Memorandum on the Republic of Eritrea's Programme Audit report

The attached audit report sets out the conclusions on Gavi Secretariat's programme audit of the Government of Eritrea's immunisation programmes as managed by the State of Eritrea's Ministry of Health (MOH).

The audit was conducted in June 2018 and the period under review was from 1 January 2014 to 31 December 2017. The scope of the audit covered the Ministry of Health's management of grants supporting its Health Systems Strengthening (HSS), Vaccine Introduction Grants (VIGs) and select vaccine management processes. The final audit report was issued to the Ministry of Health on 14 March 2019.

The audit report's executive summary (pages 2 to 4) sets out the key conclusions, the details of which are set out in the body of the report:

1. There is an overall rating of Partially Satisfactory which means that Internal controls and risk management practices were generally established and functioning but needed improvement. One or more high- and medium-risk areas were identified that may impact on the achievement of the entity's objectives.
2. Ten issues were identified, most of which related to non-compliance with the State of Eritrea and Ministry of Health's guidelines or to the financial management arrangements governing Gavi cash grants.
3. Key findings were that:
    a. Some funds used for non-immunisation activities and some long outstanding advances. Overall, including other irregular items, the Audit Team, questioned amounts totalling US$ 193,279;
    b. The internal audit function was ineffective with respect to Gavi's support, as it operated without the necessary institutional framework or resources; and
    c. Vaccine supply management was ineffective and there were significant weaknesses in the handling and management of stock. As a result of a PCV vaccine switch in 2017, approximately 60,000 doses of PCV vaccine at the central vaccines stores were near-expired at the time of the audit in June 2018. Ultimately, the country confirmed that only 4,360 doses actually expired. In addition, a parastatal in charge of the central supplies inadequately managed syringes under its control.

The results of the programme audit have been discussed and agreed with the Ministry of Health, with a commitment to remediate the identified issues. With respect to the shelf-expired syringes and vaccines, Gavi determined that the loss did not qualify as misuse. Specifically, in a letter dated 16 July 2019, the MOH committed to reimburse the unsupported and ineligible expenditure totalling of US$ 193,279 as determined by Gavi.

The Gavi Secretariat continues to work with the Ministry of Health to ensure the above commitments are met.

Geneva, November 2019

THE STATE OF ERITREA

Programme Audit of Gavi's support to the Ministry of Health

Gavi Secretariat, Geneva, Switzerland

Final Audit Report – 12 March 2019

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Abbreviations

CVS	Central Vaccine Store
EPI	Expanded Program of Immunisation
ERN	Eritrean Nakfa
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
HSS	Health Systems Strengthening
IAS	International Auditing and Assurance Standards Board
ICC	Interagency Coordinating Committee
IPV	Inactivated Polio Vaccine
ISS	Integrated Supportive Supervision
M&E	Monitoring and Evaluation
MOH	Ministry of Health
MR	Measles Rubella
PCV	Pneumococcal Conjugated Vaccine
PFA	Partnership Framework Agreement
PMU	Project Management Unit
SMT	Stock Management Tool
SOP	Standard Operating Procedures
UNICEF	United Nations Children's Fund
USD	United States Dollar
VIG	Vaccine Introduction Grant
VVM	Vaccines Vial Monitor
WB	World Bank
WHO	World Health Organisation

1. Executive Summary

In June 2018, the Audit and Investigations team (the Audit Team) conducted a programme audit of Gavi's contributions to the State of Eritrea's Ministry of Health (MOH).

The audit covered the Ministry of Health's management of Health Systems Strengthening (HSS) and Vaccine Introduction Grants (VIGs) for the four-year period from 1 January 2014 to 31 December 2017. The Audit Team reviewed 54% of MOH programme expenditures totalling USD 3,027,037.

Audit rating

The Audit Team assessed the Ministry of Health's management of Gavi grants as **partially satisfactory**, which means, "Internal controls and risk management practices were generally established and functioning but needed improvement. One or more high- and medium-risk areas were identified that may impact on the achievement of the entity's objectives".

Table 1: Summary of audit focus areas rated by programme audit

Area	Audit Rating
Budgeting and financial management	Partially Satisfactory
Grant assurance mechanisms	Partially Satisfactory
Procurement	Partially Satisfactory
Vaccine Supply Management	Partially Satisfactory
Immunisation data quality	Satisfactory
Overall rating	**Partially Satisfactory**

Key issues

The Audit Team raised 10 issues, most of which related to non-compliance with the Ministry of Health's guidelines or to the financial management arrangements governing Gavi grants. These arrangements are described in the Partnership Framework Agreement and Aide Memoire, which was signed between Gavi and the State of Eritrea, represented by the Ministry of Health and Ministry of Finance.

To address these issues, the Audit Team made 10 recommendations, of which 6 (or 60%) were rated as of critical priority, which means "action is required to ensure that the programme is not exposed to significant or material incidents. Failure to take action could potentially result in major consequences, affecting the programme's overall activities and output."

A summary of the audit findings in this report are presented below:

Table 2: Summary of the audit findings

Area	Summary of audit findings
Budgeting and financial management	USD 115,785 of expenditures incurred in 2015 immediately prior to the end of the HSS1 grant were ineligible, as the activities funded related to non-immunisation activities. Similarly, long outstanding advances totalling USD 48,553 from 2015 were not liquidated and justified. Overall, including other irregular items, the Audit Team, questioned amounts totalling USD 193,279. As a result of delays in the implementation of HSS2-related activities, the absorption rate of the HSS grant was low – remaining at a 59% rate by the end of the December 2017. However, by the close of May 2018, gradual acceleration in implementation had begun to address the low absorption rate. Other financial management weaknesses in treasury and bank management were identified.
Grant assurance mechanisms	The internal audit function was ineffective with respect to Gavi's support, as it lacked a suitable institutional framework or scope. Its unclear mandate contributed to the absence of an independent or systematic approach to consider and address the risks associated with Gavi's grants. Similarly, Gavi-specific external audits were limited in their scope, as the auditors' coverage being principally limited to a desk review at the central level. No management letter was issued for the 2017 audit.
Procurement	The Audit Team determined that the bid evaluation practices for the procurement of printing services were sub-optimal. There was no documentation justifying the basis for overriding the selection of the lowest priced technically-qualified bidder, and instead awarding the contract to a government owned supplier.
Vaccine Supply Management	In 2017, as a result of the PCV vaccine product being switched to a different vial size, "Earliest Expiry First Out" principles were suspended, resulting in approximately 60,000 doses of unused PCV vaccine at the central vaccines stores approaching expiration. In addition, various vaccine management weaknesses were identified across the sub-national level, including stock levels falling below the minimum, resulting in intermittent stock outs. The inadequate management of syringes by a parastatal managing the central supplies warehouse, also led to the expiration and wastage of 358,800 ADS 0.5ml syringes at the end of December 2017.
Immunisation Data Quality	A data anomaly was identified between the higher administrative coverage rates for pentavalent, in contrast to the lesser quantity of vaccine distributed from the central stores.

Recommendations have been made to address the findings and have been prioritised as either critical, essential or desirable. Definitions of the three-levels of prioritisation are summarised in Annex 1.

The two tables below summarise the amounts questioned by the Audit Team:

Table 3a: Summary of amounts questioned by the Audit Team

Category of questioned costs	Amount in USD	Report section
Ineligible Expenditures		
➢ Ineligible expenditure not in line with budget (HSS grant managed by PMU)	115,785	4.1.1
➢ Other ineligible costs (VIG grant managed by MOH)	13,499	4.1.2
Unsupported expenditures		
➢ Long outstanding advances	48,553	4.1.2
Other questioned amounts		
➢ Inadequately supported costs	12,689	4.1.2
➢ Irregular costs	2,753	4.1.2
Grand Total	**193,279**	

Table 3b - Summary of immunisation supplies which shelf-expired at the central level:

Product	Explanation	Doses/ Units	Report section
Expired – 0.5ml auto-disabled syringes	These syringes expired as a result of inadequate management and not applying Earliest Expiry First Out principles.	358,800	4.4.3

Table 3c - Summary of vaccines issued from the central vaccines stores with a short shelf-life:

Product	Explanation	Doses	Time until expiration	Report section
Near expired doses of PCV (associated with over-stocking)	Vaccines issued from central level, due to expire end of September 2018, as a result of the Earliest Expiry First Out principles being suspended to facilitate a 2017 PCV-product switch.	22,400	Less than 3.5 months	4.4.1
		10,100	< 3 months	4.4.1
		27,880	< 2 months	4.4.1
Total number of PCV doses distributed with a short-shelf life		**60,380**		4.4.1

2. Objectives and Scope

Objectives

In line with the Partnership Framework Agreement and Gavi's Transparency and Accountability Policy, the main objective of a programme audit is to provide assurance on whether the funds were spent in accordance with the agreed terms and conditions, and that resources were used for the intended purposes. Specifically, the audit sought to address the following questions:

i) Do the programmes' grant oversight and governance mechanisms, provide reliable assurance over the stewardship and management of Gavi's resources?
ii) Is the integrity of the national immunisation programme, as well as the resources it has available, adequate for its needs and does the programme team support the implementation of Gavi activities effectively?
iii) Is the national vaccine management and supply chain system efficient in delivering sufficient quantities of vaccines and in recording their movement accurately?
iv) Do the budgetary financial management and procurement processes function properly, so as to achieve accurate and well-defined accountability on the use of Gavi resources?

Scope

The period under review was the four-year period 1 January 2014 to 31 December 2017. During this period the total value of the vaccine and cash support provided to the MOH was USD 11,350,706 of which USD 3,446,799 consisted of cash grants. The programme audit covered both the income received and the expenditures incurred on the following grants: the Health Systems Strengthening (HSS) and the Vaccine Introduction Grants (VIG).

During their review, the Audit Team interacted with the Project Management Unit (PMU) – which manages both Global Fund and Gavi grants – as well visiting two Zobas and six sub-Zobas. The Audit Team reviewed transactions totalling USD 1,622,822, equivalent to an effective audit coverage of 54% of the total expenditure.

Table 4: Gavi disbursements to Eritrea during the period 2014-2017 in USD.

Grant type /Year disbursed	2014	2015	2016	2017	Total
Cash grants	815,250	200,000	-	2,431,549	**3,446,799**
Vaccine support	1,397,287	2,519,580	2,654,101	1,332,939	**7,903,907**
Total	**2,212,537**	**2,519,580**	**2,854,101**	**3,764,488**	**11,350,706**

Table 5: Breakdown of expenditures by grant that were reviewed by the Audit Team in USD.

