Memorandum on the Socialist Republic of Vietnam Programme Audit report

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

The audit team reviewed these stakeholders' management of Gavi support to the routine immunisation programme provided during the period 1 January 2017 to 31 December 2022. The audit scope including the following grants: health systems strengthening, graduation, post transition engagement, vaccine introduction for inactivated poliovirus vaccine, measles rubella campaign, as well as other vaccines and cold chain equipment. The audit also covered the vaccine and cash provided by Gavi's COVAX facility in the support of Vietnam's COVID-19 emergency operations in 2021 and 2022.

Funds directly executed by WHO and UNICEF were not subject to our programme audit and were considered out of scope, in accordance with the United Nations single audit principle.

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 practices have some weaknesses in design or operating effectiveness such that, until they are addressed, there is not yet reasonable assurance that the objectives are likely to be met."
2. In total, sixteen issues were identified in the following areas: (i) governance and oversight; (ii) sustainability of Gavi's transition and post transition engagement; (iii) vaccine supply management; (iv) immunisation data management; and (v) budgeting and financial management.
3. To address the risks associated with the issues, the audit team raised 22 recommendations of which 7 were rated as high priority.
4. Key findings were that:
    a. There were gaps in the EPI's governance arrangements, including challenges in planning for the transition of vaccine procurement from the central to the provincial level. In addition, the oversight over the EPI activities was not effectively integrated into the national immunisation agenda.
    b. There were gaps in the sustainability planning for the "national immunisation

information system". This system has not been handed over to the MOH and is still reliant on donor support for updates, technical support and maintenance. There is also no comprehensive plan to incorporate the system's related expenditures into the government's budget.

c. Design challenges in the "national immunisation information system" impacted upon its operating effectiveness, and limited its potential for integration and interoperability with other in-country systems associated with immunisation activities.

d. There were nationwide stock outs of several routine immunisation vaccines including DPT doses (diphtheria, pertussis, and tetanus) and pentavalent doses (a vaccine consisting of DPT, hepatitis B and haemophilus influenzae type B). Both of these vaccines were stocked out at the national vaccine store, for a total of 698 days and 358 days, respectively.

e. Gavi funds totalling approximately USD 186,000 received by the National Institute of Hygiene and Epidemiology/ National Expanded Programme on Immunisation were used to incur value added tax costs that were not yet refunded to the programme. VAT recoveries are subject to the established partnership framework agreement.

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

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

Geneva, April 2024

PROGRAMME AUDIT REPORT

Socialist Republic of Viet Nam
March 2024

Gavi
The Vaccine Alliance

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1. Executive Summary

1.1 Overall audit opinion

The audit team assessed the Ministry of Health's management of Gavi support during the five-year period 2017-2022 as **"Needs significant improvement"**, which means, "One or few significant issues were 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 vaccine supply chain, sustainability of Gavi investments in the post transition period and budgeting and financial management. To address the risks associated with the findings, the audit team raised 22 recommendations of which 7 (32%) were rated as high risk. The recommendations need to be addressed by implementing remedial measures according to the agreed management actions.

1.2 Summary of key audit issues

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

1.3 Summary of issues

Through our audit procedures, we identified 4 high risk and 12 medium risk issues relating to the use and management of Gavi support. The high-risk issues are summarised below. The detailed findings are in Section 4 of this report.

Sustainability of Gavi's transition and post-transition engagement

In the period 2011 to 2012, three distinct systems (i.e., Vaxtrak, ImmReg and fee-based reporting) were developed aimed at strengthening immunisation management. In 2013, VaxTrak underwent a transformation into a web-based platform and extensive efforts were dedicated to integrating VaxTrak and ImmReg resulting in a comprehensive system dedicated to vaccine and immunisation management (i.e., National Immunisation Information System). In 2017, the National Immunisation Information System (NIIS) was launched and rolled out to all 63 provinces down to the health facility level including private health facilities. Thereafter in 2020, the National Expanded Programme for Immunisation (NEPI) requested and received USD 0.5 million from Gavi to enhance implementation of the NIIS nationwide, particularly focusing on the last steps of the complete transition from a paper-based system to electronic reporting in Hanoi and Son La provinces. Gavi's funding consisted of 30% of the post transition engagement grant to Viet Nam.

The audit team noted gaps in the management and sustainability of the system. Since 2015, the NIIS application is still hosted by the developer i.e., Viettel, and has not been handed over to the Ministry of Health (MoH). The system is still reliant on donor support for updates, technical support and maintenance, and there is no comprehensive plan to transfer system related expenditures to the government's budget. The quantification of expenses related to server infrastructure, hardware purchase and maintenance, software updates, bug fixing, and allocation of technical support resources has not been done. The lack of a thorough cost analysis may hinder proper financial planning and allocation affecting the system's long-term sustainability.

The audit team identified several gaps in the design of the National Immunisation Information System (NIIS). These include non-compliance with Decree 12 regarding personal data protection, incomplete implementation of a unique identifier for records, absence of data validation checks, lack of a policy for data backup and restoration testing, and no evidence of such tests in the form of logs. Additionally, the NIIS contains dummy or test records, impacting data quality. The system also lacks an audit log in the application's front end which hampers the tracking of user actions, posing challenges in troubleshooting security issues and prompt system restoration in the event of a breach. Furthermore, end-user manuals within the system have not been updated since 2016 despite numerous system changes. The system dashboards exhibit significant performance challenges with load times exceeding four hours, and the e-learning platform is suboptimal, with 29 of 30 modules inactive and non-compliant with security standards.

The audit team also noted gaps in the design of the National Immunisation Information System (NIIS) limiting its integration and interoperability with other in-country systems used for recording immunisation data. Specifically, only 35% (995 out of 2,866) of private or fee-based facilities' Electronic Immunisation Records (EIRs) had been effectively integrated into NIIS. Furthermore, there is no active integration between NIIS and any other Ministry of Health (MoH) immunisation data system, including the Viet Nam Health Management Information System (HMIS) and the Covid-19 tracker.

Most of the NIIS challenges stem from the absence of a formal mechanism between the MoH/NEPI and Viettel (the system developer) in the management and maintenance of the system. This has led to delays in the finalisation, updating, and upgrading of the system. Consequently, due to the identified gaps in system design and implementation, NIIS is presently not being utilised by NEPI and provinces for planning, reporting, and decision support.

Addressing the identified gaps is crucial for ensuring the sustained success of the NIIS. The implementation of the Gavi MICs strategy in Viet Nam should also consider the lessons learned from these challenges.

Vaccine supply management

As at June 2023, there were nationwide stock outs of several routine immunisation vaccines including DPT (diphtheria, pertussis, and tetanus) and pentavalent (a vaccine consisting of DPT, hepatitis B and haemophilus influenzae type B). Both of these vaccines were stocked out at the national vaccine store, for a total of 698 days and 358 days, respectively. These stock-outs extended across the entire supply chain, as evidenced by the audit teams visits to the regional, district and health facility/commune levels. The average cumulative stock out days for the pentavalent vaccine was 111, 94, 176, and 26 days at the region, province, district and health facility levels, respectively. Stock outs compromise the country's ability to sustain its immunisation gains.

These stock outs were primarily caused by the absence of an institutionalised financing mechanism to plan, procure and distribute the necessary vaccines, supplies and equipment during the period 2021 to 2023. The modality utilised in the period 2016 to 2020 was project-based with budget allocations through the five year-Health and Population Programme. The vaccine procurement function was meant to be transferred to the provincial level starting 2021 but this process was delayed until 2023.

Budgeting and Financial Management

Gavi funds received by the National Institute of Hygiene and Epidemiology/ National Expanded Programme on Immunisation (NIHE)/(NEPI) were used to pay Value Added Tax (VAT) in contravention of article 15 of the Partnership Framework Agreement (PFA) between Gavi and the Government of Viet Nam. Expenditure funded by grants totalling USD 1,308,845 received directly from Gavi and USD 1,041,122 received from Gavi through WHO included VAT payments. The current accounting records at NEPI do not support the extraction and reporting of the actual VAT paid. From the overall expenditure incurred using Gavi's funds, the audit team estimated that USD 185,961 was spent on VAT.

1.4. Financial consequences from the audit

Table 1: Summary of questioned costs

Item	Balance (USD)	Description
Reclaimable VAT amounts (estimated)	*185,961*	See section 4.5.3

1.5 Cash balances

Table 2: Cash balances as at 30th June 2023

Description	Balance (USD)	Source of information
UNEPI	*208,581*	UNEPI financial records
MoH	*1,827,803*	MoH financial records
WHO	*619,939*	WHO reports
Total	***2,656,323***	

2. Objectives and scope

2.1 Audit Objective

In line with the respective programme agreements and with Gavi's Transparency and Accountability Policy, all countries that receive Gavi's support are periodically subject to programme audit, for which the primary objective is to provide reasonable assurance that the resources were used for intended purposes in accordance with the Gavi 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 (vaccines and cash grants) for which the MoH, NIHE (NEPI), UNICEF, and WHO were responsible, so as to assess if: vaccine supply chain management systems are effective, the existing grant oversight mechanisms provide continuous and reliable assurance on Gavi's investments, the financial management processes support the timely utilisation and accountability of Gavi grant funds, the immunisation data systems are effective and Gavi investments are sustainable beyond the period of Gavi support.

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

The audit team adopted a risk-based audit approach informed by its assessment of the risks in all the areas of the immunisation programme supported by Gavi. This included vaccine and supply chain management, programme and data management, governance and oversight, COVAX and sustainability of key Gavi post transition investments. The period in scope was from 1 January 2017 to 31 December 2022. However, for purposes of Covid 19 response and vaccination roll out the scope covered up to 30 June 2023. Gavi's accumulated cash and vaccine support provided to the Socialist Republic of Viet Nam up to 31 December 2022 is presented in Table 3 below.

