Memorandum on the Lao People's Democratic Republic Programme Audit report

The attached Audit and Investigations report sets out the conclusions of the programme audit of Gavi's support to the Lao People's Democratic Republic (PDR) Ministry of Health, executed by the National Immunisation Programme (NIP) along with other implementing partners.

The audit team reviewed the NIP and implementing partners' management of Gavi support to the routine immunisation programme provided during the period between 1 January 2018 to 31 December 2023. The audit scope including the following grants: "health systems strengthening, vaccine introductions for human papillomavirus and inactivated poliovirus vaccine, the measles rubella campaign, COVAX support to Lao PDR's COVID-19 emergency operations, as well as other vaccines and cold chain equipment.

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 later on during 2024.

The report's executive summary (pages 3 to 6) summarises 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 practices 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, 16 issues were identified in the following areas: (i) governance and oversight; (ii) programme management; (iii) vaccine management; (iv) supply chain and data management systems; and (v) immunisation data management.

3. To address the risks associated with the issues, the audit team raised 17 recommendations of which 14 were rated as high priority.

4. Key findings were that:

    a. The inter-agency coordinating committee's governance and oversight mechanisms needs to be strengthened, as it did not have the necessary level of oversight over NIP programmes.

    b. Significant grant management requirements and recommendations from various reviews are still outstanding. The NIP did not define its process for how it monitored the implementation status of these requirements or of other past audit recommendations, resulting in issues not being addressed or only partially implemented.

    c. Lao PDR entered to accelerated transition with an initial five-year preparation period from 2017 to end of 2021, and thereafter extended the length of the transition period up to end of 2025 based on Gavi's transition policy revision. The audit review revealed that this transition process is still constrained by several financial and programmatic challenges which will impact the country's ability to successfully transition by end of December 2025.

    d. At the end of 2023, a review of the EPI function was undertaken, and the review proposed many improvement actions, an improvement plan with the necessary resource allocation, priorities, and timelines has not yet been developed.

    e. The national vaccine forecasting process, and vaccine inventory management practices at both the national and subnational levels need improvement. The forecasting process has not been guided via suitable SOPs or guidelines, and there were unexplained stock variances between the records and the physical stock balances held, and intermittent stock outs were reported at the national and subnational levels.

f. The NIP operated two similar systems, *m*Supply and vaccine supply stock management (VSSM), concurrently to manage its vaccines. These systems functioned in parallel, with neither system interconnected to the other. VSSM was in use only at the central level, in contrast to *m*Supply which also is in operation at subnational down to the district level. The NIP also uses two other systems, namely an electronic immunisation register (EIR) and DHIS2 – the latter being designed to routinely record the performance of various health indicators. The audit noted limitations and vulnerabilities in the current national supply chain and data systems, including the use of outdated, non-compliant and non-integrated systems.

g. There were significant variances between the WUENIC and administrative data coverage. Immunisation denominators used to calculate vaccination coverage were inaccurate, as they were based on data from a legacy population census completed in 2015. The supervision and monitoring over various data quality aspects such as availability, completeness, validity through review and assurance mechanism was weak. Data quality review guidelines do not exist, and as such there was no data quality assurance process in place at either the national or subnational level.

The findings of the programme audit were discussed with the Ministry of Health and implementing partners. They accepted the audit findings, acknowledged the weaknesses 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, November 2024

PROGRAMME AUDIT REPORT

Lao People's Democratic Republic
October 2024

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1. Executive Summary

1.1 Overall audit opinion

Audit opinion:

The audit team assessed the Ministry of Health's management of Gavi support during the period 1 January 2019 to 31 December 2023 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 cash support related expenditures is planned in November 2024.

Through our audit procedures, we have identified high risk issues relating to: governance and oversight, programme management; vaccine management, supply chain and immunisation data management processes. To address the risks associated with the issues, the audit team raised 17 recommendations, of which 14 (82%) 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 each recommendation, are defined in Annex 3 of this report.*

1.3 Summary of issues

Through our audit procedures, we have identified 14 high risk and 2 medium risk issues relating to the programme governance, management and oversight, vaccine supply chain management, and immunisation data management processes. The high-risk issues are summarised below, followed by the detailed issues in section **4** of this report.

Governance and oversight

The national immunisation programme's (NIP) governance and oversight mechanisms need to be strengthened. The reproductive, maternal, newborn, and child health committee (RMNCH) did not have the necessary level of oversight over the programme. Linkages between the inter-agency coordination committee (ICC) and the RMNCH steering committee were inadequate. For example, there was no evidence that the ICC's immunisation technical working groups (TWGs) submitted progress reports to the RMNCH steering committee. While the NIP and the health development partners had established a joint coordination meeting mechanism, there were no terms of reference to govern operations. The linkages and relationships between the RMNCH steering committee, the technical committee and its subcommittees, the ICC and its TWGs, and the joint NIP and partner coordination meeting mechanism need to be streamlined to clarify their respective roles and mandates.

ICC meetings were held infrequently, and their discussions were limited to Gavi-supported activities. During the five-year audit period (2019-2023), only 5 out of 10 ICC meetings were held. In addition, the terms of references of the ICC's TWGs were not finalised and signed off. Only 1 out of 5 of these TWGs, namely the cold chain and logistics group, was operational and maintained minutes of its meetings.

The NIP did not define its process for how it monitored the implementation of recommendations raised by the ICC, NITAG, the joint NIP and partner coordination committee, and the TWGs. As a consequence, more than half of the grant management requirements (GMRs), external audit and Gavi audit recommendations were still outstanding or were not fully implemented. In addition, 63% of the activities associated with the effective vaccine management costed improvement plan 2023-2026, planned to be done in 2023, had not started.

Weaknesses in the programme's governance and oversight might impact on the achievement of strategic immunisation objectives and targets under the RMNCH strategy. Similarly, unresolved issues from past reviews and audits could undermine the programme implementation and grant performance.

Programme management and preparation for transition

In 2017, Lao PDR entered into accelerated transition with an initial five-year preparation period until the end of 2021. Thereafter, Gavi's transition policy was revised, extending the length of the transition period up to eight years – plus one additional year of waiting time until Gavi's policy revision was finalised. As a result, Lao PDR's preparatory timeline increased until the end of 2025.

The national programme is still constrained by several financial and programmatic challenges. If these are not addressed, they will impact the country's ability to successfully transition by the end of 2025. For example, the country does not have a national immunisation strategy nor effective linkages and alignments between related health sector strategies. The country is also behind on its commitment to spend 9% of the government budget on health, and instead achieved an average spend of 4% over the last five years. Furthermore, over the 10-year period (2013 – 2022), the Government's co-financing contributions to procure vaccines and related costs progressively increased from 8% in 2013 up to 80% by 2022. The annual stepped increases in contributions potentially further constrained the MoH's ability to spend on other maternal and child health centre (MCHC) programme segments.

The audit team noted that there was overreliance on outreach services to achieve immunisation targets. In some cases, this was because of the beneficiaries' logistical and geographic challenges in reaching a health facility to access immunisation services, and in other cases, it was because of inadequate or untimely funding of health facilities to deliver such services. In addition, programmes continued to significantly draw upon the development partners who supported several planning, implementation, and monitoring immunisation

activities. Over the period 2022-2023, Gavi's targeted country assistance (TCA) funding helped to finance 17 staff positions employed by the partners. The corresponding TCA plan for the period 2024-2025 finances 19 such positions, with a reduced level of effort in only 4 of them.

The process of tracking the implementation rate of the annual operational plan (AOP) was sub-optimal, impacting upon the programmes' performance. In April 2022, the use of the AOP tracking tool was discontinued, and as a consequence during 2022 and 2023, there was insufficient follow-up on the progress in implementing planned activities. Approximately one third of the planned activities were not completed in 2022 and 2023, translating into lower-than-expected funding absorption rates of 59% in 2022 and 65% in 2023.

At the end of 2023, a review of the EPI function was undertaken covering: a) all components of the immunisation programmes; b) challenges faced in meeting the national, regional, global immunisation goals; c) data/information on immunisation that provides evidence for strategic and programmatic directions; and d) financial constraints of the immunisation programme, within the financial transition perspective. Although the review proposed many actions, an improvement plan with the necessary resource allocation, priorities, and timelines has not yet been developed.

If the transition process is not well planned and operationalised, or if the necessary improvements including the 2023 EPI review actions, the 2023-2026 effective vaccine management assessment continuous improvement plan (EVM cIP), and data quality (including the past improvement plan) are not fully implemented, then there is a risk that immunisation gains accrued by the programme over the last 20 years could backslide.

Vaccine management

The national vaccine forecasting process is partner-led, without the inclusion of a designated owner from the NIP logistics team. In addition, the forecasting process has not been guided via suitable SOPs or guidelines. This approach hampers the transfer of relevant and necessary skills and could impact upon the future sustainability of such processes, particularly following transition.

Inventory management practices at both the national and subnational levels need to improve. There were unexplained stock variances at the central vaccine store (CVS) and in the vaccine balances in the supply stock management system (VSSM), and the *m*Supply system's records. Intermittent stock outs occurred at subnational and national levels, however, the CVS' stock management system didn't have the capability to generate stockout incidents, and the magnitude of these stockouts were not adequately reported.

Similarly, there was absence of comprehensive preventive maintenance plans and equipment maintenance logs, cold chain equipment temperature mapping and calibration of the walk-in cold rooms (WICRs) was not done, and data generated by the WICR temperature monitoring system was not used.

The gaps noted in the vaccine management processes should be addressed to ensure the effective management of vaccines, reduce stockouts, improve the forecasting/ data management and the integrity of the supply chain.

Supply chain and data management systems

The country operated two similar systems concurrently to manage its vaccines – namely: *m*Supply and vaccine supply stock management (VSSM). These systems functioned in parallel, without interconnectivity. VSSM was in use only at the central level, in contrast to *m*Supply which is also in operation sub-nationally, down to the district level.

The audit team noted weaknesses in the design, configuration and implementation of *m*Supply. The system was configured to perform a weekly data synchronisation with DHIS2, but this involved updating a limited subset of data – meaning that the range of possible data analytics was limited. In addition, there were gaps in succession planning for the staff managing and supporting *m*Supply and poor management of user accounts which potentially exposes *m*Supply to security breaches and risks of unauthorised access, compromising data integrity.

The team also noted limitations in the VSSM system. The CVS began using VSSM in 2010, with the system still operating using legacy software, even though a more up to date web-based version with improved functionality is available. Some data recorded in the system is not sufficiently disaggregated, for example the system could separate between what is viable from non-viable stock, resulting in constraining its data analysis capabilities.

The NIP also uses two other systems, namely an electronic immunisation register (EIR) and DHIS2 – the latter being designed to routinely record the performance of various health indicators. There were significant personnel gaps in the technical systems support required to oversee these systems. As at March 2024, most system upgrades and customisations were being managed by a third party, as neither the department of planning and finance (DPF) nor the NIP had the necessary skillset and bandwidth to support the necessary technical requirements. Finally, the audit team raised concerns regarding the EIR's non-compliance with the data protection Act 2017, in respect to how it handled personally identifiable information (PII).

Vulnerabilities remain in the current national supply chain and data systems, including the use of outdated, non-compliant and non-integrated systems. If not addressed, this could adversely impact operational efficiency as well as increasing the likelihood of security breaches or data being compromised.

Immunisation data management

Immunisation denominators used to calculate vaccination coverage were inaccurate, as they were based on data from a legacy population census completed in 2015. Although revised estimates from micro plans and campaigns were available, these were not used to refine the programme denominator. Consequently, there were significant variances between the WUENIC and administrative data coverage.

The team also noted significant drop-off rates when comparing the number of doses distributed by the CVS and the administrative coverage achieved. For example, over the period audited, it was reported that 1.2 million doses of the JE vaccine were distributed, in order to vaccinate 0.5 million children, a 56% drop-off rate.

The supervision and monitoring over various data quality aspects such as availability, completeness, validity through review and assurance mechanism was weak. Data quality review guidelines do not exist, and as such there was no data quality assurance process in place at either the national or subnational level.

Overall, the gaps in the management of immunisation data compromised data quality and decision making. Moreover, immunisation targets set were not supported by evidence from current activities, which could adversely impact the effectiveness of the immunisation programme on targeted population.

Overall comment on the programmatic challenges

The audit team concluded that several of the challenges managing the immunisation programme were due to ineffective EPI leadership. The team noted the critical importance of ensuring that a fully resourced national EPI team is in place, encompassing all of the necessary capabilities and skills to direct and manage the programme. This includes for example, coverage of key technical responsibilities, in addition to the operational management of EPI programmes at subnational level. Some operational duties used to be carried out by the prior deputy EPI manager, a position which became vacant in March 2024 without a succession plan. Other technical responsibilities continued to be managed by partners with minimum engagement of the EPI team.

In the short-term, Gavi will provide some support for the deputy EPI manager position and has enhanced the HSS coordinator position to a project Management Unit (PMU) coordinator role to help assure some of these critical tasks. Gavi continues to advocate the importance for the MOH to appoint the full complement of national positions and skillsets.

2. Objectives and scope

2.1 Audit objectives

According to country agreements and Gavi's transparency and accountability policy, countries that receive Gavi support are periodically subject to a programme audit. The primary objective of such audits is to provide reasonable assurance that Gavi's support is managed in a transparent and accountable manner, through systems which include appropriate oversight mechanisms, and that the support is used according to the objectives outlined in grant agreements.

The audit team assessed the various processes and programme management arrangements governing Gavi's support (vaccines, cash, equipment, and technical assistance) for which the respective entities were responsible, to assess the design and operating effectiveness of the: supply chain processes to ensure delivery of vaccines to recipients; governance, oversight, programme and technical assistance arrangements to provide support and assurance over Gavi's investments; implementation arrangements of Gavi-funded programme activities, including the country's readiness for transition; and the mechanisms governing the data quality and financial management processes.

The team also reviewed the relevance and reliability of the internal control systems in relation to: the accuracy and integrity of the books and records, management and 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 scope covered the 5-year period from 1 January 2019 to 31 December 2023. However, the review of cash support provided by Gavi is not included in this report; it will be subject to a separate audit report.

The total cash, vaccines and ancillary support provided by Gavi to the Lao People's Democratic Republic (Lao PDR) from 1 January 2019 to 31 December 2023 is presented in table 1 below:

Table 1: Cash, equipment, PEF TCA, and vaccines support (2019 to 2023) in USD

Grants	2019	2020	2021	2022	2023	Total
COVAX			1,112,744	1,056,939	2,231,717	4,401,400
EAF				389,000		389,000
HPV Campaign	134,667					134,667
HPV-VIG	185,911					185,911
HSS	442,282	1,276,022	4,207,998	1,380,222	2,567,487	9,874,011
Transition	360,070					360,070
Total cash (a)	**1,122,930**	**1,276,022**	**5,320,742**	**2,826,161**	**4,799,204**	**15,345,059**
CCEOP		693,030			(38,005)	655,025
Covax CCE			71,968	70,151	(40,515)	101,604
Total equipment (b)	**-**	**693,030**	**71,968**	**70,151**	**(78,520)**	**756,629**
PEF TCA	1,858,407	1,852,188	1,531,313	1,733,829	39,761	7,015,498
Total PEF TCA (c)	**1,858,407**	**1,852,188**	**1,531,313**	**1,733,829**	**39,761**	**7,015,498**
COVAX			24,755,952	14,529,655	692,152	39,977,759
HPV	3,251,748	858,828	39,398	422,986	154,394	4,727,354
IPV	865,004	300,433	402,703	214,019	142,555	1,924,714
Immn safety devices(ISD)	97,540	(33,871)				63,669
MR	333,209	140,066	10,407	22,491	32,799	538,972
PCV	530,386	694,220	209,602	6,724	135,429	1,576,361
PENTA	458,537	(6,176)	197,189	24,301	116,764	790,615
Total vaccines (d)	**5,536,424**	**1,953,500**	**25,615,251**	**15,220,176**	**1,274,093**	**49,599,444**
Total (cash + equip. + PEF TCA + vaccines) = (a) + (b) + (c) + (d)	**8,517,761**	**5,774,740**	**32,539,274**	**19,850,317**	**6,034,538**	**72,716,630**

Table 2: Details of PEF TCA funding to partners (amounts in USD); reprise from Table 1

Partner	2019	2020	2021	2022	2023	Total
UNICEF	611,280	691,803	542,970	930,588		2,776,641
WHO	614,084	773,432	493,896	725,067		2,606,479
CHAI		153,964	291,915	52,587	28,334	526,800
GFA	337,292	(71,200)	68,256			334,348
IBRD	200,000	200,000	100,000			500,000
University of Oslo	39,751	21,789	34,276	25,587		121,403
STERNIN					11,427	11,427
CDC	56,000	82,400				138,400
Total PEF TCA (c)	**1,858,407**	**1,852,188**	**1,531,313**	**1,733,829**	**39,761**	**7,015,498**

2.3 Audit approach

We adopted a risk-based audit approach, informed by our assessment of the risks, across the principal areas of the immunisation programmes supported by Gavi. This included: vaccine and supply chain management, programme and data management, governance and oversight, the country's readiness for transition, and the use of COVAX vaccine support. The review of cash support provided by Gavi is not included in this report; it will be subject to a separate audit later this year.

2.4. Conduct of the audit engagement

The audit was conducted in two phases. An initial scoping visit between 29 January 2024 and 2 February 2024, followed by fieldwork between 4 to 22 March 2024, both undertaken in country. During fieldwork, the audit team visited: the national vaccine store, 6 provincial offices and their vaccines stores, 9 district offices including their stores, 18 health facilities and one district hospital (see Annex 4 for the list of sites visited by the audit team).

During the engagement, the team interacted with several stakeholders including: the national immunisation programme team (NIP), the food and drugs department (FDD), the state inspection authority (SIA), MoH internal audit, and the following partners and health financing donors: UNICEF, WHO, CHAI, the World Bank, JSI and DFAT.

2.5 Progress since 2018 Gavi programme audit

The audit team noted that some moderate progress was made in addressing audit issues noted in the 2018 Gavi programme audit (see annex 12b for details of progress). This prior audit report was rated "unsatisfactory" based on the various areas in scope including governance and oversight, programme management, vaccine supply management, budgetary and financial management, procurement, and fixed asset management.

Significant improvements were noted in the financial management area, when compared to the prior 2018 Gavi programme audit, at which time the financial management processes, controls and systems were ineffective, and the accounting was inadequate.

Currently, the NIP, with the help of its fiscal agent, has put in place financial management guidelines for the HSS programme, implemented a financial system (QuickBooks), and regularly prepares monthly bank reconciliations and financial reports. Transactions are also regularly reviewed by the fiscal agent, and Gavi's grant funds are audited each year by external auditors.

2.6 Exchange rate

Most cash and in-country expenditures were incurred using the Lao KIP (KIP). For information purposes and as part of the summary of this report, overall total amounts are reflected in United States Dollars (USD). For the expenditures reviewed, the rate applied was based on the average bank rate across the audit period. The overall exchange rate equated to KIP 16,235 against USD 1.00.

3. Background

3.1 Introduction

The Lao People's Democratic Republic (Lao PDR), is the only landlocked country in Southeast Asia. Lao PDR is bordered by Myanmar and China to the northwest, Vietnam to the east, Cambodia to the southeast, and Thailand to the west and southwest. The country has a surface area of 236,880 km^2 and the capital, Vientiane, is the largest city.

Administrative arrangements

Lao PDR is an ethnically diverse and rugged country with a highly dispersed population. 80% of the land area is hilly or mountainous, including remote areas that are difficult to access. Administratively, the country is divided into 17 provinces as well as Vientiane capital, that are made up of 148 districts and around 8,500 administrative villages or urban neighbourhoods[1].

Economy and demographics

For 2022, the gross domestic product (GDP) was USD 15.47 billion; the GDP per capita was USD 2,054; and the annual growth rate was 2.7%[2]. Although Lao PDR is rich in mineral resources, it imports its petroleum and gas, and subsistence agriculture still accounts for half of the GDP and provides 80% of employment. In 2018, the country ranked 139th on the human development index, indicating medium development, and as the 36th nation in the world out of the list of the 52 nations with the worst hunger situations, according to the global hunger index.

In 2023, Lao PDR's population was estimated as 7.6 million, of which 65% of the population was aged between 15 and 64 years, and 30% aged between 0 to 14 years[3]. The most densely populated area exists in or near the capital, although the majority of the population remains dispersed, with much of the rural population residing in scattered or often hard-to-reach communities, that are isolated by distance, mountainous terrain, with poor or non-existent road infrastructure.

3.2 National health sector

The national healthcare delivery system is primarily a government owned, public system that operates at three levels via provincial hospitals, districts, and health centres. There are 10 central hospitals, 17 provincial hospitals, 135 district hospitals, 1,078 health centres and approximately 5,000 village drug dispensaries. Overall, the health personnel workforce totals around 20,000. While only 43 percent of this workforce has a mid-level or higher education, the average density of health professionals (physicians, nurses, midwives) is 13 per 10,000 population. The effective saturation and use of the health services on offer remains a major challenge due to several reasons, including: access, quality of services, staff management capacity, the uneven distribution of health staff, and language barriers within those areas with predominantly ethnic populations.

In 2013, the national assembly approved the national health sector reform strategy for the period 2013-2025 aiming at achieving universal health coverage by 2025. The strategy outlines five priorities including standardised community services, which incorporates immunisation. During phase 1 (2013-2015), progress was made in maternal and child health outcomes; thereafter, phase 2 (2016-2020) focused on ensuring the provision of quality essential services and financial protection, through the implementation of priority programmes of the 8th health sector development plan. Although the health sector in the Lao PDR has made significant strides over the past decade, there are still many health challenges ahead including the improvement of child malnutrition, and reduction of the under-five and maternal mortality rates. Immunisation rates, especially in poor rural and remote areas, need to increase significantly in order to reach the designated targets[4].

[1] Updated cMYP 2019-2023
[2] The World bank- Lao DPR Profile
[3] World Population Dashboard -Lao People's Democratic Republic | United Nations Population Fund
[4] National Health Sector Reform Strategy (2013-2025)

3.3 Immunisation in Lao PDR [5]

The NIP is considered one of the most successful public health programmes in the country. It is a structural unit of the department of hygiene and health promotion of the Ministry of Health (MoH). It works jointly with the relevant departments in the Ministry as well as the provincial and district health offices (PHO, DHO). The NIP is well-established with credible political commitment from the central and provincial governments as well as a dedicated immunisation staff across all levels. The inter-agency coordination committee (ICC) exists since 1992. Other committees associated with communicable diseases include the national certification committee for polio (NCC), the national verification committee for measles/rubella (NVC), and the national AEFI causality committee.

The introduction of new vaccines into the national immunisation schedule is based on decisions made by the national immunisation technical advisory group (NITAG), a group created in 2013 and reconstituted in 2017. The group comprises expertise from different departments of the Ministry of Health and is chaired and managed by independent public health experts. It is charged with guiding health authorities and the NIP, in the definition and implementation of national immunisation policies and strategies. It is also guided by the immunisation law, which the National Assembly approved on 25 June 2018, a law also promulgated by the President on 9 August 2018.

Immunisation services are administered at central, provincial and district hospitals and health centres, via fixed site (hospitals and health centres), outreach and mobile (health centres only) approaches. In 2022, the average proportion of Pentavalent 3rd doses (Penta3) delivered via these modality groups was: 52% for fixed site, and 48% outreach/mobile. Mass vaccination events were used to deploy COVID-19 vaccinations, particularly in larger urban centres, and periodic intensification of routine immunisation (PIRI) and supplementary immunisation campaign approaches, have also been used for several vaccines.

According to administrative reports, the national immunisation coverage significantly improved since 2005, with DTP3 coverage increasing from 49% in 2005 to 89% in 2015 and with more than 79% of districts achieving at DTP3 coverage more than 80%. Measles-containing-vaccine first-dose (MCV1) coverage also rose from 50% in 2005 to 88% in 2015.

However, from 2016, immunisation coverage declined for most vaccines. Between 2015 and 2016, the coverage for MCV1 and RCV1 declined by 12% (from 88% to 76%), and the coverage for BCG, DTP1, DTP3, OPV3, HepB3 and Hib3 also declined by up to 8%.

In 2017, there was an upswing in coverage for MCV1 (82%) and Penta3 (85%), with 63% districts attaining a DTP3 coverage of 80% or more. Worth noting that these more recent gains represent a lower achievement than the 2015 performance levels. Survey data from 2017 shows Penta3 coverage differs from the national average by up to 40% across the provinces.

As of December 2023, the NIP provided vaccinations against nine vaccine preventable diseases free of charge to its citizens. See **Annex 5** for the national immunisation schedule.

3.4 Immunisation supply chain structure

All vaccines utilised within the NIP in Lao PDR are procured and imported using UNICEF's services. The food and drug department in the ministry of health is responsible for the regulation of the vaccines and it is a requirement that all vaccines used are WHO-prequalified.

Lao PDR operates a 4-tier vaccine supply chain management system consisting of one central vaccine store (CVS), 18 provincial vaccine stores (PVSs), 148 district vaccine stores (DVSs) and 1,078 health facilities. Vaccines and related supplies and cold chain logistics are managed by the NIP. Vaccines are imported to the country by air through Wattay international airport and received at the CVS located within NIP's premises in Vientiane. Vaccine deliveries are supported by several documents including commercial invoice, packing list, certificate of origin, certificates of analysis and a release memo from the food and drug department. A vaccine

[5] cMYP, 2019-2023

arrival report is completed for all the received vaccines, documenting pertinent details on each shipment, the date and time of arrival and status of shipping indicators upon receipt of the vaccines at the CVS. The CVS is equipped with walk-in cold rooms (WICRs), walk-in freezer (WIFR), refrigerators, and ultra cold chain (UCC) freezers to store the bulk of the country's vaccine stock, in accordance with manufacturers' recommendations.