Grant type	Expenditure in the audit period	Reviewed by the Audit Team	% coverage
Health Systems Strengthening (HSS)	2,702,646	1,428,725	**53%**
Vaccine Introduction Grant (VIG)	324,392	194,097	**60%**
Total	**3,027,037**	**1,622,822**	**54%**

3. Background

3.1 Introduction

The State of Eritrea is a country in the Horn of Africa, with its capital in Asmara. It is bordered by the Red Sea to the East, Sudan in the west, Ethiopia in the south, and Djibouti in the southeast. Administratively the country is divided into six administrative zones known as Zobas: Gash Barka, Anseba, Debub, Northern Red Sea, Southern Red Sea and Maekel. Thereafter, the zones are divided into 58 sub zones, 715 administrative areas and 2,564 villages. The country's estimated population in 2016 was 3.7 million[1].

The health system in Eritrea is organised around a three-tier system and service, namely the primary level (186 health stations, 53 health centres and 13 community hospitals) where community hospitals act as first referral centres; the secondary level (Zoba regional referral hospitals and the first contact hospitals) where regional referral hospitals are second level referral centres; and the tertiary level with the national referral hospitals.

Gavi invested HSS funding in Eritrea geared towards increased access to outreach activities, supportive supervision, provision of EPI vaccines and supplies, cold chain expansion and maintenance at all levels, and data management.

The Ministry of Health is the primary recipient of Gavi support, with the MOH having delegated the management of the grants to its designated PMU, a unit which manages both Global Fund and Gavi programmes funding. The PMU is mandated to provide administrative, technical support and oversight over Gavi resources, in collaboration with the Director of Family and Community Health Division within the Department of Health Services, which is the division within which the EPI unit falls.

At the Zoba level, the provision of EPI services falls under the Family and Community Health Division. The delivery of EPI services is thus integrated with other MCH services, as part of a package across all health facilities.

According to WHO/UNICEF 2015 estimate, the penta-1 coverage was 98% while penta-3 coverage rate was 97%. Currently, eleven vaccines are being utilised in the routine immunisation programme, including four supported by Gavi, namely: Rotavirus, Pentavalent, MCV2 and PCV.

3.2 Good practices

The PMU provides a suitable grant-management framework, including oversight mechanisms and segregation of functions. The PMU was adequately staffed and equipped to manage the Gavi grants and was represented both at the National and each of the Zoba levels.

From January 2017, the PMU implemented a suitable financial management technology system, licensed by the provider SAP. The new system automated the execution and accounting processes helping to meet the country's objective of effective Public Financial Management. Once fully operational, the new system is expected to improve significantly the management and reporting on

[1] Ministry of National Development (National Statistics Office)

the use of Gavi funds. In addition to strengthen further the accounting for Gavi funding, from January 2017, a dedicated accountant to manage Gavi's monies was appointed.

The EPI successfully maintained the integrity of a functional cold chain both at the national-level (CVS) as well as the sub-national level (i.e. Zoba and Sub-Zobas), with suitable hygiene and sanitary conditions being maintained. The EPI personnel were trained and were conversant with the principles of effective vaccine management. The recording of movements in vaccine was done via a functional stock management system at both the National, as well as at the Zoba levels.

3.3 Key challenges

Significant challenges were described by the EPI team in relation to the transportation of vaccines and the communication difficulties between the national and sub-national levels. Physical and logistical obstacles included the insufficient vehicles and the poor internet connectivity. This impacted upon the vaccine supply management and hampered key activities such as routine supervision. In addition, the justification of sub-national advances was delayed due to the long lead time to obtain the necessary supporting documentation from remote or inaccessible areas.

4. Audit Findings

4.1 Budgeting and Financial Management

4.1.1. Ineligible expenditures not in line with the HSS1 budget

Description	Recommendation 1 (Critical)
Before spending Gavi grant funds, the MoH must prepare and submit suitable signed budgets to the Interagency Coordination Committee (ICC) and subsequently to Gavi for approval. Any significant reallocation or reprogramming of the approved budget therefore requires pre-approval from both the ICC and the Gavi Secretariat. In September 2014, the PMU submitted a reprogramming request to Gavi for some activities which was duly approved by Gavi. However, the Audit Team's review of the MOH's subsequent expenditure incurred in 2015, identified various additional expenditures which were not included in the reprogrammed budget. These amounts totalling USD 115,786, were therefore deemed by the Audit Team to be ineligible. A list of the items determined to be ineligible is as follows (further details in Annex 2):	In future, the PMU should ensure that expenditures are in line with the respective approved budgets. Deviations from the approved amount should be justified and discussed with Gavi, as well as supported by a suitable budget reallocation which is approved by the ICC/Gavi secretariat, in line with the Gavi guidelines on financial management. **Audit Team's additional comments** As at 6 March 2019, the country had not provided additional documents as stated in the management comments. The audit team therefore maintains its findings and conclusions for the dialysis consumables and other miscellaneous costs.

Description	Expenditure in USD
Dialysis Consumables (various purchases)	98,012
Other miscellaneous costs including: cataract and ladder	17,774
Total	**115,786**

In addition to this, the Audit Team identified a significant overspend on one of the activities, 6.7: Procure standard equipment and supplies for referral & emergency service provision at selected health facilities. The approved reprogrammed budget amount was for USD 86,000, however the total expenditure to purchase two generators and fuel totalled USD 115,785, an excess in expenditure of USD 29,785.

Management comments

Management agrees with this recommendation.

Comments for specific activities are as below:

Dialysis Consumables

The patients subjected for dialysis were equally men and women. Given the stock out of the dialysis consumables, unless immediately continued or sustained, this would endanger the lives of both sexes. As there were no other funding resources available and believing the GAVI funding by and large safeguards women and children, the funding for dialysis consumables were made. This initiative was based on the instruction letter given by the Minister of Health (see attached for easy reference).

Fixed Asset register: FAR

The expense made for FAR is eligible because this was done for identification of GAVI's fixed asset and tagging and besides we do not have running costs in GAVI to cover the FAR expenses.

Cataract expenses:

This expense was made for cataract operation for staff per-diem as this operation involves females and mothers as beneficiaries

Risk / Impact / Implications

Non GAVI related expenditure charged to Gavi and planned activities not conducted.

Responsible

PMU/ MOH Project Director

Deadline/Timeline

15 August 2018.

4.1.2. Lack of assurance that funds were used for intended purpose

Description

Paragraph 19 of Annex 2 of the Partnership Framework Agreement (PFA) instructs Eritrea to manage and use Gavi's funding solely for appropriate programme activities. Furthermore, Paragraph 20.1(c) instructs that all expenses relating to the application of such funds, should be properly evidenced with supporting documentation sufficient to permit Gavi to verify the expenses.

From its sample review, the Audit Team identified expenditures which were not adequately supported by documents in sufficient detail to give assurance that the funds were utilised for the intended purpose at the sub-national (Zoba) level as summarised below:

Unsupported expenditure (advances) – USD 48,553

The unsupported expenditure detailed below, related to long outstanding advances for PCV 13 activities dating from fiscal year 2014/2015. The issue of outstanding advances was also highlighted in the past by Gavi, during a monitoring review it carried out in 2015. At the time of the Programme Audit, details of the unsupported advances are as follows:

Date	Location – Zoba	Amount in USD
23 Jun 2015	Merkel	5,853
23 Jun 2015	Debub	13,033
23 Jun 2015	Anseba	10,433
23 Jun 2015	Gash Barka	14,333

Recommendation 2 (Critical)

In future, the Ministry of Health should ensure that the accounting undertaken at each sub- level of the health system, ensures that each transaction is matched by all of the necessary supporting documents and justifications, and that these are reviewed for completeness and accuracy; and

In addition, any unsupported or ineligible expenditures, including indirect costs not relating to the immunisation programme, should be repaid to the Gavi Secretariat.

Audit Team's additional comments

As at 6 March 2019, the country had not provided additional documents as stated in the management comments. The audit team therefore maintains its findings and conclusions.

23 Jun 2015	South Red Sea	4,900
Total		**48,553**

Inadequately supported expenditure – USD 12,689

The questioned items related to two activities carried out under the HSS grant:

- Payment on 30 Jan 2014 for training for Village Health Committee for NKF 129,631 where NKF 92,322 (USD 6,155) was inadequately supported;
- Payment on 07 Aug 2017 for training of workers on patient safety and AEFI surveillance where NKF 98,004 (USD 6,534) was inadequately supported.

Both payments were characterised by the event's attendance sheets being unavailable after the workshop, as well as missing cash payment receipts, inconsistencies between the dates on the documents, copied supporting documents and the documentation being mismatched and not corresponding to the respective grant budget line. Other weaknesses noted by the Team, related to non-compliance with procurement regulations. Details of specific transactions are set out in Annex 1.

Irregular costs – USD 2,753

The irregular costs identified related to select supporting documents with varying dates for a training for Village Health committee carried out in 22 and 24 December 2013 where the funds were retroactively disbursed in 30 Jan 2014. However, various invoices included in support of the expenditures' activities were dated March and April 2014. The same activity also had inadequately supported expenditure as described above. This expenditure related to HSS 1 grant funding from 2014. Details of specific transactions are set out in Annex 1.

Ineligible costs - USD 13,499

The ineligible costs identified related to payments for per diem, as well as for fuel for research on bilharzia and mosquito breeding sites in June 2014, which were charged to the Gavi Rotavirus VIG grant. Similarly, these activities could not be traced to the budgeted approved activities. Details of specific transactions are set out in Annex 1.

Management comments

Management agrees with the recommendation.

There was inadequately supporting documents for NKF 37,299 (USD 2,486.60) but some supporting documents including photograph was given to the auditors while in Eritrea and can be assessed from them if they cannot submit we can re-provide.

For the irregular expenditure, for the expenditure ERN 3,999.00 there was a detailed report how the activity was done and budget vs actual analysis also prepared. Payment of the stationary was done later, because they took the goods by credit.

Risk / Impact / Implications

The Audit Team could not obtain assurance that the questioned expenditures were used in accordance with the terms of the Partnership Framework Agreement, the Aide-memoire and the Transparency and Accountability Policy.