Table 3: Cash and vaccine support as of 31 December 2022

Amounts in USD		Grants in audit scope						
Cash grants	**2007 to 2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**	**Total**
HSS- and ISS	*42,615,500*	-	-	-	-	-	-	***42,615,500***
Graduation Grant	*203,300*	*1,621,050*	*1,036,550*	*348,120*	-	-	-	***3,209,020***
VIG	*3,061,000*	-	-	-	-	-	-	***3,061,000***
Product Switch Grant	-	-	*116,345*	-	-	-	-	***116,345***
MR - Operational costs	*14,901,575*	-	-	*495,000*	-	-	-	***15,396,575***
IPV-Catch-up costs & projects	-	-	-	-	*250,000*	-	*447,500*	***697,500***
Post Transition Engagement	-	-	-	-	*1,993,094*	-	-	***1,993,094***
COVAX CDS	-	-	-	-	-	*1,172,197*	*1,827,803*	***3,000,000***
Total cash	***60,781,375***	***1,621,050***	***1,152,895***	***843,120***	***2,243,094***	***1,172,197***	***2,275,303***	***70,089,034***
PEF TCA and PTE								
Technical assistance	-	-	-	-	-	***95,000***	***108,000***	***203,000***
Equipment support								
Total Equipment	-	-	-	-	***2,455,611***	***240,443***	***(79,674)***	***2,616,380***
Vaccines support								
Other vaccine support (HepB mono, MR, MCV, Rota)	*20,306,985*	-	-	-	-	-	*317,072*	***20,624,057***
IPV	*92,387*	*715,299*	*2,090,312*	*2,796,898*	*13,001,047*	*6,879,297*	*3,624,660*	***29,199,900***
Pentavalent	*90,299,095*	*1,015,075*	*1,754,639*	*(768,505)*	-	-	-	***92,300,304***
Injection Safety Devices	-	*294,630*	*(110,387)*	*141,033*	*162,394*	-	-	***487,670***
Covid-19 Vaccines*	-	-	-	-	-	*304,308,825*	*174,467,290*	***478,776,115***
Total vaccines	***110,698,467***	***2,025,004***	***3,734,564***	***2,169,426***	***13,163,441***	***311,188,122***	***178,409,022***	***621,388,046***
Total = (Vaccines + Equipment + Technical assistance + Cash)	***171,479,842***	***3,646,054***	***4,887,459***	***3,012,546***	***17,862,146***	***312,695,762***	***180,712,651***	***694,296,460***

** For purposes of Covid-19 response and vaccination deployment, the audit scope was extended up to 30 June 2023.*

2.3 Audit approach

The Gavi audit team conducted a scoping mission between 13 and 17 March 2023. A subsequent audit fieldwork mission was conducted between 29 May 2023 and 15 June 2023. As part of the audit, the team visited a range of sites, including: the national vaccine store, 4 regional vaccine stores, 8 provincial centres for disease control (CDCs), 8 provincial vaccine stores, 8 district vaccine stores and 13 communes/ health facilities. See Annex 4 for the list of sites visited by the team.

Gavi disbursed funds amounting to USD 6,510,659 to five fund recipients including NIHE(NEPI), UNICEF, WHO, PATH and CHAI over the period 2017 to 2022. The funds were to support six grants (including graduation, product switch, MR operational costs, IPV catch-up campaign, IPV projects, and post transition engagement (PTE)) and technical assistance.

Table 4: Cash disbursements by grant and recipient as of 31st December 2022

	2017-2022					
Implementer / Grant	NIHE (NEPI)	UNICEF	WHO	PATH	CHAI	Total (USD)
Graduation grant	-	1,165,320	1,840,400	-	-	**3,005,720**
PEF-PTE (Post transition engagement)	-	272,160	791,800	750,769	178,365	**1,993,094**
Product switch grant	116,345	-	-	-	-	**116,345**
MR - operational costs	495,000	-	-	-	-	**495,000**
IPV catch-up campaign	250,000	-	-	-	-	**250,000**
IPV projects	447,500	-	-	-	-	**447,500**
PEF TCA	-	108,000	95,000	-	-	**203,000**
Total	**1,308,845**	**1,545,480**	**2,727,200**	**750,769**	**178,365**	**6,510,659**

Gavi also disbursed funds to support the roll out of Covid-19 vaccines to three implementers including the Ministry of Health, UNICEF and WHO. The funds were provided to support vaccine delivery and scale-up, demand generation and advocacy.

Table 5: Covid-19 vaccine delivery support to Viet Nam as of 31st December 2022

Implementer	Grant	Amount (USD)	Period of Implementation
MOH	Covid-19 delivery support	1,827,803	2021-2022
UNICEF	Covid-19 delivery support	822,197	2021-2022
WHO	Covid-19 delivery support	350,000	2021-2022
Total		**3,000,000**	

Gavi grants related expenditure during the period 2017 to 2022 totalled USD 10,155,225 across various implementers including: Ministry of Health, WHO, UNICEF, NIHE (NEPI), PATH and CHAI.

Table 6: Reported expenditures by grant and recipient as of 31st December 2022 in USD

	2017-2022						
Grant	MOH	NIHE (NEPI)	UNICEF	WHO	PATH	CHAI	Total (USD)
HSS*	3,420,140	-	-	-	-	-	**3,420,140**
Graduation grant	215,876	1,607,028	345,261	837,554	-	-	**3,005,719**
PTE grants	188,078	104,440	27,557	154,803	418,237	124,855	**1,017,970**
Product switch grant	-	116,345	-	-	-	-	**116,345**
MR - operational costs	-	495,000	-	-	-	-	**495,000**
IPV- catch-up campaign	-	250,000	-	-	-	-	**250,000**
IPV projects	-	447,500	-	-	-	-	**447,500**
CDS	131,289	218,478	705,332	72,386	-	-	**1,127,485**
Country-Level TA preparation readiness***	-	-	107,263	-	-	-	**107,263**
COVAX CCE service bundle and leasing***	-	-	167,803	-	-	-	**167,803**
Total	3,955,383	3,238,791	1,353,216	1,064,743	418,237	124,855	**10,155,225**
Sampled for testing	1,005,023**	1,008,775**	^	^	^^	~	2,013,798

**The Health Systems Strengthening (HSS2) grant was implemented by the MoH from 2013 to 2018. The grant term ended on 30 June 2018, with two no-cost extensions granted between 2016 and 2018. USD 3,420,140 was spent in the period 2017 to 2018 and was therefore within the scope of the audit.*

*** Some of the Graduation, PTE and CDS grant funds disbursed to UNICEF and WHO (See Table 3 and Table 4 above) were sub granted to NEPI and MOH. These were sampled for testing.*

****UNICEF reported expenditure on Viet Nam for Gavi funds received through the UNICEF Global office.*

^Funds amounting to USD 2,417,959 disbursed to UNICEF and WHO were directly utilised by both organisations and are hence not subject to our audit review due to the Single Audit Principle[1].

^^ PTE grant funds received by PATH were used mainly to support the roll out of the NIIS. Detailed work was done on the NIIS design, policies and implementation at national and sampled provinces and other subnational levels.

~ Funds received by CHAI were scoped out as part of our risk assessment process.

During the audit scoping and fieldwork stages, the audit team collaborated with the Ministry of Health, NIHE/NEPI, PATH, WHO and UNICEF.

2.4 Exchange rate

Most of the in-country expenditures were incurred using the Vietnamese dong (VND). For information purposes and as part of the summary of this report, overall total amounts were reflected in United States Dollars (USD). For the expenditures reviewed, the rate applied was based on the average World bank rate (in the period 2017 to 2022) equivalent to 1 USD for VND 22,944.

[1] The Single Audit Principle is part of a common internal control and audit framework in the United Nations system organisations. The Single Audit Principle foresees a control system, where the control and audit functions are based on common methods enabling auditors of one institution to rely on the work of auditors from another institution instead of re-performing the audit themselves.

3. Background

3.1 Introduction

Viet Nam, officially the Socialist Republic of Viet Nam, is located at the eastern edge of mainland Southeast Asia, with an area of 311,699 square kilometres (120,348 square miles) and a population of 97 million (2021), making it the world's sixteenth-most populous country. Viet Nam borders China to the north, and Laos and Cambodia to the west. It shares maritime borders with Thailand through the Gulf of Thailand, and the Philippines, Indonesia, and Malaysia through the South China Sea. Its capital is Hanoi, and its largest city is Ho Chi Minh City (commonly referred to by its former name, Saigon)[2].

Viet Nam experienced prolonged conflict throughout the 20th century. After World War II, France returned to reclaim colonial power in the First Indochina War, from which Viet Nam emerged victorious in 1954. As a result of treaties signed two years later, Viet Nam was separated into two parts i.e., North, and South. The Viet Nam War began shortly after, between the communist North and the anti-communist South. Upon the North Vietnamese victory in 1975, Viet Nam reunified as a unitary socialist state under the Communist Party of Viet Nam in 1976[3].

In 1986, the Communist Party initiated economic and political reforms transforming the country to a market-oriented economy. These reforms have helped propel Viet Nam from being one of the world's poorest nations to a middle-income economy in one generation. Between 2002 and 2021, Gross Domestic Product (GDP) per capita increased 3.6 times, reaching almost USD 3,700. Poverty rates (USD 3.65/day, 2017 PPP) declined from 14 percent in 2010 to 3.8 percent in 2020. GDP growth is projected to ease to 6.3 percent in 2023, down from 8% in 2022, due to the moderation of domestic demand and exports. Viet Nam's economic growth is expected to rebound to 6.5 percent in 2024 as domestic inflation could subside from 2024 onward[4]. Viet Nam had a Gross Domestic Product (GDP) of USD 449.09[5] billion in 2023 making it the fifth-largest economy in Southeast Asia and was ranked 115[6] out of 191 countries and territories on the human development index in 2021.

The country is divided into six major geographical/ecological zones, i.e., the Red River Delta, Northern midlands and mountain areas, the North Central and Central Coastal areas, Central Highlands, Southeast and the Mekong River Delta. Administratively, the country is divided into 4 regions, 63 provinces, 704 districts, and 11,138 communes[7].

3.1.1 National health sector

The health sector structure conforms to the administrative structures with four levels i.e., central, provincial, district and commune/ward. The health service delivery system has four main service levels - grassroots level with commune health facilities, district level with district hospitals, provincial level with provincial hospitals, and central level with central hospitals under the management of the Ministry of Health. The Government issued Decree No. 75/2017/NDCP to define the functions, tasks, powers, and organisational structure of the Ministry of Health in the 2016-2020 period. At the provincial level, Decree No. 51/2015/TTLTBYT-BNV was jointly issued by the Ministry of Health and the Ministry of Home Affairs in 2015 to guide the functions, tasks, powers and organisational structure of health departments, province, and district health offices[8].

[2] Viet Nam statistics and figures
[3] Viet Nam officially reunited.
[4] World bank on Viet Nam
[5] International Monetary Fund: Viet Nam economic outlook
[6] Viet Nam Human Development Index
[7] Viet Nam Comprehensive Multi-year plan 2016-2020
[8] WHO: Viet Nam Health systems governance

Viet Nam's health system is mainly publicly funded with evolving models of private medical care sector and social health insurance. Social health insurance in Viet Nam was established in 1992 and is now regarded as the main method of public financing for health care. The government uses its tax revenues to subsidise health costs for vulnerable groups such as the poor, the ethnic minority, children under 6, and the elderly above 80. The current health insurance coverage is about 87% of the population[9]. Viet Nam's health system is also highly decentralised, with 93.9% of all facilities under the authority and management of local health authorities[10].

3.1.2 Immunisation in Viet Nam

Section 5 of the Law on Prevention and Control of Infectious Diseases has articles relevant to vaccination. Article 30 stipulates that, "*People's Committees of provinces and centrally run cities shall direct the organisation of the immunisation and use of vaccines and medical bio-products*." Articles 27 and 28 stipulate that vaccines must be used according to the agreed schedule and targets groups and must also be used at qualified establishments. A National Decree issued in 2005 asserted the rights of children under six years of age to free health care (therefore being exempted from paying user fees).

