the numbers from the cMYP we get the same allocation, year in year out." —Key informant interview

As a result of these disparate budgeting processes, the programme does not quite have a clear understanding of the costs of delivery to maintain immunisation coverage. This report highlights the urgent need for improved cost data to inform planning, budgeting, and resource mobilisation. What we found is that the absence of well-characterised costs for increasing delivery of immunisation services is partly responsible for the problem of perennial under-budgeting. The Ministry of Finance (MoF) has asked for a justification of the basis of costs and the economic basis (cost-benefit analysis) for the budget proposals in the immunisation programme. Impressions from the MOH suggest there is a lack of justification for some of the operational cost items requested by EPI. MoF staff also argue that proposals from MOH lack a convincing demonstration that resources are being allocated in the most efficient manner.

"When we look at proposals from health we need to understand the justification and also how they arrive at their budgets. It is not very clear. When you ask for a modest increment it is fine and we refer them to ministry to vary within their budgets, but when they ask for much more it is a bit more complicated and demanding." —Key informant interview

The lack of data to support EPI spending proposals is also acknowledged within EPI.

"We are building up a case to the politicians that we are saving lives. We will be able to see more and more prioritisation of EPI. The ministry and partners also helped in the push. The challenge has been lacking empirical evidence to support the argument. If we could have a way of putting evidence together stating that we have these challenges in EPI." —Key informant interview

The net result is that planning for new investments into the immunisation programme is viewed overwhelmingly as being about the introducing new vaccines or capital schemes, e.g., cold chain investment or purchasing vaccines, and less about the recurrent costs that are needed to deliver services and manage the programme. This impasse is used as a reason for underfunding, which leaves districts and facilities bereft of funds to carry out important activities to improve immunisation coverage. These critical resource shortages lead to low-quality services which can, in turn, lead to low rates of immunisation service utilisation in some parts of the country.

Finding   2.6

Delays to develop a clear medium- to long-term plan for how the government will take over the recurrent costs associated with activities that are intended to maintain immunisation coverage following Gavi support compromise programme capacity to sustain coverage.

ROBUSTNESS RANKING	B

Findings are based on widely triangulated data gathered from key staff closely connected with the programme over many years. Findings are also backed by quantitative data on budgets and cost.

Apart from the fact that there is an absolute shortage of resources, weaknesses in the planning and budgeting process are likely to make the resource problem even more challenging. For example, the indicative budget figures given for the operational budget of the EPI programme are not realistic and are disconnected from strategies for achieving sustainable programme performance.

Further, efforts for resource mobilisation appear short term and ad hoc and unable to assure a more sustained financing mobilisation even in the advent of several new vaccines having been introduced, which has created pressure for more resources. On the evidence of the level of resources that is committed to meet EPI operational cost, we argue that government is struggling to provide the appropriate level of domestic resources to ensure sustainable financing for immunisation.

> *"It is clear that so far even with Gavi support in procuring vaccines the response from the government to provide operational grants has been poor."* —Key informant interview

We also note that it is unclear how the processes that are associated with Gavi applications and grant management are affecting regular planning in the Ministry of Health. For example, the connection between cMYP and the NHSP has been a subject of debate. Are Gavi funding windows creating a situation where intermittent grant applications do not mesh well with routine medium-term immunisation services planning? Gavi grants provide opportunities for new life-saving vaccines and resources to introduce those vaccines, but we also observe that such opportunities are increasingly driving programme goals and implementation rather than the strategic direction articulated in the strategic plan. As an example, the cMYP, which should be a guiding document for planning, resource mobilisation, and rationalisation, is not harmonised with strategic planning process. As we discuss further in EQ 18, this situation makes the task of mobilising resources to support immunisation programs or activities more challenging.

As a result, the government has come to depend too heavily on Gavi and other donors for recurrent financing of major immunisation programme activities, with insufficient mobilisation of domestic resources. This situation creates a misalignment between Gavi support and the country's Medium-Term Expenditure Framework (MTEF) as well as the NHSP. As such, the programme tends to receive mostly on financing for segments of the programme rather than having a coordinated and consistent funding arrangement for all immunisation core activities and functions. Furthermore, it appears that short-term donations come at a cost of replacing or hampering careful planning for increasing domestic mobilisation to meet future costs that are being injected into the immunisation system.

