Memorandum on the Republic of Kenya Programme Audit report

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

The audit team reviewed the EPI and implementing partners' management of Gavi support to the routine immunisation programme including vaccines and cold chain equipment provided over the period between 1 January 2016 to 31 December 2021. Conclusions on the review of Gavi-funded expenditures is not included in this report, as it will be subject to a separate, forthcoming audit engagement to be conducted during 2024.

The 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 audit rating of "**ineffective**" which means, "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."
2. In total, thirteen issues were identified in the following areas: (i) governance, oversight and programme management; (ii) vaccine supply management; and (iii) immunisation data management.
3. To address the risks associated with the issues, the audit team raised 18 recommendations of which 10 were rated as high priority.
4. Key findings were that:
    a. The strategy documents which frame the immunisation programme and operations are incomplete and were not endorsed by MOH.
    b. The full portfolio planning process initiated by Gavi, including planning for the future transition away from Gavi support was inadequate.
    c. Implementation of supportive supervision activities at national and sub-national level was ineffective.
    d. Data maintained across various vaccines logistics management systems was incomplete and inaccurate.
    e. There were gaps in the operational performance of electronic logistics management information system (Chanjo eLMIS) and Chanjo KE. Moreover, transition planning for the handover of these systems was inadequate.
    f. The data quality assurance processes were inadequate.

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.

The Gavi Secretariat continues to work with the Ministry of Health to ensure that their commitments are implemented, and to agree on how to make the programme whole.

Geneva, April 2024

PROGRAMME AUDIT REPORT

Republic of Kenya
March 2024

Gavi
The Vaccine Alliance

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1. Executive Summary

1.1 Overall audit opinion

The audit team assessed the Ministry of Health's management of Gavi support during the period as **"ineffective"** which means, "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."

As noted in Section 2.2, this opinion does not include review of cash support provided by Gavi and a subsequent review of programme expenditures is planned in 2024.

Through our audit procedures, we have identified high risk issues relating to governance, programme management and oversight, vaccine supply chain and immunisation data management. To address the risks associated with the issues, the audit team raised 18 recommendations of which 10 (56%) were rated as 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 the level of priority for each recommendation, are defined in **Annex 3** of this report.*

1.3 Summary of issues

Through our audit procedures, we identified six high risk and seven medium risk issues relating to the use and management of Gavi support. The high-risk issues are summarised below and further details on all the issues are provided in Section 4 of this report.

The audit team attributed many of the below gaps in governance, data and vaccine supply chain to inadequate country ownership. It was also concerned that although the country had entered its accelerated transition phase (as defined by Gavi) this was not matched by an expected increase in the level of implication by the Ministry of Health (MOH) leadership.

At the time of the audit in November 2022, Gavi's support was largely channelled through the partners, whereas the Government's role in overseeing such partner-led implementation was not well-defined. The immunisation programme continued to rely upon the partners to lead and perform many National Vaccines and Immunisation Programme (NVIP) activities. It was not obvious whether the technical support funded by Gavi would result in meeting NVIP's capacity building needs.

Overall, the team concluded that the programme management and technical assistance arrangements needed to be restructured, to ensure that the immunisation programme becomes fully anchored within national systems, and under direct Government control.

Governance, programme management and oversight

The audit found that the MOH's preparations for key strategic initiatives were significantly delayed, including slow progress in finalising the National Vaccines and Immunisation Strategic Plan (NIS). Additionally, there were delays in planning transition out of Gavi support and finalisation of the full portfolio planning (FPP) process.

There were gaps in NVIP's supportive supervision processes, which could lead to putting off resolving issues and inaccuracies in the immunisation and vaccine stock data. The MOH has not fully complied with Gavi's grant management requirements from April 2018, with respect to instituting a functional programme coordinating unit. The audit also noted that Targeted Country Assistance (TCA) activities were insufficiently monitored, due to the absence of a joint appraisal exercise, leading to delays in the implementation of the TCA plan by the various providers.

Gaps and deficiencies were also identified in the functioning of the National Immunisation Coordination Committee (ICC), a governance mechanism designed to manage and oversee the implementation of policies and programmes at the national level. The ICC did not hold meetings as frequently as required, maintained incomplete attendance records and did not systematically follow-up on action points. The ICC also did not have the necessary representation from county officials, as mandated by its terms of reference.

Overall, the gaps in the governance, oversight and programme management could be attributed to inadequate capacity at NVIP. The recommendation to institute a programme management unit at NVIP was never implemented and attrition at the operational levels resulted in significant delays. Furthermore, there was no appropriate level of governance and oversight over programme management processes which resulted in limited engagement at senior MOH level, slow progress and over reliance on health partners to support immunisation strategic planning processes. As a result, the MOH missed the opportunity to ensure that Gavi funding is catalytic and scalable and that the programme is sustainable after Gavi support.

Vaccine and supply chain management

The NVIP had gaps in the stock management system at both the central and sub-county levels. Forecasting gaps resulted in significant variances between forecasted and actual vaccine shipments from 2018 to 2022.

There were discrepancies in stock records between the national and sub-national levels of the vaccine supply chain. The use of multiple, disparate systems led to data duplication and omission, resulting in inaccuracies in stock records. In addition, Sub-County and health facility stores had improper use of manual stock ledgers, with some lacking adequate records. Physical stock counts by the audit team revealed variances in vaccine stock records in Sub-County stores and Health-Facilities. These issues could compromise the accuracy of stock records and affect vaccine supply chain management.

In 2019 Clinton Health Access Initiative (CHAI), with Gavi's support, developed and rolled out the Chanjo electronic Logistics Management Information System (eLMIS) for the national immunisation programme. However, as at November 2022, NVIP had not yet formally adopted this eLMIS as its primary stock management system. There were discrepancies

between the manual stock ledgers and excel stock management tool (SMT) and Chanjo eLMIS at national level. Some information was missing from all three sources, making it difficult to determine which source was accurate and complete. Similarly, at the sub-county level both manual ledgers and Chanjo eLMIS were used to record stock, yet these tools were also not updated with complete and accurate information, resulting in significant discrepancies in stock data between the tools.

Additionally, there were issues with the Chanjo eLMIS system, including incomplete development, weak security controls, and how the change management process of its deployment was managed.

The management of vaccines and immunisation waste also had several issues at the sub-national level, including poor temperature monitoring, lack of clear policies for expired Covid-19 vaccines, and poor waste management.

The audit revealed deficiencies in the management of cold chain equipment (CCE), including a lack of spare parts inventory at the Central Vaccine Store, leading to delays in maintenance works. Non-functional CCE were found in four out of the five regional vaccine stores visited by the audit team. Additionally, there was no documentation to support proper management and decommissioning of obsolete equipment.

The gaps noted in the vaccine supply chain processes may be attributed to delays in implementation of the Effective Vaccine Management (EVM) recommendations. Addressing these issues is crucial for ensuring effective vaccine supply chain management, reducing stock-outs, reducing medical waste, and improving the security and integrity of data outputs and forecasts.

Immunisation data management

The audit team found several issues related to NVIP's immunisation data management. There were anomalies in the reported administrative coverage data, with reported numbers of immunised children consistently higher than the actual vaccine doses available. This was confirmed with reviews done at the sub-county level where 20 out of 30 Health-Facilities sampled were found to have discrepancies between the reported number of immunised children within the District Health Information Software (DHIS2) when compared with the immunisation register and other source documents.

The data quality assurance and monitoring processes were not consistently undertaken or effective. Inadequate training in data management and slow implementation of the data quality improvement plan (DQIP) were also identified.

The audit team noted a lack of data validation, verification, quality review, and follow-up, as well as inadequate training in data management. Additionally, integrated support supervision 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. The audit team also found a slow implementation of the data quality improvement plan, with only 10% of the interventions completed and 38% not yet started.

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 and misallocation of resources, which could negatively impact the effectiveness of the immunisation programme and the health of the targeted population.

2. Objectives and Scope

2.1 Audit Objective

In line with the respective Partnership Framework 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.

The audit team assessed the processes and programme management arrangements related to Gavi's support for which the respective entities were responsible, to assess the design and operating effectiveness of: the existing grant oversight mechanisms over Gavi's investments, the vaccine supply chain processes in accounting for and delivering quality vaccines to the intended recipients and the immunisation data management systems in providing quality data to support decision making.

The audit 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.

2.2 Audit Scope

The audit team 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; the effectiveness of targeted country assistance; and COVAX support. The audit scope covered six years from 1 January 2016 to 31 December 2021. The review of cash support provided by Gavi is not included in this report; it will be subject to a separate audit in 2024.

For the Covid-19 related support, the audit scope was extended up to 30 June 2022. The total cash and vaccine support provided by Gavi to Kenya as of 31 December 2021 is presented below.

Table 1: Cash and vaccines support to MOH as of 31 December 2021.

Grant type/Year		Scope of the audit period (amounts in USD)						
Vaccine support	**2001-2015**	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**Total**
PCV	*171,093,833*	*21,509,693*	*9,097,790*	*8,897,779*	*13,492,198*	*6,413,557*	*9,943,895*	*240,448,746*
Pentavalent	*159,621,044*	*5,432,045*	*4,787,351*	*1,621,194*	*2,166,610*	*2,265,750*	*1,412,970*	*177,306,964*
Covid-19 vaccines	-	-	-	-	-	-	*123,768,122*	*123,768,122*
Rotavirus	*14,883,277*	*3,863,129*	*5,561,327*	*4,207,442*	*3,954,538*	*4,647,751*	*4,084,989*	*41,202,453*
HPV	-	-	-	*2,990,650*	*3,655,550*	*5,980,510*	*1,872,500*	*14,499,210*
IPV	*2,160,858*	*810,266*	*588,166*	*1,683,124*	*3,260,906*	*2,031,116*	*3,485,114*	*14,019,550*
MR Campaign	*13,980,455*	*(466,631)*	-	-	-	-	-	*13,513,824*
HPV Multi-Age	-	-	-	-	-	-	*8,048,446*	*8,048,446*
Measles Rubella	-	-	-	-	-	*5,140,350*	*20,012*	*5,160,362*
Injection safety devices	*1,129,963*	*678,620*	*(102,684)*	*376,868*	*343,915*	*1,932,968*	-	*4,359,649*
Men A (campaign only)	-	-	-	*2,409,964*	-	-	-	*2,409,964*
Yellow fever	*407,413*	*38,704*	*67,950*	*328,162*	*(15,313)*	*360,846*	*167,322*	*1,355,084*
HPV Demo	*261,749*	*319,500*	*(311,850)*	*(4,061)*	-	-	-	*265,338*
Total Vaccines	***363,538,593***	***32,185,326***	***19,688,051***	***22,511,121***	***26,858,404***	***28,772,848***	***152,803,369***	***646,357,712***
Cash grants								
Total Cash	***30,880,180***	***(1,604,262)***	***12,143,181***	***1,465,302***	***9,159,899***	***9,215,930***	***7,336,856***	***68,597,086***
Grand total (Vaccines + Cash)	***394,418,773***	***30,581,064***	***31,831,232***	***23,976,423***	***36,018,303***	***37,988,778***	***160,140,225***	***714,954,798***

2.3 Audit approach

The Programme Audit was conducted in two phases: an initial scoping visit in May 2022 and three weeks of fieldwork between 1 – 18 November 2022. The audit team visited one central vaccine store, five regional vaccine stores, six sub-county vaccine stores, and 30 health facilities. They interacted with key stakeholders including the NVIP team, MOH, MOH Finance Directorate, National Treasury, Council of Governors, Office of the Auditor General, and Gavi Alliance partners such as WHO, UNICEF, and CHAI. **Annex 4** provides a list of sites visited by the audit team.

2.4 Progress since 2016 Gavi Programme Audit

There was limited progress made in addressing audit issues noted in the previous Gavi programme audit conducted in 2016. The previous report was rated “partially satisfactory" based on the areas of scope covered (vaccine supply management, budgeting and financial management, expenditure and disbursements, and procurement). This current review included an expanded and different scope as noted in section 2.2 above. One significant improvement was noted in the vaccine supply chain management processes due to the introduction of a stock management system. In 2016, NVIP relied on manual vaccine stock ledgers at central and county levels. The introduction of Chanjo eLMIS enhanced stock management practices, particularly in adhering to the "early expiry first out" (EEFO) principle. The 2022 audit did not identify instances of non-compliance with EEFO, indicating improvement in this regard.

2.5 Exchange rates

The majority of cash and in-country expenditures were in Kenyan Shillings (KES), but for this audit report purposes, total amounts were converted to United States Dollars (USD). The average bank rate provided by the Bank of Kenya at the time of conversion from USD account to KES was used to calculate the exchange rate. The average rate for the audit scope period 2016 -2021 was KES 104 to USD 1.

3. Background

3.1 Introduction

The Republic of Kenya, located in East Africa is the seventh most populous country in Africa, with a population of more than 47.6 million according to its 2019 census, with 30.2 million living in rural areas and 17.5 million in urban areas. The country achieved its independence in 1963 and was formally established in December 1964. Kenya has since devolved political power and governance across two levels of government: both at national and to 47 semi-independent Counties led by elected governors.

As of 2020, Kenya is the third-largest economy in sub-Saharan Africa after Nigeria and South Africa. Its gross domestic product per capita for 2021 is estimated as USD 2,082. In January 2022, Kenya entered into the Gavi Accelerated Transition Phase after the three-year rolling average Gross National Income (GNI) exceeded Gavi's eligibility threshold of USD1,660. As a result, Kenya will gradually phase out of Gavi support over the next 8 years and work towards becoming fully self-financing by 2030. Kenya ranks 152 out of 191 countries and territories on the 2021/22 Human Development Index.

National health sector

Health services in Kenya are decentralised, with national government providing leadership in policy development, managing national referral facilities, and focusing on capacity development. County governments are responsible for service delivery at the local level. The Kenya Health Policy 2014–2030 defines the roles and responsibilities of the health system structure across a structure of four service delivery tiers:

- Community level: This is considered the foundation of the health service delivery system. It includes both demand creation services (such as health promotion) and specific supply services that are most effectively delivered at the community level. The essential package of services includes non-facility-based health and related services, encompassing interventions provided through the Community Health Strategy.
- Primary care level: This level comprises dispensaries, health centers, and maternity/nursing homes. It serves as the first physical level of the health system, where most of the clients' health needs are addressed.
- County level: This level consists of the first-level hospitals, which complement the primary care level and offer a more comprehensive range of services in close proximity to the community.
- National level: This tier includes tertiary level hospitals that provide highly specialised services. These hospitals complete the continuum of care available to individuals in Kenya.

Immunisation in Kenya

The provision of immunisation services in Kenya is a shared responsibility between the national and County governments. According to 2023 National Immunisation Policy guidelines, the national government, through NVIP, is responsible for vaccine procurement, distribution to regional stores, policy development, research, advocacy, quality oversight, and management of the health information system. County governments are responsible for implementing policies through service delivery, including human resource management, last mile delivery of vaccines, infrastructure development, procurement and maintenance of equipment, vaccine-related supplies, and documentation tools.

In 1980, the Kenyan Ministry of Health established the Kenya Expanded Programme on Immunisation (KEPI) to provide immunisation services against various diseases for children and pregnant women. Gavi started supporting Kenya’s national immunisation programme in 2001.
Since then, KEPI has evolved into the NVIP, which manages public sector immunisation services under the MOH. NVIP contributes to the first objective of the Kenya Health Policy (KHP: 2014-2030), which aims to eliminate communicable diseases.

The operations of NVIP are guided by the National Immunisation Policy and supported by standard operating procedures for different thematic areas of work. The policy was last updated in 2023. NVIP coordinates vaccination services for all preventable diseases, including routine infant vaccines and vaccines for high-risk groups and emergency situations. As of June 2022, NVIP provided eleven different types of vaccines, including Covid-19, free of charge to its citizens, of which eight are Gavi supported.

NVIP management team is based in Nairobi and has 21 officials, including the Head of NVIP and four senior officials responsible for core thematic functions such as vaccines and logistics, training and service delivery, advocacy, communications and mobilisation, and monitoring and evaluation.

Gavi alliance partners WHO and UNICEF along with other expanded partners are expected to provide collaborative support to NVIP through technical working groups (TWGs) and technical assistance funded by Gavi Partnership Engagement Framework Targeted Country Assistance (PEF/TCA) grant. The TWGs are expected to provide support in various areas such as supply chain management, vaccine management, data management, technology utilisation, and advocacy.

Several bodies including the National Immunisation Inter-Agency Coordination committee (ICC), the Kenya National Immunisation Technical Advisory Group (KENITAG), the National Vaccine Safety Advisory Committee (NVSAC), and other disease-specific oversight and advisory bodies were created to support NVIP.

3.2 Vaccine storage and supply chain

The Kenya vaccine cold chain system consists of one central vaccine store, nine regional vaccine stores, 304 Sub-County vaccine stores, and approximately 8,000 HFs. The supply chain uses both the push and pull distribution methods, with vaccines transported from the central store to the regional stores by third-party trucks (push) and then transported to Sub-County stores and Health-Facilities upon request (pull). The County governments are responsible for managing the sub-national vaccine supply chain and maintaining cold chain equipment. There are several systems in place to manage vaccine logistics, including Chanjo KE, Chanjo eLMIS, and SMT. The Government of Kenya (GOK) and CHAI introduced an electronic logistics and management system named Chanjo to streamline the vaccine supply and logistics system and improve information flow. The goal is to ensure continuous availability of quality vaccines at all levels.

3.3 Gavi's fund flow mechanism

Immunisation in Kenya under the NVIP is currently supported technically and financially by a number of partners, including WHO, UNICEF, CHAI, and United States Agency for International Development / John Snow, Inc / Maternal and Child Survival Program, as well as Gavi. However, the Government of Kenya also contributes to the funding of NVIP through an annual co-financing arrangement which follows the GAVI co-financing policy.

UNICEF plays a significant role in the implementation of the immunisation programme in Kenya. It is responsible for the procurement of vaccines and related supplies. It managed Gavi HSS funds on behalf of the Government of Kenya during the period under review in accordance with a tripartite agreement between Gavi, GOK and UNICEF of 2017. A CSO, Kenya AIDS NGO Consortium (KANCO), also received direct funding from Gavi for the implementation of HSS grant activities.

UNICEF disbursed Gavi funds directly to commercial bank accounts managed by County Departments of Health (CDOHs), while the majority of funds for national activities were processed through direct payments by UNICEF on behalf of NVIP.

3.4 Covid-19 context and country's response

Kenya rolled out the Covid-19 vaccination campaign for its adult population in March 2021 following the emergency approval of the vaccines by the MOH. Due to limited availability of vaccine doses, the initial vaccination used a phased approach that prioritised individuals considered to be at the highest risk identified as: healthcare workers, teachers, and uniformed forces/security personnel. During the 3rd wave of the Covid pandemic, the target population was expanded to include those over 58 years of age, based on morbidity and mortality amongst this sub-population. As vaccine supplies improved, by July 2021, target groups were gradually expanded to cover all adults, and teenagers in November 2021. As of 30 June 2022, the country has received more than 27 million vaccines from various sources including the COVAX facility, AT and direct donations by partners.
The National Covid-19 Task Force (NTF) was in charge of coordinating Covid-19 vaccinations and had developed a plan with an initial target to reach 10 million individuals by December 2021, fully vaccinate 19 million adults by the end of June 2022, and cover the entire adult population of 27 million people by December 2022. According to the Kenya MOH Covid-19 Vaccination program daily situation report from 10th May 2022, 16 million adults had received at least one vaccine dose, while 8 million were fully vaccinated. The number of vaccinated teenagers stood at 1,294,191, with only 234,424 being fully vaccinated. Booster shots had been administered to 307,200 adults. The relaxation of infection control measures in early March 2022 may have impacted vaccination targets, as daily vaccinations had dropped to fewer than 30,000 as of May 2022.