Responsible

Project Director PMU/MOH

Deadline/Timeline

20 September 2018

4.1.3. Limited use of the financial system's functionalities

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Description

Section 3.2 of the PMU's Finance Manual on budgeting states that 'the budget shall be prepared at the beginning of the fiscal year and shall contain, at a minimum, the following information: Service delivery area, activity, expense category and amount either in Nakfa or USD. The MoH budgetary process also mandates that budgets should be entered into the SAP system as set down in Section 2.3 – General accounting system – of the finance manual. However, the Audit Team noted that the HSS budget was only partially recorded in SAP, as the budget did not detail the relevant expense categories and was limited only to the activities. In addition, the VIG grant budget was not entered into the system.

With respect to the efficiency of its financial management, the Audit Team noted that the PMU had helped to support the implementation of the SAP enterprise resource planning software. The Gavi-designated accountant had access and used this system. Nevertheless, the Audit Team noted that several of the SAP system functionalities were not being used. For example, the PMU payment voucher processing system was done manually using designated forms, and thereafter the same transactions were effectively recorded into SAP, only after the cheque had been issued. Thus, the practices in place did not maximise the use of the system, which was designed to minimise the need for manual processes.

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Recommendation 3 (Essential)

The PMU should consider further developing its SAP system, so as to include additional functionalities including for example batch voucher processing. In addition, budgets for Gavi's funds should be entered into the system disaggregated to an appropriate level of expenditure.

Management comments

Management agrees with the recommendation.

PMU has agreed with EPI department to handle the GAVI disbursements to pay expenses and transfer to zones and EPI to report all expenses by activities.

MoH has established accounting system (SAP) accommodating Service Delivery Area and category but there is always room for revision or change and the recommendation given above can be done or applied provided Gavi:

- *Agrees or approves the revisions; and*
- *Provides funds for TA for SAP System expert based in Mauritius to review the system*

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Risk / Impact / Implications

Risk of inefficient processes as a result of supporting a manual system, in parallel to the accounting system. The lack of real time data and suitable financial detail from capturing disaggregated budgets could also hamper the efficiency and accuracy of financial reporting.

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Responsible

Project Director PMU/MOH

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Timeline

15 October 2018

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4.2 Grant assurance mechanisms

4.2.1. Ineffective internal audit function

Description	Recommendation 4 (Critical)
Article 14.1 of the Financial Management Manual (November 2011), states that the PMU through its internal audit function, shall carry out timely and acceptable internal audits. The manual requires that the following elements be in place: 1) For internal audit staff to be qualified internal auditors with requisite accounting and auditing qualifications; 2) The auditor to have clear terms of reference; 3). The lead internal auditor to develop a comprehensive audit plan of action that should include, among other items, the names of entities to be audited, the timing of audit and expected time for releasing related audit reports. The plan should also include details regarding the nature/scope of the audit e.g. first audit, follow up audit etc.; 4) Internal audit reports to be prepared within a reasonable period and to have clear recommendations; and 5) The auditees to develop an action plan to implement recommendations made in the audit reports. Based on the Audit Team's review of the function, it was determined that in its current state and structure, the Internal Audit function is not yet effective. As at June 2018, there was only one internal auditor in post, with a mandate which covered both the Global Fund and Gavi's grants. This level of resourcing was not sufficient to cover the assigned workload, which spanned more than 15 Sub Recipients under the Global Fund grant and 6 zones related to the Gavi grant, as well as responsibility to review the PMU's financial information on both grants. This same issue regarding the function's insufficient bandwidth and lack of capacity was already noted in the August 2016 Programme Capacity Assessment, carried out by Gavi. Furthermore, the Audit Team noted the absence of suitable documentation articulating what was the internal audit function's primary role and operations, since no audit manuals, no audit plans and no risk assessments were on file. The Internal Auditor explained that he had only begun auditing Gavi grants since 2017, showing that there were no such audits undertaken before. The first Gavi internal audit that the function undertook in 2017, sampled and reviewed the financial documents received by the PMUs from the zones/Zobas.	The PMU management should ensure that it complies with the requirements of its Financial Management Manual, in particular with respect to establishing and adequately resourcing, a credible Internal Audit function. This function's capacity and purpose should be strengthened to the extent that it is able to undertake audits which are properly supported, documented, and that the overall work plan takes into consideration an overall risk assessment of the programmes.

Description (continued)	Management comments
There was no documentation clarifying what was the sampling methodology, the scope of work done, explanation of the review process followed and the overall results. The Auditor suggested that this was due to there being no issues identified from his review of the documents sampled. Finally, in May 2018, the Internal Auditor made a field visit to Maekel Zoba to carry out a compliance audit. Based on the Audit Team's review of that Auditor's assignment, a similar lack in the documentation of the scope, methodology, findings and conclusions was evident. Vaccine supply management was not in scope, and there were no apparent mechanisms clarifying how the implementation of prior recommendations were followed up and individuals held to account.	*Management agrees with the recommendation.* *PMU/MOH/ side has one internal auditor for HIV, TB and Malaria Global Fund Grants with 15 Sub-recipients which is not enough. This has previously been brought to the attention of Gavi.* *For addressing the above challenges, we suggest the following:* • *Gavi to allocate budget for salary for engaging a competent internal auditor for Gavi grants* • *PMU/MOH/ to develop TOR for internal auditor and share with Gavi* • *Gavi to provide funds for TA for developing the Audit Manual and audit plan* • *Gavi to provide funds for capacity building training on risk management and mitigation strategies for H.Q and Zones staff*

Risk / Impact / Implications	Responsible	Timeline
Weak oversight over the Gavi supported activities.	Project Director PMU/MOH	When funds are available

4.2.2. Limitations in external audit scope

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Description

Best practice requires that external audit should cover all of the key risks of the grant or programme subject to audit. Similarly, as per Gavi's guidelines for "external audits of Gavi cash-based support", the detailed audit scope should consider including areas such the physical verification of assets to confirm their existence, where there is significant procurement of goods or works.

From the Audit Team's review of prior audits for FY 2014/2015, FY 2015/2016 and 2017, it was identified that these external audits only covered a limited scope of work, as they were confined to executing a desk review of the PMU's financial records at the central level. In particular, the prior audits did not include any visits or audit work at the sub-national level. Finally, the 2017 external audit did not include a suitable management letter as expected or required.

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Recommendation 5 (Essential)

The MOH, in discussion with the Gavi Secretariat, is recommended to update the external audits' terms of reference so as to expand their scope, so their coverage is more comprehensive and they include suitable sub-national checks, including a physical inventory of fixed assets and vaccine supplies.

In addition, it should be required that a suitable, detailed management letter on internal control weaknesses is issued with each external audit.

Management comments

Management agrees with the recommendation.

We can update the external audit ToRs and there is always room for revision or change and the recommendation given above can be done or applied.

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Risk / Impact / Implications

Narrow or limited scope external audits will fail to provide the required level of assurance on the management and performance of Gavi-supported activities.

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Responsible

Project Director

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Deadline/Timeline

20 October 2018

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4.3 Procurement

4.3.1. Bid evaluation process did not assure competitive selection

Description	Recommendation 6 (Critical)		
Beginning June 2017, the MOH launched a national competitive bidding process to award the contract for the printing materials for the family and community health unit. Following advertising of the intended procurement across various national newspapers, four bids were received by the PMU. The bids were opened on 28 June 2017 and evaluated by an evaluation committee of staff from various units across the MoH. All four bidders were qualified by the preliminary evaluation. Hence, the final selection was determined based on a "least cost basis" from the most responsive financial proposal. As documented by the committee's minutes, a commercial printer was recommended, as it was both responsive and the lowest overall cost. However, despite having won the bid, this final decision was overruled, with the award being redirected to a Government-owned printing supplier, with the condition that this second supplier matches the winning bidder's price and quality. MOH management also told the Audit Team, that the decision to revoke the winning supplier's bid was officially determined by "Government Procurement Services", which had indicated that the commercial printer could not present a legal certificate for its paper import. Although the MOH management's explanations were credible, the Audit Team noted that none of the justification and basis for amending the procurement outcome, was documented on file.	For the future procurements, the MOH should always comply with the national procurement guidelines, particularly in regard to awarding a contract to the most competitive bidder. If necessary, the evaluation committees should be reminded or retrained of their respective responsibilities. Where any material exception or amendment is proposed to the procurement outcome, this should always be adequately documented, with the necessary due approval being accorded and documented as required, before the contract is awarded. **Audit Team's additional comments** The audit team maintains its findings and conclusions on the lack of documentation on the selection process.		
	Management comments *Management partially agrees with the recommendation. For this incidence, the EPI program in their request opted to go for Sabur, the government printing press for quality reasons. This printing press was used by EPI in the previous years and they possess the software for efficiency reasons. The Sabur printing press cost offer was not higher than the private company but rather was the same.*		
Risk / Impact / Implications The selection of non-competitive or non-conforming bids could lead to funds being used in a non-economic manner or could result in legal challenge from any other participating bidders, where they have grounds to contend that there was the suggestion of uncompetitive behaviour. Redirecting or favouring contract awards to government suppliers on a retroactive price-matching basis, risks creating the perception that there is not a level-playing field (operating at arms' length), undermining both the operation of market forces, as well as potentially discouraging private enterprises competing in future.	Responsible PMU/MOH Director	Deadline/Timeline 30 September 2018	

4.4 Vaccine Supply Management

4.4.1. Near-expiry of PCV vaccine

Description	Recommendation 7 (Critical)
In 2016, the EPI team wished to switch its formulation of PCV vaccine from a single dose (1) to a four (4) dose presentation in the middle of 2017. Having discussed the issue with UNICEF, on 17 January 2017 the MOH placed an order for 160,000 doses of PCV13-4, later revised upwards to 187,000 doses. However, the MOH placed this order without fully considering its existing PCV13-1 balance in stock. From discussion with MOH Management, the Audit Team noted that beginning April 2017, at the time that the Ministry took receipt of the new vaccine, its EPI team decided to postpone its PCV product-switch by 6 months from July 2017 to January 2018. In parallel, the team also elected to suspend the principle of Earliest Expired First Out, so that it could finish up using all of its PCV13-1, before issuing the PCV13-4 formulation. By the time the country finished up its stock of single dose PCV13-1 in December 2017, it was apparent that there was an issue as the country now up to 10 months' worth of PCV13-	In future, the EPI unit should liaise with UNICEF to ensure the proper forecasting of its requirements and needs (including taking into consideration existing stock balances and past track records of consumption), so as to adequately manage the risk against any vaccines from shelf-expiring or being wasted

4 of stock on hand at the central level, putting increasing time pressure on the programme to use up this formulation prior to the vaccine shelf expiring at the end of September 2018. As at the time of the Audit in June 2018, the Audit Team estimated that up to 65,000 doses of short shelf-life PCV13-4 was at risk of expiring, considering that it typically takes several months for the vaccines to travel via the cold chain to the beneficiary and that Zobas' typically held a two to three-month buffer stock.

