Memorandum on the Federal Democratic Republic of Ethiopia Programme Audit report

The attached Audit and Investigations report sets out the conclusions of the programme audit of Gavi's support to the Federal Democratic Republic of Ethiopia's Ministry of Health, executed by the Expanded Programme on Immunisation (EPI) Programme, along with other implementing partners.

The audit team reviewed these stakeholders' management of Gavi support to the routine immunisation programme provided during the period 1 January 2016 to 31 December 2021. The audit scope included the following grants: Health Systems Strengthening, COVID-19 Vaccine Delivery Support (CDS) funds, PEF TCA, measles rubella campaign, vaccine introduction grants as well as other vaccines and cold chain equipment.

Funds directly executed by WHO and UNICEF were not subject to our programme audit and were considered out of scope, in accordance with the United Nations single audit principle. Gavi funds disbursed to the Sustainable Development Goal Performance Fund as it had its own reporting, internal audit as well as independent external audit mechanism to be carried out by the Federal Auditor General or an auditor assigned by the Federal Auditor General and constituted the audit of the entire SDG-PF including the broader Health Sector Transformation Program wherein immunisation was only one component. Gavi relies on such audit reports provided by the Federal Auditor General.

The primary objective of the audit was to assess whether: the coordination and implementation arrangements are effective, the existing grant oversight mechanisms provide continuous and reliable assurance on Gavi's investments, the financial management and procurement processes support the timely utilisation and accountability of Gavi grant funds, and the vaccine supply chain management and immunisation data systems are effective.

The report's executive summary (pages 3 to 6) summarises the key conclusions, details of which are set out in the body of the report:

1. There is an overall audit rating of **"needs significant improvement"**, which means, "Internal controls, governance and risk management practices have some weaknesses in design or operating effectiveness such that, until they are addressed, there is not yet reasonable assurance that the objectives are likely to be met."
2. In total, sixteen issues were identified in the following areas: (i) programme management and oversight; (ii) vaccine supply chain management; (iii) immunisation data management; and (iv) budgeting and financial management.
3. To address the risks associated with the issues, the audit team raised 29 recommendations, of which 19 were rated as high priority.

4. Key findings were that:

    a. There was insufficient data to track the implementation of standalone grants, and the Regional Health Bureaus did not regularly report progress to the Federal Ministry of Health. Additionally, there was no evidence of regular reviews of grant implementation, and the support supervision process was not effectively designed to assess immunisation activities and the actions were not properly followed up.
    b. FMOH did not regularly monitor and review of the implementation status of the grant management requirements and audit recommendations.
    c. There were weaknesses in vaccine management and forecasting, leading to underestimation of needs and vaccine expiries at multiple storage hubs. The vaccine logistics management information system functionalities were suboptimal, resulting in inaccurate stock records, ineffective location tracking, inadequate expiries management and inadequate reporting capabilities.
    d. Immunisation targets were based on outdated denominator, resulting in overreporting of administrative coverage. Data quality assurance and monitoring mechanisms were inadequate, with weak follow-up processes to address data-related issues. There were inaccuracies in the vaccination tool resulting in errors and inconsistencies in the data in DHIS2.
    e. Inadequate controls over the management of grant funds including comingling of funds and poor budget monitoring. Additionally, there were unliquidated advances of USD 31 million of which USD 13 million were aged more than one year, and expenditure on ineligible activities totalling USD 1 million were charged to Gavi grants.

The findings of the programme audit were discussed with the Ministry of Health and implementing partners. They accepted the audit findings, acknowledged the gaps identified, and committed to implement a detailed management action plan.

On 19 May 2025, Gavi wrote to the government concerning questioned expenditure totaling USD 13,737,956 which will be further reviewed by the Assurance Provider, required follow-up actions will be determined accordingly. The Gavi Secretariat continues to work with the Ministry of Health to ensure that the above commitments are met.

Geneva, August 2025

PROGRAMME AUDIT REPORT

Federal Democratic Republic of Ethiopia
April 2025

Gavi
The Vaccine Alliance

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1. Executive Summary

1.1 Overall audit opinion

Audit opinion:

The audit team assessed the Federal Ministry of Health's management of Gavi support during the period as **"Needs significant improvement"** which means, "Internal controls, governance and risk management practices have some weaknesses in design or operating effectiveness such that, until they are addressed, there is not yet reasonable assurance that the objectives are likely to be met.

Through our audit procedures, we have identified high risk issues relating to programme management and oversight; vaccine and supply chain management; immunisation data management; and budgeting and financial management. To address the risks associated with the issues, the audit team raised 29 recommendations of which 19 (65%) are high risk. The recommendations need to be addressed by implementing remedial measures according to the agreed management actions.

1.2 Summary of key audit issues

** The audit ratings attributed to each section of this report, the level of risk assigned to each audit issue and each recommendation, are defined in Annex 2 of this report.*

1.3 Summary of issues

Through our audit procedures, we have identified 10 high risk and 6 medium risk issues relating to the programme management and oversight, vaccine and supply chain management, immunisation data, and budgeting and financial management processes. The high-risk issues are summarised below, followed by the detailed findings in Section 4 of this report.

Programme management and oversight

The national Extended Programme on Immunisation (EPI) unit did not have the data to track the implementation status of the standalone grants. Also, the Regional Health Bureau (RHB) did not routinely provide programme activity reports to the Federal Ministry of Health (FMOH), just as the reporting modalities and requirements for RHBs were not adequately defined. There was no evidence of the EPI team conducting periodic reviews of the grant implementation status at the subnational level. In addition, the FMOH's integrated support supervision process was not adequately designed to assess the implementation of immunisation activities, and the actions arising from supervision reports were not properly followed up.

The FMOH did not regularly monitor and review the implementation status of its grant management requirements and audit recommendations, and only half of the proposed actions were completed. Similarly, responsibility for follow-up was not properly assigned, so it was not possible to identify and hold anyone accountable for the lack of progress in addressing the issues identified.

Weaknesses in governance and oversight impact on the ability of the programme to achieve its objectives. Poor compliance with Gavi's GMRs may have consequences for future funding, and failure to follow up past audit issues perpetuates control weaknesses and undermines programme implementation and grant performance.

Vaccine supply chain management

The vaccine forecasting process was suboptimal as it did not consider all the available data. The balances of various vaccines reported to Gavi were overestimated, because some doses that were nearing expiry were considered as available for the following year, which led to the FMOH underestimating its future supply requirements. Actual wastage rates were not considered in the calculations, resulting in the forecasting process having to use generic, less accurate estimations. There was no process to transmit wastage and stockouts data, from the health facility to the Hub-level. Absence of an evidence-based method is likely to perpetuate errors and inaccuracies in the forecasts.

Some of the reports from Ethiopian Pharmaceuticals Supply Agency's (EPSA's) vaccine logistics management information system (e-LMIS) lacked credibility. Equally, some of the system's functionalities were limited as it could not generate the necessary aggregated reports for data analysis, nor could it track the location of vaccine batches. EPSA was constrained in its ability to: optimally manage its stocks and comply with earliest expiry first out principles, resulting in some vaccine expiries. As a result, occasionally the central vaccines store distributed some near-expired vaccines to its EPSA hubs, with some of these doses ultimately shelf-expiring. The opening and closing stock balances recorded did not reconcile, and suitable adjustments were not made to the stock records following the year-end physical reconciliation. EPSA vaccine focal points lacked the necessary skills to generate reports from the e-LMIS. A vaccine stock management tool intended for the woreda level to track vaccine movements and balances, was either not rolled out to all sites or was not used despite being available.

Vaccine expirations were noted across various storage hubs visited by the audit team. Over the audit period, several hubs reported shelf-expired doses. In addition, stockouts were experienced across all tiers of the supply chain, including at the health facility level, with several instances of protracted stockout periods lasting from 30 to over 200 days. These vaccine stockouts were attributed to inadequacies in the last-mile distribution process, as well as due to inaccurate estimates being used to forecast the amount of product which needed to be procured.

The gaps noted in the vaccine supply chain processes must be addressed to ensure effective vaccine supply chain management and reduce stock-outs and missed immunisation opportunities.

Immunisation data management

The FMOH's reliance on national census data from 15 years ago to determine its immunisation targets and coverage meant that these were unlikely to be accurate due to demographic and migratory shifts. For several regions, the administrative coverage routinely exceeded 100%, while other regions reported disease outbreaks, despite having reported achieving high coverage.

Based on the audit team's triangulation of data exercise, the number of children reported as vaccinated for pentavalent, PCV and rotavirus over the period 2016 to 2021 was consistently higher than the quantities of vaccines received and managed by the country over a similar timeframe.

Data quality assurance and monitoring mechanisms were inadequate as: immunisation supervisions did not comprehensively cover data quality aspects; the data quality review process was largely focused on a single vaccine; and the follow-up process or documentation of how weaknesses were addressed was insufficient.

Inconsistencies were identified in the vaccination tools, due to inaccuracies in how data on immunisation activities was compiled. Furthermore, these errors were further compounded when the data was transferred over to the DHIS2 health information system database. The DHIS2 system was vulnerable to manipulation as it did not adequately prevent adjustments being made to the immunisation data after monthly reporting deadline.

Overall, the gaps in immunisation data management compromised the quality of data used in decision making, targets set could not be supported by underlying reviews and achievements may have been overreported. Reliance on inaccurate or over-reported immunisation coverage data can result in incorrect programmatic interventions which could negatively impact the effectiveness of the immunisation programme and the health of the targeted population. The audit team noted that while the immunisation data challenges are known, they undermine the credibility of the reported immunisation administrative coverage and addressing them remains a challenge.

Budgeting and financial management

The FMOH's grant management practices did not fully comply with Gavi requirements as Gavi's standalone grants were commingled with other funding sources in each administrative unit's bank account located across the regions, zones, woredas. Moreover, only at the federal level was the MOH able to demonstrate that it completed the necessary monthly bank reconciliations of the commingled monies. No such control was in place across all of the other levels of the health system.

The FMOH did not use Gavi's standard financial reporting template as required. No proper budget versus actual expenditure analysis was undertaken to ensure that: expenditures were aligned with approvals, that any significant unliquidated RHB advances were promptly identified, and that actual fund absorption rates were monitored rather than solely focusing on disbursement rates. There was no process to reclaim VAT amounts incurred at the regional level, in order to maximise the funds available for the programme.

The Regional Health Bureaus (RHBs) and other institutions accrued significant unliquidated advances. As of June 2022, there were outstanding advances totaling USD 31 million, of which USD 13 million were aged more than one year. The FMOH did not have a process for reviewing and validating the expenditures incurred by the regions, nor was there a clear agreement between the FMOH and the RHBs with respect to the latter's accountability for the management of the funds disbursed. The audit team concluded that given the passage of time, the majority of these unjustified advances are questionable.

The FMOH did not fully comply with Gavi's COVID-19 vaccine delivery support (CDS) grant requirements, as approximately USD 1 million was used for ineligible activities. The FMOH received a second tranche of CDS funding before fully using its first disbursement, having accounted for less than half of the initial funding. In addition, 64% of the first tranche was allocated towards human resources costs, even though Gavi's guidelines prescribed that such expenditures should not exceed 40% of the budget.

If the process of completing the cycle of disbursements and acquittals continues to be drawn-out, along with not all of the expenditures incurred being properly supported, this will impact the programme's effectiveness, and may potentially result in funds being misused, with further consequences for Gavi's subsequent funding.

Post audit fieldwork events

In recognition of the RHBs' systemic financial management issues, in November 2023 Gavi deployed additional financial technical assistance to review RHB financial management arrangements and to suggest practical improvements to budgeting and expenditure liquidation processes. This work remains ongoing.

Also, in January 2024, the Federal Ministry of Health rolled out the Health Sector Channel Two Finance Administration Directive No. 979/2024, which gives guidance on allocations, budget revisions, funds transfer, criteria. The directive also specifies the duties and responsibilities of different stakeholders, handling funding advances. As a result, RHBs and implementors are now required to liquidate all advances within six months.

In addition, due to the time that has elapsed between the audit fieldwork in 2022 and the finalisation of this engagement, in September 2024, the Maternal, Child, and Adolescent Health Service provided updated management action points, indicating progress. It also provided a formal response to this report's executive summary, outlining the key actions

taken to address the high-risk issues highlighted by the audit. Both the updated management actions in Annex 17, and the formal response in Annex 18, are enclosed for completeness.

1.4 Financial consequences of audit issues

The table below summarises amounts questioned by the audit team:

Table 1: Summary of questioned expenditures

Category of questioned expenditures	Amount questioned ETB	Amount questioned USD	Detailed report reference
Unliquidated advances related to closed grants *(validated by technical assistance provider)*	22,002,867	431,429	4.4.1
Other unliquidated advances	628,784,270	12,329,097	4.4.1
Inadequately supported	463,498	9,088	4.4.3
Ineligible	49,385,398	* 968,341	4.4.3
Total questioned	**700,636,033**	**13,737,955**	

** As of 31 December 2022, the country refunded ETB 49,385,398, an amount equivalent to USD 968,341 associated with the above ineligible expenditures into an in-country bank account earmarked to Gavi.*

2. Objectives and scope

2.1 Audit objectives

In line with the respective programme agreements and with Gavi's Transparency and Accountability Policy, all countries that receive Gavi's support are periodically subject to programme audit, for which the primary objective is to provide reasonable assurance that the resources were used for intended purposes in accordance with the agreed terms and conditions and were applied to the designated objectives.

As a result, the audit team assessed the various processes and programme management arrangements governing Gavi's support for which the respective entities were responsible, to assess if: the coordination and implementation arrangements are effective, the existing grant oversight mechanisms provide continuous and reliable assurance on Gavi's investments, the financial management and procurement processes support the timely utilisation and accountability of Gavi grant funds, and the vaccine supply chain management and Immunisation data systems are effective.

The team also reviewed the relevance and reliability of the internal control systems relative to the accuracy and integrity of the books and records, management, and operational information; the effectiveness of operations; the physical security of assets and resources; and compliance with national procedures and regulations.

This report was prepared based on select information and documentation provided to Gavi's audit team; and visit to sampled Regions, Zones, Woredas and Health Facilities. Therefore, the report cannot be considered definitive for the entire amount of expenditures incurred during the audit period and representative for the entire country.

2.2 Audit scope

The audit scope covered the six year period from 1 January 2016 to 31 December 2021. The total cash, vaccines and ancillary support provided by Gavi to the Federal Democratic Republic of Ethiopia in this period is presented in the table below**.** For the purposes of the COVID-19 response and vaccine delivery the scope extended until to 30 June 2022.

Table 2: Cash, vaccines and devices support to FMOH during the period 2016 – 2021

	Grants in audit scope period						
Cash grants	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**Total**
HPV Demo - cash			(332)				**(332)**
Civil Service Organisations			(157,580)				**(157,580)**
Health Systems Strengthening	7,072,654	19,190,000	28,620,695	16,623,718	43,821,000	11,786,851	**127,114,918**
Measles SIA–operational costs	7,634,788		(706,460)				**6,928,328**
Men A – operational costs			(249,526)				**(249,526)**
Measles-FU Camp				9,717,555			**9,717,555**
Product Switch Grant					827,032		**827,032**
Vaccine Introduction Grants			4,745,540				**4,745,540**
Covid-19 delivery support (CDS)						14,685,613	**14,685,613**
Yellow Fever Diagnostics					19,187	3,721	**22,908**
Total cash (a)	**14,707,442**	**19,190,000**	**32,252,337**	**26,341,273**	**44,667,219**	**26,476,185**	**163,634,456**
Cold Chain Equipment				4,747,048		8,428,698	**13,175,746**
Total equipment (b)				**4,747,048**		**8,428,698**	**13,175,746**
PEF TCA				4,432,462	5,872,395	4,317,447	**14,622,304**
Total PEF TCA (c)				**4,432,462**	**5,872,395**	**4,317,447**	**14,622,304**
Vaccines and devices support	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**Total**
HPV Demo	70,040						**70,040**
HPV Routine			11,157,790	12,670,120	11,278,955	19,619,927	**54,726,792**
IPV	2,151,615	3,092,814	3,713,383	5,681,487	6,375,020	8,003,345	**29,017,664**
Measles SIA	4,767,783	(341,441)					**4,426,342**
Meningitis A – SIA	(707,053)	-					**(707,053)**
Pentavalent	10,993,362	9,746,180	5,830,641	9,057,873	8,805,773	6,921,650	**51,355,479**
Pneumococcal conjugate vaccine	42,168,945	21,408,712	13,086,499	18,810,610	19,489,336	23,265,361	**138,229,463**
Rotavirus Routine	10,343,597	9,665,281	17,344,151	6,379,182	12,247,216	7,524,323	**63,503,750**
Inj. safety devices		1,015,155	1,580,451	1,994,328	477,743	5,256,467	**10,324,144**
Measles-FU SIA			-	5,361,539	(52,446)	15,504	**5,324,597**
Measles 1st and 2nd			980,058	869,294	818,924	170,873	**2,839,149**
Covid19 Vaccines				-	-	155,853,066	**155,853,066**
Total vaccines and devices (d)	**69,788,289**	**44,586,701**	**53,692,973**	**60,824,433**	**59,440,521**	**226,630,516**	**514,963,433**
Total cash + equipment + vaccines = (a + b + c + d)	**84,495,731**	**63,776,701**	**85,945,310**	**96,345,216**	**109,980,135**	**265,852,846**	**706,395,939**

Gavi's support to Ethiopia was through two funding streams, namely a pool funding arrangement and various standalone grants.

Firstly, Gavi's health systems strengthening (HSS) grant was largely managed through the "Sustainable Development Goal Performance Fund" (SDG PF), consisting of a pooled fund mechanism governed under the joint financing agreement (JFA). The SDG-PF was scoped out by the audit team as it had its own reporting, internal audit as well as independent external audit mechanism to be carried out by the Federal Auditor General or an auditor assigned by the Federal Auditor General and constituted the audit of the entire SDG-PF including the broader Health Sector Transformation Program wherein immunisation was only one component. Gavi relies on such audit reports provided by the Federal Auditor General.

Secondly, Gavi's other grants managed outside of the SDG pooled fund mechanism were referred to as the "Gavi standalone grants". They include: the Data Quality Improvement Grant (HSS2) – USD 15.4 million; HSS3 – USD 23.5 million; Periodic Intensified Routine Immunisation (PIRI) – USD 5.1 million; Measles Campaign – USD 11.6 million; Covid-19 delivery support 1 (CDS 1) – USD 14.6 million; and Covid-19 delivery support 2 (CDS2) – USD 8.2 million.

The standalone grants were governed by the Partnership Framework Agreement dated 6 February 2013 between the Federal Democratic Republic of Ethiopia represented by the Federal Ministry of Health, the Ministry of Finance and Gavi (the "PFA").

2.3 Audit approach

We adopted a risk-based audit approach informed by our assessment of the risks in all the areas of the immunisation programme supported by Gavi. This included: vaccine and supply chain management, programme management and oversight, immunisation data management, cold chain equipment management, COVAX support, budget and financial Management, and the effectiveness of targeted country assistance

The programme audit was conducted in two phases. An initial one week in-country scoping visit in April 2022, followed by three weeks fieldwork conducted between 27 June and 15 July 2022. The audit team covered the Central Vaccine Store, 6 vaccine hubs, 6 regional health bureaus, 11 zones, 15 woredas and 39 health facilities. The team examined select fiduciary assurance elements including the internal audit and external audit mechanisms. See Annex 4 for a list of sites visited by the audit team.

During the audit scoping and fieldwork phases, the team interacted with key stakeholders including EPI case team under the Maternal and Child Health Division (MCHD), Policy Planning Monitoring & Evaluation Directorate (PPMED), Partnership and Cooperation Directorate (PCD), Primary Health Infrastructure Directorate (PHID), Finance Directorate and the Gavi Alliance partners including WHO, UNICEF, CHAI, and Acasus.

2.4 Progress since last Programme audit

The audit team conducted a prior programme audit in 2016. This current programme audit noted improvements in the supply chain processes managed through the Ethiopian Pharmaceuticals Supply Agency (EPSA), a government organisation within the FMOH. EPSA had strengthened its capacity, by increasing its storage capacity and improving its vaccine management processes. This meant that EPSA was able to meet the additional supply chain demands for the COVID-19 vaccination programme. This and other good practices are highlighted in section 3.3.

2.5 Exchange rate

Most cash and in-country expenditures were incurred using the Ethiopian Birr (ETB). For information purposes and as part of the summary of this report, overall total amounts were reflected in United States Dollars (USD). For the expenditures reviewed, the rate applied was based on the average bank rate provided according to the prevailing Bank of Ethiopia rate, at the time of conversion from USD account to ETB. This equated to an overall exchange rate of ETB 51 to the USD 1.

3. Background

3.1 Introduction

Ethiopia is located in the north-eastern part of Africa, bordered by Sudan and South Sudan on the west, Eritrea, and Djibouti on the northeast, Somalia on the east and southeast, and Kenya on the south. Ethiopia is a federal democratic republic with two levels of government covering its federal and 11 regions at the time of the audit. These regions are divided into 103 zones, thereafter, subdivided into 840 woredas.

With a population of about 101 million in 2020, Ethiopia is the second most populous country of Africa and ranks 12th in the world. The country annual population growth is estimated to be 2.6%. According to July 2013 data produced by the national Central Statistics Agency, the population is projected to reach 109.5 million by 2024 and 122.3 million by 2030[1]. The country is home to various ethnicities, with more than 80 spoken languages.

