Memorandum on the Federal Democratic Republic of Nepal Programme Audit report

The attached Audit and Investigations report sets out the conclusions of the programme audit of Gavi's support to the Federal Democratic Republic of Nepal's Ministry of Health and Population (MOHP), and resultant activities executed by the Family Welfare Division, implementing departments belonging to the Department of Health Services, and by other partners. The audit was conducted by Gavi's Programme Audit team, during mid 2022. Additional follow-up work was undertaken during 2023 to validate further updates provided by the Ministry of Health.

The principal audit scope focused on reviewing the Family Welfare Division's management of Gavi vaccine and cash support received during the period 1 January 2017 to 31 December 2021.

The primary objective of the audit was to assess whether: the coordination and implementation arrangements are effective; the existing grant oversight mechanisms provide continuous and reliable assurance over Gavi's investments; and that the vaccine supply chain management and immunisation data systems are effective.

The report's executive summary (pages 3 to 5) summarises the key conclusions, details of which are set out in the body of the report:

1. There is an overall audit rating of "**needs significant improvement**", which means, "one or few significant issues were noted. Internal controls, governance and risk management processes have some weaknesses in design or operating effectiveness such that, until they are addressed, there is not yet reasonable assurance that the objectives are likely to be met."
2. In total, eleven issues were identified in the following areas: (i) programme management and oversight (ii) vaccine supply chain management; (iii) immunisation data management; and (iv) procurement and fixed assets management.
3. To address the risks associated with the issues, the audit team raised 15 recommendations of which 10 were rated as high priority.

1. Key findings were that:
   a. There was no structured mechanism for coordinating immunisation activities between federal level and provinces. In addition, there was no documented evidence of the provinces and districts being involved in planning immunisation activities, and the provinces' accountability structures and reporting requirements associated with the immunisation programme were not defined.
   b. The Family Welfare Division's involvement on planning, implementing, reporting, and supervising immunisation activities was limited. Its structure was inadequate and several positions were vacant despite its scope having been increased following the

adoption of a federalised structure. As a consequence, the programme was reliant on the health development partners to undertake routine immunisation activities for a sustained period of time.

c. In July 2018, as part of the transition from a manual "logistics management system" to an "electronic logistics management system", there was no assurance process to oversee the quality of the data that was migrated. This resulted in perpetually carrying forward stock errors from 2018 within the new system. The audit team also noted unsupported and unapproved stock adjustments were posted into this system, both during and after the transition.
d. The federal level did not have full visibility over all of its stocks as the new logistics system was only deployed as far as district health offices level, and was not yet fully installed across subsidiary levels and health facilities. Stock levels at the district levels were not included in the forecasting assumptions and as a consequence there were insufficient vaccines held in stock at the central vaccines store, at various points throughout the audit period.
e. Since April 2022, vaccine stock-outs continued to persist for both pentavalent (at least a four-week period) and pneumococcal conjugate vaccine (at least six weeks), up until June 2022 at which time the audit team concluded its fieldwork.
f. Several lapses in immunisation data processes were noted including: quality assurance mechanisms, the absence of a data management policy, and data quality reviews. There was no evidence that weaknesses in the collation and recording of immunisation data were followed up.
g. Regarding the management of Covid-19 vaccines and data on the vaccination coverage, the cumulative number of people reported as vaccinated as of 15 June 2022 significantly exceeded the number of Covid-19 doses reported as available during the same period, by 3 million individuals. In addition, over 2.5 million doses of Covid-19 vaccines were at risk of shelf expiry during the next 1 to 4 months after the fieldwork ended in June 2022.

A review of the expenditures incurred using Gavi's cash grants by the Federal Democratic Republic of Nepal during the audit period, will be completed in a subsequent follow-up scheduled for the first half of 2024, as a complementary engagement.

The findings of the programme audit were discussed with the Family Welfare Division, the Department of Health Services, and the 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 and Population to ensure that their commitments are met.

Geneva, April 2024

PROGRAMME AUDIT REPORT

Federal Democratic Republic of Nepal
November 2023

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1. Executive Summary

1.1. Overall audit opinion

The audit team assessed the Ministry of Health and Population's management of Gavi support, during the five-year period 1 January 2017 to 31 December 2021, as **"Needs significant improvement"** which means, "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."

Through our audit procedures, we have identified high risk issues relating to programme management and oversight, vaccine and supply chain management and immunisation data management. To address the risks associated with the issues, the audit team raised 15 recommendations, of which 10 (67%) 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

Ref	Description	Rating*	Page
4.1	**Programme management and oversight**	■ (red)	**11**
4.1.1	Programme implementation and coordination arrangements were ineffective	■ (red)	11
4.1.2	There are sustainability concerns over the management of the immunisation programme	■ (red)	14
4.1.3	Implementation of grant management recommendations was outstanding	■ (red)	17
4.1.4	Gaps in monitoring and supervision of programme activities	■ (red)	20
4.2	**Vaccine and supply chain management**	■ (red)	**23**
4.2.1	Gaps in vaccine management systems and processes at the Federal Level	■ (red)	23
4.2.2	Standard operating procedures were not updated after federalisation	■ (amber)	27
4.2.3	Stock management practices at sub-national level were inadequate	■ (red)	30
4.3	**Immunisation data management**	■ (amber)	**33**
4.3.1	Immunisation data was inaccurate and incomplete	■ (red)	33
4.3.2	Data quality assurance processes were inadequate	■ (amber)	36
4.3.3	There were gaps in Covid-19 vaccines and data management	■ (amber)	39
4.4	**Procurement and fixed assets management**	■ (amber)	**42**
4.4.1	There are gaps in procurement and fixed assets management	■ (amber)	42

** The audit ratings attributed to each section of this report, the level of risk assigned to each audit issue and the level of priority for each recommendation, are defined in annex 3 of this report.*

1.3. Summary of issues

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

Programme management and oversight

The Ministry of Health and Population (MoHP) implemented new structures to guide the implementation of health programmes after the federalisation of public services. The team noted gaps across the different divisions' and sections' coordination and cross-collaboration, at both the national and sub-national levels, related to their involvement with the management of the immunisation programme.

There was no structured mechanism for coordinating immunisation activities between federal level and provinces. In addition, there was no documented evidence of engagement of the provinces and districts when planning immunisation activities. The accountability structures and reporting requirements for the provinces within the immunisation programme were not defined. As such, the provinces did not submit periodic financial and programmatic reports on the status of immunisation activities to the Family Welfare Division (FWD) for follow-up, and corrective actions and their accountabilities in relation to Gavi grant funds were unclear. Governance arrangements also need to be strengthened where the role of the interagency coordinating committee (ICC) needs to be clarified, as required by 2020 grant management requirements.

The FWD's involvement on planning, implementing, reporting, and supervising immunisation activities was limited. Its structure was inadequate and several positions were vacant despite its scope having been increased following the adoption of a federalised structure. The division had a limited number of posts to conduct the required technical support to the sub national level, in addition to its other central duties. The audit team noted that since 2017, there was significant turnover in the FWD's leadership and other critical positions were vacant between 2017 and 2021. Similarly, there was significant turnover in management at the regional and municipality levels.

Terms of reference for supervisors were not detailed and selection criteria were not defined. There was also no documented evidence of the monitoring and supervision work that supervisors undertook, and monitoring and supervision plans were not available. There were also no documents and reports to support the reviews done.

The FWD programme relied heavily on health development partners to undertake routine immunisation activities. Such activities were often implemented by partners' consultants provided in the form of technical assistance. Tasks included: forecasting and logistics management; data management and analysis; activity implementation; support supervision; monitoring; following-up of governance and oversight action points. Also, the transfer of skills and capabilities from the consultants to EPI staff was poorly structured, including weak handover mechanisms when technical assistance personnel departed.

The above gaps in the design and operationalisation of both programme management and oversight mechanisms resulted in: lessened effectiveness of the governance structures; limited involvement of the FWD in the management of immunisation activities; and delays in implementing Gavi's grant management requirements. Without the necessary clarity on governance, accountability, management structures, and roles and responsibilities, the continuity and sustainability of the immunisation programme is at risk.

Vaccine and supply chain management

The central vaccines stores (CVS) transitioned from a manual Logistics Management System to an electronic Logistics Management System (eLMIS) in July 2018. There was no assurance process overseeing the quality of the data migrated into the new system, which resulted in perpetually carrying forward stock errors from 2018. The audit team also noted unsupported and unapproved stock adjustments were posted into eLMIS, both during and after the transition.

Forecasting assumptions were based on targets set at national level i.e., doses issued and population, and not actual consumption. The federal level did not have full visibility over all of its stocks as the eLMIS system was only deployed as far as district health offices level, and was not yet installed at subsidiary levels, including

health facilities. Stock levels at the district levels were not included in the forecasting assumptions. Consequently, there were low stock levels at the CVS for several antigens at various points throughout the audit period. Thereafter, since April 2022, stock outs in both Pentavalent (at least a four-week period) and Pneumococcal Conjugate Vaccine (PCV) (at least six weeks) continued to persist, up until the team concluded its fieldwork in June 2022.

The national effective vaccine management policy approved in 2015 was not updated following the federalisation which came into effect in March 2018. A second effective vaccine management assessment was undertaken in 2020, however the resultant improvement plan was not subsequently prioritised, costed, nor were the agreed actions implemented.

The audit team observed inadequate stock management practices from its various visits to sub-national sites. It identified missing vaccine management records, and unexplained stock variances from its stock counts. Based on the team's review of pentavalent, PCV and Rota vaccines, stock outs incidents were noted at two of the provincial vaccine stores visited. The duration of the various stock outs ranged from 5 to 64 days resulting in missed vaccination opportunities due to insufficient quantities being consistently available for service delivery.

Immunisation data management

Several lapses in immunisation data processes were noted in areas including: quality assurance mechanisms; the absence of a data management policy; and data quality reviews. There was no evidence that weaknesses in the collation and recording of immunisation data were followed up. Also, data validation and review meetings were not documented for most facilities that the team visited including: 100% of the provincial vaccine stores (PVS); 83% of the district vaccine stores (DVS) and 67% of the Health Facilities (HFs). Inaccurate and incomplete data recorded at facility, sub-national and national level negatively impacts evidence driven decision making.

COVAX facility support from Gavi

Up to May 2022, Nepal received 30.4 million doses of Covid-19 vaccines from COVAX. The audit team noted some good practices in the management of these doses, as noted in section 3.3 of this report.

Notwithstanding this, the team identified significant risks in both the management of Covid-19 vaccines and coverage data, including anomalies in the vaccination coverage reported. Specifically, the cumulative number of people reported as vaccinated with Covid-19 vaccines as of 15 June 2022 exceeded the number of Covid-19 doses reported as available, by 3 million individuals. In addition, over 2.5 million doses of Covid-19 vaccines were at significant risk of expiry in the next 1 to 4 months.

2. Objectives and scope

2.1. Audit objective

In line with the respective grant agreements[1] and with Gavi's transparency and accountability policy, all countries that receive support are periodically subject to programme audit, for which the primary objective is to provide reasonable assurance that the resources were used for intended purposes in accordance with Gavi's agreed terms and conditions, and that resources were applied to the designated objectives.

The audit team assessed the various processes and programme management arrangements governing Gavi's support (both vaccines and cash) for which the respective entities were responsible, so as to assess if: the coordination and implementation arrangements are effective, the existing grant oversight mechanisms provide continuous and reliable assurance on Gavi's investments, and the vaccine supply chain management and immunisation data systems are effective.

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

2.2. Audit scope and approach

The programme audit covered the period January 2017 to 31 December 2021. During this five-year period, Gavi provided resources totalling USD 188.2 million in the form of cash grants totalling USD 36.7 million and vaccines and supplies totalling USD 151.5 million (see table below).

A review of Gavi's cash grants to the Federal Democratic Republic of Nepal (Nepal) will be completed in a subsequent follow-up, therefore relevant issues and conclusions are not presented in this report.

The Nepalese financial year runs from 16th July until 15th July. In contrast, Gavi disbursements are aggregated and presented by calendar year (January to December).

Up to May 2022, COVAX contributed a total of 30.4 million doses of Covid-19 vaccines to the programme (various products including: AstraZeneca, Sinovac, Moderna, Pfizer, Johnson & Johnson and Sinopharm) – see table 3 below.

Table 2 – Gavi cash and vaccine support to Nepal by calendar year as of 31 December 2021 in USD

Amounts in USD		Amounts in scope for programme audit					
Cash grants	**2002 to 2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**Grand Total**
Cash total	**40,374,265**	**3,480,000**	**7,634,714**	**15,138,491**	**512,122**	**9,909,275**	***77,048,867***
CCEOP			**628,633**	**(3,240)**		**669,599**	***1,294,992***
Vaccine support							
Measles	368,784	321,950	117,313	(116)	264,411		*1,072,342*
Pentavalent vaccine	35,381,674	1,950,601	913,234	1,457,224	628,035	1,623,677	*41,954,445*
Pneumococcal conjugate vaccine	26,614,519	4,559,799	4,643,482	4,438,949	3,581,485	6,771,525	*50,609,759*
Rotavirus vaccine	-				2,688,750	2,117,097	*4,805,847*
Tetra DTP-HepB	8,690,385						*8,690,385*
Inactivated poliovirus vaccine	2,731,976	135,786	799,139	1,019,917	754,005	1,421,496	*6,862,319*
Japanese Encephalitis vaccine	2,149,466						*2,149,466*
Other vaccines (INS, HepB, HPV demo)	3,340,130						*3,340,130*
Injection safety devices	-	202,399	310,565	380,354	71,945		*965,263*
Measles Rubella-follow-up campaign	-			2,184,130	(23,081)	(9,818)	*2,151,231*
Covid-19 vaccines						96,932,234	*96,932,234*
Typhoid conjugate vaccines						9,983,788	*9,983,788*
Vaccine total	***79,276,934***	***7,170,535***	***6,783,733***	***9,480,458***	***7,965,550***	***118,839,999***	***229,517,209***
Cash + CCEOP + Vaccine total	***119,651,199***	***10,650,535***	***15,047,080***	***24,615,709***	***8,477,672***	***129,418,873***	***307,861,068***

[1] This includes the Ministry of Health and Population and the Ministry of Finance signing a partnership framework agreement with Gavi, effective August 2014.