> *"I think that one of the things that the government should have done is from the onset to look internally and build in the budgeting framework all new costs associated with all these new vaccines being added to routine immunisation in order to secure domestic resources at least in the medium-term. This can be done on a year by year basis or by each new vaccine introduced."* —Key informant interview

Although on paper the budget process is unified, in practice there is a separation between the main budget process which includes mainly HR, capital, vaccines, and cold chain, and a relatively small allocation to cover administration and service delivery costs. In the data presented in this report, the allocation for service delivery costs is usually based on a marginal increment only for inflation. Then we have a budget process that focuses on raising money and expenditure for new activities which falls under the programme. As this problem of lack of coordination in budget planning and execution has persisted over the past few years, it has the potential to create a significant resource gap for the programme as less new spending is adopted into the main budget process.

There is also a realisation that NVS and other programmatic initiatives in recent years have led to a precipitous increase in recurrent costs that outstrips growth in revenue, posing a threat to sustainability. Thus the challenge of finding new domestic resources from the public budget can be exemplified in the following quote:

> "In the past 3-5 years the EPI programme ran so fast and we realised that we moved faster than the rest of the health system, making sustainability a challenge. On paper the budget is the same. But from time to time the programme has to go begging for resources to implement activities from partners." —Key informant interview

As a result of these gaps and perceived risks to sustainability, the programme is engaging other partners to ensure that some of the innovations and activities which have been implemented in recent years can be brought to scale. Securing funding and other forms of support are considered crucially important for consolidation of programme gains and sustained immunisation coverage. As a result, the programme has developed a EPI optimisation initiative to secure funds for operational efforts:

> "CMYP also does not cover all areas of the programme. Hence the genesis of EPI Optimisation. It is meant to assist with solidifying work that has already been done around Logistimo, BID, mVacc and Data management. These have been done up to various stages but now require completion and functionality so that we build up a case to show they work so that further funding can be secured for them in future. The EPI optimisation plan was for $16m initially, but this was reduced to $5.5m after removal of CCEOP component. $1.4m from HSS will also help with this. B&M Gates have been engaged on this." —Key informant interview

Great effort has gone into developing the EPI optimisation initiative document for Zambia in 2017–2018. The initiative addresses major strategic areas that are intended to improve the performance of the programme and achieve high and equitable immunisation coverage. It is hoped that funding will be mobilised to implement the plans contained in this document.

Recommendations

◎ **Urgent Attention:**

> The EPI programme should facilitate the development of accurate and reliable estimates of the operational costs of immunisation service delivery.

> The MoH/government needs to build capacity in costing, economic assessment, and financial planning to mitigate some of the factors that lead to unpredictable public funding.

> The government should invest in developing a financial sustainability plan and/or transition plan as soon as possible without waiting for Gavi support to start declining.

Next steps for FCE2 year 2

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

Alliance Systems and Processes

Gavi has many processes that are outside the normal routine processes of the EPI in its day-to-day work. Some guidelines, processes, and tools are direct requirements of Gavi for countries to fulfil—both for application and reporting purposes. Such processes often have unintended consequences, both positive and negative, that impact the EPI in various ways. In this section, we take an example of one such process, the cMYP, and discuss how it has affected the EPI.

> **EQ 18: What positive and negative unintended consequences occur as a result of Gavi support, with a focus on cMYP?**

The national comprehensive Multi-Year Strategic Plan (cMYP) for immunisation is meant to assist a country to assess current and future programme cost, by utilising its costing and financing tools. It was developed in 2005 by Gavi, in conjunction with WHO and UNICEF, to provide support for countries to improve their immunisation planning. Among the aims of the cMYP was to harmonise the many immunisation planning activities that were happening in most countries at the national level, to reduce duplication of effort and high transaction costs, and to help align national systems (WHO, 2014). A Microsoft Excel–based tool, the cMYP Costing and Financing Tool, was developed to aid with the costing relying on "credible information about how much was currently being spent, what it was spent on, from what source the funding came, and how much future funding would be needed to reach programme objectives" (WHO, 2015).