3.1.3 The National Expanded Programme on Immunisation

The National Expanded Programme on Immunisation (NEPI) was first implemented in Viet Nam in 1981 with the support of WHO and UNICEF. Administratively, NEPI reports to the National Institute of Hygiene and Epidemiology (NIHE) which in turn reports to the General Department of Preventive Medicine (GDPM) at the Ministry of Health (MoH). The programme management, thereafter, is decentralised to the four regional EPI offices, namely: Northern, Central, Southern and Highland which supervise the Provincial EPI offices[11]. The provincial offices supervise the district health centres who in turn supervise the commune health centres. Immunisation services are integrated into the health service delivery model of the commune health centres, where immunisation services are normally provided in sessions for 1-3 days per month, supplemented by mobile health strategies for remote areas and immunisation campaigns for disease elimination and control activities. Due to the decentralised structure of the Viet Nam health system, subnational governments have a significant role in setting the agenda for their local immunisation programs.

Viet Nam's EPI schedule currently provides 11 vaccines against 12 vaccine preventable diseases (VPD). See the Viet Nam immunisation schedule on Annex 5**.** The country has plans to introduce new further vaccines into its routine immunisation programme including rotavirus in 2023, PCV in 2025, HPV in 2026 and influenza in 2030[12].

Viet Nam currently operates a "dual system" of free-of-charge EPI services and non-EPI fee-based immunisation services, available in health facilities across the country in both the public and private sectors. Services provided at fee-based immunisation facilities (FIFs) are paid for directly by clients/patients out-of-pocket. FIFs are under the umbrella of the provincial health departments (PHDs) and report directly to them. Ho Chi Minh and Hanoi are two cities with the greatest number of FIFs[13].

3.1.4 Financing for the National Expanded Programme on Immunisation

The Office of the Prime Minister established the *Target Program on Health and Population for the period 2016-2020* through decree 1125/QD-TTg dated 31 July 2017. The decree identified EPI as one of the eight prioritised health projects for the period 2016 to 2020. The EPI's primary objective was to maintain the achieved results

[9] WHO: Viet Nam Health Financing

[10] Viet Nam Comprehensive Multi-year plan 2016-2020

[11] cMYP 2016-2020

[12] Government Resolution No. 104/NQ-CP dated 15th August 2022

[13] Private sector providers in immunisation

in controlling and eliminating several diseases with vaccines, strengthening, and improving the quality of the immunisation system. The decree also set out specific objectives including:

- Ensure that the annual rate of full immunisation for children under 1 year old reaches over 95%.
- Sustain polio eradication, neonatal tetanus elimination, progress towards measles elimination.

The decree defined sustainable funding for immunisation activities with the Central government responsible for securing the funding for procurement of vaccines and immunisation materials, while the provincial people's committee were responsible for allocating budget for EPI operations, syringes, and safety boxes. All funding for the immunisation activities was to transition to the provincial people's committees at the end of 2020.

3.2 Immunisation supply chain structure

Vaccines used by the National Expanded Programme for Immunisation (NEPI) are sourced either through imports or local manufacturing. At the time of the audit, three national manufacturers produced nine of the eleven vaccines listed in the national immunisation schedule, excluding Pentavalent (DPT-HepB-Hib) and Inactivated poliovirus (IPV) vaccines[14]. Imported vaccines are air-freighted to the country and stored at the National Vaccine Store (NVS) situated in the capital city, Hanoi. Beneath the NVS, four Regional Vaccine Stores (RVS) are located in the Northern (Northern EPI- Hanoi), Central (Pasteur Institute Nha Trang-Khanh Hoa), Southern (The Pasteur Institute-Ho Chi Minh), and Highland (Tây Nguyên Institute of Hygiene and Epidemiology-Dac Lak) regions. These RVSs receive vaccines either from the NVS or directly from local manufacturers, depending on their geographical location.

The RVSs initiate vaccine orders and related supplies from the NVS, with distribution occurring on a quarterly schedule. Each RVS oversees several Provincial Vaccine Stores (PVS) and the RVSs are responsible for distributing vaccines to 63 Provincial Vaccine Stores on a monthly delivery schedule. Refrigerated trucks, allocated to each RVS, facilitate the distribution.

Approximately 710 District Vaccine Stores (DVS) are under the purview of the PVSs. PVSs distribute vaccines to these DVSs according to a monthly delivery schedule, utilizing their own vehicles, as DVSs lack refrigerated trucks.

The last distribution points are health facilities/communes, which collect vaccines from the DVSs monthly, based on the stock on hand at the communes and monthly immunisation targets. Not all communes are equipped with cold chain equipment for vaccine storage. Communes possessing cold chain equipment (CCE) store their vaccines for up to one month, while those without CCE collect vaccines on the day of immunisation using cold boxes and/or vaccine carriers. The surplus vaccines are returned to the DVS at the conclusion of the vaccination session on the same day.

The country uses a combination of paper-based and electronic Logistics Management Information Systems (LMIS). The National Immunisation Information System (NIIS) features a module for recording receipt, issues and reporting vaccines, immunisation supplies, and cold chain equipment. NIIS is web-based and was designed to offer a platform for reporting vaccine management data across the tiers of the vaccine supply chain, from communes to the NVS. Vaccine stores across the various tiers also maintain paper-based stock cards and vaccine control books to record receipt, issue and adjustments to vaccine stock balances.

3.3 Covid-19 context and response

Covid-19 is a disease caused by a novel coronavirus first reported from Wuhan, China on 31 December 2019. This was later named as the severe acute respiratory syndrome-Coronavirus 2 (SARS-CoV-2). On 30 January

[14] National EPI review 2020

2020, the World Health Organisation (WHO) declared Coronavirus Disease 2019 (Covid-19) as a Public Health Emergency of International Concern (PHEIC).

On 23 January 2020, Viet Nam confirmed its first cases when two Chinese people in Ho Chi Minh City tested positive for the virus[15]. On 30 Jan 2020, the Prime Minister issued Decision 170/QĐ-TTG on the establishment of the National Steering Committee for the prevention and control of respiratory tract inflammation caused by the new strain of the Corona virus (Covid-19). On 25 March 2020, Ministry of Health (MOH) issued Decision 1338/QĐ-BYT making amendments to the terms of reference of the Steering Committee adding specific roles and responsibilities and establishing subcommittees on surveillance, epidemic prevention, treatment, communication and logistics and International Cooperation.

In March and April 2020, the number of cases increased rapidly due to the large number of people coming from European countries and the appearance of clusters which included Bạch Mai Hospital, Ha Loi Commune in Hanoi, and the Buddha Bar in Ho Chi Minh City[16]. On 31 March 2020, the Vietnamese government ordered a nationwide isolation of 15 days from 1 to 15 April 2020[17]. On 23 April 2020, the Vietnamese government lifted social isolation rules, subsequently allowing re-opening of non-essential services including restaurants. On the same day, schools across the country could be re-opened, with dates varying per each province and city case.

In August 2020, the Vietnamese government announced that they had signed up for 50 to 150 million doses of Sputnik V vaccine from Russia[18]. On 24 November 2020, MOH issued Decision 4900/QĐ-BYT on the establishment of the Working group on the Covid-19 vaccines including members from WHO, UNICEF to implement activities related to requesting for vaccine support from COVAX Facility. Responsibilities of the working group included: (i) developing and finalising the request for vaccine support from the COVAX Facility; (ii) reviewing, evaluating the readiness of Viet Nam for the introduction of Covid-19 vaccine; and (iii) advise and recommend the MOH to address remaining challenges (if any) to meet the requirements of Gavi and the COVAX Facility.

In February 2021, the Ministry of Health proposed the government approve COVID-19 vaccines from AstraZeneca, Gamaleya, and Moderna for domestic inoculation to prevent and control the ongoing pandemic in the country[19]. The Country also developed and approved the National Deployment and Vaccination plan (NDVP) on 9 February 2021.

Viet Nam's Covid-19 vaccination programme began on 8 March 2021, administering the AstraZeneca vaccine to medical workers in Hanoi, Ho Chi Minh City and Hải Dương province[20]. The first batch of vaccines sourced via COVAX mechanism, containing 811,200 AstraZeneca vaccine doses, arrived in Hanoi's Noi Bai International Airport on 1 April 2021.

The Ministry of Health coordinated with relevant ministries and branches such as the Ministry of Public Security, the Ministry of National Defence, the Ministry of Foreign Affairs to develop a plan to organise the Covid-19 vaccine campaign in line with the NDVP. The country utilised six antigens including AstraZeneca, Sinopharm, Pfizer, Moderna, Sputnik and Abdala during the vaccination campaign.

[15] Viet Nam reports first coronavirus case
[16] Increase in Covid-19 cases in Viet Nam
[17] Viet Nam orders lockdown
[18] Viet Nam to buy Covid-19 vaccine
[19] Covid-19 Vaccine approval
[20] Covid-19 vaccination launch

Between 3 January 2020 to 9 August 2023, Viet Nam recorded 11,621,997 confirmed cases of Covid-19 (highest total in Southeast Asia, and the 13th highest in the world) and 43,206 deaths, as reported to WHO. As of 30 June 2023, a total of 266.5 million Covid-19 doses have been administered[21].

3.4 Immunisation data

Viet Nam employs a dual-system approach for immunisation reporting, utilising both paper-based and electronic methods through the National Immunisation Information System (NIIS). This system was introduced nationwide in 2017, designed to monitor the immunisation status of women and children. It not only generates text reminders for caregivers when immunisation is due but also facilitates real-time data access and enables health workers to generate reports at the local and district levels. Additionally, the NIIS software application incorporates a module for vaccine and supply management. This feature aids immunisation health workers in tracking the stock of vaccines and supplies as they are received and dispatched throughout the system. It also streamlines the monthly reporting of aggregated immunisation data.

Furthermore, there exists a well-established monthly aggregate immunisation data reporting system from commune to district, province, regional, and national levels. This process involves the submission of signed manual reports and MS Excel worksheets. FIFs submit reports to Provincial Centers for Disease and Control (CDCs) through forms exclusively designed for FIF use.

3.5 Gavi's relationship with Viet Nam

The Socialist Republic of Viet Nam, through the Ministry of Health has received vaccines and cash-based support from Gavi since 2001. Viet Nam transitioned from Gavi support in December 2019 and currently receives Post Transition Engagement (PTE) support through UNICEF, WHO, CHAI and PATH. Cash support for the period 2017 – 2022 totalled USD 6.5 million for the Graduation and PTE grants, vaccine campaigns and technical assistance. Viet Nam also received vaccine and ancillaries support of USD 34.2 million for cold chain equipment, Inactivated Polio Vaccine (IPV), and injection safety devices.

Since 2020, the COVAX Facility has been administered by the Gavi Alliance with the goal of accelerating access to COVID-19 vaccines. The goals of the COVAX facility are complementary to and enhance, Gavi's mission and strategic goals including the vision to 'leave no-one behind with immunisation' and its mission to save lives and protect people's health by increasing equitable and sustainable use of vaccines. Viet Nam received Covid-19 vaccine doses valued USD 478 million, USD 3 million as Covid-19 vaccine delivery support and USD 1,081,356 for cold chain equipment from the COVAX Facility.