Table 3: Covid-19 vaccines support from Gavi's COVAX facility as of May 2022

Covid-19 vaccines distributed by COVAX	Product	Doses
Doses procured using COVAX funds	SII/Covishield	6,387,000
	AstraZeneca	348,000
	Pfizer	765,180
	Moderna	1,686,400
Sub-total		***9,186,580***
Donations	AstraZeneca	5,620,000
	Moderna	1,965,600
	Johnson & Johnson	3,711,500
Sub-total		***11,297,100***
Cost-shared doses	Sinopharm	5,936,400
	Moderna	4,000,800
Sub-total		***9,937,200***
Total		**30,420,880**

2.3. Audit approach

The audit was carried out in two phases: an initial scoping mission conducted between 14 and 18 March 2022 and subsequent fieldwork conducted between 30 May and 17 June 2022. During the course of the audit, the team visited the central vaccines stores, five provinces, 12 districts, 11 municipalities, and 25 health facilities. See Annex 4 for the list of sites visited.

During this engagement the audit team interacted with the: Family Welfare Division, Health Management Information Systems (iHMIS) team, Logistics Management Information System (LMIS) team, Financial Controller General's Office (FCGO), District Treasury Control Office (DTCO), Monitoring Agent (MA), and Gavi alliance partners - including WHO and UNICEF.

3. Background

3.1. Introduction

Nepal is a federal democratic republic with 3 levels of government comprising the central federal level, 7 provinces and 753 local governments. There are 77 districts, which were the sub-national level of administration until 2017. Since 2018, there are 753 local governments, comprising 6 metropolitan cities, 11 sub-metropolitan cites, 276 municipalities and 460 rural municipalities.

Nepal has an estimated population of 30.2 million. According to the United Nations Development Programme, the country ranks 142 out of 189 in the human development index and the country's GDP per capita was estimated to be USD 870 in 2021.

The country still faces challenges with its health sector workforce as there was a total of 9 "physicians, nurses and midwives" per 10,000 population which is below WHO's recommended average health workforce of 23 per 10,000 population ratio.[2] The national health system consists of both the public sector made up of all the government-owned health facilities, as well as the private sector. The provision of health services in Nepal is decentralised to provinces and districts who are responsible for taking the lead in managing and administering health services.

3.2. National entities involved in implementation of grant activities

The Government of Nepal is responsible for the National Immunisation Programme, which is managed by the DoHS through its divisions, Family Welfare Division (FWD) and Management Division. The FWD is responsible for the immunisation programme while the Management Division is responsible for the programme's logistics, including procuring, storing, and distributing the vaccines and vaccine commodities. FWD is also responsible for the overall coordination and planning of immunisation services across the country. At the sub-national level, service delivery is done through Provincial Health Directorates (PHDs) at provincial level, and through health sections at local level.

Nepal's immunisation supply chain is organised across four tiers (central, provincial, district and service delivery points) in line with the overall health care supply system structure. Cascading role and responsibilities for the management of stores was as follows:

- The Central Vaccine Store (CVS), located at Teku in Kathmandu, is managed by the Management Division. It stores vaccines that arrive through the nearby international airport;
- The 7 provincial stores are managed by provincial health logistic management centres (PHLMCs). They function as the sub-national stores receiving vaccines from the CVS for forward distribution on to the district vaccine stores and health facilities, i.e., 6 PHLMCS and Bagmati Provincial Vaccine Store;
- Nepal has 77 district vaccine stores which are managed by provincial governments. They receive vaccines from the sub-national stores for distribution to service delivery points; and
- Health facility vaccine stores are managed by health facilities, under the respective local governments. The service delivery points, which include hospitals, primary health care centres and health posts, receive and store vaccines before delivery to the target population. They store their vaccines in refrigerators and in the short-term in vaccine cold box and carriers, as applicable.

3.3. Good practices

The Government of Nepal enacted its Immunisation Act in 2016 and shows a strong commitment in its co-financing contributions towards vaccines. This act has led to strengthening the immunisation programme, where at least 63 out of 77 districts have been declared as fully immunised. In addition, there is good level of engagement by the Health Development Partners, such as WHO and UNICEF, at all levels. Nepal has also

[2] Global Health Observatory data repository, WHO

rolled out its eLMIS at federal and province level. With the use of eLMIS, the federal level has visibility over stock balances held at the Provincial Vaccine Stores.

The audit team noted the following good practices in the country's preparedness, response and rollout of Covid-19 vaccinations:

- The overall coordination of the Covid-19 response involved different stakeholders including health development partners at both federal and sub-national level.
- The adequate and timely involvement of the National Immunisation Advisory Committee. This Committee provided timely policy recommendations and technical guidance to FWD. These included guidance on the prioritisation of vaccination groups and the types of vaccines to be deployed in Nepal.
- Contribution of financial resources by the government towards the operational costs of deploying Covid-19 vaccines.
- The country sustained its routine immunisation coverage during the pandemic. In addition, the programme carried out a Measles Rubella campaign during the Covid-19 pandemic.
- Community participation – including involvement of a robust network of Female Health Community Volunteers (FHCV) in communicating with and directing people to service delivery points.
- Vaccination data on Covid-19 is reported through the District Health Information System (DHIS2)
- A healthy level of vaccination coverage – over 70% of its target population was reached as of March 2022.

3.4. Key challenges

The 2015 Constitution established Nepal as a federal democratic republic with three tiers of government – local, provincial and federal. Implementation of the reforms began in 2018 following the 2017 sub-national elections leading to structural and staffing challenges. The federalisation process negatively impacted the continuity and sustainability of various health programmes, including the immunisation programme.

3.5. Operational challenges due to the covid pandemic

The coronavirus disease in 2019 (Covid-19) pandemic is caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The first case in Nepal was confirmed on 23 January 2020 and it was also the first recorded case of Covid-19 in South Asia. A country-wide lockdown came into effect on 24 March 2020 and ended on 21 July 2020.[3]

Routine immunisation was halted in March 2020 and thereafter the population was reluctant to access immunisation services due to the lock down and from fear of catching Covid-19. The Department of Health Services (DoHS) carried out an analytical study, assessing the impact of Covid-19 pandemic in selected health services with an 'estimation' of excess maternal deaths. Between March 2020 and June 2020, the report noted a sharp decline in the number of children immunised with three doses of the combined diphtheria, tetanus and pertussis vaccine (DTP).

[3] COVID-19 pandemic in Nepal - Wikipedia

4. Audit Issues

4.1. Programme management and oversight

4.1.1. Programme implementation and coordination arrangements were ineffective

Context and Criteria

The MoHP is responsible for formulating policy, planning, monitoring, and coordinating of the health programmes to achieve the national targets. The Department of Health Services (DoHS) is the principal implementing agency under MoHP implementing its with health programmes through different divisions. The implementation of the immunisation programme is coordinated at federal level by the Child Health and Immunisation Service section of the FWD. Other supporting functions under DoHS are the Integrated Health Information Management Section & Logistics Management section which are under the Management Division, as well as the financial section under the DoHS. In addition, the Financial Comptroller General Office (FCGO) under the Ministry of Finance is responsible for overseeing all government expenditure against budget, tracking revenue collection and other receipts and preparation of consolidated financial statements of the government. At the provincial level, the policy, planning, budgeting, and coordination of the health programmes is the responsibility of the Financial Administration section under Administration and Planning Division and public health division reporting to the Provincial Health Directorate under the Ministry of Social Development.

Condition	Recommendation 1
The audit team reviewed the programme's implementation arrangements as defined by the MoHP and noted the following: ***Limited coordination between the different divisions under MoHP –*** There were coordination gaps across the different divisions at national level as follows: • The finance section of DoHS did not have comprehensive oversight or visibility over immunisation programme financing specifically with regards to budgeting, funds availability and expenditure incurred at various levels with respect to Gavi funded activities. This is because the provinces do not report to the finance section of DoHS but report to FCGO. • There are no linkages between FWD (programme) and DoHS Finance section to ensure coordinated financial and programmatic reporting occurs. For example, the DoHS finance section was not aware about GMR requirements (or of the monitoring agent's role) and they were not involved in budgeting process for immunisation programme, etc. • The health facilities submitted vaccine consumption data to the Integrated Health Information Management section. However, there was no data linkages or sharing mechanisms between the Health Information Management section and the Logistics section, with the latter being responsible for the distribution of vaccines. • The procurement section under the Management Division did not have any details on procurement activities related to Gavi's grants and the Asset Management section could not provide the list of assets that had been procured using Gavi funds. The audit team also noted the following gaps in the working modalities between the Federal level and sub-national level: ***Lack of a structured mechanism for coordination of immunisation activities between federal and sub national level:*** There is no structured mechanism for coordination of immunisation activities between federal and provinces. The audit team was informed that various meetings are undertaken between federal and provincial level including: one health review meetings, immunisation review meetings, and meetings for specific campaign and vaccine introductions. However, no documented evidence was provided to the audit team to confirm details of these meetings. In addition, there was no evidence of engagement of provinces, districts and palika (council) levels in the annual budgeting and planning process for the immunisation programme. ***Accountability structures between national and sub-national level are not defined*:** Upon receipt of funds from Gavi, FCGO issues fund release letters to the various offices including provinces to which corresponding budgets have been allocated. The allocation of Gavi grants to sub-national level is included in the respective Annual Work Plan (AWP). The audit team obtained and reviewed a sample of fund release letters issued by the FCGO and noted that these did not include clear accountability requirements for the provinces. In some cases, the	DoHS should establish a coordination platform which brings together all divisions involved in immunisation activities to decide on planning, implementation and monitoring of immunisation activities. Recommendation 2 MoHP should: • Formalise accountability and reporting mechanisms between the provinces and DoHS. These should include the financial and programmatic reports to ensure that donor-provided funds are used for the planned activities and that the advances of such funds are accounted for, before being liquidated. • Develop and document working modalities and implementation guidelines between the federal level and provinces in consultation with key stakeholders from the provinces, district health offices and municipalities.

<table>
<tr><td colspan="1">release letters did not include details of specific grants for which the funds relate to. Consequently, the reporting requirements for the provinces in relation to immunisation programme were not defined and as such, the provinces did not submit periodic programmatic reports showing status of implementation of immunisation activities to FWD for follow-up and corrective actions.</td><td colspan="2"></td></tr>
<tr><td>Root cause
• Absence of a coordination mechanism for all divisions involved in the implementation of immunisation activities to facilitate triangulation of different sources of data, formulation of corrective actions and take strategic decisions.
• Absence of an agreed upon and documented chain of command across the three levels in regard to the immunisation programme and documented working modalities and implementations guidelines between the federal level and provinces to define the coordination arrangements, with details on purpose, frequency of meetings, accountability mechanisms, etc.</td><td colspan="2">Management comments
See detailed management comments included in Annex 9 – Action plan.</td></tr>
<tr><td>Risk / Impact / Implications
• Fragmented implementation of immunisation activities at various levels impacted the federal level’s ability to exercise its mandate of planning, coordination, monitoring and oversight over the immunisation programme to achieve national targets.</td><td>Responsibility
Action 1: Family Welfare Division/DoHS

Action 2: Family Welfare Division & Financial Administration Section/ DoHS</td><td>Deadline / Timetable
Action 1: 31 December 2023

Action 2: 30 September 2023</td></tr>
</table>

4.1.2. There were sustainability concerns over the management of the immunisation programme

Context and Criteria

Gavi's Grant Management Actions (GMAs) dated 22 June 2017 state that "*With new constitution of Nepal, where federalisation is the key theme, it shall impact the operational/governance structure of the country and may also impact delivery of the programme. It is unclear how the immunisation programme and flow of Gavi funds would be impacted. It would be important for the MoHP and Pool fund stakeholders (including Gavi) to closely coordinate for possible consequences of changes in the country structure considering: any changes in the fund flow through government systems; the internal controls in place to manage the new flow of funds; and the staff capability and capacity required in case of a change in structure*."

Operationalisation of the federal system started since March 2018 as mandated by the new constitution. This resulted in reforms of country's management structures, including decentralising responsibilities to sub-national levels. Thus, the health sector's management structure changed from/ to:

(i) a unitary central-managed system overseeing 5 regions and 75 districts;
(ii) to a 3-tier structure consisting of the federal government, 7 provinces and 753 local governments/municipalities (palikas).

At the federal level, the former Child Health Division and the Family Health Division were merged to form the new Family Welfare Division (FWD). The Child Health and Immunisation Services Section (CHIS), a section within the FWD, is responsible for managing the immunisation programme.

Condition

The audit team noted the following gaps:

Gaps in staffing within the FWD structure - FWD is headed by a director who is in charge of 4 sections, including the Child Health Immunisation Section (CHIS) which is responsible for immunisation. CHIS is headed by a section chief. CHIS has 7 positions including 2 public health officers, 1 nursing officer, 1 public health inspector and 3 immunisation officers who are responsible for providing technical support to all 753 municipalities, in addition to other central duties. We noted that since 2017, there was significant turnover in the FWD leadership including five different FWD directors and 3 CHIS section chiefs. The public health inspector position was vacant for 3 years (2017-2019) and 2 cold chain assistant positions were vacant for 2.5 years between 2017 and 2021. Similarly, there was significant turnover in management at the regional and municipality levels. These gaps have impacted the management of the immunisation programme as detailed below and in issues 4.1.1, 4.1.3 & 4.1.4.

Heavy reliance on health development partners for programme planning, implementation, monitoring and reporting with no mechanism for handover - The CHIS was responsible for (i) preparation of national policy on immunisation and child health, strategy, quality standards, and protocols; (ii) preparation of national level vaccine supply and distribution plan and providing necessary support to the new vaccines to be included in the immunisation programme; (iii) Assessment of vaccination and child health conditions and providing technical assistance in national-level policy formulation; and (iv) development of a child-related national programme as per national policy and strategy, facilitating the implementation at sub-national level, and coordinating and facilitating with sub-national level on technical matters.

There was no evidence that FWD effectively carried out its roles in programme planning, implementation, monitoring and reporting. The audit team noted that key programme activities were undertaken by development partner consultants provided by UNICEF and WHO, funded from Gavi-provided technical assistance. Activities include for example: national level vaccine supply and distribution planning, support for sub-national programme implementation, follow-up of immunisation action points, monthly immunisation data analysis, routine immunisation monitoring and updates, and support supervision. Similarly, much of the facilitation, provision of necessary documentation for the audit work was discharged by the consultants.