As of January 2023, the Monitoring Agent (MA) report stated that the NTF had developed the first National Vaccine Deployment Plan (NVDP). The NTF comprised representatives from the MOH, National Treasury, Kenya Medical Supplies Agency (KEMSA), and non-state actors such as WHO, UNICEF, CHAI, Kenya Medical Research Institute (KEMRI), KEMRI Welcome Trust, University of Nairobi (UON), World Bank (WB), and Africa Medical Research Foundation (AMREF). The

NTF provided strategic direction while utilising the existing infrastructure for the national routine immunisation programme implementation.

3.5 Good practices observed by the audit team

Execution of the Covid-19 Vaccine Programme - Covid-19 vaccines (AstraZeneca, Pfizer, Johnson & Johnson, and Moderna) were efficiently received and distributed from the central to the sub-county level during the initial distribution covered by the audit period. The country installed four Ultra Cold-Chain (UCC) freezers at the Central Vaccine Store (CVS) which were sufficient to manage the inflow of Pfizer vaccines. The transportation of vaccine vials was carried out in carrier boxes with conditioned ice packs to ensure the safety and efficacy of doses. Additionally, routine transfers of Covid-19 vaccines were conducted between different facilities to prevent wastage and increase coverage. During the audit fieldwork, the audit team noted a significant drop in the uptake of the Covid-19 vaccine after Q1 2022 which resulted in expiries after our fieldwork.

Conduct of MR follow-up campaign and maintenance of routine immunisation during the Covid-19 pandemic: With assistance from its partners, NVIP carried out an MR campaign concurrently with the country's Covid-19 vaccination program. Furthermore, NVIP was able to continue routine immunisation services during the pandemic.

Commitment to meeting co-financing obligations: The Government of Kenya has shown its strong commitment by keeping up to date on its co-financing obligations for the Gavi supported vaccines.

Vaccine management practices: All sites visited by the audit team were equipped with functional back-up power sources and remote temperature monitors. Vaccine temperatures were regularly monitored and recorded in most HFs and there was evidence of regular physical stock counts at national level.

3.6 Operational challenges due to the COVID 19 pandemic

Kenya recorded its first Covid-19 case on March 12 2020, prompting the Government to implement measures through a multisectoral taskforce, National Emergency Response Committee (NERC) to mitigate the spread of the disease. These measures included school closures, quarantines, curfews, suspension of international flights, and lockdowns which disrupted the country's health programmes, including Gavi-supported immunisation programmes. The pandemic also strained the limited human resources in the health sector and caused challenges in vaccine logistics, as some Covid-19 vaccine formulations required ultra-cold chain storage which was only available at the central vaccine store. Additionally, vials of Covid-19 vaccines were not labelled with a Vaccine Vial Monitor (VVM), and some batches had a short shelf life, complicating compliance with the vaccine logistics principle of earliest-expiry-first-out. The audit team acknowledged the challenges created by the pandemic and their impact on Gavi-supported programme activities in Kenya.

4. Audit Issues

4.1 Governance, oversight and programme management

4.1.1 There were gaps in the operations of the national immunisation coordination committee

Context and Criteria

The 2016 Gavi Programme Capacity Assessment (PCA) reported that there was not an officially recognised ICC at the national or county level. There was a technical committee at the national level but it lacked senior leadership, appropriate membership, and regular meetings. There were no readily available Terms of Reference (TOR) for the ICC, and there was no representation of Counties, the National Treasury, and Faith-Based Organisations. The ICC meetings were not held quarterly, and there was no evidence of any interaction between the Health Sector Coordination committee (HSCC) and the ICC.

As a follow up to Grant Management Requirements and recommendations outlined in the 2016 PCA, Gavi conducted a Monitoring Review in 2019. The findings of the 2019 review revealed insufficient progress in various areas. The effectiveness of the ICC was hindered by irregular meetings, a lack of senior representation from the Ministry of Health (MOH) and development partners, and limited attendance. Although the TORs for the ICC were developed, they had not been officially endorsed, and documentation of meeting agendas and minutes was found to be insufficient. Furthermore, ICCs engagement with the Counties was inadequate, and there were deficiencies in reporting mechanisms through the ICC and the MOH hierarchy.

Several governance bodies were established to provide oversight for the National Immunisation Programme. These included the national Immunisation Coordination committee (ICC) headed by the Director of Medical Services which is responsible for programmatic oversight and coordination for the implementation of vaccines and immunisation policy. It is also tasked with interacting with appointed working groups and task forces and has representatives from MOH departments, UN agencies, implementing partners (e.g., KANCO), civil society and religious organisations, County governments, and other state departments as needed, as indicated in the ToRs. Additionally, other governance bodies included the Kenya National Immunisation Technical Advisory Group (KENITAG) for vaccine policy recommendations, the National Vaccines Safety and Advisory Committee (NVSAC) for vaccine safety and advisory, and the Covid task force.

Condition

The audit noted the following gaps in the design and operating effectiveness of the ICC governance structure:

Inadequate oversight by ICC as the committee did not have regular meetings and agreed actions were not assigned or followed up - The audit found that there was a lack of evidence indicating that the ICC had held quarterly meetings, as stipulated by its TOR. The available evidence showed that only one meeting was held in 2016, three in 2017, two in 2019, and two in 2022.

Additionally, there were various operational weaknesses within the ICC, including unsigned meeting minutes by the Chairperson, missing attendance lists, the absence of circulated agendas before meetings, insufficient notice given to ICC members for enhanced participation, and a lack of systematic follow-up on action points from meetings. Furthermore, the minutes, where available, failed to assign responsibility for action points to specific officers or provide completion deadlines.

Counties were not represented on the ICC or technical working groups - This concern was previously highlighted in the 2016 Gavi Programme Capacity Assessment and thereafter in the 2021 Advisory report on the functional review of NVIP commissioned by Gavi. The audit noted that the MOH had made no progress in establishing a clear structural arrangement for regular interaction with county health departments' leadership and management. Furthermore, coordination with other high-level committees like HSCC within the health sector was not clarified. The TOR for the various bodies also lacked signatures and dates of ratification.

Recommendation 1

The Ministry of Health should strengthen its governance structure by ensuring that:

- ICC / KENITAG / NVSAC / other meetings are supported by confirmed agreed agendas which will include (a) reminder of ToRs, (b) minutes of the previous meeting, (c) review of the previous action points tracking purpose, (d) status of immunisation activities, (e) grant implementation status. (f) brief summary of discussions at the lower technical working group, that meetings are held conducted as planned, minutes signed and that the required actions are assigned to officers for follow-up;
- Counties are invited, represented and coordination structures for county involvement at the ICC are instituted, as recommended by 2016 Gavi Programme Capacity Assessment and the 2021 Advisory report on the Functional Review of the National Vaccines and Immunisation Programme.

<table>
<tr><td>Root cause
• Insufficient prioritisation by leadership at MOH.
• Ineffective secretariat within NVIP to support the functions of the various governance mechanisms.</td><td colspan="2">
Management comments

See detailed management responses - Annex 15</td></tr>
<tr><td>Risk / Impact / Implications
• Inadequate progress in addressing representation and coordination issues highlighted since 2016 have impacted the effectiveness of governance and oversight in a devolved country context.
• Ineffective ICC oversight impacted the achievement of grant objectives and oversight over the transition process as highlighted in subsequent issues.</td><td>Responsibility

Secretariat of the ICC</td><td>Deadline / Timetable

See Annex 15</td></tr>
</table>

4.1.2 Strategic documents that support the immunisation programme are incomplete and were not endorsed by the MOH

Context and Criteria

The Ministry of Health (MOH) initiated the development of the National Vaccines and Immunisation Strategic Plan (NIS) in 2020. The purpose of NIS is to establish a comprehensive framework for resource requirements and financing needs during the period of 2021-2025. The NIS forms the basis for the Full Portfolio Planning process that supports the request for Gavi funding.

Condition

We reviewed the November 2022 version of the NIS noted the following gaps:

Strategic initiatives identified in the National Vaccines and Immunisation Strategic Plan (NIS) were delayed and the plan had not been finalised – The Ministry of Health (MOH) initiated the development of NIS to establish a comprehensive framework for resource requirements and financing needs during the period of 2021-2025. This framework was not yet completed at the time of the audit fieldwork in November 2022.

Update did not include revised targets for the period – The plan only included targets and projections for the period of 2019-2023. The updating process did not revise the timeline and targets to the actual implementation period i.e., 2023 and beyond given that half of the previous strategic period had already elapsed and no significant progress had been made.

The NIS did not provide clear direction for the vaccines management system – The NIS acknowledged the existing eLMIS, Chanjo, and the low utilisation, at 66% utilisation at sub-county levels. In setting the targets for eLMIS system, the NIS then proposes the rollout of an electronic vaccine logistics management information system by 2022. It remains unclear whether the envisioned eLMIS will be an upgrade of the existing Chanjo, given the significant investment in training and roll out or a new eLMIS will be developed.

A standalone supply chain strategy was developed by the NVIP team – A separate vaccines and immunisation supply chain strategy dated October 2022 was also shared with the audit team. The purpose of this strategy was to describe the challenges within the immunisation supply chain (iSC). This document was not finalised nor has it been endorsed by the MOH. The audit team noted the following gaps;

- Roles, responsibilities and accountabilities for strategic initiatives are not clearly defined within the governance structures for the iSC.
- The devolved nature of operations was acknowledged but the pathway for solutions was unclear – while the structure acknowledged sub-county levels, the nature of operations and responsibility for actions at the at regional and county levels is not clear.
- Missing sustainability components – the draft did not consider an iSC that integrated into other medical supply chain processes.
- Key indicators are incomplete as they are not aligned to any baselines (what is now), or planned achievements.
- The eLMIS is not defined. The draft strategy proposes roll out of a new eLMIS and no additional comments on the existing Chanjo system.
- There were no linkages to the overall NIS to ensure alignment on indicators.
- The draft did not include plans for each year of the strategy.

Recommendation 2

The Ministry of Health should ensure that:

- Finalising its updated National Immunisation Strategy, with revised targets, is prioritised.
- A suitable roadmap for the programme's transition away from Gavi support is developed as a priority.
- The revised National Immunisation Strategy is endorsed by the appropriate stakeholders and approved by the MOH.
- This revised strategy provides adequate guidance for health systems, including the vaccines logistics information management systems. This should include a way forward for the Chanjo systems (RI and Covid).
- The revised strategy includes immunisation supply chain strategy ensuring alignment with Gavi's own supply chain strategy, given that the latter framework proposes suitable pillars which should be customised and incorporated into the country context.

<table>
<tr><td>Root cause
• A fragmented approach by the multiple stakeholders with no overarching governance process resulting in siloed development of the different components in the strategies.
• Inadequate accountability process to manage the completion, approval and adoption of the strategies.</td><td colspan="2">Management comments

See detailed management responses - Annex 15</td></tr>
<tr><td>Risk / Impact / Implications
• Delayed provision of strategic direction for the NVIP programme.
• Missed opportunity to ensure that Gavi funding under the 5.1 process is catalytic and aligns with the national strategic plan. Consequently, the strategy will follow the operational planning process and may miss out on impactful strategic initiatives.
• Inability to plan for future periods, first to maximise gains from the Gavi support during the accelerated transition phase and thereafter sustainability of the programme after Gavi support.</td><td>Responsibility

EPI Manager / MOH</td><td>Deadline / Timetable

See Annex 15</td></tr>
</table>

4.1.3 Full portfolio planning, including planning for transition from Gavi support was inadequate

Context and Criteria

In January 2022, Kenya entered the Accelerated Transition Phase in the Gavi support cycle, having exceeded the 3-year average GNI eligibility threshold of USD 1660. This phase is determined using the World Bank Atlas method and countries with a three-year average increase in gross national income per capita, are prepared to transition out of Gavi support. In December 2022 Gavi Board extended the duration of the accelerated transition phase from five to eight years. During the accelerated transition, Kenya will be required to increase their co-financing obligation for the Gavi supported vaccines to ensure that all vaccines will be fully funded by the country's health budget at the end of the transition period. Kenya will remain eligible to apply for new vaccine support from Gavi as per the Gavi guidelines. Additionally, Kenya started the process for Full Portfolio Planning in 2020 to cover the 2021 to 2025 Gavi 5.1 strategic period.

The Partners' Engagement Framework (PEF) is a vital component of the Alliance Accountability Framework, which was approved by the Board in June 2015. The primary goal of PEF is to utilise the comparative strengths of Alliance partners to expedite sustainable and equitable vaccine coverage. Targeted Country Assistance (TCA) is one of the key elements of PEF, and it is governed by four overarching principles, namely differentiation, country ownership, accountability, and transparency. The principles of accountability and transparency are achieved by establishing programmatic and financial reporting requirements for the partners, as well as regular in-country joint reviews of the progress and performance of Technical Assistance (TA) by the partners and country stakeholders.

Gavi designated Kenya as a PEF 'tier 1' country, meaning that Gavi prioritised funding for technical support identified by the countries, with the assistance of partners, to overcome key immunisation bottlenecks. The audit team evaluated Gavi's TCA support to Kenya from 2019 to 2021, during which the total TCA funds disbursed amounted to USD 990,205. For the Gavi strategic period 5.0 (2021-2025), Gavi has allocated the maximum ceiling of USD 6.18 million for TCA activities.

By adhering to the principles of differentiation, country ownership, accountability, and transparency, the PEF, and its TCA component, can play a crucial role in enhancing immunisation coverage in Kenya. The continued funding and support from Gavi will help Kenya address critical immunisation bottlenecks, which will ultimately contribute to better health outcomes for the population.

Condition

The 2019 Joint Appraisal (JA) process identified the need for an immunisation financing strategy and transition plan. There was limited progress since the JA and we noted the following:

The Health Sector Transition Roadmap 2022 to 2030 was not shared with MOH leadership – While several initiatives were taken to identify some needs and make plans for transition through the roadmap, this plan was never discussed with senior leadership at MOH and was not approved.

Immunisation roadmap did not consider operational needs of the programme – The roadmap was limited to recognising the need for additional financing to meet the increasing co-financing obligation for the vaccine procurement. The transition planning task force's focus was limited to commodities, i.e., procurement of vaccines. Consequently, the 'non-commodity' programme expenditures were not adequately considered. Operational needs such as management of the central and regional vaccine warehouse, county level microplanning and annual work plan development, waste disposal, procurement, maintenance and replacement of cold chain equipment including procurement of replacement parts for the cold chain equipment were not considered.

Significant delays in the Gavi-funded TCA planned activities to support transition process – While the TCA plan included activities to help prepare MOH to transition out of Gavi support, activities were significantly delayed. The audit team noted gaps in finalisation of the following activities:

- Development of a strategic document for sustainable immunisation financing in Kenya in the context of UHC/NHI (UNICEF, deadline June 2020) – The resulting document provided to the audit team was a preliminary study based on interviews and document review at four UHC pilot counties. There was no follow through on scalability to all counties and/or review of additional information to support scalability.

Recommendation 3

We recommend that MOH:

- Appoint a governance team to manage this transition process, including senior level MOH leadership, to maintain visibility over strategic planning which is independent from the operational management of health programmes. The existing transition planning task force should periodically report to this governance body to ensure that the task-force's activities are prioritised;
- Review the roles and responsibilities of the transition planning task force to ensure suitable representation from the Ministry of Finance, Counties and relevant health partners. This task force should report to the ICC and to the governance team referred to above;
- Finalise and approve the Health Sector Transition Roadmap.
- Broaden the scope of the "*Transition Planning*" task force to cover operational needs. including both commodity (vaccines) and non-commodity aspects, i.e., maintaining infrastructure, staffing, cold chain equipment, waste disposal, microplanning etc. of the immunisation programme.
- Strengthen components of the Targeted County Assistance provided by Gavi alliance partners, to ensure that various activities supporting the "*Full Portfolio Planning*" process are completed, including the Geographic

- Immunisation Supply Chain Systems design finalised, and report adopted by ICC and used to inform Portfolio Planning (UNICEF, deadline Q3 2020) – According to UNICEF, this has been delayed due to competing priorities created by Covid-19 pandemic.
- Gavi Transition Framework for Kenya was to be finalised and adopted by the MOH by end of Q2 of 2021 TCA project cycle (UNICEF, deadline Q2 2021) – According to UNICEF, this activity was moved to 2021 TCA and the implementation was ongoing at the time of the audit in November 2022.

Delayed Full Portfolio Planning (FPP) for the period 2021 to 2025 – The FPP process started in 2020 and initial submission was made in January 2022, and as of the audit fieldwork in November 2022, the process was still ongoing. While the Covid pandemic was a cause for some delays, there were additional delays in consolidating all Gavi support for the 5.1 period to ensure that all activities are co-ordinated and align with the national strategic plan. Furthermore, while technical assistance provided to support the FPP process, the process was delayed resulting in expiry of the consultant contract before initial submission was made.

Root cause

The root causes for the issues mentioned above can be attributed to the following

- A leadership gap at NVIP, coupled with an ineffective change management process meant that with the exit of the previous EPI manager in 2021, there was a notable gap in leadership coupled with inadequate handover process to the new team.
- Insufficient understanding of all strategic and operational needs for the EPI programme, coupled with fragmented approach adopted by the various partners involved in the programme management and provision of technical support.
- Inadequate governance and oversight within the ICC structure to hold partners and NVIP team accountable.
- Numerous guidelines from Gavi for the FPP process may have created a learning curve at country level, worsened by inadequate staffing at EPI.

Risk / Impact / Implications

- Delayed provision of strategic direction for the NVIP programme.
- Delayed FPP process for a country in accelerated transition resulting in inadequate planning for transition.
- Missed opportunity to ensure that Gavi funding under the 5.1 process is catalytic and scalable.

Information System coverage assessment and the comprehensive supply chain analysis.

- Set timelines, monitor progress, and update Gavi at a predetermined frequency.

Recommendation 4

We recommend that the MOH collaborate with Gavi in setting-up a programme management unit to support the NVIP team. This PMU should be a temporary mechanism, ideally embedded within the NVIP, to ensure that adequate capacity is built within the EPI team to support the numerous operational initiatives.

Management comments

See detailed management responses - Annex 15

Responsibility	Deadline / Timetable
EPI MOH	See Annex 15

4.1.4 Planning for Targeted Country Assistance and implementation of agreed activities was significantly delayed

Context and Criteria

The Partners' Engagement Framework (PEF) is a vital component of the Alliance Accountability Framework, which was approved by the Board in June 2015. The primary goal of PEF is to utilise the comparative strengths of Alliance partners to expedite sustainable and equitable vaccine coverage. Targeted Country Assistance (TCA) is one of the key elements of PEF, and it is governed by four overarching principles, namely differentiation, country ownership, accountability, and transparency. The principles of accountability and transparency are achieved by establishing programmatic and financial reporting requirements for the partners, as well as regular in-country joint reviews of the progress and performance of Technical Assistance (TA) by the partners and country stakeholders.

Gavi has designated Kenya as a PEF 'tier 1' country, which means that Gavi prioritises funding for technical support identified by the countries, with the assistance of partners, to overcome key immunisation bottlenecks. The audit team evaluated Gavi's TCA support to Kenya from 2019 to 2021, during which the total TCA funds disbursed amounted to USD 990,205. However, for the Gavi strategic period 5.0 (2021-2025), Gavi has allocated the maximum ceiling of USD 6.18 million for TCA activities.

By adhering to the principles of differentiation, country ownership, accountability, and transparency, the PEF, and its TCA component, can play a crucial role in enhancing immunisation coverage in Kenya. The continued funding and support from Gavi will help Kenya address critical immunisation bottlenecks, which will ultimately contribute to better health outcomes for the population.