Finding 3.1

The cMYP is not being adequately utilised as a tool for bringing about harmonisation, reducing duplication, and aligning national systems.

ROBUSTNESS RANKING **B**

The finding is based on evidence from key informant interviews and some document review, but it needs further interviews from key partners. Comparison of other countries' cMYPs would be useful.

Over the years, the cMYP seems to have lost some of its initial purpose and is increasingly perceived simply as a Gavi requirement that is not very useful to the country, for several reasons. Firstly, it is not clear to some of the EPI stakeholders how the cMYP links to other planning processes and the national-level budget for EPI. The budgeting process during the cMYP process bears no relationship to the main planning and budgeting cycle of the Ministry of Health. Partly as a result of this, the cMYP figures do not bear any relationship to the parameters given in the MTEF. Granted that the purposes are slightly different, but there needs to be harmonisation of these processes in order to maximise resource mobilisation. Accordingly, the cMYP-calculated programme costs seem to be too large and beyond what both government and EPI partners can manage. As a result, it is not utilised much as it is

perceived to be unrealistic; there are huge perceived gaps in funding when actual funding is compared to cMYP projections. This is said to be the case when compared to other countries in the region that utilise the same tool but have much lower budgets and gaps. Comparison of the gap for other programs such as HIV and family planning also shows this discrepancy. For instance, last year's family planning funding gap was about two million kwacha and that of HIV was about 10 million kwacha, but the EPI gap was 99 million kwacha.

> *"cMYP is the principal document detailing funding needs and gaps. Over the years it has become an academic exercise. cMYP is used during the planning cycle to show need versus what was received. The gap is usually too large, so a funding ceiling is proposed instead and cMYP is shelved due to the huge gaps it shows."* —Key informant interview

EPI has engaged WHO, which is primarily responsible for hiring consultants for the cMYP process as well as for development of the costing tool, to assess whether the formulas and assumptions built into the tool are accurate. This has not taken place yet and thus the cMYP budget continues to be huge.

> *"We have engaged WHO over the formulas in the CMYP and whether they are accurate or not for Zambia but nothing has changed. Most partners say CMYP has unrealistic figures even for partner funding requirements and they resort to their proposed budgets instead."* —Key informant interview

The cMYP is thus not being as well utilised as it could have been nor meeting its intended purpose. Harmonisation has not occurred, and the cMYP has led to duplication, rather than reducing it, as is evidenced by the lack of alignment with other documents such as the Yellow Book that details the national budget. It is also unclear to many how the cMYP relates to other documents such as the NHSP. As a result, there is a perception that it is a cumbersome and time-consuming exercise that takes away valuable time from other activities and is not harmonised with strategic planning process. Although not intended as such, the cMYP is largely considered a Gavi requirement and not a country-owned document for programme planning and resource mobilisation. It is done because it is on a checklist of things required to apply for Gavi funding. Stakeholders describe it in this way:

> *"I personally think the CMYP is a waste of time, there is a lot that goes into that document, we don't even use it. What is difficult is what is happening on the ground with resource mobilisation. We can do it differently in the ICC. We should try to go to the partners directly. The CMYP is another tick box to check. We don't refer to it. It is a cumbersome process to have that document developed. Coordination is hard but it should be happening because a little team of people cannot check all these. Sometimes donors would be working on the EPI programme in the districts and the central level doesn't even know it."* —Key informant interview

This minimises the usefulness of the cMYP as a tool to mobilise funds from partners, resulting in a lack of coordination in budgeting, and contributing to the challenge of incorporating emerging additional recurrent costs associated with recently introduced vaccines and other programmatic initiatives into the Ministry of Health budget (as detailed in EQ 16). An illustration of the challenges that arise when mobilising resources from partners is that each time the EPI programme seeks support from partners, the partners often refer to Yellow Book allocations instead of the cMYP.