Ethiopia is a low-income country with a gross domestic product per capita of USD 772 in 2018, up from USD 340 in 2010. It is one of the fastest-growing economies in Africa, experiencing an average annual growth of about 10% between 2004 and 2014. The main sectors contributing to this economic growth are from the agriculture and service industries. According to Ethiopia's poverty assessment report, household poverty rate has diminished remarkably, by around 20%, between 2011 and 2016 (World Bank 2019). However, despite its significant economic growth, the country remains one of the world's poorest[2].

The country ranks 173 out of 189 in the United Nations Development Programme human development index and 87 out of 180 on the Transparency International corruption perception index. According to World Bank data, Ethiopia's per capita gross domestic product in 2021 was estimated to be USD 944.

Expanded Programme on Immunisation milestones in Ethiopia.

As of July 2022, the Ethiopia EPI provided 12 different types of vaccine free of charge to its citizens. In 2017, the country attained the status of Maternal and Neonatal Tetanus elimination.[3] Similarly, in 2001, it was also officially declared free of wild poliovirus.[4]

Table 3: Vaccines in the national EPI portfolio

Vaccines	Year of introduction	Gavi Support
BCG, tOPV, MCV, DTP	1980	
HepB-Hib-DTP	2007	√
PCV 10	2011	√
Rota	2013	√
IPV	2015	√
Switch: tOPV to bOPV	2016	
HPV	2018	√
MCV2	2019	√
Switch: PCV10 to PCV13	2020	√
Switch: TT to Td	2020	
Measles 5 dose vial pilot	2021	
HepB birth dose pilot	2021	
COVID-19 vaccines	2021	√

3.2 National entities involved in implementation of grant activities

National immunisation programme

The Government of Ethiopia is responsible for the national Expanded Programme on Immunisation (EPI), which is managed by the EPI case team within the Maternal, Child Health and Nutrition Directorate (MCHND). At the federal level, several other directorates are involved in planning and implementation of immunisation activities. These include

[1] Health Sector Transformational Plan II (2020/21 to 2024/25).
[2] Health Sector Transformational Plan II (2020/21 to 2024/25)
[3] Maternal and Neonatal Tetanus elimination report, accessed 22 December 2022.
[4] Polio eradication, accessed 22 December 2022.

the: Policy Planning Monitoring and Evaluation Directorate (PPMED), Partnership and Cooperation Directorate (PCD), Primary Health Infrastructure Directorate (PHID), and Finance Directorate.

The EPI taskforce has three technical working groups (TWG):

- Communications – responsible for developing social and behavioural change messages and messages tailored to combat any misinformation related to immunisation/vaccines. This TWG is also responsible for developing tools and guidelines for all forms of communication/ messaging with regards to the EPI.
- National logistics – responsible for coordination of the activities related to vaccine supply chain such as, review of monthly stock status, vaccine quantifications, and capacity building for the vaccine management and supply chain component of the national immunisation programme.
- Monitoring and evaluation – responsible for monitoring implementation status of immunisation activities; developing training manual and guidelines for new vaccine introductions; and soliciting inputs from the logistics and communication TWGs and reporting to the national taskforce.

At the subnational level, immunisation activities are managed by the Regional Health Bureaus (RHBs) and Zonal Health Bureaus (ZHBs).

The Ethiopian health sector has a three-tier health care delivery system.

- At the primary level comprising of a primary hospital (covering 60,000-100,000 people), health centres (15,000–25,000 people) and their satellite health posts (3,000-5,000 people). Arrangements within the urban and rural health services differ, as there are no health posts in the urban areas.
- Secondary level of care consists of general hospitals, in average covering populations of 1.0 -1.5 million. These hospitals are the next referral centres for the primary level of care.
- Tertiary level of care is provided by specialised hospitals, typically covering 3.5-5 million people.

Vaccine storage and supply chain

Since 2014, the Ethiopian Pharmaceuticals Supply Agency (EPSA) has been responsible for the supply quality-assured and affordable pharmaceuticals, including vaccines, to all public Health Facilities in the country. Except for vaccine procurement and forecasting for which responsibility remains with the EPI FMOH and UNICEF, all other components of vaccine storage and supply chain have been transferred to EPSA.

At the operational level, EPSA is responsible for: customs clearance; quality check and arrival reporting; storage; inventory storage and control; cold chain equipment maintenance at the EPSA central vaccine store (CVS) and EPSA-Hubs; and distribution to woredas and last mile delivery to select health facilities. Customs clearance of the vaccine and related supplies is governed by procedures established by the Ethiopian Food Medicine and Health Care Administration and Control Authority.

The EPSA-Hubs have been delegated responsibility for planning, inventory management, and delivery of vaccines, which is done using a dual-track approach. EPSA-Hubs either delivered directly to Health Facilities or to woredas for onward delivery to Health Facilities and health posts. Ethiopia currently operates its vaccine delivery system across a mixture of a three- or four-tiers, with a distribution network stretching across: 16 hubs, 901 woredas, and over 4,163 health facilities, with the CVS situated at the apex. Vaccine deliveries are scheduled every three months from the CVS to the Hubs, and monthly from the Hubs to the woreda level, or directly to Health Facilities.

3.3 Key achievements and good practices

Since 2019, there was significant increase (140%) in the storage capacity at the central vaccine store from 1,000m3 to over 2,400 m^3. EPSA consolidated its CVS from 11 sites which were spread throughout Addis Ababa, to just 3 sites. There was evidence of: regular stock counts at EPSA-CVS and EPSA-Hubs, insurance coverage for vaccines in storage and in transit, satisfactory temperature monitoring and power backup mechanisms at EPSA-CVS and EPSA-Hubs, adequate planning for future Cold Chain Equipment (CCE) expansion and consolidation, established CCE maintenance unit and workshop and a pool of trained CCE technicians. Moreover, two of the EPSA Hubs - Adamma and Hawassa - achieved ISO certification in 2021.

Under the FMOH's initiative of last-mile delivery, currently 30% of the Health Facilities receive their vaccines delivery directly from the EPSA-Hubs. EPSA plans to further scale this up. EPSA, in collaboration with the drugs regulatory authority, established a process to conduct periodic wastage disposal; with a provision of issuing disposal certificates at the end of the exercise.

The DHIS2 routine immunisation system was rolled out to all health facilities, and a dedicated Health Management Information System focal point was identified at each of the health facilities visited by the audit team and data reporting tools are available at the Health Facilities.

As of 31 July 2022, 43.1 million (65%) of the target population had received at least one dose of COVID-19 vaccine and 36.7 million (55%) had completed their primary series. In addition, 2.2 million (3.3%) of the target population had received booster doses. In 2020, during the midst of COVID-19 pandemic, the FMOH carried out the measles campaign to vaccinate 14.5 million children aged between 9-59 months. The FMOH reported overall coverage exceeding 95% of the target population. In addition, the country was able to maintain its routine immunisation coverage rates during the pandemic. The WUENIC data shows that the percentage of children who received DPT3 increased from 68% in 2019 to 71% in 2020.[5]

The FMOH demonstrated good stewardship and coordination in planning and implementation of the COVID-19 vaccine rollout. Together, the FMOH, EPI and EPSA led a coordinated intra-sectoral COVID-19 task team (including public relations, Health, Security, Health Development, etc.). The alliance partners supported the task team which developed a deployment plan and micro plans detailing the critical steps, action ownership and responsibility for implementation. There was timely policy recommendations and technical guidance from Ethiopian National Immunisation Technical Advisory Group involving prioritisation of vaccination groups and types of vaccines to be deployed in Ethiopia.

There was effective COVID-19 vaccine storage and distribution. Apart from the ultra-cold-chain (UCC) requirements for Pfizer vaccines, having recently expanded the central level storage capacity, EPSA was able to successfully store and manage the rapid and significant influx of COVID-19 vaccines. EPSA-Hubs managed the "last-mile distribution", i.e., to the selected vaccination centres and outreach programmes. In addition, as of July 2022, the country received 32 UCC units of which 16 were installed at EPSA central.

3.4 Operational challenges due to the Covid pandemic

The first COVID-19 case in Ethiopia was reported on 13th March 2020. The resulting pandemic disrupted key essential public health services, including immunisation and led to increased outbreaks of vaccine-preventable disease, such as measles. The COVID-19 vaccine uptake in urban areas was somewhat suppressed due to hesitancy, misinformation, and rumours. The ongoing conflict in four regions (Tigray, Amhara, Afar and Benishangul Gumuz) was also an obstacle in sustaining and maintaining routine immunisation coverage. In addition, there were competing national priorities between the immunisation programme and addressing the public health consequences due to widespread drought.

[5] WUENIC data

4. Audit issues

4.1 Programme Management and oversight

4.1.1 Gaps in the annual workplan development and microplanning processes

Context and Criteria

The Gavi financial management guidelines require the country to maintain budget management systems in accordance with the provisions of Gavi's Transparency and Accountability Policy for direct financial support. The budget management system should follow key principles including: health interventions directly or indirectly linked to Immunisation outcomes; budgets should be reflected within national budgets; the budget (through a narrative) should demonstrate a strong link between inputs, outputs and outcomes; the budget should be clearly presented with precise definitions and sources of data (qualitative and financial), plus well explained assumptions and costing methods. Gavi also requires standalone grant budgets to be prepared using the Gavi budget template.

The country received "standalone" grants as follows: Data Quality Improvement (HSS 2) amounting to USD 15.4 million; a HSS 3 grant amounting to USD 23.5 million; Periodic Intensified Routine Immunisation (PIRI) activities amounting to USD 5.1 million; Measles campaign amounting to USD 11.6 million, CDS1 amounting to USD 14.5 million and CDS2 amounting to USD 8.2 million. The overall value of the standalone grants in the audit period totaled USD 78.3 million. All of these grants were governed by the Partnership Framework Agreement signed on 6 February 2013 between the Ethiopian Federal Ministry of Health, the Ministry of Finance and Gavi.

Condition

Budget and workplans for "standalone" grants were not shared with the Regional Health Bureaus (RHBs): The **"**standalone" grants are supported by detailed budgets and workplans that were approved by Gavi. However, there was no evidence that these budgets and workplans were shared with the RHBs. The FMOH noted that programming for the grants included an interactive operational planning processes followed both the bottom up and top-down approaches through interactive processes, however, no documentary evidence to support this collaboration was shared with the audit team.

Furthermore, there was no information shared to support the budget allocations to the RHBs. The underlying workings and assumptions used by the EPI team to determine the allocation to each RHB were not availed to the audit team and the documents provided by the finance team did not include any basis for the budget allocation.

Gaps in the design of the Measles SIA microplanning exercise: USD 681,475 (ETB 34,755,200) was disbursed from the FMOH to the RHBs for microplanning. The audit team reviewed the microplanning process and noted that the final targets and budget allocated to the RHBs differed significantly from the outcome of the microplanning exercise conducted by RHBs. This is because the FMOH made adjustments to the target populations, while consolidating all the micro plans, to fit within the funding provided by Gavi.

The FMOH also noted that projections provided by the Central Statistical Agency, upon which the ministry relies for denominator data rely on the 2007 census data which is out of date.

Recommendation 1

To facilitate planning and monitoring of the standalone grants, FMOH should

- Establish a process of engaging RHBs in development of workplans and budgets for the stand-alone grants.
- Share final workplans and budgets with the RHBs which should in turn be used for the RHB and national level supervision and monitoring activities.

Recommendation 2

To further improve the micro planning exercises, FMOH should

- Provide RHBs with the necessary support to develop realistic micro plans for future campaigns and other immunisation activities that are reliant on the outdated population census data.
- Document all adjustments made to micro plans and ensure that adjustments are approved.
- Where funding gaps result in adjustments to fit within Gavi provided funds, these adjustments should be shared with Gavi, together with programmatic implications for activities that are not funded by government.

<table>
<tr><td>Root Cause
• The budget and workplans for the standalone grants were not shared with the RHBs because the finalisation of the processes was not differentiated from the process for funds budgeted and planned within the pooled fund.
• Due to the use of population projection based on historic 2007 census data, the micro plans prepared by the RHBs may not reflect the realistic target population.</td><td colspan="2">Management comments

Detailed management responses are included in Annex 17 of this report.</td></tr>
<tr><td>Risk / Impact / Implications
• Inadequate differentiation between the information shared with RHBs for standalone grants and pooled fund activities means that there was no visibility for the specific activities funded by Gavi at the regional levels. This may impact the quality of supervision and monitoring as activities under the standalone grants as they are not reviewed in detail by the RHBs or by FMOH.
• Use of outdated population data to set targets may not reflect realistic projections for campaign results.
• Resetting micro plans to fit within the Gavi budget contravenes Gavi's funding guidelines which require campaign operational grants to cover a portion of the required operational costs of a campaign, with countries supporting the remainder. For this campaign, the country was unable to demonstrate its contribution to the Measles SIA campaign.</td><td>Responsibility
Refer to Annex 17</td><td>Deadline / Timetable
Refer to Annex 17</td></tr>
</table>

4.1.2 Gaps in monitoring implementation of EPI activities

Context and Criteria

Paragraph 16 of Annex 2 of the PFA states that "*The Government's use of Gavi's vaccine and cash support is subject to strict performance monitoring. Gavi seeks to use the Government reports and existing country-level mechanisms to monitor performance. The Government shall monitor and report on the use of vaccines and related supplies and the funds provided by Gavi stating the progress made towards achieving the objectives of the Programme(s) during the preceding year by submitting the Annual Progress Report(s).*"

Gavi's decision letters relating to HSS grants managed outside of the SDG PF pool fund, require that the national oversight body monitor the implementation of programme proposal. Therefore, FMOH is expected to conduct periodic review of the implementation status of the programme activities and to report thereon to the Interagency Coordinating Committee (ICC), so that the Committee may discharge its oversight responsibilities.

In June 2020, Gavi's grant management requirement (GMR) included the requirement that the FMOH strengthen integrated supervision and monitoring, by developing a resource mobilisation plan and engaging ICC to mobilise resources for development of a training package on monitoring and supervision.

Condition

Suboptimal monitoring of grant and activity implementation: MCHD/EPI was unable to provide the audit team with the implementation status of standalone grants activities such as: PIRI, Data Quality Improvement, HSS 3 and CDS grants. Contrary to the expectation laid out in the PFA, there was no evidence that the EPI team conducted periodic reviews of the grant implementation status at the subnational level. Similarly, the RHBs did not submit periodic programme activity reports (except for the 2020 Measles campaign SIA) to the FMOH.

Support supervision did not adequately cover immunisation activities: To comply with the HHM guidance, the FMOH carried out an Immunisation Systems Strengthening (ISS) review at all levels using a standard checklist covering all the FMOH health programmes and directorate activities. Notwithstanding the potential efficiency gains from using such an integrated ISS approach, the audit team noted the following gaps:

- The ISS checklist did not adequately cover key immunisation related parameters such as, vaccine management and accountability, data quality and implementation of immunisation activities. The immunisation related parameters included in the ISS checklist were limited to availability of IEC materials for child immunisation, monitoring EPI dropout rate, and proper vaccine storage.
- The audit team did not identify any process in place in order for the FMOH to consistently follow up on the action plans arising from ISS. Also, there was no evidence of the FMOH using the supervision reports to feed into its decision making and subsequent interventions.

Recommendation 3

The FMOH should formally clarify the roles, responsibilities, and accountability between itself and the RHBs with regards to the monitoring and measurement of achievements of set targets of the Health Sector National Strategic Plan. This should help MCHD/EPI to periodically prepare grant implementation status reports.

Recommendation 4

The FMOH should ensure that supervision visits at all levels are documented and introduce a mechanism for the follow-up of proposed actions.

Root Cause

- Reporting requirements and modalities for the RHBs are not defined. The FMOH does not have signed MOUs with its RHBs.
- The ISS standard checklist does not adequately cover necessary immunisation parameters. In addition, the checklist is too long in comparison to the time given to the supervision teams which affects the quality of the support supervision carried out. Officers were on average assigned three units (either zonal offices or health facilities) to cover in a day. The audit team considers that one unit in per day per person would be a more reasonable expectation.

Management comments

Detailed management responses are included in Annex 17 of this report.

Risk / Impact / Implications

Missed opportunity to timely identify and rectify poor practices related to immunisation programme. Gavi funds used for monitoring and supervision activities may not provide value for money, in the absence of suitable feedback and follow up of the issues identified through the supervision process.

Responsibility	Responsibility
Refer to Annex 17	Refer to Annex 17

4.1.3 Suboptimal performance of the operational and governance structures

Context and Criteria

Clause 7.3 of the PFA requires that the Government comply with all policies, guidelines and processes of Gavi that are relevant to the programmes which shall for part of this agreement, and the GMRs are applicable accordingly. Gavi's June 2020 GMRs include a requirement that: the ICC's Terms of Reference (ToRs) should be revised, considering the respective mandates, roles and responsibilities of other health sector oversight and coordination bodies, with a view to minimising duplication and enhancing synergies. These revised ToRs should include a clear statement on the mandate, membership (including composition, selection, and rules), meeting rules, decision-making, support functions, and roles and responsibilities – including those of the ICC Secretariat, sub-committees and working groups, as applicable.

In response to this GMR, the FMOH developed ToRs for its EPI Taskforce – which consists of a coordination platform whose role is to submit periodic written reports and briefs to the ICC. The EPI Taskforce's ToRs of indicate that the EPI case team should hold monthly meetings, document its action points (with clear responsibility and deadlines) and ensure that the relevant person or team or organisation is promptly informed of the necessary actions. The EPI case team is expected to bring to Taskforce's attention all immunisation matters in need of decision making. The EPI case team lead (manager) is the chair of the Taskforce, and its members comprise of technical experts from partner organisations, including WHO, UNICEF, PATH and JSI.

Condition

Inadequate coverage of core EPI activities in ICC meetings: The audit team reviewed the minutes from eight ICC meetings held between 2016 and 2021 and noted that the ICC's deliberations mainly focused on reviewing and approving of grant applications, prior to their submission to Gavi. Per the minutes, the ICC did not cover its core objectives as prescribed its ToRs. The following examples of objectives, refer:

- Measures to improve coverage, vaccine management, quality of immunisation services, and timely generation and use of quality data related to routine Immunisation for timely decision making.
- Assist the FMOH by coordinating technical and resource mobilisation for planning, implementing, and monitoring Immunisation programs in a technically sound, socially acceptable, and efficient manner.
- Passing strategic decisions, monitor progress on key milestones of the strategic plan, and mobilise more resources to Immunisation program; and
- Leading the development, distribution, implementation, review, and monitoring of the National Immunisation Strategy; and review the annual work plan that corresponds with the five-year national immunisation strategy.

Lack of robustness in monitoring the implementation status of ICC recommendations: The audit team noted the absence of a well-defined process, for implementing ICC recommendations and monitoring their status. The actions contained in the ICC minutes were neither assigned to an officer responsible for implementation, nor was a timeline set for completion. Consequently, there was no evidence that at least 28 action points raised by the ICC between 2016 and 2021 were ever implemented. The following action points examples, refer:

- Establishment of countrywide real time data management of CCE status to support decisions in CCE procurement and distribution;
- Key Performance Indicators (KPIs) for TCA to focus on number of children vaccinated at the centre of their evaluation and not merely on the TA provided or budget utilisation rates;
- Due attention to be given to data discrepancy from the different sources; and
- Periodic head counts of eligible children to mitigate the errors arising from outdated census used to set project targets. This action point was raised during an ICC meeting held on 3 January 2018. This action point was raised following a discussion and review of the 2018 Gavi full joint appraisal report.

EPI Taskforce meetings were irregular and did not feed into the ICC deliberations and decision making and follow-up: The audit team noted that the frequency of the EPI Taskforce meeting was irregular. On average, Taskforce meetings were held once or twice a year, significantly less than the monthly frequency prescribed in the TORs. Throughout the audit period, the frequency of meetings was as follows: In 2016 and 2017 – 2 meetings; 2018 – 3 meetings; 2019 – none; 2020 – 3 meetings; and 2021 - none. Based on the audit team's review of the meeting minutes, the actions contained in the Taskforce minutes were neither assigned to an officer responsible for implementation, nor was a timeline set for completion. Therefore, the implementation status of EPI Taskforce action points was not monitored.

Recommendation 5

FMOH should work with WHO to orient all ICC members on their roles and responsibilities to ensure that core objectives as prescribed in the ICC ToRs are well covered.

Recommendation 6

FMOH should hold regular EPI Taskforce meetings and ensure that reports of the EPI Taskforce discussions and conclusions are promptly prepared and submitted to the ICC for strategic guidance.

Recommendation 7

The FMOH should develop a dashboard to track the follow-up and implementation of its ICC and EPI Taskforce recommendations. For the purposes of accountability, each recommendation should be assigned to a designated officer responsible for its implementation, along with a deadline by which time the action is to be completed.

<table>
<tr><td>Root Cause
• The EPI Taskforce's operations did not comply with its ToRs. There was no evidence that the Taskforce was regularly imparting pertinent issues to the ICC, in relation to the immunisation programme.
• Absence of planning and formalisation of process, to follow up on Taskforce action points and monitor their implementation status.</td><td colspan="2">Management comments

Detailed management responses are included in Annex 17 of this report.</td></tr>
<tr><td>Risk / Impact / Implications
• Poor accountability and reporting lines between the operational and governance organs may delay in identifying and resolving issues critical for the immunisation programme.
• Failure to comply with the GMRs may result in the suspending and/or (in the case of material non-compliance) termination of Gavi's funding.</td><td>Responsibility
Refer to Annex 17</td><td>Responsibility
Refer to Annex 17</td></tr>
</table>

4.1.4 Previous grant management requirements and programme audit recommendations are still outstanding

Context and Criteria

The audit team assessed the FMOH's progress in implementing two series of Gavi recommendations. Namely the: (i) Grant Management requirements (GMRs) (June 2020), which built upon the 2019 Programme Capacity Assessment (PCA); and (ii) the 2016 programme audit.