3.6 Entities involved in the executing and managing Gavi's funds

The Ministry of Health (MoH) is the central authority responsible for funding and oversight of various programmes and schemes in areas of family welfare, prevention, and control of major diseases. The National Expanded Programme for Immunisation (NEPI) under NIHE oversees all immunisation activities in Viet Nam including management of Gavi activities. Implementation of some of the Gavi activities is through 4 partners i.e., WHO, UNICEF, PATH and CHAI. There is an inter-agency coordination committee that meets to review performance of the lead implementers and plans where necessary, to ensure alignment and complementarity of development partners' support.

[21] Viet Nam Covid-19 vaccination coverage

3.7 Good Practices

The audit team noted the following good practices while executing the audit:

1. **Post transition support was aligned to the country's priorities**

   Viet Nam entered Gavi's final phase of support in 2015, known as the accelerated transition phase, and fully transitioned from Gavi support by the end of 2019. The country designed graduation and post transition engagement grant activities to address key challenges faced by the EPI program at the time including data strengthening, new approaches to demand generation, evidence generation for policy advocacy for a sustainable EPI programme, vaccination in emergencies, vaccine hesitancy communications and supply chain strengthening. After transitioning, the country has been able to fully self-finance most of its vaccine needs including pentavalent vaccine and take over most of the operational costs initially covered by Gavi through cash grants (especially the HSS grant).

2. **Successful roll out of the Covid-19 vaccination programme**

   The country administered over 266 million doses (including booster doses) of Covid-19 vaccines to 85 million people with 100% of the target adult and adolescent population vaccinated with the primary series. The country was able to effectively utilise all the Covid-19 vaccines received with only 0.1% wastage rate for vaccines received from COVAX. The audit noted the following key factors underpinning the successful roll out of the vaccination programme:

   - *Securing a sufficient COVID-19 vaccine supply* – Viet Nam's vaccine diplomacy efforts engaged all levels of the government, the National Assembly, line ministries, and embassies to advocate for timely delivery of vaccines and associated supplies. The private sector was also onboarded to augment human resources for the vaccination rollout.
   - *Enabling legal environment was set up for Covid-19 vaccine roll out*: Decision No. 3659/QĐ-BYT dated 21st August 20 of the MoH guiding on the research, clinical trial, registration for circulation and use of Covid-19 vaccines was promogulated. The Prime Minister issued Decision 170/QĐ-TTG on the establishment of the National Steering Committee for the prevention and control of respiratory tract inflammation caused by the new strain of the Coronavirus (Covid-19). The steering committee was multisectoral involving five ministries including foreign affairs, health, public security, national defence and transport.
   - *Operational plan to support Covid-19 vaccination*: There was a comprehensive plan for the deployment and Vaccination for Covid-19 during 2021-2022 (Decision No. 1210/QĐ-BYT dated 9th February 2021 by Minister of health) and the country developed tailored approaches for different target groups for Covid-19 vaccination.

3. **Robust vaccine supply chain system**

   Viet Nam is one of the first countries to adopt the Effective Vaccine Management 2.0 (EVM) methodology and tools, an upgraded version of the original EVM 1.0 assessment tool, featuring expanded capabilities and resources. In 2019, the country achieved an overall EVM 2.0 score of 87%, surpassing the WHO's recommended threshold of 80%. The audit team visited 34 vaccine storage points and noted several good practices. These include the presence of Standard Operating Procedures (SOPs) ensuring consistent vaccine management processes, stringent controls for vaccine receipt, and strict adherence to good storage practices for routine immunisation (RI) and Covid-19 vaccines.

   The storage points also conducted monthly physical counts resulting in 100% inventory accuracy when physical counts were conducted by the audit teams. A reliable cold chain system was evident through continuous temperature monitoring, remote temperature monitoring systems, and comprehensive preventive maintenance plans at national, provincial, and regional levels. Cold chain equipment (CCE) functionality was over 80% at all levels. The country also fulfilled its co-financing obligations to provide 250 TCW4000AC refrigerators under the Cold Chain Equipment Optimisation Platform (CCEOP 1) budget for the period 2019-20.

4. Findings

4.1 Governance and Oversight

4.1.1 There were gaps in the EPI governance arrangements

Context and Criteria

As noted in section 3.1, The office of the Prime Minister established the Target Program on Health and Population for the period 2016-2020 through decree 1125/QD-TTg.

Pursuant to decree 1125/QD-TTg, a temporary *National Steering Committee for Expanded Immunisation Project* under the Health-Population Target Program for the period 2016-2020 was also set up comprising of Director of the National Institute of Hygiene and Epidemiology, Deputy Director of National Institute of Hygiene and Epidemiology, Deputy Director of Preventive Medicine Department Director of Pasteur Institute in Ho Chi Minh City, Director of Pasteur Institute in Nha Trang, Director of the Institute of Hygiene and Epidemiology of the Central Highlands, Head of Vaccine and Test Management Department, Department of Preventive Medicine, Deputy Director of Pasteur Institute in Ho Chi Minh City, Deputy Director of Pasteur Institute in Nha Trang, Deputy Director of the Institute of Hygiene and Epidemiology of the Central Highlands, Deputy Head of National Expanded Immunisation office and the Chief Accountant of the Central Institute of Hygiene and Epidemiology. The tasks of the National steering committee were:

a) Be accountable to the Health and Population Program Management Board for 2016-2020;
b) Develop a five-year plan, an annual plan of the Open Immunisation Project, submit to the leadership of the MoH for approval and organise the implementation of the plan after approval;
c) Direct, guide, organise, implement, monitor and supervise units and localities in the implementation of activities of the Expanded Immunisation Project to detect and promptly handle issues arising during implementation;
d) Manage and use project resources for the right purposes in accordance with regulations and approval of the Management Board of the Population Health Target Program for the period 2016-2020;
e) Develop Technical and professional documents for the Project and submit for approval to MoH;
f) Approve, direct, and organise training on open vaccination;
g) Establish and maintain cooperation with international organisations, governmental and non-governmental organisations to mobilise resources for Project activities; and
h) Organise Project performance evaluation and report on Project implementation results to leaders of the MoH and relevant agencies.

The National steering committee was dissolved at the end of the project period in 2020 in line with article 4 of the legal instrument establishing it.

The country also established an Inter-Agency Committee (ICC) for immunisation in composed of representatives from the Ministry of Health of Viet Nam, National Institute of Hygiene and Epidemiology, National EPI, Local vaccine manufactures, WHO, UNICEF, PATH, AMP, JICA. The ICC had four main functions including:

a) Review and endorse EPI annual and five-year plans, country proposals and reports and other relevant documents prepared by the National EPI;
b) Review progress in achieving milestones/objectives;
c) Co-ordinate actions needed to overcome constraints and achieve milestones/objectives; and
d) Mobilise funding and assist in planning and monitoring in areas of priority as determined by the National Steering Committee for EPI.

Condition

Decree 1125/QD-TTg defined sustainable funding for immunisation activities with the Central government responsible for securing the funding for procurement of vaccines and immunisation materials, while the provincial people's committees were responsible for allocating funding for EPI operations, syringes and safety boxes. All funding for the immunisation activities (including procurement of vaccines) was to transition to the provincial people's committees at the end of 2020.

Gaps in planning for vaccine procurement transition from central to provincial level: Governance bodies (ICC and National Steering Committee for Expanded Immunisation Project) did not perform a comprehensive review and appropriately prepare the EPI for the transition of vaccine procurement responsibilities from the central to the provincial level. The operational implications of several aspects of the transition including ability of provinces to allocate sufficient funding for vaccine procurements, access to vaccine prices by provinces, mechanism (single source or competitive) of vaccine procurements, vaccine supply chain mapping including availability of sufficient cold chain capacity at the provinces and districts, use and leverage of national level cold chain infrastructure were not assessed. Provinces were not adequately prepared for the expanded roles they would be taking on especially the procurement of vaccines Additionally, it was noted that without the benefit of superior economies of scale enjoyed by the Central level, the provinces would not be able to attain favourable market prices when negotiating and purchasing vaccines.

The oversight of EPI activities was not effectively integrated into the national immunisation agenda: During the period 2017-2022, two governance bodies charged with the oversight of EPI activities. However, the audit team noted that the conduct of their respective oversight activities were not effectively integrated into the overall national immunisation agenda.

- The dissolution of the National Steering Committee occurred at the conclusion of the project period in 2020, aligning with the provisions outlined in Article 4 of the legal instrument that established it. Subsequently, the audit team observed that no alternative body was established to carry out its designated responsibilities during the period from 2021 to 2023, as outlined in the decree that initially instituted it.
- Inconsistencies were identified in the terms of reference of both the National Steering Committee for the Expanded Immunisation Project and the ICC. Notably there were instances of duplicated functions, such as the review of the annual workplan corresponds with the national Expanded Programme for Immunisation (EPI) activities.
- In reviewing the minutes of the ICC, the audit team observed a predominant focus on evaluating the performance of Gavi grants. Discussions centred around aspects such as funds absorption, challenges encountered in implementation, and the approval of grant applications to ensure alignment and complementarity with the support provided by all development partners. There was a lack of integration with the national immunisation agenda, leading to a gap in oversight once Gavi direct support ended in 2019. Furthermore, the terms of reference (TORs) of the ICC remained unaltered following the country's transition from Gavi support. Consequently, ICC meetings were not convened as stipulated in the TORs, with only 38% (9/24) of the scheduled meetings taking place during the audit period. Additionally, the ICC secretariat did not operate in accordance with the TORs, as meeting minutes were not consistently filed in a singular location and 66% (6/9) of the available minutes were found to be unsigned or unendorsed.
- The audit team noted that the ICC did not consistently follow-up on actions arising from its meetings. For example:

Recommendation 1

NIHE (NEPI) should revise and update its governance arrangements to oversee EPI activities, ongoing grants and future support from the Gavi Middle Income Countries (MICs) approach. The governance arrangements should include as a minimum:

- The scope of oversight within the immunisation programme to include all immunisation activities in addition to Gavi grants.
- Requirement for members to adhere to conflict-of-interest declarations best practice.
- Broad representation from a variety of stakeholders that implement the immunisation programme including provincial focal points.
- Designate the frequency of meetings.
- Definition of key oversight areas covered including programmatic, operational, and financial management.

<table>
<tr><td>

The ICC meeting on 19 October 2018 was informed that from 2020, to strengthen implementation of immunisation registrations using NIIS, each child will have a unique ID. This has not been implemented to date.
The ICC meeting on 28 February 2018 endorsed activities that were not subsequently implemented e.g., GIS mapping to identify and prioritize hard to reach areas with low immunisation coverage and development of an immunisation tracking system for mobile and migrant populations. The ICC also endorsed activities which were later identified as duplications between ICC members e.g., provision of technical support to build political commitment for sustainable immunisation financing through advocacy with provincial level.