Condition

The audit team noted the following weaknesses:

Inadequate monitoring of TCA plan - In absence of the Joint Appraisal (JA) in 2020 and 2021, there was no compensatory review of the implementation and effectiveness of annual TA activities. The TCA milestones reported on the PEF portal was a short summary which did not provide adequate information for a review. Additionally, the multistakeholder dialogue implemented during the Covid-19 pandemic was not held for Kenya during 2020 and 2021

Multiyear TCA plan was delayed - In 2020, Gavi allocated approximately USD1.84 million for Technical and Country Assistance (TCA) activities, with UNICEF receiving 53% of the funding, WHO receiving 33%, and CDC receiving 14%. TCA activities planned for 2020, including the implementation of the EVMA plan, Reach Every Child strategy, immunisation transition framework, and data quality improvement plan, were carried over to 2021. Additionally, new activities were added through partners like John Snow, Inc and INSCAP. The 2021 TCA activities were implemented using the remaining funds from the 2020 TCA grant, as Gavi provided a no-cost extension for the grant until December 2021.

As of the audit conducted in November 2022, the multiyear TCA plan had not been finalised. To bridge the funding gap, in 2022, Gavi disbursed a prorated portion of Kenya's multiyear TCA budget for the period of January to June 2022 to address critical TCA needs. This arrangement was extended until December 2022 for Gavi core partners but had not resulted in a multiyear plan.

Root cause

While some of the delays would be attributed to the Covid-19 pandemic, other root causes include:

- Inadequate ownership of TCA by NVIP and MOH which contravened the country ownership principle for the TCA.
- While the inadequate capacity was acknowledged at country level, the TA plan never provided for enhanced capacity at NVIP. All HR related TA remained at partner level. As such activities could not be progressed without a counterpart at NVIP.

Recommendation 5

It is recommended that the MOH, together with Gavi, review the TCA activities which have been planned to ensure that:

- The capacity building of the MoH is prioritised in the TCA activities. This should be reviewed in conjunction with recommendation 3 of this report;
- Adequate monitoring is embedded within the activities along with assigning monitoring responsibilities. Monitoring processes should cover the performance and delivery of various Technical Assistance activities on an annual basis including adherence to the timelines, and use these monitorings to revisit the multi-year TCA plans, as well as any requests for reprogramming Gavi funds or the reallocation of resources. This evaluation process should assess the effectiveness and impact of TCA interventions, identify areas for improvement, and ensure alignment with the National Immunisation Strategy (once this strategy is finalised);

Management comments

See detailed management responses - Annex 15

Risk / Impact / Implications

The lack of monitoring was non-compliant with the accountability principle for Gavi provided TCA support and may result in inadequate TCA support for the country needs to further the immunisation agenda.

Responsibility

EPI

Deadline / Timetable

See Annex 15

4.1.5 Supportive supervision activities at national and sub-national level were ineffective

Context and Criteria

The Gavi-approved health systems strengthening (HSS) grant activities include technical and financial monitoring, supervision, and program reviews from the national to sub-county levels, with County Governments also responsible for providing similar support to Sub-County administrations and Health-Facilities. The NVIPs responsible for periodic reviews of the program's implementation status and report to the oversight body, the ICC, to enable monitoring of the program activities.

Additionally, clause 16 of the 2014 PFA states that the government's use of Gavi's vaccine and cash support is subject to strict performance monitoring using country-level mechanisms. According to the World Health Organization (WHO), supportive supervision is crucial for monitoring performance towards program goals and using data for decision-making by following up regularly with staff to ensure that new tasks are being correctly implemented. The collected information should aid the supervisor in deciding on corrective action during the visit and what issues require follow-up action in the longer term.

The audit team expected a functional support supervision activity, in minimum covering vaccine availability, cold chain conditions, vaccine management, waste management, data management and AEFI reporting in relation to the routine immunisation and Covid-19 programs.

Condition

While funding was provided for supportive supervision at national and sub-county levels, several gaps were noted by the audit team and this aligned with the findings of the *2018 Kenya Comprehensive Integrated National Vaccine and Immunisation Programme Review*, which highlighted limited supervision at all levels.

Inconsistent supervision at national level coupled with inadequate follow up of supervision findings - NVIP planned to conduct supervision visits in 17 priority counties for the HSS2 grant. The supervision plans were made redundant by multiple revisions and extensions of the grant, which did not include revision of targets and activities and as such activities were only carried out in 2018 for the HSS grant. Furthermore, there was insufficient evidence to ascertain completion of all supervision visits and where reports were provided, there were no follow-up actions or assigned responsibilities for implementation. In 2021/2022, a new supervision checklist was introduced for Periodic Intensification of Routine Immunisation campaign (PIRI). The PIRI checklist was designed by WHO using Kobo, a mobile data collection platform built on the open data kit (ODK) foundation. However, there was no evidence of follow up and resolution of the gaps identified by PIRI supervisions. Further, the MOH did not adopt the checklist after PIRI and the server for the system remains hosted outside of the country.

At the sub-county level, from the sites visited, the audit team observed the following gaps:

Absence of a comprehensive supportive supervision system – The audit team observed absence of a comprehensive supportive supervision system within NVIP, lacking several key components necessary for its effectiveness. These include the identification of a core set of supervisions at the national level responsible for conducting supervision, the absence of an annual supervision plan, and the absence of HSS grant coordination unit to fulfill its role in overseeing supervision activities. NVIP also lacked clear leadership in reprioritising and reestablishing the supervision process. Additionally, there was no evidence of defined criteria for site selection in the limited instances where supervision did occur.

Inadequate training and supervision – From the review at the selected sub-county sites, the audit team noted that 50% (3/6 Sub-County stores) and 20% (6/30 Health-Facilities) had not been trained for a period of 12 months; 50% (3/6 Sub-County stores) and 23% (7/30 Health-Facilities) had not received support supervision in the past 12 months.

Recommendation 6

The MOH should improve the supportive supervision processes at national and county levels by

- Setting up a comprehensive supportive supervision system that (a) identifies roles and accountability between National Vaccines and Immunisation Programme (NVIP) and counties; (b) updates the existing supervision tool to enhance the effectiveness of supervision activities by recording observations and agreed actions enabling followup; and (c) uses the captured data to prioritise and schedule annual supervision visits and incorporates results from supervision visits into the decision-making processes;

Some supervision activities were not done and where supervision was done, there was no evidence that feedback was shared - The supervision checklists designed to be implemented at County, Sub-County, and health facility levels on a semiannual basis were not executed within the previous 12 months in 3 out of 6 Sub-Counties visited by the audit team. The visiting support supervision teams did not provide any written feedback in 5 out of 5 RVS, 2 out of 7 Counties, 5 out of 6 Sub-Counties, and 7 out of 30 Health-Facilities visited. Consequently, the supervision visits did not lead to any action plans.

Supervision outcomes were not incorporated into the decision-making processes - There was no evidence of MOH using the supervision reports to determine subsequent interventions in the sites visited by the audit team. Therefore, the effectiveness and value for money of supportive supervision were called into question.

Root cause

In addition to disruptions caused by the Covid-19 pandemic, the following root causes were identified:

- Insufficient human resources as there were many vacant positions within the NVIP organisation structure.
- Ineffective oversight over Gavi funded activities within the NVIP mandate.
- Lack of clarity on the supervision tool kit. The ODK tool provided by WHO would not be used continuously by the NVIP programme as the tool is not owned by the MOH and the data collected is hosted on a server outside the country. MOH would be reluctant to endorse a tool while maintaining minimal control on the safety of the data.
- Lack of effective oversight by ICC over the implementation of HSS program activities.

Management comments

See detailed management responses - Annex 15

Risk / Impact / Implications

- Value for money for supportive supervision activities may not have been achieved.
- Delayed resolution of known issues, which could impact the effectiveness of the immunisation programme.

Responsibility

EPI

Deadline / Timetable

See Annex 15

4.2 Vaccine and Supply Chain Management

4.2.1 Gaps in forecasting of annual vaccine procurement needs

Context and Criteria

Gavi typically pledges financial support corresponding to the span of a country's detailed multi-year immunisation plan (cMYP) or national immunisation strategy, conditional on an annual performance review and yearly renewal.

With UNICEF's support, the Ministry of Health/National Vaccine Implementation Program (MOH/NVIP) estimates the quantity of vaccine doses needed to meet the country's requirements for the forthcoming year. NVIP is tasked with declaring the necessary vaccines on a digital platform facilitated by Gavi. Also, the UNICEF country office carries out an annual vaccine projection using its unique tool to be submitted to its supply division in Copenhagen. This annual estimation process determines the number and kind of antigens to be ordered, considering program goals, the intended population, and waste rates.

While the MOH/NVIP's requests on the Gavi platform pertain solely to Gavi-funded vaccines, the UNICEF projection encompasses all vaccines on the national immunisation schedule, including those that will be procured with non-Gavi resources.

Condition

The audit team reviewed the forecasting and demand planning process and determined that the forecasting process was not well structured. The following opportunities for improvement were noted:

Lack of supporting analysis for the wastage calculations – WHO provides regional wastage rates and each country is encouraged to adjust these rates using the actual wastage rates based on additional reviews like field studies, information from vaccine supply chain systems etc. Kenya uses a wastage rate for each antigen of 15% which is significantly higher than the WHO recommended rate of 9%. There was no study provided to support the rates. Furthermore, this audit identified significant gaps in the information within the supply chain systems as noted in Finding 4.2.3.

Target populations input into the Gavi portal to support calculations differ from the official targets in DHIS2 - NVIP entered 1,549,347 as its target population for Pentavalent vaccine coverage on the Gavi portal, which NVIP adjusted downwards to 1,332,318 before entering into the DHIS2 as an official target.

Inadequate documentation of the forecasting process - The forecasting process was not documented and there was no audit trail to support the assumptions used in the forecast calculations. There was no evidence to support the use of consumption data from previous years.

Lack of periodic review **–** The audit noted that vaccine forecasting was done once a year without any further periodic reviews. Given the significant variances, and in accordance with effective forecasting principles, periodic reviews should be conducted so as to realign the forecasted quantities with actual demand and to revisit the accuracy of original assumptions.

Recommendation 7

The MOH should improve its forecast accuracy and process by documenting what is agreed including:

- Formal agreement on each data set to be used, including the accredited source, and ensuring that these data are consistently applied across all forecastings.
- Conducting a comprehensive vaccine wastage study to determine accurate wastage data in support of future forecasts. Until such a study is completed, the country is strongly encouraged to use the WHO vaccine wastage calculator[1].
- Engaging Counties within the Technical Working Groups so as to capture reliable vaccine consumption information across the various health facilities, and use this data for a more realistic forecast.
- Ensuring that each forecasting process includes appropriate supporting documentation, including the key decisions and assumptions, and for this to be formally put on record for future reference.

[1] WHO vaccine wastage calculator

Root cause The root causes of the issues identified in the vaccine forecasting process could be: (i) inaccurate target population estimates, (ii) limited involvement of Counties in the forecasting process, (iii) lack of documentation of assumptions, and (iv) use of generic wastage rates instead of actual.	Management comments See detailed management responses - Annex 15	
Risk / Impact / Implications The lack of supporting analyses and data for assumptions resulted in significant revisions of the forecast once they were received by Gavi and is reflected in the shipments for the period. See **Annex 6** for the differences noted between the country forecasts and the resulting vaccine shipments. The lack of a well-documented forecasting process may result in a knowledge gap with the continued changes in the staff involved in the forecasting process. Additional risks including stock outs and increased emergency shipments in the event of a shortage; wastage of vaccines and strain on existing storage capacity where there is an overstock.	Responsibility EPI	Deadline / Timetable See Annex 15

4.2.2 Data maintained in the various vaccines logistics management systems was incomplete and inaccurate

Context and Criteria

Effective stock data management is crucial for inventory management, accurate demand planning, and procurement processes. The country utilises three stock data sytems as follows (see also **Annex 7**):

- Manual stock ledgers – considered primary source of data and used across all levels within the supply chain
- Stock Management Tool (SMT), which is an offline Excel-based tool used only at the Central Vaccine Stores (CVS) to manage information on vaccine stocks, temperatures, and storage conditions. The CVS staff have also undertaken Gavi funded training for the eSMT tool; and
- Chanjo eLMIS, an electronic logistics management system used at CVS, RVS, Counties and Health-Facilities for managing vaccine inventory records, cold chain equipment, and training. Gavi support was also provided for the Covid-19 Chanjo platform called Chanjo KE, built off the Chanjo eLMIS platform but providing additional information on Covid-19 vaccinations, in addition to providing the Covid 19 vaccines stock data.

Section 2.5 of the WHO Guidelines on stock records for immunisation programme and vaccines store managers provides the minimum information required to be recorded during the receipt and distribution of vaccines as; type of vaccine, presentation (vial size), quantity received (doses), vaccine manufacturer, manufacturing batch or lot number or numbers (there may be more than one batch or lot in a consignment, expiry date for each batch and status of temperature monitoring indicators.

Section 3.3 of the WHO Guidelines on stock records for immunisation programme and vaccines store managers recommends that physical stock checks should be completed on a monthly or three-monthly period and in addition to monthly or three-monthly checks, an annual physical stock check is also essential. WHO further guides that corrected balances identified should be entered on a separate line in all related cards such as batch card, inventory stock card, and/or stock ledger, below the old balance, and a note should be written with responsible staff signature beside it, to indicate that a physical check has confirmed the new balance.

Condition

The audit team observed that stock data was maintained across several tools at national and sub-county levels. The following gaps were noted

Data discrepancies across data sources – The audit team reviewed the manual and electronic records for vaccine management and noted

- Discrepancies between the manual stock records and the electronic Logistics Management Information System (eLMIS) data at the Central Vaccine Store (CVS).
- Significant differences, including duplicated records when data recorded in the manual ledgers was compared to Chanjo eLMIS at sub-county levels. Data records were missing across both systems for example some counties had one entry a year in Chanjo eLMIS and issues to subcounty and health facility levels were not completed in both the manual records and Chanjo eLMIS. See **Annex 8** for details.

Variances in vaccine distribution and receipts data – There were significant differences when the audit team performed a stock reconciliation (opening balance + receipts – issuances – expiries and other wastage = closing stock). This reconciliation was performed at national, regional, subcounty and health facility stores. The audit team then analysed the underlying data and noted the following:

- *National level (CVS and RVS)* - The audit team observed significant differences between the annual cumulative CVS issuances and RVS receipts at all five RVS visited during the audit. A further comparison of the stock issuance records at CVS (manual ledgers for Pentavalent - 2017 and SMT records (2018-2022) with stock receipt records at RVS (manual ledger records and Chanjo eLMIS) for the same period. All records examined were incomplete and inaccurate with data duplications and omissions. See **Annex 9** for details.
- *Subnational level (Sub-County and HF stores)* - The audit team reviewed a sample of batches distributed from the RVS to the HFs and noted significant discrepancies between the vaccine issuance and receipts records across the supply chain, i.e., RVS issuances when

Recommendation 8

The MOH should review the current its stock management processes and related records to:

- Streamline the vaccine records across the different levels. This would include the process to phasing e out any unnecessary tools like such as manual stock ledgers and implementing a standardising the electronic Logistics Management Information System (eLMIS) as the primary stock management tool. Set specific timeframes for adopting a unified electronic logistics management system; completing this changeover should be established.
- Update the stock management guidelines and Standard Operating Procedures (SOPs) SOPs to include the approved stock management tools records;
- Improve the data completeness and quality in the approved eLMIS by ensuring that all stock issuances and receipts are recorded consistently and accurately recorded. This should includes capturing the full details of on the HFs to which where vaccines are issued, enabling better traceability and accountability;
- Conduct regular stock reconciliation exercises including distribution and receipt records at all subnational levels and investigate variances, if any;

compared to sub-county stores receipts; and sub-County store issuances when compared to HFs receipts. These differences were noted in 4 sub county stores and 22 HFs. See **Annex 10** and **Annex 11** for details.

Variances between stock balance records and actual stock – The audit team performed a stock take at the all the vaccines stores visited and noted variances between the vaccine ledgers, Chanjo eLMIs and actual stock at hand at 4 out of 6 subcounty and 13 out of 30 HF stores visited. See **Annex 12** for details.

Root cause

- While Chanjo eLMIS has been rolled out to sub county and health facility levels, the EPI team has not provided adequate guidance as to which tools are the primary records. The EPI team at central level maintains that manual records were primary stock records, while in some regions, sub counties and health facilities, the staff have adopted the Chanjo eLMIS system. This is further worsened by the inadequate stocks of manual vaccine ledgers and limited HR resources. One staff member at HF and subcounty level is required to complete the Chanjo eLMIS and manual ledgers, resulting in incomplete records.
- Inadequate supportive supervision may have failed to identify and address the gaps.
- Multiple systems are still encouraged through the multiple training courses held by EPI – At the time of the audit, the EPI team was still training for eSMT, Chanjo eLMIS at national level.

- Enhance the data quality across the supply chain by activating the various eLMIS' data assurance mechanisms within the eLMIS system which the country chooses to adopt. Thereafter, conducting regular data audits should be conducted, implementing validation checks implemented, and ensuring proper data cleaning processes ensured.
- Strengthen training and capacity building, by providing training and guidance to all relevant staff members involved in stock management at sub-county stores and HFs. This training should be focused on the approved established stock records management tools records to ensure compliance with the established/updated Standard Operating Procedures (SOP)s.
- Strengthening monitoring and supportive supervision, by conducting periodic site visits, data quality assessments, and providing feedback and follow-up processes to ensure compliance with stock management SOPs.

Management comments

See detailed management responses - Annex 15

Risk / Impact / Implications

- The use of three different platforms for vaccine data management poses a risk of incomplete and inaccurate data due to duplicate data entries and data entry omissions.
- Inaccurate data entries in Chanjo eLMIS may result in limited visibility of stock balances at regional and sub county levels.
- Inaccurate data at sub-county levels may result in use of inaccurate data for the national level forecasting processes.

Responsibility

MOH / EPI

Deadline / Timetable

See Annex 15

4.2.3 There were gaps in the operational performance of Chanjo eLMIS and Chanjo_KE; the transition planning for handover of these systems was inadequate

Context and Criteria

The Government of Kenya, in partnership with the Clinton Health Access Initiative (CHAI), implemented Chanjo eLMIS to improve the availability and management of essential health commodities. The Kenya Health Policy 2012-2030 calls for adequate health information for evidence-based decision-making. This policy forms the basis for the 2012 Kenya Health Information Policy, whose goal is to strengthen the generation, validation, dissemination, and use of health data.

Section 3 of the *Data System Governance and Change Management Framework 2018, provides guidance on information systems security, management of user audit trails, ICT infrastructure, interoperability and governance.*

Additionally, ISO 22600:2014 Health informatics - Privilege Management and Access Control (Part 1 through 3) Implementation Guideline: The ISO 22600 set of standards is provided as an advisory standard for policy-based access control. The section on audit log states that;
"All actions based on user-defined events must be recorded."
"All or a specified set of recorded audit information, upon request or at a set period of time, must be electronically displayed or printed for user/administrative review."
Kenya's Data Protection Act of 2019 governs the collection, storage, and use of personal data in the country. The act aims to protect the privacy rights of individuals and ensure that their personal data is collected, processed, and stored in a responsible and secure manner.