CVS distributes vaccines to 18 PVSs and 10 central hospitals. Distribution of vaccines is triggered by orders placed by the PVSs and central hospitals using supply vouchers that consider the monthly consumption and stock levels of the respective vaccines. The CVS delivers vaccines using its fleet of vehicles which includes cold chain and insulated trucks. Vaccines from PVSs are delivered to the DVSs and 17 provincial hospitals upon placement of orders using issue and requisition vouchers. The distribution of vaccines from PVSs to DVSs is usually done using cooler boxes. From DVSs, vaccines are then collected by health facilities and district hospitals. Health facilities place monthly orders with the DVSs using issue and requisition vouchers, and subsequently collect their vaccines from the DVSs using their own transport, mostly by motorbike. The health facilities are also the primary sources of replenishment of vaccines used by outreach and mobile vaccination services.

The country uses a combination of paper-based and electronic records for inventory management. Within the CVS, two similar electronic logistics management information systems (eLMIS) operate concurrently: (i) the vaccine supplies stock management (VSSM) system; and (ii) *m*Supply. These systems both capture data such as vaccine inflows, outflows, and current stock levels.

At the PVSs and DVSs, a hybrid recording keeping approach is adopted, using both paper-based batch cards in tandem with the *m*Supply system for vaccine logistics management. Health facilities exclusively rely on paper-based batch cards for managing their vaccine stocks. Additionally, the country has enabled a vaccine logistics module within DHIS2 for health facilities to record and report vaccine consumption and stock levels at the end of each month.

To coordinate the vaccine logistics at central level, there is a supply chain technical working group (SC TWG) that is mandated to meet regularly to discuss vaccine stock and cold chain management. The SC TWG brings together logistics staff from the NIP, with partners like UNICEF, WHO and CHAI.

3.5 Immunisation data

Lao PDR implemented DHIS2 in 2014 and started use for immunisation data in 2017. Routine immunisation data is entered directly into DHIS2 at the health facility and district levels. This happens monthly by the 5th of the subsequent month. Data validation and approval is the task of the EPI data focal points at both district and provincial levels with the help of statistics officers. The DHIS2 data is consolidated, analysed and reported at national level.

The accurate reporting of immunisation coverage is a challenge in Lao PDR and there is wide variability across data sources. Census data is the main source, used to derive target population estimates and which is an input into DHIS2. However, the Lao statistics bureau (LSB) granular population estimates, disaggregated up to the district level, i.e., coverage estimates for health facilities and villages are not available. Whilst district health offices are aware of the estimates provided by LSB, they were not using this LSB data to analyse at individual health facility and village level to identify areas of high and low performance. For example, at health facility level, different denominators are used in calculating target population for immunisation coverage including birth registry.

In 2023, the NIP has rolled out an electronic immunisation registry (EIR) across all health facilities and started using geospatial information to improve the identification of populations, and to help harmonise and validate population estimates at subnational levels.

While the country seems to be making improvement in coverage for its Penta1, Penta3, MR1 and PCV vaccinations, the coverage for HPV is declining (by 18% according to WUENIC in 2022) and MR1/MR2 drop out

is greater than 10 points and still below 80%. Key challenges for the immunisation programme include poor data accuracy and the sub-optimal human resources for health capacity both in terms of necessary skillsets and adequate numbers.

3.6 Supply chain and data management systems

In 2010, the NIP with support from UNICEF, deployed the vaccine supply stock management (VSSM) system at the CVS. This system is used to track and manage the stock of vaccines only. VSSM operates using a Microsoft Access platform, version 4.7. Thereafter, in 2015 the *m*Supply system, a web-based and mobile application was implemented across all 148 districts to manage the flow of essential medical supplies. The system was initially only utilised for HIV, TB, malaria, and family planning commodities. In 2020, the system's functionalities were upgraded to include the management of vaccines, with the support of Gavi-funded technical assistance (CHAI) and support from - Sustainable Solutions.

Since 2015, the MoH has used DHIS2 to record, track and manage its core health programmes' data (including HIV, malaria, and TB). DHIS2 is an open-source health information system supported by WHO and Gavi. In 2023, an electronic immunisation registry (EIR), built using the DHIS2 platform, was deployed to document routine vaccination records, to facilitate the scheduling of vaccination recipients and reporting at health facilities. Technical support for both DHIS2 and EIR was provided by HISP Vietnam.

3.7 COVID-19 context, response, and impact

COVID-19 is a disease caused by a coronavirus as reported on 31 December 2019, later named as the severe acute respiratory syndrome-Coronavirus 2 (SARS-CoV-2). On 30 January 2020, WHO declared Coronavirus Disease 2019 (COVID-19) as a public health emergency of international concern (PHEIC).

In Lao PDR, the first case of COVID-19 was confirmed in March 2020. As a result, the government of Lao PDR decided to enact nationwide lockdown measure between 30th March to 3rd May 2020 to contain and prevent the spread of COVID-19 pandemic. The second wave of COVID-19 in Lao PDR started in April 2021, and the number of cases rose from fewer than 50 cases in early April to over 100,000 cases in December 2021. In response to the outbreak, the Lao government announced a partial lockdown on 22 April 2021. Only businesses and restaurants in areas without community outbreaks were allowed to remain open. Vientiane Capital entered a full lockdown on 19 September 2021, but retail shops, supermarkets, minimarts, and fresh markets were allowed to remain open. Since October 2021, restrictions were gradually eased. Inter-provincial travel resumed in November 2021, but most schools remained closed. International borders remained closed since March 2020 and up to the reopening started in January 2022.

On 2 April 2021, Lao PDR introduced COVID-19 vaccines as part of its national COVID-19 response. Since then and up to 31 December 2023, Lao PDR has received a total of 21.4 million COVID-19 doses (including Astra Zeneca, Sinovac, Sinopharm, Pfizer, and J&J) and administered 13.99 million of these.

In 2022, WHO developed guidelines for considerations for integrating COVID-19 vaccination into immunisation programmes and primary healthcare for 2022 and beyond. Thereafter, in May 2023, WHO declared that COVID-19 was no longer a public health emergency of international concern (PHEIC). In accordance with WHO's integration guidelines, Lao PDR drafted guideline for the routinisation of COVID-19, however, it has not yet been operationalised.

3.8 Gavi's relationship with Lao PDR and entities involved in implementation of Gavi grants

The NIP has overall responsibility for the immunisation programme including routine immunisation, supplementary immunisation campaigns/activities (SIAs) both preventive and reactive, outbreak and pandemic response.

In June 2013, Gavi signed a partnership framework agreement with the Lao PDR which provides a framework for the management of Gavi support to the country. Since 2001, Lao PDR has received a total of USD 105 million in support from Gavi, most of which falls under the framework agreement. Table 1 above details Gavi support for this audit period (2019-2023).

On 4 June 2020, Gavi launched the COVID-19 vaccines advance market commitment (COVAX AMC) mechanism as the main funding vehicle for the COVAX facility. The Gavi COVAX AMC is the innovative financing instrument that supports the participation of low- and middle-income economies in the COVAX facility to gain access to safe and effective COVID-19 vaccines[6].

On 4 December 2020, Lao PDR joined the COVAX AMC as a participant and signed the COVAX standard terms and conditions. Since then, the country has received support totalling USD 44.5 million, primarily consisting of COVID-19 vaccines as well as COVID- 19 vaccine delivery support (CDS) funding. See table 1 above for details.

Throughout this period, Gavi has continued providing a range of cash grants, which are disbursed through a variety of funding channels including MoH, UN Gavi Alliance partners (WHO and UNICEF), and other expanded/implementing partners like CHAI. There are signed agreements between Gavi and each of these entities to guide programme implementation.

3.10 Key achievements and good practices

The audit team noted the following good practices:

Governance and oversight: In 2018, Lao PDR enacted its national immunisation law, and following the issuance of a Ministerial Decree Ref. 1228/MOH. Cab, on 23 June 2017, its NITAG was established. The MoH has also developed a national strategy and action plan for integrated services on reproductive, maternal, newborn and child health (RMNCH), 2021-2025, which includes immunisation. There is also an inter-agency coordination committee (ICC) chaired by the Minister of Health.

Programme management: The NIP together with provincial health offices (PHOs) and in-country partners have developed an annual operational plan (AOP) to guide the implementation of the immunisation programmes throughout the country. A comprehensive AOP implementation tracking and monitoring tool was developed, though this tool was no longer in-use at the time of the audit. The audit team deemed that there is an adequate involvement by the implementing partners in the TCA/TA plan development process. NIP also has a supportive supervision guideline that was developed in 2009, though it is not yet fully operationalised.

Vaccine supply chain management:

- *Availability of supporting documents for vaccines received by CVS:* all essential supporting documents and vaccine arrival reports (VARs) were maintained and completed for each vaccine consignment. Prior to delivering vaccines at the CVS, every consignment received got approval from the food and drug department. For the audit period in-scope, the audit team successfully traced and reconciled all supporting documents and their corresponding entries in the VSSM system for vaccines supplied by Gavi.
- *Capacity building in VSCM:* Lao PDR, with support from the partners, has developed a comprehensive training package tailored to EPI managers. This initiative focuses on building capacity across various domains such as: vaccine preventable diseases; forecasting and quantification; as well as vaccine and cold chain management. The training package has been rolled out in 2023, to conduct training sessions at both national and subnational levels.
- *Sufficient cold chain storage capacity:* the CVS currently has sufficient cold chain storage capacity of over 180,000 litres. With support from Gavi, the cold chain storage capacity was boosted with the installation of two additional WICRs of 40,000 litres each in 2022. The cold chain infrastructure at national and subnational levels are sufficient for current and future vaccines in the NIP schedule[7]. The audit team noted that in general, the CCE units and equipment were functional, at each of the various subnational vaccine handling points that it visited.
- *Cold chain equipment tracking*: the country has developed an inventory gap analysis (IGA) tool – consisting of a web and mobile-based application – which is envisaged to capture and record all CCE units in

[6] About Gavi COVAX AMC

[7] Lao PDR National Immunisation Programme Updated Comprehensive Multi-Year Plan 2019-2023

operation. This application, which is not yet fully operationalised, will help improve visibility over what CCE infrastructure is available across the country.

Immunisation data management: Immunisation data collection tools were available at all sites visited. In addition, there were AEFI kits and reporting forms in all the facilities visited. Micro plans including immunisation targets were available at all levels. The audit also noted improvement in data timeliness in the DHIS2 from 76.4% in 2022 to 82.9% in 2023.

Supply chain and data management systems: In 2023, the country developed its national digital health strategy, 2023-2027 to guide investments into new digital health technologies. The aim is to facilitate the alignment and harmonise coordination between all actors contributing to digital health, while improving the Ministry of Health's oversight and influence in consolidating existing systems, building the capacity of its health workforce, and improving the effectiveness of digital health investments. At the time the audit, there were four national level supply chain and data management systems in use, two eLMISs (VSSM and mSupply), EIR and DHIS2,though these systems still require some additional alignment and harmonisation.

4. Findings

4.1 Governance and Oversight

4.1.1 Governance and oversight mechanisms need to be strengthened

Context and Criteria

Maternal and Child Health Centre (MCHC) is the technical organisational unit in the Ministry of Health (MoH) under the supervision of the department of hygiene and health promotion (DHHP). Its core role is to promote the health of mothers and children and to vaccinate against diseases. The MoH issued an agreement on the organisation and activities of MCHC according to the decree on organisation and activities of the MoH No.96/Ny dated 9 March 2017. This decree defines the following key roles and rights of the MCHC: Organise and develop the policies and strategic plans of the MoH regarding the work of promoting maternal and child health and providing vaccines against diseases; develop manuals, tools and media to promote maternal and child health and provide vaccination against diseases; monitor and evaluate the implementation of programmes, plans and projects of MCHC at all levels; and build strength in the collection of data on MCHC, including vaccinations into DHIS 2. NIP under the supervision of the MCHC, is the main unit which ensures the implementation and coordination of immunisation activities at national and sub-national levels. The NIP works jointly with relevant departments at the MoH as well as with provincial and district health authorities (PHO, DHO).

The MoH developed its 10-year reproductive, maternal, newborn and child health (RMNCH) strategy and action plan 2016-2025, to provide a clear vision and framework for improving RMNCH outcomes. In 2019, there was a mid-term review of the strategy which resulted in an updated strategy for the remaining 5-year period 2021-2025. This strategy underlines the RMNCH's direction, with specific actions to be taken during the period. It addresses the critical reproductive, maternal, newborn and child health needs and rights of the Lao people through the perspective of continuum of care. To assist the implementation both at national and subnational level, the strategy identifies clearly defined specific objectives, including health system areas such as health financing, health information, human resources and drug/equipment that are directly linked to RMNCH activities. Immunisation is covered under strategic objective 6: Immunisation. Thise objective states that all children under 5 years old are protected from vaccine preventable diseases through immunisation. Specific objective 6.1 also states that by 2025, 95% of one year old children are to be fully immunised and 90% of pregnant women are to be vaccinated with a second dose of tetanus-toxoid (TT2). The RMNCH strategy instituted the following committees:

- A steering committee, responsible for the overall accountability for the RMNCH Strategy and action plan.
- Technical supervision committee, responsible for providing guidance to subcommittees on ongoing implementation and oversee the interim review and final evaluation of the strategy.
- Five subcommittees to implement the RMNCH Strategy and action plan to 2025: responsible for developing action plan for each subcommittee, integrating the plan to the health sector programmes, providing technical guidance to provincial level, monitoring progress and report the results of implementation periodically , and monitoring the planning and budgeting regularly.

According to the inter-agency coordination committee's (ICC) terms of reference of 2019, the ICC was established to facilitate the coordination and support to the EPI programme, its activities and to provide solutions to programmatic and operational challenges. Thus, one of the ICC's key functions is to regularly bring together the representatives of various departments responsible for implementing immunisation, public and institutional health activities, as well as those who provide funding and technical assistance. The ICC is chaired by Minister of Health. Membership of the ICC includes WHO, UNICEF, World Bank, CHAI, US-CDC, PATH. The ICC is required to meet at least twice a year. The ICC ToRs established four Technical Working Groups (TWGs) covering: (i) cold chain and logistics, (ii) communication for immunisation, (iii) data and M&E, and (iv) planning, budgeting, and finance. These TWGs are responsible for technical support and serve as the secretariat to the ICC, facilitating ICC meeting preparations and implementing ICC action items.

Condition	Recommendation 1
The audit team noted the following weaknesses in various governance and oversight structures: ***Inadequate oversight over the NIP by the Reproductive, Maternal, Newborn, and Child Health Committee (RMNCH).*** The audit team reviewed: the RMNCH strategy, terms of reference of the different committees of RMNCH, and their meeting minutes, and noted the following: • There is no evidence of discussion of the NIP activities during any of the RMNCH committee meeting minutes reviewed. Consequently, there is limited linkage between the ICC and the RMNCH committees. • There was no evidence of review of progress on the strategic objections and action plans using the RMNCH monitoring and evaluation framework and action plan in any of the RMNCH committee minutes reviewed by the team. • There was no evidence that the immunisation sub-committee submitted progress reports to: the steering committee; and to the technical and management supervisory committees, every six months as required. In addition, the immunisation sub-committee did not produce any annual progress reports in relation to: the achievement of its specific objectives, progress against its action plans, and progress against its indicator targets, as required by the terms of reference. • There is no evidence that the provincial RMNCH committees reported to the national RMNCH committee. In addition, there is no evidence of regular supervision and oversight over the subnational levels as required by the strategy. ***There is need to streamline the joint NIP and partner coordination meeting:*** Although NIP and the health development partners have a joint coordination meeting, the audit noted the following gaps in the operations of this mechanism: • There were no terms of reference to govern the operations of the joint NIP and partners coordination meetings. • There were no standing agenda for these meetings in years 2022 and 2023. • Although the audit team was informed that these meetings were held frequently, minutes of such meeting were not consistently recorded, which resulted in a lack of evidence, to corroborate the frequency of meetings and/or whether they actually occurred. Specifically, there were minutes for two meetings held in 2022 and two meetings in 2023. • There was no systematic mechanism to follow up the action items generated from this coordination meetings – in order to document, assign roles, and establish due dates of said actions. • There was no clear feedback or reporting mechanism from the coordination meeting back to the ICC. In addition, there was no evidence that joint NIP and partner coordination committee submitted written reports to the ICC. ***ICC executed its mandate with inadequate oversight and sub-optimal effectiveness:*** The audit team reviewed the substance of the ICC's meetings, including the: frequency of meetings, membership participation, deliberations, and action points – to assess the adequacy and effectiveness of the ICC in discharging its oversight role. The team noted the following opportunities to improve this oversight: • ICC meetings were held infrequently, and its discussions were limited to Gavi-supported activities. During the five-year period up until 2023, the ICC held five meetings out of the required ten meetings (i.e. one meeting per year). • There was no evidence that the ICC carried out any oversight or monitoring visits to any provinces, as required in its ToRs. • The ToRs for the ICC technical working groups' (TWGs) were not finalised and signed off. Only one of the four TWGs – the cold chain and logistics group – was operational and maintained minutes of its meetings.	To strengthen governance and oversight, the MoH/NIP with support from partners should: • ensure that the RMNCH committee fully adheres to the RMNCH strategy to provide adequate oversight over the NIP. This includes: (i) carrying out progress reviews against the RMNCH monitoring and evaluation framework, (ii) operationalising the immunisation subcommittee, and (iii) undertaking regular supervisions of the provincial RMNCH committees. • develop Terms of Reference to govern the "joint NIP and partner coordination committee" meetings and finalise and sign off all of the ICC's technical working groups Terms of References • develop a coordination dashboard and an action item tracking system to track the implementation status and follow up of the ICC, partner coordination committee, NITAG and TWGs action points. This dashboard should indicate the action owner and completion timeframe, for the purposes of accountability. • ensure that all TWGs of the ICC are actively involved in undertaking their technical work, so that the different roles are carried out as required. • where needed, ensure that complex, unresolved matters discussed at the joint NIP and partner coordination committee and TWGs are formally escalated to the ICC and RMNCH committee for further discussion and recommendation for appropriate decision-making authorities.

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- Although the ICC minutes indicated that discussions were held regarding strategies for future resource mobilisation post-transition from Gavi support, there were no specific resultant outcomes or recommendations, which were proposed by the ICC for adoption.

No defined process for monitoring the implementation of ICC, NITAG, joint NIP and Partner Coordination Committee and TWGs recommendations: The audit team noted the absence of a well-defined process, for tracking, following up and monitoring the implementation status of recommendations or decisions relating to the: (i) ICC, (ii) joint NIP and partner coordination committee; and (iii) TWGs.

Weaknesses in assurance mechanisms: During the five-year period (2019-2023), the MoH's internal audit department did not carry out any internal audit reviews of the MCHC departments – including Gavi's funding. In addition, based on the audit team's review of minutes of the ICC meetings, there was no evidence that the NIP's Gavi -funded projects' external audit reports were presented to the ICC.

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Root Cause

- The immunisation subcommittee of the RMNCH committee was not operational for the five-year period (2019-2023).
- There were no provincial RMNCH focal points to act as the coordinators and liaison between the national and the provinces and support on the required reporting templates.
- Absence of a dedicated secretariat for the joint NIP and partner coordination committee.
- The ToRs of the ICC TWGs were not finalised and signed off.
- The ICC did not have an annual work plan to guide their schedule of activities including monitoring visits.
- Inadequate technical capacity in the internal audit department.
- Recommendations/action points did not have timelines to follow up.
- The impact of COVID-19 pandemic between 2020-2022.

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Management comments

See Annex 16: Detailed management responses

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Risk / Impact / Implications

- Inadequate oversight may impact the ability of the programme to achieve its objectives and to sustain gains post transition.
- Limited oversight may have contributed to the under-achievement of strategic objectives. For example, the following immunisation strategic objectives and targets belonging the RMNCH strategy were not yet achieved by 2020.
  - ✓ proportion of under 1 year-old children immunised against DPTHepB-Hib3 (95%),
  - ✓ proportion of under 1 year-old children immunised against measles (%95), and
  - ✓ proportion of under 1 year-old children fully immunised (90%).

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Responsibility

See Annex 16: Detailed management responses

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Deadline / Timetable

See Annex 16: Detailed management responses

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4.1.2 Grant management requirements (GMRs) and recommendations from various reviews are still outstanding

Context and Criteria

Various reviews and assessments generate key recommendations and actions to be followed up and implemented. This includes the following:

Programme capacity assessment (PCA) – Gavi conducted a PCA in 2016, from which an initial set of grant management requirements (GMRs) were agreed with the country. Thereafter, in July 2020, Gavi provided revised Grant Management Requirements (GMRs) to the country which were updated following the November 2018 Gavi programme audit, so as to and combine some of the initial GMRs with the new audit recommendations.

External audits – In addition to the Gavi programme audit conducted in 2018, each of the projects funded by Gavi are audited by external auditors every year, resulting in the auditors issuing financial statements accompanied by a management letter with internal control recommendations.

Following an EVM assessment, countries will create an improvement plan outlining concrete activities and timelines, to address their challenges and areas of improvement. It is important for countries to prioritise, budget for, and execute their EVM action plan in order strengthen to their supply chains.

Effective vaccine management (EVM) – EVM assessments are used to monitor and evaluate vaccine supply chains, helping countries to enhance the performance of their supply chain. In 2014, Lao PDR conducted an EVM assessment that resulted in the development of a five-year EVM continuous improvement plan (cIP) to be implemented between 2015 and 2020. Due to Covid-19, the implementation of some of the cIP activities were not completed, while others were halted. The pandemic also delayed undertaking a subsequent EVM assessment for approximately two years. Thereafter in 2022, the country conducted a second national EVM assessment, with the objective of evaluating the existing performance of the immunisation supply chain, and to identify key strengths, weaknesses and bottlenecks. Based on the EVM assessment's findings and recommendations, this culminated in elaborating a new cIP plan to be implemented between 2023 and 2026, including 50 various targets and 216 activities[8].

Condition

Delays in implementation of GMRs: The audit team noted that 8 out of 14 GMRs were not fully implemented (refer to annex 12 for detailed status of GMRs). Examples of the wording of GMRs which are not fully implemented, includes:

- MoH will ensure that the relevant Technical Working Groups (TWGs) are constituted and meet regularly.
- MoH shall ensure that staff responsible for accounting, data management and vaccine management are supported by a training needs assessment, appropriate capacity building and suitable onsite experience.
- MoH will ensure that supportive supervision at subnational level is completed, action points raised and followed up at national and subnational levels with the aim of strengthening capacities of EPI staff.
- MoH/NIP will develop the National Vaccine Management guidelines and SOPs for Vaccine and Cold Chain management or adopt the recommended WHO Vaccine and Cold Chain Management procedures and Stock Management guidelines.
- Develop the guidelines for monitoring vaccine wastage at national level for NIP managers, operationalise the maintenance plan including specific guidelines on preventative and curative maintenance processes with defined roles and responsibilities at national and subnational levels.
- MoH will ensure that internal audits are performed annually to ensure timely risk deterrence and identification of controls weaknesses.
- The MOH will prepare a plan for monitoring the recommendations made by the external auditors, the internal auditors and the Gavi auditors, which will be updated on a regular basis.

Recommendation 2

To enhance oversight and accountability over the status and implementation of actions or recommendations from the NIP's various reviews and assessments, the MoH/NIP should:

- develop a tracking system at the NIP operational level. Thence, ensure that all recommendations are captured in the system, assign a priority ranking to each of them (high, medium, low), and rationalise any recommendations which recur across various reviews, so that these are included in the system with one unique action owner responsible for closing the action, and use a suitable dashboard to facilitate the oversight and status mapping.
- Include semi-annual status reporting on implementation at the ICC meetings; and share status updates with Gavi after endorsement from ICC.
- review the EVM cIP 2023-2026 schedule, and prioritise, cost, and attach the activities to available

[8] Lao PDR National Effective Vaccine Management Continuous Improvement Plan 2023-2026

Delays in implementing the effective vaccine management costed improvement plan (EVM cIP) 2023-2026: The EVM assessment cIP 2023-2026 outlined timelines for completing 216 activities between 2023 and 2026.

Overall, there was little notable progress in improving the vaccine supply chain following the 2022 EVM assessment, and a considerable number of activities remain unimplemented. Examples of activities not yet implemented, which arguably fully or partially contributed to some of this programme audit's observations, include:

- An assessment of the strengths and weaknesses of the existing web-based vaccine stock management system (*m*Supply) across all levels of supply chain including the system's: data fields, accessibility, data quality and implementation challenges.
- Reviewing existing supportive supervision checklists and delivery mechanisms.
- Assessing the status of the human resources (including training need) currently employed at the regional DVS and health facilities.
- Reviewing the current status of the national logistics working group, revision of its composition and its ToR, as required.

Based on the audit team's review of the plan in March 2024, 59 activities scheduled for completion by the end of 2023 were identified. However, 63% of these earmarked activities for 2023 had not commenced. See annex 15 for details. Minutes from the Supply Chain TWG meetings indicate that EVM-related discussions were primarily focused on engaging a suitable consultant and conducting the 2022 EVM assessment, with no subsequent discussions on the status of EVM assessment cIP 2023-2026 implementation.

Gavi programme audit 2018 recommendations were not fully implemented: While some progress was made in addressing recommendations from the 2018 programme audit, the audit team noted that 23 out of 50 recommendations were not fully implemented (see annex 12 for detailed status of open audit recommendations). Significant issues such as: inadequate governance and oversight, weaknesses in EVM, and data management remained unaddressed. The team also noted that these remain recurring issues as per the findings of this report: e.g. 4.1.1, 4.3.3, 4.3.5, 4.5.2 and 4.6.1.

Some recommendations from external audits were not implemented: Gavi's grants are audited annually by external auditors and financial statements were accompanied by a management letter and expressed an opinion on the control environment. From the audit team's review of the management letters issued, it was noted that 10 out of the 18 recommendations had not been fully implemented, leading to the auditors' recurring several findings and recommendations over the years, as shown below:

funding sources and budget lines. Apply for reallocation of funds for critical activities that may not be attached to any budget line.