</td><td colspan="2"></td></tr>
<tr><td>Root Cause
• Delay in transitioning vaccine procurement from national to provincial level.
• The ICC terms of reference were not updated after transition from Gavi support and disbandment of the National Steering Committee for EPI.
• Minutes for the ICC were documented in summary format with no section for follow up of previous meeting recommendation.
• Similar roles for governance committees.</td><td colspan="2">Management comments
See detailed management responses on Annex 8</td></tr>
<tr><td>Risk / Impact / Implications
• Provinces were unable to procure vaccines after the transition from central level procurement which led to nationwide vaccine stock outs as elucidated on section 4.3.1.
• Some Gavi grant activities were not executed. See Section 4.5.1</td><td>Responsibility
NIHE(NEPI)</td><td>Deadline / Timetable
Q2 2024</td></tr>
</table>

4.2 Sustainability of Gavi's transition and post transition engagement

4.2.1 Gaps in sustainability planning for the National Immunisation Information System

Context and Criteria

In the period 2011 to 2012, the Bill and Melinda Gates Foundation funded a collaborative effort between PATH and the Viet Nam National Expanded Program on Immunisation (NEPI) that led to the development of three distinct systems aimed at strengthening immunisation management. The first system, Vaxtrak, served as an independent platform for vaccine stock transaction tracking and reporting and covered three provinces during its pilot phase. The second system, ImmReg, focused on monitoring immunisation events for children under one year, with a pilot conducted in a district comprising seventeen communes in Ben Tre province. The third system was a fee-based reporting system was also developed and implemented to support reporting from private (fee) based facilities. In 2013, VaxTrak underwent a transformation into a web-based platform, successfully expanding nationwide across all 63 provinces and from 2014 to 2015, extensive efforts were dedicated to integrating VaxTrak and ImmReg resulting in a comprehensive system dedicated to vaccine and immunisation management (i.e., National Immunisation Information System NIIS). Concurrently, the ImmReg module achieved an extended coverage, encompassing 164 communes across nine districts in Ben Tre province.

In 2017, the Bill and Melinda Gates Foundation funded another collaborative partnership between the General Department of Preventive Medicine (GDPM) of the MoH, the National EPI (Expanded Program on Immunisation), PATH and Viettel to support further development of NIIS.

- The General Department of Preventive Medicine (GDPM) was responsible for coordinating connections among stakeholders and providing administrative support.
- The National EPI (Expanded Program on Immunisation) acting as the technical lead for immunisation workflows and devising user requirements, reporting systems, and mechanisms.
- PATH offered technical support and served as the liaison between the immunisation, general health, and technology sectors while also serving as the focal point for global standards and goods.
- Viettel was charged with system development and maintenance of the NIIS system.

This partnership laid the groundwork for the nationwide launch of the National Immunisation Information System (NIIS) in Viet Nam.

On 24 March 2017, Viet Nam's Deputy Prime Minister, Vu Duc Dam, officially launched the National Immunisation Information System (NIIS) in Hanoi[22] and by June 2017, the NIIS had successfully been rolled out to all 63 provinces in the country including private health facilities.

In 2018, The Gates Foundation provided funding to PATH, Viettel and the Ministry of Health/NEPI for the IDEAL-Viet Nam project (**I**ntroducing **D**igital Immunisation information systems–**E**xchange **A**nd **L**earning from Viet Nam), which aims to facilitate a successful transition to an entirely paperless immunisation system and capture lessons learned from the NIIS for worldwide dissemination.

In 2019, the electronic reports (e-reports) Module within the National Immunisation Information System (NIIS) was implemented the provinces of Hanoi and Son La. In the period 2020-2021, the e-reports module was further expanded to cover four additional provinces i.e., Nam Dinh, Phu Yen, Dak Nong, and Vinh Long. In 2023, the e-reports module was deployed to two more provinces i.e., Thai Nguyen and Tay Binh.

In 2020, NEPI and PATH requested for support from Gavi to enhance implementation of the NIIS nationwide (across all four health regions of Viet Nam), particularly focusing on the last steps of the complete transition from a paper-based system to the electronic reporting system (NIIS) in Hanoi and Son La provinces. The support was to strengthen the capacity of NEPI staff at all levels for sustaining and maximizing the impact of NIIS and was to be linked with the Gates Foundation support to PATH and the Ministry of Health/NEPI for the IDEAL-Viet Nam project. Gavi provided a grant of USD 534,309 to PATH as part of the Post transition engagement grants to Viet Nam.

[22] Viet Nam launches NIIS

NIIS currently serves as a digital immunisation register specifically designed to optimize the management and monitoring of immunisation programs across the entire country by integrating both immunisation and vaccine stock transaction data. NIIS had 16,357 active facility accounts as of June 2023.

The Gavi's Health Systems and Immunisation Strengthening Policy Version 1.0, places strong emphasis on *country ownership and sustainability* of immunisation systems[23]

Condition

PATH and NEPI have engaged Viettel in 2017 to support the development and implementation of the National Immunisation Information System (NIIS) in Viet Nam. The partnership aimed to capitalize on Viettel's expertise in information and communication technology to modernise and enhance the country's immunisation management system. Viettel was responsible for designing and developing the NIIS platform, encompassing essential features like a digital immunisation register, data management tools, reporting mechanisms, and other functionalities to facilitate and streamline the immunisation process. Viettel continues to provide ongoing support for the NIIS, including continuous system upgrades and maintenance to ensure its smooth operation. Viettel has also established a support centre to provide a dedicated support hotline, offering prompt troubleshooting, user assistance, and technical issue resolution to communes and provincial health authorities in effectively utilising the NIIS.

The NIIS application has not yet been handed over to the MoH for management: The audit noted that the NIIS application is still hosted by the service provider/developer i.e., Viettel. There is no formal mechanism (agreement or contract) between MOH/NEPI and Viettel (the service provider for NIIS) for managing, maintaining, updating and upgrading the NIIS. The system is still reliant on donor support for updates, technical support and maintenance.

There was no comprehensive plan to transition NIIS related costs to the MoH and provinces: The audit team observed that no comprehensive quantification of costs essential for the efficient operation of NIIS had been conducted. This includes the quantification of expenses related to server infrastructure, hardware purchase and maintenance, software updates, bug fixing, and allocation of technical support resources. The lack of a thorough cost analysis may hinder proper financial planning and allocation, possibly leading to resource constraints and affecting the system's long-term viability.

NIIS is not utilised by NEPI for planning, reporting and decision support: The audit team noted that NIIS is not utilised by NEPI as a planning, reporting and decision support system owing to challenges in the design and operating effectiveness of the system. These have been elucidated on 4.2.2. The audit team noted that the immunisation data in NIIS is incomplete (see 4.4.3) and NEPI utilises a parallel reporting system where monthly aggregate immunisation data is reported from the commune to district, province to region and region to national level through signed manual reports and MS Excel worksheets.

Recommendation 2

The MoH should:

- Establish a formal contract or agreement with a suitable service provider to support NIIS maintenance and upgrades.
- Migrate NIIS data over to government ownership in order to safeguard the system's sustainability beyond donor support.

Recommendation 3

The MoH should work with Viettel to:

- prepare comprehensive quantification of all fixed and recurring operational costs for NIIS maintenance.
- Develop a comprehensive transition plan detailing all associated costs required to operate and maintain NIIS at Provincial and national level; and
- perform a data growth projection to anticipate the current and future storage and processing requirements for NIIS. This will facilitate adequate planning for the necessary resources, such as disk space, memory, and processing power, to ensure optimal performance and avoid capacity constraints and slow system performance as the data volume exceeds server capacities.

The plan could be used as resource mobilisation tool with the MoH to ensure NIIS operational costs are budgeted for and fully financed.

[23] Gavi Alliance Health Systems and Immunisation Strengthening Policy

<table>
<tr><td>Root Cause
The MoH was not engaged on the contracting process for Viettel at the onset of system development in 2017 and therefore justification for single sourcing of Viettel later has been difficult.
NEPI and PATH have not prepared a comprehensive schedule of costs required to transition NIIS to the MoH.
System design challenges are limiting its use.</td><td colspan="2">Management comments
See detailed management responses on Annex 8</td></tr>
<tr><td>Risk / Impact / Implications
As a full self-financing country, Viet Nam should prudently consider the sustainability of operationally vital systems such as NIIS including issues such as those noted above. While there are inherent limitations imposed when implementing a system in a decentralised context, there is a risk that the inability to plan how future operational costs will be absorbed will impact upon whether NIIS continues to be used by the country for planning and decision making.</td><td>Responsibility
MoH and NIHE/NEPI</td><td>Deadline / Timetable
Q4 2025</td></tr>
</table>

4.2.2 Design challenges of the National Immunisation Information System impacted the system's operating effectiveness

Context and Criteria

As noted on 4.2.1, Gavi, via a Post Transition Engagement grant, is funding PATH to implement the following activities:

- Build the capacity of health workers by providing technical support on the paperless reporting system and increasing engagement of the private sector in data-sharing.
- Create internal and external opportunities to review lessons learned and experiences in transitioning to a digital immunisation information system.
- Strengthen data management in hospital-based facilities.
- Develop e-learning modules.
- Monitoring, help desk facilitation, and supportive supervision.

On April 17, 2023, the Government of Viet Nam issued "Decree 13 on personal data protection, *Section 6*, outlines the rights of a data subject. These rights include the right to know how and why their personal data is processed, the right to provide consent for data processing, the right to access their own data, the right to withdraw consent, the right to request data deletion, the right to restrict data processing, the right to request data provision, the right to object to data processing, the right to lodge complaints and denunciations, the right to initiate lawsuits, the right to claim damages, and the right to take measures for self-protection

ISO 22600:2014 Health informatics – Privilege Management and Access Control (Part 1 through 3) implementation guideline provides an advisory standard for policy-based access control. The section on audit log states that:

- *"All actions based on user-defined events must be recorded.*
- *All or a specified set of recorded audit information, upon request or at a set period of time, must be electronically displayed or printed for user/administrative review."*

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

ISO 27799:2016 – Health informatics as the basic advisory standard for security management for systems and web applications. ISO 27799 states the following on encryption and its use on web and mobile applications:

- *"Generally, all electronic health information must be encrypted and decrypted as necessary according to organisation defined preferences in accordance with the best available encryption key strength (minimum 256-bits key*).
- *During data exchange all electronic health information must be suitably encrypted and decrypted when exchanged in accordance with an encrypted and integrity protected link.*
- *Secure Transmission standards and mechanisms must be used to allow access to health information as well as transmit data from one application / site to another. For this purpose, HTTPS, SSL v3.0, and TLS v1.2 standards should be used."*.

Sharable Content Object Reference Model (SCORM) is a set of technical standards for eLearning products. It provides the communication method and data models that allow eLearning content and LMSs to work together. It tells programmers how to write code so that what they build will "play well" with other eLearning software. SCORM is the most widely used eLearning standard available[24].