Thereafter in November 2018, following a post fieldwork review of the central store's records (see Annex 5 for details), it was noted that:

- 22,400 doses of the PCV 13-4 were issued in June 2018; and
- 37,980 doses of the PCV 13-4, were issued in July and August 2018 (up to 15 August 2018).

Thus, as expected, more than 60,000 doses of near-expired PCV 13-4 expiring on 30 September 2018, were belatedly issued from the central vaccines stores with less than 3- or 4-months' shelf-life left, respectively.

Management comments

Management agrees with the recommendation.

Initially the county planned to make switch from one dose formulation of PCV-13 to 4 doses formulation of PCV-13 in August 2017. But considering the remained doses of PCV-13 of one dose vials in stock, the switch plan postponed to December 2017 to utilise all of one dose formulation at sub national and service levels. At the same time, implementation of the switch plan was not on the same date and month in all health facilities at service delivery level. Because, the health facilities were informed to finish the one dose PCV-13 on hand before going to use the 4 doses vial of PCV-13.

At the time of the audit work in June 2018, at national level there had been 65,000 PCV13-4 doses on stock with expiry date of 30 September 2018.

But, considering our county set-up and associated transport shortages to deliver vaccines to sub national and district levels, most of the Zobas and districts collect vaccines almost every month and it takes a maximum of two months to deliver vaccines from national to service delivery level. The SMT in the country is also in place at national and sub national levels to make a close follow-up and monitor the stock status of the vaccines.

Based on the monthly consecutive SMT information at national and sub national levels, all the PCV-13 with expiry date of 30 September 2018 reached service delivery level by the first week of September. Moreover, the program has a practice of making a push to utilise vaccines near expiry by doing outreach visits in areas with less access for timely uptake of the vaccine doses by the children in these areas.

According the guidelines, every health facility is supposed to prepare certificate of destruction for expired vaccines and vaccines with VVM3 or VVM4 and report to higher levels. But we cannot say that each health facility is appropriately implementing this plan. There could be some unutilised PCV-13 vaccines as at end of September at some health facilities which may be disposed.

Risk / Impact / Implications	Responsible	Deadline/Timeline
Vaccines which shelf-expire due to inadequate systems or poor forecasting procedures, potentially constitutes wastage.	EPI Manager	Ongoing

4.4.2. Weaknesses in vaccine stores management

Description

The Standard Operating Procedures (SOPs) for "Effective Vaccine Management" (EVM) promotes the need to establish straightforward, standardized vaccines management processes both within the vaccine stores, as well at service delivery facilities, so as to minimize wastage and improve the quality of immunization service delivery. These SOPs underline the required activities and tasks to be routinely carried out, and the correct sequence required, so as to ensure the quality of stocks throughout the supply chain, including for example: (i) forecasting vaccines and related supplies; (ii) ordering and receiving vaccines and related supplies; (iii) temperature monitoring in cold and freezer rooms; (iv) procedures for vaccines vial monitor (VVM); (v) handling vaccines and supplies stock; and (vi) distribution/ issuance of vaccines and supplies. Once established, the EPI unit widely disseminated the SOPs across the national and sub-national levels.

The Audit Team observed a selection of the actual vaccine management practices at the Central Vaccine Store, the Zoba vaccine stores, the Sub-Zoba vaccines stores and the facility level.

In general, at the central level, the vaccine stores were well maintained, and the stock records were up to date.

From its review at the sub national level, the Audit Team noted the following:

- Failure to update and errors in recording in the SMT system including wrong batch numbers;
- Lack of established minimum, reorder and maximum quantities;
- Missing documents such as EPI vaccine Stock forms and temperature charts due to poor filing;
- Lack of serialisation/ pre-numbering of requisition and delivery forms;
- Failure to record vaccine information including VVM status, batch numbers, expiry dates etc. during receipt from Zoba;
- Failure to prepare requisite documents such as monthly temperature review reports, store vouchers/delivery forms and wastage reports;
- Lack of evidence on periodical physical stock count of vaccines;
- Variances between actual stock held and books balance at the time of the audit;
- Lack of preventive maintenance;
- Instances of overstocking (understocking); and

Recommendation 8 (Critical)

All staff responsible for managing and handling vaccines should comply with the established SOPs, which clearly outline the necessary management guidelines and procedures for vaccines.

In addition, and in line with the EVM improvement plan, the MoH should: 1). Conduct refresher training on the SOPs to EPI officers, 2). Provide reference documentation through booklets and wall posters for ease of reference and 3). Intensify supervision activities to ensure its staff comply in full with the SOPs.

Management comments

Management agrees with the recommendation.

There is one SOP document in every health facility in the EPI corner providing routine immunization services which serves as a reference for vaccine cold management. For most of the EPI focal persons working in health facilities training and refresher training has been provided on SOPs and IIP Modules and we will keep on with these activities for the rest of the health facilities every year using the GAVI HSS grants and other opportunities such as introducing new vaccines.

For the concerns raised on vaccine stock management and appropriate archiving of EPI monitoring and reporting tools at the sub national level, we will make close follow-up and we will provide them supportive supervision to address the issues.

• Direct issuances from Zoba to Health Stations (HSs) without reconciliation between the Zoba, sub-Zoba and HS. Additional information on the business entities affected and the incidence of the concerns identified are presented in more detail on Annex 3: Weaknesses in Vaccine Supply Management.		
Risk / Impact / Implications Failure to follow existing Standard Operating Procedures may result in the risk of unavailability of vaccines, lost potency of vaccines and ultimately missed immunisation opportunities.	Responsible EPI Manager	Deadline / Timetable 31 December 2018

4.4.3. Weaknesses in syringe management resulted in wastage

Description

Due to lack of storage space at the national vaccine stores, syringes were stored with a parastatal government agency that was in charge of the central health commodities and supplies warehouses and having the overall responsibility for the management of the storage of health commodities, dry goods and immunisation supplies. A review of the parastatal's stock records identified that:

- The parastatal was not consistently complying with Earliest Expiry First Out (EEFO) with respect to the turnover of the syringes;
- The parastatal's stock records failed to track the expiry date of health commodities, including syringes; and
- Physical stock counts/ inventories were only done on an annual basis, which was insufficient, and the approach adopted to how the counts were done was not effective. Similarly, with respect to the 2016 central-level physical inventory, there were errors in the expiry dates of the ADS 0.5ml syringes recorded per the count.

The inadequate management of syringes and non-compliance with EEFO ultimately culminated in the shelf-expiry and wastage of 358,800 x 0.5ml auto-disabled syringes at the end of Dec 2017.

Both EPI Management and the parastatal commented that there was a significant accumulation of syringes during the period 2014-2015. However, based on the Audit Team's review of this period, it was noted that the amount of stock up until 2018 was manageable and should not have resulted in any wastage, had EEFO principles continued to be respected for the duration of the period. The MOH management commented that there are plans to increase its dry-goods storage capacity at the national vaccine stores in the future, so that responsibility for the management of syringes will revert back to the EPI programme and removing the need for the parastatal.

Recommendation 9 (Essential)

Until the stock management of syringes reverts to EPI, the programme should ensure that it get regular updates on its stock holdings from the Parastatal, indicating the shelf-expiry dates of the immunisation supplies, including from the parastatal that Earliest Expiry First Out principles are complied with.

In addition, the parastatal should regularly undertake a physical inventory of its key stocks and supplies, and should communicate to the EPI unit accordingly, including a mandatory once a year itemised stock count of all supplies. The parastatal should consider introducing a rolling physical inventory of its stock holdings, with sufficient frequency to ensure that it minimises all future stock wastage and expiry.

Management comments

Management agrees with the recommendations.

The EPI program is aware of that there was an overstock of 0.5ml AD syringes in the parastatal coming from the various sources. Given this, the program did not order additional 0.5ml AD syringes since 2016.

In the GAVI HSS II grant, there is a budget allocated to build dry store in NVS site. After completion of the dry store, all injection safety materials will be managed by the EPI program. For the time being, the program will make a close follow-up and will work jointly with the parastatal unit to monitor the EEFO protocols of the injection safety materials.

Risk / Impact / Implications	Responsible	Deadline / Timetable
Poor management of syringes leading to wastage of resources.	EPI Manager	1 September 2018

4.5 Immunisation data quality

4.5.1. Inconsistencies in pentavalent coverage data

Description

In line with the principles agreed in the Partnership Framework Agreement (PFA) between the MOH and Gavi on the accuracy of information, the Audit Team reviewed the country's administrative data relating to its pentavalent vaccine immunisation.

Per Article 8.1 (d) of this Agreement on the accuracy of information, the government represents to Gavi that all information that it provides to Gavi: "including its applications, reports, supporting documentation, and other related operational and financial information/reports, is accurate and correct as of the date of the provision of such info."

In addition, Article 16, Annex 2, Section C of 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," such that: "Gavi seeks to use the Government's reports and existing country-level mechanisms to monitor performance."

The Audit Team compared the administrative immunisation coverage reported by the country to the actual volume of vaccine issued by the central level warehouse to the six Zobas during the four-year period, 2014 –2017. The analysis as set out on Annex 4, showed:

- For Anseba and Debub, each of these Zobas average administrative coverage reported during the 4-year period was 100% and 98% of the number of doses of pentavalent issued during the period, respectively. Debub is the second largest contributing Zoba (after G/Barka) across the country;
- During the period review for four of the Zobas, there were years when the administrative coverage was inexplicably higher for one year than in prior years. The unexplained anomalies noted by the Audit Team were as follows:

Recommendation 10 (Essential)

As part of the upcoming DQA planned in 2018, it is recommended that the MOH should follow up on this data anomaly by examining its process of administrative data collection, in order to ensure that it accurately captures the immunisation coverage rates.

Management comments

Management agrees with the recommendation.

The data report of immunization services from the service providers to districts; from district to Zoba and entering the vaccine dose data in to HMIS software is not 100% correct.

From data quality audit and data quality desk review exercise in Gash barka, some problems were observed in tallying of the administered doses, summarizing the monthly report and data entry into the computer. After the data quality self-assessment (DQS) was done in the Zoba, much improvement has been observed in the year 2018. This plan will be implemented in all Zobas in the upcoming month after we have completed the MR Catch-up campaign.