Root cause

- The federalisation process was not followed up with a detailed human resource assessment within FWD leading to suboptimal implementing arrangements, including a lack of clarity in roles at central, regional and municipal levels.
- There was significant staff-attrition from the immunisation programme management who left the government programme to work at development partner agencies.
- A lack of a transition planning to manage the staff handovers and skills transfer within the technical assistance programme. Moreover, to date, no sustainability plan has been developed, in order to prepare the programme for reduced human resource administrative support from health development partners.

Recommendation 3

MoHP should:

- Carry out an assessment of its Human Resource needs at all levels, to establish what are its additional capacity and resource requirements, in order to effectively implement the immunisation programme.
- Ensure that there are documented roles and responsibilities for the FWD and ensure that there is a documented handover process to ensure skills transfer whenever there are personnel changes (both for government staff as well as for partner provided technical assistance functions).
- Improve the capacity of the FWD to ensure increased involvement of the FWD in the immunisation programme.

Management comments

See detailed management comments included in Annex 9 – Action plan.

Risk / Impact / Implications	Responsibility	Deadline / Timetable
• Ownership of the immunisation programme at sub-national level including supervision is lacking. • Future sustainability of the immunisation programme will be impacted by limited involvement of government structures should Gavi and other development partners' technical assistance cease.	**Action 3:** Family Welfare Division/DoHS	**Action 3:** 30 September 2023

4.1.3. Implementation of grant management recommendations was outstanding

Context and Criteria

Gavi carried out a Programme Capacity Assessment (PCA) of the MoHP in November 2016, covering the following programme management areas: financial management (including evaluation of the funding mechanism); and vaccine and cold chain management. The PCA process concluded by agreeing on a set of grant management requirements (GMR) with the MoHP in 2017. In September 2019, Gavi carried out a monitoring review to: (i) assess progress in implementing these GMR recommendations; (ii) ensure that the Gavi grants' fiduciary arrangements were adequate; and (iii) that programmes were implemented in a cost-effective, transparent and efficient manner. The monitoring review was concluded by agreeing on a set of updated grant management requirements (GMR) with the MoHP in May 2020.

Condition

The audit noted delays in implementation of the GMRs. Several GMRs were related to weaknesses in the assurance mechanisms as highlighted below:

- There were no risk-based internal audit plans and the work done by the district treasury offices was not documented by issuing internal audit reports.
- There were no annual external audit reports from the auditor general's office since FY2015/16 though these were required by the GMRs.
- Follow-up and tracking of the assurance service providers recommendations was inadequate – FWD did not maintain a comprehensive matrix or tracker, documenting the follow-up and implementation of recommendations from external and internal audits.

Below is a summary of the nine GMRs whose status was still pending, as based on the Gavi programme audit team's review in June 2022:

Table 4: Pending GMRs as per audit team verification.

GMR – May 2020	Status as per the Gavi audit team verification
The Ministry of Health and Population (MoHP) and the Department of Health Services (DoHS) will ensure that the TORs of the Interagency Coordination Committee (ICC) are revised to include the mandate, membership (including composition, selection and rules), meeting rules, decision making rules, support functions, roles and responsibilities including those of the ICC secretariat, TORs for sub committees or working groups, as applicable. Gavi's guidance for Coordination Forums (see http://www.gavi.org/support/coordination/) will be referenced in the revision of the ToRs to the extent practicable.	The ToRs of the ICC are yet to be revised as required by the GMRs. The audit team was informed that the revision will be completed by end of 2022. In addition, the audit team did not see any evidence of ICC's oversight role from the reviewed ICC minutes, as meeting deliberations mainly covered the review and approval of grant applications submitted to Gavi.
A suitable integrated financial management system will be implemented as planned by MoF/Financial Comptroller General Office (FCGO), and rolled out across spending units at federal, provincial and health offices, to include at a minimum, the following: - ***Integration with budget information systems (LMBIS, Provincial LMBIS (PLMBIS)) and treasury management systems (Treasury Single Account (TSA) and State TSA systems)*** - ***Module for tracking of advances to lower levels and to staff, with ability to provide ageing analysis for outstanding advances.*** - ***Coding of budgets and expenses as well as generating financial reports in line with Gavi Guidelines on Financial Management and Audit Requirements.*** - ***Assets management module***	Multiple financial management systems across the administrative structures are not integrated. Although all these systems are managed under the same office (FCGO) across all administrative structures, LMBIS is not integrated with PLMBIS nor SUTRA. In addition, there was no documented plan to integrate these systems to ease financial management and reporting. As a result: advances are not adequately tracked; ageing analysis are not performed; and Gavi grants financial reports are generated manually (excel). The provincial asset management module (PAMS) has also not been rolled out to sub-national level.

Recommendation 4

FWD should:

- Provide an update of the pending GMRs, with timelines for completion of each requirement.
- Develop a tracker to include all recommendations from various assurance providers and instigate an escalation mechanism to ensure the adequate follow-up of the long outstanding items. These items should be monitored by the ICC to ensure timely and effective implementation.

MoHP/DoHS will ensure that the financial accounting and reporting capacity at national level and at each of the provincial levels is adequate to meet Gavi's financial management requirements. Appropriate capacity building measures will be put in place to ensure designated finance staff are available at the DoHS and each of the seven provinces and equipped with necessary skills and tools for countrywide consolidation of activity-wise project expenditures and preparation of Gavi financial reports.	Gavi has contracted the monitoring agent (MA) in 2022 to carry out various roles including financial management training for account and immunisation officers based at provinces and districts and the trainings will be roll out early next fiscal year. Hence, capacity building of staff at national level and sub-national level is still to be initiated by the MA.		
MoHP and DoHS 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. Requisite exemptions will be provided to any third party carrying out procurements on behalf of MoHP/DoHS as applicable.	There is no adequate mechanism for the tracking of VAT paid from Gavi grants at various levels, and reimbursing the tax back to the programme. Accounting system does not record VAT paid separately and hence VAT paid from Gavi grant can only be seen from physical vouchers. The audit team noted instances of VAT paid and charged to Gavi grants, at both the national as well as sub-national levels.		
A consolidated (covering all levels) and comprehensive Fixed Asset Register (FAR) for all assets, including but not limited to cold chain equipment, vehicles and IT equipment procured or to be procured through Gavi grants to Nepal will be maintained. This Fixed Assets Register will be maintained and updated regularly. All assets procured with Gavi funds will be tagged with unique identifiers and asset verification will be carried out at least annually, reconciling the physical assets count and condition to the FAR at all levels. In the absence of a computerised assets management module (expected to be included in GARIS), MoHP/DoHS will consider maintaining the FAR in MS Excel spreadsheets, to enhance compliance with the requirement to have a consolidated and comprehensive FAR.	At the federal level, assets are recorded in PAMS and cold chain equipment are recorded in eLMIS. We noted that asset identification numbers are not assigned to assets and identification tagging was not done. At the sub-national level, we noted the absence of comprehensive asset registers at all sites visited by the audit team. The register and records maintained at the federal level could not generate Gavi-specific asset records.		
The MoHP shall maintain at its own expense where available at a reasonable cost, all risk property insurance on the programme assets (including vaccines and related supplies, vehicles, cold chain equipment, etc.) and comprehensive general liability insurance with financially sound and reputable insurance companies.	As observed and reported to the audit team across all levels and sites visited, there is no provision for insurance of the assets.		
In the absence of a risk-based internal audit practice in the country, FCGO, PTCOs and DTCOs (as per the Government's normal procedure) will provide oversight for financial management transactions for Gavi programmes related to routine compliance and transactional matters.	Risk-based internal audit is not undertaken/ performed. From our review, there was no evidence of internal audit work carried out by DTCO as internal audit reports were not shared.		

Requirement	Observation
Annual external audits of Gavi grants channelled outside the pool fund and not covered by the audit arrangements specified in the JFA will be outsourced to suitably qualified audit firms approved by the Office of Audit General of Nepal (OAG). The audits will be carried out using Terms of Reference (ToRs) to be agreed in advance with Gavi by OAG, and in line with Gavi's Financial Management and Audit Requirements. The external audit as specified here will be funded by Gavi.	No financial audits of Gavi grants have been performed after Fiscal Year 2015-16. Gavi, the OAGN and the MA are working together on the selection of auditors for the audit of Gavi direct cash grant for the fiscal year 2016-17 onwards. The monitoring Agent is helping Gavi and the OAGN in finalising the ToRs for the auditor. The audit selection process and contracting was finalised in July/August 2023 (at the time of finalisation of this report).
DoHS (FWD, and MD if applicable) will prepare a plan to follow up on the recommendations made by the internal auditors, external auditors, and Gavi auditors for submission to Gavi and for internal dissemination internally within the MoHP and DoHS. The DoHS will be responsible for monitoring all audit recommendations and a status of the fulfilment or recommendations will be submitted to the ICC and Gavi.	FWD does not maintain a comprehensive matrix or tracker for following up on the implementation of recommendations from external audits and internal audits.

Root cause

- Status of implementation of GMRs is not discussed at the ICC.
- Absence of a mechanism to escalate re-occurring issues to ensure that suitable measures are in place to ensure their implementation.
- There was no process to prioritise the recommendations for follow-up.

Management comments

See detailed management comments included in Annex 9 – Action plan.

Risk / Impact / Implications	Responsibility	Deadline / Timetable
Failure to comply with the GMRs may result in the suspension or termination of Gavi's funding, and consequently would impact on the country leveraging some of the opportunities afforded (as stated in the signed grant agreement). Outstanding audit issues indicate that internal control weaknesses may remain unresolved, potentially undermining programme implementation and grant performance.	**Action 4:** Family Welfare Division/DoHS	**Action 4:** 31 December 2023

4.1.4. Gaps in monitoring and supervision of programme activities

Context and Criteria

There are no specific policies for the monitoring and supervision of programmatic activities at provinces, districts, and local level. However, annual directives are issued by the FWD which includes the provision for monitoring and supervision. As per the directives published by the FWD for annual operation of programme for fiscal year 2079-80 (FY 2022-23) under procedures of operation of programme: "*For management of effective operation of the programs at provinces, districts and local level, the federal level shall coordinate with the Family Welfare Division (FWD) and development partner body for technical help, facilitation, supervision and monitoring as required. Plans in advance shall be requested from the Provincial Health Directorate (PHD) and shall prepare plans for facilitation supervision and monitoring for the programmes that run at district level.*"

Condition	Recommendation 5
Monitoring and supervision by government oversight mechanisms - There were no workplans, status reports, ToRs for supervisors or defined criteria for selecting the supervisors to carry out the monitoring and supervision work at provincial, district or municipality levels. There was also no evidence of monitoring and supervision work plans as well as the implementation status of these plans. The CHIS management team did not provide a list of PVS, DVS and HFs that it had visited and supervised during the audit period. For the various sites visited by the audit team, it was observed that there was no evidence of monitoring and supervision activities having been conducted: (i) by the federal level to any of the 5 PVS (ii) by the province level to the DVS visited; and (iii) by the district level for 18 HFs. For the other 7 HFs visited, the team noted that these had received at least 1 monitoring and supervision visit. In addition, all 10 (100%) palikas/municipalities visited were not able to evidence if they had conducted any monitoring and supervision activities to HFs. See details in Annex 5 - details of support supervision. There were no reports provided to support the expenses charged for monitoring and supervision totalling up to USD 86,458 as budgeted in the AWPs for monitoring and supervision for fiscal year 2018/19 to 2021/22. The audit team did not receive reports or evidence of how monitoring and supervision completed was incorporated into the decision-making process. ***Monitoring and supervision provided through GAVI TCA activities -*** WHO Nepal, through its field offices, carried out monitoring and supervision for the following Gavi TCA activities: • Technical support for joint supervision and monitoring of the immunisation programme at province, district, health facility and immunisation session levels, to drive high coverage and equity. The immunisation supervision and monitoring mechanisms also established and standardised various tools, in order to document the activities conducted across sub-national levels. • Strengthening/support to the National Immunisation Programme through independent monitoring to improve immunisation coverage and equity. Independent monitoring conducted in low-performing areas/health facilities and immediate feedback of monitoring given to sub-national level (district, health facilities) by WHO field office. While these supervision activities were monitored by WHO, they were no mechanisms to include such activities in the government oversight plans to ensure adequate coverage and sustainability of supervision processes.	FWD should strengthen the monitoring and supervision mechanisms by: • Developing annual supervision workplans, ToRs for supervisors as well as proper supervision tools; • Documenting feedback from supervision and ensuring follow-up of action points; and • Incorporating the monitoring and supervision activities, funded through the Gavi supported TCA plan, within the national monitoring and supervision work plans to ensure capacity building of national supervisors and continuity of monitoring activities.

<table>
<tr><td colspan="1">Root cause
• Absence of an activity workplan for support supervision to map out critical activities and accountability mechanisms for supervision undertaken/not undertaken.
• There are no specific policies for the monitoring and supervision of programmatic activities at province, districts, and local level. However, annual directives are issued by the FWD which includes the provision for monitoring and supervision.</td><td colspan="2">Management comments

See detailed management comments included in Annex 9 – Action plan.</td></tr>
<tr><td>Risk / Impact / Implications
Without proper supervision and monitoring, weaknesses in programme implementation are not identified or corrected, impacting on immunisation outcomes.</td><td>Responsibility
Action 5:
Family Welfare Division/DoHS</td><td>Deadline / Timetable
Action 5:
30 September 2023</td></tr>
</table>

4.2. Vaccine and supply chain management

4.2.1. Gaps in vaccine management systems and processes at the Federal Level

Context and Criteria

Stock data management plays a vital role in the management of inventory, feeds into the forecasting, procurement, and demand planning processes. The signed 2014 Partnership Framework Agreement (PFA) (Article 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.

Clause 6.2 of Cold Chain and Vaccine Management Policy (Karyaniti) 2070 (2013) *provides for maximum (11 months) and minimum (6 months) vaccine stock levels that should be held at the central vaccine store; and*

Clause 14.2.2 of National Immunisation Program Effective Vaccine Management Standard Operating Procedure 2015 requires that central and regional medical stores should conduct a physical stock count of all vaccines, diluents, syringes and safety boxes every three months.