[24] SCORM model explained

Gavi developed specific software standards (Gavi Target software standard (TSS)) to optimize vaccine supply chain information systems, focusing on key reporting and decision support functions including intuitive dashboards and reports with drill-down capabilities. Furthermore, incorporating open standards to facilitate seamless data exchange of essential metadata, facilities, and products, promoting interoperability among different systems.

Condition

We noted the following gaps with NIIS:

Uniform unique identifier not fully implemented **-** A unique identifier for NISS records has not been fully implemented. The absence of a uniform unique identifier in NIIS has led to several issues, including inaccurate and incomplete immunisation records and the creation of multiple records for the same individual.

Non-compliance with Decree 12 on personal data protection**-** The audit team noted that there was no specific policy or consent mechanism for handling personal data in NIIS despite the system storing personally identifiable information (PII). This oversight raises concerns regarding compliance with the data protection regulations and highlights the need for the prompt implementation of appropriate policies and consent mechanisms to ensure the lawful and secure management of personal data within NIIS.

Data validation checks were not inbuilt in the system- The audit team noted gaps in system validation controls to prevent data entry errors and incomplete or duplicate record entries. Ensuring the quality and accuracy of data within the NIIS is crucial for effective immunisation management.

Gaps in SOPs and Policy on Data backup and restoration testing- The audit team noted that there was no policy or SOP to guide the process of data back-up and restoration testing. The system developer (i.e., Viettel) indicated that daily backups were being performed but no evidence of this in form of back logs was presented to the audit team. The audit team also noted that there was no evidence of restoration tests performed to evaluate the viability and completeness of any data backups.

Test data present on Live / Production system: The audit team noted that the NIIS system contains dummy or test records of dummy user accounts which adversely impacts data quality and accuracy. For live systems, it is essential to conduct periodic data cleaning procedures to ensure that only validated and accurate records are retained. Furthermore, all test data should be confined to a designated and isolated test environment to prevent any interference with the live system's integrity and usability.

Recommendation 4

To address the challenges and ensure the successful adoption of a unique identifier system, the MoH should ensure that the following considerations are met during the selection process of a unique identifier:

- Uniqueness: The chosen identifier must be inherently unique to avoid any potential confusion or duplication within the system.
- Consistency: Consistent usage of the identifier across all healthcare facilities and vaccination centres is paramount to ensure seamless data integration and accuracy.
- Standardisation: Adherence to international standards for identifier formats and coding systems will facilitate interoperability and smooth data exchange among different health systems.
- Security: Robust security measures must be in place to safeguard the confidentiality and privacy of patient information associated with the unique ID.
- Compatibility: Compatibility with existing health information systems and electronic health record platforms is vital to ensure smooth integration and data sharing.
- Accessibility: The ID system should be user-friendly and easily accessible for healthcare providers, enabling efficient data capture and retrieval processes.
- Scalability: The selected identifier system should have the capacity to scale effectively to accommodate the growing needs of vaccinations and the increasing population.

Recommendation 5

The MoH should perform a comprehensive systems vulnerability and functionality audit to:

- identify and correct errors and bugs in the system including data validation checks;
- Identify and remove dummy data in the production environment;
- Update end-user manuals and TOT guides;
- Incorporate policies related to Decree 13 on personally identifiable information;
- Establish a policy on data backup and restoration testing; and
- Enhance performance of system dashboards and reports

The review should aim to support the new vaccine introductions under the MICs strategy and include lessons learned from the parallel systems run for Covid19 vaccination data.

There was no audit log for the system: The audit team noted that the front end of the application lacks an audit log to track user actions, which poses significant challenges in troubleshooting security issues and promptly restoring the system in the event of a security breach. Without an audit log, there is no comprehensive record of user activities, making it difficult to identify unauthorized access or potential security threats. Additionally, the absence of an audit trail hinders the ability to analyse incidents and take appropriate remedial actions quickly and accurately. ***End user manuals and Training of Trainers (TOT) guides on NIIS application were not updated***: While NIIS underwent a system application update in May 2023, the end-user manuals accessible within the system have not been updated since 2016. This lack of updated user guides presents a critical limitation, significantly affecting the end users' ability to effectively utilize the system. The importance of up-to-date and accurate user manuals cannot be overstated. End users heavily rely on these guides to navigate and comprehend the system's functionalities and processes. Outdated manuals fail to incorporate the latest features, changes, and enhancements introduced with the recent update, leading to confusion and inefficiency in system usage. ***System had functionality errors***: The audit team noted that errors were present in the export functionality of specific reports and the barcode scanning feature in the e-immunisation book app. These unresolved errors significantly affect the overall user experience and can have adverse implications on the adoption and usability of the system. ***Suboptimal performance of system dashboards and reports*** - The audit team noted that the national immunisation dashboards had significant performance challenges, with load times exceeding four hours. Additionally, the dashboards lacked the necessary capabilities to support drill down and access detailed data analysis or custom data querying. Relatedly, the dashboards offer only basic visualisations, which fall short in meeting the demands for comprehensive and actionable insights. The absence of drill-down features further hampers the ability to explore specific data points and perform in-depth analysis, impeding the decision-making process for the immunisation programme. ***Suboptimal performance of the e-Learning platform –*** The project progress report dated 21 December 2020 submitted to Gavi indicated that the development of an eLearning platform to facilitate capacity building for health workers was a completed activity. However, the audit team noted that: • 97% (29 of 30) listed modules were not active and/or operational.	Recommendation 6 NIHE (NEPI) and PATH should perform a comprehensive review of the e-Learning module in NIIS to: • Rectify security issues identified. • Ensure SCORM standards are incorporated in the design. • Complete the development of the 29 outstanding modules.

<table>
<tr><td colspan="2">

- The e-Learning platform was not compliant with security standards as defined by ISO 27799:2016 – The e-learning platform system is within the public domain and required to be accessible at province and district levels. However, first level authentication using Secure Sockets Layer (SSL) was not installed on the web application or any of the modules. This means that the data sent between the e-learning platform, and the web server was not secured from malicious attacks or manipulation.
- The eLearning platform did not effectively implement Learning Management System (LMS) standards as defined by SCOR (Sharable Content Object Reference) Model for secure and effective data exchange between e-Learning platform users and other systems.

</td><td></td></tr>
<tr><td>Root Cause
There is lack of a clear mechanism between MOH/NEPI and Viettel (the service provider for NIIS) in managing, maintaining, updating and upgrading the NIIS that is resulting in delays in finalizing, updating and upgrading systems.</td><td colspan="2">Management comments
See detailed management responses on Annex 8</td></tr>
<tr><td>Risk / Impact / Implications
• NIIS is not utilised by NEPI as a planning, reporting and decision support system owing to challenges in the design and operating effectiveness of the system.</td><td>Responsibility
MOH, NEPI/NIHE, Viettel, PATH</td><td>Deadline / Timetable
Action 4: Q4 2024
Action 5: Q2 2025
Action 6: Q4 2025</td></tr>
</table>

4.2.3 Limited interoperability of NIIS with digital health tools utilised by the Ministry of Health

Context and Criteria

Viet Nam's MoH states in its work plan on the application and development of intelligent digital health for 2019–2025 that the Vietnamese health system will use digital technology to contribute to Viet Nam's health system modernisation, improving quality, efficiency, and *integration*, so that people can easily access health information and use health services[25].

Viet Nam has several digital health tools including:

- Viet Nam HMIS (DHIS2 Aggregate + Tracker*):* Viet Nam's HMIS is the MoH's implementation of DHIS2[26]. DHIS2 supports the collection, analysis, visualisation, and sharing of both aggregate and individual-level data, including mobile and offline data collection using the DHIS2 Android app.
- National Immunisation Information System (NIIS): As already noted on 4.2.1, NIIS is an integration of two different applications of ImmReg (electronic immunisation registry) and VaxTrak (vaccine tracking) into one comprehensive system. NIIS has been rolled out nationwide to all public and private health facilities.
- Bao Cao BTN/eCDS system (electronic communicable disease surveillance system): Bao Cao BTN/eCDS is a sentinel system that allows patient management at the provincial and subnational levels and is currently used for 34 infectious diseases (in accordance with MoH Circular 54/2015/TT-BYT). The system generates reports, manages, and provides surveillance of cases and outbreaks of infectious diseases.
- Covid-19 tracker on Health Management Information System (BootStrap https://cdc.kcb.vn/) used for case management and event-based surveillance.

As already noted under section 3.1, Viet Nam operates a "dual system" of free-of-charge Expanded Program on Immunisation (EPI) services and non-EPI fee-based immunisation services, available in health facilities across the country in both the public and private sectors. Services provided at fee-based immunisation facilities (FIF) are paid for directly by clients/patients out-of-pocket. FIFs are under the umbrella of the Provincial Health Departments (PHDs) and report directly to them. The FIFs have their own electronic immunisation systems.

Gavi developed target software standards for vaccine supply chain information systems to include open standards for data exchange of key metadata, facilities, and products, (*interoperability*) using industry data standards (e.g., GS1 and HL7), support for data acquisition from barcode readers and remote temperature monitoring devices.[27]

Condition

The audit evaluated the interoperability of the systems operating within the immunisation space, including those supported by Gavi. We noted the following:

- Only 35% (995 of 2,866) of private or fee-based facilities Electronic Immunisation Records (EIRs) had been actively integrated to NIIS using Application Programming Interfaces (APIs).
- There is currently no active integration between NIIS and any other MoH system including Viet Nam HMIS and the Covid-19 tracker.

There are challenges inherent in the interoperability of existing systems, as their operation is reliant on limited human resources at subnational level to ensure that data is complete and accurate. There is therefore a need for integration of systems to ensure:

Recommendation 7

NIHE (NEPI) should consider establishing a process to integrate its systems containing vaccine and logistics data, by establishing a singular data warehouse to improve visibility and reduce cases of duplication of data points.

[25] Landscape analysis of Viet Nam digital systems

[26] DHIS2 is an open source, web-based platform, typically used as a national health information system for data management and analysis purposes, for health program monitoring and evaluation, facility registries and service availability mapping, logistics management, and mobile tracking of pregnant mothers in rural communities

[27] Gavi targeted software standards

<table>
<tr><td>

- one point of data entry for required immunisation information i.e., immunisation data entered should be accessible at national and subnational levels.
- one point of entry for vaccines and vaccines logistics information to enable management of the vaccine supply chain.
- An interface with required dashboards to support decision making at national and subnational levels.
- Integrated support at national and provincial levels to provide trouble shooting and other system support.

</td><td colspan="2"></td></tr>
<tr><td>Root Cause
MoH has not taken on full ownership of the NIIS system to integrate it with other systems. See 4.2.1</td><td colspan="2">Management comments
See detailed management responses on Annex 8</td></tr>
<tr><td>Risk / Impact / Implications
Limited interoperability creates data redundancies and potentially creates vulnerabilities in the ongoing operation of systems, and as a result their continued usage may not be sustainable.</td><td>Responsibility
NIHE (NEPI)</td><td>Deadline / Timetable
Q4 2025</td></tr>
</table>

4.3 Vaccine supply management

4.3.1 Nationwide vaccine stock outs may limit the achievement of zero dose and hinder the plans for routinisation of Covid-19 vaccination

Context and Criteria

Successful immunisation programmes are built on functional, end-to-end supply chain and logistics systems. These systems enable effective vaccine storage, distribution, handling, and management, ensure rigorous temperature control in the cold chain; and leverage logistics management information systems to promote resilient and efficient system performance. The ultimate goal is to ensure the uninterrupted availability of quality vaccines from manufacturer to service-delivery levels, so that opportunities to vaccinate are not missed because vaccines are unavailable[28].