Some key features of the Data Protection Act of 2019 in Kenya include:

- Definition of personal data: The act defines personal data as any information that can be used to identify an individual, such as their name, address, identity number, and biometric information.
- Principles of data protection: The act outlines several principles that organisations must follow when collecting, processing, and storing personal data, including transparency, fairness, and accountability.
- Rights of individuals: The act gives individuals several rights with respect to their personal data, including the right to access, correct, and delete their personal data.
- Obligations of data controllers: Data controllers, or organisations that collect and process personal data, are required to comply with the provisions of the act and ensure the security of personal data.

ISO/IEC 27002:2013(Information security standard) statement on operations security, states that backup copies of information, software and system images should be taken and tested regularly in accordance with an agreed backup policy.

Section 3.6 – System Integration and Interoperability of the *Data System Governance and Change Management Framework 2018, guiding principles state the need for systems to build upon existing infrastructure and maintain interoperability. Additionally, the GAVI Target Software Standards under System Characteristics-compatibility, indicate the need for interoperability between systems using open standards to facilitate data exchange.*

In 2018 Gavi established targeted software standards for vaccine logistics management information systems (eLIMS) to provide guidelines and recommendations for the design, implementation, and use of vLIMS to ensure the effective and efficient distribution of vaccines in countries. The TSS under the category -System Characteristics , stipulate the need for eLMIS to have the following ; Performance: speed of processing, load capacity, efficient use of communication data channels; Usability: ease of use and learning, user-centred configuration, real-time data verification and feedback, calculated values, user guides/faq/training manual; Reliability: recoverability, accommodates irregular power and connectivity ; Security: firewall, access privileges, auditability; Maintainability: documentation, software support, local administration control.

Condition

The audit team reviewed the Chanjo eLMIS and Chanjo KE systems and noted the following:

There were gaps in the operational performance of the systems

- Data validation checks were suboptimal. The Chanjo eLMIS had no restriction in issuing expired product or product above available quantities; Chanjo_KE allowed for retrospective data entry and entry of numbers where text inputs were expected;

Recommendation 9

The Ministry of Health, in consultation with Gavi, should:

- Require the Clinton Health Access Initiative (CHAI) to develop a comprehensive change management framework, that includes a costed plan for transferring ownership of the Chanjo electronic Logistic

- System development for CCE management was incomplete. While the CCE module was introduced in 2021, some components like remote temperature monitoring were not accessible on the system. Additionally, there was no check for the status of CCE equipment to ensure timely repair and maintenance.
- Test Data was not cleaned from live system and as a result, the system had several dummy records.
- There was no offline mode support for mobile application. The Chanjo_KE vaccinator app did not support offline data collection and can only be used when an internet connection is available this limits usage of the app in areas with poor internet connectivity.
- Dashboards developed within Chanjo_KE did not support detailed data analysis and only provided basic visualisation. This made them difficult to query and limited support for decision making.

Systems security applications and audit trail management was inadequate

- There were gaps in compliance with policy and laws governing Personally Identifiable Information (PII) on ELMIS -There are no data privacy policies available on the Chanjo KE portal to ensure compliance with the data protection act.
- Gaps in documentation to support data backup and restoration tests – There were no documented policies, SOPs to guide key processes of data backup and restoration testing frequency and reporting.
- Gaps in change management processes - Change requests through the system were managed in an ad hoc manner contrary to the guidance within the data system framework.
- Gaps in documentation of recurring costs required for management of CHANJO eLMIS - The transition overview plan prepared by CHAI did not include quantification of costs such as patch updates, technical development, server infrastructure, staffing requirements to ensure that the necessary support was provided during the transition process by enabling the MOH to absorb all costs at national and sub-county levels.

There was limited interoperability with existing systems **-** Though there have been efforts to integrate Chanjo eLMIS with DHIS2 to improve the visibility of vaccine data some elements like CCE and stock 360 visibility dashboards on the Chanjo app are still not fully integrated with DHIS2. Chanjo eLMIS developed a DHIS2 summary dashboard to visualise data from DHIS2, however DHIS2 reporting rates were not available in the Chanjo eLMIS application. Similarly, the excel based SMT tool doesn't integrate with any other system supporting Vaccine Logistics Management and hence limits end-to-end visibility of the vaccine supply chain downstream from national to sub-national levels.

Root cause

Several root causes were identified including;

- Suboptimal Quality Assurance checks performed on web and mobile applications prior to roll out;
- Inadequate encryption increasing the risk of data breaches and theft. Poor coding practices such as hardcoding formulas as opposed to auto configuring and not performing quality checks on security measures employed on applications;
- Inadequate technical resources for project management and implementation. CHAI team lacked essential staff positions crucial for maintaining a comprehensive change management framework, such as Health Information System (HIS) staff, Information Communication Technology (ICT) staff, eHealth staff support partners, and Monitoring and Evaluation (M&E) staff. Requests from NVIP and Counties for system changes in Chanjo eLMIS were managed in an adhoc manner;
- While transition planning had commenced, there was no overall cost schedule to ensure all fixed and operational costs were known and budgeted for;

Management Information System (eLMIS) over to the Government of Kenya.

- This plan should, at minimum, include key recurring costs such as: patch updates, technical development, server infrastructure, and staffing requirements. This will ensure that the transition is financially sustainable, and that the system is properly maintained and updated to meet the needs of end-users.

Recommendation 10

Improve the accuracy and completeness of the eLMIS' content by implementing data validation, quality assurance checks, data cleaning, and integrating Chanjo electronic Logistic Management Information System with existing systems like DHIS2.

Recommendation 11

Conduct a thorough assessment of the security vulnerabilities in Chanjo eLMIS and then plug any critical weaknesses.

Management comments

See detailed management responses - Annex 15

• Gaps in policies and guidance to support project management at partner and MOH levels. There was limited technical ability at the governance levels at ICC and other MOH departments to provide oversight; and • Gaps in policy and guidance to support integration of systems developed by partners.		
Risk / Impact / Implications • As Kenya is in the accelerated transition phase, meaningful and specific consideration of the performance of Chanjo eLMIS is critical. The issues noted above impact the sustainability of the system. There is a risk that user challenges and inability to absorb operational costs especially at sub-county levels may result in switches to other systems. The audit team noted with concern, that the MOH had not yet accepted and validated the Chanjo eLMIS as the vaccine supply chain management system and there was talk at national level to switch from this system to another eLMIS. This switch would disorient the momentum gained in rolling out Chanjo eLMIS to sub-county level, including all the training and adoption costs that had already been incurred. • Systems security concerns raise a risk to the optimal operation efficiency and data protection risks in event of data loss due to system failures, ransomware, or malicious action by internal staff or external vendors. • Inaccurate and incomplete vaccine data throughout the system limits the states and UIP's ability to use system driven real time	Responsibility EPI / MOH	Deadline / Timetable See Annex 15

4.2.4 Vaccine waste management practices at sub-county levels need to be strengthened

Context and Criteria

The 2020 EVM assessment concluded that 40% of the waste burial facilities at Sub-county vaccine stores and 20% at Health facilities met the minimum requirements and gaps were noted in provision of appropriate personal protective equipment for waste management. The EVM recommended that MOH develop a waste management plan that includes assessing the immunisation waste facilities (incinerators, and burial pits), and ensure the compliance of all sites with these standards.

Condition

Lack of policy on disposal process and timelines for date expired Covid-19 vaccines - The audit team noted absence of a clear policy outlining the disposal process and timelines for expired Covid-19 vaccines. The audit team found a significant quantity (202,800 doses) of expired AstraZeneca Covid-19 vaccines at Nairobi RVS, and the depot manager lacked knowledge regarding disposal instructions and procedures when questioned. Furthermore, the audit team observed several shelf-expired vaccines during their review of both manual and electronic inventory reports and observations at the other regional and sub-county vaccine stores, see **Annex 14**for details.

Poor waste management at subcounty and HF levels - The National Guidelines for Safe Management of Health Care Waste were not complied with, resulting in practices such as open burning of waste using pits with incomplete combustion of waste. There was also a poor understanding amongst health workers regarding proper disposal of waste accumulated from unusable open multi-dose-vials. 15 out of 30 HFs reported not to have previously received any training in vaccine waste management.

Root cause

There was no standard operating procedures (SOPs) to guide waste management processes at sub-county levels and no approved reverse logistics for transferring immunisation waste to other sites with safe disposal capacity.

Recommendation 12

The Ministry of Health should ensure all health facilities have temperature monitoring devices and record-keeping procedures to track vaccine temperatures and the status of vaccine vial monitoring (VVM) indicators.

Recommendation 13

The Ministry of Health should:

- Institute a formal process to dispose of any expired Covid-19 vaccines at all levels. This process can be further instituted/ formalised to manage disposal of routine vaccines.
- Update the 2011 National guidelines for Safe Management of Health Care Waste, to establish proper waste disposal systems at sub-County and health facility levels. This includes clarifying roles, responsibility and accountabilities at the subnational levels for medical waste.
- Include review of waste management practices in the supportive supervision processes.

Management comments

See detailed management responses - Annex 15

Risk / Impact / Implications

- Improper waste management practices may pose a risk to the environment and may be a health risk to those who may come in contact with the waste.

Responsibility	Deadline / Timetable
EPI Manager / MOH	See Annex 15

4.2.5 Previous EVM assessment recommendations were not implemented

Context and Criteria

Effective Vaccine Management (EVM) is essential for the EPI planning processes, endorsed and supported by WHO and UNICEF to assess and prioritise improvements in the immunisation supply chain. EVM is an essential component contributing to the Immunisation Supply Chain (ISC) continuous improvement process.

Immunisation Supply Chain (ISC) continuous Improvement Plans (cIP) also help countries to build an evidence-based case for further supply chain investments and to advocate and engage relevant stakeholders in support the improvement plan which can set the immunisation programme on a path for successful implementation.

Condition

Delayed implementation of previous EVM assessment recommendations **-** In 2020, Kenya carried out an EVM assessment using the EVM 2.0 tool. WHO's standard benchmark for an acceptable supply chain system components is set at 80% and the summary for the country was as below

Table 2: Kenya EVM assessments summary

		Infrastr ucture	Equip't	IT	HR	Policies and Procedures	Financial resources			
		C1	C2	C3	C4	C5	C6	Outputs	Performance	Overall score
Pre–shipment and arrival	E1			100	100	33		74		77
Storage temperature	E2			81	90	95		73	74	79
Capacity	E3	94	75		88	95	100	79	91	84
Building, equipment and transport	E4	59	83	66			100	87		78
Maintenance	E5			50	95	88	100	70	84	86
Stock management	E6			92	86	97		81	66	84
Distribution	E7		97	88	67	68	100	84	71	81
Vaccine Management	E8				86	86		70		84
Waste management	E9		88		91	79	100	47	96	79
Annual needs forecasting	M1				98	86		67	95	83
Annual work planning	M2				85	59	85	68	29	77
Supportive supervision	M3	100	97	75	91	84	100	68		84
iSC perf. monitoring	M4			89	90	88		61		75
Overall EVM score		76	82	81	89	85	95	71	84	81

Recommendation 14

MOH should:

- review the progress made on the EVM recommendations, prioritise, cost and budget actions to respond to the recommendations.
- Understand the root causes of the low scores in the outputs of the various processes reviewed and ensure that all significant gaps are addressed.

<table>
<tr><td colspan="2">Overall, the EVM score showed that the outputs of several processes did not score well with overall score of 71% with 10 out of 13 criteria assessed were below 80% and the lowest score was for performance of the annual work planning processes. Also, the audit team noted that only four of the 51 improvement actions had been completed.</td><td colspan="2"></td></tr>
<tr><td rowspan="2">Root cause
Only one year had elapsed between the establishment of the improvement plan and this programme audit. Furthermore, several actions had not been prioritised and funded to support the implementation of activities.</td><td colspan="2">Management comments

See detailed management responses - Annex 15</td></tr>
<tr><td>Risk / Impact / Implications
The delay in prioritising actions may result in inadequate funding and inability to demonstrate continuous improvement in the supply chain processes during the period of accelerated transition from Gavi support.</td><td>Responsibility

EPI Manager</td><td>Deadline / Timetable

See Annex 15</td></tr>
</table>

4.2.6 Management of cold chain equipment needs strengthening

Context and Criteria

The 2014 Effective Vaccine Management (EVM) plan was prepared by NVIP following its 2013 EVM assessment. The plan outlined key actions, including the procurement of cold chain spare parts, repairing non-functional equipment, and maintaining an updated cold chain inventory data, activities which were funded by Gavi's Cold Chain Equipment Optimisation platform (CCEOP). Kenya was eligible to use Gavi-provided HSS grant to co-invest in the cold chain under Gavi's CCEOP. As of December 2021, Gavi's investment in cold chain was USD 4.77 million with a further USD6.1 million invested in 2022 (after the audit scope period).

Condition

Significant delays in repair and maintenance of cold chain equipment **-** The audit team noted that the Central vaccine stores (CVS) lacked an inventory of spare parts, causing delays in essential maintenance works. Planned preventive maintenance was not always carried out on schedule, primarily due to the absence of spare parts. The audit noted delays of over six months in the locations visited. Furthermore, there were non-functional cold chain units in 4 out of the 5 regional vaccine stores (RVS) visited, including 1 cold room and 2 freezers at Kisumu RVS, 2 freezers and 1 refrigerator at Kakamega RVS, 1 cold room at Nakuru RVS, and 1 cold room at Nairobi RVS. The responsibility for the management and maintenance of the CCEs along with the provision of the budget lies with the respective counties and EPI only provides guidelines for repair and maintenance of CCE.

Lastly, no documentation was maintained, throughout the supply chain systems at national and sub-county levels (RVS, sub county stores and HFs), to support the proper management and decommissioning of obsolete and redundant machinery.

CCE provided for management of Covid-19 vaccines was not in use - At the time of the audit visit, 4 UCC had been placed at the CVS and over 8 UCC machines placed at the different 5 RVS. The audit team noted that some of the machines had been turned off due to redundancy, pending arrival of new Covid-19 vaccines with no clear protocols established to manage the equipment given the high-power demands.

Root cause

- Inadequate and/or ineffective supportive supervision.
- Lack of a centralised inventory tracking system.
- Insufficient planning and monitoring of preventive maintenance.
- A lack of necessary training, skills, and resources to address repair and maintenance.
- Absence of decommissioning guidelines.
- The assessment of the need for UCC for Covid 19 vaccines may have overestimated the needs of the country and NVIP has not developed a plan for use of such equipment for routine immnunisation.

Recommendation 15

The Ministry of Health should enhance the overall management of the cold chain system by:

- Implementing a centralised inventory tracking system for spare parts;
- Establishing a preventive maintenance schedule for cold chain equipment with clear timelines and personnel responsibilities;
- Developing budgets for repair and maintenance of CCE and determine ownership and responsibility for such costs between the respective national and subnational levels;
- Developing a plan for decommissioning obsolete equipment, including the drafting of proper disposal guidelines for unusable CCE; and
- Re-evaluating the country's CCE needs assessment to determine any residual gaps, and formulating a plan for the use of the CCE supplied during the Covid 19 pandemic. In addition sources of funding for acquiring future equipment should be identified, and all such costs should be transitioned into the MOH budget.

Management comments

See detailed management responses - Annex 15

Risk / Impact / Implications

- Vaccine damage due to exposure to inappropriate temperature.
- Disruption to supply chain and reduced availability of vaccines.
- Increased programme cost due to lack of preventive maintenance

Responsibility

EPI
Procurement, Public assets and disposal committee

Deadline / Timetable

See Annex 15

4.3 Immunisation Data Management

4.3.1 There were inconsistencies in the immunisation data

Context and Criteria

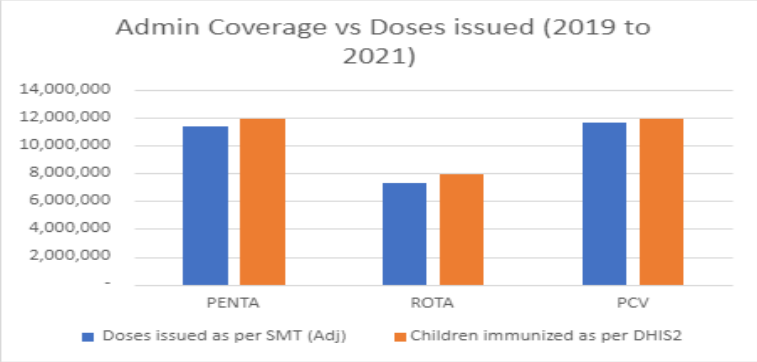
Gavi requires countries it supports to improve data availability, quality, and usage for planning, program management, and documentation of results. The Partnership Framework agreement mandates accurate information provision and strict monitoring of government's use of Gavi's support. Gavi's health systems strengthening grant includes activities to improve national immunisation data accuracy and has a budget allocation of USD1,220,930 for data-related activities.

Condition

Lack of documentation regarding target setting in the District Health Information System 2 – NVIP is required to conduct annual data harmonisation meeting with stakeholders to determine target population projections for the upcoming year. There were no documents to support this process, or the assumptions considered to support the targets derived in these meetings. There was no records of the meetings and no evidence that county governments were represented in the meetings. Revised data targets resulting from the harmonisation were not shared with the counties.

Potential errors in denominators used for planning – The latest 2019 population census conducted by the Kenya National Bureau of Statistics projected a decline in the number of children under one year old, with a decrease in the number of children under one year old, from 1.5 million to 1.1 million. This was significantly lower than the targets used by NVIP for prior years. While there seemed to be a consensus at NVIP, counties and partners that the 2019 census data did not reflect the reality and needed adjustment, it remained unclear when this would be done and how it would impact planning at national and sub-county levels. Consequently, NVIP continues to utilise is own data derived from harmonisation meetings. This data is not supported by any assessments and microplanning from other interventions like campaigns.

Potential overreporting of administrative coverage data – During a three-year period from 2019 to 2021, a comparison of vaccine doses issued (per SMT) by the National Vaccine and Immunisation Programme (NVIP) with the number of children reported as vaccinated in the District Health Information System 2 (DHIS2) showed that the reported number of immunised children was consistently higher than the actual vaccine doses available. The audit team sampled three types of vaccines, pentavalent, PCV, and Rotavirus, and concluded that it was likely that the data in DHIS2 was over-reported. This likelihood is supported by the errors in data records noted at the health facilities.



The Ministry of Health / National Vaccines and Immunisation Programme should:

Recommendation 16

- Collaborate with the Kenya National Bureau of Statistics, Gavi alliance partners, Counties and other in-country stakeholders, to validate population numbers and set appropriate denominators be used in DHIS2;
- Improve its documentation and record-keeping by ensuring that all outcomes, assumptions and decision made during the annual data harmonisation meetings are documented and cosigned by parties involved;
- Ensure active involvement of Counties in the annual data harmonisation meetings to capture their insights and perspectives on population projections. Establish a mechanism to ensure County representation in these meetings, to enable collaborative decision-making and the inclusion of local context in target setting; and
- Establish a monitoring and review mechanism address data gaps.

<table>
<tr><td colspan="2">Errors in data records - The audit team compared pentavalent vaccination data for June 2018, 2020, and 2022 in the monthly reports used for data entry into DHIS2 and the tally records and noted data discrepancies in the data were found in 66% of Health-Facilities, with most monthly summary sheets having higher data than the daily tally sheets. See Annex 13.</td></tr>
<tr><td>Root cause
• Absence of robust processes and procedures for documentation and record-keeping has led to lack of transparency and accountability in target setting and reporting.
• Weak data management and reporting processes due to inadequate training, supervision, and quality control measures.</td><td>Management comments

See detailed management responses - Annex 15</td></tr>
<tr><td>Risk / Impact / Implications
Reliance on inaccurate or over-reported immunisation coverage data can result in incorrect programmatic interventions and misallocation of resources, which could negatively impact the effectiveness of the immunisation programme and the health of the targeted population.</td><td>Responsibility

EPI

Deadline / Timetable

See Annex 15</td></tr>
</table>

4.3.2 Data quality assurance processes were inadequate

Context and Criteria

The Partnership Framework agreement (PFA) signed in 2014 requires Gavi-supported countries to provide accurate and correct information to Gavi, including progress reports and financial information. The agreement also includes provisions for monitoring and reporting, with Gavi seeking to use the country's reports and existing mechanisms to monitor performance. Gavi's application guidelines encourage countries to improve data availability, quality, and use for better planning, program management, and understanding and documenting of results. Countries are encouraged to develop a strategic data improvement plan based on the latest assessment and to identify key priority areas to be addressed.