The country adopted an eLMIS at central vaccine store in July 2018 as an upgrade from its prior LMIS. The eLMIS system was funded by a development partner and has been rolled out up to the district vaccine stores.

Condition

Lack of evidence for quality assurance on vaccines data: In July 2018, the CVS launched its eLMIS at the central vaccine store, replacing its previous LMIS. There was no evidence documented on file that quality assurance or checks were done on the LMIS data, prior to the stock data being migrated into eLMIS. As a result, errors totalling 22,040 vials of Penta and 21,300 vials of PCV-13, have been carried forward since 2018 in the new system. (see table 5 for more details).

There was no documented process of transition from LMIS to eLMIS and as such the mandate and requirement for review of data transfer was not defined. After the transition, various adjustments to vaccine balances were posted into eLMIS at federal level to correct for errors without any explanation and approval. Therefore the balance amendments did not represent actual receipts or issuances of vaccines. In addition, management was not able to provide any evidence of having reviewed the system data prior to migrating it.

Table 5: Unexplained adjustments in eLMIS data

Transaction Date	Nepal Calendar Date	Product	Unit of Measure	Received quantity	Issued quantity
14-Apr-2018	1/1/2075	Penta	Vial	20,313	-
14-Apr-2018	1/1/2075	Penta	Vial	6,087	-
04-Jun-2018	2/21/2075	Penta	Vial	32,370	-
04-Jun-2018	2/21/2075	Penta	Vial	9,000	-
16-Jul-2019	3/31/2076	Penta	Vial	-	7,360
16-Jul-2019	3/31/2076	Penta	Vial	-	32,370
15-Jul-2020	3/31/2077	Penta	Vial	-	6,000
15-Jul-2020	3/31/2077	PCV	Vial	-	21,300

Forecasting assumptions were based on doses issued and population, and not actual consumption: The federal level did not have visibility over the health facility level's actual quantities of vaccine on hand nor their consumption rate. Similarly, actual wastage rates remain unknown, with the country using the WHO wastage rate estimates instead. As a result, issuances from the federal level and population estimates were used as a proxy for consumption, due to the lack of suitable data being feedback from the health facilities. Paper based LMIS records were still being used at service delivery points and it was noted that the LMIS data fields were not corresponding to those in DHIS2 (which only reported on the number of vaccinations done). Equally, suitable data triangulation exercises could not be undertaken due to missing data records as per issue 4.2.3.

Low CVS stock levels at time of review of several antigens - The audit team noted that the minimum and maximum vaccine stock levels were not consistently observed with buffers frequently being exhausted. From the audit team's review of stock records, several separate stock-out events occurred, including: 9 distinct events involving pentavalent vaccines, the longest lasting for a total of 65 days (in 2018); 6 events of PCV vaccines, with the longest lasting for 52 days (in 2021); and 6 events concerning Rota virus vaccines, with the longest lasting 67 days (in 2022). The audit team also noted that as at 17 June 2022, there were ongoing stock-outs of both Pentavalent (since 24 May 2022) and PCV (since 9 May 2022). At the time, FWD did not have visibility on when precisely the next shipment delivery of these vaccines was scheduled to arrive.

Recommendation 6

MoHP should ensure that:

- Quarterly stock counts are carried out at the central vaccine store and results documented. Any variances noted should be investigated and approved before posting;
- Ensure that the eLMIS rollout plan is finalised and proper data quality assurance mechanisms are put in place.
- Review forecast assumptions and ensure that suitable processes are put in place, to strengthen the capture and recording of actual vaccine utilisation at health facility level, and that this data is subsequently transmitted to national level.
- Proactively manage stocks and ensure that any low stock, is immediately reported to Gavi Alliance partners, to avoid protracted stock-out incidences.
- Institute a process to capture data on wastage of vaccines, for the country to develop its own wastage rate computations, given the role this data can play in increasing the accuracy of the forecast estimates.

Table 7: Analysis of stock at year-end illustrating stock holding balances consistently below the minimum stock level (6 months)

Vaccine	SOP		Months of stock at FY end (July 15)				
	Max	Min	2017-18	2018-19	2019-20	2020-21	2021-22*
Pentavalent	11 months	6 months	0.93	3.04	1.8	3.39	0
PCV			1.15	2.48	1.2	0.59	0
Rota virus			0	0	0	0.01	0

**** 2021/22 stock as counted on 1 June 2022.*

Variances in stock identified from physical counts done by the audit team: The audit team performed physical stock counts on 1 June 2022 at the CVS and noted the following unexplained variances (below). There was no evidence that quarterly physical stock counts were done by the vaccine management team, as required by the national vaccine management operating procedures.

Table 8: Variances between physical counts of Covid-19 vaccines and stock records

Name of Vaccine	Unit	Batch No.	Expiry date	Quantity counted	Quantity per eLMIS	Variance
COVISHIELD (10 doses)	Vials	4121Z257	23/7/2022	1,250	1,948	(698)
Pfizer/PFE-BNT0.5.m.l COVIDUX (6 doses)	Vials	FT5336	30/9/2022	97,500	97,890	(390)
Moderna (10 doses)	Vials	015L21A	23/6/2022	8,280	7,440	840

<table>
<tr>
<td>Root cause
• Absence of documented evidence that quality assurance was done on LMIS before data was migrated into eLMIS and lack of periodic review of eLMIS.
• Incomplete rollout of eLMIS.
• No evidence of quarterly stock counts as required by the national vaccine management operating procedures.
• Lack of actual wastage data at the different levels.</td>
<td colspan="2">Management comments

See detailed management comments included in Annex 9 – Action plan.</td>
</tr>
<tr>
<td>Risk / Impact / Implications
• Where vaccine records lack integrity, this can undermine the management, custody and decision-making regarding the effective use of vaccines.
• Unaccounted for vaccines;
• Incomplete forecasting assumptions may result in vaccine stock-outs, leading to missed vaccination opportunities due to insufficient quantities being consistently available for service delivery.</td>
<td>Responsibility
Action 6:
On stock counts - District Vaccine store, PHLMC, Central Vaccine store within Management Division/DoHS.

On eLMIS - iHMIS section, Management Division/DoHS

On forecasting - Vaccine Procurement Section, Management Division/DoHS

On wastage, Management Division/DoHS</td>
<td>Deadline / Timetable
Action 6:
1 June 2024

1 June 2024

31 December 2023

30 June 2024</td>
</tr>
</table>

4.2.2. Standard operating procedures not updated after federalisation

Context and Criteria

The May 2020 GMRs require the following:

- *"FWD and the Management Division will ensure that implementation of actions recommended in the latest Effective Vaccine Management Assessment improvement plan (EVM IP) and any subsequently carried out EVM assessments, is tracked and reported to Gavi and the ICC, on a 6-monthly basis. The EVM IP plan shall be costed and prioritised to facilitate the inclusion in the AWPB. The EVM IP actions shall be clearly reflected in the AWPB's activities, in line with availability of funds and budget ceilings.*
- *The Logistic Management Information System (LMIS), eLMIS or manual stock registers will be maintained and updated on a continuous basis at all points of storage of vaccines and related supplies (central, provincial and district vaccines stores, as well as facilities) as the case might be. All requisitions and issues of vaccines and related supplies will be properly documented, as well as other critical stock data parameters (physical inventory counts, vaccine consumption, stock outs, wastage, and expiries) to ensure completeness and reliability of stock data.*
- *Consolidated stock status reports (central and provincial level) showing stock balances by batches, their expiries, average months of stock and expected shipments will be prepared and submitted to the ICC through National Vaccine Management Committee."*

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Condition

The Effective Vaccine Management Standard Operating procedures were not updated following the federalisation process – The federal system came into effect in March 2018. It created 7 provincial vaccine stores, and 77 district vaccine stores. However, currently the country still continues to follow the National Immunisation Programme Effective Vaccine Management SOPs which were approved in 2015, prior to national devolution and reform. These 2015 SOPs have several gaps including:

- They do not specify vaccine stock records to be maintained at each vaccine store;
- They do not provide guidance on review and monitoring for any adjustment in the eLMIS / stock records and its authorization;
- There is no guidance on reverse logistics of vaccines from HFs to Sub stores/ district vaccine stores. There are no guidelines to be followed by the sub-stores, when health facilities revert unused vaccines back to them; and
- The guidelines have not been updated to adjust to the implementation of eLMIS, as the current system in use since 2018.

The 2021 EVM improvement plan is yet to be costed based on priorities identified – The 2021 EVM assessment resulted in an overall score of 81% which means that the country had shown significant improvements. There were 32 recommendation/ action points of which 26 were rated high and 6 as medium priority. The action points were consolidated into an EVM Comprehensive Improvement Plan (CIP). This improvement plan has not yet been costed to facilitate mobilisation of resources to be used to implement the action points. A summary of all EVM findings and recommendations is included on Annex 9.

Lack of equipment maintenance plans – At the central level, there were no cold chain equipment (CCE) maintenance plans for items that had passed beyond their warranty period. The audit team noted that there were 27 CCE units at the CVS that were no longer under warranty, for which no preventive maintenance plan was in place. Similarly based on the team’s visits to various sub-national sites, it was noted that 60% of PVS and 92% (11) of DVS also did not have a preventive maintenance plan. Moreover, it was observed that no routine and preventive CCE maintenance activities were carried out at any of the PVS or DVS.

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Recommendation 7

MoHP should:

- Revise the EVM SOPs and align them to the current federal system. The revised SOPs should also include procedures on eLMIS and should be disseminated at all levels and suitable trainings conducted thereon.
- Cost the EVM CIP and use these estimates to mobilise and advocate for the necessary resources to improve the vaccine and supply chain management processes.

Recommendation 8

MoHP should come up with CCE preventive maintenance plan at all levels and ensure that these plans are adhered to.

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Root cause

Lack of review of the vaccine supply chain management processes after federalization.

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Management comments

See detailed management comments included in Annex 9 – Action plan.

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Risk / Impact / Implications	Responsibility	Deadline / Timetable
• Outdated guidelines may no longer be relevant or complete, leading to inconsistent vaccine supply management practices at various levels.	**Action 7:** Management Division/DoHS **Action 8:** Management Division/DoHS	**Action 7:** 31 August 2023 **Action 8:** 31 October 2023

4.2.3. Stock management practices at sub-national level were inadequate

Context and Criteria

The national immunisation programme EVM SOP 2015 states:

- *Section 5.2 Personnel who are responsible for looking after vaccines should know how to operate and interpret the temperature monitoring devices that are used in their workplace. They should also know how to keep daily temperature records and how to carry out periodic temperature reviews.*
- *Section 10.2 Responsible personnel should know how to operate the refrigeration, temperature monitoring and alarm equipment, know when routine maintenance is required, and know how to recognize common faults. They should also understand the principles of planned preventive maintenance and routine equipment replacement and their importance for the maintenance of a reliable cold chain.*
- *Section 14.2 Responsible personnel should know how to carry out a systematic physical stock count and how to reconcile any errors found in the stock records.*
- *Errors can occur when counting and recording the quantities of vaccines, diluents and other immunisation supplies entering or leaving a store. A regular physical check is the only way to ensure that stock records and running balances are accurate and complete.*
- *The aim of vaccine distribution management is to ensure that vaccines are transported within the correct temperature range to eliminate vaccine losses due to freezing and/or excessive heat exposure. Records must be kept ensuring that this policy is being achieved. The status of the freeze indicator(s) and of the Vaccine Vial Monitors (VVMs) must be checked at the time of arrival in the receiving store and details must be recorded on the form.*

Condition

The Audit Team visited 5 provincial vaccine stores (PVS), 12 district vaccine stores (DVS) and 25 health facilities (HFs). The following issues were noted at the sub-national level.

Incomplete and missing vaccine management records - FWD uses eLMIS as the primary system to account for vaccine deliveries and receipts at PVS and vaccine stock books as the primary records accounting for deliveries and receipts at the district and HF levels. The audit team noted missing vaccine management records in: (i) 3 out of 5 PVS (60%); (ii) in 10 out of 12 DVS (83%); and (iii) in 15 out of 25 (60%) of HFs visited. This illustrates that there were significant gaps in accounting for the vaccines. See Annex 6a – "Missing vaccine management records" for details.

Unexplained stock variances from stock counts done by audit team - The audit team performed physical stock counts covering a sample of vaccines: Penta, PCV, Rota and COVID-19 on visiting each site and compared these to the vaccine ledger balances. 3 of 5 PVS (60%) and 11 of 12 DVS (92%) visited by the team had variances between the vaccine ledger balances and the stock on hand. See Annex 6b, 6c, 6d and 6e for details. These variances were due to inadequate inventory control practices and incomplete records.

Stock reconciliation variances – The audit team reconciled stock levels (opening stock plus receipts less issuances) and noted variances in 1 PVS; and 4 DVS visited. See Annex 6f. These variances were mainly because of data entry omissions, incorrect entries in the vaccine control books and other errors. Such incidents were likely to contribute to the variances in the stock balances as already discussed. However, this analysis could not be completed in 1 PVS (Province 7) and 5 DVS (Sunsari, Dhanusha, Mahottari, Kathmandu, and Bhaktapur) due to missing stock records.

Weaknesses in design and implementation of physical counts - Monthly physical counts were not regularly carried out by the stock keepers in 3 of 5 PVS (60%) and 10 of 12 DVS (83%) visited. Where such stock counts were done, often pertinent details were not recorded - for example information on which batches were counted, what expired or was damaged, and the VVM status of the vaccines counted. Also, these physical counts were not reviewed by supervisors at district and provinces. Also, variances identified between the vaccine control book and the physical count were not investigated, prior to adjustments being made.

Stockouts observed at PVS and DVS - 2 of 5 PVS (40%) and 1 of 12 DVS visited, reported a stock-out of at least one of the sampled vaccines (Penta, PCV, Rota and AZ). Stock-outs ranged between 5 and 64 days. Stock-outs of more than 30 days were noted at province 1 and Morang DVS as detailed in Annex 6g and 6h. However, this analysis could not be completed in 1 PVS (Province 7) and 5 DVS (Sunsari, Dhanusha, Mahottari, Kathmandu, and Bhaktapur) due to missing stock management records.