➢ Anseba – anomaly in the 2016 admin coverage > 112% of penta issued; ➢ Debub – anomaly in the 2016 admin coverage > 103% of penta issued; ➢ Maekel - anomaly in the 2014 admin coverage > 114% of penta issued; ➢ NR Sea – anomaly in the 2017 admin coverage > 103% of penta issued; The above anomalies remained even after considering the maximum amount of pentavalent vaccine available which could have been brought forward from the prior year's order. Thus, the impact of any open and closing balances of pentavalent held at the Zoba level was shown to be negligible for these identified anomalies. The Audit Team did not adjust its analysis to account for the country's 5% stated wastage rate of pentavalent, even though this factor would widen the unexplained gap between the already elevated administrative coverage rates, in contrast to the lesser quantities of vaccine supplied. The Team's analysis of the pentavalent coverage data, suggests that there are data inconsistencies in select Zobas between the number of children vaccinated, compared to the volume of vaccine issued at central level. The Team therefore questions the quality of administrative data, as reported to Gavi via the Performance Framework.		
Risk / Impact / Implications Potential, unexplained inconsistencies in the administrative coverage data, which are reported as official data could have the following adverse consequences: • Non-compliance with the terms of the Partnership Framework Agreement and inaccurate reporting in the Performance Framework; • Possible vaccine losses going unreported; • Undermining the level of confidence in administrate immunization data; and • Ultimately potentially overstating the administrative immunisation coverage data for pentavalent.	Responsible EPI Manager	Deadline / Timetable 31 March 2019

Annex 1: Questioned costs

Date and ref.	Description	Amount (NKF)	Amount (USD)	Inadequate	Irregular	Ineligible	Comments
30.01.14 **JV-13009**	Conduct training for village Health committee - Zoba Merkel	129,631	8,642	92,332	37,299		No activity report, deviation from budget, no evidence of procurement for hotel, no evidence of activity carried out since there were no attendance sheets for the participants hence inadequately supported cost of ERN 92,332 and supporting documents had varying dates, resulting in the Audit Team determining that ERN 37,299 was irregular.
07.08.17 **CP 03795**	Train Health workers on patient safety, AEFI surveillance, reporting system and case management within five years in Zoba and Sub-Zoba health facilities - Zoba Merkel	98,004	6,534	98,004	-		No detailed report showing how the activity was done for the days in the hotel, the areas of training, etc. Budget vs actual analysis was also not prepared against the approved budget. There were no attendance sheets for the participants listed. There was also no evidence of activity carried out.
31.12.17 **JV - 0039**	Train CHWs in basic AEFI surveillance so as to minimize missed opportunities of capturing information on AEFI at community level within the first two years of the grant period - Zoba Debub	139,999	9,333		3,999		There was no detailed report showing how the activity was done. Budget vs actual analysis was also not prepared against the approved budget. Receipt for stationery for ERN 3,999 was dated 28/11/2017 after the activity was carried out in October 2017 hence expenditure considered irregular.
28.06.14 **PV 56/14**	Per diem for research for bilharzia and mosquito breeding sites - MoH	145,000	9,666			145,000	The expense was not Gavi grant related.
27.06.14 **PV 54/14**	Purchase of fuel for research for bilharzia and mosquito breeding sites in Zoba Debub MoH	57,486	3,832			57,486	The expense was not Gavi grant related.
	Total ERN			**190,336**	**41,298**	**202,486**	
	Total USD			**12,689**	**2,753**	**13,499**	

Annex 2: Detailed listing of expenditure not in line with the HSS 1 budget

Transact N°		Key word	Description as per cash book	Amount (USD)	Amount (USD)
Jv. 465	610102	Dialysis	Dialysis Consumable PO# 1/20 -Frese	12,720.00	
Jv. 465	610302	Dialysis	Dialysis Consumable PO# 1/20 -Frese	4,903.59	
Jv. 465	201001	Dialysis	Dialysis Consumable PO# 1/20 -Frese	23,000.00	
Jv. 465	201001	Dialysis	Dialysis Consumable PO# 1/20 -Frese	20,379.43	
Jv. 443	611201	Dialysis	B ch Dialysis Consumable PO#1/20	497.57	
Jv. 465	611201	Dialysis	Dialysis Consumable PO# 1/20 -Frese	36,511.54	98,012.13
Pv. 4250	610102		Transport PreFab Contain to GB	7,333.33	
Jv. 451/NR	610302		Theortic class operat room tech -NR	6,556.67	
Pv. 4270	610302		Car rent for diff purpose	1,906.04	
Jv. 451/NR	610901		Cataract surgery travel allowa -NRS	853.53	
Pv. 4275	201001		Ladder for Physioteraphy Center	466.67	
Pv. 4247	611101		Uniform, Shoe for cleaner &load unl	513.93	
Pv. 4248	611101		Diff supp Loading unload of medical	143.33	17,773.50
				115,785.63	115,785.63

Annex 3: Weaknesses in Vaccine Supply Management

Particulars	Massawa	Foro	Ghindae	Debub	Mendefera	Debarwa	Maekel	Serejeka	Berik
Failure to update and errors in recording in the SMT system including wrong batch numbers	√			√			√		
Lack of established minimum, reorder and maximum quantities					√	√		√	√
Missing documents such as EPI Vaccine Stock forms, temperature charts due to poor filing	√	√	√	√	√	√	√	√	√
Lack of serialization/ pre-numbering of requisition and delivery forms	√	√	√	√	√	√	√	√	√
Failure to record vaccine information including VVM status, batch numbers, expiry dates etc. during receipt from Zoba	√	√	√		√	√	√	√	√
Failure to prepare requisite documents such as monthly temperature review reports, store vouchers/delivery forms, wastage reports	√	√	√	√	√	√	√	√	√
Lack of evidence on periodical physical stock count of vaccines	√	√	√	√	√	√	√	√	√
Variances between actual stock held and books balance at the time of the audit	√	√	√	√	√	√	√	√	
Lack of preventive maintenance	√	√	√	√	√	√	√	√	√
Instances of overstocking (understocking)	√	√	√	√	√	√	√	√	
Direct issuances from Zoba to Health Stations (HSs) without reconciliation between the Zoba, sub Zoba and HS								√	√

Key

Colour code	Particulars
	Zoba
	Sub-Zoba

We present some of the details below:

a) Missing vaccine batch in the SMT system: At the CVS, Batch no number 137Q6035C, Penta, had been wrongly updated in the SMT system upon receipt as 137Q6035D. As a result, the batch was distributed downstream recorded in the SMT system as batch number 137Q6035D. The omission was also noted at the Zobas visited at the Northern Red Sea, Debub and Markel.

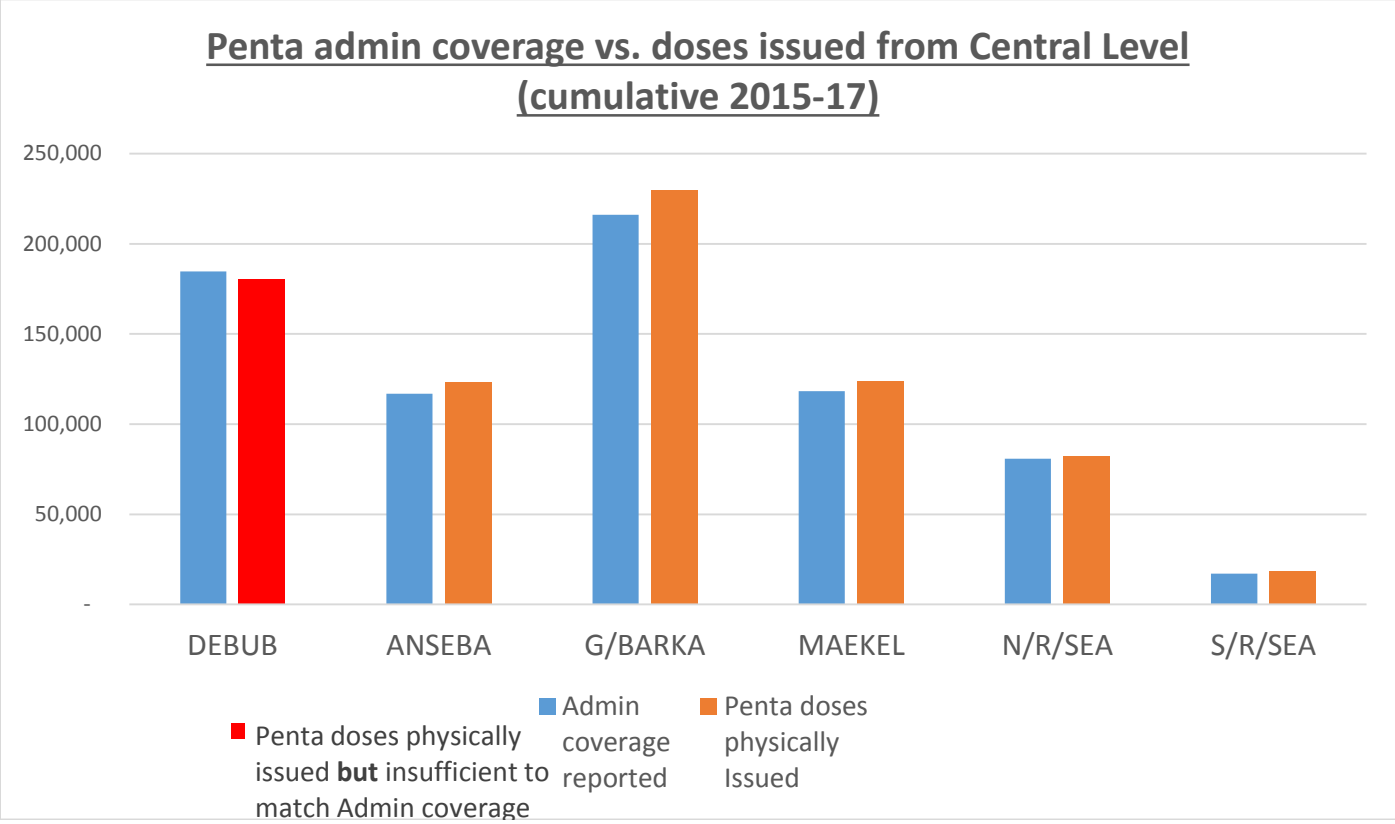
b) Stock challenges: To review accuracy of variance stock levels we conducted sheet to floor stock count and made comparison with the actual as well as calculated vaccine stock levels (minimum, maximum and buffer) for the respective stations. The following variances were noted:

- At the CVS, we noted variances in Penta where the actual stock was above the stock in SMT by 6,770 doses.
- At Zoba Massawa the PCV minimum stock was set at 3,000 doses and a re-order level of 6,000. However, in April 2018, the closing stock was 100 doses.
- At Sub-Zoba Foro the station made a requisition of PCV and Rota on 6 March 2018. These were however not processed since there were inadequate stock at Zoba level. A new requisition for the same was made on 15 March 2018, 9 days later after adequate stock were available at the Zoba level.
- At Zoba Debub the PCV minimum stock was set at 6,000 doses and a re-order level of 7,500. However, on 24 Jan 2018, the actual stock on hand, when an order form was submitted had reduced to 30 doses, as identified on the requisition order form.
- There were cases of stock-out attributed to supply chain inefficiencies and slow lags in response time from the central level and Zobas. At Zoba Massawa we noted a stock out of PCV from 19 to 29 May 2018; in Sub Zoba Ghindae there was a Stock out of Penta, Rota and PCV on 15 May 2018 and at Sub-Zoba Mendefera a stock out of Rota was noted on 17 May 2018.