Immunisation data is generated at Health-Facilities which record data using manual tools such as EPI daily tally sheets and immunisation permanent registers. The Health-Facilities consolidate the tally sheet into a monthly immunisation summary report and submit to Sub-Counties by the 5th of each month. The Sub-County health records information officers uploads the data from the monthly reports to DHIS 2 by the 15th of each month.

Condition

Inconsistent and ineffective data quality monitoring processes – While several data quality assurance and monitoring mechanisms such as national quarterly review of immunisation performance, annual data quality self-assessments, data quality audits, data review meetings (Sub County level), quarterly County-Sub-County and health facility support supervision, biannual national-County support supervision, data quality audits and monthly data quality checks at health facility level were established, the audit team noted that these processes were not undertaken consistently and were not effective in monitoring of data inputs.

Lack of data validation, verification, data quality review and follow up - The audit team noted that the NVIP had not undertaken any onsite sub-county level supportive supervisions or meetings pertaining to data quality for the period under audit. Consequently, NVIP relied on remote review of data already in DHIS2 with no reviews of underlying data records. This process did not include data quality supervision reviews, data quality audits at the sub-county level and periodic data triangulation by the NVIP team. Furthermore, there was no evidence provided to demonstrate such remote reviews. Equally lacking was the evidence of follow up communication and correction of data after any errors were found.

Integrated support supervision did not cover data quality aspects - National, county, and sub-county monitoring and evaluation teams are expected to conduct quarterly integrated support supervision using a comprehensive checklist. The audit team noted that there was no feedback on data gaps identified during support supervision at 2 out of 7 Counties, 5 out of 6 Sub-Counties, and 7 out of 30 Health-Facilities.

Slow development and implementation of the data quality improvement plan (DQIP) - The development of the Data Quality Improvement Plan (DQIP) 2021-2025 was significantly delayed. While the Data Quality Assessment (DQA) conducted in 2017, the NVIP only finalised the DQIP 2021-2025 in December 2020. Consequently, at the time of the audit, 10% of the interventions were completed, while 38% had not started and 52% were only partially implemented. There was no evidence to support the completed or partially completed activities.

Root cause

The root causes identified for the poor data quality in the immunisation programme include inadequate onsite data verification at the health facility level, skill gaps resulting from inadequate training at the health facility level, and insufficient oversight arrangements surrounding the monitoring and evaluation (M&E) function. The Ministry of Health (MOH) and the National Vaccine and Immunisation Programme (NVIP) did not perform the required onsite sub-county level supportive supervisions or meetings pertaining to data quality.

The Ministry of Health and National Vaccine and Immunisation Programme should:

Recommendation 17

Design and establish interventions aimed at enhancing immunisation data capture, processing, and management capacity at all levels, with the support of technical partners.

Recommendation 18

- Expedite the implementation of the Data Quality Improvement Plan 2021-2025, while also ensuring that this plan is adequately financing and that appropriate oversight measures are in place; and
- Engage the Immunisation Coordination Committee (ICC) in monitoring the progress of the plan's interventions and provide the ICC with evidence-based updates on completed, partially implemented, and pending activities to ensure transparency and accountability.

Management comments

See detailed management responses - Annex 15

Risk / Impact / Implications	Responsibility	Deadline / Timetable
Inadequate attention to key priority areas for data quality can lead to unreliable immunisation data, which hinders optimal coverage and disease prevention. Weak use of immunisation data can result in missed opportunities for better planning, resource management and suboptimal outcomes for both the country targeted beneficiaries.	EPI Manager ICC Secretariat	See Annex 15

5. Annexes

Annex 1 – Acronyms

CCE	Cold chain equipment
CCEOP	Cold Chain Equipment Optimisation Platform
CU	Coordinating Unit
CHAI	Clinton Health Access Initiative
cMYP	Comprehensive Multi-Year Plan
CVS	central vaccine store
DQA	Data Quality Assessment
DQIP	Data Quality Improvement Plan
EVM	Effective Vaccine Management
HF	Health Facility
HRIO	Health Records Information Officer
HRIS	Human Resource Information System
HSS	Health Systems Strengthening
HSTP	Health Sector Transformation Plan
ICC	Interagency Coordination committee
IPLS	Integrated Pharmaceutical Logistics System
iSC	Immunisation supply chain
iSCM	Immunisation supply chain management
JSI	John Snow, Inc.
KANCO	Kenya AIDS NGOs Consortium
KDHS	Kenya Demographic Health Survey
KEMSA	Kenya Medical Supply Agency
KENITAG	Kenya National Immunisation Technical Advisory Group
LMIS	Logistics Management Information System
LTWG	Logistics Technical Working Group
M&E	Monitoring and Evaluation
MOH	Ministry of Health
NGO	Non-Governmental Organisation
NVIP	Extended Programme on Immunisation
PCV	Pneumococcal Conjugate Vaccine
PII	Personally Identifiable Information
PLMP	Pharmaceuticals Logistics Master Plan
RTMD	remote temperature monitoring devices
RV	Rotavirus
RVS	regional vaccine store
SDG	Sustainable Development Goals
SDG-PF	Sustainable Development Goals Pool Fund
SOH	stock on hand
SOP	standard operating procedures
TOR	Terms of reference
ToT	Training of Trainers
UCC	Ultra-Cold Chain
UNICEF	United Nations Children's Fund
USD	United States Dollars
VIG	Vaccine Introduction Grant
WHO	World Health Organization
WICR	Walk in cold room

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 definition of Internal Auditing, the Core Principles, 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: 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.

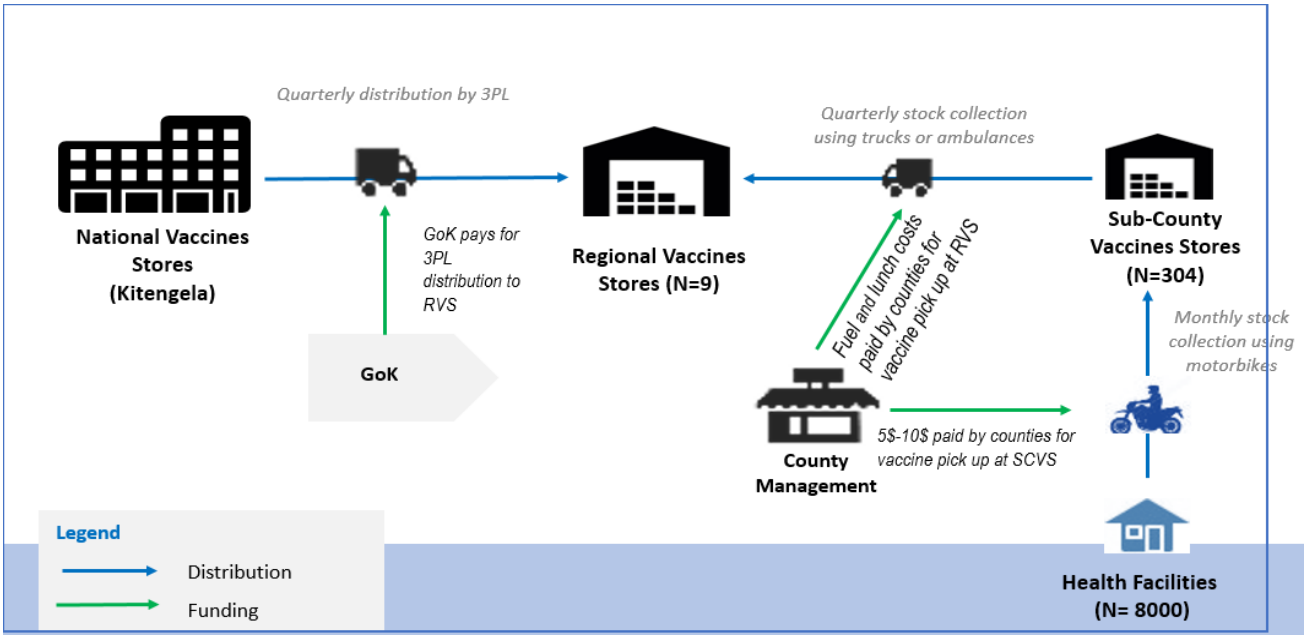
Rating	Implication
High	At least one instance of the criteria described below is applicable to the issue raised: • Controls mitigating high inherent risks or strategic business risks are either inadequate or ineffective. • The issues identified may result in a risk materialising that could either have: 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. • Management attention is required as a matter of priority. • Fraud and unethical behaviour including management override of key controls.
Medium	At least one instance of the criteria described below is applicable to the issue 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 issue 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 – Sub-central sites visited by the audit team

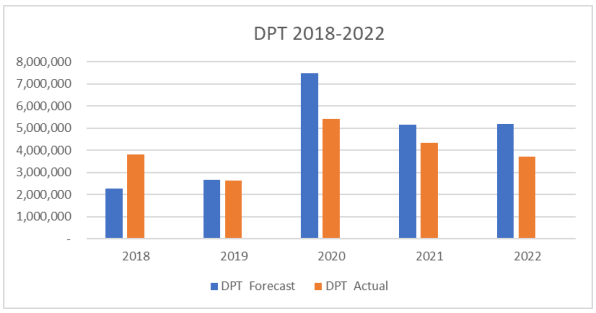
Regional vaccine store (Vaccine Store) [5]	Sub Counties [6] (Vaccine Store & Immunisation data)	Health-Facilities [30] (Vaccine Store & Immunisation data)
Kisumu	Ndiwa	Ndiwa, Lambwe forest, Got, Kojowi, Kobodo
Nakuru	Naivasha	Naivasha District, Karagita, Mai, Mahiou , Ndabibi
Mombasa	Kasauni	Junda, Skans, Shimo La Tewa Annex, Mwakirunge
	Galole	Hola, Pumwani, Chewani, Makere, Hola GK Prisons, Wayu Boru
Kakamega	Malaba	Malaba Sub-County, Kimageti, Namagara, Selaberere, Chevyoso, Makhwabuye
Nairobi	Narok North	Narok County referral hospital, Naisoya, Enabelbel, Entontol, Olochoro, Fountain Health-Facilities

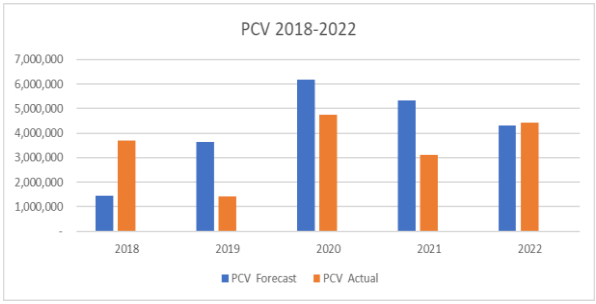
Annex 5 – Kenya's supply chain structure

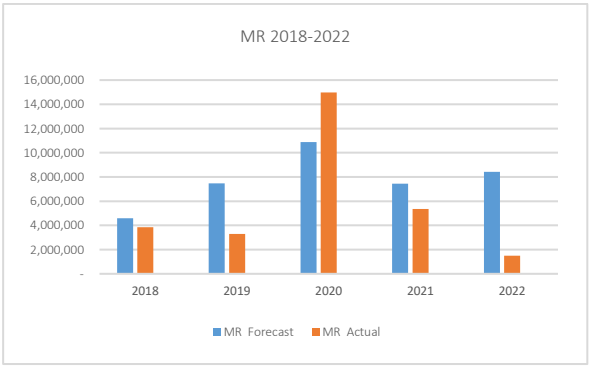
A. Supply Chain Model System

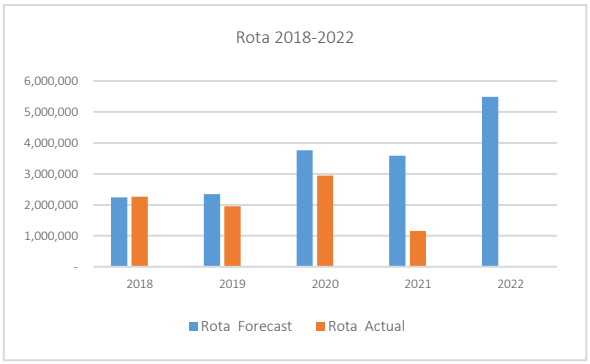


Annex 6 - Mismatch between Forecasts and Actual Procurements (2018-2022)



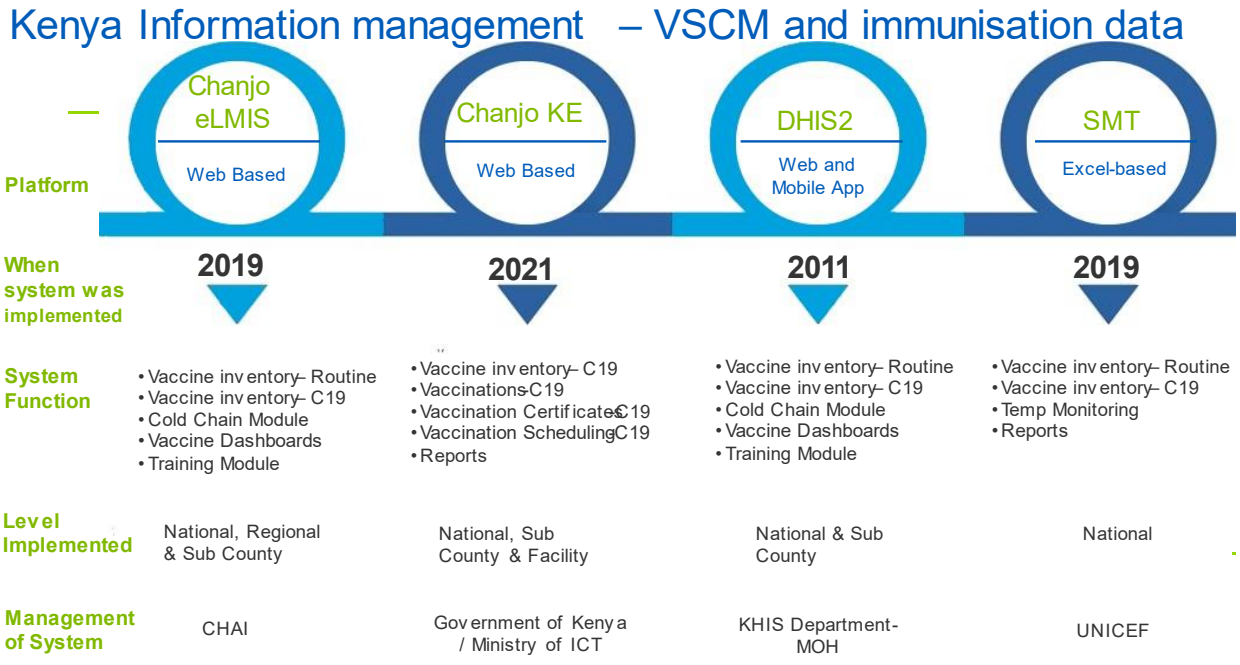






Annex 7 – Kenya Information Management systems for vaccine supply chain and immunisation data management

INTERNAL



Annex 8 - Data Discrepancy between stock record tools at Sub-national level

Sub-County	Name of Vaccine	Batch No.	Quantity on stock card / stock ledger / Bin Card (Doses)	Quantity recorded in ELMIS (Doses)
Mombasa	Pentavalent Vaccine	2861X003A, 2860X035A, 2862X005B	3,000	6,050
Mombasa	Pneumococcal Conjugate Vaccine (PCV)	2091Y024A	2,685	3,035
Mombasa	Measles Rubella Vaccine	0121W100, 0121W101	8,770	9,020
Mombasa	Johnson & Johnson (J&J)	217D21A	0	55
Nakuru	Pneumococcal Conjugate Vaccine (PCV)	2091Y024A	3,470	3,930
Nakuru	Johnson & Johnson (J&J)	NA	0	125
Narok	Pentavalent Vaccine	2861X006B	2,150	0
Narok	Pneumococcal Conjugate Vaccine (PCV)	ASP4A320BA	2,024	0
Narok	Measles Rubella Vaccine	0121W101	2,740	0
Narok	Pfizer Vaccine	GA2988	1,170	0
Health Facility (HF)	**Name of Vaccine**	**Batch No.**	**Quantity on stock card/ledger/Bin Card (Doses)**	**Quantity recorded in ELMIS (Doses)**
Skans	Pentavalent Vaccine	2862x005B	180	0
Skans	Pneumococcal Conjugate Vaccine (PCV)	2091Y024A	235	0
Skans	Measles Rubella Vaccine	0120W058	220	0
Shimo	Pentavalent Vaccine	2862X005B	110	0
Shimo	Pneumococcal Conjugate Vaccine (PCV)	2091y024a	40	0
Shimo	Measles Rubella Vaccine	0120w058	140	0
Mwakirunge	Pneumococcal Conjugate Vaccine (PCV)	2091Y0230	10	0
Naivasha	Pentavalent Vaccine	2861X014B	540	0
Naivasha	Pneumococcal Conjugate Vaccine (PCV)	2091Y024A	403	0
Naivasha	Measles Rubella Vaccine	0121W099	240	0
Karagita	Pentavalent Vaccine	2861X0148	30	0
Karagita	Pentavalent Vaccine	2861X003B	190	0
Karagita	Pneumococcal Conjugate Vaccine (PCV)	2091Y024A	180	0
Karagita	Measles Rubella Vaccine	0121W099	100	0
Mai	Pentavalent Vaccine	2861X014B	120	0
Mai	Pneumococcal Conjugate Vaccine (PCV)	20191Y024A	100	0
Mai	Measles Rubella Vaccine	0121W099	30	0
Ndabibi	Pentavalent Vaccine	2861X014B	50	0
Ndabibi	Pneumococcal Conjugate Vaccine (PCV)	2091Y024A	72	0
Ndabibi	Measles Rubella Vaccine	0121W099	70	0
Ndihwa	Pentavalent Vaccine	2861X014B	200	0
Ndihwa	Pneumococcal Conjugate Vaccine (PCV)	2091Y024A	125	0
Ndihwa	Measles Rubella Vaccine	0121W099	100	0
Ndihwa	Measles Rubella Vaccine	0120w093	130	0
Ndihwa	AstraZeneca Vaccine (AZ)	NA	0	405
Ndihwa	Moderna Vaccine	NA	0	375
Ndihwa	Pfizer Vaccine	NA	0	322
Got	Pentavalent Vaccine	2861X014B	110	0
Got	Pentavalent Vaccine	2860X0358	180	0
Got	Pneumococcal Conjugate Vaccine (PCV)	2091Y024A	115	0
Got	Measles Rubella Vaccine	0120w093	130	0
Got	Johnson & Johnson Vaccine (J&J)	ACB6958	80	100
Kobodo	Pentavalent Vaccine	2861X014B	190	0
Kobodo	Pneumococcal Conjugate Vaccine (PCV)	2091Y024A	120	0
Kobodo	Measles Rubella Vaccine	0120W093	120	0
CHEWANI	Pentavalent Vaccine	2861x003A	20	0
CHEWANI	Pneumococcal Conjugate Vaccine (PCV)	20911024A	10	0
CHEWANI	Measles Rubella Vaccine	0121W099	80	0
MAKERE	Pentavalent Vaccine	2860x035b	100	0
MAKERE	Pneumococcal Conjugate Vaccine (PCV)	2091y02AA	80	0
MAKERE	Measles Rubella Vaccine	0121W099	80	0
PUMWANI	Pentavalent Vaccine	2861X003A	80	0
PUMWANI	Pneumococcal Conjugate Vaccine (PCV)	2091Y024A	95	0
PUMWANI	Measles Rubella Vaccine	0121W099	30	0
HOLA	Pentavalent Vaccine	2861X003A	190	0