Condition

Delayed implementation of GMRs: As of 15 July 2022, the FMOH had implemented only 17 of 36 GMRs. Some of these GMRs – that were critical for the programme – but not yet implemented, included:

- Plan for HR sustainability for health, including measures for skills transfer from technical assistance personnel to government staff as well as HR needs assessment and filling of vacant positions;
- Document and report to the ICC and Gavi on progress made, and lessons learnt from the implementation of the activities contained in the data quality improvement component of the Gavi HSS grant;
- Address the gaps in management of funds advances, the FMOH/F&PD to ensure that no new advances will be issued to staff and regions before liquidating at least 80% of older advances which are due;
- Submit financial reports to Gavi every six months in line with the Gavi "Guidelines on Financial Management and Audit Requirements". This will include ensuring proper linking of activities to budgets and source of funding at all levels of spending, appropriate adjustment of advances to subnational levels, and staff from reported expenditure and clear consolidation of reports at the federal level; and
- Follow-up of Gavi grant recommendations from External Auditors, Internal Auditors and Gavi Programme Auditors. FMOH will prepare a plan to follow up on the recommendations made by the external auditors, internal auditors and Gavi auditors, for internal dissemination within the FMOH and submission to the ICC and Gavi.

Delayed implementation of programme audit recommendations: Regarding the 2016 programme audit, the status of the 11 recommendations was: 4 implemented; 3 partially implemented; and 4 not implemented. The recommendations not yet implemented included that:

- The FMOH management should put in place suitable mechanisms to ensure that it follows up and formally closes all valid and accepted external audit issues;
- The FMOH should ensure that regions account for funds advanced within the financial year to which funded activities relate. The RHBs should then account for activities implemented close to year-end within a period of six months after the financial reporting date;
- The FMOH should work with development partners and regional governments to increase the capacity and capabilities of accounting departments at the RHBs by deploying and training additional staff so that primary responsibilities, such as the turnaround and forwarding of zonal SOEs to the FMOH never takes longer than one month; and
- The FMOH's support and supervision should ensure that all Gavi-related expenditure has the appropriate supporting documentation linking the expense to a Gavi activity.

Recommendation 8

The FMOH is recommended to:

- setup a comprehensive and rolling action plan and processes, with clear responsibility to implement, monitor and report on GMRs, audit (internal/external) recommendations, and action points from critical assessments.
- engage ICC or its governance body to provide oversight of the progress and hold individual/team accountable for long outstanding issues.

Root Cause

- The FMOH did not periodically monitor and review the implementation status GMRs and programme audit recommendations.
- The FMOH did not mandate for the EPI Taskforce and ICC to: assign responsibility, monitor progress and hold officers accountable for the implementation of the GMRs and audit recommendations.

Management comments

Detailed management responses are included in Annex 17 of this report.

Risk / Impact / Implications

Failure to promptly implement recommendations arising from assurance processes, may perpetuate control weaknesses and compromise the ability of programmes to achieve objectives.

Responsibility

Refer to Annex 17

Responsibility

Refer to Annex 17

4.1.5 Suboptimal monitoring of TCA milestones and deliverables

Context and Criteria

Gavi classifies Ethiopia as a Partnership Engagement Framework (PEF) "tier 1 priority country". This means that Gavi significantly invests in targeted country assistance (TCA) activities, part of the PEF funding modality. The audit team reviewed the TCA support covering the three-year period 2019 – 2021 during which Gavi disbursed approximately USD 13 million to various technical assistance (TA) providers, drawn primarily from the Gavi Alliance core and extended partners.

Condition

Absence of a process to validate TCA milestones: Based on the information provided by the partners via the Gavi PEF reporting portal, the number of "completed" milestones progressively improved over the period 2018 - 2021. Nevertheless, the status for between 33% - 56% of the remaining milestones were reported as: "delayed", "on-track", "reprogrammed" or "without status update". One limitation of the Gavi PEF portal, is that it does not provide visibility over the outcome of prior year milestones that were still incomplete at the year end, and for which outstanding actions remained. Similarly, within Ethiopia, no process had been adopted to either validate the submission milestone responses reported as completed, or to monitor milestones until completion of the prior year actions which had not yet been achieved.

Table 4: Analysis of TCA milestones reported in Gavi PEF portal for the period 2018 -2021

Milestone Year	#Milestones	Completed	Other than completed
2018	102	45 [44%]	57 [56%]
2019	120	71 [59%]	49 [41%]
2020	120	54 [45%]	66 [55%]
2021	126	85 [67%]	41 [33%]

The audit team was informed that the status of the PEF TA support is to be reviewed every year during the "Joint Appraisal" (JA) process, including a high-level update from the various TA providers on their activities. In practice, the JA process does not involve holding TA providers accountable for their milestones' delivery.

For the past two years, this usual process was interrupted. In 2020, the JA was substituted by a virtual "multi-stakeholder dialogue" (MSD) involving the FMOH and key partners, as the JA could not be conducted due to the COVID-19 pandemic disruption. For 2021, neither MSD nor the JA process was undertaken. In addition, the audit team noted that the annual EPI meetings, at which TA support progress is expected to be reviewed (among other tasks), were held less than once a year.

Recommendation 9

The FMOH should strengthen the TCA monitoring processes by: (i) Providing coordination guidelines to TA partners to ensure that the TCA performance milestones are validated by FMOH before these are reported and submitted to Gavi; and (ii) set up a process to collate, monitor and track all overdue TCA activities.

Root Cause

Lack of systematic follow up on the reported and outstanding status of TCA milestones.

Management comments

Detailed management responses are included in Annex 17 of this report.

Risk / Impact / Implications

Reduced accountability, could translate into under-performance or the incomplete provision of TCA services by the Gavi alliance and expanded partners, in furthering the immunisation programme.

Responsibility

Refer to Annex 17

Responsibility

Refer to Annex 17

4.1.6 Need for TCA sustainability and transition plan

Context and Criteria

Arguably, some of the TCA support should translate into a short-term increase in the national EPI programme's human resources and capabilities. At the time of the fieldwork in July 2022, approximately 100 individuals were funded through the technical assistance support under both regular PEF and COVAX grants. The sum of these individuals' resources and capacities were dispersed across both the FMOH and RHB levels.

Condition

The audit team noted that:

- **The immunisation programme is reliant on TCA/partner inputs for some core EPI activities such as vaccine forecasting, support supervision, data analysis etc**. The primary purpose for TCA support is provide catalytic support and promote innovation and improvements in the immunisation programme while maintaining the core principles of: (i) differentiation; (ii) country ownership; (iii) accountability; (iv) transparency; (v) targeted, (vi) harmonisation, and (vii) efficiency and effectiveness. To date, despite the importance of country ownership principles, the FMOH does not have a suitable plan in place, for how to transition and absorb some of these key functions and capabilities, particularly at the regional level, within respective health budgets.
- **Lack of follow-up on action points and recommendations arising from the TA providers' activities:** Based on the audit team's interviews with TA providers, it was reported that there was a lack of governance and accountability, regarding ownership and follow-up on action points and recommendations arising from the TA providers' activities. In particular, the RHBs' responsibility to appropriate and address issues identified by the TA providers was lacking, resulting in some gaps and problems being left unresolved.

Recommendation 10

The FMOH should:

- identify those key resources and capabilities which are currently augmented and financed using external support (including TCA), so as to develop a comprehensive transition plan, with appropriate timelines and funding sources, such that the public health system can replace or absorb the necessary functions and roles into its immunisation programme;
- establish clear expectations between the TA providers and the RHBs regarding respective roles and responsibilities, in relation to the appropriation of future TCA activities, issues and outcomes; and
- ensure that the RHBs commit to following-up on any action points identified by the TA providers, which are mutually agreed to be a priority.

Root Cause

- Inadequate planning for how to sustain key immunisation activities which TCA significantly contributes to.
- Absence of mechanisms to ensure that RHBs are empowered and accountable for appropriating, addressing and following-up on actions arising from TA activities.

Management comments

Detailed management responses are included in Annex 17 of this report.

Risk / Impact / Implications

- Risk of the EPI programme being disrupted post transition; and
- The national EPI not being able to fully capitalise and benefit from the catalytic TA support potentially risks it perpetuating an expressed need for continued support.

Responsibility

Refer to Annex 17

Responsibility

Refer to Annex 17

4.2 Vaccine supply chain management

4.2.1 Vaccine forecasts need improvement

Context and Criteria

Every year during Q3 and Q4, the FMOH/EPI, with support from key partners (e.g., UNICEF, WHO and CHAI), forecasts the number of doses needed to meet the country's target population in the following year. This annual forecast process determines the quantity and type of each vaccine to be procured after factoring in: target population, coverage rates, allowable wastage rates, and programme targets. The FMOH/EPI sets its targets based on a projection of the current population as derived from 2007 census.

In general, to mitigate the risk of inaccurate targets derived from the historic census data, countries are encouraged to move toward consumption-based forecasting methodology, accompanied by regular forecast reviews to manage operational risks of stockouts or overstocking.

Condition

The audit team noted the following gaps in the vaccine forecasting process:

- Use of vaccine consumption in vaccine forecasts - Vaccine consumption patterns were not sufficiently factored into the forecasting decision making processes;
- Actual wastage rates while reported (at national and subnational levels) were not considered in the forecasting process which used WHO wastage rates; and
- Vaccine expiry dates were not sufficiently factored into the vaccine forecasting process. As a result, in the past batches of near-expired vaccines were considered as available for the following year, which led to a significant underestimation of the volume of doses that needed to be procured. For example, in 2017, EPI/ESPA communicated to Gavi that it still held a significant stock balance of PCV (6.67 million doses), of which approximately 2.5 million doses were expiring in less than 3 months. Without the knowledge of the near-expiry stock-on-hand, Gavi reduced the quantity to be procured to 4.6 million doses. Consequently, this resulted in shortage and stockouts of PCV during 2018 – 2020. Intermittently during this review period, the audit team noted that PCV stockouts occurred, ranging from 26 to 58 days, and in part due to a failure of maintaining sufficient minimum buffer stocks of three months at the central level. For details, see Annex 10 and Annex 11.

Recommendation 11

To improve the accuracy of vaccine forecasts, the EPI and EPSA should use vaccine consumption patterns, including stockouts incidents and data on the aging of stock balances.

Recommendation 12

The FMOH/EPI should monitor and track its wastage rates, using tools such as the Vaccine Wastage Rate Calculator[6] (developed by WHO) to improve the overall accuracy of estimates.

Recommendation 13

The FMOH/EPI should conduct a wastage rate study (as was planned for 2022) to inform the forecasting process by using more realistic wastage rates that are based on actual practice.

Root Cause

- Forecasts based on outdated census data and inaccurate target population estimates.
- Near expired, time sensitive end-of-year stock balances not adequately factored into forecasting.
- Supplemental analytical data (e.g., consumption patterns) not used to increase the accuracy of forecasts.
- Unknown actual wastage rates contributing to influencing the accuracy of supply needs.

Management comments

Detailed management responses are included in Annex 17 of this report.

Risk / Impact / Implications

Inaccurate, underestimated vaccine forecasts can result in stockouts or rationing; and thus, missed immunisation opportunities.

Responsibility

Refer to Annex 17

Responsibility

Refer to Annex 17

[6] Vaccine wastage calculator. Accessed 13 December 2022.

4.2.2 Gaps in vaccine logistic management information systems and records

Context and Criteria

Good visibility over supply chain data and its usage for decision-making, is a key component of immunisation supply chain. Also, stock data is vital to inventory management as it informs key processes including turnover, forecasting, and anticipating resourcing and procurement requirements.

Currently, Ethiopia uses a combination of integrated and interoperable information systems to manage its vaccine logistics. This includes an e-LMIS system (named VITAS) as its health commodity inventory, warehouse, and logistics management information system. The system was developed by JSI (with USAID funding) and has been implemented across both the CVS and EPSA-Hub levels. Beyond that, the system does not inform on stock balances at subsidiary levels. EPSA used its e-LMIS data to report its stock holdings to the EPI and Gavi, to feed into the process of determining the doses to be procured the next year.

In addition, the EPI explained that at the Woreda level, a vaccine stock management tool operating off a smart-phone platform (named mBrana), was used to manage inventory. The system was developed and rolled out by JSI in 2017, intended as a complementary element of the VITAS ecosystem, due to its potential to augment visibility over vaccine balances from a broader base of subsidiary stores. Based on documentation reviewed by the audit team, the system is currently deployed across 190 out of 901 woredas, with plans to scale-up and roll it out across another 600 woredas. However, in the 15 woredas, visited by the audit team mBrana was not in use, reportedly due to funding constraints.

Condition

Central level

The audit team observed gaps in the operation and use of e-LMIS at both EPSA's CVS and Hubs:

- **Significant stock variances were observed between annual opening and closing stock balances during the period 2016/2017 – 2018/2019** for Penta, Pneumococcal and Rota vaccines. Thereafter from 2020 onwards, these variances were progressively eliminated due to improvements in EPSA's vaccine stock management practices, including undertaking regular stock count and the consolidation of the central level storage sites from 11 to 3 locations.

Table 5: Global reconciliation 2017 to 2021 - Variance between opening and closing balance

	2016/2017 Period			2017/2018 Period			2019/2020 Period			2020/2021 Period		
Vaccine	Closing Balance	Opening Balance	Var. (doses)	Closing Balance	Opening Balance	Var. (doses)	Closing Balance	Opening Balance	Var. (doses)	Closing Balance	Opening Balance	Var. (doses)
Penta	4,184,727	4,194,658	9,931	780,272	780,921	649	215,262	215,262	-	588,301	588,301	-
PCV	2,874,650	2,922,783	48,133	1,094,384	1,153,936	59,552	53,307	55,757	2,450	44,428	44,428	-
Rota	1,617,946	1,652,213	34,267	206,606	233,062	26,456	169,346	169,346	-	2,379,457	2,379,457	-

- **The credibility of various e-LMIS reports was questionable.** For example, a vaccine expiry report for 2016/2017 suggested that 2.5 million doses of PCV had expired by during the 12-month period July 2016 to June 2017. Both, EPSA and JSI confirmed that the system did generate erroneous reports, while clarifying that a significant volume of PCV doses was not known to have expired.
- **The "bin location" e-LMIS functionality was not enabled,** hence the system did not track in which cold room specific vaccine batches were located. Consequently, EPSA's compliance with earliest expired first out (EEFO) principles were weakened. EPSA logistics staff at CVS and Hubs lacked the necessary skills to run essential e-LMIS reports including expiry by product; stock aging; and consumption trends. Instead, there was dependence on JSI's support to generate the necessary e-LMIS reports.
- **The e-LMIS design could not generate suitable data analytic and aggregated reports.** As a result, EPSA was required to generate a range of standalone reports, in order to transfer these over to excel for further consolidation and analysis offline. The manual nature of such analyses presents a significant risk of human error.

Recommendation 14

The EPSA CVS and Hubs should investigate and adjust its stock records in response to the discrepancies arising from routine stock counts and the end-of-year stock reconciliations. These adjustments should be independently validated by an authorised officer while documenting the process.

Recommendation 15

The FMOH/EPSA should develop a clear roadmap with timelines for the intended rollout of the new ERP system while ensuring that the system meets Gavi's target software standards for vaccine supply chain information systems.

Recommendation 16

Until its new ERP is fully functional, the FMOH/EPSA should introduce compensatory controls, such as tracking bin locations and ensuring that all vaccine issuances are EEFO compliant.

Recommendation 17

FMOH should review and reposition the mBrana system in the context of last-mile distribution and the intended rollout of a new ERP system. This should include plans for future integration of mBrana and new ERP as needed.

<table>
<tr><td>In an acknowledgment of its e-LMIS' limitations, EPSA plans to replace this system with a suitable Enterprise Resource Planning (ERP) system, with the Global Fund's support.

Sub-national level observations

The audit team visited 6 Hubs, 15 woreda and 39 health care facilities and noted the following gaps:
• Variances in general vaccine reconciliation: The audit team reconciled vaccine movement between the woreda and Health Facilities and noted differences at 44% of Health Facilities (17 out of 39) it visited, for at least one of three antigens. Refer to Annex 14 for details. These differences were due to data omissions; erroneous entries; or unreconciled balancing figures.
• Missing stock management tools: The team also noted the lack of stock records (vaccine control books) in two Health Facilities (Denkaka and Gobeseye) and for one Woreda (gaps in the records for various vaccines over a period ranging from one to twelve months).
• The vaccine stock management tool (mBrana) was not in use across all 15 woredas visited by the audit team, even though the tool had been deployed at those sites, and it should have been used to record vaccine inventory movements (for example between Hubs and woredas; and woredas and Health Facilities).
• None of the Hubs were able to access the vaccine stock management tool (mBrana) at the time of the audit team's site visits, even though system was intended to provide them with remote visibility over subsidiary vaccine balances.
• No evidence of routine physical counts in 5 of 15 woredas and in 12 of 39 Health Facilities. Where physical counts are done and variances noted, these variances were not being investigated, and unexplained differences remained between the records and physical stocks.</td><td colspan="2"></td></tr>
<tr><td>Root Cause
• While mBrana was deployed to several woredas, all 15 woredas visited were not using the system due to funding, user acceptance and access challenges.
• Inherent system challenges related to data quality, traceability, report generation that had not been addressed.
• Incomplete transfer of skills and capabilities in manipulating the e-LMIS from the system support partner to EPSA logistics staff.</td><td colspan="2">Management comments

Detailed management responses are included in Annex 17 of this report.</td></tr>
<tr><td>Risk / Impact / Implications
Inaccurate stock data compromises the national EPI's ability to accurately forecast its vaccine needs. For example, errors in stock records can exaggerate the volume of vaccines available, and use of erroneous data can impact on procurement decisions, resulting in purchasing too few (or too many) doses. Any potential or actual stockouts will impact the programme and could result in missed vaccination opportunities across service delivery points.</td><td>Responsibility
Refer to Annex 17</td><td>Responsibility
Refer to Annex 17</td></tr>
</table>

4.2.3 Improvements needed in stockouts and expiries management

Context and Criteria

EPSA's five-year vaccine distribution strategy (2018-2023) provides a roadmap to ensure safe, accurate, and timely delivery of potent vaccines and consumables through a cost-effective and efficient distribution system (refer to sections 3.13.and 3.14).

FMOH/EPSA currently operates a mixture of three- and four-tier level supply chain – see Annex 5 for current distribution system. At the apex, the CVS distributes vaccines every three-months to 16 Hubs. the other 3 remaining Hubs being dormant. Thereafter, these Hubs distribute vaccines either (i) to Woredas (90% of these) for onward distribution, or (ii) directly to 30% of the Health Facilities. Every month, Woredas deliver vaccines to health facilities and posts, using transport options facilitated by the RHB. Some Woreda onward issuances target the hard-to-reach health facilities or posts.

Condition

The audit team reviewed the vaccine distribution process including both long haul (CVS to Hubs); and last mile deliveries (Hubs to Woreda and/or Health facilities) – noting the following gaps:

Stockouts – central and subnational level

Across three vaccines – e.g., Penta, PCV and Rota, and based on a sample of sites visited by the audit team, it was noted that intermittent stockouts occurred in 4 out of 6 Hubs, 6 out of 15 woredas, and 11 out of 39 Health Facilities. Given that the sufficient supplies were usually available at the preceding store – i.e., one tier up, these stock-out were attributed to inadequate "last-mile" distribution inefficiencies. The duration of the stockout was established from stock records, by measuring the time each vaccine's balance was zero until replenishment. See **Annex 9**, **Annex 10** and **Annex 11** for details.

Table 6: Instances of significant stockouts incidents (i.e. stockouts exceeding 30 days or more) represented by three vaccines, across select health facilities which were visited by the audit team

Facility Name	Vaccine: Penta			Vaccine: PCV		Vaccine: Rota	
	Incident 1 (stock out)	Incident 2 (stock out)	Incident 3 (stock out)	Incident 1 (stock out)	Incident 2 (stock out)	Incident 1 (stock out)	Incident 2 (stock out)
Denkaka Health Centre (HC)					221 days	186 days	
Gobeseye HP	45 days			44 days			
Gulale Boru Bodecha HP		35 days		222 days			
Sagure HC			30 days	109 days	66 days	110 days	114 days
Seka HC		214 days	166 days				
Serbo HC					47 days		32 days

EPSA assigned one refrigerated truck to each of its 13 Hubs. However, EPSA would requisition and pull back these trucks every three months to the CVS, so that it could fulfil its long-haul deliveries out to each of the Hubs using them. As a result, this would frequently impact upon the Hub's onward distribution cycle for that respective month.

As part of the Hubs' deliveries to their respective woredas, additional direct deliveries are made to those health facilities located along the delivery route. In effect, this meant that woredas were left with the responsibility to cover the "harder-to-reach" facilities. EPSA has no visibility on such onward downstream deliveries managed by the woredas.

Recommendation 18

FMOH/EPSA should review and access the feasibility of scaling up the 3PL model piloted in Hawassa region to other locations to increase the direct deliveries.

Recommendation 19

Through the available Standard Operating Procedures (SOPs), FMOH should provide a clear practical process to EPSA for reporting and handling of the near-expiry stocks. If short shelf-life stocks are identified at the EPSA CVS or Hubs, then the EPSA and EPI should closely monitor the stock utilisation for effective expiries management.