Another recent development that could be a sign of such duplication and lack of usefulness of the cMYP is the EPI Optimisation plan. This was arrived at with a view to taking components of the cMYP that are "doable" and making a case for financing them, outside of the cMYP. It is meant to assist with solidifying work that has already been done around Logistimo, BID (ZEIR), mVacc, and data management. These have been done up to various stages but now require completion and proof of functionality so that a case can be made to show that they work in order to secure further funding for them in future. This could point to a perception that the cMYP is not a useable nor realistic document and thus other means of engaging partners and potential funders have to be found.

> *"We don't consider the CMYP, it has nothing, it doesn't have clear direction, we seemed to be in a hurry to develop it. Just a few weeks ago, we are considering the EPI optimisation plan. I suggested that we use and solidify the CMYP rather than having two documents that are similar."* —Key informant interview

Recommendations

◎ **Urgent Attention:** There is need for WHO, in collaboration with EPI, to review the cMYP costing assumptions to ensure that they are realistic and free from errors.

⌕ **Study further:** The cMYP needs to be better aligned to and utilised with other country processes and documents, such as the budgeting process and Yellow Book, to be more useful to the EPI.

Conclusion

Zambia has continued to record an increase in coverage rates of fully immunised children aged under 1 year from 2013 to 2017. Despite this overall progress, inequalities in coverage remain considerable with many districts, especially rural areas lagging behind. Our report also notes that inadequate investments in improving immunization data quality continue to hamper better monitoring of coverage. Despite progress, concerns about sustainability have been raised. A major component of the cost of immunization are driven by support from Gavi and EPI partners. As new vaccines are now fully integrated into the routine, the costs of vaccines and delivery will need to be met by increasingly regular, sustainable financing. Our analysis of the macroeconomic context shows that growth in domestic immunization spending has not kept pace with rising programme costs. We suggest that the EPI programme should invest in planning for increased domestic resource mobilization in order to overcome the current and future funding challenges. Finally, improving programme sustainability also requires further investments into scaling up some of the initiatives that have been introduced the past 5-6 years to improve Programme performance which include logistics management, data quality, vaccine management, and programme management.

NEXT STEPS FOR FCE2 YEAR 2 REPORT

In this report, the FCE2 team has outline several next steps that will be further investigated in year 2. The FCE2 team will continue to explore Gavi's approach to financial and programmatic sustainability and will also continue to monitor and analyze the implementation and effectiveness of Gavi coverage and equity strategies and the impact of SCMs and Gavi's strategic focus areas on improving coverage and equity. In year 2, the FCE2 Consortium will undertake the following activities:

> In Year 2, subnational district case studies will be conducted to further investigate district-level coverage trends, challenges and barriers, such as financial management, LMC, and data quality.
> In year 2, national resource tracking surveys will be implemented to further understand expenditures and costs at the national level.
> The Zambia FCE2 team will implement a subnational expenditure tracking survey, and if possible will partner with the MOH on the HSS baseline survey to measure how costs vary by subgroups and how this aligns with district level expenditures and coverage. Further investigation will be done on the root causes of sub-optimal disbursement of immunization operational funding from national to sub-national levels.

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 13 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 13. 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

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 22) based on FCE evidence regarding the most important drivers of sustainable coverage and equity. The FCE2 TOC builds off the FCE1 TOC by examining subnational-, national-, and global-level drivers of immunization coverage and equity. The expanded FCE2 TOC (Figure 23) 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 22. FCE1 Theory of Change