Gaps in management of reverse logistics from HFs to District Sub Stores – HFs collected vaccines from their DVS on the scheduled immunisation days and were required to return any unused vaccines. However, the audit team noted that there were no records maintained detailing what unused doses were returned by the HFs to the DVS. Additionally, VVM status were not monitored for returned vaccines.

Recommendation 9

FWD should ensure proper accountability for vaccines at all levels by:

- Requiring that accurate and complete records be maintained at all levels and instituting proper handover mechanisms during staff transition.
- Providing all HFs with the required stock keeping tools/records and job aids to avoid data entry gaps.

Recommendation 10

FWD should train and provide job aids to all staff responsible for managing and handling vaccines to comply with the established SOPs, particularly on:

- Recording batch numbers, expiry dates and VVM status in the vaccine control books/ledgers.
- Recording the results of each physical stock counts, investigating the variances, reconciling these with the stock records, and documenting the whole process along with justification for any adjustments to the stock records.

Recommendation 11

MOHP should ensure that waste management policies are properly disseminated to all levels, to ensure practices are consistent with national guidelines.

Inadequate Temperature Monitoring **-** All PVS, DVS and HFs visited did not track and record temperature and VVM on receipt of vaccines, as the stock receipt and stock recording tools do not capture these aspects. Similarly, the same PVS and DVS did not track, record, and monitor temperature or VVMs during transit when distributing vaccines, and the DVS did not monitor the temperature status for vaccines returned by HFs.

Waste management gaps **–** The MoHP through the department of Health Services developed "National Health Care Waste Management Standard Operating Procedures" in 2020. However, these SOPs are not clear on the preferred and recommended waste disposal methods to be followed by the health facilities. Also, the audit team did not find evidence that these SOPs were disseminated to the sub-national level. In addition, 60% of the PVS, 100% of the DVS and 100% of the HFs the team visited, were not trained on waste management processes. As a consequence, 64% of HFs opted to bury their waste while the rest (36%) were burning and burying the waste.

Root cause

- Reasons for the unexplained variances included: arithmetical errors when recording vaccine receipts, missing stock management records/tools, inconsistencies in completing stock management records, irregular physical counts, physical count variances not being investigated.
- Ineffective and inadequate support supervision – there was no evidence of Federal-level supervision to 5 of 5 (100%) PVS, Province-level supervision to 11 of 12 (92%) DVS; and District-level supervision to 17 of 25 (68%) HFs.
- Lack of vaccine management SOPs and job aids - there were no SOPs available in 100% of PVS, DVS and HFs visited; no job aids in 3 of 5 (60%) PVS, 3 of 12 (25%) DVS and 22 of 25 (88%) HFs visited.
- Lack of training for vaccine supply chain management. – not training on VSCM processes, observed in 3 of 5 (60%) PVS, 8 of 12 (67%) DVS and 100% of the HFs visited.
- Lack of training and SOPs on waste management. All PVS, DVS and HF visited did not have guidelines on waste management. Also 60% of PVS, 100% of DVS and 100% of the HFs visited have not been trained in Waste Management.

Management comments

See detailed management comments included in Annex 9 – Action plan.

Risk / Impact / Implications

- Stock out and wastage because of poor vaccine handling at facilities
- Inaccurate data collected impacting effective decision making e.g., for stock order replenishment and management resulting in stockout and missed vaccinations.
- Inadequate monitoring and supervision and lack of feedback and follow-up results in missed opportunities to address issues in a timely manner and may hinder demonstration of value for money for the Gavi investment in monitoring and supervision activities.
- Non-compliance with the NMS vaccine handling requirements
- Unaccounted for vaccines

Responsibility	Deadline / Timetable
Action 9: Management Division and Family Welfare division/DoHS	**Action 9:** 30 June 2025
Action 10: Management Division and Family Welfare division/DoHS	**Action 10:** 30 June 2025
Action 11: Management Division/ DoHS	**Action 11:** 30 June 2025

4.3. Immunisation data management

4.3.1. Immunisation data was inaccurate and incomplete

Context and Criteria

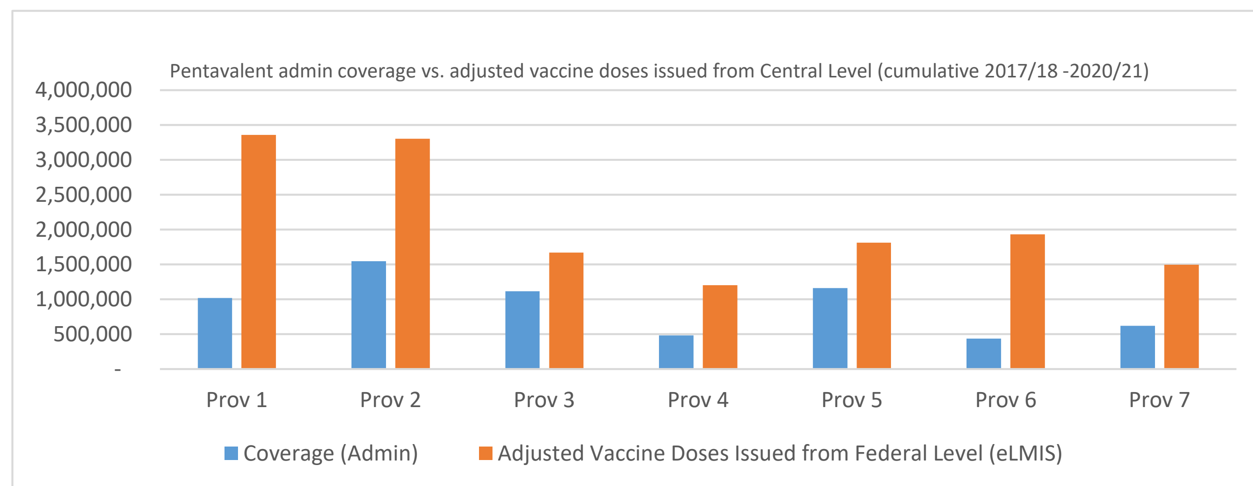
PFA article 8 (d) requires that all information that is provided to Gavi including its applications, progress reports, any supporting documentation, and other related operational and financial information or reports, is accurate and correct as of the date of the provision of such information. In addition,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

Condition

Use of outdated denominator data to monitor coverage - Nepal carried out a population census in 2011 which resulted into the 2014 population monograph (study and analysis of the results of a population census). The monograph provided a population projection for Nepal from 2011 to 2031. DHIS2 has been using this population data from the 2011 census to monitor immunisation indicators. As per DHIS2 data, population has been growing at an average rate of 1.3% during the audit period whereas population for under 1 year has been reducing at an average of 0.2%. The HMIS denominator data did not factor in current population figures and migrant populations to support review of sub-national coverage numbers. We noted that the country carried out a new census in 2021 but the results have not been released.

Anomalies in reported administrative coverage – There were inconsistencies in the administrative coverage reported by the country for the period under review. A comparison between the total number of doses issued by the Central Vaccine Store and the administrative coverage reported, indicated that the number of children reported as vaccinated for Penta and Rota over the 4-year period 2017/18 to 2020/21 was consistently lower than the quantities of vaccines utilised. The Audit Team's calculations were adjusted for wastage using the lowest available wastage rate (5% across the three antigens) and opening and closing balances for provinces and districts, as reported by the Logistics Management Section. Given that the computation was adjusted with closing and opening balances, the significant variances noted could be an indication of unaccounted for vaccines, unreported immunisation data or huge vaccine wastage. Over the audit period, there was an average of 57% (8.4 million) of pentavalent doses and 5% (0.05 million) rotavirus doses which could not be accounted for, based on the reported immunisation data. These variances do not align with the vaccine expirations or stock-outs reported. In addition, the comparison indicated that administrative coverage for PCV was higher than the total number of doses distributed and used. MoHP did not provide any explanations for these anomalies. The variances noted are as per illustrations below:

Penta

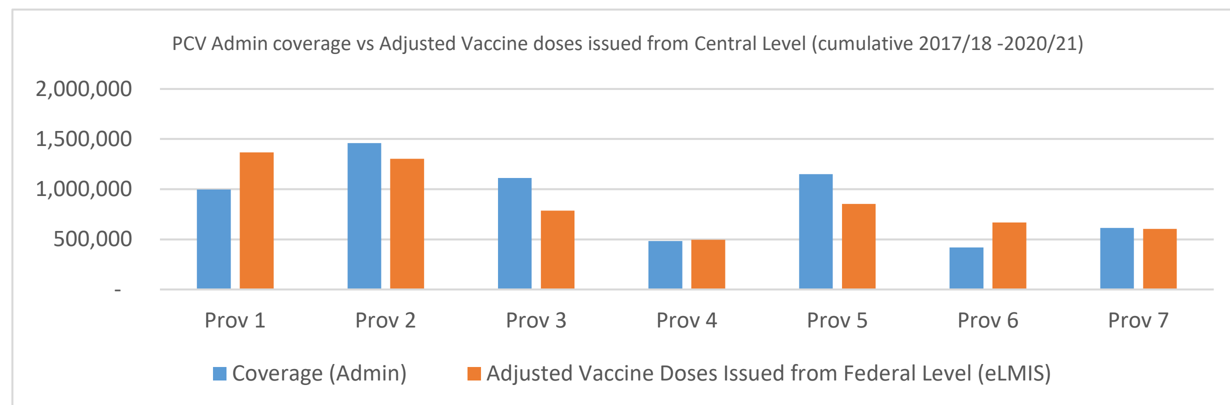


Recommendation 12

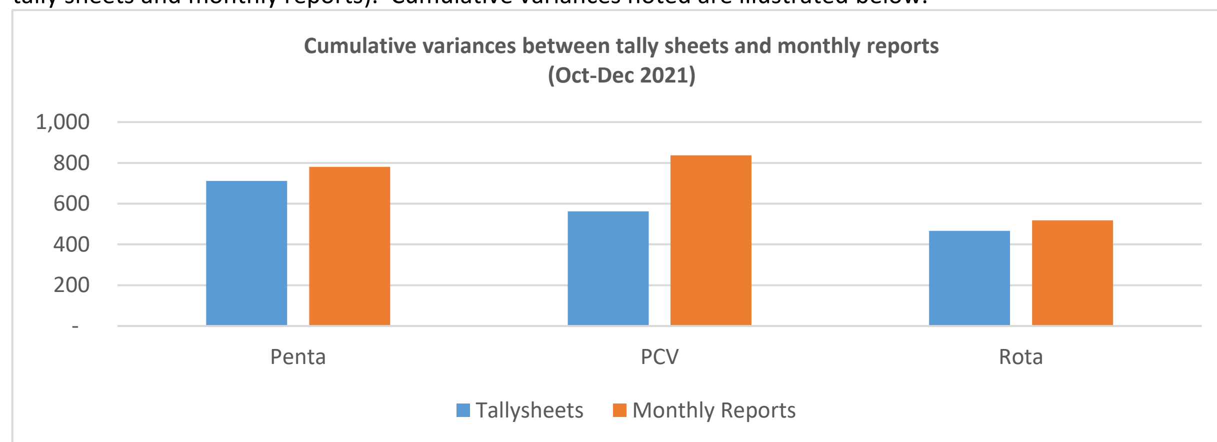
MoHP through the HMIS and Logistics sections should:

- Routinely triangulate available data, including an assessment of administrative coverage data and vaccine availability / utilisation to check for accuracy of the data reported. Such analyses should be completed at national and sub-national levels, and any data inconsistencies noted should be validated and explained.
- Ensure that all primary data collection tools are completed correctly and that the data reported is consistent and correlates with other sources.
- Update the population projections based on the latest 2021 census.
- Ensure adequate supervision at sub-national level over data collection and management, including the follow-up of recommendations to address data management gaps, as based on routine supervision visits and programme audit issues.

PCV



Inaccuracies in data at the point of collation at the HFs - HFs use the "health facility monthly reports" to consolidate immunisation data from tally sheets. These monthly reports are used to enter data into the DHIS2 system at either HF level or Municipality level. Consequently, the audit team compared the coverage in the monthly report to the Tally sheets at the HF for a sample of three months (Oct to Dec 2021). We noted that 33% of HF visited had unexplained variances between their tally sheets and their monthly reports for at least one of the sampled antigens (Annex 7a-variances between tally sheets and monthly reports). Cumulative variances noted are illustrated below.



Consistent under-reporting and delayed reporting of immunisation data – The audit team noted that over the five-year period 2017 to 2021, there was a progressive improvement in the percentage of health facilities reporting immunisation

<table>
<tr><td colspan="2">data on time. Nevertheless, approximately 53% of HFs did not report their immunisation data on time (i.e., within 15 days of end of month) during this period.</td><td colspan="2"></td></tr>
<tr><td colspan="2">Root cause
• Weaknesses in data quality assurance.
• Multiple reporting systems being used which are not connected to each other. Some HFs, including private hospitals for example, used more than one data management system in addition to DHIS2.
• There are infrastructure challenges, such as poor internet access or power outages, which frequently resulted in delaying reporting.
• There is limited human resources capacity at both the HF and palika levels. In addition, significant staff attrition disrupted regular flows of monthly reporting.</td><td colspan="2">Management comments

See detailed management comments included in Annex 9 – Action plan.</td></tr>
<tr><td colspan="2">Risk / Impact / Implications
• Inconsistencies in the reported administrative coverage data is non-compliant with the terms of the signed Partnership Framework Agreement and may undermine the confidence in the reported administrative coverage data.
• Inconsistent immunisation and consumption data deters effective strategic decision making thus affecting grant performance and subsequent funding decisions.
• Inaccurate and incomplete data recorded at facility, sub-national and national level impacting effective evidence driven decision making.</td><td>Responsibility
Action 12:
FWD in coordination with iHMIS and the Management Division (with technical support from the partners)</td><td>Deadline / Timetable
Action 12:
Timelines as indicated for each action.</td></tr>
</table>

4.3.2. Data quality assurance processes were inadequate

Context and Criteria

PFA article 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, PFA article 16 sets out additional provisions on the monitoring and reporting, specifying that "*the Government's use of Gavi's vaccine and cash support is subject to strict performance monitoring,*" such that*: "Gavi seeks to use the Government's reports and existing country-level mechanisms to monitor performance."*

Condition

Lack of a data management policy and data quality improvement plan: Nepal has never carried out a national-wide data quality audit (DQA) to assess the extent of gaps in the data quality. Consequently, the country has no costed data quality improvement plan with clear action points and strategies to address the data quality challenges. In addition, the country does not have a data management policy.