Recommendations	2019	2020	2021	2022
Liquidation of the advances should be assessed by the management and relevant supporting documents should be obtained. The project should have a clear schedule or deadlines for settlement of advances after the activities are completed. Any long outstanding advances should be promptly followed up.	Yes	Yes	Yes	
Documented policies and procedures should be maintained to assist in achieving the project objectives.	Yes	Yes		
Implementation of activities should be made in accordance with the schedule set by the donor and to avoid any delays in carrying out the activities.	Yes	Yes	Yes	Yes
Liquidation of advances should be made within the timeframe stipulated in the guidelines after completion of the activities.	Yes	Yes	Yes	Yes

Root Cause

- Actions and recommendations were not tracked by the ICC. The ICC had no standing agenda on reviewing progress in implementing recommendations from various assessments.
- There is no mechanism in place to track the implementations of the recommendations from various reviews. In addition, not all recommendations were assigned to action owners for follow-up to ensure follow through and implement.
- While the activities in the EVM assessment cIP 2023-2026 were scheduled for implementation by year 2023, there was lack of prioritisation and estimates of the resources/cost to complete.
- There is insufficient oversight, tracking and follow-up of the EVM assessment cIP.

Management comments

See Annex 16: Detailed management responses

Risk / Impact / Implications

- Outstanding issues from past audits and reviews could result in unresolved internal control weaknesses which ultimately undermine the programme implementation and/or grant performance.

Responsibility

See Annex 16: Detailed management responses

Deadline / Timetable

See Annex 16: Detailed management responses

4.2 Programme management and preparation for transition.

4.2.1 Lack of a national immunisation strategy (NIS), and inadequate linkages or alignments within related health sector strategies

Context and Criteria

The WHO immunisation agenda 2030 (IA2030) sets out an overarching strategic direction and guidance for the development of country specific national immunisation strategy (NIS), focusing on seven strategic priorities: i) Immunisation programmes for primary health care and universal health coverage, ii)commitment and demand, iii) coverage and equity, iv) life course and integration, v) outbreaks and emergencies, vi) supply and sustainability, vii) research and innovation, and four core principles: i) people centred, ii) country owned, iii) partnership based, and iv) data-guided, to help countries develop their priorities for vaccines and immunisation programmes, and in order to determine their country's specific activities and what other support is required from stakeholder. Gavi's overall corporate strategic principles, objectives and performance indicators are benchmarked and aligned with these IA2030 strategic priorities.

In line with the IA2030, and Gavi's corporate strategy, countries are required to have a central ownership and accountability mechanism, to oversee the existence and monitor the linkages and alignments, between various health sector related strategic documents. Countries should define their own targets and timelines, to achieve the IA2030 goals, and to articulate what support if any, each country requires according to the needs of its national immunisation programmes, so as to take advantage of synergies and promote integration across the health sector. A robust monitoring and evaluation framework should be developed to measure progress towards the IA2030's vision and goals, and which is aligned with the country's operational plans, to ensure transparency and accountability.

Thus, the existence of an NIS is the basis for establishing strategic and programmatic direction in the immunisation space and helps to articulate what partner support is required to address country needs, and how best to integrate this support into the strengthening of primary health care (PHC), and the achievement of universal health care (UHC) goals. In addition, the development of an NIS is a useful approach in enabling countries reflect on how to integrate their immunisation programmes with other health interventions, UHC targets and national strategic health plan, while placing more focus on key priorities, including country ownership and clarifying how to tailor partner support (if any) to meet the local and national context.

Condition

The audit team noted the following gaps:

No national immunisation strategy (NIS) exists: Lao PDR does not have a national immunisation strategy (NIS) to guide the planning and implementation of its immunisation programme. This risk impacting upon: the strategic and programmatic direction of immunisation; the ability to integrate this programme with other health interventions and UHC targets; and the opportunity to assess and consider alignment with national strategic priorities.

Inadequate ownership and accountability mechanism to oversee the linkages and alignments within health sector strategic documents: Although the country has developed various strategic documents including: (i) the health sector reform strategy (HSRS, 2021-2030); (ii) the national strategy and action plan for integrated services on reproductive, maternal, newborn, adolescent and child Health (RMNCAH, 2021 – 2025); and (iii) a health sector development plan (2021-2025), there was inadequate ownership or accountability to monitor and oversee the linkages and alignments across these existing strategic documents. In addition, while the roles and responsibilities, priorities of activities, timetables and targets are defined in HSRS and RMNCAH action plan, the source of funding for these strategies were not clearly articulated (i.e., it was stated as a challenge for the country).

Recommendation 3

To ensure that the MoH (with NIP's support) exercises its ownership and accountability in overseeing and monitoring the linkages and alignments between existing strategic documents, it should:

- develop a fully costed national immunisation strategy (NIS) in accordance with WHO's IA2030 guidance, which incorporates the seven strategic priorities and four core principles, and which extends across the national, subnational, and service delivery levels.
- establish an accountability mechanism, to monitor and oversee the linkages and alignments across the health-sector's strategic plans.

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• While developing an NIS is a primary foundational component as set out in Gavi's corporate strategy, the requirement for an NIS was overtaken by the necessity to prioritise COVID-19 response activities, and subsequently Gavi's instruction regarding conducting country full portfolio planning (FPP) process.
• Inadequate resources and skills within MoH/NIP to facilitate the design of an NIS. For example, no evidence that an adequate budget to support the development of NIS, was allocated in the FPP or in the 2024-2025 PEF/TCA.
• Ownership, accountability, and oversight mechanism not clearly defined.</td><td colspan="2">Management comments

See Annex 16: Detailed management responses</td></tr>
<tr><td>Risk / Impact / Implications
• There is no clear roadmap to guide the planning and implementation of immunisation programmes that are focused on the agreed strategic and programmatic priority areas, and helps design and tailor appropriate partner support, which are aligned and integrated with strengthening of primary health care (PHC), and the achievement of universal health care (UHC) goals.
• Insufficient cross-linkages between the NIS strategy and other agreed national health strategies may lead to the fragmented implementation of programmes and the non-achievement of strategic goals.</td><td>Responsibility

See Annex 16: Detailed management responses</td><td>Deadline / Timetable

See Annex 16: Detailed management responses</td></tr>
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4.2.2 Weaknesses in programme management and support supervision

Context and Criteria

The NIP, along with the provincial health offices (PHOs), are responsible to develop the annual operation plan (AOP) to guide and ensure a cohesive approach in implementing the national immunisation programme. One of the key responsibilities of the MoH/NIP is to regularly monitor progress of the NIP activities against the approved AOP, and to report to Gavi on the programme implementation status, consistent with the agreed requirements (e.g. as per the partnership framework agreement (PFA) and grant agreements). Part of the process of developing the AOP, involves preparing micro plans for each health facility. These plans are then compiled and aggregated by the district, and subsequently submitted to the provincial health office for final review and submission to the NIP.

The NIP is also responsible to manage the coordination, supervision, monitoring, and evaluation of AOP activities, at both national and subnational level. This includes communication and collaboration with the development partners through the "joint NIP and partners coordination committee" meeting. Key opportunities for such collaboration include: at the time that the annual plan is developed, and during the monthly meetings, when progress in implementing the AOP is monitored and reviewed.

To assist in tracking and monitoring AOP progress, a formal, systematic tracking and monitoring tool was developed by CHAI using Gavi's TCA funding. This tool was activated in January 2020 and was subsequently used to accompany the joint NIP and partners coordination meetings (held each month) to discuss progress in implementing the AOP, based on the relevant analytic data dashboards. As a result, the performance and status of the AOP activities could be discussed in the presence of all the participating partners.

A review of the immunisation programme was conducted between 28 November and 8 December 2023, (consisting of a field review, subsequent data synthesis, and concluding with a presentation to the ICC). The overall goals and objectives of this review were to: a) evaluate the current situation of the immunisation programme including all of its system components; b) highlight the challenges faced in achieving national, regional, and global immunisation goals; c) generate information on immunisation that provides evidence for future strategic and programmatic directions; and d) understand the programme's financial constraints, in the perspective of the imminent transition. The programme review concluded in proposing many recommendations and action items.

Condition

The audit team noted the following areas of improvement:

Sub-optimal tracking of AOP implementation impacting on programme performance: Although the AOP implementation tracking tool is comprehensive and instrumental for validating implementation of programmes and reporting on achievement of objectives, (i.e., by Gavi grant types, by responsible for implementation and by fund utilisation level, etc.,), its use to monitor the status of implementation of AOP was discontinued from April 2022. Thereafter, the audit team noted that the level of implementation of planned programme activities during the rest of 2022 and 2023 remained low, resulting in only modest absorption of funds. For instance, approximately one third of activities were not completed, including: 14 out of 46 activities during 2022; and 13 out of 30 activities during 2023, resulting in an overall fund absorption rate of 59% (2022) and 65% (2023).

Inadequate allocation of funding for critical improvement plans: As part of the future full portfolio planning (FPP), during the 2-year period 2024-2025, the audit team noted that 67% of the HSS and EAF funding has been allocated to salaries, per diems and travel-related allowances for supportive supervision, trainings, conferences, workshops, etc., as shown in table 6 herein below. The NIP carried out an EPI review in 2023, recently developed an EVM assessment cIP, 2023-2026, and has demonstrated the need for DQIP. As a result, the audit team is of the opinion that the future FPP projected fund allocation will not be enough to fully

Recommendation 4

To enhance the immunisation's programme management and performance, MoH/NIP should:

- regularly review progress in implementing the AOP using the tracking and monitoring tool, and dashboard, to increase the rate of completion of planned activities and funds absorption to a higher level, and to accomplish the intended programme objectives, including capacity building support from partners.
- ensure that the AOP and associated micro-plans include a detail cost breakdown, with clear cost drivers. In addition, the planned activities should be mapped out and linked to the required capacities and skillsets to avoid competing priorities for lean EPI staff (both at national and subnational level).

address the existing recommended actions contained in these improvement plans and could adversely impact the country's transition out of Gavi support, anticipated to happen at the end of 2025.

Table 3: FPP (HSS and EAF) Fund allocation

Category	Amount (USD)	Weighting
Salaries	220,000	6 %
Per diem and allowances	2,215,652	61%
Cold chain equipment	121,000	3%
Cold chain maintenance	235,750	7%
Communication	770,274	21%
Office related costs	35,000	1%
Consultancy	20,000	1%
Total	**3,617,676**	

Ineffective supportive supervision: Although the NIP developed a supportive supervision guideline in February 2009, this guideline was not operationalised across all support supervisions at national and subnational levels. Hence, health facilities are receiving feedback in the form of debrief comments in visitor's registry books rather than a formal report, with clear actions points and a mechanism to follow up the implementation of these actions. In addition, there was no evidence of supportive supervision had been conducted at 5 out of 6 PHOs, 6 out of 9 DHOs and 1 out of 18 HFs, upon being visited by the team as part of this audit. The team further noted that no minutes were maintained for the subnational maternal and child health centre (MCHC) committee meetings, and that there was no mechanism to follow up any action points raised .

Lack of an EPI improvement plan: While a review of the EPI was done in the fourth quarter of 2023, and raised many action points, this was not followed up by developing an improvement plan including clear timelines, identification of funding sources, and an indication of what actions to prioritise first.

***The COVID-19 integration into RI*.** Though there was a discussion on the strategy to integrate COVID-19 and routine immunisation (RI) at a meeting held on 25 October 2021, thereafter the COVID-19 vaccination component was not included in the micro-plans developed in years 2022 and 2023, nor was it included as part of RI schedule.

- develop ToRs for supportive supervisions, and enforce the operationalisation of the supervision guidelines, for all such missions across all levels.
- establish a systematic mechanism to follow up on the implementation status of supportive supervision actions, including documenting, and assigning an owner to each task, along with the completion/due dates.
- develop and operationalise an implementation action plan to address the 2023 EPI review recommendations.

Root Cause

- From mid-2022, the use of AOP tracking and monitoring tool to review progress on AOP implementation was discontinued, coinciding with when the partner-led support stopped (i.e. CHAI's support ceased).
- The AOP and budget estimates did not include the cost breakdown or details of resources by cost driver and budget line and were not mapped over and aligned with the necessary capacity and skill requirements (i.e., adequate human and financial resources).
- Suitable ToRs for support supervision were not established, so as to clearly outline the timelines, deliverables, reporting, and follow-up requirements.
- Delay in implementing the 2022 activities may have been due to the prioritisation of COVID-19 response activities.

Management comments

See Annex 16: Detailed management responses

• Lack of accountability and oversight among different stakeholders, including development partners, in areas of implementation and monitoring of activities.		
Risk / Impact / Implications • There are several important future improvement plans in the pipeline including the: EPI review 2023 action items, the EVM assessment cIP (2023-2026) and the DQIP whose failure would affect the NIP's operations.	Responsibility See Annex 16: Detailed management responses	Deadline / Timetable See Annex 16: Detailed management responses

4.2.3 Inadequate tracking and monitoring on partners targeted country assistance (TCA) performance

Context and Criteria

Gavi's partner engagement framework for targeted country assistance (PEF TCA) guidance, 2022-2025, (annex 4) outlines the roles and responsibilities of key stakeholders in the PEF-TCA planning, monitoring, and reporting processes. Clarity in correctly attributing PEF-TCA stakeholders' roles and responsibilities, is critical in ensuring the success and impact of all such assistance. Some key MoH/NIP responsibilities of include: leading the process in developing the oneTA plan, overseeing the identification of TCA needs, overseeing the activities assigned to the core and expanded partners, and convening quarterly meetings to review progress on TCA implementation. Similarly, the TCA partners are required to report against their respective milestones at the end of both June and November each year via the online partner portal.

By design, country ownership is best facilitated through regular involvement and engagement of the MoH/NIP during the TCA process. The PEF TCA guidance advocates for mutual accountability to be embedded into the PEF TCA model, through mandating programmatic and financial reporting requirements for the partners, as well as conducting regular joint in-country reviews including the MoH, partners and national stakeholders to examine TCA progress and performance. Part of the process of reviewing TCA progress consists of the inter-agency coordinating committee's quarterly reviews.

For the five-year period 2019 - 2023, Lao PDR received approximately USD 7million in targeted country assistance (see table 2 for details). The nature of the support provided was determined based on needs identification process via country- level discussions, such as the "joint NIP and partners coordination meeting". The TCA plan covers the eight Gavi TCA investment areas (i.e., i) service delivery; ii) human resources for health; iii) supply chain; iv) health information systems and monitoring & learning; v) vaccine preventable disease surveillance; vi) demand generation and community engagement; vii) governance, policy, strategic planning and programme management, and viii) health financing). The TCA activities are consolidated into a joint plan for TCA activities (the oneTA plan), aligned with the relevant programmatic areas. The national TCA plan aimed to address capacity gaps in MoH/NIP by drawing upon the in-country partners' core competencies. In practice, this resulted in most of the TCA activities being implemented by the Gavi alliance UN partners (i.e., WHO, UNICEF) and the Clinton Health Access Initiative (CHAI).

Condition

The audit noted the following gaps in the tracking and monitoring of TCAs:

The MoH/NIP is not tracking and monitoring the partners' progress in implementing TCA against the approved plan: - While the MoH and NIP are the intended beneficiaries of targeted country assistance, there was no evidence that the implementation progress and performance of this assistance was reviewed or discussed during the joint NIP and partners coordination meeting, or in the ICC meetings (every three months) as per the Gavi PEF TCA guidance. In addition, from mid-2022 the usage of the AOP tracking and monitoring tool was discontinued, a tool which in the past helped the joint NIP and partners coordination meeting to discuss the programme's performance based on an analytical, data-driven dashboard.

Overall, there were significant delays in implementing most of the planned TCA, as during the period 2022-2023 only 19% (55 out of 293) of the activities were completed on time. 16% (48) of these activities had delays (either major or minor), and 13 (4%) were re-programmed and for another 11 (4%) the status not indicated. See details in the table 4 below.

Table 4: TCA activities implementation status indicator (2022-2023)

Status indicator	Count of activities	Percentage count
Completed	55	19%
Major delays	4	1%
Minor delays	44	15%
Re-programmed	13	4%
No status indicated	11	4%
On track	166	57%
Total activities	**293**	**100%**

The main contributing factor cited as causing implementation delays, as reflected in the Gavi reporting portal, was the COVID-19 pandemic. However, in the absence of a thorough assessment by the MoH/NIP and TCA implementors on the reasons for delays, the audit team was unable to substantiate and evidence that the sole justification was the pandemic.

No formalised process to validate the achievement of TCA milestones and deliverables – No monitoring or validation of the TCA activity milestones and deliverables was performed in-country. Specifically, the MoH did not review and/or receive any form of report from the partners on what TCA milestones and deliverables had been achieved, in order for the NIP to be able to validate the legitimacy of these claims, prior to them being self-reported by the partners in the Gavi portal.

Recommendation 5

To strengthen the coordination and monitoring of PEF/TCA performance, the MoH/NIP's management should coordinate intelligence-sharing with the implementing partners (i.e., core and expanded) on the implementation and outcome of TCA activities, by:

- Using the existing NIP and partner coordination meetings, to review TCA performance regularly and assess progress of implementation against the approved workplan.
- Ensuring that the implementation status and performance of TCA activities, is quarterly reviewed by the ICC, in accordance with Gavi's PEF TCA guidance.
- Ensuring that the implementation of all Gavi-funded priorities which are allocated and executed by the partners, are subsequently reviewed and validated against a written status report documenting progress against the PEF TCA milestones.

Root Cause

- Absence of a review and follow-up mechanism, to ascertain that implementation of the planned TCA programme of activities was undertaken in line with Gavi TCA guidance, 2022-2025.
- The roles and responsibilities for PEF TCA coordination and monitoring in Lao PDR were not well defined.
- The partners were able to report on their TCA milestones and deliverables, directly to Gavi through the PEF reporting portal, without the need for MoH/NIP validation, undermining overall ownership and accountability.

Management comments

See Annex 16: Detailed management responses

Risk / Impact / Implications	Responsibility	Deadline / Timetable
• The under-usage of TCA funding may lead to incomplete or poorly executed TCA investments, as well as missed opportunities for achieving the planned TCA objectives. Shortcomings in overall technical assistance are likely to adversely impact upon the development of sustainable capacity in-country, especially for a country which has entered its accelerated transition phase.	See Annex 16: Detailed management responses	See Annex 16: Detailed management responses

4.2.4 Financial and programmatic challenges in the context of transition

Context and Criteria

According to Gavi's strategy, *"empowering countries to take ownership of their vaccination programmes is a core component of the Gavi business model. Based on their gross national income (GNI) per capita, countries are expected to allocate an increasing amount of their resources to vaccination. The long-term goal is for countries to achieve financial sustainability."*
In 2015, Gavi's Board first approved the eligibility and transition policy. This states that countries' eligibility will be determined by their average GNI per capita over the past three years. Two subsequent policy updates were approved in June 2018 and December 2022. The current policy, which is in effect since 1 January 2023, indicates that either the latest GNI per capita, or the average over the past three years, must be below the threshold.

Lao PDR entered its accelerated transition in 2017, with an initial five-year preparation period up to the end of 2021. Following the revision of Gavi's eligibility and transition policy this accelerated transition period was extended up to eight years. As a result, Lao PDR's preparation timeline was revised up until December 2025(including one year waiting time until the policy revision is finalised, by the Gavi CEO's guidance). Overall, Lao PDR's programmatic performance in immunisation has improved over the last 20 years, but the country is currently constrained by an economic crisis and pronounced underfunding in public health.

Once a country enters the accelerated transition phase, it is eligible to apply for new vaccine support during the eight years allotted, provided that any vaccine introductions in this phase effectively contribute to strengthening routine immunisation and increasing coverage and equity. After the eight-year transition phase, a country becomes fully self-financing.

Condition

The audit noted the following challenges in the country's readiness to transition:

The country is behind on its commitment to spend 9% of the national budget on health: In 2012, Lao DPR committed to spend a minimum of 9% of its national budget on health. However, over the last 5 years only 4% of the government budget has been allocated to health. In 2021, the current health expenditure (CHE) for Lao PDR was 2.74% of GDP which is low when compared to other countries in the ASEAN region (i.e., Cambodia at 7.53%, Vietnam at 4.59% and Myanmar at 5.63%)[9].

***Government contributions towards financing vaccines are expected to continue increasing through to 2025*:** In 2022 and 2023, Lao PDR funded USD 0.50 million towards traditional vaccines each year; and contributed to Gavi new vaccines co-financing of USD 1.35 million in 2022 and USD 1.52 million in 2023. It is forecasted that within the next two years, the total co-financing amount will be more than double to USD 3.61 million by 2025. Equally by 2025, Lao PDR's total annual cost of financing immunisation will be USD 21 million, in effect approximately 1.75 times the annual cost incurred in 2019 (USD 12 million).

Co-financing of the traditional vaccines is constraining other health spending: Looking back over the past 10 years up to last year (i.e. 2013 until 2022), the proportion of Government's annual co-financing contribution towards the total cost of vaccines progressively increased from 8% in 2013 to 80% in 2022. The last five-year period has been particularly pronounced, given that the significance of the co-financing as a share of the overall health budget, has begun to detract against other MCHC budget allocations, including nutrition and reproductive health. Consequently, the Government budget has funded only about 60% of the NIP's operational expenditures in the last 5 years. Gavi's FPP forecast budget indicates that these operational costs will continue to be

Recommendation 6

To ensure the country's readiness for transition, MoH/NIP should:

- develop a transition plan and roadmap that is linked to the future national immunisation strategy and national reform strategy, to direct the country's transition planning processes.
- continuously review the health sector workforce with the objective of: assessing capabilities, recruiting for new skill sets, and developing the capacity of existing HRH.
- review all the costs related to immunisation activities at the national and subnational levels, (including operational costs, vaccine co-financing and HR) against all available funding sources (Government, partners, and donors) to identify what funding gaps exist and still need to be addressed.

[9] https://data.worldbank.org/indicator/SH.XPD.CHEX.GD.ZS?locations=VN-MM-KH-LA&name_desc=false,

covered by Gavi during the next 2 years, i.e. 2024-2025. Other donors also contribute to the national immunisation programme. For example, in 2023, the World Bank and Japanese Government fundraised USD 1 million to help procure vaccines for Lao PDR. These funds were earmarked against doses not financed or supported by Gavi. Similarly, UNICEF has separately mobilised and invested over USD 0.8 million in outreach activities and more than USD 1 million in direct cash transfers to the Government between 2019 and 2023. ***There is no comprehensive visibility over financing for immunisation:*** As at March 2024, the country was unable to tell how much of its health financing comes from available Government revenues, grants, or debt. Consequently, it was not possible to establish: how much the country currently spends on its immunisation programme; what were the resource requirements of this programme; and to what extent the current national spending covers these requirements. In addition, the country has not yet determined its projected total resource requirements verses its existing available resources, and what specific sources of financing it plans to tap into or to target post-transition. ***Health financing targets in the Health Sector Reform Strategy 2021-2025 have not been achieved:*** The country's health sector reform strategy has targets structured around five pillars, including health financing. However, key targets such as: increasing the state budget to the health sector to 9%; increasing health expenditure from domestic sources by 40%; and reducing out-of-pocket expenditure to 35% have not been achieved. Furthermore, the strategy highlights that the current pool of health insurance contributions from beneficiaries of the national health insurance (NHI) is too small, causing constraints on the available budget for medicines, medical equipment, and medical consumables, and which has led to reported stockouts of essential medicines in public hospitals. ***Overreliance on outreach services:*** There is an overreliance on outreach services to reach immunisation targets. The justification often provided for the outreach approach is because of geographic challenges in reaching the health facilities and communities. Also, it was pointed out that the funding flows to health facilities which provide fixed site immunisation services are often inadequate/ or untimely. In 2022, the average proportion of Penta3 services delivered through fixed sites compared to outreach plus mobile approaches, was 52% to 48%. ***Staffing gaps with no succession planning:*** In May 2023, the data manager resigned from NIP to join UNICEF. However, for almost one year thereafter, he still continued to also perform his former duties at the NIP. The NIP deputy Director is expected to retire in July 2024. Currently, no staff capacity needs assessment or evaluations of the NIP have been undertaken, to assess what are its existing capabilities and future capacity requirements. Some NIP skill gaps are already evident, for example there is limited capacity for immunisation planning, programme management, and monitoring/oversight at all levels (central, provincial and district). Similarly, the MoH/NIP's oversight mechanisms are still weak (refer to finding on 4.1.1). The audit team reviewed the FPP budget and noted that it includes USD 0.22 million which is to be spent on HRH as salaries for 2024-2025. However, there is no indication of how these human resource needs which are to be met by Gavi in the short term, will subsequently be absorbed into the NIP's ongoing resourcing and financing thereafter. ***There is an overreliance on development partners for programme planning, implementation, and monitoring:*** Gavi's TCA 2022-2023 funding, financed 17 staff positions assigned within the partners. Similarly, Gavi's 2024-2025 TCA plan includes 19 positions, of which only 4 had a reduced level of effort. In addition, the audit team noted instances where the agendas and minutes of meetings were directly managed by partners. It was suggested that the NIP also relies on the partners for key activities such:	• through the ICC and RMNCH TWG, advocate for additional funds while maximising the impact from the existing funds available. • Have a dedicated team managing the transition plan with the view that the Government takes more ownership and agree and establish a roles and responsibility matrix with partners.