FCE Theory of Change:
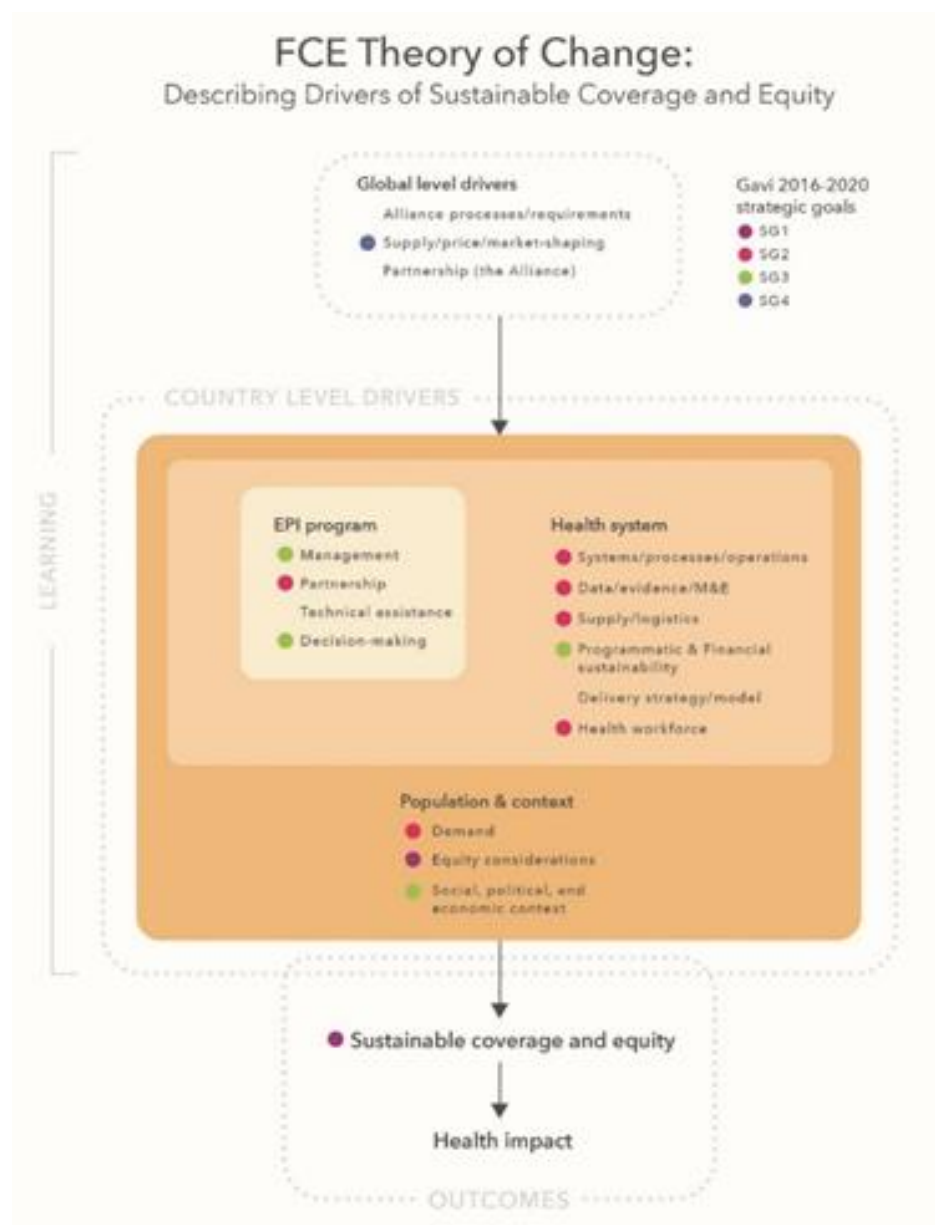