HOLA	**Pneumococcal Conjugate Vaccine (PCV)**	2091Y024A	210	0
HOLA	**Measles Rubella Vaccine**	0121W101	220	0
WAYU BORU	**Pentavalent Vaccine**	2861X003A	50	0
WAYU BORU	**Pneumococcal Conjugate Vaccine (PCV)**	2091Y023C	25	0
WAYU BORU	**Measles Rubella Vaccine**	0121W101	140	0
GK PRISON	**Pneumococcal Conjugate Vaccine (PCV)**	2091Y024A	45	45
Narok Hosp	**Pentavalent Vaccine**	2861X006B	500	0
Narok Hosp	**Pentavalent Vaccine**	2862X005B	640	0
Narok Hosp	**Pneumococcal Conjugate Vaccine (PCV)**	ASP4A320BA	340	0
Narok Hosp	**Measles Rubella Vaccine**	0121W101	290	0
Narok Hosp	**Johnson & Johnson Vaccine (J&J)**	ACB6958	0	530
Narok Hosp	**Moderna Vaccine**	N/A	0	270
Narok Hosp	**Pfizer Vaccine**	GA2988	1170	102
Naisoya	**Pentavalent Vaccine**	2861X0031	80	0
Naisoya	**Pneumococcal Conjugate Vaccine (PCV)**	ASP4A320BA	84	0
Naisoya	**Measles Rubella Vaccine**	0121W101	90	0
Enabelbel	**Pentavalent Vaccine**	2862X005B	240	0
Enabelbel	**Pneumococcal Conjugate Vaccine (PCV)**	ASP4A320BA	212	0
Enabelbel	**Measles Rubella Vaccine**	012W101	250	0
Enabelbel	**AstraZeneca Vaccine (AZ)**	NA	0	200
Enabelbel	**Johnson & Johnson Vaccine (J&J)**	NA	300	400
Enabelbel	**Pfizer Vaccine**	NA	0	60
Entontol	**Pentavalent Vaccine**	2862X005B	127	0
Entontol	**Pentavalent Vaccine**	2861X003A	109	0
Entontol	**Pneumococcal Conjugate Vaccine (PCV)**	ASP4A260AA	124	0
Entontol	**Measles Rubella Vaccine**	0120W092	180	0
Olochoro	**Pentavalent Vaccine**	2861X003E	230	0
Olochoro	**Pneumococcal Conjugate Vaccine (PCV)**	ASP4A320BA	224	0
Olochoro	**Measles Rubella Vaccine**	0121W101	230	0
Kimangeti	**Pentavalent Vaccine**	2861X006A	120	0
Kimangeti	**Pneumococcal Conjugate Vaccine (PCV)**	2091Y024A	65	0
Kimangeti	**Measles Rubella Vaccine**	0121W101	90	0
Kimangeti	**Johnson & Johnson Vaccine (J&J)**	ACB6047	50	0
Namagara	**Pentavalent Vaccine**	2861X0038	140	0
Namagara	**Pneumococcal Conjugate Vaccine (PCV)**	2091Y024A	110	0
Namagara	**Measles Rubella Vaccine**	0121w101	200	0
Namagara	**Johnson & Johnson Vaccine (J&J)**	ACB6958	145	0
Shamberere	**Pentavalent Vaccine**	2861X006A	140	0
Shamberere	**Pneumococcal Conjugate Vaccine (PCV)**	2091Y024A	120	0
Shamberere	**Measles Rubella Vaccine**	0121w101	270	0
Shamberere	**AstraZeneca Vaccine (AZ)**	ACB6958	85	0
Chevoso	**Pentavalent Vaccine**	2861X006A	130	0
Chevoso	**Pneumococcal Conjugate Vaccine (PCV)**	2091Y024A	80	0
Chevoso	**Measles Rubella Vaccine**	0121W101	150	0
Chevoso	**Johnson & Johnson Vaccine (J&J)**	ACB6047	100	0
Makhwabuye	**Pentavalent Vaccine**	2861X006A	50	0
Makhwabuye	**Pneumococcal Conjugate Vaccine (PCV)**	2091Y024A	40	0
Makhwabuye	**Measles Rubella Vaccine**	0121W101	160	0
Makhwabuye	**Johnson & Johnson Vaccine (J&J)**	ACB6047	106	0
Makhwabuye	**Pfizer Vaccine**	GA2988	60	0

Annex 9- Variances between CVS issuances and RVS receipts

RVS	Vaccine Type	Sample Year	Aggregate CVS Issuances in Doses (A)	Aggregate RVS Receipts in Doses (B)	Variance (A-B) Doses
Mombasa	Measles Rubella Vaccine	2019	234,000	256,000	**-22,000**
Mombasa	Rotavirus Vaccine	2020	224,900	221,850	**3,050**
Mombasa	AstraZeneca Vaccine (AZ)	2021	511,280	581,840	**-70,560**
Nakuru	Pneumococcal Conjugate Vaccine (PCV)	2018	393,600	444,800	**-51,200**
Nakuru	AstraZeneca Vaccine (AZ)	2021	713,040	823,040	**-110,000**

Nakuru	Johnson & Johnson Vaccine (J&J)	2021	217,900	210,400	**7,500**
Nakuru	Pfizer Vaccine	2022	706,680	759,310	**-52,630**
Kisumu	Pneumococcal Conjugate Vaccine (PCV)	2018	632,200	565,000	**67,200**
Kisumu	AstraZeneca Vaccine (AZ)	2021	676,460	731,620	**-55,160**
Kisumu	Pfizer Vaccine	2022	1,551,420	911,430	**639,990**
Nairobi	Pentavalent Vaccine	2017	1,027,400	1,014,900	**12,500**
Nairobi	Pneumococcal Conjugate Vaccine (PCV)	2018	994,000	974,800	**19,200**
Nairobi	Measles Rubella Vaccine	2019	1,152,000	1,208,900	**-56,900**
Nairobi	Rotavirus Vaccine	2020	797,400	798,900	**-1,500**
Nairobi	AstraZeneca Vaccine (AZ)	2021	3,463,580	3,405,460	**58,120**
Nairobi	Pfizer Vaccine	2022	1,278,810	1,673,844	**-395,034**
Kakamega	Pentavalent Vaccine	2017	331,300	385,600	**-54,300**
Kakamega	Pneumococcal Conjugate Vaccine (PCV)	2018	492,200	422,400	**69,800**
Kakamega	Measles Rubella Vaccine	2019	309,000	331,000	**-22,000**
Kakamega	Rotavirus Vaccine	2020	264,300	302,000	**-37,700**
Kakamega	AstraZeneca Vaccine (AZ)	2021	531,880	655,480	**-123,600**
Kakamega	Pfizer Vaccine	2022	1,359,540	1,186,380	**173,160**

Annex 10 – Variances between RVS issuances and Sub- County store receipts

Region	Vaccine Type Vaccine Type	Sample Year	Region Store Issues		County Store receipt		Store	VARIANCE
			Delivery Record		Receipt Note/Register		Stock Card	
			Batch No.	Quantity (Doses)	Batch No.	Quantity (Doses)	Stock Quantity (Doses)	**Quantity (Doses)**
Nakuru	Pneumococcal Conjugate Vaccine (PCV)	2018	ASPNB108AA	8,000	ASPNB108AA	7,000	7,000	**-1,000**
Nakuru	Measles Rubella Vaccine	2019	0129M082	9,250	0129M082	0	0	**-9,250**
Nakuru	Rotavirus Vaccine	2020	AR0LC665AA	17,500	AR0LC665AA	5,000	5,000	**-12,500**
Nakuru	AstraZeneca Vaccine (AZ)	2021		66,673		73,986	73,896	**7,223**
Nakuru	Pfizer Vaccine	2022		59,965		54,420	54,420	**-5,545**
Kakamega	Pneumococcal Conjugate Vaccine (PCV)	2018	ASPNB108AA	8,000	ASPNB108AA	9,000	9,000	**1,000**
Kakamega	AstraZeneca Vaccine (AZ)	2021		13,404		6,460	6,460	**-6,944**
Kakamega	Johnson & Johnson Vaccine (J&J)	2021		31,200		33,200	33,200	**2,000**
Kakamega	Pfizer Vaccine	2022		39,780		43,290	43,290	**3,510**

Note: sample batches were traced for Routine vaccines and aggregate quantities by year for Covid-19 vaccines.

Annex 11 – Variances between Sub- County store issuances and Health-Facilities store receipts.

Sub-County	Health Facility (Health-Facilities)	Vaccine Type	Sample Year	Sub-County Issues		Health Facility (Health-Facilities) Receipt		Store	VARIANCE
				Delivery Record		Receipt Note/Register		Stock Card	
				Batch No.	Quantity (doses)	Batch No.	Quantity (Doses)	Stock Quantity (Doses)	**Quantity (Doses)**
Mombasa	Junda	Pentavalent Vaccine	2017	124X7003A	500	124X7003A	810	810	**-310**
Mombasa	Mwakirunge	Pneumococcal Conjugate Vaccine (PCV)	2018	ASPNB043AA	100	ASPNB043AA	96	96	**4**
Mombasa	Mwakirunge	Pfizer Vaccine	2022		2,070		796	796	**1,274**
Nakuru	Naivasha	Pneumococcal Conjugate Vaccine (PCV)	2018	ASPNB108AA	1,880	ASPNB108AA	2,000	2,000	**-120**
Nakuru	Naivasha	Measles Rubella Vaccine	2019	0129M082	1,300	0129M082	1,460	1,460	**-160**
Nakuru	Naivasha	Rotavirus Vaccine	2020	AR0LC665AA	1,293	AR0LC665AA	1,200	1,200	**93**
Nakuru	Naivasha	AstraZeneca Vaccine (AZ)	2021		32,464		15,056	15,056	**17,408**
Nakuru	Naivasha	Johnson & Johnson Vaccine (J&J)	2021		12,000		2,005	2,005	**9,995**

Sub-County	Health Facility (Health-Facilities)	Vaccine Type	Sample Year	Sub-County Issues		Health Facility (Health-Facilities) Receipt		Store	VARIANCE
				Delivery Record		Receipt Note/Register		Stock Card	
				Batch No.	Quantity (doses)	Batch No.	Quantity (Doses)	Stock Quantity (Doses)	Quantity (Doses)
Nakuru	Naivasha	Moderna Vaccine	2022		0		140	140	**-140**
Nakuru	Naivasha	Pfizer Vaccine	2022		5,233		4,188	4,188	**1,045**
Nakuru	Karagita	Measles Rubella Vaccine	2019	0129M082	800	0129M082	0	0	**800**
Nakuru	Mai	Measles Rubella Vaccine	2019	0129M082	640	0129M082	530	530	**110**
Nakuru	Mai	Rotavirus Vaccine	2020	AR0LC665AA	700	AR0LC665AA	500	500	**200**
Nakuru	Mai	AstraZeneca Vaccine (AZ)	2021	NL0251,NJ0139,210304,AB0024,210180	1,920	41202030,ABW4805,210005,210005,AB0024,NJ0139,NL0251	5,454	5,454	**-3,534**
Nakuru	Mai	Pfizer Vaccine	2022	FR8225,FT5331,FL3208,FG3532,3401BD	9,850	340J5BD, FL3208, FL5331, PAA736696, PAA736, FR8225	6,170	6,170	**3,680**
Nakuru	Ndabibi	AstraZeneca Vaccine (AZ)	2021	NL0251, NJ0139,201304, AB0024	720	AB0024, 210304, NJ0139, NL01251	870	870	**-150**
Nakuru	Ndabibi	Pfizer Vaccine	2022	FR8225, FT5331,FL3208,FG3532, 34015BD	1,006	3401BD, FG3532, FT53331	1,104	1,104	**-98**
Kisumu	Ndhiwa	Measles Rubella Vaccine	2019	0129M082	1,210	0129M082	600	600	**610**
Kisumu	Lambwe	Pneumococcal Conjugate Vaccine (PCV)	2018	ASPNB108AA	50	ASPNB108AA	100	100	**-50**
Kisumu	Got	Pentavalent Vaccine	2017	124x7002A	400		0	0	**400**
Kisumu	Got	Pneumococcal Conjugate Vaccine (PCV)	2018	ASPNB108AA	550	ASPNB108AA	100	100	**450**
Kisumu	Got	Measles Rubella Vaccine	2019	0129M082	500	0129M082	150	150	**350**
Kisumu	Got	Rotavirus Vaccine	2020	AR0LC803AB	0	AR0LC803AB	42	42	**-42**
Kisumu	Got	AstraZeneca Vaccine (AZ)	2021	NH0239	0	NH0239	50	50	**-50**
Kisumu	Got	Johnson & Johnson Vaccine (J&J)	2021	XE442	0	XE442	50	50	**-50**
Kisumu	Got	Pfizer Vaccine	2022	350658B	0	350658B	48	48	**-48**
Kisumu	Kobodo	Pneumococcal Conjugate Vaccine (PCV)	2018	ASPNB108AA	290	ASPNB108AA	290	240	**50**
Tana river	CHEWANI	Pentavalent Vaccine	2017	124X7003A	100	124X7003A	280	280	**-180**
Tana river	MAKERE	Pneumococcal Conjugate Vaccine (PCV)	2018	ASPNB043AA	100	ASPNB043AA	96	96	**4**
Tana river	PUMWANI	Pneumococcal Conjugate Vaccine (PCV)	2018	ASPNBO43AA	0	ASPNB043AA	100	100	**-100**
Tana river	PUMWANI	Measles Rubella Vaccine	2019	029M082	0	0129M082	60	60	**-60**
Tana river	PUMWANI	Rotavirus Vaccine	2020	AROLC661AA	100	AROLC661AA	0	0	**100**
Tana river	HOLA	AstraZeneca Vaccine (AZ)	2021		0		3,990	3,990	**-3,990**
Tana river	HOLA	Johnson & Johnson Vaccine (J&J)	2021		0		600	600	**-600**

Sub-County	Health Facility (Health-Facilities)	Vaccine Type	Sample Year	Sub-County Issues		Health Facility (Health-Facilities) Receipt		Store	VARIANCE
				Delivery Record		Receipt Note/Register		Stock Card	
				Batch No.	Quantity (doses)	Batch No.	Quantity (Doses)	Stock Quantity (Doses)	Quantity (Doses)
Tana river	HOLA	Pfizer Vaccine	2022		0		1,050	1,050	**-1,050**
Narok	Enabelbel	Measles Rubella Vaccine	2019	0129M081	100	0129M081	350	350	**-250**
Narok	Enabelbel	Rotavirus Vaccine	2020	AR0LC809AA	150	AR0LC809AA	105	105	**45**
Narok	Enabelbel	AstraZeneca Vaccine (AZ)	2021	ABZ8962, ACA1948, ABZ8962, NH0239	850	NH0239, AB28962,ACA1948	450	450	**400**
Narok	Enabelbel	Johnson & Johnson Vaccine (J&J)	2021	XE442, XE443, XE436	850	XE436, XE442	1,050	1,050	**-200**
Narok	Enabelbel	Pfizer Vaccine	2022	GA2988, FR8225,33040 BD	174	33040BD	60	60	**114**
Narok	Entontol	Pneumococcal Conjugate Vaccine (PCV)	2018	ASPNB108AA	330	ASPNB108AA	0	0	**330**
Narok	Entontol	Measles Rubella Vaccine	2019	0129m082	220	0129m082	50	50	**170**
Narok	Olochoro	Rotavirus Vaccine	2020	AR0LC809AA	130	AR0LC809AA	300	300	**-170**
Narok	Olochoro	AstraZeneca Vaccine (AZ)	2021	NL0251, ABZ8962, ACA1948	800	NL0251, ABZ8962, ACA1948	1,000	1,000	**-200**
Narok	Olochoro	Johnson & Johnson Vaccine (J&J)	2021	XE528, XE442, XE443	450	XE528, XE442, XE443	350	350	**100**
Narok	Olochoro	Pfizer Vaccine	2022	GA2988, FR8225	162	FR8225	108	108	**54**
Kakamega	Kimangeti	AstraZeneca Vaccine (AZ)	2021		280		290	290	**-10**
Kakamega	Kimangeti	Johnson & Johnson Vaccine (J&J)	2021		810		460	460	**350**
Kakamega	Kimangeti	Pfizer Vaccine	2022		860		660	660	**200**
Kakamega	Namagara	AstraZeneca Vaccine (AZ)	2021		28		20	20	**8**
Kakamega	Namagara	Johnson & Johnson Vaccine (J&J)	2021		1,150		1,300	1,300	**-150**
Kakamega	Namagara	Pfizer Vaccine	2022		3,606		900	900	**2,706**
Kakamega	Shamberere	Pneumococcal Conjugate Vaccine (PCV)	2018	ASPNB108AA	446	ASPNB108AA	466	466	**-20**
Kakamega	Shamberere	AstraZeneca Vaccine (AZ)	2021		1,678		660	660	**1,018**
Kakamega	Shamberere	Johnson & Johnson Vaccine (J&J)	2021		1,000		100	100	**900**
Kakamega	Shamberere	Pfizer Vaccine	2022		1,860		252	252	**1,608**
Kakamega	Chevoso	Measles Rubella Vaccine	2019	0129M082	580	0129M082		620	**-40**
Kakamega	Chevoso	Rotavirus Vaccine	2020	AROLC803AB	50	AROLC803AB	100	100	**-50**
Kakamega	Chevoso	AstraZeneca Vaccine (AZ)	2021		200		420	420	**-220**
Kakamega	Chevoso	Johnson & Johnson Vaccine (J&J)	2021		2,200		1,950	1,950	**250**
Kakamega	Chevoso	Pfizer Vaccine	2022		606		918	918	**-312**
Kakamega	Makhwabuye	Rotavirus Vaccine	2020	AR0LC803AB	0	AR0LC803AB	50	50	**50**

Note: sample batches were traced for Routine vaccines and aggregate quantities by year for Covid-19 vaccines.