<table>
<tr><td colspan="2">forecasting, data quality assessments and training on EPI data management. There was also a dependency on the financing of voluntary HWs or workers for certain immunisation activities, given that the individuals concerned were paid for by the partners.</td><td></td></tr>
<tr><td colspan="2">Root Cause
Gavi's process for transition readiness was not fully understood, other than the co-financing for vaccines component.
The FPP process includes limited guidance on transition arrangements for finance and programme management. It is not necessarily clear which activities are the most catalytic (i.e. yielding a high return on investment), as compared to operational activities which in principle should be funded by Government. Notably, 67% of the HSS and EAF funding approved in Gavi's FPP budget, has been allocated to cover salaries and per diem related costs for trainings, workshops, conferences, and outreaches.
The necessary support required by the MoH in the future – associated with preparing for its transition and for it to become fully engaged in its critical processes – is not yet documented or planned, with respect to how best to channel the technical assistance in creating the conditions for sustainability.
Trainings and capacity building initiatives over the last few years didn't necessarily achieve the intended target.
Due to lack of monitoring and assessing the quality of capacity building, there was little clarity on what were the trainings' outcomes.</td><td>Management comments

See Annex 16: Detailed management responses</td></tr>
<tr><td>Risk / Impact / Implications
There is a risk that the gains accrued by the immunisation programme over the last 20 years, may be lost if the transition process is not adequately planned and managed.</td><td>Responsibility

See Annex 16: Detailed management responses</td><td>Deadline / Timetable

See Annex 16: Detailed management responses</td></tr>
</table>

4.3 Vaccine Management

4.3.1 Partner-led forecasting impacting the sustainability of the process

Context and Criteria

Vaccine forecasting requires calculating the number of vaccines that are needed to cover the needs of the target groups in and outside the catchment area receiving vaccination services[10]. This process adheres to predefined steps tailored to the country's context. In Lao PDR, the annual forecasting of vaccines and related supplies is conducted using the UNICEF/WHO forecasting tool. This tool necessitates data input such as target population, wastage rates, buffer stock, and current stock levels at the time of forecast generation. The various data inputs are sourced from existing data repositories and assumptions, which are usually either historical or derived from credible sources and involves the engagement of various stakeholders supporting vaccine management. In addition, data regarding the target population is sourced from national statistics office; wastage rates are calculated based on WHO guidelines; buffer stock is estimated at approximately 25% of the total required doses; and data on current stock levels is obtained from the CVS.

The Gavi immunisation supply chain strategy for 2021–2025 highlights the risks of how "limited specialised staff capacity leads to poor forecasting," making it important that countries have access to the necessary competent technical staff to manage and oversee this process.

Condition

A partner-led forecasting process may undermine sustainability: The audit team observed that the vaccines and related supplies forecasting process was led by partners, with no designated owner or individual within the NIP logistics team who was concretely involved. As a result, only the NIP manager was involved in the forecasting process, but his attention was divided given he was typically occupied in juggling various competing priorities. Given the prominent lead role assigned to the partners on forecasting with little overlap with the NIP, the current setup hampers imparting transferable, forecasting skills over to the Ministry, and ultimately challenges the sustainability and continuity of the process. This all the more given the context of that the country is in accelerated transition, with Lao PDR's direct partner support likely discontinuing at the end of 2025.

There are no SOPs or guidelines in place to guide the forecasting process: The forecasting of vaccines and related supplies should adhere to a systematic process which generates a comprehensive, precise, and representative outcome. The audit team noted that the UNICEF/WHO forecasting tool is accompanied with guidelines for how to complete it. However, these guidelines do not provide for every context, including individual countries with unique data sources, as is the case for Lao PDR. In addition to these guidelines, it is therefore necessary to also develop standard operating procedures which are tailored and aligned to the country's processes and context. The absence of sufficient specificity could detract from the predictability and reproducibility of the process.

Limited data visibility at the subnational level: NIP does not have complete visibility over all of its key data, including the level of vaccines consumed and the stock-on-hand, across its entire supply chain. These are valuable data points in order to inform the forecasting process. The implementation of the *m*Supply system has helped to enhance data visibility, however the system is only installed down to the district level and is not yet deployed further down to the health facilities. In addition, whereas DHIS2 allows health facilities to report on essential logistics data like consumption and stock levels, the audit team noted that this overall dataset generated from DHIS2 was inaccurate and incomplete, including less than 60% of health facilities having reported that they used DHIS2. As a result, the national forecasts were largely generated using national level stock-on-hand data only.

Recommendation 7

To improve the forecasting process and ensure its sustainability, the MoH/NIP should:

- with UNICEF's support – identify and train focal persons within the national logistics team, to lead the vaccine forecasting process in collaboration with other stakeholders such as WHO.
- develop SOPs/guidelines governing the forecasting of vaccines and supplies, which are tailored to the specific country context.
- Through enrolling the help from the provincial and district health teams, enforce the use of the DHIS2 logistics module, with the objective of collecting accurate and complete data.
- conduct regular forecast reviews and evaluations, to refine its forecasting assumptions, and carry these forwards to subsequent forecasts.

[10] EPI Managers Module-Lao PDR

<table>
<tr><td colspan="2">Forecasting accuracy not measured: As the forecasting process relies on various assumptions, it is important to evaluate the accuracy of the forecast at the end of the forecasting period, and potentially finetune it, by comparing the actual utilisation of vaccines and related supplies with the forecast. The audit noted that no such evaluation was ever conducted during the five-year period, 2019 to 2023. In effect, this represents a missed opportunity to potentially refine and strengthen past assumptions, with a view to generating more accurate forecasts in the future.</td><td></td></tr>
<tr><td>Root Cause
Limited availability and capacity among the NIP staff in the area of forecasting and the quantification of vaccines and related supplies.
Lack of clear roles and responsibilities for NIP logistics staff.
Underutilisation of the logistics module in DHIS2 by health facilities, in order to improve the visibility of stock data.</td><td colspan="2">Management comments

See Annex 16: Detailed management responses</td></tr>
<tr><td>Risk / Impact / Implications
Overreliance on partners could create a culture of dependency, impacting on the NIP’s ability of developing its own capabilities, and missed opportunities in benefiting from any knowledge and skills transfer from partners.
The absence of suitable SOPs/guidelines presents the risk of inconsistences and errors accruing during the forecasting process.
Incomplete input data, may result in the under or over forecasting of vaccine requirements.</td><td>Responsibility

See Annex 16: Detailed management responses</td><td>Deadline / Timetable

See Annex 16: Detailed management responses</td></tr>
</table>

4.3.2 Need to revitalise regional vaccine stores (RVSs) and adhere to good storage practices

Context and Criteria

The terrain of Lao PDR is mostly mountainous, with much of the population widely dispersed, making access to remote parts of the country challenging. Given the country's geography, two regional vaccine stores were established in Oudomxay and Champasak provinces in 2017, with a mandate to facilitate the strategic holding and replenishment of vaccines for subnational stores within their jurisdiction. It was envisaged that both regional stores would help to routinely replenish stocks for the surrounding PVSs and DVSs,[11] to improve the continuous flow of supplies[12] and enhance the efficiency of delivery fulfilment. Vaccines are largely distributed from the CVS, using domestic flights or public transport. At present, deliveries are still made to both the 2 regional and the 18 provincial vaccine stores.

Dry supplies need to be kept in a suitable storage space and temperature range, to protect them from hazardous or environmental conditions, to preserve their sterility and utility, in accordance with the manufacturers' recommendations.

Condition

The regional vaccine stores were non-functional: The two RVSs functionality and mandate was not clear. The audit team noted that across both Oudomxay and Champasak provinces, the respective PVSs were functioning as if they were equivalent to an RVS (i.e. there was no distinction between the RVS and PVS in terms of stock holding capacity, record separation, and human resources). The audit team did not see any review and study undertaken to optimise the supply chain infrastructure of the RVS' to achieve an effective and efficient stock holding and replenishment process including assessing adequacy of human resources and minimum and maximum stock holdings.

Inappropriate storage of dry supplies: The storage of dry supplies did not adhere to the principles of good storage practices. Needles and syringes were kept in the open shade and on a veranda at the NIP storage facility. Additionally, some needles and syringes were partially unpacked, and kept solely in their secondary packaging, increasing their exposure to external climatic conditions (see Annex 7 for details). For instance, in Oudomxay PVS, cartons of needles and syringes were loosely stored on the floor, and viable stock was mixed with expired stock. Additionally, the audit team noted that overall, 2 out of 9 DVSs visited had insufficient space for the storage of dry supplies.

Recommendation 8

To fully operationalise the role of the Regional Vaccine Stores (RVSs), MoH/NIP should:

- Undertake a supply chain optimisation study, and subsequently design a suitable cold chain infrastructure that achieves the objective of an efficient and effective stock holding and replenishment process, such that commodities and information flow in and out of the RVS', in support of the subnational stores within their catchment area.
- clarify and reinforce the RVS' mandate, to ensure they can hold sufficient supplies to promptly replenish their catchment area. Establish and enforce suitable minimum and maximum stock holding thresholds and ensure these are respected; and
- allocate sufficient resources, including the recruiting and/or assigning of designated staff to the RVS' to operate and manage their supply chain operations, including any expanded responsibilities.

Recommendation 9

To free up storage space for dry supplies, the NIP should timely dispose (or destroy) all of its expired vaccines and immunisation supplies, in line with the national regulations governing the destruction of medical waste.

[11] Lao PDR National Immunisation Programme updated Comprehensive Multi-year plan 2019-2023.
[12] Lao PDR Health Sector Reform Strategy and Framework till 2025

<table>
<tr><td>Root Cause
• Insufficient human resources to operate a fully functional RVS.
• Constrained budgets to support the maintenance and sustainability of a fully operational RVS.
• The inability to optimise the available dry storage space, was partly attributed to the delayed disposal of expired commodities.</td><td colspan="2">Management comments

See Annex 16: Detailed management responses</td></tr>
<tr><td>Risk / Impact / Implications
• The lack of clarity regarding the cold chain infrastructure, including the RVS configuration and mandate, represents a missed opportunity in establishing operational storage hubs, that are responsive and efficient, and provide continuity by promptly replenishing and meeting the supply needs of the PVSs and other subnational stores located across the Northern and Southern regions.
• The sterility of needles or syringes could become compromised while held in store.</td><td>Responsibility
See Annex 16: Detailed management responses</td><td>Deadline / Timetable
See Annex 16: Detailed management responses</td></tr>
</table>

4.3.3 Inventory management practices at national and subnational level need improvement

Context and Criteria

Inventory management is one of the challenges of operating an efficient supply chain, involving the stock management, storage, rationing, and demand-side management of the supply chain[13]. For immunisation programmes, the goal of the inventory management system is to ensure the uninterrupted availability of quality vaccines at service-delivery levels, so that opportunities to vaccinate are not missed because products are unavailable[14]. Such systems can help enable the good management of vaccines and promote performance.

One such category of systems, includes the electronic logistics management information systems (eLMIS) which help to accurately record all stock inflows and outflows, and ensure accountability and traceability of commodities within the supply chain system, enabling the availability, accessibility, and safety of products, including vaccines. Additionally, the eLMIS' analytic capabilities can help assess and optimise the efficiency and effectiveness of the immunisation programmes.

Lao PDR Health Sector Reform Strategy states that, *"Pharmacy staff should be trained on inventory management and good storage techniques to ensure sustainable availability of essential medicines and medical supplies at health facilities".*

Condition

Unexplained stock variances at the CVS: The audit team conducted reconciliations of the CVS' vaccine stock records maintained during the 5-year period 1 January 2019 to 31 December 2023, by comparing opening stock plus receipts, minus issuances and wastages. Variances were observed between the expected stock balance and the actual stock balance – as indicated in the table below, highlighting several challenges in maintaining accurate records using the logistics management information system.

Table 5: Unexplained stock variances at CVS

#	Vaccine	Opening balance – 1 Jan 2019 (a)	Receipts Jan 2019 – Dec 2023 (b)	Distributions Jan 2019 – Dec 2023 (c)	Expected closing balance (d)	Actual closing balance 31 Dec 2023 (e)	Variance (e) –(d)
1	BCG	654,600	3,778,000	4,296,180	136,420	96,800	-39,620
2	BCG-diluent	654,600	3,778,000	4,296,180	136,420	96,800	-39,620
3	bOPV	1,050,620	3,073,000	3,809,800	313,820	316,200	2,380
4	HPV		1,121,040	1,135,235	-14,195	30	14,225
5	IPV	95,515	562,050	838,755	-181,190	42,310	223,500
6	JE	342,900	1,411,000	1,618,455	135,445	134,100	-1,345
7	JE – diluent	342,900	1,411,000	1,618,455	135,445	134,210	-1,235
8	MRV	301,680	4,430,850	4,508,340	224,190	211,500	-12,690
9	MRV diluent	301,680	4,430,850	4,508,340	224,190	211,500	-12,690
10	PCV	378,250	1,779,400	2,074,030	83,620	61,708	-21,912
11	Pentavalent	311,102	1,921,940	2,140,290	92,752	85,227	-7,525

Recommendation 10

To ensure accurate recording in tracking the movement of CVS' vaccines and stocks, the MoH/NIP should:

- ensure that all entries in the inventory management system/ stock include damaged and expired vaccines.
- conduct periodic checks and reconcile the separate data sets maintained in *m*Supply and VSSM until it is determined which eLMIS system is confirmed as the primary source for maintaining the CVS' records.
- conduct a rapid assessment of PCV stock levels across the country, as well as a gap analysis of this product, in preparation leading up to the planned PCV switch and so as to avert stock outs during the switch.
- generate a comprehensive organogram to illustrate the roles, responsibilities and reporting modalities of the CVS logistics staff. The organogram should be supported by a detailed document defining which positions or roles require partner support in the short and long term.
- develop comprehensive vaccine management SOPs, thereafter, train its personnel on the SOPs, and

[13] Lim et al, (2017). Process redesign and simplified policies for more effective vaccine inventory management. Engineering Management Journal, 29(1), 17–25.

[14] Essential Programme on Immunisation (who.int)

Stock variances between mSupply and VSSM data sets: The audit team conducted a physical count at the CVS and compared the stock counted with the stock balances recorded in VSSM and *m*Supply. The team noted variances between both the VSSM and *m*Supply systems' balances and the physical stock count. This applied to all the 5 vaccines in VSSM records, and to 4 out of 5 vaccines in *m*Supply records. In addition, a cross-system comparison also exposed differences, as the same 5 vaccines balances recorded in each eLMIS system did not match.

Table 6: Physical Count vs. VSSM vs. mSupply stock quantities, at the CVS

Name of Vaccine	Physical stock counted (A)	System balance recorded in *m*Supply (B)	System balance recorded in VSSM (C)	Physical variance with *m*Supply (A-B)	Physical variance with VSSM (A-C)	Cross-system variance (B-C)
Pentavalent	110,700	118,750	118,677	-8,050	-7,977	73
IPV	73,500	73,500	73,460	0	40	40
PCV	14,460	14,800	13,008	-340	1,452	1,792
M&R	849,675	868,175	856,250	-18,500	-6,575	11,925
BCG	341,000	372,000	381,800	-31,000	-40,800	-9,800

Similar reconciliations conducted at subnational stores comparing physical to stock records, also revealed variances between the recorded balances as per *m*Supply batch cards, and the physical stock counted. Such variances were systematically identified in at least one of the sampled vaccines across nearly all of the vaccine stores, including : All 6 out of 6 PVSs; all 9 out of 9 DVSs; and for 13 out of 18 health facilities that the team visited. See Annex 8.

Unexplained stock balance differences between the end and the beginning of the subsequent period: The audit team compared subnational DVS closing stock record balances as at 31 December 2022 with the opening stock balances recorded as at 1 January 2023, and identified differences in 3 out of 9 DVSs visited. See Annex 9

Low physical stock balance of PCV at the CVS: The audit team noted that the stock level for PCV vaccine at the CVS was below the minimum (i.e. buffer) stock. On 12 March 2024, it was estimated that the remaining supplies were equivalent to 0.4 months of supply. Given the average monthly consumption[15] of approximately 35,000 doses, it was self-evident that the available stock-on-hand of about 15,000 doses, was not enough by itself, to meet the next distribution cycle requirement, in June 2024. Although there was a basis for running down existing stock balances, as the country is planning on switching PCV presentations from 4 to a 5 doses per vial in September 2024, the audit team remains concerned that overall, there is insufficient stock available in the pipeline to meet the country's ongoing routine immunisation needs until that time.

Stockouts of vaccines at national and subnational level: Within the five-year period January 2019 to December 2023, the audit team identified several instances of vaccine stockouts at national and subnational levels (i.e. at all four levels of the supply chain, namely: the CVS, PVS, DVS, and health facilities). Although, the existence of stockouts at the CVS was reported in several SC TWG meetings, details on the frequency and magnitude of stockouts were not available. Specifically, both eLMISs (mSupply and VSSM) did not maintain an audit trail, and does not have the capacity to generate 2019-2023 stockout records, to be reviewed after the

disseminate hard copies of these SOPs to all vaccine storage points.

- in collaboration with the PHOs and DHOs, strengthen supportive supervision, by developing comprehensive support supervision plans and standardised supervision checklists. These should be used to document: the objectives for the visit, its key observations, and any remedial actions to address identified gaps. There should also be a systematic mechanism to follow up the remedial actions.

[15] Average monthly consumption is computed as a proxy of distribution data from VSSM.

fact. In addition, stockouts were also reported at the subnational levels, i.e., at 4 out of 6 PVSs, 5 out of 9 DVSs, and 5 out of 18 health facilities visited. The gravity of these subnational stockouts could frequently not be gauged, due to the unavailability of records or because batch cards were incomplete. Similarly, the *m*Supply system was unable to retroactively generate stockout reports with explanatory details on the subnational stockouts. Based on the records available, the longest average stockout period identified for PCV vaccine is 97 days, with one outlier case of 171 stockout days reported by one DVS. BCG recorded an average of 42 stockout days, while MR experienced 80 stockout days at a single health facility. See Annex 10 for details.

Long lead times until expired health commodities were formally disposed of : The audit team noted that for a seven month period, from August 2023 up to our audit period of March 2024, approximately 2.7 million expired doses of Covid-19 vaccines were set aside and stored at the CVS. Similarly, for the past four months beginning October 2023, there has been an unknown quantity of expired needles and syringes set aside and stored at the CVS.

Root Cause

- Some of the stock data recorded in each eLMIS system is inaccurate or incomplete. For example, there is no record of expiries of RI vaccines in VSSM, despite the fact that expired vaccines were reported at a SC TWG meeting held in 2021 and 2022.
- If stock records were not adjusted to account for expired doses, this may have caused unreconciled differences between the records and the physical stock-on-hand.
- The stock records datasets in both VSSM and *m*Supply are not periodically reviewed and harmonised, to reflect the fact that both systems currently operate in parallel and are managed by different personnel.
- Incomplete information on what quantum of PCV stock remained, was provided to Gavi in 2023, in order to facilitate the release of Gavi's decision letter. This letter was time sensitive, as it was needed to initiate the procurement and replenishment of PCV supplies via Gavi's procurement agent. Thus, the incorrect information provided, could have contributed to lower than expected PCV stock levels, which became apparent in March 2024.
- Lack of proper role definitions for NIP logistics staff. While the organogram indicates that eight positions are working at the CVS, their roles and responsibilities are not properly defined, resulting in a lack of accountability for managing the various processes. For example, it was pointed out that technically four individuals are responsible for vaccine supply and distribution, but in practice no substantive details were documented clarifying in practice what each of them was responsible for.
- There was no indication that routine physical stock counts were conducted at approximately one third of subnational stores, including 2 out of 6 PVS, 3 out of 9 DVS and 5 out of 18 health facilities, being the sites sampled and visited by the audit team.
- Lack of updated vaccine management SOPs to guide personnel through the entire processes of vaccine management.
- Ineffective support supervision at the various vaccine handling points.

Management comments

See Annex 16: Detailed management responses

Risk / Impact / Implications

- Inadequacies in the management of stock records, and the failure to undertake regular reconciliation processes between different data sources, is creating unexplained differences and gaps between the physical stock and the data recorded on file.
- Vaccine stockouts could disrupt immunisation coverage targets being attained, as well as the overarching goal of reducing the number of zero dose children.

Responsibility

See Annex 16: Detailed management responses

Deadline / Timetable

See Annex 16: Detailed management responses

4.3.4 Distribution planning and accountability need to be strengthened

Context and Criteria

Vaccines are distributed down through the tiers of the supply chain until they reach the service delivery points. The planning of logistical supply chains and distribution process can be disrupted where there are difficulties in accessing the regions[16]. Equally unexpected vaccines losses can occur when the integrity of the cold chain is compromised. In Lao PDR, several vaccine distribution bottlenecks and logistical challenges[17] were frequently cited across provinces, by those collecting or receiving vaccine doses from higher up the supply chain. To improve the design of immunisation supply chain and enhance its efficiency and effectiveness, especially for the last mile, a pilot project which integrates the distribution of vaccines with other commodities was initiated in Oudomxay and Champassak provinces. Lessons from this project are expected to help inform, and if successful, in future the project could potentially be scaled up and rolled out to other provinces.

To optimise the country's distribution model, it is crucial to develop comprehensive distribution plans. These plans should provide sufficient guidance and clarity to the various stores along the supply chain, regarding their order fulfilment, who is supplying their vaccines and from where, and the anticipated delivery timing . All vaccine distributions should be properly supported with appropriate documentation in order to track and validate the movement of vaccines along the supply chain.

Condition

Distribution plans and schedules were not available: At the apex of the supply chain, CVS is responsible for distributing vaccines to subnational vaccine stores and national hospitals. However, the audit team observed that there were no comprehensive distribution plans in place, nor were there any delivery schedules for when vaccines were to be distributed to the provincial and district level stores. In addition, the 2023 CVS distribution plan, which remained in draft, was never approved.

Integrated distribution of vaccines not implemented: In 2021, CHAI completed its project piloting an integrated distribution model, by combining the distribution of vaccines with other supplies, an approach which was trialled in Oudomxay and Champasak provinces. The project's lessons and recommendations were shared with NIP through the SC TWG, reproductive, maternal, new-born, child and adolescent health (RMNCH), as well as at the EPI annual review meetings. However, the audit team noted that the integrated distribution approach is no longer operational and that currently, no scale up is planned yet.

Untraceable stocks: The audit randomly selected samples of vaccine stocks distributed across the various tiers of the supply chain, included from the CVS to PVSs, from PVSs to DVSs, and from DVSs to health facilities, so as to verify whether the respective vaccine consignment was accurately received and recorded by the corresponding stores. It was observed that the arrival of these consignments could not be traced in the records of: 1 out of 6 PVSs, 2 out of 9 DVSs, and 10 out of 18 health facilities. See annex 11. The discrepancies that the team identified were primarily attributed to missing stock records, including one facility (i.e., Namor DVS) which reported that its supporting documents were washed away in a flood.

Recommendation 11

To strengthen the distribution of vaccines along the supply chain, the MoH/NIP should:

- in collaboration with PHO and DHO, develop comprehensive vaccine distribution plans and ensure that these plans are properly approved and disseminated to the subsidiary stores.
- with support from the partners and using the lessons learnt from the integrated distribution of vaccines pilot, assess the feasibility of scaling this approach up and trialling it in other provinces.
- in collaboration with PHO and DHO, conduct regular checks as part of the support supervision visits to reconcile distributed versus received vaccines and investigate any anomalies.

[16] Anparasan et al. (2018). Data laboratory for supply chain response models during epidemic outbreaks. Annals of Operations Research, 270, 53–64. https://doi.org/10.1007/s10479-017-2462-y.
[17] Lao PDR immunisation Programme review, 2023

<table>
<tr><td>Root Cause
The staff capabilities in logistics distribution planning and scheduling was limited. Also, there was no designated focal person in charge of the CVS' distribution.
There is a lack of resources available, in order to build upon the prior vaccines integrated distribution pilot project and expand this approach further.
There was no independent process (either by the national or the subnational health offices) to validate that the underlying records documenting the distribution of commodity consignments to subsidiary vaccine stores, were accurate and that the distributor and the recipient's records matched and reconciled.</td><td colspan="2">Management comments

See Annex 16: Detailed management responses</td></tr>
<tr><td>Risk / Impact / Implications
50% of the CVS' vaccine distributions to the of PVS were unplanned or ad-hoc.
The perception that subsidiary stores only have limited accountability over vaccines and other consignments that they receive, presents a risk that commodities are neglected or lost.</td><td>Responsibility

See Annex 16: Detailed management responses</td><td>Deadline / Timetable

See Annex 16: Detailed management responses</td></tr>
</table>

4.3.5 Cold chain management practices need to be strengthened

Context and Criteria

Cold chain infrastructure is central to enabling supply chain challenges. As additional new vaccines are rolled out, many cold chain systems are struggling to continue to support national immunisation programmes[18]. Hence the need for reliable, cost-effective, well maintained cold chain equipment as a key component of the supply chain. Best practices also highlight the importance of ensuring that: there is adequate vaccine storage for current and future products; and that maintenance requirements and ongoing running costs are minimised. WHO's effective vaccine management standards also require that temperature mapping exercises are done for all the vaccine cold rooms and freezer rooms every 2 years.

The Lao PDR government has expanded its cold chain capacity at the central level, to ensure that it has adequate space for the current and future vaccines in the NIP schedule. However, a significant portion of the CVS' cold chain equipment is older than 10 years, or the equipment does not comply with WHO's performance, quality, and safety (PQS) standards. It is important to routinely conduct maintenance, and assess the equipment's service record and status, to maintain temperature conditions in range. Gavi's grant guidelines relating to the cold chain equipment optimisation platform, also specify and require that the national logistics team should conduct regular CCE preventive maintenance.

Condition

No comprehensive preventive maintenance plans or maintenance logs for CCE: The audit team noted that there were no comprehensive CCE preventive maintenance plans in place. For example, the CVS did not maintain individual preventive maintenance checklists for each of its 17 CCE units. Instead, a single checklist was purportedly used for all the equipment. However, there were no historical records kept for the CVS' past preventive maintenance activities, and no CCE maintenance logs were maintained. As a result, the audit team was unable to verify whether preventive maintenance activities were carried out on each CCE unit. Similarly, at the subnational level, based on the sites that the team visited, preventive maintenance plans were not maintained in 4 out of 6 PVSs and in all 9 DVSs.

The temperature mapping and calibration of WICRs was not conducted: The audit noted that there was no evidence of temperature mapping for 3 out of 5 WICRs, all of these being CVS units over 5 years old. Similarly, the temperature mapping records for the remaining 2 WICRs – both newly installed in 2022 - were not also available, though it was explained that this was done at the time of installation. For those subnational stores with WICRs, no temperature mapping exercises were conducted of any of the 5 WICRs. Similarly, no temperature calibration was done for any of the WICRs – this includes units at the CVS and across the subsidiary level.