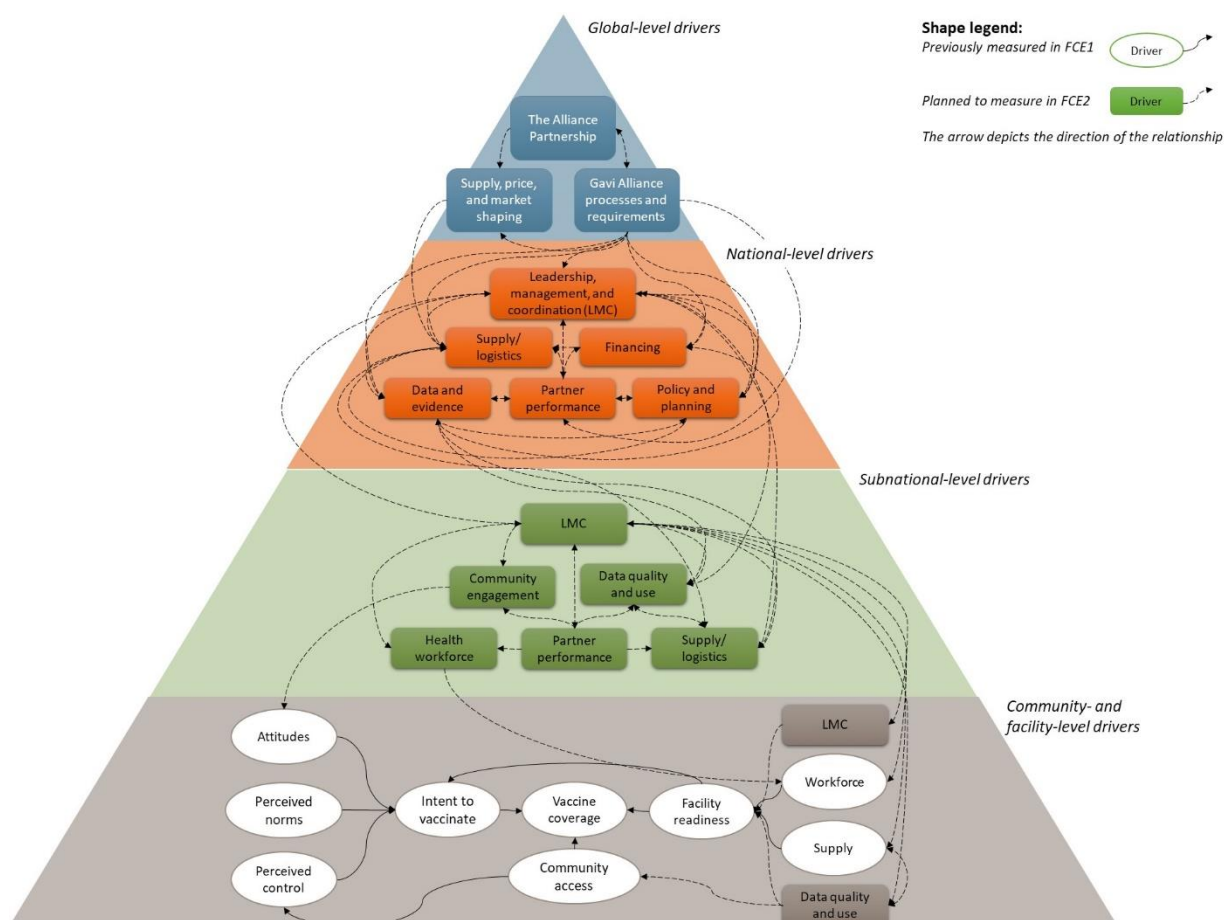Describing Drivers of Sustainable Coverage and Equity