Gaps in data quality review: The audit team noted that data reviews carried out at Federal level only focus on data timeliness and completeness of reporting without emphasis on data quality aspects like triangulation of coverage data to logistics data, reconciliations between tally sheets and monthly reports. In addition, the audit team noted that Districts and health facilities carried out self-assessments to review data and identify any gaps in the immunisation data. However, there was no evidence that reports from district and HF self-assessments were synthesised and analysed by FWD for decision making and follow up.

No documented evidence of onsite data verifications and annual review meetings: The audit team was informed that the FWD, through the HMIS directorate and Provincial Health Offices, carries out periodic onsite data verifications and support supervisions at health facilities. However, the audit team did not receive any evidence to verify that on site data verifications and support supervision were carried out during the audit period. In addition, there was no evidence of annual data review meetings taking place at the federal level. Without the documented feedback, there is no mechanism for tracking implementation of any action points raised.

Weaknesses in immunisation data validation, verification, and collation at the health facility level: The HFs are required to carry out monthly data validation and verification meetings, to review immunisation data before it is entered into DHIS2. However, the audit team did not find documented evidence of data validation and review meetings in 100% of PVS, 83% of DVS and 17 (67%) of HFs visited. Refer to annex 7b & 7c.

Root cause

Lack of data management policy and data quality improvement guidelines.

Recommendation 13

We recommend that the MoHP through the HMIS and Logistics sections:

- Carries out a national-wide data quality audit, to assess the quality of data reported and develop a costed data quality improvement plan, which can be used to raise resources towards data quality improvement.
- Consistently complete and document data verification and validation exercises, at the health facility and district levels, as required by the guidelines.
- Ensures adequate supervision over data collection/ data management components is conducted at sub-national levels, including the follow-up of recommendations to address data management gaps from routine supervision visits and programme audits.

Management comments

See detailed management comments included in Annex 9 – Action plan.

Risk / Impact / Implications	Responsibility	Deadline / Timetable
• Sub-optimal data quality assurance mechanisms contribute to inconsistent reported administrative coverage data. This is not in accordance with the Partnership Framework Agreement provisions on information and may undermine confidence in the reported administrative coverage data. • Inaccurate and incomplete data recorded across health facilities, sub-national and national levels, will impact on the accuracy of evidenced-based decision making.	**Action 13:** FWD and the Management Division (WHO is currently supporting in drafting)	**Action 13:** 2025/26

4.3.3. There were gaps in Covid 19 vaccines and data management

Context and Criteria

Covid-19 negatively disrupted the regular functioning of the vaccine supply chain, because of the lockdowns and travel restrictions. In addition, intermittent scarcity of vaccines and short shelf-life doses, resulted in rapidly deploying a national Covid-19 campaign, and requiring robust implementation planning. The corresponding planning process requires: adequate financial backing, infrastructure systems, and dedicated human resources. Consequently, in February 2021, NIP developed its Covid-19 vaccine deployment plan, micro plans for the implementation and rollout of vaccines.

Condition

The country had a success story on the achievement of its Covid-19 vaccination targets. The audit team noted some opportunities for improvement as below:

Anomalies in reported Covid-19 vaccination coverage – A comparison between the number of doses issued by the Central Vaccine Store and the coverage reported indicated that the number of people reported as vaccinated with Covid-19 vaccines from the period February 2022 (the start of vaccination) up to of 15 June 2022 was higher than the number of Covid-19 vaccine doses utilised. The team's calculations were adjusted for wastage using the lowest wastage rate of 5% and closing balances in the provinces and districts, as reported by the Logistics Management Section. The unexplained variance of an additional 3 million people being reported as vaccinated than the doses physically available, is illustrated below:

Table 11: Variances between Covid-19 doses and coverage

	Doses (adjusted) available for vaccination during period	Total vaccinations administered (up to 15 Jun 2022)	(Excess) numbers of vaccinated individuals
Covishield	5,756,915	7,698,050	(1,941,136)
AZ	6,204,199	5,900,061	304,138
Sinopharm	18,021,853	19,869,640	(1,847,787)
J&J	3,354,446	3,607,262	(252,816)
Pfizer	1,295,944	854,349	441,595
Moderna	7,131,574	6,872,742	258,832
Total	**41,764,932**	**44,802,104**	**(3,037,172)**

Over 2.3 million doses of Covid-19 vaccines were at imminent risk of expiry: The delayed settlement of vaccination allowances for vaccinators from districts caused a bottleneck in the distribution and consumption of Covid-19 vaccines. Consequently, this led to a pile-up of unused vaccines with only a short shelf-life remaining (1 to 4 months), as illustrated below.

Table 12: Covid-19 doses at a risk of expiry as of 17 May 2022.

	CVS level	PVS or DVS level	Doses	Expiry Date	Approx. time interval until expiration
Moderna	41,220	117,960	159,180	23-Jun-22	5 weeks
Covishield		105,890	105,890	10-Jul-22	8 weeks
Covishield	19,480	1,201,740	1,221,220	23-Jul-22	10 weeks
Pfizer	587,340	313,958	901,298	30-Sep-22	19 weeks
Total	**648,040**	**1,739,548**	**2,387,588**		

Recommendation 14

MoHP should triangulate its Covid-19 vaccination data with its logistics data, to ensure accountability for all of its vaccines, congruent with accurate and reliable coverage data.

<table>
<tr><td colspan="1">Although the country had developed strategies to accelerate the utilisation of these doses, including: (i) rolling out of Pfizer vaccines to 5-11 years, and (ii) using Moderna doses as a booster for 12-17 years adolescents, there is still a high risk that a considerable quantity of these doses will shelf-expire.</td><td colspan="2"></td></tr>
<tr><td>Root cause
The Covid-19 pandemic represents a worldwide humanitarian crisis which has tested the resilience and agility of countries' health systems, including some unexpected disrupting effects which they were not fully prepared for.</td><td colspan="2">Management comments

See detailed management comments included in Annex 9 – Action plan.</td></tr>
<tr><td>Risk / Impact / Implications
The attention and focus given to the Covid-19 response, risks overshadowing important elements of the routine immunisation programme. An added challenge is that in general, most of the human resources drawn upon to manage both the response and RI were in common, but were not formally integrated. This could result in missed vaccination opportunities occurring.

Wastage of Covid-19 vaccines due to expirations.</td><td>Responsibility
Action 14:
Family Welfare Division and Management Division/ DoHS</td><td>Deadline / Timetable
Action 14:
Immediate effect - monthly basis</td></tr>
</table>

4.4. Procurement and fixed asset management

4.4.1. There were gaps in procurement and fixed assets management

Context and Criteria

PFA article 10 requires that "*unless otherwise agreed with Gavi, the Government shall maintain, where available at a reasonable cost, all risk property insurance on the Programme assets (including vaccines and vaccine related supplies) and comprehensive general liability insurance with financially sound and reputable insurance companies. The insurance coverage shall be consistent with that held by similar entities engaged in comparable activities.*"

The GMRs require that "*A consolidated (covering all levels) and comprehensive Fixed Asset Register (FAR) for all assets, including but not limited to cold chain equipment, vehicles and IT equipment procured or to be procured through Gavi grants to Nepal will be maintained. This FAR will be maintained and updated regularly. All assets procured with Gavi funds will be tagged with unique identifiers and asset verification will be carried out at least annually, reconciling the physical assets count and condition to the FAR at all levels. In the absence of a computerised assets management module (expected to be included in GARIS), MoHP/DoHS will consider maintaining the FAR in MS Excel spreadsheets, to enhance compliance with the requirement to have a consolidated and comprehensive FAR.*"

Condition

Incomplete cold chain equipment (CCE) logistics register (in eLMIS) – the eLMIS system did not include all the CCE items procured by UNICEF that were financed from Gavi's CCEOP grant (an overall consignment of equipment of total approximate value of USD 1.3m). The audit team compared the full inventory listing of CCE items distributed by UNICEF, with the eLMIS system and noted that the following items were missing from the register, as indicated below.

Table 20: Variances between the UNICEF CCE distribution list and eLMIS

Designated CCE (Model #)	Type of CCE	Number of items distributed by UNICEF	Number of items recorded in eLMIS	Difference - number of items missing from eLMIS
HBC- 80	Refrigerator	327	171	156
HBD-116	Freezer	249	141	108
HTCD- 90	Combo	26	0	26
HTCD-90 SDD	Combo	19	0	19
Total item count		**621**	**312**	**309**

Assets registers in the PAMS and eLMIS systems were not reconciled to manual registers – There was no comprehensive assets register in place. The fixed assets register was maintained in the Provincial Asset Management System (PAMS), while CCE items were separately recorded in eLMIS. The management division also maintained a separate manual register. However, these three assets registers were not reconciled. There were also no comprehensive asset registers at all sites visited by the audit team. We noted inventory lists in place at only three (60%) PVS and four (33%) DVS.

There was no CCE preventive maintenance – Preventative maintenance is a requirement according to Gavi's CCEOP grant conditions. Preventative maintenance would include regular cleaning, dusting, checks on functionality among other maintenance procedures. There was no preventative maintenance plan in place, nor any evidence that routine preventative maintenance was undertaken at either the central or sub-national levels. Not maintaining assets properly could impact upon the validity of the equipment warranty.

No fixed assets verification exercises – At all levels, there was no evidence that fixed assets verification exercises were undertaken during the audit period. Additionally, assets were not tagged with a unique identifier, making a comprehensive asset verification exercise difficult to accomplish.

The DoHS procurement plan did not include Gavi-funded procurements: The DoHS prepares and publishes its annual procurement plan on the Government of Nepal website under the Public Procurement Monitoring Office. The procurement plan includes the timelines (approval of estimated cost to date of completion of work), mode of procurement and details of goods or services. However, these annual plans did not include Gavi supported procurements.

Recommendation 15

MoHP should ensure that:

- The eLMIS assets register is updated to include all CCE items. This register should be reconciled to the UNICEF CCE distribution list;
- Assets registers in the Provincial Asset Management System (PAMS) and eLMIS systems are reconciled to the manual registers;
- A comprehensive assets register is put in place and used for fixed assets verification purposes, in accordance with Gavi's GMR;
- Assets are properly tagged for their easy identification and verification.
- A procurement plan for Gavi-funded procurements is prepared either separately or included in the DoHS procurement plan.
- Preventative maintenance plans are completed and implemented at all CCE points.

<table>
<tr><td>Root cause
Several root causes were identified including;
• Inadequate oversight over asset and procurement management and lack of proper coordination between various divisions of DoHS.
• No asset verification exercises were conducted during the period under audit review.
• Supervision and monitoring visits did not incorporate asset management reviews as a necessary activity.
• The MoHP’s procurement team had no visibility over what assets were procured using Gavi funds, via UNICEF.</td><td colspan="2">Management comments

See detailed management comments included in Annex 9 – Action plan.</td></tr>
<tr><td>Risk / Impact / Implications
• Incomplete assets registers and lack of regular asset verification exercises may result in the misappropriation of assets;
• Lack of preventative maintenance may affect the efficiency of CCE and warranties governing equipment;
• Lack of maintenance plans could result in more frequent breakdowns of CCE, limiting the useful life of items;
• Exclusion of Gavi-supported assets from procurement plans inhibits a comprehensive overview when budgeting for capital asset expenditure, potentially affecting planning for future replacement and ongoing maintenance costs, including when items are no longer directly supported by donors.
• Non-compliance with grant management requirements.</td><td>Responsibility
Action 15:
Management Division/DoHS</td><td>Deadline / Timetable
Action 15:
See timelines per action above.</td></tr>
</table>

Annexes

Annex 1 – Acronyms

AWPB	Annual Work Plan
CHIS	Child Health immunisation Section
CIP	Costed Improvement Plan (linked to the EVM)
DTCO	District Treasury Control Office
DoHS	Department of Health Services
DVS	District Vaccine Stores
eLMIS	Electronic Logistics Management Systems
EVM	Effective Vaccine Management
FAR	Fixed Asset Register
FCGO	Financial Comptroller General Office
FHCV	Female Health Community Volunteers
FWD	Family Welfare Division
GMR	Grant Management Requirements
HF	Health Facility
HMIS	Health Management Information Systems
ICC	Inter agency Coordination Committee
LMIS	Logistics Management Information System
MA	Monitoring Agent
MoHP	Ministry of Health and Population
NIAC	National Immunisation Advisory Committee
NPR	Nepalese Rupee
PAMS	Provincial Asset Management System
PHLMC	Provincial Health Logistic Management Centre
PVS	Provincial Vaccine Stores
SOE	Statement of Expenditure
UNICEF	United Nations Children's Fund
USD	United States Dollars
VIG	Vaccine Introduction Grant
WHO	World Health Organisation
WUENIC	WHO UNICEF Estimates of National Immunisation Coverage

Annex 2 – Methodology

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

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

In general, the scope of A&I's work extends not only to the Secretariat but also to the programmes and activities carried out by Gavi's grant recipients and partners. More specifically, it 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.

Annexe 3 – Definitions: opinion and audit rating

A. Overall Audit Opinion

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

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

B. Issue Rating

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

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

Annex 4: Sites visited by the audit team.