None of the data generated by the WICR temperature monitoring system was downloaded: The audit team noted that although the 5 WICRs at the CVS were equipped with fridge tags to capture temperature at regular intervals, the data generated was not downloaded, reviewed or archived by the CVS cold chain team. This represents a missed opportunity for detecting any temperature excursions and taking remedial steps. The same observation relates to all of the subnational vaccine stores visited, (i.e., there was no periodic downloading of temperature data from the fridge tags). Based on a review of the cold chain temperature documentation, temperature excursion incidents occurred in 3 of the 9 DVSs and in 4 out of 18 health facilities. It could not be substantiated whether there was any further follow up to determine what were the root causes or if any remedial actions were taken.

Recommendation 12

To strengthen its cold chain management the MoH/NIP – with partner support – should:

- develop cold chain equipment maintenance plans, preventive maintenance checklists, and equipment maintenance logs at both the national and subnational levels.
- train its cold chain officers on the new maintenance tools. Equally, the checklists and equipment maintenance logs should be printed and disseminated to all vaccine handling points.
- Regularly conduct routine temperature mapping of its WICRs.
- put in place a process to regularly download data from the temperature monitoring devices and follow up with suitable remedial actions, as necessary.
- develop cold chain management SOPs to guide cold chain management and maintenance processes.
- consider procuring and installing solar powered refrigerators, in areas with frequent power outage.
- develop a decommissioning plan to dispose of the obsolete CCE units that are located at the national and subnational levels.

[18] Ashvin et al, Improving cold chain systems: Challenges and solutions, Vaccine, Volume 35, Issue 17, 2017.

<table>
<tr><td colspan="2">No documented contingency plans: At all PVSs, DVSs, and health facilities visited by the audit, there were no documented contingency plans detailing what steps to follow in the event of equipment breaking down. Although some staff members were able to explain their past actions in case of breakdowns, there was no formalised process to ensure that such actions would be consistently and systematic undertaken, should the experienced incumbent staff not be present.

Power backup systems were not available for CCE: The audit team observed that there was no power backup system in place for 2 out of 6 PVSs, 7 out of 9 DVSs, and for all the health facilities visited. As a result, the CCE at the subsidiary levels primarily relied on the electricity grid as the power source.

No cold chain equipment decommissioning plan: During the audit field visits, the team noted obsolete CCE located at the subnational vaccine handling points. The NIP did not have a plan for how to decommission such obsolete items.</td></tr>
<tr><td>Root Cause
Inadequate oversight over cold chain management operations at national and subnational levels.
No cold chain management SOPs or operational manual was in place, to guide the cold chain technicians to apply a standardised, step-by-step process for maintaining the cold chain equipment.</td><td>Management comments

See Annex 16: Detailed management responses</td></tr>
<tr><td>Risk / Impact / Implications
The absence of preventive maintenance plans increases the risk of equipment breaking down, potentially shortening the service life of equipment. This may have contributed to the existence of several non-functional items that the team observed across various sites.
Inability to detect temperature fluctuations in the cold rooms, could lead to vaccines being exposed to the improper conditions, compromising their shelf-life.
Vaccines could lose potency due to the integrity of the cold chain being disrupted in the event of power outage or failure. The team noted several vials of OPV at VVM stage 4 (i.e. damaged due to heat exposure) at two health facilities.
The lack of maintenance equipment logs, and curative activities not being documented, means that useful data which could inform a cost-benefit analysis in the future will not be available, including a comparison of the cost of maintenance versus decommissioning equipment items. The absence of such data could also result in delaying a decision as to when to replace equipment, potentially resulting in higher than necessary maintenance expenditures.
The team noted several non-functional CCE items located in 3 out of 6 PVSs, 5 out of 9 DVSs, and 1 out of the 18 health facilities, visited. These, obsolete CCE reduces the remaining amount of scarce working space, and over time could potentially develop into an environmental hazard.</td><td>Responsibility

See Annex 16: Detailed management responses</td><td>Deadline / Timetable

See Annex 16: Detailed management responses</td></tr>
</table>

4.4 Supply chain and data management systems.

4.4.1 Weaknesses in design and implementation of *m*Supply

Context and Criteria

In 2015, the electronic logistics management information system – *m*Supply – was implemented by the food and drug department (FDD) of the Lao PDR Ministry of Health, with support from CHAI and technical support from Sustainable Solutions, to increase the management efficiency of the health commodities' supply chain. The system was first implemented to manage essential supplies for the HIV, TB and malaria programmes, and for family planning. In 2020, a vaccine management module was built in *mSupply*. *m*Supply consists of a combination of a web based as well as a mobile application. The system is deployed across all 148 national districts, offers access to a limited number of core health personnel across the central, provincial, and district levels. As at March 2024, the system was running a legacy version (v7.12) including functionalities encompassing stock inventory management, supplier management, receipts, stock issuance, and basic reporting. Lao PDR is using a proprietary version of the system and its data storage; and system management and technical requirements are supported by Sustainable Solutions as per licensing agreements.

In 2018, Gavi developed target software standards[19] (TSS) for vaccine supply chain information systems, offering a framework for the design and implementation of digital solutions, and setting out guidelines as to how such systems should provide end to end visibility over the supply chain, as well as the necessary data analytics to support decision making.

Condition

The following gaps were noted in the design and configuration of *m*Supply, and concerns with respect to how it is currently operated:

Not all of the desired eLMIS functionalities are available: The *m*Supply system implemented in Lao PDR, does not meet six of the ten target software standards proposed by Gavi for a vaccine eLMIS (see annex 14). Specifically, it lacks integration capabilities for various modules such as Cold Chain Equipment (CCE) management, remote temperature monitoring, early warning systems, and distribution planning.

The number of user accounts is limited due to licensing costs: As at March 2024, there were only 16 licenses available (costing a total USD 55,000 per year) for the use of the whole country. The NIP estimates that the optimal number of user access accounts it requires totals 148 licenses (i.e., one license per district). However, each additional user license costs USD 2,400 per year, in effect increasing annual licencing fees to approximately USD 0.4 million.

Gaps in vaccine stock indicator tracking: *m*Supply is configured to perform a weekly data synchronisation with DHIS2. However, this process only updates a narrow subset of the dataset, specifically stock-on-hand, opening balances, and stock items expiring within 90-days. Unless a more comprehensive dataset is interfaced with DHIS2, it is not possible to analyse other indicators, such as wastage rate.

Recommendation 13

To optimise the use of *m*Supply, MoH/NIP should:

- conduct a feasibility study on the cost and implementation requirements of upgrading and rolling-out the next generation "open *m*Supply" and integrate additional core features as guided by GAVI's Target Software Standards (TSS).
- conduct a comprehensive needs assessment to identify the required skillset to manage systems at centrally. Subsequently the MoH/NIP should work with the provider - Sustainable Solutions - to develop and implement a plan for how to build the national personnel's capacity, so that they can acquire the necessary capabilities to fully take on the responsibility for managing mSupply.

[19] Gavi targeted software standards

No mSupply access at health facility level data, potentially impacting data quality: As at March 2024, *m*Supply was only deployed down to district level, i.e. excluding health facilities. Hence there was no digital visibility over what stock was held at the last subsidiary level of the supply chain. As demonstrated by the audit team's review, the facilities' reliance on manual stock records which could result in inaccuracies in the data.

mSupply succession planning gaps: The audit team noted lapses in the CVS' management of mSupply user accounts. For example, in March 2024 the staff member responsible for CVS stock updates resigned and left the CVS. But his user account still remained active for three months after he had left the organisation. The lapse in managing user accounts exposes *m*Supply to potential security breaches or the risk of access by unauthorised individuals, potentially compromising the integrity of the data.

Data inconsistencies between parallel CVS systems impacting decision support: The audit team compared closing vaccine balances between *m*Supply to and VSSM on 15 March 2024. The comparison revealed that none of the vaccine balances matched when compared to the other parallel system, as per the detail illustrated in table below.

Table 7: Comparison of vaccine balance data (in doses) between VSSM vs. mSupply.

#	Vaccine type	VSSM (a)	*m*Supply (b)	Variance = (a) – (b)
1	BCG 20 doses	381,000	372,000	9,000
2	HepB	127,829	128,429	(600)
3	OPV 10 doses	247,500	248,100	(600)
4	IPV 5 doses	73,460	73,500	(40)
5	Penta	121,650	118,750	2,900
6	PCV	14,460	14,800	(340)
7	MR 10, 5 doses	849,160	868,175	(19,015)

Root Cause

- Inconsistencies and delays in updating stock data in both systems (VSSM and *m*Supply).
- Although the national digital strategy 2023-2027, recommends setting up a digital atlas, to guide the selection and implementation of digital solutions, this has not yet been implemented.
- High licensing costs related to providing access to *m*Supply

Management comments

See Annex 16: Detailed management responses

Risk / Impact / Implications

- Data inconsistencies across different immunisation systems.
- Risk to the continuity and sustainability of operating health systems due to dependencies on key staff, who could retire, depart or change affectation, and
- NIP staff capacity gaps remaining unaddressed.

Responsibility

See Annex 16: Detailed management responses

Deadline / Timetable

See Annex 16: Detailed management responses

4.4.2 Limitations of the vaccine supply stock management (VSSM) System

Context and Criteria

In 2010, NIP implemented its vaccine supply stock management system (VSSM) with UNICEF's support. The system is currently used as the CVS primary stock management tool. It is an open-source, desktop based application that uses the Microsoft Access platform, and currently the NIP is operating version 4.7 of the system, which includes modules such as: vaccine receipts, stock-on-hand, stock adjustments, dispatches, and basic reports.

In 2018, Gavi developed target software standards[20] (TSS) for vaccine supply chain information systems, offering a framework for the design and implementation of digital solutions, for how they should provide end to end visibility over the supply chain, as well as data analytics to support decision making.

In 2023, the MoH developed its digital health strategy (2023-2027), to provide strategic direction over any digital investments or solutions deployed under the Ministry[21].

Condition

The audit team noted the following gaps:

Use of outdated software: The CVS' VSSM, uses Microsoft Access platform version 4.7, which is an outdated version of the software. This might increase the system's vulnerability to security threats, and impact how it operates. A newer web-based version of VSSM exists. The audit team noted that the NIP did not explore more up to date solutions, to get an improved functionality; and enhance data security, user access and reporting. This could have been done for example, by undertaking a comprehensive evaluation which considers all key stock management factors, to identify an optimal solution for vaccine management. The evaluation should include assessing interoperability with other existing country systems, and the potential to scale up digital systems in the future.

No integration between VSSM and mSupply: The VSSM system is used for vaccine stock management at the central vaccine store. *m*Supply is used for vaccine stock management at three levels including: central, provinces and districts. However, VSSM and *m*Supply are not integrated, resulting in them operating in parallel at the CVS. Moreover, as reported in issue 4.3.3, both systems' datasets are not consistent.

VSSM design limitations preventing effective report generation, data analysis and validation: The audit team noted the following operational limitations in VSSM:

- The system is unable to separate non-viable (i.e. stock that is expired or condemned) from viable stock. Thus, expired commodities and non-usable stock with less than 2 weeks shelf life, remained in VSSM's records, and were not segregated from the listing of available stock.

Recommendation 14

To optimise the use of VSSM, MoH/NIP should:

- explore more up to date solutions, that can offer improved functionality; and enhance data security, user access and reporting. This could be done for example, by undertaking a comprehensive evaluation which considers all key stock management factors, to identify an optimal solution for vaccine management.
- include interoperability with other existing country systems, and the potential to scale up digital systems in the future as part of the assessment.

[20] Gavi targeted software standards

[21] LAO PDR digital Health Strategy 2023- 2027

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- VSSM' data analytic functionalities are limited: The report module does not facilitate the exportation of data in usable formats such as CSV and excel, for further analysis.
- Inadequate validation mechanisms on data entry forms: - The data validation checks accept entry of duplicate records that compromise the integrity and reliability of the stock record in VSSM.
- Suboptimal backup processes of VSSM data: There is only one desktop operating the VSSM application, and the primary data is backed up on the same machine and using portable USB drives. The audit team observed that these backups were undertaken irregularly and infrequently. Additionally, the desktop used unlicensed software, potentially exposing VSSM to the risk of core data being compromised or a security breach occurring. There was no also immediate contingency if the hardware was damaged.

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Root Cause

- Design limitations in VSSM, adversely impacting other systems, including integration restrictions.
- Limited technical oversight over VSSM.

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Management comments

See Annex 16: Detailed management responses

</td></tr>
<tr><td>

Risk / Impact / Implications

- Exposure to data being compromised or loss, in case of failure of the VSSM hardware.
- Reduced operational efficiency.
- Inability in tracking quarantined stock adequately, due to VSSM being unable to properly distinguish between viable and non-viable stock.

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Responsibility

See Annex 16: Detailed management responses

</td><td>

Deadline / Timetable

See Annex 16: Detailed management responses

</td></tr>
</table>

4.4.3 Design and sustainability limitations impacting operating effectiveness of Electronic Immunisation Register (EIR) and DHIS2

Context and Criteria

Since 2015, the MoH, through its department of planning and finance, has been using DHIS2. It is an open-source health management information system, which aggregates the collection of various health indicators (e.g. for HIV, malaria, TB, family planning, and immunisation) across decentralised health units, by directly collecting data from service delivery points practitioners. The system facilitates generating scalable analytics and reporting across multiple levels, including central, provincial, district, and facility. It can be customised for each country, as is the case for Lao PDR. The system continues to receive technical support from HISP Vietnam.

The generic DHIS2 platform includes an electronic immunisation register (EIR) module, which Lao PDR deployed in 2021 to track its COVID-19 vaccinations. In 2023, the country further adopted the EIR by extending it to track its routine immunisation target population. The EIR functionality encompasses: recording vaccinations, appointment scheduling, and reporting. The EIR is operational across the whole country, all the way down to subsidiary local health facilities.

Condition

Capacity gaps in managing both the EIR and DHIS2 systems: As at March 2024, for both the DHIS2 and EIR, the systems upgrades and customisations are managed by an external entity, named HISP Vietnam. This is because it was deemed that neither the department of planning and finance nor the NIP, have the necessary capacity or skillset, to provide the level of technical support required by these two systems.

The EIR cannot be operated without internet: The EIR system does not operate without an active internet connection, i.e. there is no standalone modality, that users can temporarily use while offline. This could be a disincentive to using the system, particularly where internet connections are not stable or not reliable, or where there are additional costs to accessing the internet.

The EIR does not comply with Lao PDR's Electronic Data Protection Act (2017) in respect of personally identifiable information (PII): The data protection act requires that subjects (being any individual person who can be directly or indirectly identified by their name, ID, location, or personal physical attributes) are informed of their data rights. However, the EIR tracker did not inform or request consent for the purposes of PII data collection, nor did it include a privacy policy, or terms of use statement.

Use of outdated DHIS2 platform versions: In March 2024, the MoH was operating out of date DHIS2 software – namely version 2.36 which is no longer supported since December 2022, instead of the current version 4.0. Using old versions increases the risk of security vulnerabilities, and potentially reduces DHIS2's compatibility with new systems.

Challenges in DHIS2 report generation: The process of generating the consolidated EPI coverage reports involves multiple steps due to limitations in the DHIS2 system. This is because in order to generate a country-wide coverage report for a particular vaccine, the necessary data elements, including details on the vaccine, province, and district, must be downloaded by each

Recommendation 15

To optimise the use of electronic immunisation, register module and the wider DHIS2 system, the MoH/NIP should:

- conduct a comprehensive needs assessment to identify the required skillset to manage these systems centrally. Subsequently the MoH/NIP should work with the provider HISP Vietnam, to develop and implement a plan for how to build the national personnel's capacity, so that they can acquire the necessary capabilities to fully take on the responsibility for managing the entire systems technical upgrades and support components.

<table>
<tr><td colspan="2">individual district. As a consequence, it was necessary to download 148 separate reports (one for each district), so that this data could be manually aggregated (typically using Excel), in order to create a consolidated national-level report. The audit team deemed the current approach of consolidating district-level vaccine data into a customised, aggregated report, is a time-consuming process which is prone to human error.</td><td></td></tr>
<tr><td>Root Cause
• No terms of reference for the EIR development and roll out team that specify the requirements and deliverables of the system.
• The NIP's supportive supervision checklist did not include component on how to check and review the accuracy and validity for how a health facility's immunisation information data is recorded and managed.</td><td colspan="2">Management comments

See Annex 16: Detailed management responses</td></tr>
<tr><td>Risk / Impact / Implications
• Disincentive or constrained operability of the EIR in areas of poor internet connectivity, as there is no offline modality.
• DHIS2 report generation was inefficient, due to the requirement of a multi-step manual process of aggregating the data.
• Compatibility issues or security vulnerabilities, due to use of outdated software versions.</td><td>Responsibility

See Annex 16: Detailed management responses</td><td>Deadline / Timetable

See Annex 16: Detailed management responses</td></tr>
</table>

4.5 Immunisation data management

4.5.1 Inconsistencies in administrative coverage and use of an outdated denominator

Context and Criteria

The Gavi HSS and new vaccine support (NVS) general guidelines (2015-2018), recommend that Gavi-supported countries ensure that their population projection of live births is consistent with external projections. Furthermore, the guidelines also recommend that countries should conduct a high quality, nationally representative household survey every five years.

PFA Clause No. 8 (d), requires that "all information that is provided to Gavi including its applications, progress reports, any supporting documentation, and other related operational and financial information or reports, is accurate and correct as of the date of the provision of such information." In addition, the PFA (Annex 2, Article 16) also sets out additional provisions on monitoring and reporting, specifying that "the Government's use of Gavi's vaccine and cash support is subject to strict performance monitoring," such that: "Gavi seeks to use the Government's reports and existing country-level mechanisms to monitor performance."

Gavi's application guidelines require countries to improve the availability, quality and use of data, for their planning, programme management, and documentation of results. The guidelines encourage the routine use of immunisation coverage data as part of an established process for better planning, programme performance and the management of resources.

Condition

The denominator used for decision making is inaccurate: The Lao PDR Statistics Bureau (LSB) determines the immunisation target population denominator by applying a population growth rate to demographic data available from the most recent population census, last conducted in 2015. Although more recent data from micro plans and campaigns was also available, the audit team noted that this was not used to recalibrate these denominators. In addition, the LSB estimates only apply up to the district level, i.e., there were no disaggregated coverage estimates at HF and village levels. Consequently, there were variance between WUENIC and administrative data coverage. For example, the variance of the coverage data for Penta3 between WUENIC and administrative over the last 5 years has been more than 10% percentage points. See details in the table below.

Table 8 Variance of coverage data between WUENIC and administrative (Penta3 and MCV1)

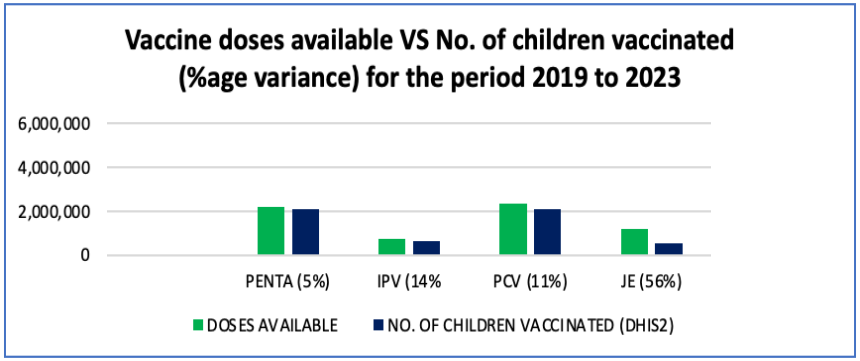
	Penta3			MCV1		
Year	Administrative coverage (DHIS2)	Estimated coverage (WEUNIC)	% points difference	Administrative coverage (DHIS2)	Estimated coverage (WEUNIC)	% points difference
2019	92.5	80	12.5	88.9	83	5.9
2020	90.4	79	11.4	85.3	79	6.3
2021	86.7	75	11.7	79.1	73	6.1
2022	92.2	80	12.2	81.6	76	5.6

Anomalies in reported administrative coverage: The audit team also noted inconsistencies in the administrative coverage data compared to the total number of doses distributed by the CVS, based on an analytical review contrasting both sources, given that they are correlated. This analysis demonstrated that for several vaccines, a significantly higher number of doses was reported as used, when compared to the lower number of children reported as vaccinated. For example, for the JE vaccine, 1.2 million doses were used and only 533,000 children reported as vaccinated, a 56% variance. In computing its analysis, the audit team adjusted the number of doses distributed by applying the WHO recommended wastage rates, which in effect reduced the number of doses available.

Recommendation 16

To ensure accurate and reliable immunisation data is available for decision making, the MOH/NIP should:

- review the denominator with the support of partners.
- routinely triangulate available data, including an assessment of the administrative coverage data and the number of doses available or consumed to validate data accuracy and that the correlation of data sources is credible. Such analyses should be undertaken at both the national and the subnational levels and any inconsistencies identified should be followed up and explained further.
- set up coordination mechanisms for the data and M&E technical working groups to guide the development, review and implementation of data management policies and guidelines.
- develop and implement the NIP data and immunisation coverage management policy.
- operationalise and monitor the status of implementation of the DQIP.
- develop and operationalise pre-and post-training assessments.



Further, variances were also noted at provincial level as well. See graphs below.

- recruit a replacement for the data management officer at PMU.

Root Cause

- Weaknesses in governance and oversight structures due to inadequate structures to support policy making and data reviews. While the data and monitoring and evaluation (M&E) technical working group (coordination framework for all immunisation M&E actors) was established in Feb 2019, there was no evidence that the data and M&E TWG was meeting during the period 2019 – 2023.
- Although there are more frequent meetings as part of joint NIP and partners coordination mechanism, there was no specific agenda item discussed in data quality, this impedes the country's ability to handle data management issues post-translation.
- Weaknesses in design and implementation of the DQIP. The country's most recent DQIP was done in 2019. However, its design was inadequate, as its activities were not fully detailed or prioritised by rank, the resources required to operationalise the plan were not costed out, and no monitoring framework was incorporated into the DQIP with clear indicators, targets and milestones, to facilitate the subsequent follow up and review of what progress was achieved in implementing the plan.
- There is no up to date data management standard operating procedure (SoP) as the only version dates from 2018, is in draft, and was never finalised or rolled out. In effect, this draft is now out of date given the recent developments and changes including the addition of an EIR and updates to various immunisation tools.
- Monitoring, training and supervision of staff at the health facility level was conducted only in 4 out of 18 HFs visited. Corrective actions arising from the monitoring/ supervision visits were not properly ~~monitored or~~ followed up.

Management comments

See Annex 16: Detailed management responses

Risk / Impact / Implications

- Use of inaccurate target population denominators may result in inaccurate administrative coverage data which is non-compliant with the terms of the signed PFA and may undermine the confidence in the reported administrative coverage data.
- Unreliable data on immunisation coverage estimates, compromises the ability of the immunisation programme's staff to identify under immunised and un-immunised children.

Responsibility

See Annex 16: Detailed management responses

Deadline / Timetable

See Annex 16: Detailed management responses

4.5.2 Weaknesses in data quality assurance mechanisms

Context and Criteria

PFA Clause. 8(d) requires that the Government represents to Gavi that "all information that is provided to Gavi including its applications, progress reports, any supporting documentation, and other related operational and financial information or reports, is accurate and correct as of the date of the provision of such information". In addition, PFA Annex 2, paragraph 16 sets out additional provisions on monitoring and reporting, specifying that "the Government's use of Gavi's vaccine and cash support is subject to strict performance monitoring," and that: "Gavi seeks to use the Government's reports and existing country-level mechanisms to monitor performance."

Furthermore, Gavi's grant application guidelines require also applicant countries to improve access to good quality immunisation data by (a) conducting annual desk reviews to monitor coverage data; (b) have routine mechanisms in place to independently assess the quality of administrative data. This includes possibility of using Gavi support to develop a plan to improve the quality of data over time; and (c) undertake regular population-based surveys to assess immunisation coverage.

It is expected that individual health and disease programmes will use the findings of a completed data quality review (DQR) to inform their respective detailed assessments of data quality and programme-specific information systems. The goal of the DQR is to contribute to the improvement of the quality of data used by countries for reviews of progress and performance – such as annual health sector reviews, programme planning, and monitoring and evaluation – in order to facilitate decision-making[22].

Condition

There were no data quality assurance processes in place at both the national and subnational levels: The audit team noted that there are no guidelines on how to undertake data quality reviews (DQR) at national or subnational levels. The scope of the DQR is to support routine, annual and periodic independent assessments of facility-reported data. Although the last DQR was completed in 2019 and covered 2 provinces, there was no subsequent data quality assessment (DQA) conducted during 2020 to 2023. In addition, there was weak supervision and monitoring over data aspects at subnational levels. Furthermore, there was no evidence for the conduct of DQA at 6 out of 6 PHOs, 7 out of 9 DHOs and 17 out of 18HFs visited by the audit team. There was also no evidence of data reviews done at 14 out of 18 HFs visited. The EPI review conducted in 2023 identified poor data verification as a key issue that the programme needs to address.

Recommendation 17

To improve data availability, quality and use, MoH/NIP should:

- routinely review and follow up significant data anomalies including any arising from data quality reviews and investigate unexplained variances/ root causes.
- design and implement a new data quality improvement plan.
- develop a monitoring and supervision plan that covers all facilities over a period. Supervisors should ensure that any corrective actions identified, are followed-up during subsequent visits.
- training evaluations should be conducted regularly to determine the impact of training. Trainings should also be based on a training needs assessment to ensure gaps are identified before sessions are designed.

Root Cause

- Weaknesses in the design and implementation of the data quality improvement plan (refer to 4.5.1 above)
- Gaps in data management policy and implementation guidelines. There is no current data management SoP. The draft SoP from 2019 was never finalised/rolled out. Additionally, the draft is now outdated given the ongoing developments in EIR and related tools.