EPSA engaged a third-party logistics (3PL) provider (together with Global Fund support) to a pilot direct "last-mile deliveries" across the city Hawassa, in Sidama region. By July 2022, 67% of the Health Facilities/posts in that zone were successfully receiving direct deliveries of their stocks from the Hawassa Hub.

Expiries - central and subnational level

Inventory reports highlighted significant shelf-expired vaccines during the period 2018 – 2022. Based on the audit team's selection of 3 antigens and 6 Hubs, it was concluded that at least 4 of these Hubs, 1 of the woredas and 6 of the health facilities experienced vaccine expirations for at least one of the antigens. See Annex 6 **and Annex 7** for details.

Prior to 2019, the CVS stock holdings were spread out across 11 locations, complicating the storage and movement of vaccines due to the dispersed cold-chain capacity. As a consequence, EPSA was not able to systematically and consistently issue its vaccines, in compliance with earliest expired first out principles, resulting in the CVS occasionally sending out near-expired vaccines to its Hubs. Since 2019, due to the expansion of CVS' cold-chain capacity, increased routine physical counts, and the consolidation of eleven storage sites to three sites), the quantities of shelf-expired doses at the CVS and Hub level, has decreased.

For example, the audit team noted one incident in April 2017 when the EPSA-CVS issued 88,490 near-expired doses of PCV (i.e. with less than 2 months shelf life) to its Hubs, see Annex 8 for details. EPSA did not have clear policy in place for how to handle near-expired vaccines. Consequently, the audit team noted expirations occurring for batches of short shelf-life vaccines in Hawassa, Jimma and Arbramich Hubs – as they did not distribute these stocks before expiry.

Root Cause

- Intermittent stockouts in health facilities are attributable to distribution operational inefficiencies (from Hubs and woredas – i.e. stock supplied by the previous tier), resulting in delays in completing last mile deliveries to the affected sites.
- The dispersed capacity of CVS' cold-chain storage across multiple locations, during the three-year period (2018-2020) meant that vaccine distributions were not consistently compliant with EEFO principles.

Management comments

Detailed management responses are included in Annex 17 of this report.

Risk / Impact / Implications

If "last-mile" distribution processes are not effective or efficient, vaccines will not be delivered on time to the required locations, resulting in missed vaccination opportunities, and potentially putting additional stress on the health system (e.g. improvisation by health workers , which is not sustainable).

Responsibility

Refer to Annex 17

Responsibility

Refer to Annex 17

4.2.4 Gaps in cold chain maintenance

Context and Criteria

Section 2.2 of EPSA's five-year vaccine distribution strategy (2018-2023) emphasises the importance of expanding and strengthening the cold-chain infrastructure across both central and subnational levels. Key activities include decommissioning of obsolete equipment; implementing preventive maintenance plans; and establishing a repair and maintenance workshop.

EPSA's five year distribution strategy highlighted that "in general, the cold chain capacity at both central and Hub levels is adequate for requirements over the next five years." However, this claim was not supported, as neither storage capacity assessment nor future volume projection was undertaken. EPSA suggested that it had carried out storage capacity assessment, but it was unable to provide the relevant report and its findings. See Annex 12 and Annex 13 for current volumes. The combined investments in CCE from SDG-PF and Cold Chain Equipment Optimisation Platform (CCEOP) grants was able to cover 4,077 (100%) Health Facilities and 11,676 of 16,447 (71%) of health posts.

Condition

The audit team reviewed the status of a sample of cold chain units across the central level and subnational sites and noted the following:

- **Lack of an inventory of spare parts:** The EPSA preventive maintenance and repair workshop established in 2020 at the central level, did not maintain an inventory of spare parts to service routine and preventive maintenance activities. Consequently, technicians were often unable to perform scheduled maintenance works. As of July 2022, EPSA was in the process of procuring the necessary spare parts.
- **Workshop does not support preventative maintenance at woreda and health facility level:** The maintenance and repair workshop were set-up to service the Hubs' needs. However, there was no mechanism for this central-level function to also support preventive maintenance at the woreda and health facility levels, as it did not have any visibility on the status and functionality of cold-chain units operating at these subsidiary levels.
- **Absence of serviceable parts and dedicated resources for repair and preventive maintenance** at the RHBs to support the woreda and Health Facilities.
- **19 of 39 (49%) of health facilities visited by the audit team did not have logbook to record their preventive maintenance activities**, and the audit team could not substantiate on whether regular maintenance took place. The audit team noted non-functional CCE at two woredas (Digalu and Lode Hetosa).
- **EPSA did not have a process for decommissioning of obsolete equipment such as, cold chain equipment and cold chain trucks**. The April 2018 CHAI cold-chain capacity assessment reported that significant number of cold-chain units at the subnational level, were non-functional, could not be repaired or were obsolete. At the time of the assessment approximately, 1,774 equipment units across 4,077 health facilities and 2,855 units from 16,447 health posts, were in need for disposal and replacement.
- **Lack of adequate capacity and training** for the CCE maintenance technicians at the woreda level to support the health facilities.

Recommendation 20

EPSA-CVS and the Hubs should maintain a current inventory of all necessary spare parts for repair and routine maintenance.

Recommendation 21

FMOH should set up a suitable forum enabling EPSA to engage with RHBs' management to mobilise and allocate adequate resources for cold chain maintenance and repairs. EPSA should develop and implement a suitable CCE maintenance plan to train technicians at the woreda level.

Root Cause

- Poor coordination between EPSA, EPI and the RHBs on preventive and restorative maintenance.
- Unclear roles and responsibilities for the concerned stakeholders (EPSA, EPI and the RHBs).
- No policy in place for decommissioning obsolete cold-chain equipment.

Management comments

Detailed management responses are included in Annex 17 of this report.

Risk / Impact / Implications

- Risk of equipment breakdown due to inadequate planned or executed maintenance, and consequently the integrity of the cold chain could be compromised, resulting in vaccines being exposed to unsafe temperatures.

Responsibility

Refer to Annex 17

Responsibility

Refer to Annex 17

4.2.5 Waste management practices need improvement

Context and Criteria

EPSA's EPI/30/31 standard operating procedure (SOP) (from April 2015) provides guidance on the management of obsolete and damaged vaccines and diluents. The SOP requires that the officers managing vaccines (across all levels of the health system) identify each month, any items within the supply chain which need to be written off. Where such vaccines or diluents are to be condemned, EPSA should generate an e-LMIS "expiry report" and submit it to the EPI for validation. Following approval, the written-off items should be handed over by the logistics team to the quality assurance team. Condemned stocks need to be quarantined until they can be destroyed, in compliance and under authority of the Ethiopia Food and Drug Administration's (EFDA) "stores and operations manual".

Condition

The audit team compared the existing wastage management policies against the actual practices across a sample of sites from all levels of the supply chain and noted the following:

- **EPSA's e-LMIS was unable to produce the necessary expiry reports accurately (see also issue 0).** In addition, EPSA did not routinely/habitually generate the necessary "expiry reports" and share these with EPI.
- **The existing policies governing the management and disposal of medical waste were not fully operationalised** - Responsibility for waste management disposal was delegated to each level that is central, woreda and HF levels. The policies were not consistently applied with some woredas using incinerators, and other facilities disposing of medical wastage through the burn and bury process i.e. open burning of waste in a pit.

Recommendation 22

FMOH/EPSA should implement the policy and procedures for the safe management of medical waste generated from immunisation. The sites lacking infrastructure for safe disposal should be allowed for reverse logistics so that the waste is collected at Hub or Woreda level with the necessary disposal capabilities.

Root Cause

- Insufficient or inadequate infrastructure for medical waste management at subsidiary levels.
- Absence of approved reverse logistics to relay medical waste to other sites with safe disposal measures.

Management comments

Detailed management responses are included in Annex 17 of this report.

Risk / Impact / Implications

- Inadequate waste management may result to usage of expired vaccines and leading to adverse health impacts.
- Inappropriate waste disposal mechanisms may have serious environmental impacts and unauthorised usage in the market.

Responsibility

Refer to Annex 17

Responsibility

Refer to Annex 17

4.3 Immunisation data management

4.3.1 Inconsistencies in administration data coverage and use of outdated denominator

Context and Criteria

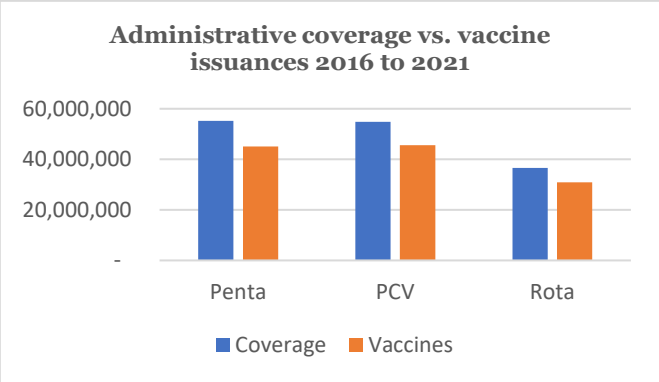
Clause 8.1 (d) of the PFA requires that the Government represents, on the date of each disbursement by Gavi (per clause 8.2) that all information provided to Gavi including its applications, progress reports, any supporting documentation, and other related operational and financial information or reports, is accurate and correct as of the date of the provision of such information. In addition, paragraph 16 of Annex 2 of the PFA sets out additional provisions on monitoring and reporting, specifying that "the Government's use of Gavi's vaccine and cash support is subject to strict performance monitoring," and that: "Gavi seeks to use the Government's reports and existing country-level mechanisms to monitor performance."

Condition

Outdated denominator data used to set targets and monitor administrative coverage: Ethiopia has not conducted a national census since 2007. The FMOH sets its annual immunisation targets based on projections using the 2007 census data. By discussion, it was established that the denominator data used to determine targets and coverage is unlikely to be accurate because:

- For regions such as, Oromia, Sidama and Harari, the immunisation coverage subsequently reported consistently exceeded 100%, suggesting inaccurate targets (i.e., set too low) or that the coverage results were inflated.
- Use of census data fifteen years old, will not provide a close approximation to current population figures, due to shifts demographics and exogeneous events such as, conflicts and migration.
- Some regions reported diseases outbreaks despite achieving sufficiently high coverage against their set target.

Anomalies in reported administrative coverage – There are inconsistencies in the administrative coverage reported by the country for the period under review. A comparison of the number of doses issued by EPSA, and the administrative coverage reported over a five-year period (equivalent to the number of children vaccinated between 2016 and 2021) indicates that the coverage was consistently higher than the doses available, which is not physically possible. The same finding applied across all three vaccines examined: Penta, PCV and Rota. The audit team's analysis was adjusted for wastage using the lowest available wastage rate (5% across the three antigens). The over-reporting of coverage signifies either data entry inefficiencies or data manipulation. The audit team calculated that during the audit period, there were variances of between 23% to 38%, in comparing the coverage reported and doses issued for Penta and PCV, respectively. These differences are illustrated below:



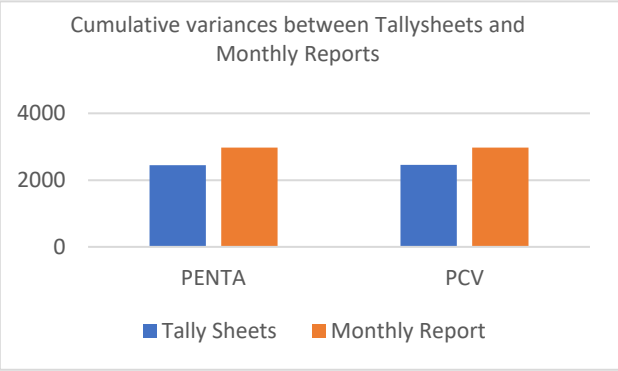
Data consolidation inaccuracies: Health facilities use the "HF monthly service reports" to collate and consolidate immunisation data from their tally sheets. These reports are used to enter data into DHIS 2 at HF level. Consequently, at the HFs visited, the audit team reviewed and compare a sample of monthly reports to the tally sheets, for three different months (Mar-18, Jun-19 and Dec-21). 25% of the health facilities had unexplained variances between their monthly reports and tally sheet, for at least one of the three antigens selected (refer to Annex 15). The audit team also noted differences between the

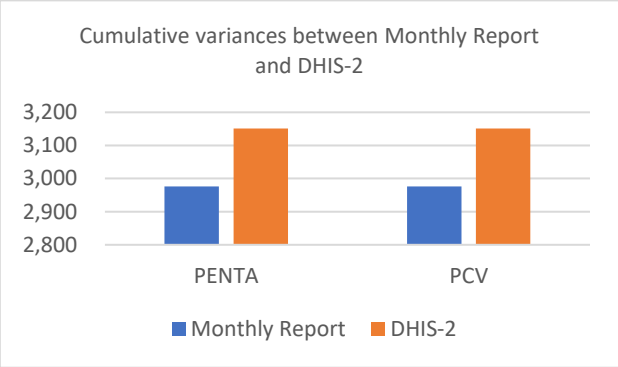
Recommendation 23

FMOH/PPMED should:

- Routinely undertake data triangulation to verify accuracy of its coverage data. Such analyses should be completed at national and subnational levels and any data inconsistencies noted should be followed up and investigated.
- Ensure that all primary data collection tools are completed correctly and correlate or support each other.
- Consistently have the PMTs complete and document data verification and validation exercises at the health facility, woreda and regional levels as required by the guidelines.
- Conduct the required surveys and use the results to review the administrative coverage.
- Ensure adequate supervision at subnational level over data collection and management including follow up of recommendations to address data management gaps from routine supervision visits and programme audits.

monthly service reports and the respective data input into DHIS-2. Cumulative aggregate variances in the 39 HFs visited by the audit team (focusing on the selected 3 months) are illustrated below:





Significant variances between the WUENIC coverage and DHIS2 admin data: The audit team compared the administrative coverage data reported by the country with the WHO UNICEF Estimates of National Immunisation Coverage (WUENIC) for the period 2016 - 2020 and noted significant variance between the two data sets, with the administrative data being consistently higher than the WUENIC data.

Table 7: Variances between administrative data and WUENIC data

Vaccine:	Penta		PCV		Rota	
Year	WUENIC	Admin	WUENIC	Admin	WUENIC	Admin
2016	66%	98%	61%	96%	63%	97%
2017	68%	97%	64%	96%	67%	95%
2018	67%	96%	63%	95%	66%	93%
2019	68%	97%	64%	97%	68%	95%
2020	71%	99%	67%	98%	70%	97%

Variations between the incidence of Penta and PCV immunisations: According to the national immunisation schedule, both Penta and PCV doses are to be administered at the same time, i.e., at intervals of 6 weeks, 10 weeks and 14 weeks. Therefore, it can be expected that the coverage for both vaccines should be close, if not identical. However, the audit team noted a consistent difference in the higher incidence of Penta, when compared to the PCV immunisations reported as illustrated below.

Table 8: Variances between PCV and Penta coverage

	Penta (1+2+3)	PCV (1+2+3)	Variance
2017/18	9,078,164	8,997,918	80,246
2018/19	9,311,802	9,197,425	114,377
2019/20	9,814,261	9,681,926	132,335
Total	**28,204,227**	**27,877,269**	**326,958**

<table>
<tr><td>Root Cause
• Weaknesses in data quality assurance: The Policy Planning Monitoring & Evaluation Directorate has taken steps to ensure improvements in data quality. However, there still remain disparities at the points of data collection. This is evidenced by the results of the FMOH's periodic data quality reviews (2017 & 2018), which showed that only 51% of the verified data matched source documents.
• Ethiopia has not conducted a national census since 2007 and thus the FMOH sets its annual immunisation targets based on projections using the 2007 census data which is outdated.</td><td colspan="2">Management comments

Detailed management responses are included in Annex 17 of this report.</td></tr>
<tr><td>Risk / Impact / Implications
Reliance on inaccurate or over-reported immunisation coverage data may adversely impact upon decisions regarding whether supplemental activities are needed, to increase actual coverage or the quality of data processes. Exaggerated subnational level coverage rates, could also result in scarce resources being reallocated to other public health priorities, thereby increasing the likelihood that disease outbreaks occurring due to inadequate levels of immunisation protection.</td><td>Responsibility
Refer to Annex 17</td><td>Responsibility
Refer to Annex 17</td></tr>
</table>

4.3.2 Weaknesses in data quality assurance mechanisms

Context and Criteria

Clause 8.1 (d) of the PFA requires that the Government represents, on the date of each disbursement by Gavi (per clause 8.2) that all information provided to Gavi including its applications, progress reports, any supporting documentation, and other related operational and financial information or reports, is accurate and correct as of the date of the provision of such information. In addition, paragraph 16 of Annex 2 of the PFA sets out additional provisions on the monitoring and reporting, specifying that "the Government's use of Gavi's vaccine and cash support is subject to strict performance monitoring," and that "Gavi seeks to use the Government's reports and existing country-level mechanisms to monitor performance."

Gavi's application guidelines require Gavi-supported countries to improve data availability, quality and use the data for planning, programme management and understanding and documenting of results. The guidelines encourage the use of immunisation coverage data as an ongoing institutionalised process for better planning, improved programme performance and resource management.

Condition

Unsatisfactory data quality assurance and monitoring mechanisms: The FMOH instituted various data quality assurance and monitoring mechanisms including establishment of performance monitoring teams (PMT) at Health Facilities; consistency checks using "lot quality assurance sampling" (LQAS); routine data quality assessment (RDQA); and data quality reviews (DQR). The audit team noted the following gaps in these data assurance processes:

- **Weaknesses in immunisation data validation and verification:** Performance Monitoring Teams (PMT) are required to review Health Facilities using the LQAS, 12 indicators on a monthly to check for their accuracy against source documents. The team noted that although PMTs meetings were held, there was no evidence of follow-up of data gaps once identified by the PMT at respective HFs. As such, the team could not confirm if the necessary corrective actions were taken to improve data quality. We also noted that some Health Facilities (such as Yergalem health centre and Areka health centre) consistently reviewed the same indicators throughout the year, while avoiding data checks for the remaining indicators.
- **Integrated support supervision (ISS) did not comprehensively cover data quality aspects** related to routine immunisation and there was no evidence of feedback provided on data gaps noted during support supervision at the HFs. In addition, there was no evidence of linkage between the PMT reviews and ISS.
- **The ISS guidelines require that woreda health offices should supervise their health centres** every two months and health posts every month. However, we noted that the frequency of support supervision and onsite data verification was sporadic, and that 10% of the Health Facilities visited by the team, had not received a supervision visit for at least twelve months.
- **The data quality review process was incomplete as it was limited to focusing on Penta 3 coverage only**. In addition, routine data quality review (2017) and health data quality review (2018) showed data quality gaps without specific data quality improvement recommendations. The FMOH did not carry out any data quality reviews in 2019, 2020 and 2021. There was also lack of follow-up on the recommendations from the routine data quality reviews (2017) and health data quality review (2018) .
- **DHIS2 safety or data protection measures to avoid post facto adjustments have not been activated**. Consequently, the audit team noted variances between Tally sheet, monthly reports and DHIS 2 at HFs visited which suggests data inaccuracies or errors in compilation/consolidation.
- **Human resources capacity gaps at HF level.** Of the 39 facilities visited, 8 hadn't received training in data management in the past 12 months.

Delay in DHIS2 reporting - According to the Ethiopian "Health Management Information System" procedural manual, Health Facilities are expected to report by the 26th day of the subsequent month. From a review of the DHIS2 reports, the audit team noted that significant number of the Health Facilities were reporting later than this deadline as illustrated below:

Table 9: Late reporting in DHIS-2

Year	Percentage of HFs reporting on time	Percentage of HFs reporting late
2018/2019	63%	37%
2019/2020	52%	48%
2020/2021	57%	43%

Recommendation 24

FMOH/PPMED should conduct a routine data quality assessment on an annual basis, as required by the HMIS guidelines. Based on the findings of the assessment, it should ensure that the ensuing recommendations are followed up and implemented.

Recommendation 25

FMOH/PPMED should strengthen data quality review processes at the national and subnational levels. ISS should be revised to include data quality indicators. Similarly, subnational level reviews should be improved by PMT refresher training, and the ISS checklist should be reviewed to include adequate aspects of data quality. When undertaking the data quality reviews, these should be documented resulting in an action plan, as well as implementation and follow up thereof.

Recommendation 26

FMOH/PPMED should lock DHIS2 after a specific interval or reporting period, in order to retroactive data entries and institute a post facto process to record belated (but necessary) data entries subject to exceptional approval.

<table>
<tr><td>Root Cause
• There was no evidence of follow-up on recommendations from PMT meetings. This leaves a gap in data quality assurance if recommendations to correct gaps are not addressed.
• DHIS2 is not locked to prevent any post-facto adjustments to the system.
• There are skill gaps at the health facility level.
• Infrastructure challenges like access to internet and power outages which lead to delayed reporting.</td><td colspan="2">Management comments

Detailed management responses are included in Annex 17 of this report.</td></tr>
<tr><td>Risk / Impact / Implications
• Inaccurate or incomplete health data can compromise the accuracy of public health decision making.</td><td>Responsibility
Refer to Annex 17</td><td>Responsibility
Refer to Annex 17</td></tr>
</table>

4.4 Budgeting and financial management

4.4.1 Gavi standalone grants were not adequately ring-fenced and their grant management practices did not fully comply with Gavi requirements

Context and Criteria

Paragraph 23 of Annex 2 of the PFA requires that "the Government shall maintain accurate and separate accounts and records of each of the programmes prepared in accordance with internationally recognised standards that are sufficient to establish and verify accurately the costs and expenditures under the programmes."