In almost all the stations visited, there were various examples where the quantities of vaccines ordered varied from the physical quantity of vaccines actually received.

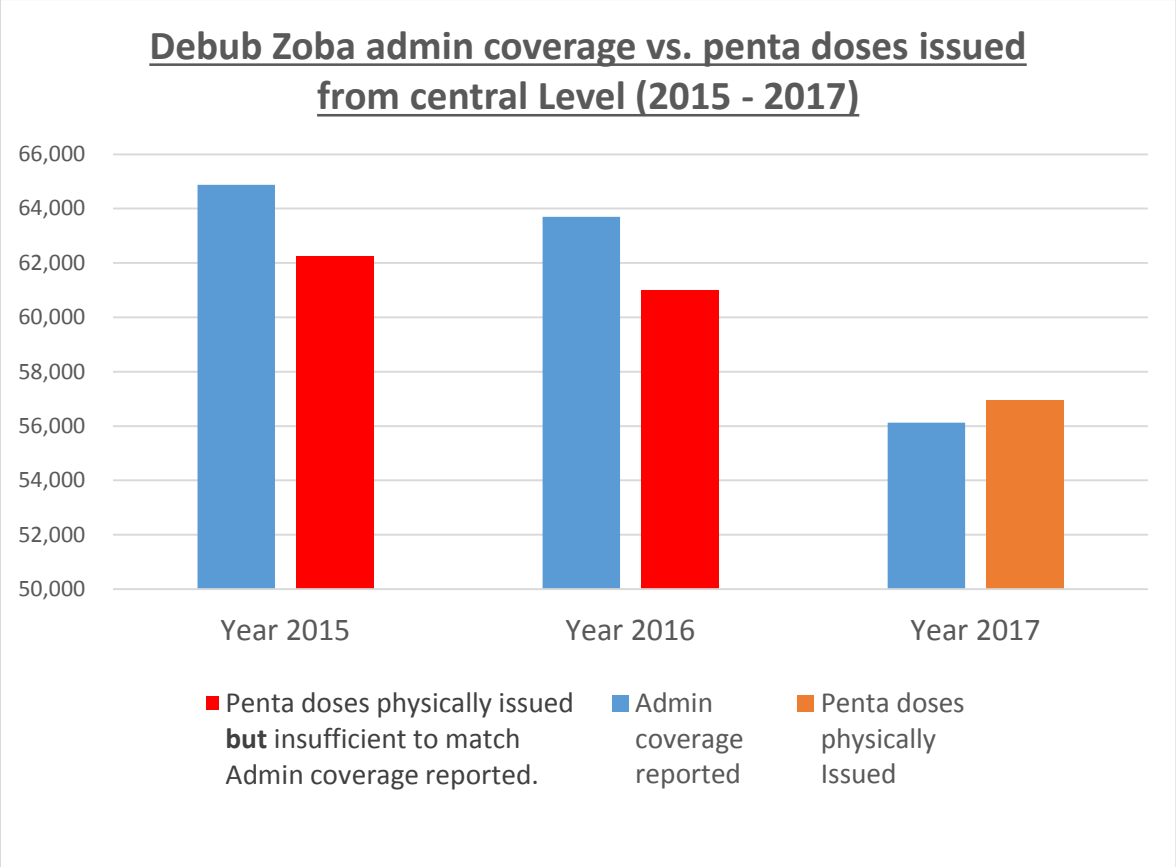
Annex 4: Data anomalies - Immunisation coverage vs. supply of pentavalent

Annex 4.1: Penta admin coverage vs doses issued from Central level



The analysis illustrated above was not adjusted for the country's stated vaccine wastage rates which would increase the unexplained gap between the reported administrative coverage rates and the actual quantities of pentavalent issued by the central vaccines store. The Audit Team also considered the potential error due to opening and closing balances together with residual supplies across the lower levels of the supply chain. This error was negligible as three years' worth of data was used, and we noted that the supplies of penta vaccine distributed to each respective Zoba were consistent and followed a routine 45 to 60-day pattern (as illustrated on Annex 4.4).

Annex 4.2: Debub Zoba admin coverage vs penta doses issued from central level (2015-2017)



The analysis illustrated above was not adjusted for the country's stated vaccine wastage rates which would increase the unexplained gap between the reported administrative coverage rates and the actual quantities of pentavalent issued by the central vaccines store. The Audit Team also considered the potential error due to opening and closing balances together with residual supplies across the lower levels of the supply chain. This error was negligible as three years' worth of data was used, and we noted that the supplies of penta vaccine distributed to each respective Zoba were consistent and followed a routine 45 to 60-day pattern (as illustrated on Annex 4.4).

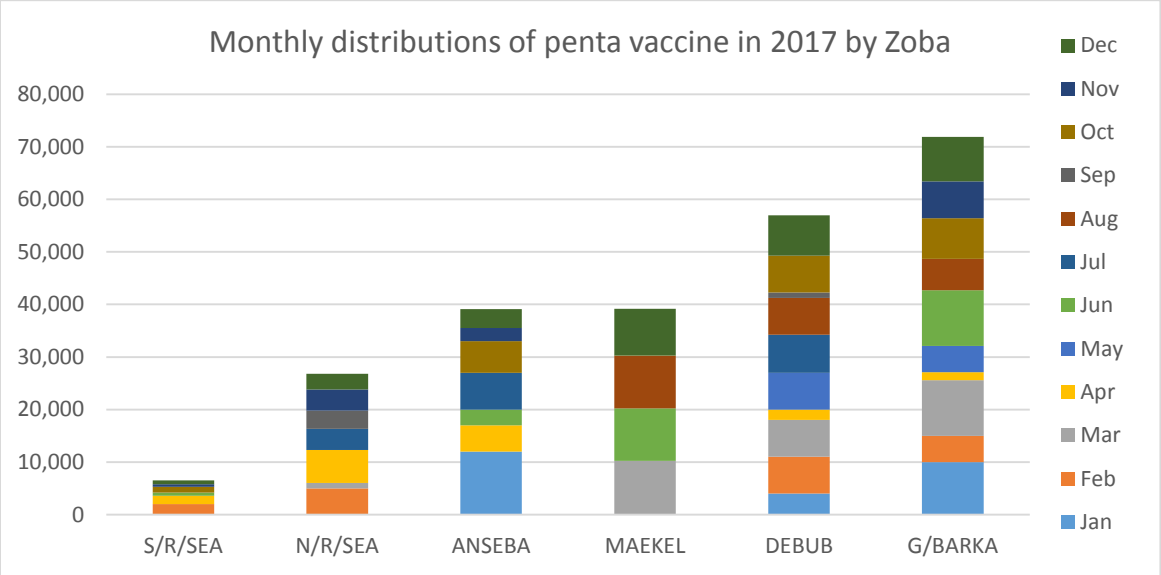
Annex 4.3: Administrative coverage compared to the supply of penta vaccine to Zobas

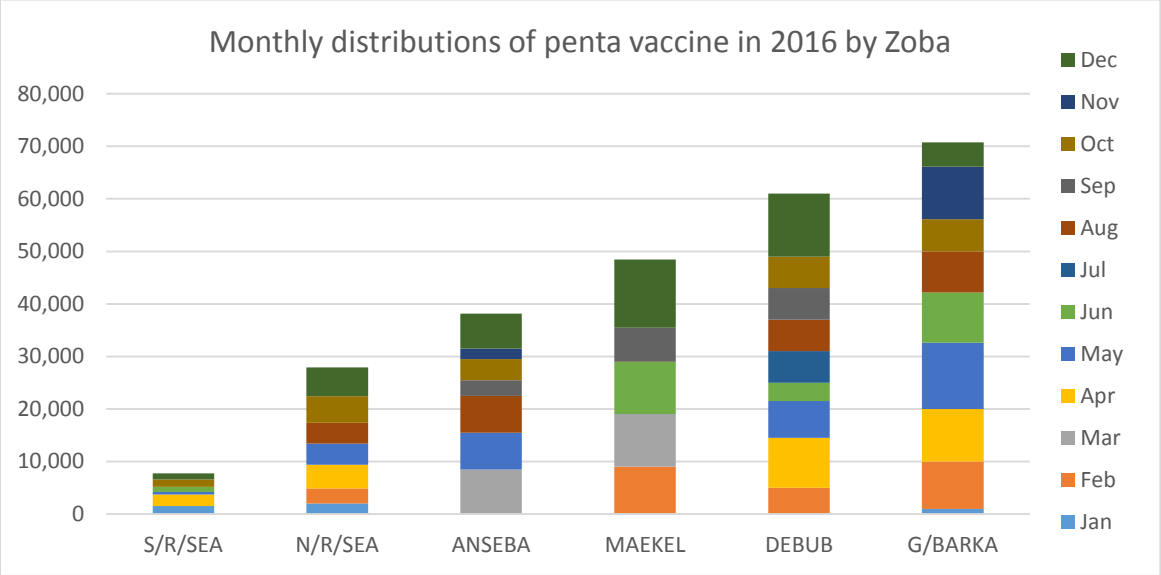
	Administrative coverage as a % of Pentavalent stock issued centrally				
Zoba:	**2014**	**2015**	**2016**	**2017**	**Average**
ANSEBA	119%	90%	112%	83%	100%
DEBUB	95%	97%	103%	99%	98%
G/BARKA	94%	83%	96%	93%	91%
MAEKEL	97%	114%	82%	97%	96%
N/R/SEA	90%	96%	94%	103%	95%
S/R/SEA	77%	109%	75%	89%	85%
TOTAL	**97%**	**94%**	**97%**	**94%**	**95%**