Management comments

See Annex 16: Detailed management responses

[22] Data quality review - framework and metrics

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- Corrective actions were not monitored or followed up.
- Classroom trainings at subnational levels have not resulted in on-job improvements. While training was budgeted and implemented, at the cost of (over $65,000) in 2022 to 2023, there was no monitoring or measurement of impact of training. For the period 2024 to 2025, approximately USD 1 million was allocated for training. Value from future trainings may not be obtained.

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Risk / Impact / Implications

- Data quality priority areas may not be promptly addressed or followed up, which could lead to inaccurate, incomplete, inconsistent, and unreliable immunisation data.
- Failing to implement necessary priority data quality activities, affects the quality of immunisation results and management's ability to provide overall direction and guidance to the programme.
- Without good quality DQAs, In Vitro Diagnostics is unable to demonstrate improvements in the quality of its coverage data.

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Responsibility

See Annex 16: Detailed management responses

</td><td>

Deadline / Timetable

See Annex 16: Detailed management responses

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5. Annexes

Annex 1 : Acronyms.

AEFI	Adverse Events Following Immunisation
AZ	Astra Zeneca
BCG	Bacillus Calmette Guerin
COVID-19	COVID-19
CCE	Cold Chain Equipment
CCEOP	Cold chain equipment optimisation plan
CDC	Centre for Disease Control
CDS	Covid 19 Delivery Support
COSO	Committee of Sponsoring Organisations of the Treadway Committee
COVAX	Covid 19 Vaccine Global Access
CVS	County Vaccine Store
DG	Director General
DHIS2	District Health Information System
DQA	Data Quality assessment
DQIP	Data Quality improvement plan
DTP	Diphtheria, Tetanus, Pertussis
EAW	Early Access Window
EPI	Expanded Programme for Immunisation
EVM	Effective Vaccine Management
FAR	Fixed Asset Register
FPP	Full Portfolio Planning
FY	Financial Year
GBP	Great Britain Pound
GDP	Gross Domestic Product
GF	Global fund
GMR	Grant Management Requirement
HCW	Health Care Worker
HF	Health Facility
HIV	Human Immunodeficiency Virus
HMIS	Health Management Information System
HPV	Human Papillomavirus
HR	Human resources
HSS	Health Sector Strengthening
HSSP	Health Sector Strengthening Plan
HSWG	Health Sector Working Group
ICC	Interagency Coordination Committee
IP	Implementing Partner
IPV	Inactivated poliovirus Vaccine
iSC	Immunisation Supply Chain
ISS	Integrated support Supervision
JAR	Joint Annual Review
LMIS	Logistic Management Information System
MCV	Meningococcal Vaccine
MR	Measles Rubella
MYP	Multi Year Plan
NDVP	National Deployment Vaccine Plan
NGO	Non-Governmental Organisation

NVS	National Vaccine Store
OPV	Oral Polio Vaccine
PCA	Programme Capacity Assessment
PEF	Partnership Engagement Framework
PFA	Partnership Framework Agreement
PIRI	Periodic Intensification of Routine Immunisation
RI	Routine Immunisation
SARA	Service Availability and Readiness Assessment
SARS	Severe Acute Respiratory Syndrome
SDG	Sustainable Development Goals
SDP	Service Delivery Points
SIA	Supplementary Immunisation Activities
SOP	Standard operating procedures
SVS	State Vaccine Store
TA	Technical Assistance
TB	Tuberculosis
TCA	Targeted Country Assistance
TWG	Technical Working Group
UHC	Universal Health Coverage
UN	United Nations
UNICEF	United Nations Children Fund
USAID	United States Agency for International Development
USD	United States Dollar
VAR	Vaccine Arrival Report
VCB	Vaccine Control Book
VIG	Vaccine Introduction Grants
VVM	Vaccine Vial Monitor
WHO	World Health Organisation
WICR	Walk in Cold Room
WUENIC	WHO / UNICEF estimates of national immunisation coverage
YF	Yellow Fever

Annex 2 : Methodology.

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

The principles and details of the A&I's audit approach are described in its Board-approved terms of reference and audit manual, as well as 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. 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 Gavi Secretariat but also to the Programmes and activities carried out by Gavi's grant recipients and partners. More specifically, its scope encompasses the examination and evaluation of the adequacy and effectiveness of Gavi's governance, risk management processes, system of internal control, and the quality of performance in carrying out assigned responsibilities to achieve stated goals and objectives.

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

A. Overall audit opinion

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

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

B. Issue rating

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

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

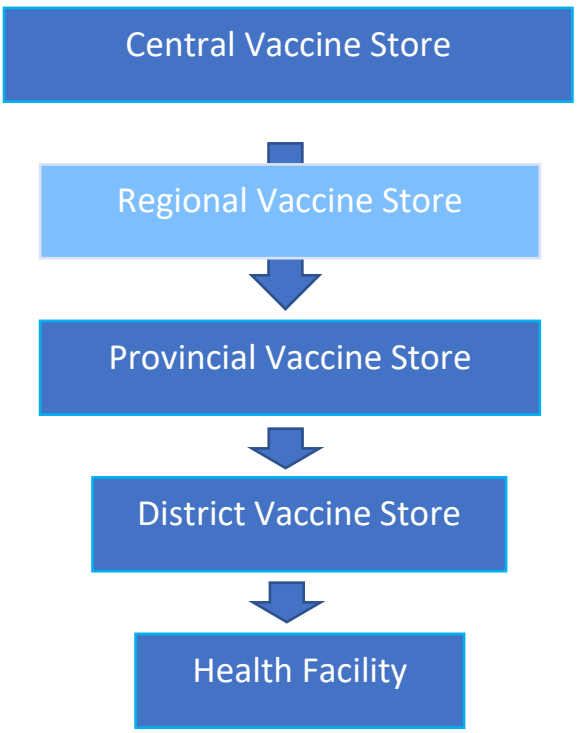
Annex 4 : List of Facilities Visited

Provinces – 6	Districts – 9 in total	Health Facilities and one district hospital – 18 sites in total
Oudomxay	Muang Xay, and Namor.	Konoy, Phon Hom, Nakham, Pangsa.
Champassak	Pakse, and Phonthong	Nonghai, Nonkoun, Bon Son, and Nonsavang.
Luang Prabang	Luang Prabang, and Xieng Ngeun	Pakseuang, Kokvane, Sankhalok, Thapan, Ber Sip, Saunluang, Kiewyar, and Nam Ming.
Bolikhamxai	Pakxan	Phon Ngam.
Khammouan	Thakhek	Dong Song.
Vientiane	Chantabouly	Chantabouly District Hospital.

Annex 5 : Immunisation schedule.

BCG	At birth
HepB	
OPV1	At 6 weeks or soon after
PCV1	
DTP HepB-Hib 1	
OPV 2	4 weeks after the 1st dose of the above vaccines
PCV 2	
DTP HepB-Hib 2	
OPV 3	4 weeks after the 2nd dose of the above vaccines
PCV 3	
IPV 1	
DTP HepB-Hib 3	
MR1	At 9-11 months
JE	
MR2	At 12-18 months
HPV	10-year old girls

Annex 6: Vaccines Process Flow



Annex 7: Inappropriate storage of dry supplies.

Dry supplies stored under open shade

Secondary package of needles & syringes directly exposed to external conditions

Viable dry supplies stored with expired vaccines

Annex 8: Variances in Physical Counts and Records

a) Variances between physical counts and batch cards at PVSs

	Pentavalent			IPV			PCV			MR			BCG		
Province Vaccine Store Name	Total Quantity Counted (a)	Quantity on Manual register/Stock card (b)	Variance in Quantities counted (a - b) - Penta	Total Quantity Counted (a)	Quantity on Manual register/Stock card (b)	Variance in Quantities counted (a - b) - IPV	Total Quantity Counted (a)	Quantity on Manual register/Stock card (b)	Variance in Quantities counted (a - b) - PCV	Total Quantity Counted (a)	Quantity on Manual register/Stock card (b)	Variance in Quantities counted (a - b) - MR	Total Quantity Counted (a)	Quantity on Manual register/Stock card (b)	Variance in Quantities counted (a - b) - BCG
Champassak	5,876	194	5,682	1,205	0	1,205	4,352	208	4,144	2,780	425	2,355	580	7,700	-7,120
Luang Prabang	6,656	6,642	14	3,000	2,345	655	9,836	9,716	120	9,950	7,554	2,396	8,840	9,820	-980
Oudomxay	12,500	12,500	0	5,300	5,300	0	8,000	8,000	0	4,500	4,500	0	13,000	13,000	0
Bolikhamxai	11,172	5,042	6,130	1,110	1,140	-30	3,600		3,600	5,600	4,600	1,000	3,400	3,400	0
Vientiane Capital	5,930	6,690	-760	4,200	4,200	0	9,200	6,250	2,950	5,050	4,100	950	9,600	10,500	-900
Khammouan	32,064	31,032	1,032	1,120	1,220	-100	5,800	5,800	0	6,320	6,320	0	4,820	4,800	20

b) Variances between Physical Counts and *m*Supply at PVS

	Pentavalent			IPV			PCV			MR			BCG		
Province Vaccine Store Name	Total Quantity Counted (a)	Quantity recorded in mSupply (C)	Variance in Quantities counted (b - c) - Penta - mSupply	Total Quantity Counted (a)	Quantity recorded in mSupply (C)	Variance in Quantities counted (b - c) - IPV - mSupply	Total Quantity Counted (a)	Quantity recorded in mSupply (C)	Variance in Quantities counted (b - c) - PCV - mSupply	Total Quantity Counted (a)	Quantity recorded in mSupply (C)	Variance in Quantities counted (b - c) - MR - mSupply	Total Quantity Counted (a)	Quantity recorded in mSupply (C)	Variance in Quantities counted (b - c) - BCG - mSupply
Champassak	5876		5876	1205		1205	4352		4352	2780		2780	580		580
Luong Prabang	6656		6656	3000		3000	9836		9836	9950		9950	8840		8840
Oudomxay	12500	9712	2788	5300	2195	3105	8000	8000	0	4500	8750	-4250	13000	5000	8000
Bolikhamxai	11,172	0	11172	1,110	0	1110	3,600	0	3600	5,600	0	5600	3,400	0	3400
Vientiane Capital	5930		5930	4200		4200	9200		9200	5050		5050	9600		9600
Khammouan	32,064	0	32064	1,120	0	1120	5,800	0	5800	6,320	0	6320	4,820	0	4820

c) Variances between Physical Counts and Batch Card at DVS

	Pentavalent			IPV			PCV			MR			BCG		
District Name	Total Quantity Counted (a)	Quantity on Batch card (b)	Variance in Quantities counted (a - b)	Total Quantity Counted (a)	Quantity on Batch card (b)	Variance in Quantities counted (a - b)	Total Quantity Counted (a)	Quantity on Batch card (b)	Variance in Quantities counted (a - b)	Total Quantity Counted (a)	Quantity on Batch card (b)	Variance in Quantities counted (a - b)	Total Quantity Counted (a)	Quantity on Batch card (b)	Variance in Quantities counted (a - b)
Pakse	363	356	7	160	75	85	420	516	-96	275	190	85	520	580	-60
Luang Prabang	354	927	-573	105	265	-160	380	450	-70	650	615	35	480	560	-80
Paksan District	363	374	-11	300	295	5	284	288	-4	850	850	0	2,080	2,080	0
Muang Xai	1,061	1,060	1	290	290	0	1,188	1,164	24	550	555	-5	1,780	1,780	0
Phonthong	435	435	0	95	95	0	124	124	0	330	330	0	820	940	-120
Chantabouly	234		234	335		335	276		276	200		200	300		300
Namor	225	573	-348	880	465	415	604	694	-90	1,760	1,650	110	640	960	-320
Xieng Ngeun	20	0	20	355	440	-85	88	112	-24	750	355	395	600	710	-110
Thakhek District	96	166	-70	155	170	-15	204	284	-80	305	315	-10	320	320	0

d) Variances between Physical Counts and *m*Supply at DVS

	Pentavalent			IPV			PCV			MR			BCG		
District Name	Total Quantity Counted (a)	Quantity in mSupply (c)	Variance in Quantities counted (b - c)	Total Quantity Counted (a)	Quantity in mSupply (c)	Variance in Quantities counted (b - c)	Total Quantity Counted (a)	Quantity in mSupply (c)	Variance in Quantities counted (b - c)	Total Quantity Counted (a)	Quantity in mSupply(c)	Variance in Quantities counted (b - c)	Total Quantity Counted (a)	Quantity in mSupply (c)	Variance in Quantities counted (b - c) - BCG
Pakse	363	441	-78	160	215	-55	420	516	-96	275	400	-125	520	580	-60
Luang Prabang	354	0	354	105	0	105	380	0	380	650	0	650	480	0	480
Paksan District	363	0	363	300	0	300	284	0	284	850	0	850	2080	0	2080
Muang Xai	1,061	1076	-15	290	305	-15	1188	1220	-32	550	595	-45	1780	1960	-180
Phonthong	435	15	420	95	95	0	124	140	-16	330	345	-15	820	940	-120
Chantabouly	234	220	14	335	320	15	276	280	-4	200	225	-25	300	300	0
Namor	225		225	880		880	604		604	1760		1760	640		640
Xieng Ngeun	20	240	-220	355	440	-85	88	128	-40	750	355	395	600	700	-100
Thakhek District	96	0	96	155	0	155	204	0	204	305	0	305	320	0	320

e) Variances between Physical Counts and Batch Card at Health Facility

	Pentavalent			IPV			PCV			MR			BCG		
Health Facility	Total Quantity Counted (a)	Quantity on Batch Card (b)	Variance in Quantities counted (a - b)	Total Quantity Counted (a)	Quantity on Batch Card (b)	Variance in Quantities counted (a - b)	Total Quantity Counted (a)	Quantity on Batch Card (b)	Variance in Quantities counted (a - b)	Total Quantity Counted (a)	Quantity on Batch Card (b)	Variance in Quantities counted (a - b)	Total Quantity Counted (a)	Quantity on Batch Card (b)	Variance in Quantities counted (a - b)
Bon Song HF	35	37	-2	35	40	-5	12	9	3	40	40	0	80	80	0
Sankhalok Health Centre	20	21	-1	40	42	-2	12	15	-3	15	25	-10	40	40	0
Thapan Health Centre	13	13	0	0	0	0	20	20	0	25	25	0	60	60	0
Phon ngam HF			0	15	15	0	8	4	4	65	65	0	60	60	0
Nonsavang	43	45	-2	45	53	-8	40	53	-13	90	95	-5	80	100	-20
Kokvane Health Centre	59	59	0	70	70	0	68	70	-2	45	45	0	240	240	0
Konoy Health Center	15	16	-1	10	10	0	4	10	-6	75	60	15	120	180	-60
Pakseuang Health Centre	17	17	0	20	20	0	16	25	-9	30	30	0	140	140	0
Phon Hom HF	6	7	-1	45	45	0	48	52	-4	10	10	0	40	40	0
Nonkoun	18	18	0	5	5	0			0			0	20	20	0
Nongghai	9	9	0	15	17	-2	0	0	0	20	25	-5	80	60	20
Nakham	39	41	-2	55	55	0	48	48	0	50	50	0	120	120	0
Ber Sip Health Centre	2	0	2	30	0	30	6	0	6	10	0	10	80	0	80
Suanluang Health Centre	38	43	-5	35	64	-29	12	39	-27	10	35	-25	140	180	-40
Pangsa	34	55	-21	55	65	-10	32	44	-12	45	85	-40	120	140	-20
Kiewyar Health centre	18	18	0	30	60	-30	12	23	-11	15	45	-30	60	60	0
Nam Ming Health Centre	21	21	0	40	40	0	16	16	0	35	35	0	100	100	0
Dongsong Health Facility	11	13	-2	5	5	0	4	8	-4	5	5	0	20	20	0

Annex 9: Variation between Closing and Opening Balances at DVS

	Pentavalent			IPV			PCV			MR			BCG		
District Name	Closing Balance as at 31 Dec 2022 (a)	Opening Balance at 1 Jan 2023 (b)	Variances in Opening Balances (a - b)	Closing Balance as at 31 Dec 2022 (a)	Opening Balance at 1 Jan 2023 (b)	Variances in Opening Balances (a - b)	Closing Balance as at 31 Dec 2022 (a)	Opening Balance at 1 Jan 2023 (b)	Variances in Opening Balances (a - b)	Closing Balance as at 31 Dec 2022 (a)	Opening Balance at 1 Jan 2023 (b)	Variances in Opening Balances (a - b)	Closing Balance as at 31 Dec 2022 (a) - BCG	Opening Balance at 1 Jan 2023 (b)	Variances in Opening Balances (a - b)
Pakse	450	450	0	0	0	0	0	0	0	0	0	0	560	560	0
Luang Prabang	569	0	569	530	0	530	865	0	865	375	0	375	1130	0	1130
Paksan District	187	187	0	250	250	0	68	68	0	700	700	0	740	740	0
Muang Xai	194	194	0	1250	1250	0	332	332	0	930	930	0	20	20	0
Chantabouly		95	-95		190	-190		272	-272		210	-210		80	-80
Namor	455	455	0	620	620	0	912	912	0	735	735	0	1700	1700	0
Thakhek District	356	500	-144	250	200	50	228	400	-172	440	495	-55	320	340	-20

Annex 10: Vaccine stockouts

a) Stockout of vaccines at DVS

	Pentavalent		IPV		PCV		MR		BCG	
District Name	Average No. of Days	Maximum No. of Days	Average No. of Days	Maximum No. of Days	Average No. of Days	Maximum No. of Days	Average No. of Days	Maximum No. of Days	Average No. of Days	Maximum No. of Days
Pakse	3	3						53	58	58
Muang Xai	13	21	8.4	14	18.5	32		36	14.6	29
Phonthong								38		
Namor			11.5	15	97	171	15	15	10.5	20

b) Stockout of vaccines at Health Facility

	Pentavalent		IPV		PCV		MR		BCG	
Health Facility Name	Average No. of Days	Maximum No. of Days	Average No. of Days	Maximum No. of Days	Average No. of Days	Maximum No. of Days	Average No. of Days	Maximum No. of Days	Average No. of Days	Maximum No. of Days
Sankhalok Health Centre	6	6							1	1
Phon Hom HF					10	10	20	20		
Nonkoun	29	29	32	49	16.5	27	21	40		
Nongghai							37	80		
Nakham							30	30		
Pangsa	26.5	33	20.6	26	30.2	53	16.5	41	41.6	68
Dongsong Health Facility			10	10	11	11				

Annex 11: Untraceable stock

a) Untraceable stock at PVS (dispatched from CVS to PVS)

Province vaccine store receiving:	Variance in Quantities - Pentavalent	Variance in Quantities – IPV	Variance in Quantities – PCV	Variance in Quantities – MR
Oudomxay	8,000	4,200	7,200	12,000

b) Untraceable stock at DVS (dispatched from PVS to DVS)

District vaccine store receiving:	Variance in Quantities - Pentavalent	Variance in Quantities - IPV	Variance in Quantities - PCV	Variance in Quantities - MR
Pakse	0	300	0	0
Muang Xai	0	0	0	2,000
Namor	624	250	600	1,000

c) Untraceable stock at Health Facilities (dispatched from DVS to Health Facility)

Health facility store receiving:	Variance in Quantities - Pentavalent	Variance in Quantities – IPV	Variance in Quantities – PCV	Variance in Quantities – MR
Bon Song HF	0	0	0	50
Thapan Health Centre	10	10	12	3
Nonsavang	0		0	50
Kokvane Health Centre	12	25	20	0
Konoy Health Center	100	25	40	50
Phon Hom HF	0	0	0	50
Nonkoun	25	0	0	0
Nongghai	-41	0	0	0

Annex 12: Status of implementation recommendations

a) Implementation of GMRs

Requirement	Audit Teams status	Audit Teams Remarks
GOVERNANCE AND PROGRAMME MANAGEMENT		
Oversight on immunisation activities Ministry of Health (MoH) will ensure that the Interagency Coordinating Committee (ICC) is appropriately constituted to provide effective oversight and governance of activities funded by Gavi support. The Government will develop Terms of Reference (ToRs) for the ICC with clear requirements for the committee's membership, quorum, and items to include on a standing agenda, expectations for technical support and identification of the various channels for escalating the ICC's key proposals and recommendations, aligned where possible with Gavi's. Guidance on national coordination forums). In connection with this, the Government will be expected to do the following: - Review the ICC membership to ensure the inclusion of Gavi partners' representation as well as other relevant stakeholders (donors and civil society representatives); - Ensure that the relevant Technical Working Groups (TWGs) are constituted and meet regularly. TWGs should have the responsibility for follow up of the specific recommendations from the various reviews for example NIP Programme review, EVM, Data quality reviews. - Ensure the HSS Steering Committee (SC) meets at least quarterly to ensure oversight over Gavi-funded HSS activities and their integration into the countries HSS priorities. The SC shall consist of representatives from the MCH/EPI, Department for Health Promotion (DHP), Department of Finance (DoF), Department of Planning and International Cooperation (DPIC) and Gavi Alliance Partners; - Ensure through DPIC linkages with other HSS initiatives which could benefit NIP (e.g. computerized data management, mSupply roll-out) - Produce and file minutes of every meetings including action list of issues to be followed up.	Partially Implemented	Although the ICC ToRs were developed, the ICC meetings were infrequent. In addition, the TWG ToRs are still in draft form. Apart from the supply chain TWG, all the TWGs were not operational. Details are under finding 4.1.1.
Temporary Oversight Measures The following measures will apply in respect of Gavi-funded activities until further notification from Gavi: **Fiscal Agent** - The Government agrees and acknowledges to the introduction of a Fiscal Agent (FA) within NIP to conduct a variety of oversight, assurance and capacity building activities for all Gavi cash grants provided to GoL (except for procurement activities by UNICEF). These activities will cover a breadth of topics, including those detailed in this Annex, to ensure compliance with Gavi requirements - The recruitment of and payment for the services of the FA will be made by Gavi and the latter will report to Gavi - The NIP will facilitate the work of the FA by providing access to all the systems, documentation and personnel processing Gavi grants and will guarantee reasonable cooperation with the FA - Periodic reviews of the scope of work of the FA will be carried out by Gavi in order to determine any possible additional need or re-define the scope of the FA's mission **No objection basis** Following the results of the Gavi Programme Audit carried out in 2018, only essential and critical activities will be approved for Gavi support. A clear working plan and budget will be presented to Gavi for "no objection" on a quarterly basis in accordance with the management letter dated 19th December 2018. The "No objection basis" will be removed through formal Gavi communication once Gavi's Programme Audit reimbursement matters are satisfactorily resolved.	Implemented	GFA was contracted in 2018 as a Fiscal Agent (FA) to provide support to the National Immunisation Programme (NIP) unit of the Ministry of Health (MoH). The contract of the GFA ended at the end of November 2023 and Gavi appointed EY as the Assurance Providers starting on 1 November 2023.
Human Resources **Filling of vacant positions** The MoH will appoint or recruit staff to ensure established and Gavi funded positions within the NIP are properly and timely filled: - Dedicated EPI Manager - Finance Manager and responsible for Gavi grants - HSS Project Manager/Coordinator	Partially Implemented	Although all the three positions outlined in the GMR are filled, the position of the Programme Data Management Officer was vacant by the time of the audit. The deputy EPI programme manager position, the position in charge of the EPI operations was also vacant by the end of the audit after the expiration of the contract. We recommend that this deputy EPI manager position become a permanent position in the EPI team to ensure ongoing operations. In addition, the capacity building

Requirement	Audit Teams status	Audit Teams Remarks
MoH will clearly define the mandates of all Gavi funded positions and agree with Gavi on their TORs. **Capacity Development** MoH shall: - Ensure that staff responsible for accounting, data management and vaccine management are supported by a training needs assessment, appropriate capacity building and suitable onsite experience - Develop training plans for all capacity building activities identifying training target groups, training objectives, methods, materials, experts to be engaged, testing methods and documentation of training activities (attendance lists, group photos, test results) Ensure that supportive supervision at sub-national level is completed, action points raised and followed up at national and subnational levels with the aim of strengthening capacities of EPI staff through the country.		components including the training needs assessment have not been implemented.
BUDGETING AND FINANCIAL MANAGEMENT		
Budgeting for Gavi funding The MOH, in collaboration with the NIP will: - Liaise with the Ministry of Finance and ensure that Gavi funding (including in-kind funding of vaccines and related devices) is included in the government budgetary estimates, including, where necessary, supplementary budget estimates in line with Government Budget Preparation Guidelines - Ensure that estimates for co-financing requirements are included in the government budgets - Ensure that a consolidated NIP budget is formulated every year, which details all funding sources including national contributions; - Work with the Ministry of Finance to ensure that government contributions are received in a timely manner; and - Disseminate and thereafter review subsidiary budgets to the relevant NIP sub-national units, as well as holding them accountable with appropriate budget monitoring.	Implemented	CHAI supported the development of an annual EPI plan for 2023. The plan included all immunisation activities and all sources of funds. However, there were no such plans between 2019 and 2022 and by the time of the audit, the 2024 plan was not available. The Public Financial Management for Health Sector guideline was signed off by the MoH last year. The Ministry has started rolling out trainings at national level and subnational level.
Financial accounting and reporting **Financial accounting software** The MoH will ensure an appropriate accounting software is used for budgeting, management, reporting and asset management with respect to Gavi grants. This software will be paid for by and agreed with Gavi and configured to enable MoH/NIP to adhere to the Gavi Guidelines on Financial Management and Audit Requirements as well as provide for the appropriate segregation of duties and access associated with its setup and use. **Financial Reporting** The MOH will ensure that regular controls on financial management are carried out at the NIP to provide assurance of acceptable accounting and reporting and that the NIP: - submits financial reports to Gavi, based on the actual expenditures incurred across the Programme , in conjunction with a formal process of liquidating Programme advances provided to the sub-national level - confirms proper flow of financial information up from the sub-national level, in the form of financial reports from district to province, from province to the centre, and thereafter collation of this information at the central level, before submitting a consolidated financial report to Gavi - complies with the Gavi reporting timelines, and that its submissions consistently use the financial report template provided by Gavi - strengthens its internal controls supporting the preparation of financial reports to ensure that its submissions to Gavi are accurate and supported by adequate documentation (transaction listing and supporting documents) - ensures that supporting documents are obtained, reviewed and filed to provide appropriate audit trail. Additionally, the MOH will ensure that: - All expenditures are adequately supported using documents such as signed and dated minutes of meetings, attendance sheets, payment schedules for allowances and per diems, third party receipts and invoices, acknowledgement forms and activity reports; and - Payroll expenses charged to the Programme align with those positions approved and supported by Gavi.	Implemented	QuickBooks was installed and grants are audited on an annual basis