Clause 7.3 of the PFA requires that the Government "comply with all policies, guidelines and processes of Gavi that are relevant to the Programmes which shall form part of this agreement" and the guidelines on financial management and audit requirements are applicable accordingly.

Clause 15 of the PFA states that "Gavi funds provided under [the PFA] shall not be used to pay any taxes, customs, duties, toll, or other charges imposed on the importation of vaccines and related supplies. The Government shall use its reasonable efforts to set up appropriate mechanism to exempt from duties and taxes all purchases made locally and internationally with Gavi funds."

Gavi's grant management requirements (June 2020) state that:

- The FMOH will submit financial reports to Gavi every six months in line with the Gavi Guidelines on Financial Management and Audit Requirements. This will include ensuring proper linking of activities to budgets and source of funding at all levels of spending, appropriate adjustment of advances to subnational levels and staff from reported expenditure and clear consolidation of reports at the federal level.
- To achieve optimal management of advances at subnational levels, the FMOH will consider signing Memoranda of Understanding (MOU) with Regional Health Bureaus detailing responsibilities on financial management among other provisions.
- The FMOH will ensure that an ageing list of advances issued to staff and subnational levels is maintained and updated on a continuous basis. A consolidated status of outstanding advances will be included in the financial reporting to Gavi as outlined in the Gavi financial reporting guidelines and template.
- To address the gaps noted in relation to management of advances, the Finance and Procurement Directorate (F&PD) of the FMOH will ensure that no new advances will be issued to staff and regions before liquidating at least 80% of older advances which are due.

Condition

Traceability of Gavi funds: The grant management requirements require that Gavi's standalone grants are channelled through the same bank accounts as those used for the SDG PF monies – to be managed in accordance with the PFA and the applicable laws and regulations of the country. As a result, Gavi's grants standalone funds were commingled with other funding sources (both Gavi and other donors' funds) in the bank accounts in place at each administrative unit located across the regions, zones, woredas, as well as the federal level. At the federal level, bank reconciliations of the comingled bank account were performed by the Finance Directorate every month. However, there was no evidence that such monthly bank reconciliations of the respective comingled bank accounts, situated across regional, zonal and woreda levels, were done.

Gaps in financial reporting: Section 12 of Gavi's "guidelines on financial management and audit requirements" (Nov 2017) requires every country to use the Gavi standard reporting template for their financial reporting. However, the audit team noted that as of July 2021 the FMOH had never reported using Gavi's standard reporting template.

Inadequate budget monitoring practices at the federal level: The audit team noted the following gaps in the budget monitoring process:

- Gavi standalone grants were managed using an accounting system (Peachtree) that was incapable of analysing budget versus actual expenditures.
- Since 2017, so that the Finance Directorate could monitor its budget, it initiated an internal "budget versus actual analysis" reporting process. Because these analyses treat disbursements as expenditures, they do not convey the actual grant absorption status. The disparity in budgetary analyses from focusing on disbursement instead of absorption, is significant given that an important proportion of advances disbursed to the RHBs, remains unliquidated for an extended period.

Recommendation 27

The FMOH should:

- redesign its management processes for Gavi standalone grants to comply with Gavi's guidelines on financial management, including specifically using the financial reporting template provided;
- Mandate that memorandum of understandings (MOU) are put in place between the FMOH and each RHB. These MOUs establish directives on the use of Gavi funding including, that: funds be utilised in accordance with agreed workplans; RHBs' regularly report back using the Gavi financial reporting template; dedicated bank accounts for Gavi standalone grants be established; and agreement upon deadlines by which advances must be liquidated; and
- finalise the "FMOH financial management manual" to address gaps. The MOU should mandate and underline the importance that the manual's prescriptions are complied with.

Review and validation of regional level expenditure by the FMOH: RHBs submit statements of expenditure (SOEs) to the FMOH, to justify the advances disbursed to them by the FMOH. The SOEs were neither intended to provide specific details on the activities implemented, nor were they accompanied with accounting or supporting documentation. Based on the audit team's review, it observed that there was no evidence of the FMOH formally reviewing or validating RHBs expenditures, and no compensatory mechanism was in place to provide the FMOH with any assurance prior to its closing out and retiring the RHBs' advances based on the SOEs.

No evidence of VAT refunds at the regional level: The FMOH has a process to track and claim any VAT it incurred at the federal level, with the VAT claims being refunded by the Ministry of Finance. In contrast, at the regional level, the audit team noted that there was no evidence of an equivalent process to track, claim and validate regional level VAT refunds.

Advances disbursed to the RHBs remained unliquidated for an extended period: In July 2018, Gavi wrote to the FMOH requesting that it settle all unliquidated advances by 31 December 2018, in particular for the vaccine introductory grants and campaign operational support funds. Thereafter by 15 January 2019, the FMOH was to share an update summary on the refunds and remaining unliquidated advances. The audit team noted that these tasks were still not completed by July 2022. As of 30 June 2022, the overall RHBs unliquidated advances position that was over 1 year totaled USD 13,515,348, of which USD 554,338 (4.1%) had been outstanding for more than two years. These amounts exclude CDS and HSS grants of USD 17,454,844 (ETB 890,197,058) that were less than one year at the time of fieldwork. The outstanding advances position for funds over one year is summarised below:

Table 10: unliquidated advances for Gavi standalone grant only

Grant	Between 1-yr and 2-yr	>2 years	Total ETB	Equivalent USD
SIA (measles 2nd dose) – *subsequently reviewed by FTA*	214,880	2,503,879	2,718,759	*53,310*
HPV Vaccine Introduction Grant (VIG) – *subsequently reviewed by FTA*	28,599	2,817,020	2,845,619	*55,796*
Measles SIA (Campaign) – *subsequently reviewed by FTA*	51,214,166	3,720,201	54,934,367	*1,077,144*
HSS 2	24,389,697	15,525,689	39,915,386	*782,654*
HSS 3	569,756,311	0	569,756,311	*11,171,688*
PIRI	0	901,546	901,546	*17,677*
HSS Re-programming to COVID-19 Response	15,408,092	0	15,408,092	*302,120*
PCV VIG	0	2,802,935	2,802,935	*54,959*
TOTAL ETB	**661,011,745**	**28,271,270**	**689,283,015**	
***Total USD** equivalent*	***12,961,010***	***554,338***	***13,515,348***	***13,515,348***

**Refer to section 2.2 for details of standalone grant funds disbursed.*

Events subsequent to the audit

After the audit, the Gavi secretariat engaged financial technical assistance (FTA) to review several historic grants to help facilitate their closure and determine which residual expenditures for specific grants could be validated and whether any advances remained outstanding. This review also included HPV VIG and Measles SIA grants which were reviewed by the audit team and unliquidated advances were noted as detailed in Table 10. The audit team relied on the work performed by the FTA and adjusted the unliquidated advances for those grants to the amounts confirmed by them. The table below summarises the residual unjustified advances/ expenditures from the various grants which the FTA reviewed.

Table 11: Unjustified balances based on the financial technical assistance agent review

Grant:	Cash and receivable balances @ 07/07/23 (A)	Commitments/ liabilities (B)	Total ETB (A – B)	USD Equivalent
Pneumo	8,101,003	-	8,101,003	***158,843***
ROTA	170,682	-	170,682	***3,347***
IPV	240,313	-	240,313	***4,712***
HPV	6,779,044	18,142	6,760,902	***132,567***
Men A	5,314,144	11,050	5,303,094	***103,982***
Measles 2016	1,435,306	8,432	1,426,873	***27,978***
Total	**22,040,492**	**37,624**	**22,002,867**	***431,429****

**Used average exchange rate of ETB 51 to USD 1*

After considering the financial technical assistance agent's work, the remaining unjustified advances amounted to USD 12,760,526. Given the passage of time, the audit teams considers these amounts to be questionable as summarised below

Table 12: Total expenditures questioned by the audit team

Grant Name	Questioned amount USD
HSS 2	***782,654***
HSS 3	***11,171,688***
PIRI	***17,677***
HSS Re-programming to COVID-19 Response	***302,119***
PCV VIG	***54,959***
Total (A)	***12,329,097***
Amount questioned by TA (B)	***431,429***
Total USD (= A+B)	***12,760,526***

Additionally, in recognition of the systemic financial management issues at the RHBs, Gavi deployed additional financial technical assistance to review financial management at RHBs and provide practical solutions for budgeting and expenditure liquidation. This work started in 2023 and is ongoing.

Root Cause

- The Government's "FMOH financial management manual" was still in draft form at the time of our review. This manual sets out various financial management processes including: budget monitoring; reconciliation of commingled bank accounts; validation of expenditure documents; the treatment of advances; and reporting.
- Absence of understanding between the FMOH and RHB regarding the: use of Gavi grants as per agreed workplans; use of Gavi financial reporting template; maintenance of dedicated bank accounts; and timelines for liquidating advances.

Management comments

Detailed management responses are included in Annex 17 of this report.

Risk / Impact / Implications

- Risk of misuse of Gavi grants.
- Lack of visibility on workplan execution and grant performance.
- Gavi could delay its future grant disbursements, due to noncompliance with its financial management requirements.

Responsibility

Refer to Annex 17

Responsibility

Refer to Annex 17

4.4.2 Non-compliance with COVID-19 vaccine delivery support funding guidelines

Context and Criteria

COVID-19 vaccine delivery support (CDS) programme funding guidelines (July 2021) state that "countries which applied for the CDS Early Access Window funds should be able to utilise the funds within six months of receiving the funds. The CDS grant recipients are required to provide both programmatic and financial reporting to Gavi. Recipients will be required to report on a semi-annual (six-monthly) basis on activity completion rates as well as progress against a set of core programmatic performance metrics". In addition, expenditures relating to per diems and allowances should not exceed 40% of the grant amount.

Clause 7.3 of the PFA requires that the Government "comply with all policies, guidelines and processes of Gavi that are relevant to the Programmes which shall form part of this agreement" and the guidelines on financial management and audit requirements, as well as COVID-19 vaccine delivery support guidelines are applicable accordingly.

Condition

In order to support countries in rapidly and equitably scaling-up their Covid19 immunisation, Gavi supported eligible countries with COVID-19 operational funding. Such funds were intended to be aligned and complementary to other funding sources available to the government, for example resources financed from: domestic sources, other donors, and multilateral development banks and agencies. Gavi's CDS support was meant to enable the rapid roll-out and scale up of COVAX-funded doses until the end of 2022. Gavi approved and disbursed two separate CDS grants to the FMOH as follows: USD 14.5 million in September 2021; and USD 8.2 million in April 2022. The audit team noted the following non-compliance elements:

- **Delayed programmatic and financial reporting:** By July 2022, the FMOH had not yet submitted the required programmatic and financial reports to Gavi. These reports were due by March 2022 against the first CDS disbursement.
- **Unused CDS funds:** A significant proportion of the CDS funds received by the FMOH in September 2021 were not yet used as of June 2022 more than nine months since receiving the funds. 58% (USD 14,136,445) of the funds were reported as unliquidated advances to RHBs.
- **64% of the first CDS disbursement was allocated by the FMOH for per diem and allowances expenditures.** This exceeds the maximum cap of 40% as instructed by Gavi's CDS programme funding guidelines (July 2021).

Recommendation 28

FMOH should comply with the Gavi funding requirements and COVID-19 vaccine delivery support funding guidelines. Any proposed deviations from these instructions should be explicitly approved by Gavi and documented by the FMOH, prior to allocating funds.

Root Cause

Noncompliance with the CDS funding guidelines.

Management comments

Detailed management responses are included in Annex 17 of this report.

Risk / Impact / Implications

Material noncompliance with the PFA could lead to termination of funding.

Responsibility

Refer to Annex 17

Responsibility

Refer to Annex 17

4.4.3 Expenditure inadequately supported or ineligible

Context and Criteria

Paragraph 23 of Annex 2 of the PFA requires that "the Government shall maintain accurate and separate accounts and records of each of the Programmes prepared in accordance with internationally recognised standards that are sufficient to establish and verify accurately the costs and expenditures under the Programmes. The Government shall maintain such accounts and records and any other supporting documents evidencing expenses made with Gavi's funds according to the Country's fiscal requirements for a minimum of five years after the completion of a Programme."

Condition

The audit team reviewed ETB 1,549,701,331 (USD 30,386,301) of expenditures incurred across various administrative entities drawn from the FMOH, RHBs, ZHBs and woredas. This was equivalent to 67% of Gavi-funded expenditures incurred during the audit period. The audit team determined that 3.2% of the expenditures reviewed were questionable, as summarised in the table below. For details, refer to Annex 16**.**

Table 13: Expenditures questioned by the audit team

Entities:	Inadequately supported	Ineligible	Total (ETB)	Total (USD)
FMOH	-	49,385,398	49,385,398	*968,341*
Sidama	445,048	-	445,048	*8,726*
Amhara	18,450	-	18,450	*362*
Total	**463,498**	**49,385,398**	**49,848,896**	***977,429***

Inadequate supporting documents: Documentation evidencing training and workshop activities, was limited to payment sheets (occasionally attendance sheets were also available). However, training reports were not available, and in some cases the attendance sheets provided were undated. Consequently, the audit team could not obtain adequate assurance that the expenditures were related to Gavi-funded activities.

Ineligible expenditures: The ineligible expenditures relate to the FMOH's use of Gavi's CDS funds to print data recording tools, that were unrelated to programme. The FMOH did not obtain approval from Gavi to use these funds for non-COVID-19 related activities.

Post-audit

As of 31 December 2022, ineligible expenditures totalling ETB 49,385,398 were refunded into an in-country bank account earmarked to Gavi, including the supporting bank statement.

Recommendation 29

In future, the FMOH should ensure that all expenditures are:

- Filed with sufficient, accompanying supporting documents to evidence the validity and accuracy of the transactions, including activity reports, attendance sheets, fuel/vehicle logbooks.
- Incurred in compliance with the relevant Gavi funding guidelines.

Root Cause

- Lack of FMOH review and validation of regional level expenditures.
- Management oversight to ensure compliance with Gavi's CDS funding guidelines.

Management comments

Detailed management responses are included in Annex 17 of this report.

Risk / Impact / Implications

Material noncompliance with the PFA could lead to termination of funding.

Responsibility

Refer to Annex 17

Responsibility

Refer to Annex 17

5. Annexes

Annex 1 : Acronyms

CCE	Cold chain equipment
CCEOP	Cold Chain Equipment Optimisation Platform
EPI	Extended Programme on Immunisation
EPSA	Ethiopian Pharmaceuticals Supply Agency
FMOH	Federal Ministry of Health
HCMIS	Health Commodity Management Information System
HSS	Health Systems Strengthening
HC	Health Centre
ICC	Interagency Coordinating Committee
LMIS	Logistics Management Information System
RHB	Regional Health Bureau
SDG	Sustainable Development Goals
SDG-PF	Sustainable Development Goals Pool Fund
SOP	standard operating procedures
USD	United States Dollars
VIG	Vaccine Introduction Grant

Annex 2 : Methodology

Gavi's Audit and Investigations (A&I) audits are conducted in accordance to the Institute of Internal Auditors' ("the Institute") mandatory guidance which includes the Core Principles for the Professional Practice of Internal Auditing, the definition of Internal Auditing, the Code of Ethics, and the International Standards for the Professional Practice of Internal Auditing (Standards). This mandatory guidance constitutes principles of the fundamental requirements for the professional practice of internal auditing and for evaluating the effectiveness of the audit activity's performance. The Institute of Internal Auditors' Practice Advisories, Practice Guides, and Position Papers are also be adhered to as applicable to guide operations. In addition, A&I staff will adhere to A&I's standard operating procedures manual.

The principles and details of the A&I's audit approach are described in its Board-approved Terms of Reference and Audit Manual and specific terms of reference for each engagement. These documents help our auditors to provide high quality professional work, and to operate efficiently and effectively. They help safeguard the independence of the A&I's auditors and the integrity of their work. The A&I's Audit Manual contains detailed instructions for carrying out its audits, in line with the appropriate standards and expected quality.

In general, the scope of A&I's work extends not only to the Secretariat but also to the programmes and activities carried out by Gavi's grant recipients and partners. More specifically, its scope encompasses the examination and evaluation of the adequacy and effectiveness of Gavi's governance, risk management processes, system of internal control, and the quality of performance in carrying out assigned responsibilities to achieve stated goals and objectives.

Annex 3 : Definitions – audit opinion, audit rating and prioritisation

A. Overall Audit Opinion

The audit team ascribes an audit rating for each area/section reviewed, and the summation of these audit ratings underpins the overall audit opinion. The audit ratings and overall opinion are ranked according to the following scale:

Effective	**No issues or few minor issues noted**. Internal controls, governance and risk management processes are adequately designed, consistently well implemented, and effective to provide reasonable assurance that the objectives will be met.
Partially Effective	**Moderate issues noted.** Internal controls, governance and risk management practices are adequately designed, generally well implemented, but one or a limited number of issues were identified that may present a moderate risk to the achievement of the objectives.
Needs significant improvement	**One or few significant issues noted.** Internal controls, governance and risk management practices have some weaknesses in design or operating effectiveness such that, until they are addressed, there is not yet reasonable assurance that the objectives are likely to be met.
Ineffective	**Multiple significant and/or (a) material issue(s) noted.** Internal controls, governance and risk management processes are not adequately designed and/or are not generally effective. The nature of these issues is such that the achievement of objectives is seriously compromised**.**

B. Issue Rating

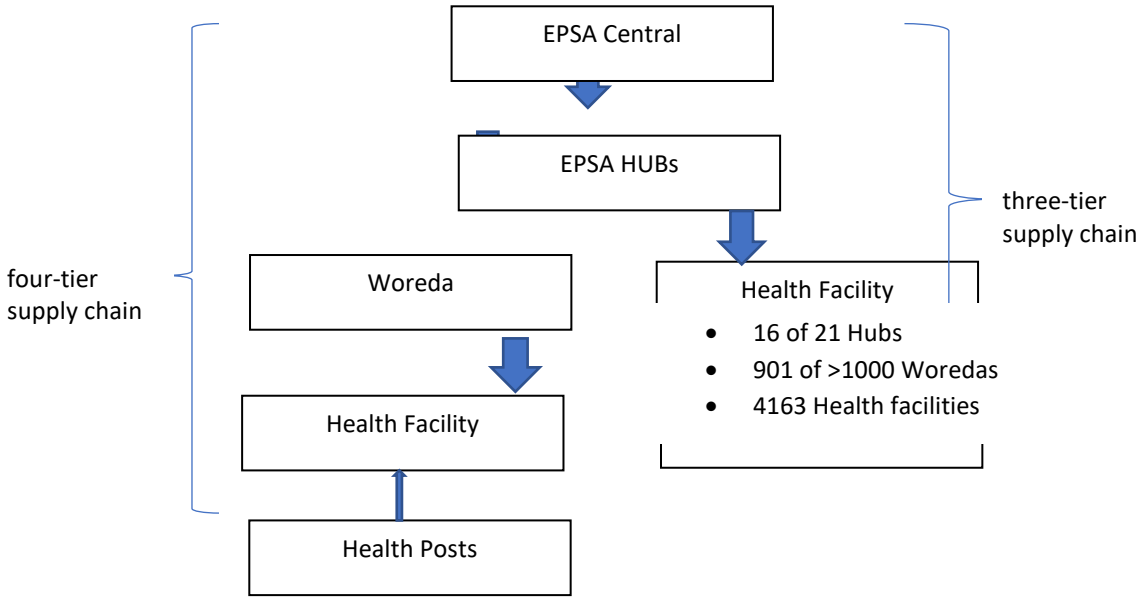
For ease of follow up and to enable management to focus effectively in addressing the issues in our report, we have classified the issues arising from our review in order of significance: High, Medium and Low. In ranking the issues between 'High,' 'Medium' and 'Low,' we have considered the relative importance of each matter, taken in the context of both quantitative and qualitative factors, such as the relative magnitude and the nature and effect on the subject matter. This is in accordance with the Committee of Sponsoring Organisations of the Treadway Committee (COSO) guidance and the Institute of Internal Auditors standards.

Rating	Implication
High	At least one instance of the criteria described below is applicable to the finding raised: • Controls mitigating high inherent risks or strategic business risks are either inadequate or ineffective. • The issues identified may result in a risk materialising that could either have: a major impact on delivery of organisational objectives; major reputation damage; or major financial consequences. • The risk has either materialised or the probability of it occurring is very likely and the mitigations put in place do not mitigate the risk. • Fraud and unethical behaviour including management override of key controls. • Management attention is required as a matter of priority.
Medium	At least one instance of the criteria described below is applicable to the finding raised: • Controls mitigating medium inherent risks are either inadequate or ineffective. • The issues identified may result in a risk materialising that could either have: a moderate impact on delivery of organisational objectives; moderate reputation damage; or moderate financial consequences. • The probability of the risk occurring is possible and the mitigations put in place moderately reduce the risk. • Management action is required within a reasonable time period.
Low	At least one instance of the criteria described below is applicable to the finding raised: • Controls mitigating low inherent risks are either inadequate or ineffective. • The Issues identified could have a minor negative impact on the risk and control environment. • The probability of the risk occurring is unlikely to happen. • Corrective action is required as appropriate.