Figure 23. 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

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.[1]

> **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.[2,3,4] 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.[5]

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.[6,Error! Bookmark not defined.] These existing analyses focus on national-level indicators of coverage and equity. FCE1 was also largely focused on national-level data collection. To complement and avoid duplicating this important work, we use the TOC as a guiding framework for analysis of the drivers of coverage and equity at national and subnational levels. Understanding the role of the drivers and relationships between drivers was achieved through monitoring TOC drivers and conducting district-level cast studies.

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

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

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

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

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

For this report, Uganda implemented the district case study approach to answer EQs 1 through 3, as well as EQ6 (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 subregions, and the presence of immunization inequities according to the Uganda Immunization Equity Assessment[7] 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 24).

Figure 24. DHIS2 DPT3 coverage rates in 2017.
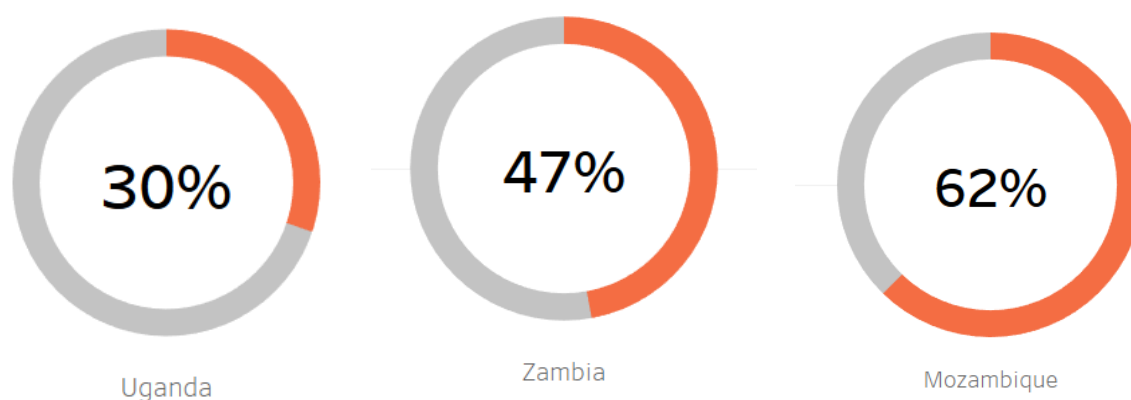
In addition to the issue of the population denominator, there are concerns that data quality may be affected by the completion and accuracy of forms at the district level.[8] In spite of the poor validity of coverage calculations of DHIS data, we expect that trends observed in the DHIS data are reliable, 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.[9] 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.[8] 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 14 summarizes the strengths and weaknesses of both data sources.

Table 14. 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 estimates are more accurate due to use of standardized household surveys > Using survey data, we are able to estimate historical coverage rates from 1999	> Coverage accuracy is dependent on the availability and quality of survey inputs, particularly at the subnational level > There is lack of country ownership in creating and understanding SAE estimates

	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 25. Coverage estimate comparisons, SAE and DHIS.
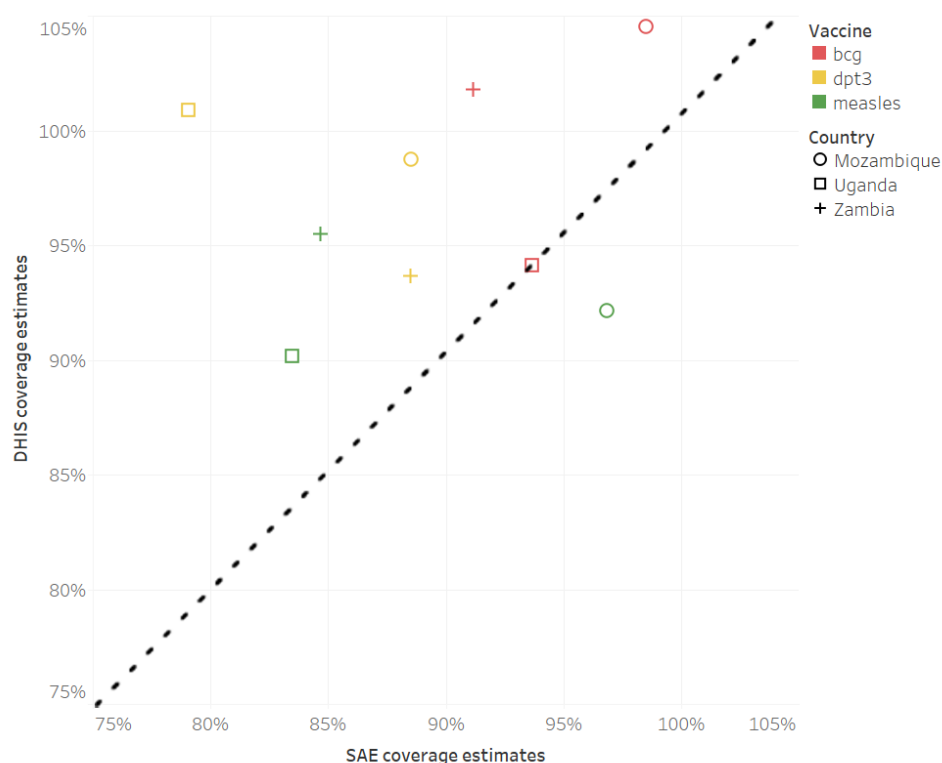
When comparing the data from the SAE estimates and DHIS, they show similar patterns over time, though the relative volatility of the DHIS data makes the comparison imprecise. Absolute estimates of coverage do not align precisely between DHIS data and SAE; DHS estimates are about 10 percentage points higher across all FCE countries. Figure 25 shows the comparison between annual SAE estimates and DHIS estimates for 2016 (the most recent year where both data sources are available); DHIS is higher, due to the challenges of data validity, with the exception of measles coverage estimates in Mozambique.