Annex 12 – Stock count Issues at Sub-national level on day of visit by GAVI audit team

Sub-County	Name of Vaccine	Quantity counted (Doses) (A)	Quantity on stock card / stock ledger / Bin Card (Doses) (B)	Quantity recorded in ELMIS (Doses) (C)	Variance (A-B)	Variance (A-C)
Mombasa	Pentavalent Vaccine	5,680	3,000	6,050	2,680	-370
Mombasa	Pneumococcal Conjugate Vaccine (PCV)	2,685	2,685	3,035	0	-350
Mombasa	Measles Rubella Vaccine	8,000	8,770	9,020	-770	-1,020
Mombasa	Johnson & Johnson (J&J)	0	0	55	0	-55
Nakuru	Pneumococcal Conjugate Vaccine (PCV)	3,470	3,470	3,930	0	-460
Nakuru	Johnson & Johnson (J&J)	0	0	125	0	-125
Narok	Pentavalent Vaccine	1,410	2,150	0	-740	1,410
Narok	Pneumococcal Conjugate Vaccine (PCV)	1,520	2,024	0	-504	1,520
Narok	Measles Rubella Vaccine	2,880	2,740	0	140	2,880
Narok	Pfizer Vaccine	180	1,170	0	-990	180
Tana River	Johnson & Johnson (J&J)	0	0	55	0	-55
Health Facility (HF)	**Name of Vaccine**	**Quantity Counted (Doses) (A)**	**Quantity on stock card/ledger/Bin Card (Doses) (B)**	**Quantity recorded in ELMIS (Doses) (C)**	**Variance (A-B)**	**Variance (A-C)**
Skans	Pentavalent Vaccine	180	180	0	0	180
Skans	Pneumococcal Conjugate Vaccine (PCV)	235	235	0	0	235
Skans	Measles Rubella Vaccine	220	220	0	0	220
Shimo	Pentavalent Vaccine	110	110	0	0	110
Shimo	Pneumococcal Conjugate Vaccine (PCV)	40	40	0	0	40
Shimo	Measles Rubella Vaccine	140	140	0	0	140
Mwakirunge	Pneumococcal Conjugate Vaccine (PCV)	15	10	0	5	15
Naivasha	Pentavalent Vaccine	540	540	0	0	540
Naivasha	Pneumococcal Conjugate Vaccine (PCV)	420	403	0	17	420
Naivasha	Measles Rubella Vaccine	240	240	0	0	240
Karagita	Pentavalent Vaccine	30	30	0	0	30
Karagita	Pentavalent Vaccine	190	190	0	0	190
Karagita	Pneumococcal Conjugate Vaccine (PCV)	180	180	0	0	180
Karagita	Measles Rubella Vaccine	100	100	0	0	100
Mai	Pentavalent Vaccine	120	120	0	0	120
Mai	Pneumococcal Conjugate Vaccine (PCV)	100	100	0	0	100
Mai	Measles Rubella Vaccine	30	30	0	0	30
Ndabibi	Pentavalent Vaccine	70	50	0	20	70
Ndabibi	Pneumococcal Conjugate Vaccine (PCV)	95	72	0	23	95
Ndabibi	Measles Rubella Vaccine	60	70	0	-10	60
Ndihwa	Pentavalent Vaccine	260	200	0	60	260
Ndihwa	Pneumococcal Conjugate Vaccine (PCV)	125	125	0	0	125
Ndihwa	Measles Rubella Vaccine	100	100	0	0	100
Ndihwa	Measles Rubella Vaccine	130	130	0	0	130
Ndihwa	AstraZeneca Vaccine (AZ)	0	0	405	0	-405
Ndihwa	Moderna Vaccine	0	0	375	0	-375
Ndihwa	Pfizer Vaccine	0	0	322	0	-322
Got	Pentavalent Vaccine	60	110	0	-50	60
Got	Pentavalent Vaccine	40	180	0	-140	40
Got	Pneumococcal Conjugate Vaccine (PCV)	115	115	0	0	115
Got	Measles Rubella Vaccine	130	130	0	0	130
Got	Johnson & Johnson Vaccine (J&J)	80	80	100	0	-20
Kobodo	Pentavalent Vaccine	190	190	0	0	190
Kobodo	Pneumococcal Conjugate Vaccine (PCV)	120	120	0	0	120
Kobodo	Measles Rubella Vaccine	120	120	0	0	120
CHEWANI	Pentavalent Vaccine	20	20	0	0	20
CHEWANI	Pneumococcal Conjugate Vaccine (PCV)	10	10	0	0	10
CHEWANI	Measles Rubella Vaccine	80	80	0	0	80
MAKERE	Pentavalent Vaccine	100	100	0	0	100
MAKERE	Pneumococcal Conjugate Vaccine (PCV)	80	80	0	0	80
MAKERE	Measles Rubella Vaccine	80	80	0	0	80
PUMWANI	Pentavalent Vaccine	90	80	0	10	90
PUMWANI	Pneumococcal Conjugate Vaccine (PCV)	95	95	0	0	95
PUMWANI	Measles Rubella Vaccine	30	30	0	0	30
HOLA	Pentavalent Vaccine	190	190	0	0	190

HOLA	Pneumococcal Conjugate Vaccine (PCV)	220	210	0	10	220
HOLA	Measles Rubella Vaccine	190	220	0	-30	190
WAYU BORU	Pentavalent Vaccine	50	50	0	0	50
WAYU BORU	Pneumococcal Conjugate Vaccine (PCV)	25	25	0	0	25
WAYU BORU	Measles Rubella Vaccine	140	140	0	0	140
Narok Hosp	Pentavalent Vaccine	500	500	0	0	500
Narok Hosp	Pentavalent Vaccine	110	640	0	-530	110
Narok Hosp	Pneumococcal Conjugate Vaccine (PCV)	328	340	0	-12	328
Narok Hosp	Measles Rubella Vaccine	270	290	0	-20	270
Narok Hosp	Johnson & Johnson Vaccine (J&J)	585	0	530	585	55
Narok Hosp	Moderna Vaccine	0	0	270	0	-270
Narok Hosp	Pfizer Vaccine	180	1170	102	-990	78
Naisoya	Pentavalent Vaccine	80	80	0	0	80
Naisoya	Pneumococcal Conjugate Vaccine (PCV)	84	84	0	0	84
Naisoya	Measles Rubella Vaccine	90	90	0	0	90
Enabelbel	Pentavalent Vaccine	200	240	0	-40	200
Enabelbel	Pneumococcal Conjugate Vaccine (PCV)	204	212	0	-8	204
Enabelbel	Measles Rubella Vaccine	240	250	0	-10	240
Enabelbel	AstraZeneca Vaccine (AZ)	0	0	200	0	-200
Enabelbel	Johnson & Johnson Vaccine (J&J)	100	300	400	-200	-300
Enabelbel	Pfizer Vaccine	0	0	60	0	-60
Entontol	Pentavalent Vaccine	90	127	0	-37	90
Entontol	Pentavalent Vaccine	50	109	0	-59	50
Entontol	Pneumococcal Conjugate Vaccine (PCV)	28	124	0	-96	28
Entontol	Measles Rubella Vaccine	80	180	0	-100	80
Olochoro	Pentavalent Vaccine	120	0	0	120	120
Olochoro	Pentavalent Vaccine	90	230	0	-140	90
Olochoro	Pneumococcal Conjugate Vaccine (PCV)	224	224	0	0	224
Olochoro	Measles Rubella Vaccine	230	230	0	0	230
Kimangeti	Pentavalent Vaccine	120	120	0	0	120
Kimangeti	Pneumococcal Conjugate Vaccine (PCV)	65	65	0	0	65
Kimangeti	Measles Rubella Vaccine	90	90	0	0	90
Kimangeti	Johnson & Johnson Vaccine (J&J)	50	50	0	0	50
Namagara	Pentavalent Vaccine	140	140	0	0	140
Namagara	Pneumococcal Conjugate Vaccine (PCV)	110	110	0	0	110
Namagara	Measles Rubella Vaccine	200	200	0	0	200
Namagara	Johnson & Johnson Vaccine (J&J)	145	145	0	0	145
Shamberere	Pentavalent Vaccine	140	140	0	0	140
Shamberere	Pneumococcal Conjugate Vaccine (PCV)	115	120	0	-5	115
Shamberere	Measles Rubella Vaccine	270	270	0	0	270
Shamberere	AstraZeneca Vaccine (AZ)	85	85	0	0	85
Chevoso	Pentavalent Vaccine	130	130	0	0	130
Chevoso	Pneumococcal Conjugate Vaccine (PCV)	80	80	0	0	80
Chevoso	Measles Rubella Vaccine	150	150	0	0	150
Chevoso	Johnson & Johnson Vaccine (J&J)	100	100	0	0	100
Makhwabuye	Pentavalent Vaccine	50	50	0	0	50
Makhwabuye	Pneumococcal Conjugate Vaccine (PCV)	40	40	0	0	40
Makhwabuye	Measles Rubella Vaccine	160	160	0	0	160
Makhwabuye	Johnson & Johnson Vaccine (J&J)	106	106	0	0	106
Makhwabuye	Pfizer Vaccine	60	60	0	0	60

Annex 13 -Variances between immunisations in tally sheets and monthly reports

County	Health Facility	Total No. of immunisations in tally sheets	Total No. of immunisations in monthly reports	Difference
Mombasa	Mwakirungye	15	14	1
Nakuru	Naivasha	1278	1976	- 698
	Karagita	581	567	14
	Mai	854	843	11

	Ndabibi	135	129	6
Kisumu	Ndihwa	163	508	- 345
	Got	85	152	- 67
	Kobodo	160	195	- 35
Tana River	Hola MOH	252	253	- 1
	Chewani Health-Facilities	56	62	- 6
	Makere Health-Facilities	183	193	- 10
	Pumwani Health-Facilities	228	240	- 12
Narok	Narok Hosp	601	602	- 1
	Naisoya	152	151	1
	Enabelbel	152	49	103
	Entontol	63	62	1
	Olochoro	189	75	114
Kakamega	Kimangeti	147	154	- 7
	Namagara	191	138	53
	Chevoso	107	0	107

Annex 14 – Details of vaccine expiries

REGIONAL VACCINE STORES

Region	Name of vaccine	Date	Batch No.	Doses
Mombasa	AstraZeneca Vaccine (AZ)	28-Feb-22	NL0249	14,700
Mombasa	AstraZeneca Vaccine (AZ)	28-Feb-22	210216	8,000
Mombasa	AstraZeneca Vaccine (AZ)	28-Feb-22	ACB3580	24,000
Mombasa	Johnson & Johnson Vaccine (J&J)	26-Oct-22	217D21A	19,965
Nakuru	AstraZeneca Vaccine (AZ)	31-Jan-22	77946	420
Nakuru	AstraZeneca Vaccine (AZ)	04-Feb-22	94096	14
Nakuru	AstraZeneca Vaccine (AZ)	28-Feb-22	210217	26,780
Nakuru	Johnson & Johnson Vaccine (J&J)	28-Oct-22	202E21A	5,100
Nakuru	Moderna Vaccine	04-Feb-22	940906	686
Nakuru	Pfizer Vaccine	31-Jan-22	321318D	666
Nakuru	Pfizer Vaccine	30-Jun-22	340158D	438
Nakuru	Pfizer Vaccine	31-Aug-22	FG3532	3,954
Nairobi	AstraZeneca Vaccine (AZ)	28-Feb-22	21017	15,300
Nairobi	AstraZeneca Vaccine (AZ)	28-Feb-22	210216	187,500
Kakamega	AstraZeneca Vaccine (AZ)	17-Jul-22	4121Z253	130
Kakamega	AstraZeneca Vaccine (AZ)	28-Feb-22	210216	130
Kakamega	AstraZeneca Vaccine (AZ)	31-Jan-22	79946	110
Kakamega	Moderna Vaccine	17-Jan-22	940906	210
Kakamega	Pfizer Vaccine	07-Mar-22	FJ8759	690
Kakamega	Pfizer Vaccine	15-Apr-22	FJ8759	618
Kakamega	Pfizer Vaccine	29-Sep-22	FJ8759	4,044

SUB COUNTY VACCINE STORES

Sub-County	Name of vaccine	Date	Batch No.	Doses
Mombasa	Johnson & Johnson (J&J)	26-Oct-22	217d21A	1,330
Nakuru	AstraZeneca Vaccine (AZ)	31-Jan-22	77946	1,450
Nakuru	Johnson & Johnson (J&J)	28-Feb-22	210217	2,690
Homa Bay	AstraZeneca Vaccine (AZ)	02-Jun-22		200
Homa Bay	Pfizer Vaccine	14-Apr-22	FT5331	282
Narok	AstraZeneca Vaccine (AZ)	17-Jul-22	4121Z253	390
Narok	Pfizer Vaccine	31-Aug-22	PAA193696	37,365
Tana River	Johnson & Johnson (J&J)	26-Oct-22	217d21A	1,330
Kakamega	Pentavalent Vaccine	01-Nov-16	124P5026B	3,440
Kakamega	Measles Rubella Vaccine	01-Jun-16	012n5046	2,860
Kakamega	AstraZeneca Vaccine (AZ)	25-Aug-22	4121Z253	120
Kakamega	Johnson & Johnson (J&J)	25-Aug-22	XE528	100

Kakamega	Pfizer Vaccine	28-Aug-22	XE528	100

HEALTH FACILITIES

Sub-County	Health Facility (Health-Facilities)	Name of vaccine	Date	Batch No.	Doses
Mombasa	Junda	Pfizer Vaccine	28-May-22	FJ8759	66
Mombasa	Shimo	AstraZeneca Vaccine (AZ)	17-Jul-22	4121z253	90
Mombasa	Shimo	Johnson & Johnson Vaccine (J&J)	26-Oct-22	217D21A	45
Mombasa	Shimo	Moderna Vaccine	28-Oct-22	054c22a	20
Mombasa	Shimo	Pfizer Vaccine	23-Aug-22	FR2458	30
Nakuru	Naivasha	Pfizer Vaccine	20-Apr-22	FT5331	6
Nakuru	Karagita	AstraZeneca Vaccine (AZ)	28-Feb-22	ACB3580	50
Nakuru	Karagita	AstraZeneca Vaccine (AZ)	31-Mar-22	NN0195	60
Nakuru	Mai	Johnson & Johnson Vaccine (J&J)	31-Oct-22	202E21A	65
Nakuru	Mai	Pfizer Vaccine	31-Aug-22	FE8225	12
Nakuru	Ndabibi	AstraZeneca Vaccine (AZ)	31-Mar-22	NN0195	150
Nakuru	Ndabibi	Johnson & Johnson Vaccine (J&J)	16-Apr-22	XE442	15
Nakuru	Ndabibi	Pfizer Vaccine	05-May-22	FG3532	24
Nakuru	Ndabibi	Pfizer Vaccine	08-Jun-22	FT3531	24
Kisumu	Ndhiwa	AstraZeneca Vaccine (AZ)	22-Jun-22	N044A	20
Kisumu	Got	Pfizer Vaccine	16-May-22	FT5331	60
Tana river	MAKERE	AstraZeneca Vaccine (AZ)	01-Feb-22		10
Tana river	MAKERE	Johnson & Johnson Vaccine (J&J)	01-Sep-22	XE 528	95
Tana river	MAKERE	Johnson & Johnson Vaccine (J&J)		ACB6047	20
Tana river	PUMWANI	AstraZeneca Vaccine (AZ)	17-Jul-22	4121z253	10
Tana river	HOLA	AstraZeneca Vaccine (AZ)	30-Oct-22	ACB4067	15
Narok	Naisoya	AstraZeneca Vaccine (AZ)	28-Feb-22	ACB3796	40
Narok	Naisoya	AstraZeneca Vaccine (AZ)	31-Mar-22	NN195	20
Narok	Olochoro	AstraZeneca Vaccine (AZ)	03-Jun-22	N044A	40

Annex 15 - Management (MOH) action plan

Issues	Audit Recommendations	Management Action	Action Owner	Timelines
There were gaps in the operations of the national immunisation coordination committee	Recommendation 3 The Ministry of Health should strengthen its governance structure by ensuring that: • ICC / KENITAG / NVSAC / Other meetings are supported by confirmed agreed agendas which will include (a) reminder of ToRs, (b) minutes of the previous meeting, (c) review of the previous action points tracking purpose, (d) status of immunisation activities, (e) grant implementation status. (f) brief summary of discussions at the lower technical working group, that meetings are held conducted as planned, minutes signed and that the required actions are assigned to officers for follow-up; • Counties are invited, represented and coordination structures for county involvement at the ICC are instituted, as recommended by 2016 Gavi Programme Capacity Assessment and the 2021 Advisory report on the Functional Review of the National Vaccines and Immunisation Programme; and	**Action 1** A covid 19 vaccine Task force was formed drawing membership from various Ministries, health departments and immunisation stakeholders who are also members of the ICC. As such there were reduced meetings during this period to focus on the pandemic. The EPI team and respective secretariats will ensure that the standing agendas cover the recommended areas, meetings are conducted as planned, are minuted, minutes are signed off in subsequent meetings and the actions include responsible officers. **Action 2** The recommendation aligns with the current approach. This will be reviewed and adjusted as necessary to ensure optimal implementation and adherence to best practices in immunisation. The secretariat will ensure that the invitations are sent out to all the counties and COG, however, their attendance cannot be assured.	**Action 1** Secretariat of the ICC **Action 2** Secretariat of the ICC	**Action 1** June 2024 **Action 2** June 2024
Strategic documents that support the immunisation programme are incomplete and were not endorsed by the MOH	Recommendation 4 The Ministry of Health should ensure that: • Finalising its updated National Immunisation Strategy, with revised targets is prioritised. • A suitable roadmap for the programme's transition away from Gavi support is developed as a priority. • The revised National Immunisation Strategy is endorsed by the appropriate stakeholders and approved by the MOH. • This revised strategy provides adequate guidance for health systems, including the vaccines logistics information	**Action 3** The completion of the National Immunisation Strategy faced significant challenges, primarily due to the evolving landscape of the COVID-19 pandemic. This unprecedented health crisis presented complexities in seamlessly integrating COVID-19 considerations into the NIS framework. Despite these hurdles, efforts are underway to finalise the NIS, ensuring it encompasses a comprehensive Life Course Approach and effectively integrates COVID-19 management within the broader health system as well as include the revised targets based on the prevailing scenario in the country. **Action 4** The Ministry of Health leadership will set up a multistakeholder task group to support the Gavi transition planning and funds routinisation. This	**Action 3** EPI Manager **Action 4** MoH	**Action 3** December 2024 **Action 4** June 2025

Issues	Audit Recommendations	Management Action	Action Owner	Timelines
	management systems. This should include a way forward for the Chanjo systems (RI and Covid). • The revised strategy includes immunisation supply chain strategy ensuring alignment with Gavi's own supply chain strategy, given that the latter framework proposes suitable pillars which should be customised and incorporated into the country context.	taskforce will lead the process. This is expected in Q1 2024. The transition planning is being done for all the development partner supported programs. After the formation of the multistakeholder taskgroup, the transition roadmap will be developed. **Action 5** The NIS will be endorsed by the Ministry of Health Leadership once its finalised within Q1 2024. **Action 6** The recommendation will be reviewed and adjusted as necessary to ensure optimal implementation and adherence to best practices in immunisation. A separate Directorate of Digital Health has been set up to look after the digitisation and automation of the entire health sector. Further, it would also look at the integration of the existing tools that would eliminate duplication. This will be covered in NIS from a strategy perspective and a separate roadmap will be developed. **Action 7** NIS includes the immunisation supply chain strategy and is customised to the country context.	**Action 5** MoH **Action 6** EPI / MoH **Action 7** EPI	**Action 5** September 2024 **Action 6** June 2025 **Action 7** December 2024
Full portfolio planning, including planning for transition from Gavi support was inadequate	Recommendation *3* We recommend that MOH: • Appoint a governance team to manage this transition process, including senior level MOH leadership, to maintain visibility over strategic planning which is independent from the operational management of health programmes. The existing transition planning task force should periodically report to this governance body to ensure that the task-force's activities are prioritised; • Review the roles and responsibilities of the transition planning task force to ensure suitable representation from the Ministry of Finance, Counties and relevant health partners. This task force should report to the ICC and to the governance team referred to above;	**Action 8** The Ministry of Health leadership will set up a multistakeholder task group to support the Gavi transition planning and funds routinisation. This taskforce will lead the process. This is expected in Q1 2024. The taskforce would look into the transition of all the donor funded programs including the immunisation program. The role and responsibilities of the task force would also be approved as soon as the taskforce comes into existence. **Action 9** The Government will develop a new transition roadmap as the previous roadmap had several gaps. The new roadmap would take into account the learning from the previous roadmap and develop a robust and implementable roadmap. The taskforce would look into the transition requirements and would develop the roadmap for all the donor funded programs. **Action 10**	**Action 8** MoH **Action 9** MoH **Action 10** MoH	**Action 8** June 2025 **Action 9** June 2025 **Action 10** September 2024