Annex 4 : List of Facilities Visited

RHBs (6)	Zones (11)	Woredas (15)	Health Facilities (39)
Oromia	Jima, Arsi, East Shewa	Kersa, Seka, Digalu, Lode, Adae, Lume	Gobeseye, Biyu, Sharan, Gulale, Huruta, Ashabaka, Sagure, Seka, Ulaukkea, Tikur, Serbo
SNNPR	Woloyita, Gamo	Areka city, Dugunafango, Arbminch city, Arbminch Zuria	Areka HC, Seferesahari HP, Dimtu HC, Dunguna Bolaso HP, Shecha HC, Shele HC, Shele Mele HP.
Amhara	Bahir dar, Awi ZHQ, West Gojjan ZHQ	Guagusa Shikodad Wereda, Fagita Lukuma, Yilmanadensa wereda, Dembecha Zuria Wereda	Zenzelema HC, Tilili HC, Absila HP, Addis Kidam HC, Zenbela HC, Adet HC, Ayba HC, Dembecha HC, Yetsed HP.
Sidama	Yerigalem Town Admin, Hawasa City Admin	Aleta Woreda	Yerigalem HC , Morgis HC, Sheicha HP, Kurba HP
Harari			Harar Arategna HC, Harar Kebele HP, Dus Megala HP, Denkaka HC
Addis Ababa	Bole Sub city		Bole 17/20 HC, Bole bulbula HC, Addis Ketema HC, Kuas Meda HC

Annex 5 : Ethiopia's supply chain structure in current (four-tier) and proposed three-tier redesign



Annex 6 : Hub-level shelf-life expirations for select vaccines

	Penta			PCV			Rota		
Hub name	Date	Batch	Quantity	Date	Batch	Quantity	Date	Batch	Quantity
Hawassa	31/01/2022	2859y032f	28,485				30/06/2020	AROLC304AA	5,592
	23/07/2021	2859y004d	18,606						
Arbramich				30/04/2019		14,363			
Jimma	30/12/2018	279X6018D	35	30/06/2017	ASPNA6568A	295,958			
				30/04/2018	ASPNA817AA	62			
Adama	04/07/2021		204	17/05/2018		37,874	17/05/2018		255
Totals			**47,330**			**348,257**			**5,847**

Note: These expiries were from the 4 of 6 Hubs visited by the audit team.

Annex 7 : Vaccine expirations at woreda and health facility levels

Routine immunisation programme

	PCV			Rota		
Facility name	Date	Batch	Quantity	Date	Batch	Quantity
Lume wereda				01-Feb-22	AROLC883AA	50
Kuas Meda HC	2/1/2017	ASPNA645AB	34			

COVID-19 programme

	AZ			Pfizer			J&J		
Facility name	Date	Batch	Quantity	Date	Batch	Quantity	Date	Batch	Quantity
Tilili HC	1-Sep-21	PV46704	336						
Dembecha HC	1-Oct-21	PV46686	8						
Kuas Meda HC				2-Feb-22	PA173696	12			
Bulbula HC	10/1/2021	210005	50	2/1/2022	PAA173398, PAA173696, FM3137	5712	1/23/2022	1.8228E+20	7,150
Bole 17/20 HC				1/22/2022, 12/17/2021, 5/25/2022	FH8029, 33006BD, FL3201	2712	1/25/2022	1.8228E+13	360
Addis Ketama HC				2/1/2014	33006BBD	34			

Annex 8 : Example of short shelf-life PCV issued from EPSA-CVS to EPSA-Hubs

Vaccine:	Batch No.	Expiry date	Date of issue	Quantity	Remaining shelf life (in months)
PCV	ASPNA653AA	15/06/2017	19/04/2017	10,000	1.9
	ASPNA653AA	15/06/2017	19/04/2017	5,000	1.9
	ASPNA653AA	15/06/2017	19/04/2017	1,510	1.9
	ASPNA818AA	30/06/2017	19/04/2017	8,490	2.4

Note: Annex 8 illustrates an extract of 2.5m doses of PCV which were issued by EPSA-CVS with short shelf-expiration. The audit team noted follow-on expiration incidents of some of these PCV doses in three Hubs that it visited: Adama, Jimma and Arbamich.

Annex 9 : Length of stockout incidents at the Hub level (source: Hub data collection Tool)

	Penta			PCV			ROTA		
HUB Name	Stockout 1 (in days)	Stockout 2 (in days)	Stockout 3 (in days)	Stockout 1 (in days)	Stockout 2 (in days)	Stockout 3 (in days)	Stockout 1 (in days)	Stockout 2 (in days)	Stockout 3 (in days)
Jimma	10								
Arbramich Hub				10	39				
Addis 1				10					
Addis 2				10					

Annex 10 : Length of stockout incidents at the woreda level (source: woreda data collection tool)

	Penta			PCV			Rota		
Woreda Name	Stockout 1 (in days)	Stockout 2 (in days)	Stockout 3 (in days)	Stockout 1 (in days)	Stockout 2 (in days)	Stockout 3 (in days)	Stockout 1 (in days)	Stockout 2 (in days)	Stockout 3 (in days)
Digalu wereda	53	58	55	21	23	26	116	85	107
Lode Hetosa wereda	16	22	12	3	13	32	38	18	12
Adae wereda	0	0	0	0	0	0	7	6	0
Lume wereda	22	34	18	13	29	21	6	13	11
Kersa wereda	9	6	21	7	4	13	2	24	14
Seka wereda	153	31	8	0	0	0	3	120	64

Annex 11 : Length of stockout incidents at health facility level (health facility collection tool)

	Penta			PCV			Rota		
Facility Name	Stockout 1 (in days)	Stockout 2 (in days)	Stockout 3 (in days)	Stockout 1 (in days)	Stockout 2 (in days)	Stockout 3 (in days)	Stockout 1 (in days)	Stockout 2 (in days)	Stockout 3 (in days)
Yerigalem HC	3	10							
Areka HC							4		
Shele HC	3						5		
Denkaka HC	5	6	6	16	221		186	22	6
Gobeseye HP	45	18		44	11	15	14	11	17
Biyu HC				5			7		
Gulale Boru Bodecha Health Post	10	35		222					
Huruta HC	26	18	18				7	13	
Sagure HC	19	14	30	109	66	12	110	26	114
Seka Health Centre	23	214	166						
Serbo HC	6	11	18	10	47	16	14	22	32

Annex 12 : CCE Capacity at EPSA Central and EPSA Hubs Current

SN	Location		Equipment type	CR manuf. Name/ Model	Year installed	Qty	Total storage capacity		Total in m^3
							Per litres	Per m^3	
1	EPSA main	Main 3	Cold room	Gerlof	2008	1	300,000	300	300
			Cold room	Gerlof	2008	1	470,000	470	470
		Main 8	Cold room	Haier bio medical	2020/2021	4	300,000	300	1200
			Freezer room	Haier bio medical	2020/2021	2	100,000	100	200
		Central Urael	Cold room	Misa	1992	1	120,000	120	120
				HUURRE	2005	2	30,000	30	60
					2006	2	30,000	30	60
2	Addis Ababa	# 1 (Hana Mariam)	Cold room	HUURRE	2018	2	40,000	40	80
				Foster	2008	1	20,000	20	20
		# 2 (Jackros)	Cold room	Haier bio medical	2019	1	300,000	300	300
3	Adama		Cold room	HUURRE	2016	4	40,000	40	160
4	Hawassa		Cold room	HUURRE	2013	1	40,000	40	40
				Haier bio medical	2016	3	75,000	75	225
			Freezer room	Haier bio medical	2016	1	20,000	20	20
5	Bahir dar		Cold room	Haier bio medical	2016	2	46,000	46	92
				Foster	2008	1	20,000	20	20
				HUURRE	2006	1	30,000	30	30
6	Dessie		Cold room	Haier bio medical	2016	3	46,000	46	138
				Co.A.F	1996	1	30,000	30	30
7	Arbaminch		Cold room	Haier bio medical	2016	1	46,000	46	46
					2016	1	72,000	72	72
8	Gonder		Cold room	Haier bio medical	2016	2	46,000	46	92
9	Dire dawa		Cold room	Haier bio medical	2016	1	72,000	72	72
				HUURRE	2006	1	30,000	30	30
10	Jijiga		Cold room	dagard	2011	1	30,000	30	30
11	Jimma		Cold room	HUURRE	2013	1	30,000	30	30
				Haier bio medical	2016	2	46,000	46	92
				Co.A.F	1996	1	30,000	30	30
12	Nekemte		Cold room	HUURRE	2006	1	30,000	30	30
				Foster	2008	1	30,000	30	30
				Haier bio medical	2016	1	30,000	30	30
13	Negele		Cold room	Haier bio medical	2016	2	46,000	46	92
14	Gambella		Cold room	Haier bio medical	2016	1	20,000	20	20
15	Mekele		Cold room	HUURRE	2005/06	2	30,000	30	60
				Haier bio medical	2016	2	46,000	46	92
16	Shire		Cold room	Haier bio medical	2016	1	30,000	30	30
				Foster	2008	1	20,000	20	20
17	Semera		Cold room	HUURRE	2005	1	30,000	30	30
					2018	1	40,000	40	40
18	Assosa		Cold room	HUURRE	2008	1	30,000	30	30
					2019	1	40,000	40	40
19	Kebridahar		Cold room	HUURRE	2010	1	30,000	30	30
	Cold rooms not installed/ to be installed soon								
	EPSA main office	Main 8	Cold room	Haier bio medical	HRZK300G	1	300,000	300	300

Annex 13 : Subnational storage capacity based on 2018 assessment [source: EPSA]

	Health centres	Health posts	Total
Total number of facilities (a)	4,077	16,447	**20,524**
Number of functional CCE (current) (b)	2,595	4,175	**6,770**
% functional CCE coverage (current) (= b/a)	63.65%	25.38%	**32.99%**
Number of equipment to be replaced (c)	1,774	2,855	**4,629**
Number of CCE that meets the quality to stay in the system (d)	821	1,320	**2,141**
Number of CCE to be procured by SDG-PF (e)	2,000	6,000	**8,000**
Number of CCE meeting the quality after SDG-PF (= d+e)	2,821	7,320	**10,141**
CCE coverage after SDG-PF (d+e/a) = (f)	69.19%	44.51%	**49.41%**
CCE to be procured by CCEOP (g)	1,666	4,356	**6,022**
% CCEOP contribution (g/a) = (h)	40.86%	25.5%	**29.2%**
Number of CCE coverage after current SDG and CCEOP (= d+e+g)	4,487	11,676	**16,163**
CCE coverage after the current SDG and CCEOP (= f+h)	100%	71.0%	**78.8%**
Number of health facilities needing expansion or replacement	**0**	**4,771**	**4,771**

Annex 14: Global stock reconciliation Summary

		Penta vaccine			PCV vaccine			Rota vaccine		
Region	Woreda/ health facility	Calculated	Stock Record	Variance	Calculated	Stock Record	Variance	Calculated	Stock Record	Variance
Oromia	Digalu wereda	29	29	-	100	-	100	70	-	70
	LodeHetosa wereda	1,384	1,384		1,384	1,384		1,300	1,000	300
	Adea wereda	822	796	26	938	876	62	598	599	(1)
	Kersa wereda	698	642	56	1,543	1,740	(197)			
	Seka wereda	1,161	1,174	(13)	1,168	1,160	8	566	616	(50)
	Biyu HC	203	189	14	526	527	(1)	131	130	1
	Huruta HC	48	48		(11)	33	(44)	699	799	(100)
	Sagure HC	28	28		140	130	10			
	Seka Health Center	520	472	48	843	615	228			
	Serbo HC	1,238	220	1,018	1,084	16	1,068	776	368	408
Sidama	Yerigalem HC	540	551	(11)	646	663	(17)	370	365	5
	Morgis HC	361	371	(10)	384	384		108	108	
SNNPR	Areka HC	48	503	(455)	362	400	(38)	229	260	(31)
	Dimtu HC	(74)	36	(110)	(32)	58	(90)	112	274	(162)
	Shecha HC	209	145	64	9		9	(20)		(20)
	Shele HC	306	437	(131)	230	496	(266)	524	326	198
Addis	Bulbula HC	139	143	(4)	176	176		59	83	(24)

Annex 15: Variances between Tally sheets and Monthly reports

Region	Zone/Woreda	HF Name	Tally Sheets *(a)*	Register *(b)*	Monthly report *(c)*	DHIS2 *(d)*	Variance 1 *(= a-b)*	Variance 2 *(= a-c)*	Variance 3 *(= c-d)*
PENTA vaccine									
Sidama	Yerigalem TA	Yerigalem HC	681	527	951	951	154	(270)	-
SNNPR	Gamo	Shecha HC	711	693	572	755	18	139	(183)
	Wolayita	Dimtu HC	98	89	98	94	9	-	4
	Wolayita	Areka HC	866	763	1297	1297	103	(431)	-
	Gamo	Shele HC	90	92	58	54	(2)	32	4
PCV vaccine									
Sidama	Yerigalem TA	Yerigalem HC	689	527	951	951	162	(262)	-
SNNPR	Gamo	Shecha HC	711	693	572	755	18	139	(183)
	Wolayita	Dimtu HC	98	89	98	94	9	-	4
	Wolayita	Areka HC	866	763	1297	1297	103	(431)	-
	Gamo	Shele HC	90	94	58	54	(4)	32	4
Oromia	Jimwa Zone	Serbo HC	515	515	549	549	-	(34)	-
	East shewa	Denkaka HC	146	58	146	146	88	-	-
ROTA vaccine									
Sidama	Yerigalem TA	Yerigalem	491	380	980	1137	111	(489)	(157)
SNNPR	Gamo	Shecha HC	480	468	564	513	12	(84)	51
	Wolayita	Dimtu HC	98	97	98	94	1	-	4
	Wolayita	Areka HC	865	530	866	866	335	(1)	-
Oromia	Jimwa Zone	Serbo HC	493	493	516	516	-	(23)	-
	East shewa	Denkaka HC	101	40	101	101	61	-	-
	East shewa	Biyu HC	80	23	80	80	57	-	-
COVID-19 RD3 campaign vaccines									
SNNPR	Gamo	Shecha HC	12915	-	13186	-	12,915	(271)	13,186
	Wolayita	Dimtu HC	10880	-	10548	-	10,880	332	10,548
	Wolayita	Areka HC	25294	-	18255	-	25,294	7,039	18,255
	Gamo	Shele HC	67	68	67	63	(1)	-	4

Annex 16: Questioned expenditure

Name of RHB	Voucher n°	Value date	Transaction description	Grant	Amount	Inadequately supported	Ineligible	Missing Supporting Documentation
Federal Level								
FMOH	BPV 282165	20-12-21	Birana Printing		6,441,573		6,441,573	Funds used to print data tools which do not relate to COVID-19 response
FMOH	BPV 282165	20-12-21	Birana Printing		42,943,824		42,943,824	
Total					49,385,397		49,385,397	
RHB Level								
Sidama	CPV 295852	17/02/22	Payment for field work perdiem of birr 450 per day to orient and Covid Vacination for 11 professionals for 10 to 12 days (from 18/02/2022 to 29/02/2022)	CDS I	24,448	24,448		Activity Report and Evidence of participation in activity
Sidama	CPV 295853	18/02/22	Payment for field work perdiem of birr 450 to orient and Covid vaccination for 6 professionals for 10 days (from 19/02/2022 to 28/02/2022)	CDS I	27,000	27,000		Activity Report and Evidence of participation in activity
TOTAL					**51,448**	**51,448**		
Zonal Level								
West Gojjan ZHQ	PVTR 551/14	08/08/14	PERDIME FOR DRIVER FOR TRANSPORTING SUPERVISION GIVERS TO DIFFERENT WEREDAS FROM 13/07/14-15/08/14	CDS	10,800	10,800		Activity Report
West Gojjan ZHQ	PVTR 467/14	06/08/14	PERDIME FOR DRIVER FOR TRANSPORTING SUPERVISION GIVERS TO DIFFERENT WEREDAS FROM 13/07/14-15/08/14	CDS	7,650	7,650		Activity Report
TOTAL					**18,450**	**18,450**		
Woreda Level								
Aleta Town Admin	CPV273804	24/3/22	Perdiem payment for 83 professionals for campaign work that they have carried out	CDS I	393,600	393,600		Activity Report
TOTAL					**393,600**	**393,600**		
Total						**463,498**	**49,385,398**	

Annex 17: Management (FMOH) action plan

Issue	Audit Recommendation	Management Action	Action Owner	Timeline
Gaps in the annual workplan development and microplanning processes	**Recommendation 1** To facilitate planning and monitoring of the standalone grants, FMOH should • Establish a process of engaging RHBs in development of workplans and budgets for the stand-alone grants. • Share final workplans and budgets with the RHBs which should in turn be used for the RHB and national level supervision and monitoring activities.	**Action 1 – April 2023** The audit team asked MoH to reflect on the details and process of the standalone GAVI grants within the health sector annual and strategic plans based on Gavi financial management guidelines in place. MoH noted the comment as the planning process lacks detail matters and processes of the activities with the Woreda plan which was produced with the engagement and dissemination process along with RHBs. The FMOH will create a more robust mechanism to include the detail matters and processes of the standalone Gavi grants in the planning, engagement and dissemination processes across the board. **Update September 2024** The MoH developed a Gavi Full Portfolio Planning (FPP) strategic work plan and budget by engaging RHBs and key stakeholders. The Ministry of Health (MoH) is enhancing its documentation of the entire planning process and reinforcing its engagement platform.	Maternal child and adolescent Health CEO (MCAH-CEO) and Strategic Affairs CEO	31 December 2025
	Recommendation 2 To further improve the micro planning exercises, FMOH should • Provide RHBs with the necessary support to develop realistic micro plans for future campaigns and other immunisation activities that are reliant on the outdated population census data. • Document all adjustments made to micro plans and ensure that adjustments are approved. • Where funding gaps result in adjustments to fit within Gavi provided funds, these adjustments should be shared with Gavi, together with programmatic implications for activities that are not funded by government.	**Action 2 – April 2023** The ministry believes that the MP exercise across all level has value for money because most of the MP components within the RHBs MP were maintained and included in the national consolidated MPs. Therefore, the ministry noted that realistic MP exercises are very important and the ministry will work on it with responsible stakeholders to have updated population data. The ministry can take this recommendation as an essential recommendation because it will help to create ways for the MP exercise impoverishment especially on the real quantification of the target population and the number of teams to be deployed for the SIAs implementation. For future campaigns, FMOH is committed to support RHBs to develop a more realistic micro plans which meet optimal expectation of both FMOH and RHBs; and to ensure these micro plans should be used to determine how to allocate funding. MOH and RHB joint MP validation mechanism will be in place. **Update September 2024** The FMOH and regions have started utilising headcount data at certain levels to create more realistic microplans for routine immunisation and campaigns until new population census data is available. For example, in campaigns like HPV MAC and Big Catch-up (BCU), the MoH and regions are using headcount or triangulated data for planning purposes. The Federal Ministry of Health (FMOH) and Regional Health Bureaus (RHBs) will collaborate to establish realistic target populations by utilising headcount data or triangulating data from various sources until a new census is conducted.	Maternal child and adolescent Health CEO (MCAH-CEO) and Strategic Affairs CEO	During next campaigns, dependent on the schedule of the campaigns and by 31 December 2025
Gaps in monitoring implementation of EPI activities	**Recommendation 3** The FMOH should formally clarify the roles, responsibilities, and accountability between itself and the RHBs with regards to the monitoring and measurement of achievements of set targets of the Health Sector National Strategic Plan. This should help MCHD/EPI to periodically prepare grant implementation status reports.	**Action 3 – April 2023** FMOH has indicated the roles, responsibilities, and accountability between FMOH and RHBs with regards to the monitoring and measurement of achievements of set targets of the Health Sector National Strategic Plan. For the previous standalone Gavi grants, RHBs were reported all the programmatic implementation status reports. However, there were some delays and incompleteness of reporting which need improvement in the future. With those gaps, considering MOH effort in place, the ministry can take this as an essential recommendation and will work for improvement. Regarding the allocated time shortage for ISS, MOH will consider it as well. Per the	Strategic Affairs Executive Office and MCAH-CEO	Per the given reporting period for each standalone Gavi grants and by 31 December 2025.