In this report we primarily use SAE data to present the historical trends in vaccine coverage. To present current coverage and emerging trends, we primarily utilize DHIS data. This is in part due to

lessons learned from the FCE phase 1, where there was limited uptake of SAE results among country stakeholders who did not feel ownership of the modeled data. Given the importance of HMIS data as a country-owned resource to manage immunization performance, and to further encourage the use of these data, we use HMIS data to present the current portrait of coverage in countries.[8]

Robustness ranking

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

> Triangulation refers to the breadth of qualitative and quantitative data sources (e.g., surveys, documents, key informants, etc.) that inform the same finding, where greater triangulation equates to more robust findings.

> Where the finding lies on the continuum between fact and perception, this dimension complements triangulation in that factual information generally requires less triangulation in order to be considered robust. However, it is important to note that some of the EQs are largely perception-based (e.g., the added value of partnership, or caregiver knowledge of disease) and rely on inferences based on more subjective than objective evidence. As long as these findings are supported by well-triangulated data, they could be considered robust even though they are based on more subjective evidence.

> The quality of the data from each source is the third dimension, where high-quality data clearly contribute to greater robustness. Indicators of quality in qualitative data include, but are not limited to:

> > Recentness (e.g., timing of interview or group discussion relative to topics discussed to minimize recall bias).

> > Conditions of an interview or group discussion (e.g., rapport with respondent, interruptions, appropriate pacing, appropriate level of privacy for interview, balanced as opposed to one-sided group discussions).

> > Degree of proximity to the topic or event in question (e.g., first-hand observation by the evaluation team's or respondent's first-hand experience as opposed to second-hand information).

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

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

Using the dimensions above, we developed the following four-point scale (Table 15) as a general guide for ranking findings and for describing the rationale behind the ranking. A ranking is provided for each key finding in both the cross-country and country-specific sections of the report.

Table 15. Robustness of rankings overview.

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

References

[1] LaFond A, Kanagat N, Steinglass R, Fields R, Sequeira J, Mookherji S. Drivers of routine immunization coverage improvement in Africa: findings from district-level case studies. *Health Policy and Planning*. 2015;30(3):298–308.

[2] Ajzen I. The theory of planned behavior. *Organizational Behavior and Human Decision Processes*. 1991;50(2):179–211.

[3] Rosenstock IM. Why people use health services. *Milbank Quarterly*. 2005;83(4):10.

[4] Katz IT, Ware NC, Gray G, Haberer JE, Mellins CA, Bangsberg DR. Scaling up human papillomavirus vaccination: a conceptual framework of vaccine adherence. *Sexual Health*. 2010;7(3):279–286.

[5] Barros FC, Victora CG, Scherpbier RW, Gwatkin D. Chapter 4: Health and nutrition of children: equity and social determinants. In: Blas E, Kurup AS, Eds. *Equity, Social Determinants and Public Health Programmes*. Geneva: World Health Organization, Commission on Social Determinants of Health; 2010.

[6] Dansereau E. Political stability, fertility, Gavi support and other factors associated with national DTPCV3 and MCV1 coverage: a cross-country multivariable analysis, 2000-2015. 2017. Manuscript in preparation.

[7] Uganda Immunization Equity Assessment Report, August 2016; Communities and Districts Affected by Immunisation Inequities. UNICEF.

[8] Cutts FT, Claquin P, Danovaro-Holliday MC, Rhoda DA. Monitoring vaccination coverage: Defining the role of surveys. *Vaccine*. 2016;34(35):4103-4109. doi:10.1016/j.vaccine.2016.06.053

[9] Lim SS, Stein DB, Charrow A, Murray CJ. Tracking progress towards universal childhood immunisation and the impact of global initiatives: a systematic analysis of three-dose diphtheria, tetanus, and pertussis immunisation coverage. The Lancet. 2008;372(9655):2031-2046. doi:10.1016/S0140-6736(08)61869-3