	Administrative coverage data			
Zoba:	**2014**	**2015**	**2016**	**2017**
ANSEBA	40,388	41,575	42,678	32,417
DEBUB	63,823	60,181	63,020	56,301
G/BARKA	75,871	72,580	68,167	67,037
MAEKEL	39,791	41,153	39,835	37,813
N/R/SEA	30,550	26,387	26,249	27,643
S/R/SEA	5,151	4,860	5,824	5,766
TOTAL	**255,574**	**246,736**	**245,773**	**226,977**

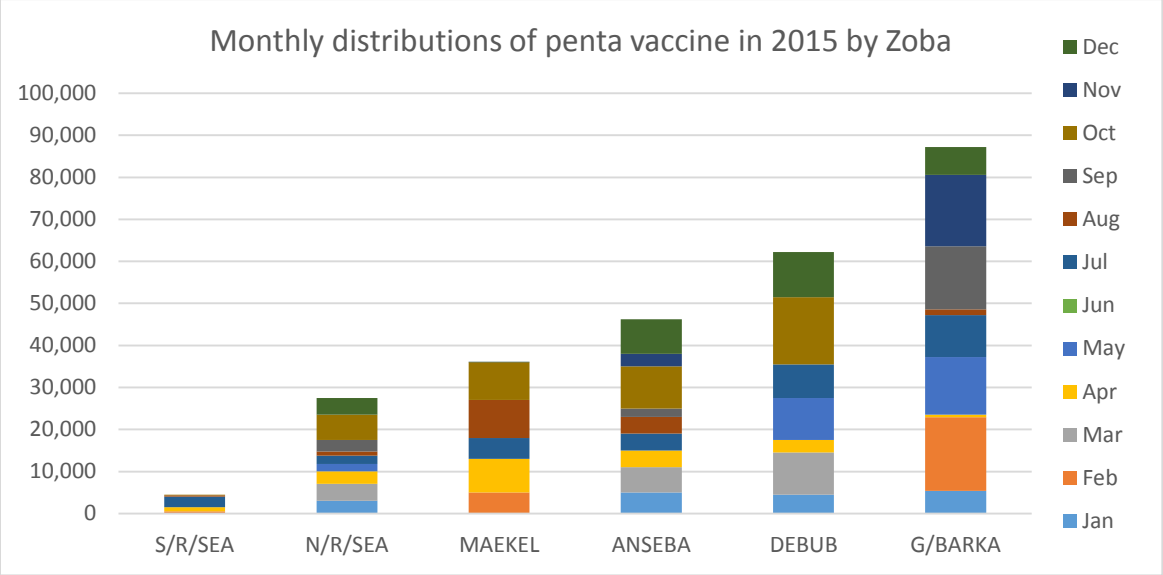
	Penta issuances from central level as per SMT			
Zoba:	**2014**	**2015**	**2016**	**2017**
ANSEBA	34,000	46,250	38,150	39,100
DEBUB	66,850	62,250	61,000	56,950
G/BARKA	80,550	87,200	70,750	71,900
MAEKEL	41,050	36,045	48,445	39,150
N/R/SEA	34,000	27,500	27,900	26,800
S/R/SEA	6,650	4,450	7,760	6,500
TOTAL	**263,100**	**263,695**	**254,005**	**240,400**

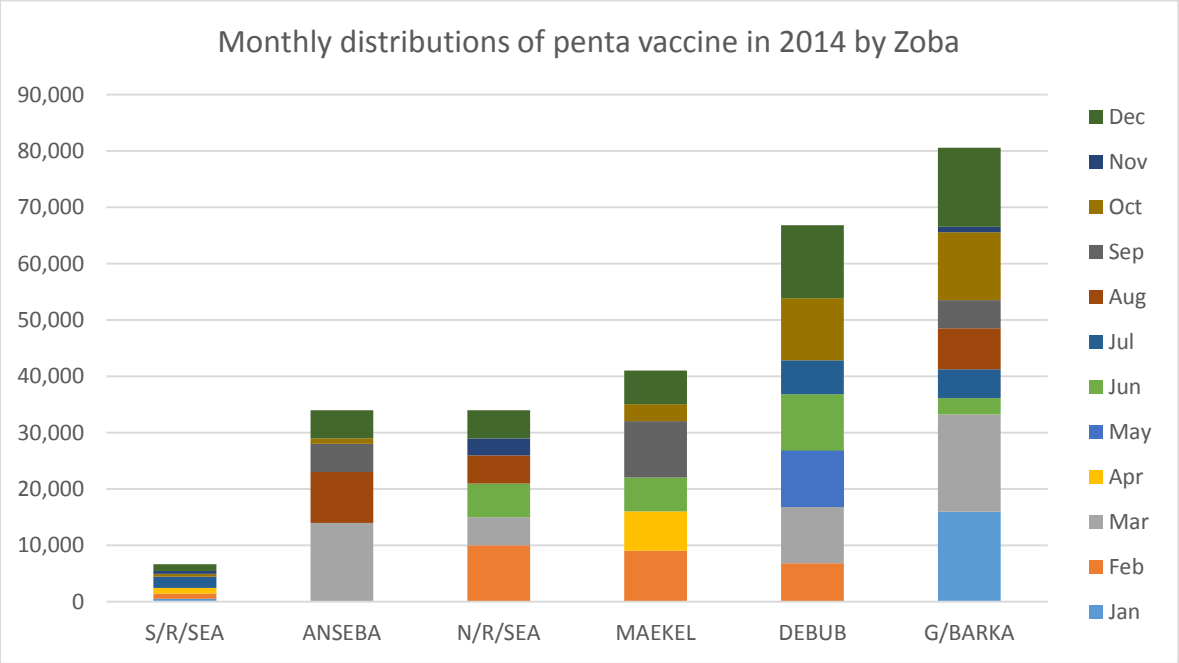
Annex 4.4: Monthly distributions of pentavalent vaccine





Annex 4.4: Monthly distributions of pentavalent vaccine (continued)





Annex 5: Definitions of audit ratings and prioritisations

A. Audit ratings

The Gavi Programme Audit Team's assessment is limited to the specific audit areas under the purview and control of the primary implementing partner administrating and directing the programme of immunisation. The three audit ratings are as follows:

- **Satisfactory –** Internal controls and risk management practices were adequately established and functioning well. No high-risk areas were identified. Overall, the entity's objectives are likely to be achieved.
- **Partially Satisfactory –** Internal controls and risk management practices were generally established and functioning but needed improvement. One or more high- and medium-risk areas were identified that may impact on the achievement of the entity's objectives.
- **Unsatisfactory –** Internal controls and risk management practices were either not established or not functioning well. The majority of issues identified were high risk. Hence, the overall entity's objectives are not likely to be achieved.

B. Prioritisation of recommendations

The prioritisation of the recommendations included in this report includes proposed deadlines for completion as discussed with the Ministry of Health, and an indication of how soon the recommendation should implemented. The urgency and priority for addressing recommendations is rated using the following three-point scale, as follows: Critical – Essential – Desirable.

Annex 6: Classification of questioned expenditures

Adequately supported – Expenditures validated on the basis of convincing evidence (evidence which is sufficient, adequate, relevant and reliable) obtained by the auditors during the carrying out of their mission on the ground.

Inadequately supported – This covers two sub-categories of expenditure:

a. Purchases: This is expenditure for which one or more of the essential items of documentary evidence required by the country's regulations on procurement are missing such as procurement plan, tender committee review, request for quotation, invoice, contract, purchase order, delivery note for goods and equipment, pro-forma invoice, the final invoice, etc.
b. Programme activity: This is expenditure where essential documentation justifying the payment is missing. This includes but is not limited to travel without a travel authorisation, lack of a technical report or an activity report showing completion of the task, signed list by participants. Lack of the same documents to support liquidation of advances/floats given for meetings/trainings/workshops etc.

Irregular Expenditure – This includes any deliberate or unintentional act of commission or omission relating to:

a. The use or presentation of documents which are inaccurate, incomplete/falsified/inconsistent resulting in the undue use or payment of Gavi provided funds for activities, or the undue, withholding of monies from funds granted by Gavi,
b. The embezzlement or misappropriation of funds to purposes other than those for which they were granted.

Ineligible expenditures – Expenditure which does not comply with the country's programme/grant proposal approved by Gavi or with the intended purpose and relevant approved work plans and budgets.

Annex 7: Audit Procedures and Reporting

Using risk-based audit procedures, the audit shall include, an analysis of reported expenditure (in periodic financial reports), inquiry/ discussions, computation, accuracy checks, reconciliation and inspection of records/ accounting documents, interviews of individuals receiving cash disbursements, and the physical inspection of assets purchased and works performed using grant funds.

The following procedures were carried out:

- Review of the Financial Management arrangements for the programmes, focusing on the control procedures e.g. appropriation and approval, segregation of duties, roles and responsibilities, reconciliation, verification of delivery of goods and services, invoice verification, retirement of advances controls and imprest;
- Review of the arrangements for managing the bank accounts, including tracing withdrawals and transfers from the programme and designated accounts to determine that they are for eligible expenditures for the programmes;
- Verification, on a sample basis, of procurement undertaken to ensure that the applicable policies and procedures are strictly adhered to and that transparency and value for money is maintained;
- Review of the mechanism for channelling cash advances from the MOH to the various budget management centres at the various levels (regional and district) to ensure that there are adequate internal controls in place to timely liquidated such advances;
- Undertaking field visits to regions and districts to review flow of funds and to determine whether principal activities took place according to the work plan/ schedule of cash advances;
- Visit to the central, Zoba and sub- Zoba stores to ensure that stock management procedures are being well implemented;
- Physical verifications, on a sample basis, to check the actual delivery of goods, works and services purchased as per the source documents;
- Review of expenditure and identifying expenditures which are not eligible for funding from Gavi programme funds.

At the end of the audit, key findings were discussed with the senior management team at Ministry of Health on 14 June 2018 and a presentation which contained a summary of these findings was shared with the Ministry of Health and other partners.