Issue	Audit Recommendation	Management Action	Action Owner	Timeline
		existing programmatic and financing systems, the ministry will follow RHBs to report both programmatic and financial status of the standalone Gavi grants. MOH will work to address the delays, incompleteness, and time allocation of the supportive supervision. During the coming ISS sessions more time be allocated by revising the schedule or assigning more individuals in the team as per the recommendations. ISS will be conducted in March 2023. **Update September 2024** Strengthening the monitoring of EPI activities and documenting standalone grant activities will be a key focus for the Ministry of Health (MoH). The MoH will implement both targeted and integrated supportive supervision activities, alongside regular review meetings, to effectively track the implementation of these activities. The MoH will also advocate for the importance of establishing and signing a Memorandum of Understanding (MoU) between stakeholders. The MoH has developed a National-Level Grant Coordination Terms of Reference (TOR) to guide this process. To ensure comprehensive grant oversight, the MoH will conduct grant-focused supportive supervision at the regional level on a semi-annual basis, at the zonal level quarterly, and at the woreda level monthly.		
	Recommendation 4 The FMOH should ensure that supervision visits at all levels are documented and introduce a mechanism for the follow-up of proposed actions.	**Action 4 – April 2023** At national level, supervision will be conducted at least once in a year and MOH will introduce electronic feedback and action point tracking mechanisms for supervised sites. MOH will conduct advocacy and follow-up for regular SS and feedback documentation during supervisory visits at regional, zonal and Woreda levels. Integrated Supportive Supervision guideline will be revised and share with regions to strengthen feedback provision and documentation as well as action point tracking at all levels of the health system. For Program specific supportive supervision, MOH will also work with key stakeholders to digitalise supportive supervision tools with tracker mechanisms for follow up actions and visualisation **Update September 2024** The MoH has conducted advocacy and follow-up to ensure regular supportive supervision and feedback documentation during visits at the regional, zonal, and woreda levels. Supportive supervision guidelines have been revised and shared with regions to strengthen feedback provision, documentation, and action point tracking across all levels of the health system. Following regional Integrated Supportive Supervision (ISS), discussion sessions were held with RHB senior officials to plan next steps and interventions based on the findings. The Ministry of Health (MoH) will enhance electronic feedback and action point tracking systems for supervised sites.	Strategic Affairs Executive Office and MCAH-CEO	31 December 2025
Suboptimal performance of the operational and governance structures	**Recommendation 5** FMOH should work with WHO to orient all ICC members on their roles and responsibilities to ensure that core objectives as prescribed in the ICC ToRs are well covered.	**Action 5 – April 2023** The MoH has two ways of coordination mechanisms within to run the activities. One is pure government owned coordination mechanism like Case Team Forums, Transformation Forums,	MCAH-CEO	31 December 2025 and beyond

Issue	Audit Recommendation	Management Action	Action Owner	Timeline
		Directorate Forum, Program wing forum, MOH Management, Core Ministerial meeting and joint steering committee meeting (with engagement of RHBs and agencies heads). The second one is the coordination that involves stakeholder (including donors and partners) like EPI TWGs, EPI Task Force and EPI ICC. With this, the ministry has in place robust coordination mechanisms at national level. The ICC made many useful deliberations especially on the new vaccine applications and vaccine renewals. However, the ministry has noted around the adequacy of coverage on the core EPI activities in ICC meetings compared to the existing ICC TOR. The ministry take this recommendation to strengthen given for the aforementioned gap and will work on its improvement with the following actions: (i)Revise ICC TOR and orient the ICC members. (ii) Implement all the Core EPI Activities and objectives per the revised ICC TOR (iii) Make a regular follow up on the implementation of the ICC recommendations and action points **Update September 2024** The MoH has revised the Terms of Reference (ToR) for the ICC, which is set to be endorsed. The ministry has committed to addressing the identified gaps and will take necessary actions to further strengthen the coordination mechanisms. The Ministry of Health (MoH) will orient ICC members on the revised Terms of Reference (ToR), which clearly delineates their roles, responsibilities, and the scope of the ICC. This revision emphasises the ICC's complementarity with the government's coordination and management system.		
	Recommendation 6 FMOH should hold regular EPI Taskforce meetings and ensure that reports of the EPI Taskforce discussions and conclusions are promptly prepared and submitted to the ICC for strategic guidance.	**Action 6 – April 2023** EPI Taskforce is one of the active coordination platforms within immunisation program in the country. Effective meetings and deliberation made since its establishment. All the agendas tabled to the ICC were prior discussed and reviewed by the Technical Working groups and EPI task force. The meeting outputs did feed into the ICC deliberations and decision making process. However, there were gaps in adhering its regularity, proper documentation and filing of each meeting and tracking and follow up of the implementation of the actions points. Therefore, the ministry will ensure to address the gaps observed and strengthen the good progresses mentioned above and work on further gains. The EPI desk will coordinate and implement the EPI Taskforce meetings regularly based on the TOR and ensure the regularity of the meetings. The desk will also make sure that the deliberations of the Task Force will feed into the ICC deliberations and decision-making process and follow-up of action points for implementation. **Update September 2024** The Terms of Reference (ToR) for the EPI Taskforce have been revised and endorsed, and members have been informed and oriented accordingly. Minutes from each EPI Taskforce meeting, along with follow-up action points, will be documented and shared with all stakeholders for implementation. MCAH will enhance the documentation of EPI Taskforce meetings and ensure the regular scheduling of Taskforce meetings.	MCAH-CEO	31 December 2025 and beyond

Issue	Audit Recommendation	Management Action	Action Owner	Timeline
	Recommendation 7 The FMOH should develop a dashboard to track the follow-up and implementation of its ICC and EPI Taskforce recommendations. For the purposes of accountability, each recommendation should be assigned to a designated officer responsible for its implementation, along with a deadline by which time the action is to be completed.	**Action 7 – April 2023** The ICC and Task Force coordination platforms are among the robust coordination mechanisms in the immunisation program of the country. Both are utilised well specially during reviewing and endorsing applications, making renewals and sending other requests to Gavi. The recommendations and decisions in line with those critical core agenda and activities were well followed up and implemented accordingly. But, there were gaps in its comprehensiveness and coverage across the immunisation system components and levels especially issues related the internal purpose/use. Considering efforts made before and those gaps observed , the ministry can take this recommendation as an essential recommendation and work for its improvement, We will develop a dashboard to track the follow-up and implementation of its ICC and EPI Taskforce recommendations. **Update September 2024** The MoH has begun to specify action items along with the responsible departments to ensure accountability and better documentation. The Ministry of Health (MoH) will link action items to the responsible departments to enhance accountability, ensure proper documentation, and monitor regular implementation.	MCAH-CEO	31 December 2025 and beyond
Previous grant management requirements and programme audit recommendations are still outstandin	**Recommendation 8** The FMOH is recommended to: • setup a comprehensive and rolling action plan and processes, with clear responsibility to implement, monitor and report on GMRs, audit (internal/external) recommendations, and action points from critical assessments. • engage ICC or its governance body to provide oversight of the progress and hold individual/team accountable for long outstanding issues.	**Action 8 – April 2023** Following the results and recommendation of the Fiduciary Risk Management (FRM) performed by SDG- PF partners the ministry has taken remedial actions. The actions are supported by directives. These directives and steps are being applicable to all funds managed by the ministry. Some of the activities are: 1) Financial management manual is developed and approved, and orientation provided to all finance experts 2) Comprehensive directive for channel-2 financing is developed, and the directive is in the final phase for approval, the directive has passed discussions with the members of the MoH management, and members of the joint string committee, it is also commented by the attorney general and Ministry of Finance. Some of the components of the directive are the following: 3) A budget committee will be established soon. The budget committee will have the responsibility to allocate the budget with full transparency, to discuss the overall process with the major implementers particularly the regional health bureau, implementation of proper budget reprogramming, and other related (ToR developed). 4) Audit oversight team will be established following the approval. The team will follow all the recommendations and their implementations and report all the material findings to top leadership for further action. The directive is also expected to solve issues and challenges related to the disbursements of funds and liquidation. The other component of the directive is the disbursement protocol. The additional milestone is the implementation of the MoU which is expected to implement among MoH and all implementers. In general, the directive enhances strong internal control and transparency, and accountability across all the implementers, managers of MoH, and others. The ministry is working to address periodic audit findings systematically by developing a Guiding manual. The newly developed manual includes about the Establishment of Audit committee and the detail tasks and	Finance Executive Office and Strategic Affairs CEO	31 December 2025 and beyond

Issue	Audit Recommendation	Management Action	Action Owner	Timeline
		responsibility are clearly described on the manual. The basic responsibility of the committee is to address the internal and external Audit findings. MOH will work on the functionality of the Manual. The manual will be functional from February 25, 2023 and onwards **Update September 2024** In response to identified financial risks, the Ministry of Health (MoH) has taken corrective measures by developing and implementing new guidelines and directives for fund management. A central component of this initiative is the Financial Management Manual, which standardises financial processes and ensures that finance experts adhere to best practices. Furthermore, the newly approved Channel-2 Financing Directive aims to enhance fund distribution and accountability, supported by an audit team responsible for monitoring implementation and addressing any arising issues. Additionally, the MoH has established an Audit and Risk Management Committee to oversee the implementation of all audit recommendations from both internal and external audit reports. Finance Executive Office and Strategic affairs CEO will ensure the effective implementation of all recommendations from both internal and external audit reports.		
Suboptimal monitoring of TCA milestones and deliverables	**Recommendation 9** The FMOH should strengthen the TCA monitoring processes by: (i) Providing coordination guidelines to TA partners to ensure that the TCA performance milestones are validated by FMOH before these are reported and submitted to Gavi; and (ii) set up a process to collate, monitor and track all overdue TCA activities.	**Action 9 – April 2023** The FMOH has an interactions and discussion with the TA providers partners, in order to ensure that each of the TA providers is held accountable for the delivery of TCA services. The FMOH is also required to validate the TCA performance milestones before these reported and submitted to Gavi; and to set up a process to collate, monitor and track all overdue TCA activities. For further effectiveness, efficiency and value for money, FMOH will strengthen all these activities, monitoring, follow-up and accountability implementations. FMOH can take this recommendation for further improvement. The FMOH will create TCA coordination guide to coordinate TCA implementation, monitoring, reporting and track all TCA activities in quarterly base. **Update September 2024** The MoH EPI team has developed a TA Coordination and Management Guideline to ensure the timely delivery of required outputs. Additionally, the MoH organised an annual partners forum to review, evaluate, and guide partner implementation status. The MoH also conducted a Joint Appraisal (JA) meeting with Gavi and partners to assess the implementation of TCA activities. The Ministry of Health (MoH) will strengthen TCA coordination platforms, including newly introduced mechanisms such as the annual partner forum and Joint Appraisal (JA) meetings with Gavi.	MCAH-CEO	Starting 31 December 2025
Need for TCA sustainability and transition plan	**Recommendation 10** The FMOH should: • identify those key resources and capabilities which are currently augmented and financed using external support (including TCA), so as to develop a comprehensive transition plan, with appropriate timelines and funding	**Action 10 – April 2023** The TCA plans have identified the priority TA gaps at national and sub-national level that hindered the country to achieve the universal immunisation agenda to reach all eligible with lifesaving vaccines. The MoH has experience of taking absorb TA for some activities like HPV and MCV2 at regional and subnational levels. However, due to the Covid 19 pandemic, Climate change the country facing right now and presence of huge Zero dose children the country still demand TA support. To address staffing challenges the MOH in collaboration with partners and donors has	MCAH-CEO	Starting 31 December 2025

Issue	Audit Recommendation	Management Action	Action Owner	Timeline
	sources, such that the public health system can replace or absorb the necessary functions and roles into its immunisation programme; • establish clear expectations between the TA providers and the RHBs regarding respective roles and responsibilities, in relation to the appropriation of future TCA activities, issues and outcomes; and • ensure that the RHBs commit to following-up on any action points identified by the TA providers, which are mutually agreed to be a priority.	tried to deploy technical assistances to high priority areas to support the immunisation program and majorities are from TCA and other Gavi support. However, the ministry in the long run will work in the future to TA transitioning. The MoH has clear TCA plan with partners and based on that will follow the support and the excepted TA need also indicated. The ministry regularly follow the TA performance and achievement with government monitoring system. Every partner have an agreement and follow up process for TA at the regional health bureau and evaluate the performance of TA support every 6 month with platform of the public servant performance evaluation mechanisms. (i) TCA plan will include TA role and expectations and evaluation of TA will be done periodically. (ii) The MoH will prepare TA coordination guide for the regions to facilitate the monitoring, and performance evaluation to create uniformity across the regions **Update September 2024** (i) The TCA plan has been developed, clearly outlining the roles, expectations, and schedule for periodic evaluations of technical assistance (TA). (ii) The Ministry of Health (MoH) has also developed a TA coordination guide for regions to enhance monitoring and performance evaluation, ensuring uniformity across all regions. MCAH will further identify the key resources and capabilities currently supported and funded through external assistance, including TCA, to develop a comprehensive transition plan. This plan will include clear timelines and funding sources to enable the public health system to integrate or absorb these essential functions and roles into its immunisation program. MCAH will also ensure that RHBs are committed to following up on action points identified by TA providers, with mutual agreement on prioritising these actions.		
Vaccine forecasts need improvement	**Recommendation 11** To improve the accuracy of vaccine forecasts, the EPI and EPSA should use vaccine consumption patterns, including stockouts incidents and data on the aging of stock balances.	**Action 11 – April 2023** The ministry in consultation with EPSS, local partners and GAVI conducts annual vaccine and related supplies forecast regularly. Vaccine forecasts were done by using a standard template (GAVI/UNICEF) and in addition to the target population, vaccine consumption patterns and shelf life of stock balance are considered. Due to challenge of population denominator estimation (as result of outdated census) and absence of local wastage data, our forecasting lacks some accuracy. To mitigate this recently we are trying to triangulate service and consumption data as well. There are efforts to improve this challenge and the MoH is working for, thus, the ministry is keen to accept the recommendation as an essential recommendation to improve the missing component of the forecasting by A. Revising national Vaccine Quantification/ Forecasting manuals by clearly stating the role and responsibility of MOH, EPSS and Partners. B. Conducting the vaccine forecast by using different methods (Population and/or Consumption) based on the data available and the regional context C. Regularly monitoring the supply planning for decision making.	EPSS and MCAH-CEO	A. 31 December 2025 for document revision B. 31 December each year C & D. Continuous starting 31 December 2025

Issue	Audit Recommendation	Management Action	Action Owner	Timeline
		D. Establish system to generate essential data elements for improve forecasting accuracy such as stock out rate and wastage rate. **Update September 2024** Vaccine forecasting has been improved by integrating demographic data with historical proxy consumption data. Consumption patterns have been used to estimate minimum and maximum inventory levels and guide vaccine replenishment. The vaccine forecasting process will continue using various methods, including population-based and consumption-based approaches. The supply plan will be regularly monitored to ensure adherence to predefined minimum and maximum inventory levels.		
	Recommendation 12 The FMOH/EPI should monitor and track its wastage rates, using tools such as the Vaccine Wastage Rate Calculator[7] (developed by WHO) to improve the overall accuracy of estimates.	**Action 12 – April 2023** Unopened vial wastage at the EPSS center and hub level is known and reported regularly (quarterly), it is tracked by the Health Commodity Management Information System (HCMIS). EPSS considered wastage rate reduction as one of its corporate-level key performance indicators and achieved a major improvement in recent years. Open vial Vaccine wastage rates were tracked along with the admin coverage report (DHIS 2), however, this is not sufficient for decision-making. The MoH will continue to monitor the wastage through DHIS 2, especially the opened vial wastage and for unopened vial wastage at SDP through ledger book and VRF. The MoH is working to have local wastage data and improve this. Thus, the ministry accepted the recommendation. MoH will start using the Wastage Assessment/Study as a reference for calculating wastage rate during national vaccine forecasting and similarly disseminating the result to the lower supply chain level for using this wastage factor during vaccine requisition. **Update September 2024** Activities have been planned for a national vaccine wastage rate study (GAVI-FPP), which will be executed accordingly. The MoH/EPSS will continue to monitor wastage through DHIS 2, focusing particularly on open vial wastage, as well as tracking unopened vial wastage at service delivery points (SDPs) using ledger books, Vaccine Return Forms (VRF), and DHIS 2.	EPSS and MCAH-CEO	31 December 2025
	Recommendation 13 The FMOH/EPI should conduct a wastage rate study (as was planned for 2022) to inform the forecasting process by using more realistic wastage rates that are based on actual practice.	**Action 13 – April 2023** There have been preparatory activities for waste study, unfortunately, because of other competing priorities and the COVID-19 pandemic the study is not conducted. It has been also planned for this year and the preparatory activities were continued. And we are using WHO indicative wastage rate	EPSS and MCAH-CEO	31 December 2025

[7] Vaccine wastage calculator. Accessed 13 December 2022.

Issue	Audit Recommendation	Management Action	Action Owner	Timeline
		for our forecasting practice. Thus, the ministry is keen to accept the recommendation as an essential recommendation. MoH will conduct district and Service Delivery Point level wastage rate assessment regularly (at least every two years) and set country-specific wastage rates. **Update September 2024** The study has been planned, and the budget has been secured as outlined in the GAVI-FPP. The Ministry of Health (MoH) will conduct wastage rate assessments at the district and service delivery point levels regularly, at least every two years, and establish country-specific wastage rate benchmarks.		
Gaps in vaccine logistic management information systems and records	**Recommendation 14** The EPSA CVS and Hubs should investigate and adjust its stock records in response to the discrepancies arising from routine stock counts and the end-of-year stock reconciliations. These adjustments should be independently validated by an authorised officer while documenting the process.	**Action 14 – April 2023** The significant stock variance during the earlier period of the audit (2016/2017) was due to the transition period of vaccine supply chain management from MOH to EPSS. During that period, there was no adequate and consolidated cold storage capacity at EPSS Centers and hubs. Due to high investment exserted on HR capacity, cold chain capacity development, system strengthening, strategy and policy development, by the Ministry and EPPS significant improvements and achievements gained on this aspect. As the audit, the Global reconciliation report (Refer to the Table) showed almost there was no significant variance in 2019/20 and even the variance is nil in 2020/2021. In general, this is indicated; there has been an improvement both in inventory control and cold chain management. With this, EPSS has tried to manage stock recording variances happened at 2016/2017 by the following years, this show the system is in place to solve this which is working well. EPSS will also A. Increase cold storage capacity and reducing storage location at EPSS CVS B. Carry-out annual Stock reconciliation (Quantity received, issued and remaining stock) and take timely intervention on gaps **Update September 2024** EPSS has implemented an ERP system to enhance overall inventory management across EPSS, with plans to integrate it with the existing e-LMIS system at lower levels. A new initiative, the Warehouse Center of Excellence (CoE), has been established in each EPSS warehouse to monitor overall warehouse operations. EPSS will conduct regular stock reconciliation to monitor quantities received, issued, and remaining in stock, and implement timely interventions to address any identified gaps.	EPSS and MCAH-CEO	A. 31 December 2025 B. Year end starting 31 December 2025
	Recommendation 15 The FMOH/EPSA should develop a clear roadmap with timelines for the intended rollout of the new ERP system while ensuring	**Action 15 – April 2023** The MoH/EPSS acknowledged some the gaps observed by current eLMIS system and over last year EPSS has been working to solve the eLMIS system with reliable software called ERP. EPSS ERP project is undergoing the procurement completed and contractual agreement already signed with the service provider and consultant, service requirements identified and business blueprint developed, planned to make it functional as of August 2023. And it is fully used for vaccine and related supplies stock management by 2023, since ERP is standard software that meets Gavi requirement and we will make sure standard information of vaccine supply and stock will be there. (ERP is going working with ERP implementation team to address vaccine SC peculiarities and the	EPSS and MCAH-CEO	A &B. Continuous starting 31 December 2025 C. 31 December 2025

Issue	Audit Recommendation	Management Action	Action Owner	Timeline
	that the system meets Gavi's target software standards for vaccine supply chain information systems.	program interest.) Even though we didn't see any significant gap at the moment, future concerns raised by this audit will be considered as EPSS: A. Prioritises ERP implementation for EPI products to strengthen LMIS; B. Follows-up and closely work with ERP implementing team to incorporate key EPI logistic data/ parameters in the ERP system C. Develops a clear roadmap with timelines for the intended rollout of the new ERP system in the way that meets Gavi's target software standards of immunisation supply chain management. **Update September 2024** EPSS is currently implementing the ERP system across both EPSS centers and all EPSS hubs, enabling real-time data access for monitoring essential supply chain performance. A central dashboard has been established for enhanced monitoring and decision-making. Coordinate and collaborate closely with the ERP implementation team to ensure the integration of key EPI logistics data and parameters into the ERP system.		
	Recommendation 16 Until its new ERP is fully functional, the FMOH/EPSA should introduce compensatory controls, such as tracking bin locations and ensuring that all vaccine issuances are EEFO compliant.	**Action 16 – April 2023** The significant bin-location inaccuracies were observed during the earlier period of the audit (2016/2017) which is mainly due to the transition period of vaccine supply chain management from MOH to EPSS and at that time the HCMIS system was under test. Currently there is notable improvements and bin location accuracy is regularly monitored. The problems in bin location and not comply with EEFO is not directly related e-LMIS/ VITAS, it is mainly related with challenges during data entering, receiving and dispatching process. The EPSS noted the gaps identified and will continually work on data recording improvements by: A. Conducting regular annual physical counts and Perpetual inventory and reconcile against VITAS until the ERP will be fully implemented B. Implementing BIN Location to strengthen/improve put away and picking accuracy **Update September 2024** Dedicated staff have been assigned to conduct perpetual inventory, ensure put-away and picking accuracy, and reconcile physical counts with stock locations in the SAP/ERP system. Staff will ensure that bin locations are consistently maintained for all products.	EPSS and MCAH-CEO	Every year quarterly starting 31 December 2025
	Recommendation 17 FMOH should review and reposition the mBrana system in the context of last-mile distribution and the intended rollout of a new ERP system. This should include plans for future integration of mBrana and new ERP as needed.	**Action 17 – April 2023** The MoH is working to have visualisation of stock at 3rd level of storage majorly (Districts), So far the mBrana was deployed in different districts and due to minor challenges the functionality is irregular. However, MoH has made an efforts to revitalise the mBrana system, (consultative meeting with stakeholders, user acceptance test) and MOU were prepared to govern different	EPSS and MCAH-CEO	A & B: 31 December 2025