Requirement	Audit Teams status	Audit Teams Remarks
Standard Operating Procedures (SOP) and Documentation MoH will develop SOPs for grant specific financial and programmatic reporting to include a diagram showing fund and reporting flows, procedures for cash disbursement and reporting with exact roles and responsibilities, verification procedures for expenditures incurred, procedures for fixed assets registration and management, templates for budget monitoring and control, guidelines for supporting documentation of expenditure incurred, summary of procurement thresholds and procurement procedures with reference to Public Procurement rules and regulations, reference to per diem payments and travel costs guidelines of the MoH, terms of reference of key staff involved in implementation of the grant and terms of reference for the external audit.	Implemented	PMU developed the HSS financial management guidelines
Tax exemption MoH will ensure that the relevant exemptions from taxes and duties are obtained from the respective ministries, departments, and agencies in line with the provisions of the Partnership Framework Agreement dated January 2017.	Not implemented	Although, NIP/PMU has not yet received a tax exemption status, requests for tax waivers are made and granted by the ministry of finance on a case-by-case basis
Non-vaccine procurement Procurement of all cold chain equipment (CCE) including cold rooms, freezer rooms and other related vaccine store equipment; refrigerators, freezers; insulated cooling containers, temperature monitoring devices, cold chain accessories, spare parts for CCE; sharp disposal equipment will be conducted by UNICEF. MoH will be responsible to meet all costs related to in-country clearing and warehousing of all items procured through Gavi funds, including those procured through UNICEF. For any procurement other than that conducted through UNICEF, MoH will: - Ensure compliance with the national procurement manual and all related regulations so that all goods, works and services are procured in a transparent and competitive manner - Mandate that the NIP maintains an annual procurement plan for the assets it plans to purchase, including details such as the funding source - Review and approve procurements conducted by the NIP team for compliance before the payments processes are completed - Implement a controls process to ensure that national procurement guidelines are not circumvented. Gaps in compliance will be documented and signed off at a senior level to ensure accountability - Ensure that supplier contracts have relevant clauses relating to warranties and after-sale services and that these are invoked where necessary.	Implemented	
Asset Management MOH will: - Require that updated Fixed Assets Registers are maintained at both the central and sub-national levels. These registers will include at a minimum information such as: each item's purchase cost including a benchmark currency valuation; date of purchase; serial numbers; unique identifiers; location and condition. This will help to ensure that assets are tracked, managed and used for their designated purpose. - Require that physical asset verifications are conducted at least annually. Thereafter, the resultant details on all assets from the sub-national level will be collated and summarised in an overall consolidated master list that is maintained at the central level. Such regular verification exercises will ensure the existence and working condition of all assets is monitored, and moreover, this should feedback and inform the schedule of both the maintenance plan, as well as the timing of future replacement of assets, as informed by the procurement plan.	Partially Implemented	PMU requests provinces to submit a schedule of available assets in the provinces on an annual basis. Provinces submit these schedules after being signed by the provincial directors together with photos of the verified assets. In addition, the FAR was not complete.
Bank account and Funds Flow Modalities Gavi will disburse funds into the Gavi dedicated bank account at the Banque pour le Commerce Exterior Lao (BCEL) held in USD with the following details: - Account name: Gavi (EPI) - Account number: 010110100391105001 - Currency: USD - Bank name and address: Banque pour le Commerce Exterieur Lao Public - Swift code: COEBLALA	Implemented	

Requirement	Audit Teams status	Audit Teams Remarks
- Correspondent bank: Wells Fargo Bank N.A. The signatories on the account shall be the Director of Department for Health Promotion (DHP) and Director of NIP. The MOH and NIP will: - Maintain the funds in the USD account and transfer to the operational local currency account on a "need basis" to minimise foreign exchange risk - Regulate the bank signatory controls at central, province and district levels to ensure oversight and accountability, and that no payments are ever made without two signatories involved - Ensure that bank reconciliations are prepared on a monthly basis and fully matched to the detailed accounting records - Review reconciliations of cash at sub-national level on an annual basis to recorded expenditure		
VACCINE STOCK AND COLD CHAIN MANAGEMENT		
Vaccine and supply chain management MoH/NIP will: - Develop the National Vaccine Management Guidelines and SOPs for Vaccine and Cold Chain management or adopt the recommended WHO Vaccine and Cold Chain Management procedures and Stock Management guidelines - Develop the Guidelines for Monitoring Vaccine Wastage at National level for NIP managers - Operationalise the maintenance plan including specific guidelines on preventative and curative maintenance processes with defined roles and responsibilities at national and subnational levels - Review the functionality of the VSSM inventory management system and ensure that system gaps are addressed - Link capacity gaps at national and subnational levels to ensure that practical hands on training is delivered to the appropriate levels within the supply chain - Conduct regular supportive supervision that reviews he status of all recommended vaccine management and cold chain equipment repair processes - Continuously monitors the EVM improvement plan in a structural way through action plans, assigning responsible units and timelines - Schedule the next EVM assessment	Partially Implemented	
Vaccine Stock Management MoH/NIP will: - Ensure that vaccine stock movements are supported with documents e.g. Requisition vouchers, issue Vouchers and bin cards - Ensure that stock records and supporting documents have complete records and systematically filed - Document the minimum and maximum stock levels in the Guidelines and SOPs - Implement a system of recording and tracking vaccine batch numbers and expiry dates across the supply chain - Comply with the "Earliest Expiry, First Out (EEFO)" principle and document the evidence	Partially Implemented	
ASSURANCE		
External and internal audit arrangements **External Audit** Annual external audit of the Gavi grants will be outsourced to suitably qualified audit firm approved by the Auditor General and will be carried out using Terms of Reference (ToR) to be agreed in advance with Gavi. Five years rotation policy will be observed. Copies of audit reports, management letters and responses of the MoH in addressing previous audit findings will be submitted to Gavi. **Internal Audit** MoH will ensure that internal audits are performed annually to ensure timely risk deterrence and identification of controls weaknesses. **Following up on audit recommendations of external, internal and Gavi audits** The MOH will prepare a plan for monitoring the recommendations made by the external auditors, the internal auditors and the Gavi auditors, which will be updated on a regular basis. The MoH will be responsible for following up and implementing all audit recommendations, including those carried out by Gavi auditors.	Partially Implemented	By the time of the audit, the department of inspection had not issued any internal audit reports to MCH and/or NIP. In addition, during the audit planning mission, the department informed the audit team that IA reports could not be shared as these were internal. In addition, NIP does not a mechanism for tracking and following up of audit recommendations.
Insurance The MoH shall maintain where available at a reasonable cost, all risk property insurance on the programme assets (including	Not implemented	

Requirement	Audit Teams status	Audit Teams Remarks
vaccines and related supplies, vehicles, cold chain equipment, etc.) and comprehensive general liability insurance with financially sound and reputable insurance companies. Where no insurance is available at reasonable costs, the country may budget on national funds the replacement of programme assets in case of damage or loss. The MoH will share details on the cost and policy for any insurance cover obtained. The MoH will develop contingency plan in case of failure of vaccine warehousing at central and provincial levels.		

b) Implementation of Gavi Programme Audit Recommendations

Issue	Recommendation	Status	Remark
Absence of oversight body for the NIP	Finalization of comprehensive TORs for the ICC, with clear requirements for the committee's membership, quorum, and items to include on a standing agenda, expectations for technical support and identification of the various channels for escalating the ICC's key proposals and recommendations	Implemented	
	Ensuring that the relevant TWGs are constituted and meet regularly. TWGs should have the responsibility for follow up of the specific recommendations from the various reviews for example NIP Programme review, EVM, Data quality reviews etc.	Partially Implemented	
	Revitalize the HSS steering committee as required by the GMRs to ensure oversight over Gavi-funded HSS activities and their integration into the countries HSS priorities.	Not Implemented	The HSS Steering committee does not exist in the governance structures of the Programme
	Ensure that the technical, financial, and capacity building roles of the ICC are operationalized to address the challenges highlighted in this report.	Implemented	
Weaknesses in timeliness and effectiveness of external and internal audit assurance mechanisms	Ensure that TORs for external audits are well defined to include examination of internal controls on Gavi grants. These TORs should be agreed with Gavi as required by the GMRs. Audit reports should be submitted to Gavi annually in accordance with the PFA.	Implemented	
	Ensure that internal audits are performed annually to ensure timely risk deterrence and identification of controls weaknesses.	Not Implemented	
	Ensure that the ongoing internal audit is completed by providing outstanding documents to the department of inspection. Findings from this review should be used to strengthen internal controls in the NIP department.	Not Implemented	
Absence of leadership for NIP	The MOH should ensure that a dedicated, credible NIP manager is appointed as soon as possible, given this post's importance to the leadership of the management of NIP and activities, including addressing significant gaps and other critical areas identified.	Implemented	
Capacity challenges within the NIP	Ensure that key positions funded by Gavi are filled with qualified and competent staff;	Implemented	
	Staff responsible for accounting, data management and vaccine management are supported by a training needs assessment, appropriate capacity building and suitable onsite experience; and	Not Implemented	
	Ensure that supportive supervision is completed, action points raised and followed up at national and subnational levels.	Partially Implemented	There is no mechanism for following up of actions, etc
Ineffective oversight of Immunisation Data	Develop suitable guidelines and SOPs for managing immunisation data including roles and responsibilities for staff. These guidelines should be distributed at all levels to promote uniformity in data collection, collation, and reporting;	Not Implemented	
	Build data management capacity at the central and sub-national and conduct relevant staff training on the Guidelines and SOPs at the Central and sub-national levels.	Not Implemented	
	Establish the Data Technical Working Group of the ICC with robust terms of reference;	Not Implemented	
	Develop and implement annual data quality supportive supervision plan supported by analysis of data to address data inaccuracies and untimely reporting; and	Not Implemented	

Issue	Recommendation	Status	Remark
	Fully integrate the NIP reporting system into DHIS2 to eliminate parallel reporting system of NIP data and define the supply chain management key performance indicators in DHIS2.	Implemented	
Administrative coverage data quality anomalies – pentavalent and PCV	We recommend that the MOH routinely triangulates available data, including an assessment of administrative coverage data and vaccine availability / utilisation (like the one completed by the Audit Team) as a check for accuracy of data reported. Data anomalies noted should be included in the review of accuracy of vaccine stock and utilisation data and coverage data."	Partially Implemented	
Inadequate budget preparation and management processes	Ensure that a consolidated NIP budget is formulated every year, which details all funding sources including national contributions;	Implemented	NIP prepared the 2023 EPI workplan which includes all funding sources. This was developed together with the partners
	Ensure that government budget preparatory processes are complied with and completed on time;	Implemented	
	Work with the MoF to ensure that government contributions are received in a timely manner.	Implemented	
	Disseminate and thereafter review subsidiary budgets to the relevant NIP sub-national units, as well as holding them accountable with appropriate budget monitoring.	Implemented	
Inadequate financial reporting	Submit financial reports to Gavi, which are based on the actual expenditures incurred across the Programme, in conjunction with a formal process of liquidating programme advances provided to the sub-national level	Implemented	
	Confirm the proper flow of financial information up from the sub-national level, in the form of financial reports from district to province, then from province to the centre, and thereafter collation of this information at the central level, before submitting a consolidated financial report to Gavi;	Implemented	
	Comply with the Gavi reporting timelines, and that its submissions consistently use the financial report template provided;	Implemented	
	Strengthen internal controls supporting the preparation of financial reports to ensure that its submissions to Gavi are accurate and supported by adequate documentation (transaction listing and supporting documents).	Partially Implemented	
Inadequate banking and accounting records	Maintain one US$ bank account at the central level for the receipt of Gavi disbursements and payments of foreign currency:	Implemented	
	Regulate the bank signatory controls at central, province and district levels to ensure oversight and accountability, and that no payments are ever made without two signatories involved:	Implemented	
	Ensure that bank reconciliations are prepared monthly and fully matched to accounting records;	Implemented	
	Review reconciliations of cash at sub-national level on an annual basis to recorded expenditure;	Implemented	
	Ensure that a proper accounting system, supported by appropriate processes and adequate controls is put in place and maintained by the NIP. All recorded expenditure should be referenced to complete supporting documents.	Implemented	
Questioned expenditure.	All expenditures are adequately supported using documents like signed and dated minutes of meetings, attendance sheets, payment schedules for allowances and per diems, third party receipts and invoices, acknowledgement forms and activity reports	Implemented	
	Payroll expenses charged to the programme align with those positions approved and supported by Gavi; and	Implemented	
	Taxes are not charged as part of Gavi's funded expenditures, as per the PFA agreement	Implemented	
Non-compliance with the national procurement manual	Ensure compliance with the national procurement manual so that all goods, works and services are procured in a transparent and competitive manner. Procurements conducted by the NIP team should be reviewed and approved for compliance before the payments processes are completed;	Implemented	
	Ensure that supporting documents are obtained, reviewed and filed to provide appropriate audit trail.	Implemented	
Irregularities in the procurement processes	MOH implement a controls process to ensure that national procurement guidelines are not circumvented. Gaps in compliance should be documented and signed off at a senior level to ensure accountability.	Implemented	
Ineffective controls over Fixed Assets	Mandate that the NIP maintains an annual procurement plan for the assets it plans to purchase, including details such as the funding source;	Not Implemented	NIP does not maintain a procurement plan but follows the procurements as included in the approved budget

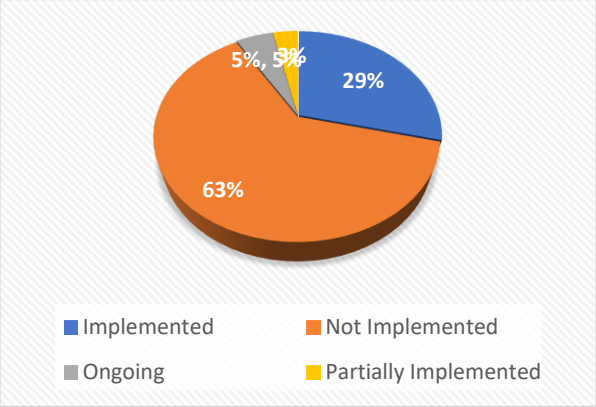
Issue	Recommendation	Status	Remark
	Require that updated fixed assets registers are maintained at both the central and sub-national levels. These registers should include pertinent information, such as: each item's purchase cost including a benchmark currency valuation; date of purchase; serial numbers; unique identifiers; location and condition.	Implemented	
	Require that physical asset verifications are conducted. Thereafter, the resultant details on all assets from the sub-national level should be collated and summarized in an overall consolidated master list that is maintained at the central level. Such regular verification exercises will ensure the existence and working condition of all assets is monitored, and moreover, this should feedback and inform the schedule of both the maintenance plan, as well as the timing of future replacement of assets, as informed by the procurement plan.	Partially Implemented	Although the NIP has not carried out a structured asset verification exercise, NIP requests provinces, to confirm the assets within their provinces. In addition, spot checks are also carried out during support supervision visits
Non-compliance with basic Vaccine Management Guidelines and Standard Operating Procedures	Develop the National Vaccine Management Guidelines and SOPs for Vaccine and Cold Chain management or adopt the recommended WHO Vaccine and Cold Chain Management procedures and Stock Management guidelines;	Not implemented	As at the time of the audit, National Vaccine Management Guidelines and SOPs for Vaccine and Cold Chain management were neither developed nor the WHO Vaccine and Cold Chain Management procedures and Stock Management guidelines adopted.
	Develop the Guidelines for Monitoring Vaccine Wastage at National level for NIP managers;	Not implemented	There were no guidelines for monitoring vaccine wastage.
	Operationalize the maintenance plan including specific guidelines on preventative and curative maintenance processes with defined roles and responsibilities at national and subnational levels;	Not implemented	There was no evidence of operationalising preventive and curative maintenance processes at national and sub national levels.
	Review the functionality of the VSSM inventory management system and ensure that system gaps are addressed;	Not implemented	There were notable gaps in VSSM for example the stock reports lacked key parameters like batch number and expiry dates of the respective commodities.
	Link capacity gaps at national and subnational levels to ensure that practical hands-on training is delivered to the appropriate levels within the supply chain;	Not implemented	No evidence that this activity was done
	Conduct regular supportive supervision that reviews the status of all recommended vaccine management and cold chain equipment repair processes	Not implemented	There was no evidence of vaccine management and cold chain management focused support supervision visits at all levels.
Weaknesses in stock management practices	Ensure that vaccine stock movements are supported with documents e.g. Requisition vouchers, issue Vouchers and bin cards.	Implemented	
	Ensure that stock records and supporting documents have complete records and systematically filed.	Partially implemented	Whereas its required to enter the stock receipts in batch cards, these were found incomplete at the sites visited.
	Document the minimum and maximum stock levels in the Guidelines and SOPs.	Not implemented	There is no document defining the minimum and maximum stock levels at all the vaccine handling points.
	Define a system of recording and tracking vaccine batch numbers and expiry dates across the supply chain.	Not implemented	Stock reports from VSSM at the CVS don't not indicate the batch numbers of the respective commodities. The situation is much worse at subnational level with incomplete batch cards
	Comply with the "Earliest Expiry, First Out (EEFO)" principle and document the evidence.	Implemented	This appears to be implemented basing on the visits to the vaccine storage points conducted by the audit team

Annex 14: GAVI Targeted Software Standards for VX eLMIS vs mSupply score

GAVI TSS Key Features	Description	Present in mSupply
Forecasting & Supply Planning	Configure and use calculations for ideal stock amounts (ISA) for supply planning.	No

Requisition and Issue	Stock requests and issues workflows	Yes
Orders & Receipts, Supplier Management	Order fulfilment and supplier management	Yes
Distribution management	Vaccine distribution & delivery management	No
Inventory Management	Inventory data and stock movements to provide an overview of full stock availability	Yes
CCE module	Track cold chain equipment inventory	No
Temperature Monitoring	Integration with RTM devices (fridge tags)	No
Analytics and Dashboards	Stock indicator dashboards available through google studio	No
Early warning alerts	Stock alarms	No
Interoperability	Integration with other systems	Yes

Annex 15: EVM cIP 2023-2026 status



Annex 16: Detailed management responses

Issues	Audit Recommendations	Management Action	Action Owner	Timelines
Governance and oversight mechanisms need to be strengthened	Recommendation 2 To strengthen governance and oversight, the MoH/NIP with support from partners should: • ensure that the RMNCH committee fully adheres to the RMNCH strategy to provide adequate	**Action 1** In the short-term, the existing oversight structures, ICC and its TWGs, the NITAG, and the joint NIP and partners coordination group will continue to fulfil the governance and oversight functions and responsibilities.	**Action 1** MCHC / RMNCAH Secretariat / NIP	**Action 1** April 2025

Issues	Audit Recommendations	Management Action	Action Owner	Timelines
	oversight over the NIP. This includes: (i) carrying out progress reviews against the RMNCH monitoring and evaluation framework, (ii) operationalising the immunisation subcommittee, and (iii) undertaking regular supervisions of the provincial RMNCH committees.	NIP is part of the Strategic Objective (SO) 4 sub-committee, and the progress of each SO and sub-committee (including NIP) has been reported in the RMNCAH Technical Working Group (TWG) meeting every quarter. Proper documentation will be maintained highlighting adequate oversight over the NIP. As part of endline evaluation of the RMNCAH Strategy 2021 -25 NIP and MCHC will support review of how the functions and performance of each sub-committee including SO 4. Regular review will be undertaken going forward as per the monitoring and evaluation framework to strengthen oversight and follow-up actions taken by each sub-committee based on the recommendations from the TWG meeting, including for immunisation activities. The collaboration within the SO4 sub-committee will also need to be strengthened, between MCHC (child promotion division) /NIP, the Nutrition Center to plan, operationalise and monitor SO4 activities through an integrated approach. The RMNCAH Sub-Committees and TWG at the sub-national level is supported by a sub-national coordinator and RMNCAH Secretariat. NIP (central and provincial levels) will work closely with the sub-national coordinator and RMNCAH Secretariat regularly monitoring and supervision of the implementation of immunisation activities at the provincial level.		
	• develop Terms of Reference to govern the "joint NIP and partner coordination committee" meetings and finalise and sign off all of the ICC's technical working groups Terms of References	**Action 2** NIP and partners will agree on terms of reference and frequency of meetings for NIP - partner coordination group, which will be led by NIP. MoH / NIP will undertake a review of the ToRs of the ICC's technical working groups and will finalise the same.	**Action 2** NIP	**Action 2** Q4- 2024
	• develop a coordination dashboard and an action item tracking system to track the implementation status and follow up of the ICC, partner coordination committee, NITAG and TWGs action points. This dashboard should indicate the action	**Action 3** The joint NIP - partner Annual Operational Plan will be finalised and visualised in a dashboard as described (draft existing). The dashboard will also include action points of ICC, NITAG, TWG and partner coordination meeting indicating the action owner and completion timeline. It will be and tracked regularly by a designated	**Action 3** NIP - Planning Unit with CHAI	**Action 3** Q4 - 2024

Issues	Audit Recommendations	Management Action	Action Owner	Timelines
	owner and completion timeframe, for the purposes of accountability. • ensure that all TWGs are actively involved in undertaking their technical work, so that the different roles are carried out as required. • where needed, ensure that complex, unresolved matters discussed at the joint NIP and partner coordination committee and TWGs are formally escalated to the ICC and RMNCH committee for further discussion and recommendation for decision making authorities.	focal point within NIP, for review and necessarily follow up will be undertaken with the concerned action owner. **Action 4** As above, the ToR of the TWGs would be reviewed and finalised including the role and responsibilities of the respective TWGs. Going forward proper documentation would be maintained for the activities, deliberations and decisions taken by the TWGs including the action points, action owner and items requiring strategic guidance from ICC. **Action 5** The ICC, RMNCAH Sub-Committees and TWGs are advisory not decision-making bodies vis a vis the MoH and Minister of Health. Delegations for decision making within MoH and Lao government structures (cabinet and Departments) are established in relevant policies and matters of concern formally escalated in accordance with these structures. Issues requiring strategic guidance are escalated to the ICC by NIP-partner coordination committee and TWG as needed. Proper documentation would be maintained. In the mid-term, the appropriate governance structures will be further discussed and determined in the nation immunisation strategy (NIS) development and formalised process.	**Action 4** NIP-Planning Unit with DPs support **Action 5** NIP and Partner support	**Action 4** Q4-2024 **Action 5** Q1-2025
Grant management	Recommendation 2 To enhance oversight and accountability over the status and implementation of actions or recommendations from the NIP's various reviews and assessments, the MoH/NIP should: • develop a tracking system at the NIP operational level. Thence, ensure that all recommendations	**Action 1** As noted above, review recommendations have and will continue to be incorporated and prioritised into annual	**Action 1** NIP	**Action 1** Q4 - 2024

Issues	Audit Recommendations	Management Action	Action Owner	Timelines
requirements (GMRs) and recommendations from various reviews are still outstanding	are captured in the system, assign a priority ranking to each of them (high, medium, low), and rationalise any recommendations which recur across various reviews, so that these are included in the system with one unique action owner responsible for closing the action, and use a suitable dashboard to facilitate the oversight and status mapping. • Include semi-annual status reporting on implementation at RMNCAH SO 4 sub-committee and be tabled at the ICC meetings; and share status updates with Gavi after endorsement from ICC. • review the EVM cIP 2023-2026 schedule, and prioritise, cost, and attach the activities to available funding sources and budget lines. Apply for reallocation of funds for critical activities that may not be attached to any budget line.	operational planning and budgeting of available resources (e.g., through Gavi FPP). The status of implementation of actions and recommendations would be monitored using AOP monitoring tool, however, specific tracking would be maintained for review of recommendations. **Action 2** Regular reporting being undertaken to under auspices of the RMNCAH SO 4 sub-committee, including immunisation components, will be tabled at ICC meetings and shared with Gavi in line with reporting requirements under the current and forthcoming RMNCAH strategies. **Action 3** EVM Assessment was conducted in Oct 2022 and Improvement plans were formulated and approved in April 2023. There was no budget to implement the EVM Improvement plans and therefore key activities were budgeted under FPP application. The actual implementation is expected to start once the funds are available hopefully from Q3/2024 onwards and will be monitored through TWG meetings.	**Action 2** MCHC/RMNCAH Secretariat / NIP **Action 3** NIP in liaison with UNICEF	**Action 2** Q3-2025 **Action 3** Q4-2025
Lack of a national immunisation strategy (NIS), and inadequate linkages or alignments within related health sector strategies	Recommendation 3 To ensure that the MoH (with NIP's support) exercises its ownership and accountability in overseeing and monitoring the linkages and alignments between existing strategic documents, it should: • develop a fully costed national immunisation strategy (NIS) in accordance with WHO's IA2030 guidance, which incorporates the seven strategic priorities and four core principles, and which extends across the national, subnational, and service delivery levels. • establish an accountability mechanism, to monitor and oversee the linkages and alignments across the health- sector's strategic plans.	**Action 1** An NIS will be developed starting in quarter 4 of 2024 and will be finalised in the quarter 1 of 2025, aligned to the current and forthcoming RMNCAH strategies and other relevant MoH strategies and policies. **Action 2** In development and implementation of the NIS, current and forthcoming RMNCAH Strategies, NIP and MCHC will seek to maximise linkages with health sector strategic plans and documents.	**Action 1** NIP / MCHC with DPs support **Action 2** NIP / MCHC	**Action 1** Q2- 2025 **Action 2** Q1 of 2025