Section 2.3 of the WHO Guidelines on stock records for Immunisation programme and vaccines store managers states that, "*Minimum/maximum (min/max) inventory control system is recommended in vaccine stock management in which, each organisational level of the programme is assigned maximum and minimum levels for its supplies. Using a min/max inventory control system will help managers to prevent both over-stocking (which leads to higher wastage) and shortages or stock outs of vaccine and other Immunisation supplies.*" NEPI has set a min-max stock holding thresholds of 3-6 months for national, 2-4 months for regional, 1-3 months for provincial and 1-2 months for district levels.

Immunisation supply chains are a key component of the health system for reaching zero-dose children, enabling delivery of services to underserved communities, ensuring vaccine availability and potency, and maximizing efficiency where possible. The equity goal of Gavi's 5.0 strategy is, *"Health systems sustainably reach all zero-dose and under-immunised children and their communities with the full range of vaccines as the first step towards providing integrated Primary Health Care (PHC) services"*. Gavi defines zero-dose children as those children who lack the first dose of the diphtheria-pertussis-tetanus containing vaccine (DPT1)[29].

Condition

Nationwide stock out of key routine immunisation vaccines: During the audit fieldwork conducted in June 2023, it was observed that the country was experiencing nationwide stockouts of essential routine immunisation vaccines at both the national and sampled sub-national level vaccine stores. The last recorded stock of pentavalent vaccine at the national vaccine store dated back to 17 June 2022. Furthermore, all 33 sub-national vaccine stores included in the sample were found to be stocked out of at least one of Pentavalent, DPT, and IPV.

The audit team extended its review to vaccine stock records at both the national and sampled sub-national vaccine storage points. This review spanned the period from January 2018 to May 2023 and revealed instances of stockouts in key routine immunisation vaccines, including:

Table 7: Stock outs of sampled routine immunisation vaccines at National level

Name of Vaccine	Stock on Hand (as at 7 June 2023)	Total stock out days	Maximum stock out days
Pentavalent vaccine*	0	358	355
DPT	0	698	288

**Pentavalent vaccine is presented in three brands i.e., ComBE Five, Quinvaxem and DPT-VGB-Hib (SII))*

Recommendation 8

NIHE (NEPI) should finalise the current consultation processes on vaccine procurement with MoH, MoF and National Assembly to develop a long-term solution on vaccine procurement arrangements.

[28] WHO: Importance of vaccine supply chains

[29] Gavi: Defining zero dose.

Table 8: Stock outs of sampled routine immunisation vaccines at sub-national level

Level	Vaccine	Number of sampled vaccine stores with stockouts	Average Cumulative Stock Out Days	Maximum number of Stock Out Days
Regional	Pentavalent vaccine	4/4	111	136
	Inactivated Polio vaccine	4/4	234	126
Province	Pentavalent vaccine	8/8	94	56
	Inactivated Polio vaccine	7/8	136	76
District	Pentavalent vaccine	8/8	176	161
	Inactivated Polio vaccine	7/8	299	97

See Annexes 6a, 6b, 6c and 6d for details.

Stock outs of Covid-19 vaccines: The audit team also noted that the country was stocked out (zero balance) of Covid-19 vaccines at the national vaccine stores when physical stock verification exercises were carried out during audit field work i.e., June 2023. For a sample of three vaccines, the audit team noted that Pfizer Vaccine had been stocked out for a total of 50 days, the Moderna Switzerland GMBH mRNA-12 vaccine was stocked for a total of 143 days and although the AstraZeneca AB AZD1222 vaccine was not stocked out, only 40 doses were available at the national vaccine store.

Table 9: Stock outs of sampled Covid-19 vaccines at National level

Name of Vaccine	Stock on Hand (7-06-23)	Total stock out days	Maximum stock out days
Pfizer Vaccine	0	50	50
AstraZeneca	40	0	0
Moderna	0	143	143

- See Annex 6a for details

Root Cause

Lack of an institutionalised financing and procurement mechanism for vaccines in the period 2021 to 2023: The country did not have a sustained and institutionalized financing mechanism for planning, procurement and distribution of all vaccines, injection devices and cold chain equipment in the period 2021 to 2023. The modality in the period 2016 to 2020 was project-based with budget allocations through the five year-Health and Population Programme. The gaps in planning for immunisation financing transition from central to provincial level are elucidated on issue 4.1.1.

In June 2023, NIHE(NEPI) was engaged in consultation with the MoH, MoF and National Assembly to maintain vaccine procurements at the national level.

Delays in initiation of the procurement for pentavalent in 2022: On 9th of December 2022, the Ministry of Health granted the National Institute of Hygiene and Epidemiology (NIHE) the authority to procure 2,500,000 doses of pentavalent (DPT-VGB-Hib) vaccine. Subsequently, the tender for this procurement was published on the national bidding network on the same day, extending invitations to both national and international suppliers to partake in the bidding process. The deadline for submitting bids was set

Management comments

See detailed management responses on Annex 8

for the 29th of December 2022 at 18:45 hrs. However, no bidder responded to the solicitation document mainly due to the limited time bidders were given to respond. There was no opportunity for re-tendering as the funds allocated for the procurement had expired by the end of December 2022.		
Risk / Impact / Implications • Stock out pentavalent and DPT vaccines for over 200 days may lead to a decline in demand for immunisation services consequently affecting the national efforts to reduce zero-dose children. • Replacing pentavalent with DPT vaccine may result in children missing out the Haemophilus influenzae type B and Hepatitis B antigen that is not contained in the DPT vaccine. • Routine immunisation vaccine stock-outs result in targeted recipients being turned away from vaccination sites. • Covid-19 vaccine stock outs could derail planned routinisation efforts for the period 2023 onwards.	Responsibility MoH and NIHE(NEPI)	Deadline / Timetable Q1 2024

4.3.2 Variances between the UNICEF reference and the NIHE negotiated prices for pentavalent vaccines

Context and Criteria

As noted in Section 3.5, Viet Nam transitioned out of Gavi support in December 2019.

Gavi's has a Transition Policy whose stated vision is that, *when countries transition out of Gavi support, they have successfully expanded their national immunisation programmes with vaccines of public health importance and sustain these vaccines post-transition with high and equitable coverage of target populations, while having robust systems and decision-making processes in place to support the introduction of future vaccines*. Low vaccine prices are necessary for supporting countries to sustain immunisation programmes and introduce new vaccines after they no longer receive Gavi financial support. [30]

WHO produced two fact sheets in 2017 and 2018 to address questions that Ministry of Health and Ministry of Finance officials may have about vaccine pricing in countries that are transitioning or have transitioned out of Gavi support. The fact sheets aimed to provide information on public sector vaccine prices that can assist Gavi transitioning countries' financial planners in establishing appropriate budgets when countries assume full self-financing of previously Gavi supported vaccines. While fully self-financing countries can no longer access new financial support from Gavi, several manufacturers made commitments to continue providing these countries with access to prices similar to those Gavi pays, under specific circumstances and for a certain period of time, depending on commitment terms. These vaccines included human papillomavirus vaccine (HPV), pneumococcal conjugate vaccine (PCV) and rotavirus vaccine (Rota). Manufacturers also made commitments for Gavi-transitioning countries for pentavalent vaccines. However, as of 2017 and 2018, all UNICEF suppliers of *pentavalent vaccine were offering the same price to all countries buying through UNICEF, irrespective of their Gavi status.*[31]

In December 2020, the Gavi Board approved a new approach to engagement with middle-income countries in the Gavi 5.0 strategic period (the "MICs Approach"). Serving as a key tool for addressing threats to the equity and sustainability of routine immunisation programmes, the MICs Approach contributes to Gavi's overall vision of leaving no one behind with immunisation. Some former-Gavi-eligible countries are missing critical, life-saving vaccines, presenting a threat to inter-country equity. Of the 19 countries that have transitioned as of 2022, 13 have not yet introduced at least one of pneumococcal conjugate vaccine (PCV), rotavirus vaccine, or human papillomavirus (HPV) vaccine. The MICs Approach has two overarching objectives: to prevent backsliding in vaccine coverage in former-Gavi eligible countries; and to drive the *sustainable introduction of key missing vaccines in both former- and select never-Gavi eligible countries*.[32]

Viet Nam is one of the former-Gavi eligible countries under the MICs approach and Gavi will offer a suite of targeted and catalytic tools to help drive the sustainable and equitable introduction of PCV, rotavirus, and HPV vaccines to the country.

Condition	Recommendation 9
V*ariances between Viet Nam Government vaccine procurement prices and UNICEF reference prices*: The Government of Viet Nam started procurement of pentavalent vaccine in 2018. While NIHE/NEPI negotiated prices for procurement of pentavalent vaccines after transition from Gavi support, there were notable variances between the UNICEF reference prices and Viet Nam procurement prices for pentavalent vaccine in the period 2018 to when procurement of the vaccine was done through the government mechanism. The country could have saved USD 3,159,741 over the four-year period 2018 to 2021 by utilising UNICEF reference prices. See details in Annex 6e.	In accordance with UNICEF and Gavi's advice, the NIHE should consider putting in place a suitable mechanism in order to access the UNICEF negotiated prices for its future procurements where there is a comparative advantage in price.

[30] Gavi Transition Policy

[31] Fact sheet on Vaccine Pricing for GAVI Transitioning Countries, WHO 2017 and 2018

[32] Gavi MICs Approach

<table>
<tr><td colspan="2"></td><td colspan="2">Recommendation 10
NIHE and MOH should include a provision for price market surveys in the bid solicitation process.</td></tr>
<tr><td colspan="2">Root Cause
• NIHE/NEPI did not have visibility on UNICEF available vaccine purchase prices and NIHE/NEPI did not carry out price benchmarking to compare the negotiated with Gavi/UNICEF reference prices at the time of procurement.
• Bidders for the supply of pentavalent vaccines to Viet Nam were not among the manufacturers who had pledged to provide countries transitioning away from Gavi support access to pricing on par with that provided to Gavi-supported countries.</td><td colspan="2">Management comments
See detailed management responses on Annex 8</td></tr>
<tr><td colspan="2">Risk / Impact / Implications
The country missed an opportunity to obtain savings of approximately USD 789,935 per annum for procurement of pentavalent vaccine from 2018 to 2021.
While financing for the ongoing procurement of new vaccines is not available under the MICs Approach, Gavi may provide vaccine financing for half the first birth (or target) cohort while the country finances the other half. Pricing for both procurements (country led and Gavi) must be aligned to ensure programme efficiencies.</td><td>Responsibility
NIHE and MoH</td><td>Deadline / Timetable
Action 9: Q4 2024
Action 10: Q1 2024</td></tr>
</table>

4.3.3 Challenges in forecasting and supply planning resulted in stock wastage

Context and Criteria

Section 2.3 of the WHO Guidelines on stock records for Immunisation programme and vaccines store managers states that, "*The minimum stock level is the level below which stocks should never drop without having placed an order. It is the amount of stock you will use in the time between placing and receiving an order plus the reserve or safety stock*[33] *that is kept for emergencies and unanticipated demand or delivery delays.* NEPI has set a min-max stock holding thresholds of 3-6 months for national, 2-4 for regional, 1-3 months for provincial and 1-2 months for district levels.