Issue	Audit Recommendation	Management Action	Action Owner	Timeline
		stakeholders working in this. In the future the mBrana will be deployed in the health facility after fully implemented in all districts. There is a plan to: A. Revitalise the system in 660 Woreda B. In the long term, it will be interoperable with ERP **Update September 2024** Dedicated staff have been assigned to conduct perpetual inventory, ensure accuracy in put-away and picking processes, and reconcile physical stock counts with the system. Smartphones and IT materials have been procured and will be distributed to Woredas to support the implementation. Staff will enhance stock data visibility at the 3rd and 4th levels of storage and ensure ERP interoperability with Dagu-2 and mBrana systems.		
Improvements needed in stockouts and expiries management	**Recommendation 18** FMOH/EPSA should review and access the feasibility of scaling up the 3PL model piloted in Hawassa region to other locations to increase the direct deliveries.	**Action 18 – April 2023** To reduce the number of vaccine supply chain tiers and directly reach most health facilities, MOH/EPSA in collaboration with partners have been working on a plan which has been included in EPSS 10 year's strategic documents, Pharmaceutical Supply Transformation Plan(2020/21 – 2029/30). This direct delivery improvement was designed to address two approaches:- Scale-up of last-mile delivery piloted project started in EPSA Hawassa hub and planned to start in EPSS Jijiga and Negele. - During the vaccine supply chain management transition (2016), the vaccine distribution was only at the Woreda level there were no health facilities that directly received vaccines from EPSS hubs but this distribution performance was more than 30% in 2021. Similarly, all hubs planned to reach more than 50% at the end of 2015 EFY (June 30/2023) by using the existing resource at hand and by using vehicles and CCE procured through the GAVI HSS3 grant and as such: a) All EPSS hubs will plan to increase direct delivery by using resources at hand b). Scale-up of 3PL to other 2 EPSS Hubs (Negele B & Jigjiga) c). Increase Vaccine Direct Delivery HFs as equal as other health program commodities direct delivery (~66%). **Update September 2024** In addition to the EPSS Hawassa hub, the 3PL (third-party logistics) delivery model has been implemented in seven EPSS hubs: Negele Borena, Jigjiga, Kebri Dehar, Bahir Dar, Addis Ababa-1 & 2, and Jimma. To improve vaccine availability at the health facility level, the remaining 11 EPSS hubs have enhanced direct vaccine delivery to health facilities. The new vaccine delivery initiative (DRIVE) at the outreach level is in its final stages of pilot implementation.	EPSS and MCAH-CEO	A, B & C: 31 December 2025
	Recommendation 19 Through the available SOPs, FMOH should provide a clear practical process to EPSA for reporting and handling of the near-expiry stocks. If short shelf-life stocks are identified at the EPSA CVS or Hubs, then the EPSA and EPI should closely monitor the stock utilisation for effective expiries management.	**Action 19 – April 2023** As the stock transaction showed, it seemed a short-expiry vaccine was issued to the hubs but the actual practice was not this. The vaccine was cross docked directly from Airport to Hubs due to a shortage of Cold storage at the EPSS Center. At the same time, hubs issued the vaccine to a lower level based on HFs request by using EPSS Manual Delivery Note (Temporary invoice). For this type of consignment, the Good Receiving Voucher (GRV) was lately generated at the Central level by maintaining or keeping the actual expiry date on the original invoice received from Manufacturer and Stock transaction documents including Bin Cards. Regarding reporting and handling of near	EPSS and MCAH-CEO	31 December 2025

Issue	Audit Recommendation	Management Action	Action Owner	Timeline
		expiry stock the EPSS has clear standard operating procedures manual called SOP for Warehousing and inventory management process which clearly explain the how to handle and manage reporting and handling of near expiry stocks. the reference is attached for review if it in case missed during the review period. Though the SOP there on how to manage near expiry vaccine stocks the actual practice has limitation and we noted to improve this gaps, only it considers the HCMIS transaction that was not capture manual delivery. And most importantly there is no such practices in the last two-three years. A. Regularly assessing stock status with shelf-life at each level. B. Strengthen the system to track short-expiry vaccines and then determine whether to redistribute among EPSS hubs, Woreda, and HCs and minimise wastage.		
Gaps in cold chain maintenance	**Recommendation 20** EPSA-CVS and the Hubs should maintain a current inventory of all necessary spare parts for repair and routine maintenance.	**Action 20 – April 2023** Spare parts stock transactions (receiving, storing & issuing) is maintained by the existing HCMIS system similar to vaccines and other commodities. Majority of the spare parts from CCEOP project has been handled and stored with supplier. However we noted the gaps, and we will arrange to have spare part safety stock at hubs for frequently used items of spare parts. Based on equipment specification MoH will avail spare parts at hubs as safety stock for frequently requested items of spare parts. **Update September 2024** Cold Chain Equipment (CCE) spare parts are stocked and managed at both EPSS and RHB levels. Maintenance of refrigerated vehicles is outsourced, covering all required services. Stock of spare parts will be monitored continuously.	EPSS and MCAH-CEO	31 December 2025
	Recommendation 21 FMOH should set up a suitable forum enabling EPSA to engage with RHBs' management to mobilise and allocate adequate resources for cold chain maintenance and repairs. EPSA should develop and implement a suitable CCE maintenance plan to train technicians at the woreda level.	**Action 21 – April 2023** The role of EPSS in CCE maintenance at woreda level is to avail spare parts and accessories when RHBs are placing orders. Woredas are under the regional and zonal health bureau administrative structure. To conduct maintenance of cold chain equipment, Biomedical engineers and Technicians has been deployed at RHB, ZHD and even at most Woreda level. The role of these professionals is mainly monitoring the functionality of cold chain equipment and taking corrective action upon gaps identified. Additionally, the majority of the CCE has bundled service for maintainable through LSP and a 10-year warranty is in place for maintenance at SDP. By design, system for CCE maintenance is there, however the MoH/ EPSS, regional health Bureau and zonal health office will work to improve its efficiency. The MoH/EPSS will create suitable coordination forum with regional hubs and regional health bureau in regular modality, so far during review meetings regions and hubs has	EPSS and MCAH-CEO	A, B, C & D: 31 December 2025

Issue	Audit Recommendation	Management Action	Action Owner	Timeline
		platform for engagement to discuss the challenges and performance. The following actions will be taken: A. Conducting CCE Inventory at all levels on a regular basis; B. Strengthening the system of CCE maintenance at the EPSS level C. Improving CCE spares part inventory system; and D. Improving recording and reporting system on corrective and preventive maintenance conducted at each level **Update September 2024** The MoH has developed a Medical Equipment Management Information System (MEMIS) to monitor the inventory and functionality of medical equipment, including CCE. Maintenance workshops at the RHB/ZHD level are staffed with trained professionals equipped with various maintenance toolkits. Capacity-building initiatives, including pre-service and in-service training, have been implemented to enhance skills for both preventive and corrective maintenance. We will enhance the capabilities of regional maintenance workshops and monitor the maintenance recording and reporting system		
Waste management practices need improvement	**Recommendation 22** FMOH/EPSA should implement the policy and procedures for the safe management of medical waste generated from immunisation. The sites lacking infrastructure for safe disposal should be allowed for reverse logistics so that the waste is collected at Hub or Woreda level with the necessary disposal capabilities.	**Action 22 – April 2023** There is a policy in place for managing Cold Chain Equipment Decommissioning and Disposal including the reverse logistics which was developed by MoH/EPI in consultation with EFDA. And there is also, Medicines Waste Management Disposal Directive (EFDA-August 2011). The implementation of this policy has been started (Reference to Guidelines developed in 2020). Regarding infrastructure for safe disposal at woreda and health facility level the MoH has been working to improve infrastructure through SDG funds and others. For some vaccines waste like nOPV2 the MoH has reverse logistics for disposal due to the nature of waste. Further actions to be taken are: A. Conduct advocacy workshop of the guideline at all levels; B. The MoH/EPSS will create platform for regional health Bureau and respective EPSS hubs; and C. Follow-up implementation of Decommissioning and Disposal Guidelines **Update September 2024** FMOH and EPSS will enhance disposal sites and infrastructure at the health facility level. Monitor the implementation of Decommissioning and Disposal Guidelines.	EPSS and MCAH-CEO	A and C . 31 December 2025 B. 31 December 2025
Inconsistencies in administration data coverage and use of outdated denominator	**Recommendation 23** FMOH/PPMED should: • Routinely undertake data triangulation to verify accuracy of its coverage data. Such analyses should be completed at national and subnational levels and any data inconsistencies noted should be followed up and investigated.	**Action 23 – April 2023** Quarterly report review and data analytics, Desk reviews and data triangulations will be conducted in selected program areas including EPI. MOH will support strengthening of PMT at all levels through SS, advocacy during Health data week celebrations and by providing feedback on the data entered via DHIS-2. MOH will advocate for consistent use of the PMT logbook in documenting LQAS results and performance review of selected indicators.	Strategic Affairs Executive Office	31 December 2025

Issue	Audit Recommendation	Management Action	Action Owner	Timeline
	• Ensure that all primary data collection tools are completed correctly and correlate or support each other. • Consistently have the PMTs complete and document data verification and validation exercises at the health facility, woreda and regional levels as required by the guidelines. • Conduct the required surveys and use the results to review the administrative coverage. • Ensure adequate supervision at subnational level over data collection and management including follow up of recommendations to address data management gaps from routine supervision visits and programme audits.	EPI coverage cluster survey will be planned and conducted for next year. **Update September 2024** Quarterly data quality and performance analyses are now conducted, with feedback provided on selected program areas, including EPI. A program-specific data quality assessment for EPI has also been undertaken. The PMT functionality is evaluated through PRISM assessments, and advocacy efforts are made during the national health data week ceremonies across the country. The FMOH will strengthen PMT at all levels through supportive supervision and by providing feedback on data entered into DHIS-2.		
Weaknesses in data quality assurance mechanisms	**Recommendation 24** FMOH/PPMED should conduct a routine data quality assessment on an annual basis, as required by the HMIS guidelines. Based on the findings of the assessment, it should ensure that the ensuing recommendations are followed up and implemented.	**Action 24 – April 2023** FMOH will conduct RDQA regularly **Update September 2024** In line with the plan, the MoH conducted a national RDQA in 2023, collecting data from 379 health institutions, including 88 woreda health offices, 45 hospitals, 149 health centers, and 97 health posts. The findings indicate an improvement in the consistency of EPI data between the data sources and reported values compared to previous RDQ assessments. The MOH will enhance regular RDQA activities, with the next assessment scheduled for November 2024. Additionally, the FMOH will promote the consistent use of the PMT logbook for documenting LQAS results and performance reviews of selected indicators	Strategic Affairs Executive Office	31 December 2025
	Recommendation 25 FMOH/PPMED should strengthen data quality review processes at the national and subnational levels. ISS should be revised to include data quality indicators. Similarly, subnational level reviews should be improved by PMT refresher training, and the ISS checklist should be reviewed to include adequate aspects of data quality. When undertaking the data quality reviews, these should be documented resulting in an action plan, as well as implementation and follow up thereof.	**Action 25 – April 2023** Routine data quality check is done regularly at all levels. Some of the data quality checking mechanisms include content completeness, lot quality assurance Sampling, and checking consistency at facility level, whereas report timeliness, completeness and review for consistency are conducted at Administrative Health Units. Moreover, routine data quality assessment is conduct at Woreda, region and nation levels, however, there are some irregularities that should be strengthen. Nationally, DHIS2 is used to monitor data completeness and timeliness monthly, where the report review, data analytics and triangulation activities are being conducted quarterly. These routine data validation and verification activities will be strengthened. Besides, the routine data verification, ISS visit includes some data quality validation and verification mechanisms focusing on selected indicators. For instance, the existing checklists include assessment of prerequisites for data quality, techniques used to check data quality, data verification for Penta3 with some indicators from other programs as well as the functionality of PMT and so on. Considering the resources and time required for field visits, the questions about data quality will be revised for the next ISS to include more indicators on EPI. Documentation will be given due attention at all levels. To this end, the ministry is accept the recommendation as data quality issues remain as a challenge. Monthly report review for data completeness, timeliness and consistency, Quarterly report review for data quality and data triangulations will be conducted in selected program areas including EPI to strengthen data quality. ISS will be conducted using updated version of checklists that includes more indicators for data	Strategic Affairs Executive Office	31 December 2025

Issue	Audit Recommendation	Management Action	Action Owner	Timeline
		verification and data quality metrics. PMT functionality assessment will be conducted in sampled health facilities and based on the findings interventions will be implemented to strengthen PMT at all levels. **Update September 2024** The ISS utilises checklists that encompass data verification and quality metrics, employing electronic data collection to minimise biases. PMT functionality assessments have been conducted in selected health facilities to enhance PMT effectiveness across all levels. The integrated ISS is designed with consideration for previous feedback, ensuring adequate time is allocated for addressing major programmatic activities and involving at least one EPI focal personnel in the ISS team. Training of Trainers (TOT) on the revised Health Management Information System (HMIS) and DHIS2 is provided at national, sub-national, and facility levels. Quarterly reviews of data quality and triangulation will be routinely conducted in selected program areas, including EPI, to enhance data quality.		
	Recommendation 26 FMOH/PPMED should lock DHIS2 after a specific interval or reporting period, in order to retroactive data entries and institute a post facto process to record belated (but necessary) data entries subject to exceptional approval.	**Action 26– April 2023** There were discussions and orientations to avoid unnecessary data entry. DHIS2 will be locked after three months of data entry routinely, HR capacity building activities will be conducted, connectivity improvement activities will be done. **Update September 2024** Capacity-building sessions on the new version (v2.40) of DHIS2 have been provided for health facility Health Information Technology (HIT)/Health Management Information System (HMIS) focal points and facility leaders. Starting July 2024, the Ministry of Health has implemented a policy to lock data entry in DHIS2 three months after the data is entered. The FMOH will enhance capacity-building efforts focused on addressing needs and gaps in DHIS2, as well as improving integrated data quality and information utilisation.	Strategic Affairs Executive Office	31 December 2025
Gavi standalone grants were not adequately ring-fenced and their grant management practices did not comply with Gavi requirements	**Recommendation 27** The FMOH should: • redesign its management processes for Gavi standalone grants to comply with Gavi's guidelines on financial management, including specifically using the financial reporting template provided; • Mandate that memorandum of understandings (MOU) are put in place between the FMOH and each RHB. These MOUs establish directives on the use of Gavi funding including, that: funds be utilised in accordance with agreed workplans; RHBs' regularly report back using the Gavi financial reporting template; dedicated bank accounts for Gavi standalone grants be established; and agreement upon deadlines by which advances must be liquidated; and	**Action 27 – April 2023** FMOH is working to alleviate the issues that may hinder the achievement of the grant objectives. Based on MoH fiduciary assessment result, as part of the reinforcement of grant performance, MOH has developed the Financial and grant management manual (FMM). FMM related gaps can be addressed by the channel 2 grant and financial management manual. The FMM will help to strengthen the Channel two grants in the MoH with the aim of ensuring consistent and uniform accounting policies are followed, roles and responsibilities are clearly laid out, and good standards in financial management are upheld in grant recipient regions and agencies. The FMM aims to establish a complete understanding of Risks of misuse of grants, inadequate grant monitoring practices at different levels of the government structures, and expenditures review which are relevant to the specific donor, including GAVI. In addition, the FMM possess procedures how to open separate dedicate account for specific grant, who does what, when and how, how it can be tracked, verified and relevant taxes can be accounted for the donors and the country rules and regulation.	Finance Executive Office and Strategic Affairs Executive Office	30 June 2025 onwards

Issue	Audit Recommendation	Management Action	Action Owner	Timeline
	• finalise the "FMOH financial management manual" to address gaps. The MOU should mandate and underline the importance that the manual's prescriptions are complied with.	The full-fledged manual implementation will be initiated at the end of April 2023. The Strategic Affairs Executive Office (SAEO) will lead the implementation in collaboration with Finance Executive office. Additionally, to strengthen the capacity of the regions and zones the MoH is working on the recruitment of accountants by the world bank project. Accountants will be deployed at regional and zonal levels. The MoH is working with regional health bureaus to refund VAT as well. Even before the full-fledged implementation of the manual, the GAVI dedicated accounts have been opened at MOH and regional health bureaus and have started using the GAVI reporting templates as per the recommendation by GAVI PA team. In addition, the MOU have been designed to be signed among MOH and regional health bureaus recently. The manual will be functional 3rd Quarter 2023 **Update September 2024** The Channel 2 Grant finance directive has been approved by the Ministry of Finance and distributed to all regions. This manual addresses the signing of MOUs, reporting, timely fund utilisation, and all grant-related matters. Over 70 additional finance officers have been seconded by the World Bank project and deployed to regions to enhance the financial management system. Dedicated bank accounts for the GAVI grant have been established in all regions, with a fund transfer letter attached to confirm subsequent actions. A GAVI-supported digitalisation project is underway, involving a consultant to strengthen the grant finance management system. This initiative aims to connect regional systems with the ministry, ensuring timely tracking and reporting of all financial data. A project status report is attached to update management on the actions taken. Regular and thorough follow-up on all recommendations is being implemented. FMOH will advocate for and provide training on Channel 2 directives, finalise the pilot and launch the digital grant and finance management system.		
Noncompliance with COVID-19 vaccine delivery support funding guidelines	**Recommendation 28** FMOH should comply with the Gavi funding requirements and COVID-19 vaccine delivery support funding guidelines. Any proposed deviations from these instructions should be explicitly approved by Gavi and documented by the FMOH, prior to allocating funds.	**Action 28 – April 2023** • Within three months, the Finance and the grant management manuals will be printed and distributed to all regions this will address all the financial recommendations. • The ministry is working on the GAVI grant advance follow-up and reviewing the periodic financial reports as usual. • GAVI bank accounts have been opened in all regions. **Update September 2024** The MoH has implemented measures to liquidate the CDS budgets by conducting regular liquidation activities. Unspent budget allocations have been utilised once sufficient vaccine	Strategic Affairs Executive Office and MCAH-CEO	31 December 2025

Issue	Audit Recommendation	Management Action	Action Owner	Timeline
		supplies became available. The Finance and Grant Management manuals will be printed and distributed to all regions within three months to address all financial recommendations. The ministry continues to follow up on GAVI grant advances and reviews periodic financial reports as part of standard procedures. GAVI bank accounts have been established in all regions. The Channel 2 directive has been approved and distributed to all regions, addressing all financial and grant management compliance recommendations. The directive is attached for reference. The manual includes guidelines for advance follow-up, timely fund settlements, and periodic financial report reviews, with a planned follow-up system in place. The MoH remains committed to adhering to GAVI funding requirements and will continue to fulfil the terms and conditions outlined for each program. Regular and thorough follow-up on all recommendations is underway. In light of this, GAVI funding requirements will be a key agenda item during ISS, SS, and review meetings. The finance and grant management manuals will be printed and distributed to all regions. Dedicated GAVI funding accounts opened by the Regional Health Bureaus will be utilised exclusively for GAVI funds.		
Expenditure inadequately supported or ineligible	**Recommendation 29** In future, the FMOH should ensure that all expenditures are: • Filed with sufficient, accompanying supporting documents to evidence the validity and accuracy of the transactions, including activity reports, attendance sheets, fuel/vehicle logbooks. • Incurred in compliance with the relevant Gavi funding guidelines.	**Action 29 – April 2023** The MoH has taken immediate measure for the ineligible expenditure finding for the amount ETB Birr. 49,385,398 at MOH level the amount is deposited to GAVI account and adjusting entry is taken to the transaction (CRV-201357). The ministry committed to work according to Gavi framework agreement per the proposal in the now and in the future. **Audit note** No further action required as funds have been reimbursed to the Gavi in country account.	Finance Executive Office	Closed

Annex 18: Management Response to Executive Summary

Response to Executive Summary to the 2016-2021 Gavi Programme Audit Draft Report from MCHS – received by Programme audit 23 September 2024

The Ethiopian Ministry of Health acknowledges and appreciates Gavi's invaluable support in safeguarding the lives of Ethiopian children through the enhancement of the Expanded Immunisation Program (EPI). From 2016 to 2021, Gavi provided $706,395,939 to bolster the Ethiopian health system, focusing on vaccine supply, cold chain equipment, capacity building, and cash grants. Key achievements facilitated by this support include the expansion of vaccine storage capacity from 1,000 m^3 to over 2,400 m^3 since 2019, the consolidation of central storage sites, successful new vaccine introductions, last-mile deliveries, and the restoration of EPI services.

Recognising the significance of the Programme Audit, Ethiopia has actively engaged with Gavi to enhance program implementation, ensuring greater transparency, accountability, and efficiency in resource use. The current audit aims to assess various aspects of program management, including vaccine and supply chain management, immunisation data management, and budgetary oversight for Gavi-supported initiatives.

The audit identified several areas for improvement, including program implementation, supply chain management, immunisation data integrity, financial management, and governance. The Ministry has carefully reviewed these findings and recommendations, committing to address each identified gap through a comprehensive action plan.

Subsequent to the audit's fieldwork, the following key actions have been implemented:

- Approval of Channel 2 finance directives by the Ministry of Finance (Directive number 979/2024) to expedite timely fund disbursement and utilisation.
- Establishment of separate bank accounts for Gavi standalone grants at all regional health bureaus to enhance tracking.
- Deployment of the new DHIS2 V2.40 to improve data quality.
- Implementation of SAP/ERP by EPSS for supply chain management, providing reliable, real-time vaccine supply data and streamlining processes.
- Refund of ineligible funds (49,385,398 Birr) to Gavi, with receipt #201357, to ensure compliance with recommendations and proper utilisation.

The actions outlined above, along with the revised management response and proposed action items, will be executed as per the established timeline. The Ministry of Health is confident that these measures will significantly enhance EPI programme implementation and requests that all efforts be duly considered in your final audit report.

Lastly, the Government of Ethiopia reaffirms its commitment to strengthening immunisation programs as a strategic priority. The Ministry of Health is dedicated to implementing the detailed activities specified in the attached management response.