Provinces	Districts	Municipalities	Health Facilities
Province 1	Morang, Sunsari	Dhanpalthan RM, Itahari Sub Metro	Dadar Bariya, BHSC – 5, Thalaha, Pakali, Khanar
Province 2	Dhanusha, Mahottari	Mathiyani	Dhalkebar HP, Naktajhi HP, Majhaura Bishanpur, Dhirapur
Province 3	Kathmandu, Lalitpur, BhaktaPur, Kavre	Gokarneshwor, Lalitpur Metropolitan, Changunarayan, Dhulikhel	Balua, Changu Narayan, Tathali, Bugmati, Saibu, Kavre, Sankhu Party Chaur
Province 5	Palpa, Rupandehi	Rainadevi Palika, Mayadevi	Chhahara, Mujung, Hattibangai, Kamariya, Semara Bazar
Province 7	Kailali, Kanchanpur	Bedkot	Phulwari, Urma, Suda, Pipladi

Annex 5: Details of support supervision

	Health Post (HF)	Evidence of supervision
1	Dadarbariya	No
2	Basic Health Service Center Ward No 5, Dhanpalthan	No
3	Khanar Health Post	No
4	Pakali Health Post	No
5	Thalaha Health Facility	No
6	DHALKEBAR	No
7	NAKLAJISH	No
8	Dhirapur Health Post	No
9	Majhaura Bisanpur	No
10	Baluwa	Yes
11	Tathali	Yes
12	Changunarayan	Yes
13	Bugmati	Yes
14	Saiba	Yes
15	KAVRE Health Facility	Yes
16	Sankhapatichaur Health Facility	Yes
17	Chhahara Health Post	No
18	Mujung Swasth Chowki	No
19	Hattiban Gai Health Post	No
20	Kamhariya Health Post	No
21	Semara Bazar Health Post	No
22	Phulbari Health Post	No
23	Urma Swasth Chowki	No
24	Pipladi Swasth Chowki	No
25	Suda Swasth Chowki	No

Annex 6: Gaps in Vaccine Supply Chain Management

a) Missing vaccine management records – exceptions only

Key:

X -Missing records

Partial – Some documents were provided and not all.

Green cell – No exceptions

Provinces

S.N.	VSCM	Period	Province 2	Province 3	Province 7
1	Details of vaccines (Covid, PCV, Penta and Rota) received from Federal during 2017-2021	2017-18	N/A	X	X
		2018-19	N/A	X	
		2019-20	N/A	Partial	
		2020-21	N/A	Partial	
		2021-22		Partial	
2	Details of vaccines (Covid, PCV, Penta and Rota) transferred to districts during 2017-2021	2017-18	N/A	X	X
		2018-19	N/A	X	
		2019-20	N/A	X	
		2020-21	N/A	Partial	
		2021-22		Partial	

District

S.N.	VSCM and data management	Period	Morang	Sunsari	Dhanusha	Mahottari	Kathmandu	Lalitpur	Bhakta Pur	Kavre	Palpa	Rupandehi	kailali	Kanchanpur
1	Details of	2017-18			X	X	X	X		X	X		X	X
		2018-19			X	X	X	X		X			X	

S.N.	VSCM and data management	Period	Morang	Sunsari	Dhanusha	Mahottari	Kathmandu	Lalitpur	Bhakta Pur	Kavre	Palpa	Rupandehi	kailali	Kanchanpur
	vaccines (Covid, PCV, Penta and Rota) received from Province during 2017-2021	2019-20		Partial	X	X	X		X	X			X	
		2020-21		Partial	X	X			X					
		2021-22		X	X	X		X	Partial					
2	Details of vaccines (Covid, PCV, Penta and Rota) transferred to HFs during 2017-2021	2017-18			X	X	X	X		X	X		X	X
		2018-19			X	X	X	X		X			X	
		2019-20			X	X	X		X	X			X	
		2020-21		Partial	X	X			X					
		2021-22		X	X	X		X	Partial					

Health Facility exceptions only

Health facility name:	Vaccine records (Covid, PCV, Penta and Rota) received from districts/municipality during 2017-2021-
Dadar Bariya	Partial
Thalaha	X
Pakali	X
Khanar	X
Dhalkebar HP	Partial
Naktajhi HP	X
Dhirapur	X
Mujung	Partial
Phulwari	X
Urma	X
Suda	X
Pipladi	X

b) Unexplained stock count variances at PVS

	Penta			PCV			Rota			Johnson and Johnson		
	Stock Record	Physical Count	Variance	Stock Record	Physical Count	Variance	Stock Record	Physical Count	Variance	Stock Record	Physical Count	Variance
Prov 1	5,300	5,050	250	5,300	4,900	400	49,600	48,550	1,050	4,920	4,850	70
Prov 5	10,750	10,750	-	34,000	33,800	200	23,150	21,500	1,650			
Prov 7	3,650	3,950	-300	12,700	12,600	100	33,750	33,800	-50			

c) Unexplained stock count variances at DVS

	Vaccine type:	Penta			PCV			Rota		
	DVS:	Stock Record	Physical Count	Variance	Stock Record	Physical Count	Variance	Stock Record	Physical Count	Variance
Prov 1	Morang	448	448	-	1,516	1,519	-3	2,110	2,060	50
	SUNSARI	200	-	200	3,000	3,138	-138	2,000	2,090	-90
Prov 2	DHANUSA	-	6,015	-6,015	500	500	-	-	1,235	
	MAHOTTARI	350	367	-17	1,200	1,241	-41	-	943	-943
Prov 3	Kathmandu	424	377	47	1,500	1,416	84	1,425	1,540	-115
	BHAKTAPUR	315	495	-180	504	719	-215	385	855	-470
	LALITPUR	639	770	-131	967	936	31	2,365	2,245	120
	KAVREPALANCHOK	216	216	-	354	354	-	1,345	1,345	-
Prov 5	Palpa	648	648	-	929	975	-46	3,995	3,988	7
	RUPANDEHI	663	663	-	1,303	1,303	-	3,742	3,742	-

Prov 7	kailali	329	322	7	1,076	1,076	-	691	691	-
	KANCHANPUR	950	962	-12	261	262	-1	3,400	3,547	-147

d) Unexplained stock count variances at DVS

	Vaccine type:	AZ			Pfizer			Covishield		
	DVS:	Stock Record	Physical Count	Variance	Stock Record	Physical Count	Variance	Stock Record	Physical Count	Variance
Prov 1	Morang	2,800	2,841	-41	-	-	-	2,800	2,841	-41
	SUNSARI	1,800	1,800	-	15,795	15,795	-	1,800	1,800	-
Prov 2	DHANUSA	5,350	5,486	-136				5,350	5,486	-136
	MAHOTTARI	6,720	-	6,720				2,400	3,250	-850
Prov 3	Kathmandu	-	-	-	687	587	100	447	480	-33
	BHAKTAPUR	-	-	-	335	350	-15	1,173	198	975
	KAVREPALANCHOK	-	-	-	-	-	-	-	104	-104

e) Unexplained stock count variances at DVS

	Vaccine type:	Sinopharm			Moderna			JJ		
	DVS:	Stock Record	Physical Count	Variance	Stock Record	Physical Count	Variance	Stock Record	Physical Count	Variance
Prov 1	SUNSARI	2,400	2,400	-	420	420	-	920	960	-40
Prov 2	DHANUSA	7,310	8,103	-793				1,156	1,107	49
	MAHOTTARI	-	92	-92				130	80	50
Prov 3	Kathmandu				1,633	1,360	273	960	950	10
	BHAKTAPUR				1,090	250	840	-	-	-
	KAVREPALANCHOK				-	-	-	-	58	-58
Prov 7	kailali				130	57	73			

f) Stock reconciliation variances (in doses)

Name	Penta	PCV	Rota
Province 1	(190)		
Morang	200	100	
Palpa	(228)	403	475
kailali	694	2,700	7,200
Kanchanpur	694	2,900	21,050

g) Stockout days observed at PVS.

Vaccine type:	Penta		PCV		Rota	
PVS Name	Low	High	Low	High	Low	High
Province 1			5	26	5	33
Province 5	7	7			12	13

h) Stockout days observed at DVS:

Vaccine type:	Penta		PCV		Rota	
DVS Name	Low	High	Low	High	Low	High
Morang	29	55	22	66	22	64

i) Availability of preventive maintenance plan – exceptions only

	Preventive maintenance plan available (Yes/No)
Provinces with no plan:	
Province 2	No
Province 3	No
Province 7	No
Districts with no plans:	
Morang	No
Sunsari	No
Mohottari	No
Dhanusha	No
Kathmandu	No
Bhaktapur	No
Lalitpur	No
Kavrepalanchwok	No
Palpa	No
Kailali	No
Kanchanpur	No

Annex 7: Gaps in immunisation data management

a) Variances between tally sheets and monthly reports

		Penta			PCV			Rota		
		Tally sheets	Monthly report	Vari-ance	Tally sheets	Monthly report	Vari-ance	Tally sheets	Monthly report	Vari-ance
Prov 1	BHSC: - ward no. 5	48	48	-	61	61	-	42	41	(1)
	Khanar HP	270	276	6	248	251	3	106	105	(1)
Prov 2	Dhalkebar HP	43	80	37	54	98	z4	41	77	36
	Naklajish HP	30	68	38	41	85	44	30	49	19
	Majhaura Bisanpur	182	182	-		191	191	158	158	-
Prov 3	Baluwa HP	68	61	(7)	84	84	-	44	44	-
	Kavrebhangyang HP	31	31	-	34	34	-	21	20	(1)
	Sankhu Patichaur HP	40	35	-	40	33	(7)	25	25	-

b) Evidence of data validation at DVS

Province	Name of DVS	Is there evidence of data review meeting? (Yes/ No)
Prov 1	Morang Health Office - District	No
	SUNSARI Health Office-District	No
Prov 2	DHANUSA Health Office-District	No
	MAHOTTARI Health Office-District	Yes
Prov 3	Kathmandu District Health Office (DHO)	No
	BHAKTAPUR Health Office-District	No
	LALITPUR Health Office-District	No
	KAVREPALANCHOK Health Office	Yes
Prov 5	Palpa Health Office-District DHO	No
	RUPANDEHI Health Office-District (DHO)	No
Prov 7	kailali District Health Office (DHO)	No
	KANCHANPUR Health Office-District	No

c) Evidence of data validation at HFs

Province	Name of HF	Is there evidence of data review meeting?	Where there variances between Tally sheets and monthly reports?
Prov 1	Dadarberiya HP	NO	NO
	BHSC:- ward no. 5	NO	Yes
	Pakali HP	NO	NO
	Khanar HP	NO	Yes
Prov 2	Dhalkebar HP	NO	Yes
	Naklajish HP	NO	Yes
	Majhaura Bisanpur HP	NO	Yes
	Dhirapur HP	NO	NO
Prov 3	Baluwa HP	Yes	Yes
	Changunarayan Hospital	Yes	NO
	Tathali HP	Yes	NO
	Bagmati HP	Yes	NO
	Lubu PHC	Yes	NO
	Kavrebhangyang HP	Yes	Yes
	Sankhu Patichaur HP	Yes	Yes
Prov 5	Chhahara HP	NO	NO
	Mujung HP	NO	NO
	Haatibangai HP	NO	NO
	Damariya HP	NO	NO
	HP Semara Bazaar	NO	NO
Prov 7	Phulbari HP	Yes	NO
	Urma HP or UHC 12	NO	NO
	Suda HP	NO	NO
	Pipladi	NO	NO

Annex 8: Summary of EVM 2021 assessment findings

Section	Findings	Mitigation Plan
E2 Temperature monitoring	• The suboptimal use of manual temperature monitoring systems • Not carrying out periodic reviews of temperature data	• The use of thermometers and standardized registers for monitoring the temperature of vaccines • The weekly downloading of 30 DTRs • Conducting a temperature monitoring study
	• The unavailability of dedicated human resources for monitoring temperatures twice daily including at weekends and holidays • Lack of training on temperature management during transportation and storage	• Identify the personnel responsible for monitoring he temperature of vaccines twice daily including at weekends and holidays. • Train concerned personnel on temperature management during transportation and storage
	• Inadequate space for conditioning ice packs	• Provide adequate space for conditioning ice packs. • Use job aids for temperature management and conditioning. • Code and store freeze tags
E3 Storage and transport capacity	• The unavailability of dynamic data on the cold chain storage of vaccines • The lack of facility-wise data on freezing capacity availability and the requirement to meet transportation needs and contingencies	• Carry out a national cold chain assessment. • Review cold and dry space requirements to ensure adequate space for peak stocks. • Ice pack freezing capacity needs to be reviewed and augmented
E4 Building, CCE and transport	• The irregular release of funds for generator fuel	• Regularly provide funds on time for generator fuel
E5 Maintenance	• The limited availability of cold chain technicians • Lack of a cold chain management information system • Inadequate SOPs and job aids for the preventive maintenance of supply chain equipment.	• Place closed circuit TV systems in all provincial stores (2 per store) and build capacity on their use. • Establish a cold chain MIS for monitoring the performance and spare parts requirements. • Introduce SOP and job aids for the preventive maintenance of supply chain equipment.
	• There are no key performance indicators (KPI) on the functioning of the cold chain	• Establish a system for maintaining cold chain equipment allowing maximum downtimes of 10 days with a response time of 3 days to begin maintenance and repair jobs. • Repair, and as far as possible make functional, all cold chain equipment and dispose of nonrepairable equipment
	• Lack of knowledge of staff on planned periodic preventive maintenance	• Train maternal and child health staff at hospitals and other health facilities on vaccine management and basic cold chain equipment maintenance.
E6 Stock management	• Mismatches between the number of physical vaccines and diluent stocks • The incomplete documentation of stock levels	• Regularly count physical vaccine and diluent stocks and reconcile with stock records. • All issuing stores to know the minimum, maximum and reorder levels of all vaccines and dry goods at receiving stores
	• There are no standardized registers for stock management. • There is no logistics management information system (LMIS) at all levels of the vaccine supply chain	• Introduce standardized vaccine registers, indent books, issue vouchers for all levels of the vaccine supply chain. • Develop an online vaccine management system
	• The early expiry first out (EEFO) approach is not used in all vaccine stores	• Reorganize the storage of dry vaccine goods to facilitate an EEFO approach to storage and do stock reconciliations.
E7 Distribution	• The unavailability of SOPs for vaccine distribution • The insufficient and untimely availability of funds for distributing vaccines	• Develop required SOPs and guidelines for vaccine distribution planning. • Make adequate funds available on time for vaccine distribution to outreach sites and intermediary stores
E9 Waste management	• The widespread open burning of immunisation waste along with general waste and without disinfection • The lack of SOPs on vaccine waste management	• Produce a SOP and job aids on immunisation waste disposal, establish an immunisation waste disposal system and train all healthcare staff on implementing it. • Train all medical waste handlers and disposers on the proper management of medical waste