Annex 8: Management comments and action plan

Recommendation	Management Comments (Agreement/Disagreement)	Definitive Date and Responsible Person/ unit for implementing the recommendation.
Recommendation 1 (Critical) In future, the PMU should ensure that expenditures are in line with the respective approved budgets. Deviations from the approved amount should be justified and discussed with Gavi, as well as supported by a suitable budget reallocation which is approved by the ICC/Gavi secretariat, in line with the Gavi guidelines on financial management.	Management agrees with this recommendation. Comments for specific activities are as below: **Dialysis Consumables** The patients subjected for dialysis were equally men and women. Given the stock out of the dialysis consumables, unless immediately continued or sustained, this would endanger the lives of both sexes. As there were no other funding resources available, and believing the GAVI funding by and large safeguards women and children, the funding for dialysis consumables were made. This initiative was based on the instruction letter given by the Minister of Health (see attached for easy reference). **Fixed Asset register: FAR** The expense made for FAR is eligible because this was done for identification of GAVI's fixed asset and tagging and besides we do not have running costs in GAVI to cover the FAR expenses. **Cataract expenses:** This expense was made for cataract operation for staff per-diem as this operation involves females and mothers as beneficiaries	15 August 2018, PMU Director

Recommendation	Management Comments (Agreement/Disagreement)	Definitive Date and Responsible Person/ unit for implementing the recommendation.
Recommendation 2 (Critical) In future, the Ministry of Health should ensure that the accounting undertaken at each sub- level of the health system, ensures that each transaction is matched by all of the necessary supporting documents and justifications, and that these are reviewed for completeness and accuracy; and In addition, any unsupported or ineligible expenditures, including indirect costs not relating to the immunisation programme, should be repaid to the Gavi Secretariat.	Management agrees with the recommendation. There was inadequately supporting documents for NKF 37,299 (USD 2,486.60) but some supporting documents including photograph was given to the auditors while in Eritrea and can be assessed from them if they cannot submit we can re-provide. For the irregular expenditure, for the expenditure ERN 3,999.00 there was a detailed report how the activity was done and budget vs actual analysis also prepared. Payment of the stationary was done later, because they took the goods by credit.	20 September 2018, PMU Director/MoH
Recommendation 3 (Essential) The PMU should consider further developing its SAP system, so as to include additional functionalities including for example batch voucher processing. In addition, budgets for Gavi's funds should be entered into the system disaggregated to an appropriate level of expenditure.	Management agrees with the recommendation. PMU has agreed with EPI department to handle the GAVI disbursements to pay expenses and transfer to zones and EPI to report all expenses by activities. MoH has established accounting system (SAP) accommodating Service Delivery Area and category but there is always room for revision or change and the recommendation given above can be done or applied provided Gavi: • Agrees or approves the revisions; and • Provides funds for TA for SAP System expert based in Mauritius to review the system	15 October 2018, PMU Director

Recommendation	Management Comments (Agreement/Disagreement)	Definitive Date and Responsible Person/ unit for implementing the recommendation.
Recommendation 4 (Critical) The PMU management should ensure that it complies with the requirements of its Financial Management Manual, in particular with respect to establishing and adequately resourcing, a credible Internal Audit function. This function's capacity and purpose should be strengthened to the extent that it is able to undertake audits which are properly supported, documented, and that the overall work plan takes into consideration an overall risk assessment of the programmes.	Management agrees with the recommendation. PMU/MOH/ side has one internal auditor for HIV, TB and Malaria Global Fund Grants with 15 Sub-recipients which is not enough. This has previously been brought to the attention of Gavi. For addressing the above challenges, we suggest the following: • Gavi to allocate budget for salary for engaging a competent internal auditor for Gavi grants • PMU/MOH/ to develop TOR for internal auditor and share with Gavi • Gavi to provide funds for TA for developing the Audit Manual and audit plan • Gavi to provide funds for capacity building training on risk management and mitigation strategies for H.Q and Zones staff	PMU Director Once funds are available.
Recommendation 5 (Essential) The MOH, in discussion with the Gavi Secretariat, is recommended to update the external audits' terms of reference so as to expand their scope, so their coverage is more comprehensive and they include suitable sub-national checks, including a physical inventory of fixed assets and vaccine supplies.	Management agrees with the recommendation. We can update the external audit ToRs and there is always room for revision or change and the recommendation given above can be done or applied.	20 October 2018, PMU Director

Recommendation	Management Comments (Agreement/Disagreement)	Definitive Date and Responsible Person/ unit for implementing the recommendation.
In addition, it should be required that a suitable, detailed management letter on internal control weaknesses is issued with each external audit.		
Recommendation 6 (Critical) For the future procurements, the MOH should always comply with the national procurement guidelines, particularly in regard to awarding a contract to the most competitive bidder. If necessary, the evaluation committees should be reminded or retrained of their respective responsibilities. Where any material exception or amendment is proposed to the procurement outcome, this should always be adequately documented, with the necessary due approval being accorded and documented as required, before the contract is awarded.	Management partially agrees with the recommendation. For this incidence, the EPI program in their request opted to go for Sabur, the government printing press for quality reasons. This printing press was used by EPI in the previous years and they possess the software for efficiency reasons. The Sabur printing press cost offer was not higher than the private company but rather was the same	30 September 2018, PMU Director
Recommendation 7 (Critical) In future, the EPI unit should liaise with UNICEF to ensure the proper forecasting of its requirements and needs (including taking into consideration existing stock balances and past track records of consumption), so as to adequately manage the risk against any vaccines from shelf-expiring or being wasted.	Management agrees with the recommendation. Initially the county planned to make switch from one dose formulation of PCV-13 to 4 doses formulation of PCV-13 in August 2017. But considering the remained doses of PCV-13 of one dose vials in stock, the switch plan postponed to December 2017 to utilize all of one dose formulation at sub national and service levels. At the same time, implementation of the switch plan was not on the same date and month in all health facilities at service level. Because, the health facilities were	Ongoing, EPI Manager

Recommendation	Management Comments (Agreement/Disagreement)	Definitive Date and Responsible Person/ unit for implementing the recommendation.
	informed to finish the one dose PCV-13 on hand before going to use the 4 doses vial of PCV-13. At the time of the audit work in June 2018, at national level there had been 65,000 PCV13-4 doses on stock with expiry date of 30 September 2018. But, considering our county set-up and associated transport shortages to deliver vaccines to sub national and district levels, most of the Zobas and districts collect vaccines almost every month and it takes a maximum of two months to deliver vaccines from national to service delivery level. The SMT in the country is also in place at national and sub national levels to make a close follow-up and monitor the stock status of the vaccines. Based on the monthly consecutive SMT information at national and sub national levels, all the PCV-13 with expiry date of 30 September 2018 reached service delivery level by the first week of September. Moreover, the program has a practice of making a push to utilise vaccines near expiry by making an outreach visits in areas with less access for timely uptake of the vaccine doses by the children in these areas. According the guidelines, every health facility is supposed to report and prepare certificate of destruction for expired vaccines and vaccines with	

Recommendation	Management Comments (Agreement/Disagreement)	Definitive Date and Responsible Person/ unit for implementing the recommendation.
	VVM status of 3rd and 4th stage and shared to higher levels. But we cannot say that each health facility is appropriately implementing this plan. There could be some of unutilised PCV-13 vaccine on September at some health facilities which may be disposed.	
Recommendation 8 (Critical) All staff responsible for managing and handling vaccines should comply with the established SOPs, which clearly outline the necessary management guidelines and procedures for vaccines. In addition, and in line with the EVM improvement plan, the MoH should: 1). Conduct refresher training on the SOPs to EPI officers, 2). Provide reference documentation through booklets and wall posters for ease of reference and 3). Intensify supervision activities to ensure its staff comply in full with the SOPs.	Management agrees with the recommendation. There is one SOP document in every health facility in the EPI corner providing routine immunization services which helps as a reference for vaccine cold management. For most of the EPI focal persons working in health facilities training and refresher training has been provided on SOPs and IIP Modules and we will keep on with these activities for the rest of the health facilities every year using the GAVI HSS grants and other opportunities such as introducing new vaccines. For the concerns raised on vaccine stock management and appropriate archiving of EPI monitoring and reporting tools at the sub national level, we will make close follow-up and we will provide them supportive supervision to address the issues.	31 December 2018, EPI Manager

Recommendation	Management Comments (Agreement/Disagreement)	Definitive Date and Responsible Person/ unit for implementing the recommendation.
Recommendation 9 (Essential) Until the stock management of syringes reverts to EPI, the programme should ensure that it get regular updates on its stock holdings from the Parastatal, indicating the shelf-expiry dates of the immunisation supplies, including from the parastatal that Earliest Expiry First Out principles are complied with. In addition, the parastatal should regularly undertake a physical inventory of its key stocks and supplies, and should communicate to the EPI unit accordingly, including a mandatory once a year itemised stock count of all supplies. The parastatal should consider introducing a rolling physical inventory of its stock holdings, with sufficient frequency to ensure that it minimises all future stock wastage and expiry.	Management agrees with the recommendations. The EPI program is aware of that there was an overstock of 0.5ml AD syringes in the parastatal coming from the various sources. Given this, the program did not order additional 0.5ml AD syringes since 2016. In the GAVI HSS II grant, there is a budget allocated to build dry store in NVS site. After completion of the dry store, all injection safety materials will be managed by the EPI program. For the time being, the program will make a close follow-up and will work jointly with the parastatal unit to monitor the EEFO protocols of the injection safety materials.	1 September 2018, EPI Manager
Recommendation 10 (Essential) As part of the upcoming DQA planned in 2018, it is recommended that the MOH should follow up on this data anomaly by examining its process of administrative data collection, in order to ensure that it accurately captures the immunisation coverage rates.	Management agrees with the recommendation. The data report of immunization services from the service providers to districts; from district to Zoba and entering the vaccine dose data in to HMIS software is not 100% correct. From data quality audit and data quality desk review exercise in Gash Barka, some problems were observed in tallying of the administered doses, summarizing the monthly report and data entry into the computer. After the data quality self-assessment (DQS) was done in the Zoba, much improvement has been observed in the year 2018. This plan will be	31 March 2019, EPI Manager

Recommendation	Management Comments (Agreement/Disagreement)	Definitive Date and Responsible Person/ unit for implementing the recommendation.
	implemented in all Zobas in the upcoming month after we have completed the MR Catch-up campaign.	