Issues	Audit Recommendations	Management Action	Action Owner	Timelines
	• Finalise and approve the Health Sector Transition Roadmap. • Broaden the scope of the "*Transition Planning*" task force to cover operational needs. including both commodity (vaccines) and non-commodity aspects, i.e., maintaining infrastructure, staffing, cold chain equipment, waste disposal, microplanning etc. of the immunisation programme. • Strengthen components of the Targeted County Assistance provided by Gavi alliance partners, to ensure that various activities supporting the "*Full Portfolio Planning*" process are completed, including the Geographic Information System coverage assessment and the comprehensive supply chain analysis. • Set timelines, monitor progress, and update Gavi at a predetermined frequency.	County Governments are responsible for the several of the activities listed here are are critical stakeholders in the overall transition process. The Ministry, COG and county Governments are working together as part of the overall donor transitions. There are several donor transitions ongoing where the broad scope is currently being discussed at Ministerial and donor level as well. The transition task force will consider the needs and requirements of the counties as well as the operational needs of immunisation. **Action 11** Several of the highlighted issues have been addressed as reflected in the recent application that was recommended for approval. Discussions would be undertaken with Gavi on deciding the activities to be allocated to the alliance partners. **Action 12** Reporting would be done based on the timelines agreed in the FPP and TCA plan.	**Action 11** EPI **Action 12** EPI	**Action 11** September 2024 **Action 12** September 2024
	Recommendation 4 We recommend that the MOH collaborate with Gavi in setting-up a programme management unit to support the NVIP team. This PMU should be a temporary mechanism, ideally embedded within the NVIP, to ensure that adequate capacity is built within the EPI team to support the numerous operational initiatives.	**Action 13** The Ministry will ensure that the Ministry staff be availed to manage the PMU. As part of Donor transition it is imperative that MoH staff lead for Government ownership. Further this would be aligned to the needs of the new grants and adequate administrative support would be built-in within the PMU. Will be discussed with Gavi on a rolling basis.	**Action 13** MoH	**Action 13** December 2024
Planning for Targeted Country Assistance and implementation of agreed activities was significantly delayed	Recommendation 5 It is recommended that the MOH, together with Gavi, review the TCA activities which have been planned to ensure that: • The capacity building of the MoH is prioritised in the TCA activities. This should be reviewed in conjunction with recommendation 3 of this report; • Adequate monitoring is embedded within the activities along with assigning	**Action 14** Gavi transition and Government ownership. Government desire for local procurement and manufacture of vaccines and consumables are critical changes currently overhanging the current approaches. The TCA activities also need to align with Government agenda and require close oversight from the Ministry of Health. Thes TCA supervision will also be integrated into current taskforce being set up by the PS. There is need to ensure local entities, bodies, institutions are involved in the overall TCA and Gavi process. This is also to ensure sustainability and Government ownership. The TCA activities will include both capacity building of the MoH as well as	**Action 14** EPI	**Action 14** September 2024

Issues	Audit Recommendations	Management Action	Action Owner	Timelines
	monitoring responsibilities. Monitoring processes should cover the performance and delivery of various Technical Assistance activities on an annual basis including adherence to the timelines, and use these monitorings to revisit the multi-year TCA plans, as well as any requests for reprogramming Gavi funds or the reallocation of resources. This evaluation process should assess the effectiveness and impact of TCA interventions, identify areas for improvement, and ensure alignment with the National Immunisation Strategy (once this strategy is finalised);	undertaking necessary activities for implementation of the program. Discussions would be undertaken with Gavi on the identification of the TCA activities as the next set of grants has been approved. Allocation of activities to alliance partners would be undertaken. **Action 15** The Ministry will ensure monitoring will be inline with overall immunisation and Ministry of health supervision and leadership structures. The mechanism will ensure that the monitoring and supervision of TCA activities undertaken by the alliance partners are provided to the EPI and sanctioned before reporting to Gavi.	**Action 15** EPI	**Action 15** June 2025
Supportive supervision activities at national and sub-national level were ineffective	Recommendation 6 The MOH should improve the supportive supervision processes at national and county levels by • Setting up a comprehensive supportive supervision system that (a) identifies roles and accountability between National Vaccines and Immunisation Programme (NVIP) and counties; (b) updates the existing supervision tool to enhance the effectiveness of supervision activities by recording observations and agreed actions enabling followup; and (c) uses the captured data to prioritise and schedule annual supervision visits and incorporates results from supervision visits into the decision-making processes;	**Action 16** There is a support supervision system in place within the KHIS that is used by both National and County teams. The support supervision checklist was put in place in 2019 with financial support from CDC and University of Nairobi through the Health IT departments. The checklist / immunisation scorecard has all the components of immunisation program covered and its accessible to all National, County and immunisation stakeholders who have access to the system. The immunisation scorecard provides details of the past supervision activities undertaken as well as other reviews based on which the county can identify the low performing facilities and support supervisions are planned based on the same. The information from KHIS wil be used in quarterly meeting to decide on the support supervision to be undertaken for the next quarter. The functionalities of the KHIS will be reviewed by the Directorate of Digital Health in view of the changes in laws including the data protection act / digital health bill and any gaps identified will be addressed along with the review of the checklist which will be duly updated to cover areas which are not adequately addressed in the existing tool. The challenge remains in operationalisation of the system in KHIS and	**Action 16** EPI	**Action 16** December 2024

Issues	Audit Recommendations	Management Action	Action Owner	Timelines
		ensuring consistent use at all levels to plan for and execute supportive supervision.		
Gaps in forecasting of annual vaccine procurement needs	Recommendation 7 The MOH should improve its forecast accuracy and process by documenting what is agreed including: • Formal agreement on each data set to be used, including the accredited source, and ensuring that these data are consistently applied across all forecastings. • Conducting a comprehensive vaccine wastage study to determine accurate wastage data in support of future forecasts. Until such a study is completed, the country is strongly encouraged to use the WHO vaccine wastage calculator[2]. • Engaging Counties within the Technical Working Groups so as to capture reliable vaccine consumption information across the various health facilities, and use this data for a more realistic forecast. • Ensuring that each forecasting process includes appropriate supporting documentation, including the key decisions and assumptions, and for this to be formally put on record for future reference.	**Action 17** Highly mobile, Highly dense to low density populations. Vaccination wastage rates varies from these different site and a vaccine wastage study might not adequately address these varying issues. The estimates used take into account the vary representation of the different populations to determine the appropriate wastage rate. Consolidated reports are available for all the deliberations undertaken for determining the parameters for the forecasts. **Action 18** No wastage study was planned. The EPI team will review the approved FPP activities and ensure that this is covered under the Supply Chain review. **Action 19** CoG and counties representatives through the county pharmacist, county EPI managers and county health directors are involved in several working groups. The Forecasting process is a multistakeholder process that includes UNICEF supply division, UNICEF KCO, WHO, CHAI, JSI as partners. There is also representation of 47 counties, COG, KNBS, HIS, M&E Dept Ministry of Health involved in the forecasting process. The forecasting process has several steps which are all collaborative. The challenge was ensuring that the documentation for all the workshops and deliberations undertaken at the national and regional levels is filed and readily accessible to ensure that the consolidated reports and finalised estimates are adequately supported. This has been done for the last forecasting process for 2024 and will continue going forward.	**Action 17** EPI **Action 18** EPI **Action 19** EPI	**Action 17** June 2025 **Action 18** June 2025 **Action 19** March 2024
Data maintained in the various vaccines logistics management systems was	Recommendation 8 The MOH should review the current its stock management processes and related records to:	**Action 20** There are several significant changes that have happened. The Data Protection (Compliance and Enforcement regulation 2021) and Kenya Digital Health Information Act 2023 will govern several of the	**Action 20** MOH / EPI	**Action 20** June 2025

[2] WHO vaccine wastage calculator

Issues	Audit Recommendations	Management Action	Action Owner	Timelines
incomplete and inaccurate	• Streamline the vaccine records across the different levels. This would include the process to phasing e out any unnecessary tools like such as manual stock ledgers and implementing a standardising the electronic Logistics Management Information System (eLMIS) as the primary stock management tool. Set specific timeframes for adopting a unified electronic logistics management system; completing this changeover should be established. • Update the stock management guidelines and Standard Operating Procedures (SOPs) SOPs to include the approved stock management tools records; • Improve the data completeness and quality in the approved eLMIS by ensuring that all stock issuances and receipts are recorded consistently and accurately recorded. This should include capturing the full details of on the HFs to which where vaccines are issued, enabling better traceability and accountability; • Conduct regular stock reconciliation exercises including distribution and receipt records at all subnational levels and investigate variances, if any; • Enhance the data quality across the supply chain by activating the various eLMIS' data assurance mechanisms within the eLMIS system which the country chooses to adopt. Thereafter, , conducting regular data audits should be conducted, implementing validation checks implemented, and ensuring proper data cleaning processes ensured. • Strengthen training and capacity building, by providing training and guidance to all relevant staff members involved in stock management at sub-county stores and	recommendations. These laws are very prescriptive and have hefty fines for noncompliance. The Ministry is currently rolling out the guidance for the agreed approach under the responsibility of the Directorate of Digital Health. This means that all the existing IT systems will be reviewed, including the eLMIS to strengthen the existing eLMIS and address known gaps. All unnecessary tools will be discontinued and old tools will be phased out after the eLMIS is fully stabilised. With the implementation of the Digital health initiatives, the country plans to phase out the manual records over a period of 2-3 years, however, the manual records are going to be continued for the time being to ensure accurate records are available. In the meantime, a review of the existing manual process will be undertaken to identify any gaps. Completeness and Quality of the data will be ensured through the support supervision visits, mentorship, review meetings, reminder communication at frequent intervals. The support supervision checklist will be reviewed, and gaps identified addressed. SOPs and guidelines will be updated after the completion of the digital health tools. Training and capacity building activities would be undertaken as part of the overall EPI training activities.		

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	HFs. This training should be focused on the approved established stock records management tools records to ensure compliance with the established/updated Standard Operating Procedures (SOP)s. • Strengthening monitoring and supportive supervision, by conducting periodic site visits, data quality assessments, and providing feedback and follow-up processes to ensure compliance with stock management SOPs.			
There were gaps in the operational performance of Chanjo eLMIS and Chanjo_KE and transition planning for handover of the systems was inadequate	Recommendation 9 The Ministry of Health, in consultation with Gavi, should: • Require the Clinton Health Access Initiative (CHAI) to develop a comprehensive change management framework, that includes a costed plan for transferring ownership of the Chanjo electronic Logistic Management Information System (eLMIS) over to the Government of Kenya. • This plan should, at minimum, include key recurring costs such as: patch updates, technical development, server infrastructure, and staffing requirements. This will ensure that the transition is financially sustainable, and that the system is properly maintained and updated to meet the needs of end-users.	**Action 21** Discussions are going on with CHAI on the development of appropriate change management framework as well as the Costed Plan for the transition and handover, however has not been completed yet. The change management would also require involvement of local partners. The change management and transition has also been factored in the FPP. Evaluation of all the existing system including CHanjo eLMIS, DHIS2 would be undertaken by the Directorate of Digital Health and upgrade requirements will be identified including implementing data validation, quality assurance checks, data cleaning and integration among others. Based on the identification, necessary activities will be undertaken by the Directorate of Digital Health.	**Action 21** EPI / MOH	**Action 21** June 2025
	Recommendation 10 Improve the accuracy and completeness of the eLMIS' content by implementing data validation, quality assurance checks, data cleaning, and integrating Chanjo electronic Logistic Management Information System with existing systems like DHIS2.			
	Recommendation 11 Conduct a thorough assessment of the security vulnerabilities in Chanjo eLMIS and then plug any critical weaknesses.	**Action 22** Directorate of Digital Health will complete an assessment of all the existing IT system, identify critical weakness and take necessary action.	**Action 22** MoH	**Action 22** June 2025

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Vaccine waste management practices at sub-county levels need to be strengthened	Recommendation 12 The Ministry of Health should ensure all health facilities have temperature monitoring devices and record-keeping procedures to track vaccine temperatures and the status of vaccine vial monitoring (VVM) indicators.	**Action 23** The Ministry working with partners is procuring Fridge Tags and temperature monitoring devices.	**Action 23** EPI Manager	**Action 23** December 2024
	Recommendation 13 The Ministry of Health should: • Institute a formal process to dispose of any expired Covid-19 vaccines at all levels. This process can be further instituted/ formalised to manage disposal of routine vaccines. • Update the 2011 National guidelines for Safe Management of Health Care Waste, to establish proper waste disposal systems at sub-County and health facility levels. This includes clarifying roles, responsibility and accountabilities at the subnational levels for medical waste. • Include review of waste management practices in the supportive supervision processes.	**Action 24** A waste management was constituted by the Principal secretary to provide oversight in the disposal of expired Covid 19 vaccines. The committee draws membership from various health departments with immunisation Program and Environmental health as secretariat to the committee. A nationwide reverse logistics was undertaken in 2023, after the audit, and destruction completed. The lessons learnt in the process will be used to update the National Guidelines for waste management. The report for the lessons learnt will be available in March 2024. **Action 25** This is recommendation will be provided to the relevant department in the Ministry of Health for implementation. The implementation of the policy will be the responsibility of the Enironment and Health Department. **Action 26** The KHIS support suppervision check list includes all aspects of immunisation program include waste management and injection safety. The support supervision checklist is being updated and will ensure coverage of this aspect as well.	**Action 24** MoH **Action 25** MoH **Action 26** EPI Manager	**Action 24** March 24 **Action 25** June 2025 **Action 26** December 2024
Previous EVM assessment recommendations were not implemented	Recommendation 14 MOH should: • review the progress made on the EVM recommendations, prioritise, cost and budget actions to respond to the recommendations. • Understand the root causes of the low scores in the outputs of the various processes reviewed and ensure that all significant gaps are addressed.	**Action 27** This recommendation will be integrated into activities. The program is implementing the EVM and ensuring that all the good practices are implemented as routine program activities. Prioritisation has been undertaken and some of the activities were covered under the FPP. The next EVM is planned in June 2026 and has also been covered as part of the FPP.	**Action 27** EPI Manager	**Action 27** June 2025
The management of cold chain equipment was suboptimal	Recommendation 15	**Action 28** This recommendation will be integrated into activities. SOPs and guidelines were developed for implementation by the respective counties. However,	**Action 28** EPI	**Action 28** December 2024

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	The Ministry of Health should enhance the overall management of the cold chain system by: • Implementing a centralised inventory tracking system for spare parts; • Establishing a preventive maintenance schedule for cold chain equipment with clear timelines and personnel responsibilities; • Developing budgets for repair and maintenance of CCE and determine ownership and responsibility for such costs between the respective national and subnational levels; • Developing a plan for decommissioning obsolete equipment, including the drafting of proper disposal guidelines for unusable CCE; and • Re-evaluating the country's CCE needs assessment to determine any residual gaps, and formulating a plan for the use of the CCE supplied during the Covid 19 pandemic. In addition sources of funding for acquiring future equipment should be identified, and all such costs should be transitioned into the MOH budget.	the budget for implementation needs to be provided by the counties and the implementation is also to be undertaken by the counties. The EPI will include this during the support supervision visits as well as creating awareness through the council of governors. **Action 29** This recommendation will be integrated into activities **Action 30** This recommendation will be integrated into activities. The procurement plan is duly prepared at the national level. **Action 31** This is regulated by the laws of Kenya on the public procurement and disposal acts. Advocacy would be undertaken through the council of governor to maintain adequate documentation. **Action 32** This recommendation will be taken up and has been covered as part of the FPP	**Action 29** EPI **Action 30** EPI **Action 31** Procurement, Public assets and disposal committee **Action 32** EPI	**Action 29** December 2024 **Action 30** December 2024 **Action 31** December 2024 **Action 32** June 2025
There were inconsistencies in the immunisation data	The Ministry of Health / National Vaccines and Immunisation Programme should: Recommendation 16 • Collaborate with the Kenya National Bureau of Statistics, Gavi alliance partners, Counties and other in-country stakeholders, to validate population numbers and set appropriate denominators be used in DHIS2; • Improve its documentation and record-keeping by ensuring that all outcomes, assumptions and decision made during the annual data harmonisation meetings	**Action 33** Ministry of Health, through the National Vaccines and immunisation Program and Division of Health Informatics in collaboration with the Kenya National Bureau of Statistics carries out annual target setting and forecasting meeting. The exercise is conducted between the National and Counties and the agreed targets are documented and shared with the counties. Projections are done for 2 years before the next target setting is conducted. The challenge was ensuring that adequate documentation is maintained for the data harmonisation meeting being undertaken in all the 47 counties and consolidated reports are readily available. This was addressed and consolidated reports on which the data estimates for target setting and population projection are now available. Evidence for how this is used to set targets in DHIS2 will be available going forward.	**Action 33** EPI	**Action 33** March 2024

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	are documented and cosigned by parties involved; • Ensure active involvement of Counties in the annual data harmonisation meetings to capture their insights and perspectives on population projections. Establish a mechanism to ensure County representation in these meetings, to enable collaborative decision-making and the inclusion of local context in target setting; and • Establish a monitoring and review mechanism address data gaps.	**Action 34** There were historical gaps in engagement of sub-counties and health facilities due to huge costs required to engage the service delivery points. **Action 35** Active involvement of Counties in annual data harmonisation meetings will be ensured to capture local insights and perspectives on population projections. We will establish mechanisms to guarantee County representation, thereby enabling collaborative decision-making and the inclusion of local context in target setting. **Action 36** There is an immunisation scorecard that is used by National and County levels to monitor and address data quality issues. The immunisation scorecard helps in identifying the low performing health facilities and decide on the support supervision to be undertaken. The scorecard should be reviewed on quarterly basis. The support supervision checklist will be reviewed and updated to check the use and review of the scorecard. Some additional activities were identified and included in the FPP to strengthen data gaps.	**Action 34** EPI **Action 35** EPI **Action 36** EPI	**Action 34** March 2024 **Action 35** March 2024 **Action 36** March 2024
Data quality assurance processes were inadequate	The Ministry of Health and National Vaccine and Immunisation Programme should: Recommendation 17 Design and establish interventions aimed at enhancing immunisation data capture, processing, and management capacity at all levels, with the support of technical partners.	**Action 37** Activities were identified and included in the new TCA plan. These activities will be implemented in a timely manner to address data gaps at all levels.	**Action 37** EPI Manager	**Action 37** December 2024
	Recommendation 18 • Expedite the implementation of the Data Quality Improvement Plan 2021-2025, while also ensuring that this plan is adequately financing and that	**Action 38** The implementation of the Data Quality Improvement Plan 2021-2025 will be expedited, ensuring that it is adequately financed and that appropriate oversight measures are in place for its execution. Prioritisation has been undertaken for the activities to be implemented based on which the	**Action 38** EPI Manager	**Action 38** December 2024

Issues	Audit Recommendations	Management Action	Action Owner	Timelines
	appropriate oversight measures are in place; and • Engage the Immunisation Coordination Committee (ICC) in monitoring the progress of the plan's interventions and provide the ICC with evidence-based updates on completed, partially implemented, and pending activities to ensure transparency and accountability.	activities are being implemented. Some of the activities have already been completed. **Action 39** The Immunisation Coordination Committee (ICC) will be engaged in monitoring the progress of the plan's interventions. We will provide the ICC with evidence-based updates on completed, partially implemented, and pending activities to ensure transparency and accountability throughout the implementation process. This would be covered as part of the standing agenda of the ICC.	**Action 39** ICC Secretariat	**Action 39** June 2024