Issues	Audit Recommendations	Management Action	Action Owner	Timelines
		However, it is beyond the remit of NIP / MCHC to establish new accountability mechanisms, noting sector wide mechanisms (e.g., health sector coordination committee under the Health Sector development Plan) already exists.		
Weaknesses in programme management and support supervision	Recommendation 4 To enhance the immunisation's programme management and performance, MoH/NIP should: • regularly review progress in implementing the AOP using the tracking and monitoring tool, and dashboard, to increase the rate of completion of planned activities and funds absorption to a higher level, and to accomplish the intended programme objectives, including capacity building support from partners. • ensure that the AOP and associated micro-plans include a detail cost breakdown, with clear cost drivers. In addition, the planned activities should be mapped out and linked to the required capacities and skillsets to avoid competing priorities for lean EPI staff (both at national and subnational level). • develop ToRs for supportive supervisions, and enforce the operationalisation of the supervision guidelines, for all such missions across all levels.	**Action 1** AOP tracking will also incorporate monitoring of activity implementation and funds absorption, including to support decision making by NIP / MCHC and partners of when / where / how to reallocate funds as needed to increase effective utilisation in achieving programme objectives. **Action 2** The recommendation is being implemented. Please note for Lao NIP and health sector, distinction between: (i) AOP - national level focused on strengthening activities administered largely by NIP, only includes only activities costed and funded, with responsible persons identified (ii) Microplans - developed from bottom up by health centre and districts to specific how, where and with whom services must be delivered to reach EPI and other targets across the country. It should be costed with clear roles and responsibilities identified. Work is ongoing with NIP and partners to strengthen both top down and bottom- up planning is prioritised and realistic within resource constraints, to ensure best results with resources (HR, finance) available. **Action 3** Supportive supervision guidelines already exist but are not fully utilised or when used, do not necessarily lead to discernible capacity building. Moving forward and as outlined in the FPP application, emphasis will be placed on coupling supportive supervision with a more intensive, repeated on-the-job training and coaching approach for priority districts and health centres, which has been shown to be more effective where already implemented compared to off-	**Action 1** NIP Planning Unit / EY **Action 2** NIP Planning Unit **Action 3** NIP- M&E unit with WHO & UNICEF support	**Action 1** Q4-2024 **Action 2** Q1 - 2025 **Action 3** Q1-2025

Issues	Audit Recommendations	Management Action	Action Owner	Timelines
		site and /or ad hoc supportive supervision visits alone. Implementation of this approach will be continually monitored for results including independent capacity of staff particularly at HF and district level to perform key EPI functions (service delivery, stock management, reporting etc). This approach has been included in the FPP application.		
	• establish a systematic mechanism to follow up on the implementation status of supportive supervision actions, including documenting, and assigning an owner to each task, along with the completion/due dates.	**Action 4** Feedback from supportive supervision and on-the-job training visits will be reported and analysed as part of ongoing monitoring and evaluation of the packages of support funded through the FPP, and AOP monitoring.	**Action 4** NIP – M&E Unit	**Action 4** Q2 of 2025
	• develop and operationalise an implementation action plan to address the 2023 EPI review recommendations.	**Action 5** Please see 02.1 above	**Action 5** NIP Planning Unit	**Action 5** Q4 - 2024
Inadequate tracking and monitoring on partners targeted country assistance (TCA) performance	Recommendation 5 To strengthen the coordination and monitoring of PEF/TCA performance, the MoH/NIP's management should coordinate intelligence-sharing with the implementing partners (i.e., core and expanded) on the implementation and outcome of TCA activities, by: • Using the existing NIP and partner coordination meetings, to review TCA performance regularly and assess progress of implementation against the approved workplan.	**Action 1** TCA activities have been and will continue to be incorporated and reported on during NIP - DP coordination meetings and in AOP tracking.	**Action 1** NIP Planning Unit	**Action 1** Q4 - 2024
	• Ensuring that the implementation status and performance of TCA activities, is quarterly reviewed by the ICC, in accordance with Gavi's PEF TCA guidance.	**Action 2** Please see 2.2 above. Also, Regular PEF TCA reporting from partners to Gavi will be tabled at ICC meetings for information, agenda and schedules permitting.	**Action 2** Partners	**Action 2** Q1-2025
	• Ensuring that the implementation of all Gavi-funded priorities which are allocated and executed by the partners, are subsequently reviewed and validated against a written status	**Action 3** Regular reporting on TCA in the PEC TCA portal will be validated by NIP / MCHC prior to submission, including	**Action 3** NIP / DPHE / Partners	**Action 3** Q1 - 2025

Issues	Audit Recommendations	Management Action	Action Owner	Timelines
	report documenting progress against the PEF TCA milestones.	using information from regular tracking of TCA funded activities under the joint NIP-DP AOP.		
Financial and programmatic challenges in the context of transition	Recommendation 6 To ensure the country's readiness for transition, MoH/NIP should: • develop a transition plan and roadmap that is linked to the future national immunisation strategy and national reform strategy, to direct the country's transition planning processes.	**Action 1** Planning (including staged transfer of key functions and costs from donors and DPs to NIP and MoH) for transition of NIP from Gavi funding will be incorporated into NIS development, and review of other relevant strategies.	**Action 1** NIP / MCHC	**Action 1** Q1 - 2025
	• continuously review the health sector workforce with the objective of: assessing capabilities, recruiting for new skillsets, and developing the capacity of existing HRH.	**Action 2** This is outside the remit of NIP but has been shared with the Department of Health Personnel and Education (DHPE) for information. The role of NIP will be coordinating with DHPE to obtain the skillset of required staff to fill the capacity gap of NIP.	**Action 2** NIP and DHPE	**Action 2** Q4 of 2025
	• review all the costs related to immunisation activities at the national and subnational levels, (including operational costs, vaccine co-financing and HR) against all available funding sources (government, partners, and donors) to identify what funding gaps exist and still need to be addressed.	**Action 3** This work is underway with support of partners (e.g., resource mapping indicated for TCA 2024-2025) and will be completed in order to inform the NIS.	**Action 3** NIP	**Action 3** Q1- 2025
	• through the ICC and RMNCH TWG, advocate for additional funds while maximising the impact from the existing funds available.	**Action 4** Advice will be sought on an ongoing basis from ICC and RMNCAH TWG on how best to advocate within Government of Lao PDR budgetary processes for additional funds and how to maximise health outcomes from existing funds, including through achieving savings and efficiencies.	**Action 4** NIP / MCHC	**Action 4** Q2 - 2025
	• have a dedicated team managing the transition plan with the view that the government takes more ownership and agree and establish a roles and responsibility matrix with partners.	**Action 5** Regarding day-to-day operations, division of responsibilities already exists and in the next phase of capacity building, in lead up to Gavi transition, dedicated "transition" plans will be developed and monitored to oversee the phased transfer of capacity in core functions	**Action 5** NIP	**Action 5** Q3-2025

Issues	Audit Recommendations	Management Action	Action Owner	Timelines
		from DPs / externally funded staff to NIP / GoL staff. Please refer to FPP application for further details.		
Partner led forecasting process could impact sustainability of the forecasting process	Recommendation 7 To improve the forecasting process and ensure its sustainability, the MoH/NIP should: • with UNICEF's support – identify and train focal persons within the national logistics team, to lead the vaccine forecasting process in collaboration with other stakeholders such as WHO. • develop SOPs/guidelines governing the forecasting of vaccines and supplies, which are tailored to the specific country context. • Through enrolling the help from the provincial and district health teams, enforce the use of the DHIS2 logistics module, with the objective of collecting accurate and complete data. • conduct regular forecast reviews and evaluations, to refine its forecasting assumptions, and carry these forwards to subsequent forecasts.	**Action 1** Recommendation is well accepted and will be implemented. UNICEF team will work on transition of knowledge and handover to ensure sustainability of forecasting process. **Action 2** The guidelines exist and will be reviewed and tailored specific to Laos. **Action 3** The decision to use appropriate tool for logistics is under review and discussions. No agreement/decision has been yet reached. This will can be part of agenda/discussion points for the data team to deliberate when they convene their TWG meeting. **Action 4** The forecasting assumptions were adjusted based on latest lead times in 2023. Similarly going forward, the forecasting assumptions will be reviewed appropriately.	**Action 1** MOH/NIP in liaison with UNICEF **Action 2** NIP in liaison with UNICEF **Action 3** MOH/NIP in liaison with WHO **Action 4** NIP in liaison with UNICEF	Action 1 Q4-2024 **Action 2** Q1 - 2025 **Action 3** Q1-2025 **Action 4** Q1-2025
Need to revitalise regional vaccine stores (RVSs) and adhere to	Recommendation 8 To fully operationalise the role of the Regional Vaccine Stores (RVSs), MoH/NIP should: • Undertake a supply chain optimisation study, and subsequently design a suitable cold chain infrastructure that achieves the objective of an efficient and effective stock holding and replenishment process, such that commodities and information flow in and out of the RVS', in support of the subnational stores within their catchment area.	**Action 1** The concept of RVS did not materialize due to challenges in vaccine management processes, warehousing mechanism, inventory tool, vaccine distribution, roles and responsibilities of MPSC/NIP/provincial staff, and funding. From supply chain optimization point of view- suitable cold chain infrastructure and vaccine stock holding, and replenishment will be reviewed and designed as per global standards. Yes, there is no distinction between PVS and RVS or we can say that no provincial level store functions as	**Action 1** MoH/NIP	**Action 1** Q1-2025

Issues	Audit Recommendations	Management Action	Action Owner	Timelines
good storage practices		regional vaccine store. However, there is a sufficient cold chain infrastructure to designate 5 cold chain hubs as regional vaccine stores. This was the idea behind installation of cold rooms and deployment of cold chain technicians at 5 provincial stores. However, the vaccine management is done through mSupply which is further managed by MPSC.		
	• clarify and reinforce the RVS' mandate, to ensure they can hold sufficient supplies to promptly replenish their catchment area. Establish and enforce suitable minimum and maximum stock holding thresholds and ensure these are respected; and • allocate sufficient resources, including the recruiting and/or assigning of designated staff to the RVS' to operate and manage their supply chain operations, including any expanded responsibilities.	**Action 2** Refer comment above **Action 3** Refer comment above	**Action 2** NIP **Action 3** NIP	**Action 2** Q1-2025 **Action 3** Q1-2025
	Recommendation 9 To free up storage space for dry supplies, the NIP should timely dispose (or destroy) all of its expired vaccines and immunisation supplies, in line with the national regulations governing the destruction of medical waste.	**Action 1** There is a need to free up storage space by disposing of expired vaccines and immunisation supplies in accordance with national regulations on routine basis. This recommendation will be implemented.	**Action 1** NIP/MOH	**Action 1** Q2-2025
Inventory management practices at national and subnational level need improvement	Recommendation 10 To ensure accurate recording in tracking the movement of CVS' vaccines and stocks, the MoH/NIP should: • ensure that all entries in the inventory management system/ stock include damaged and expired vaccines. • conduct periodic checks and reconcile the separate data sets maintained in *m*Supply and VSSM until it is determined which eLMIS system is confirmed as the primary source for maintaining the CVS' records.	**Action 1** This recommendation will be implemented. **Action 2** This recommendation will be implemented. **Action 3**	**Action 1** MoH/NIP **Action 2** MoH/NIP **Action 3** MOH/NIP	**Action 1** Q4-2024 **Action 2** Q4-2024 **Action 3** Done

Issues	Audit Recommendations	Management Action	Action Owner	Timelines
	• conduct a rapid assessment of PCV stock levels across the country, as well as a gap analysis of this product, in preparation leading up to the planned PCV switch and so as to avert stock outs during the switch.	PCV levels are being monitored via mSupply (central-district), and DHIS2 (HCs), although there are issues with routine, on time reporting. PCV switch currently being implemented and stock levels are being monitored.		
	• generate a comprehensive organogram to illustrate the roles, responsibilities and reporting modalities of the CVS logistics staff. The organogram should be supported by a detailed document defining which positions or roles require partner support in the short and long term.	**Action 4** This recommendation will be implemented.	**Action 4** NIP	**Action 4** Q4 - 2024
	• develop comprehensive vaccine management SOPs, thereafter, train its personnel on the SOPs, and disseminate hard copies of these SOPs to all vaccine storage points.	**Action 5** Lao is reviewing the feasibility of using current LMIS systems in place. This recommendation will be implemented once the decision on use of LMIS is made. The vaccine management SOPs will depend on the kind of LMIS to be implemented. For example- mSupply is going to be implemented and then the SOPs will follow coordination with MPSC and data flow accordingly. However, if DHIS2 is going to be implemented then SOPs will be totally different as the accountability and responsibility will shift to NIP/EPI. In short term, mSupply is only system and NIP will continue to use till future decision is made on use of LMIS.	**Action 5** MOH/NIP/MPSC	**Action 5** Q2-2025
	• in collaboration with the PHOs and DHOs, strengthen supportive supervision, by developing comprehensive support supervision plans and standardised supervision checklists. These should be used to document: the objectives for the visit, its key observations, and any remedial actions to address identified gaps. There should also be a systematic mechanism to follow up the remedial actions.	**Action 6** Partners can support NIP on Development of comprehensive supervision plans. These plans will outline clear objectives for each visit, ensuring that supervision is targeted and effective. In addition, standardized supervision checklists will be used during supervision visits. These checklists will help document key observations and ensure that all critical aspects of the supervision are consistently reviewed. A robust follow-up mechanism will be implemented to monitor the progress of remedial actions. This will involve regular follow-up reviews and updates to ensure that issues are addressed in a timely manner.	**Action 6** MOH/NIP in liaison with Partners	**Action 6** Q1-2025

Issues	Audit Recommendations	Management Action	Action Owner	Timelines
Distribution planning and accountability need to be strengthened	Recommendation 11 To strengthen the distribution of vaccines along the supply chain, the MoH/NIP should: • in collaboration with PHO and DHO, develop comprehensive vaccine distribution plans and ensure that these plans are properly approved and disseminated to the subsidiary stores. • with support from the partners and using the lessons learnt from the integrated distribution of vaccines pilot, assess the feasibility of scaling this approach up and trialing it in other provinces. • in collaboration with PHO and DHO, conduct regular checks as part of the support supervision visits to reconcile distributed versus received vaccines and investigate any anomalies.	**Action 1** This recommendation will be adhered to once the decision on use of LMIS is made. **Action 2** NIP and MPSC will support staged roll out integrated distribution in select provinces starting 2024. **Action 3** This recommendation will be implemented.	**Action 1** MOH/NIP in liaison with Partners **Action 2** NIP/MPSC with CHAI support **Action 3** NIP in liaison with UNICEF	**Action 1** Q2-2025 **Action 2** Q1 - 2025 **Action 3** Q3-2025
Cold chain management practices need to be strengthened	Recommendation 12 To strengthen its cold chain management the MoH/NIP – with partner support – should: • develop cold chain equipment maintenance plans, preventive maintenance checklists, and equipment maintenance logs at both the national and subnational levels. • train its cold chain officers on the new maintenance tools. Equally, the checklists and equipment maintenance logs should be printed and disseminated to all vaccine handling points. • Regularly conduct routine temperature mapping of its WICRs. • put in place a process to regularly download data from the temperature monitoring devices and follow up with suitable remedial actions, as necessary.	**Action 1** The implementation of this recommendation is ongoing. Some tasks already implemented and ongoing. **Action 2** This recommendation will be implemented. **Action 3** The activity is planned in Q4/2024. Routine temperature mapping would be undertaken as per WHO recommendation **Action 4** This recommendation is being implemented. Regularly reviewed in TWG meetings. **Action 5** This recommendation is being implemented.	**Action 1** MOH/NIP in liaison with UNICEF **Action 2** MOH/NIP in liaison with UNICEF **Action 3** NIP in liaison with UNICEF **Action 4** NIP in liaison with UNICEF	**Action 1** Q2-2025 **Action 2** Q4 - 2024 **Action 3** Q4 - 2024 **Action 4** Q4-2024 **Action 5** Q4-2024

Issues	Audit Recommendations	Management Action	Action Owner	Timelines
	• develop cold chain management SOPs to guide cold chain management and maintenance processes. • consider procuring and installing solar powered refrigerators, in areas with frequent power outage. • develop a decommissioning plan to dispose of the obsolete CCE units that are located at the national and subnational levels.	**Action 6** Solar CCE will be procured and provided if there are any facilities with frequent power outage. **Action 7** This recommendation will be implemented. Decommissioning plan for CCEs does not exist in Laos. UNICEF is supporting this activity. An RFP has been published already to engage appropriate TA and start the development work.	**Action 5** NIP in liaison with UNICEF **Action 6** MOH/NIP in liaison with UNICEF **Action 7** MOH/NIP in liaison with UNICEF	**Action 6** Q1-2025 **Action 7** Q4 - 2024
Weaknesses in design and implementation of *m*Supply	Recommendation 13 To optimise the use of *m*Supply, MoH/NIP should: • conduct a feasibility study on the cost and implementation requirements of upgrading and rolling-out the next generation "open *m*Supply" and integrate additional core features as guided by GAVI's Target Software Standards (TSS). • conduct a comprehensive needs assessment to identify the required skillset to manage systems at centrally. Subsequently the MoH/NIP should work with the provider - Sustainable Solutions - to develop and implement a plan for how to build the national personnel's capacity, so that they can acquire the necessary capabilities to fully take on the responsibility for managing mSupply.	**Action 1** As part of ongoing work in strengthening use of the current eLMIS, mSupply, feasibility and cost of rolling out open mSupply particularly at the HC level is underway. This will include consideration of core features of Gavi TSS, pending advice from NIP on specifications relevant and critical for the Lao context. **Action 2** Similar assessments and plans have already been implemented both re: mSupply overall, and in relation to inclusion of vaccines at national and sub-national levels. mSupply is already independently managed. Ongoing capacity gaps can be monitored and addressed as they arise through routine monitoring, supportive supervision and on-the-job training.	**Action 1** NIP / MPSC in liaiuson with CHAI **Action 2** NIP / MPSC	**Action 1** Q1-2025 **Action 2** Q1-2025
Limitations of the Vaccine Supply stock	Recommendation 14 To optimise the use of VSSM, MoH/NIP should: • explore more up to date solutions, that can offer improved functionality; and enhance data security, user access and reporting. This could be done for example, by undertaking a comprehensive evaluation which considers all key	**Action 1** This recommendation will be considered/adhered to once the decision on use of LMIS is made.	**Action 1** MOH/NIP	**Action 1** Q4-2025

Issues	Audit Recommendations	Management Action	Action Owner	Timelines
management (VSSM) System.	stock management factors, to identify an optimal solution for vaccine management. • include interoperability with other existing country systems, and the potential to scale up digital systems in the future as part of the assessment.	**Action 2** mSupply already interoperable and data pushed regularly into DHIS2, which is the country's main health information system. MoH will look into the feasibility of interoperability of VSSM and mSupply as both perform separate functions.	**Action 2** NIP / DPC	**Action 2** Q4 2024-2025
Design and sustainability limitations impacting operating effectiveness of Electronic Immunisation Register (EIR) and DHIS2	Recommendation 15 To optimise the use of electronic immunisation, register module and the wider DHIS2 system, the MoH/NIP should: • conduct a comprehensive needs assessment to identify the required skillset to manage these systems centrally. Subsequently the MoH/NIP should work with the provider HISP Vietnam, to develop and implement a plan for how to build the national personnel's capacity, so that they can acquire the necessary capabilities to fully take on the responsibility for managing the entire systems technical upgrades and support components.	**Action 1** Capacity gaps in managing both the EIR and DHIS2 systems. Ministry of Health (MoH) has established the Center for Statistic and Health Information (CHSI) separated from Department of Planning and Finance (DPF) in 2023, to take care of all health data/indicators under MoH. The CHSI is supposed to be responsible for HMIS and EIR, but this will take time. Contracted officer at DPF and HISP Vietnam are supposed to transfer the technical skill on software maintenance and server management to the CHSI gradually. The plan of completely transferring full responsibility to government staff is ideally by the end of 2025 (said the CHSI Director). The EIR cannot be operated without internet. EIR system is designed to operate with internet connection in order to assign unique health ID and enter/retrieve information real time. Currently there are about 90 out of 1,078 health centers with no or unstable internet connection, which is only less than 10%. At this stage, MoH instructs these 90 health centers to record on paper forms and submit their monthly aggregate report. When they go to DHO once a month, HC staff can enter backlogs from the paper forms into EIR and they usually have very few visits (10-30) a month. During the implementation, NIP also observed that HC staff felt more comfortable this way. Most importantly, using the standalone offline modality is technically complicated since it has to solve the possible duplication of unique ID. The EIR does not comply with Lao PDR's Electronic Data Protection Act (2017) in respect of personally identifiable information (PII).	**Action 1** MoH/MCHC/NIP	**Action 1** Q4 2024-2025

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		There is no procedure of informing or getting consent. NIP will add an agreement form possibly on the MCH book so that clients are informed on their personal data collected on EIR. Use of outdated DHIS2 platform versions. DPF, CHSI and HISP Vietnam are working on upgrading the current version of 2.36 to 2.40. Upgrading software with massive data should be done with caution and takes many steps including testing and compatibility check. It will be done by the end of 2024. Challenges in DHIS2 report generation. EIR has started nation-wide since January 2024, and not every reporting function was in place when the Audit Team visited Laos. It is true that generating district-level coverage was manual and time-consuming. However, standard reports have been functional to get provincial and district-level data all at once since June 2024.		
Inconsistencies in administrative coverage and use of an outdated denominator	Recommendation 16 To ensure accurate and reliable immunisation data is available for decision making, the MOH/NIP should: • review the denominator with the support of partners. • routinely triangulate available data, including an assessment of the administrative coverage data	**Action 1** The data provided by the Lao PDR statistics Bureau is the only available data source that country used formally for EPI coverage calculation since establishment of EPI program. The data on population and target children collected from micro plan is not standardized, and not up to date in many of the districts. Health care workers collect this data/information which does not have a standardised data collection methodology. • MoH together with Ministry of Home Affairs is currently conducting family folder's data collection to obtain the real target children in order to update population figure from 2019 with a hope to announce for use under MoH programs in 2025. • Country is in the preparation process of conducting the national census survey that will commence in 2025 and updated population data will be used as new denominator for EPI program once the census is published. **Action 2** This exercise can be done only when vaccine doses data are available. NIP and UNICEF are working on the	**Action 1** MoH **Action 2** NIP in liaison with UNICEF	**Action 1** Q2-2025 **Action 2** Q1 - 2025

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	and the number of doses available or consumed to validate data accuracy and that the correlation of data sources is credible. Such analyses should be undertaken at both the national and the subnational levels and any inconsistencies identified should be followed up and explained further. • set up coordination mechanisms for the data and M&E technical working groups to guide the development, review and implementation of data management policies and guidelines. • develop and implement the NIP data and immunisation coverage management policy. • operationalise and monitor the status of implementation of the DQIP. • develop and operationalise pre-and post-training assessments. • recruit a replacement for the data management officer at PMU.	mechanism to collect vaccine dose regularly from each HF in order to monitor the vaccine wastage (among other tasks). This issue will bring to discuss and monitor regularly at TWG of vaccine supply chain, cold chain and logistics meeting and NIP-DPs coordination meeting to find a best solution. Data triangulation will be undertaken to the extent possible based on the data collected by NIP and UNICEF. **Action 3** NIP has taken a lead in forming up a data TWG which will meet regularly, either in person or online, with CHSI and DPs to monitoring and analyse immunisation data. **Action 4** NIP to work closely with DPF, CHIS and DPs to review the digital health policy and develop a road map/POA for implementation of data and immunisation coverage management policy **Action 5** This task will be included in the data TWG to operationalise, review the status and update the DQIP. **Action 6** Development of the pre and post assessment guideline/questionnaire will be undertaken based on the result of the EIR early-stage assessment by Sydney university of Australia. **Action 7** This is in the process of procurement and will be finalized in January 2025	**Action 3** NIP in liaison with WHO **Action 4** NIP in liaison with WHO **Action 5** NIP in liaison with WHO **Action 6** NIP in liaison with WHO **Action 7** NIP in liaison with WHO	**Action 3** Q1 - 2025 **Action 4** Q1 - 2025 **Action 5** Q1 - 2025 **Action 6** Q1 -2025 **Action 7** Q4 -2024
Weaknesses in data quality	Recommendation 17 To improve data availability, quality and use, MoH/NIP should: • routinely review and follow up significant data anomalies including any arising from data quality	**Action 1** CHSI and NIP are now working closely on monitoring of immunisation data from all HFs in order to find outstanding data entry/report including review of the	**Action 1** MoH/CHSI/NIP	**Action 1** Dec-2024

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assurance mechanisms	reviews and investigate unexplained variances/ root causes.	reports and take immediate action/response. Such review will be undertaken at regular intervals.		
	• design and implement a new data quality improvement plan.	**Action 2** Since the previous draft DQIP is already outdated without EIR, a new DQIP will be developed.	**Action 2** NIP in liaison with WHO	**Action 2** Q2-2025
	• develop a monitoring and supervision plan that covers all facilities over a period. Supervisors should ensure that any corrective actions identified, are followed-up during subsequent visits.	**Action 3** Monitoring and supervision plan on routine immunisation data was developed after EIR started. Followed by EIR, a new supervision checklist combined with data quality assessment and interviews has been actively used during the supervision. NIP, provincial and district EPI managers were trained to supervise and follow up health facilities on data entry and use using both HMIS and EIR. The plan will be reviewed to ensure all facilities are covered over a period of time.	**Action 3** NIP in liaison with WHO	**Action 3** Q1-2025
	• training evaluations should be conducted regularly to determine the impact of training. Trainings should also be based on a training needs assessment to ensure gaps are identified before sessions are designed.	**Action 4** Training is undertaken based on the data issues identified during routine monitoring and supervision visits. Training evaluation will be conducted, and necessary action will be taken.	**Action 4** NIP	**Action 4** Q1-2025