Annex 9 – Action plan

Issue	Audit recommendation	Management Action	Action Owner	Timelines
Programme implementation and coordination arrangements were ineffective.	**Recommendation 1** DoHS should establish a coordination platform and mechanism which brings together all divisions involved in immunisation activities to deliberate decide on planning, implementation and monitoring of immunisation activities.	**Action 1** • Going forward, FWD/DoHS will initiate the formation of a steering committee proposed to be chaired by Director General specifically for a coordination platform to deliberate planning, implementation and monitoring of related aspects of the National Immunization Programme including for Gavi-funded activities with representation from different divisions under MoHP, partners and other stakeholders. The ToRs of this committee will be prepared that includes but is not limited to representation, meeting frequency, quorum, matters to be discussed, roles and responsibilities, documentation etc.	Family Welfare Division/DoHS	31 December 2023
	Recommendation 2 MoHP should: • Formalise accountability and reporting mechanisms between the provinces and DoHS. These should include the financial and programmatic reports to ensure that donor-provided funds are used for the planned activities and that the advances of such funds are accounted for, before being liquidated. • Develop and document working modalities and implementation guidelines between the federal level and provinces in consultation with key stakeholders from the provinces, district health offices and municipalities.	**Action 2** • Under the guidance of DoHS and MoHP, FWD/DoHS will initiate the formation of an Inter-Governmental Coordination Committee proposed to be chaired by Director General with the representation of various stakeholders of federal and provincial governments to deliberate programme planning, implementation, monitoring and reporting related aspects/challenges for National Immunization Programme including for Gavi-funded programme activities. • FWD/DoHS will enhance the current reporting mechanism through the issue of separate reporting requirements in Programme Implementation Guidelines requesting provincial and district-based health offices to comply with the reporting requirements for Gavi. If required, the health coordination division's support would be requested to address any challenges in the programme implementation and reporting.	Family Welfare Division & Financial Administration Section /DoHS	30 September 2023
There were sustainability concerns over the management of the immunisation programme.	**Recommendation 3** MoHP should: • Carry out an assessment of its Human Resource needs at all levels, to establish what are its additional capacity and resource requirements, in order to effectively implement the immunisation programme. • Ensure that there are documented roles and responsibilities for the FWD and ensure that there is a	**Action 3** • The issue of inadequate HR for the immunization programme has also been included in National Immunisation Strategy 2030 which is under development, this could be a basis for the advocacy for additional HR needs. • The terms of reference of the Child Health and Immunisation Section under the Family Welfare Division	Family Welfare Division/DoHS	30 September 23

Issue	Audit recommendation	Management Action	Action Owner	Timelines
	documented handover process to ensure skills transfer whenever there are personnel changes (both for government staff as well as for partner provided technical assistance functions). • Improve the capacity of the FWD to ensure increased involvement of the FWD in the immunisation programme.	are clearly documented. ***(Refer to the attachment Annex 1 MoHP ToR – page 13)***. Further, the newly introduced Internal Control System Guidelines 2079 of the Department of Health Services has also clearly mentioned the roles and responsibilities of the Director General, Division heads, Section heads and Chief of Financial Administration Section under Chapter 2 of the Guidelines. • Handover and takeover processes are done in the government system, however, the documentation of it will be improved in future for changes in key staff.		
Implementation of grant management recommendations was outstanding.	**Recommendation 4** FWD should: • Provide an update of the pending GMRs with timelines for completion of each requirement. • Develop a tracker to include all recommendations from various assurance providers and have an escalation mechanism to ensure adequate follow up of the long outstanding items and these should be adequately monitored by the ICC to ensure timely and effective implementation	**Action 4** • The status update for pending GMR has been provided. • The terms of reference of ICC will be revised in line with the Immunisation Act and guidance of the National Immunisation Advisory Committee by 31 December 2023. Terms of reference of ICC will include one of the roles being monitoring of compliance of grant management requirements to be done on six-monthly basis.	Family Welfare Division/DoHS	31 December 2023
Gaps in monitoring and supervision of programme activities	**Recommendation 5** • FWD should strengthen the monitoring and supervision mechanisms by • Developing annual supervision workplans, ToRs for supervisors as well as proper supervision tools; • Documenting feedback from supervision and ensuring follow-up of action points; and • Incorporating the monitoring and supervision activities funded through the Gavi supported TCA plan within the national monitoring plan to ensure capacity building of national supervisors and continuity of monitoring activities.	**Action 5** FWD/DoHS will prepare supervision work plans and ToRs of supervision as well as proper supervision tools. A system of documentation of monitoring visits and action plans will be introduced, and this will be discussed in staff meetings as well as bi-weekly immunization meetings on a quarterly basis.	Family Welfare Division/DoHS	30 September 2023
Gaps in vaccine management systems and processes at the federal level	**Recommendation** 6 MoHP should ensure that: • Quarterly stock counts are carried out at the central vaccine store and results documented. Any variances noted should be investigated and approved before posting; • Ensure that the eLMIS rollout plan is finalised and proper data quality assurance mechanisms are put in place.	**Action 6** 1. Stock counts to be done every month by Provincial and district vaccine stores. Central Vaccine store will conduct stock counts every 3 months. Documentation to be maintained. 2. eLMIS strengthening, training and expansion activities are planned in AWPB for FY 2023/24 (2080/81). By end of FY 2023/24 (2080/81), at least 60 districts will be using eLMIS for	**1.** District Vaccine store, PHLMC, Central Vaccine store within Management Division/DoHS 2. iHMIS section, Management Division/DoHS	1 June 2024 1 June 2024

Issue	Audit recommendation	Management Action	Action Owner	Timelines
	• Review forecast assumptions and ensure that processes are put in place to strengthen the capture and recording of actual utilisation at health facility level, and transmission of this data to the centre. • Proactively manage stock and ensure that any low stock is immediately reported to Gavi Alliance partners to avoid stock out incidences. • Institute a process to capture data on wastage of vaccines, for the country to develop its own rates as these play a critical role in the forecast outcome and accuracy.	vaccine management 3. Use of UNICEF's forecasting tool developed by the UNICEF Supply Division. At the last quarter of the year, vaccine forecasting is to be done using this tool and the forecast sent to UNICEF Supply Division for next year's supply. Indicators considered in forecasting are: - Actual wastage rate in the country; - Birth cohort; - Buffer stock needed. 4. Wastage data is captured through calculations using the vaccine received, vaccine supplied to service points and the coverage data. This wastage is captured and recorded every month in the Health facility monthly recording sheet but may not have been recorded in electronic DHIS2 database.	3. Vaccine Procurement Section, Management Division/DoHS 4. Management Division/DoHS	31 December 2023 30 June 2024
Standard operation procedures were not updated after federalisation.	**Recommendation 7** MoHP should: • Revise the EVM SOPs and align them to the current federal system. The revised SOPs should also include procedures on eLMIS and should be disseminated at all levels and suitable trainings conducted thereon. • Cost the EVM CIP and use these estimates to mobilise and advocate for the necessary resources to improve the vaccine and supply chain management processes. •	**Action 7** • The new SOP based on EVM 2.0 Assessment report is currently in draft form and is being cleaned. This will be presented to PMT in July 2023 for review. • The costed CIP has now been prepared and is available for review.	Management Division/DoHS	31 August 2023
	Recommendation 8 MoHP should come up with CCE preventive maintenance plan at all levels and ensure that these plans are adhered to.	**Action 8** With support from UNICEF, a third-party maintenance team has been hired. The team will develop and share the preventive maintenance curriculum by July 2023. This curriculum will serve as an SOP moving further.	Management Division/DoHS	31 October 2023
Stock management practices at subnational level were inadequate.	**Recommendation 9** FWD should ensure proper accountability for vaccines at all levels by: • Maintaining accurate and complete records at all levels and instituting proper handover mechanisms during staff transition. • Availing all HFs, the required stock keeping tools/records and job aids to avoid data entry gaps.	**Action 9** FWD and MD will coordinate with provincial and local government to ensure staff and health workers are held accountable to their work and to ensure provincial and local level gets adequate skills, tools and job aids to do their work with quality and efficiently. In addition: 1. Management Division/DoHS will train cold chain focal points at province and local level.	**1.** Management Division/DoHS 2. Family Welfare Division/ DoHS	30 June 2025 30 June 2025

Issue	Audit recommendation	Management Action	Action Owner	Timelines
		2. Family Welfare Division/ DoHS will train immunization focal points at province and local level. 3. Management Division/DoHS will develop and distribute job aids at all levels on vaccine management and cold chain. 4. Family Welfare Division/ DoHS will develop and distribute job aids at all levels on immunization and new vaccines.	3. Management Division/DoHS 4. Family Welfare Division/ DoHS	31 December 2024 31 December 2024
	Recommendation 10 FWD should train and provide job aids to all staff responsible for managing and handling vaccines to comply with the established SOPs, particularly on: • Recording of batch numbers, expiry dates and VVM status in the vaccine control books/ledgers. • Recording the results of each physical stock counts, investigating the variances, reconciling with the stock records, and documenting the whole process along with justification for adjustments.	**Action 10** There are several campaigns being rolled out in 2024 and we will use some opportunities to train vaccinators and cold chain handlers during those activities as below: 1. Train all cold chain personnel and vaccinators on updated immunisation and supply chain development by Jun 2025. 2. Harmonise and update training contents by Mar 2024. 3. Develop and distribute job aids to all cold chain points by December 2024. 4. Make functional the mechanism to document, sign and approve any variances on stocks between eLMIS and the physical count.	**1.** Family Welfare Division/ DoHS 2. Family Welfare Division/ DoHS 3. Management Division/ DoHS 4. Management Division/ DoHS	30 June 2025 31 March 2024 31 December 2024 31 December 2023
	Recommendation 11 • MOHP should ensure that waste management policies are properly disseminated to all levels to ensure practices are consistent with national guidelines.	**Action 11** Management Division will work in the next Fiscal year 2080/81 (2023/24 AD) to develop an immunisation specific waste management guideline keeping within the national health care waste management guidance. This new immunisation waste guideline will provide clear guidance on how Nepal should move forward to mitigate the immunisation waste management issue. 1. Develop Immunisation Waste Management Guideline and/or SOP keeping within the National Health Care Waste Management Guideline by 30 June 2024 2. Disseminate and roll out immunisation waste management guidance by 30 June 2025	Management Division/ DoHS	30 June 2025
Immunisation data is inaccurate and incomplete.	**Recommendation 12** MoHP through the HMIS and Logistics sections should: • Routinely triangulate available data, including an assessment of administrative coverage data and vaccine availability / utilisation to check for accuracy of data reported. Such analyses should be completed at national and subnational levels and any data inconsistencies noted should be validated and explained.	**Action 12** 1. HIS strengthening activities will be incorporated in NIS (currently being drafted) – 2023. 2. Data quality guidelines and training package will be developed to build capacity of health workers on data quality and use for evidence-based decision making (triangulation) – 2024/25. 3. FWD will develop a certified e-training package on data quality and use, and eLearning platform. This will be	FWD in coordination with iHIMS and MD (technical support from partners)	1. 31 December 2023 2. 31 December 2025 3. 31 December 2026 4. 31 December 2023 5. 31 December 2024

Issue	Audit recommendation	Management Action	Action Owner	Timelines
	• Ensure that all primary data collection tools are completed correctly and correlate or support each other. • Update the population projections based on the 2021 census. • Ensure adequate supervision at subnational level over data collection and management including follow up of recommendations to address data management gaps from routine supervision visits and programme audits.	implemented through online training and in-person training- 2025/26. 4. CBS will start the projection of population using census - 2021. DoHS/ iHIMS will consult with CBS for the upcoming yearly population projection – 2023 (in line with CBS timeline). 5. Nepal will conduct an assessment for IT maturity level for introducing individual-level vaccination records and will explore the DHIS2.0 tracker for recoding individual level vaccination records. However, roll-out will be planned in consultation with interested palika/s from 2024 onward.		
Data quality assurance processes were inadequate.	**Recommendation 13** We recommend that the MoHP through the HMIS and Logistics sections: • Carries out a national wide data quality audit to assess the quality of data reported and develop a costed data quality improvement plan which can be used to raise resources towards data quality improvement. • Consistently complete and document data verification and validation exercises at the health facility and district levels as required by the guidelines. • Ensure adequate supervision at subnational level over data collection and management including follow up of recommendations to address data management gaps from routine supervision visits and programme audits.	**Action 13** HMIS and FWD (with support from WHO) is developing various guidelines and analytical documents on data quality and use in immunisation which are: i) RDQA process and outcome - lesson learnt from five districts – draft version 2023 Q4 ii) data quality assessment guideline in immunisation - 2023 Q4; and iii) training material: DHIS, eLMIS Q4 and data triangulation for immunisation. Refer to previous recommendation for timeline as the e-learning tool is envisioned here.	FWD and MD (WHO is currently supporting in drafting)	31 December 2023
There were gaps in Covid-19 vaccines and data management.	**Recommendation 14** MoHP should triangulate Covid-19 vaccination data with logistics data to ensure full accountability of vaccines as well as accurate and reliable coverage data	**Action 14** FWD will present the Covid-19 vaccination and logistics situation once a month during the FWD bi-weekly meetings.	FWD/MD (with technical support from partners)	Immediate effect - monthly basis
There are gaps in procurement and fixed assets management.	**Recommendation 15** MoHP should ensure that: • The eLMIS assets register is updated to include all CCE. This register should be reconciled to the UNICEF CCE distribution list;CCE • Assets registers in the PAMs and eLMIS systems are reconciled to the manual registers; • A comprehensive assets register is maintained and used for fixed assets verification; • Assets are properly tagged for their easy identification and verification. • Procurement plan for Gavi funded procurements be	**Action 15** Management Division will: 1.Establish and institutionalise a mechanism of entering the assets procured by Gavi. 2. Develop and disseminate SOP to inventorise Gavi-fund procured assets. 3. Develop and institutionalise a mechanism to use stickers on assets procured by Gavi funds. 4. Develop and disseminate preventive maintenance SOP.	Management Division/DoHS	1.31 December 2023 2. 31 July 2024 3. 31 December 2023 4. 31 December 2023

Issue	Audit recommendation	Management Action	Action Owner	Timelines
	prepared either separate or included in the DoHS procurement plan. • Preventative maintenance plans are completed and implemented at all CCE points.			