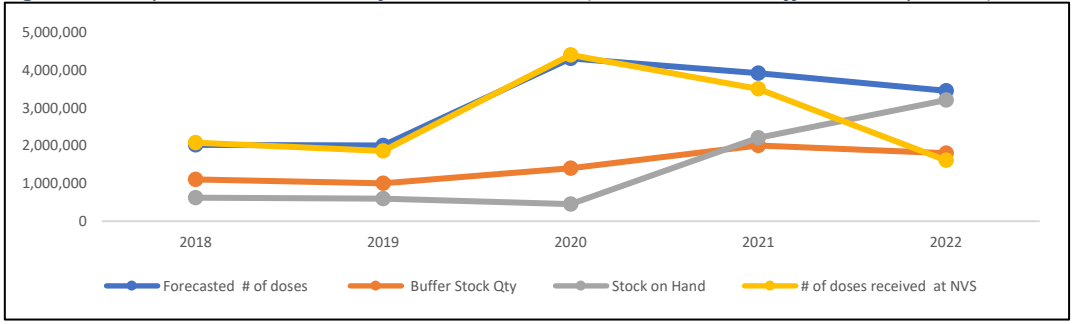
Strengthening data driven forecasting and agile supply planning is one of the opportunity areas within the investment priorities of the Gavi immunisation supply chain strategy for 2021 - 2025[34]. It's imperative that Countries generate accurate and representative forecasts to ensure adequate supply of vaccine needs, minimize expenses incurred in transportation and distribution of vaccines and any potential, wastages.

Condition

Viet Nam conducts annual forecasts utilising the UNICEF forecast tool for vaccines and related supplies. Data inputs in the forecasting tool include target population, estimated immunisation coverage, estimated vaccine wastage, buffer stock quantity and the stock on hand for the respective antigens as of the time of generating the forecast. The forecasting tool also includes a shipment plan for products to be procured showing the quantity and month of arrival for the respective products.

Inadequate buffer stock levels of the Inactivated polio vaccine (IPV): A review of the forecasts during the period 2018 -2022 indicated that the stock levels for IPV were consistently below buffer stock levels during the period prior to 2021. This indicates that the country consistently had low stock levels of IPV. The stock levels were raised in 2022 above the buffer stock levels due to remaining stock from an IPV catchup campaign in 2020 as shown in the graph below.

Figure 1: Comparison between IPV forecast and Stock (Stock on hand, buffer and shipments) at NVS



Recommendation 11

NIHE (NEPI) should institute mechanisms to carry out:

- Periodic review of its stock levels at the NVS and other peripheral stores
- Regular monitoring of stock and the supply plan

[33] The safety stock is the reserve stock used to protect against stock outs due to delivery delays, product shortages at the supplier level, or when stock is dispensed at an unexpectedly high rate. The level of safety stock required is usually different for each programme and should be based on past consumption data.

[34] Gavi immunisation supply chain strategy for 2021 - 2025

<table>
<tr><td colspan="2">Gaps in supply planning: NEPI did not have a mechanism for scheduling vaccine orders to manage the vaccine pipeline. The country received 1,608,000 doses of IPV on 19 January 2022 with two different expiry dates i.e., 30.11.2023 for batch U1F99 and 31.08.2023 for batches U3L71 and U3M13. The audit noted that 159,496 doses of batch U1F99 (10% of total 2022 receipts) will not be utilised before expiry.</td></tr>
<tr><td>Root Cause
Inadequate review of the forecast
No evidence of periodic review of the supply plan to inform decisions of staggering or call off orders in the pipeline.
The IPV catch up campaign in 2021 led to unutilized stock of IPV.</td><td>Management comments
See detailed management responses on Annex 8</td></tr>
<tr><td>Risk / Impact / Implications
Inadequate buffer stock levels can lead to sub optimal order fulfilment of vaccines by the NVS to the Regional Vaccine Stores
Gaps in supply planning can lead to wastage of vaccines</td><td>Responsibility
NIHE(NEPI)
Deadline / Timetable
Q4 2024</td></tr>
</table>

4.3.4 Large quantities of obsolete stock are taking up storage space

Context and Criteria

The large scale of Covid-19 vaccination activities generates vast quantities of waste consisting of vaccine vials, sharps waste and other ancillary waste. This poses a challenge for countries with limited resources and capacity to safely manage and process for final disposal in a manner safe for population and the environment. In general, disposal of Covid-19-related waste should follow the practice used for other health care and vaccination-related wastes, in accordance with national policies, guidance and standards[35].

Viet Nam has guidelines detailing the procedures to be undertaken for destruction of expired vaccines. The guidelines are derived from circulars generated by Minister of Health and the Minister of Natural Resources and Environment on regulations on medical waste management including Joint Circular No. 58/2015/TTLT-BYT-BTNMT, Circular No. 36/2015/TT-BYT-BTNMT, Circular No. 29/2020/TT-BYT, Circular No. 36/2018/TT-BYT, Circular 03/2020/TT-BYT, among others.

The guidelines include:

- drafting plans for the write-off of the vaccines;
- listing all vaccine to be written off including quantity, expiry date and unit price;
- setting up a vaccine council to oversee write off process;
- inspecting the transportation and destruction of vaccines in accordance with the contract signed with the environmental company under the stewardship of the council; and

Drafting a report by the Office of National Finance Program and National Merit Office to be sent to the Department of Health and the Drug Administration of Viet Nam, the Ministry of Health, together with the minutes, evidence and documents related to the destruction of vaccines.

Condition

***Delayed destruction of obsolete vaccine stocks*:** The audit team noted that the country was still storing obsolete/expired vaccine stocks at both the national and sub national levels. At the national level, we noted that 832,046 doses out of 833,200 doses of pentavalent vaccine donated in 2018 was unused and expired on 31 March 2020. Gavi was informed about these unused vaccines through various reports, however, these were not destroyed remained stored in quarantine for over 38 months. Whereas expiries of Covid-19 vaccines were minimal, stock that expired during the period June 2022 to January 2023 was still held at the NVS in June 2023. At subnational level, the RVS, PVS, DVS and communes were holding approximately 52,000 doses of expired routine immunisation vaccines for 4 - 18 months and 320,000 doses of expired Covid-19 vaccines for 3 - 8 months.

Table 10: Duration of storage of Vaccine Expiries at NVS

Vaccine	Quantity	Expiry Date	Storage duration (Months)
Com BE Five	832,046	31-Mar-20	38.8
IPV	257,500	31-May-23	0.2
Moderna	26,500	20-Jan-23	4.6
Pfizer	43,650	30-Jun-22	11.4

Recommendation 12

NIHE (NEPI) should work with the MoH to escalate the disposal process for the existing expired vaccines. In addition, the MoH should establish timeframes and standards of service, so that all future disposals of obsolete stocks are promptly scheduled, initiated and executed.

[35] WHO on disposal of Covid-19 vaccine waste

<table>
<tr><td>Root Cause
• The guidelines for medical waste destruction do not provide timelines within which the different activities should be undertaken to complete a vaccine destruction process.
• Delayed approval by MoH to dispose of the expired stock.</td><td colspan="2">Management comments
See detailed management responses on Annex 8</td></tr>
<tr><td>Risk / Impact / Implications
Large quantities of obsolete stock taking up valuable storage space</td><td>Responsibility
NIHE(NEPI) and MoH</td><td>Deadline / Timetable
Q3 2024</td></tr>
</table>

4.3.5 Gaps in management of cold chain equipment at subnational level

Context and Criteria

The installation of WHO Performance, Quality and Safety (PQS) cold chain equipment (CCE) and maintaining it in good working condition is critical in ensuring that the cold chain of vaccines is preserved throughout the supply chain until when they are administered to the beneficiary. WHO PQS process prequalifies equipment and assures their suitability for use in immunisation programs. Ensuring that the CCE maintain their optimal temperature range, requires regular preventive maintenance, defined as procedures that reduce the likelihood of equipment failure and extend the life of equipment, for example calibration, routine part replacement, lubrication, or cleaning[36].

Similarly, due to the temperature sensitivity of vaccines, any interruption to the normal functioning of cold chain equipment is an emergency situation that can be mitigated by development of a contingency plan and ensuring that the staff are aware of the plan and its implementation.

Condition

There were no documented contingency and preventive maintenance plans at district vaccine stores- Although contingency plans were found at majority of the vaccine storage points visited, there were no documented contingency plans in three of eight DVS to guide the staff on the actions to take in case of any exigency like equipment malfunction, equipment breakdown and power failure. It was not clear what actions the staff would take in the event of equipment failure.
The audit team also noted that preventive maintenance plans were not available at four of eight DVS which are critical storage points for Communes as they returned their vaccines to the DVS daily upon completion of an immunisation session.

Health communes were utilising domestic refrigerators for vaccine storage- The audit team noted that five communes (Thang Phuoc, Hoa Binh, Duy Tan, Dong Kinh, Son vi) visited were storing vaccines in domestic refrigerators that did not conform to WHO PQS standards (See Annex 6f). Domestic refrigerators in most cases are unable to meet temperature uniformity standards leaving some areas of the units unsafe for vaccine storage in addition to long recovery time after door opening to keep the temperatures in range.
A related observation was made during the EVMA 2020 where most of the vaccine refrigerators at the service delivery level were not freeze protected Grade A equipment[37]

Recommendation 13

NIHE (NEPI) should work with provinces to ensure that:

- The cold chain contingency plans are circulated nationwide, and that appropriate on-the-job mentorship is provided.
- Cold chain equipment used to store vaccines are WHO PQS compliant.

Root Cause

- Lack of distribution of contingency plans to all vaccine handling points and training staff on the same.
- Lack of implementation of preventive maintenance plans at all vaccine storage points in the Country

Management comments

See detailed management responses on Annex 8

[36] WHO Vaccine Management Handbook Module VMH-E5-01.1

[37] Effective Vaccine Management Assessment (EVM) in Viet Nam, 2021

Risk / Impact / Implications	Responsibility	Deadline / Timetable
• Storage of vaccines in non-WHO PQS equipment increases the risk of exposing the vaccines to poor conditions making them unsuitable for use in the immunisation programme. • Risk of vaccine loss in case of equipment breakdown	NIHE(NEPI)	Q4 2024

4.4 Immunisation data management

4.4.1 Decline in routine immunisation coverage over last five years

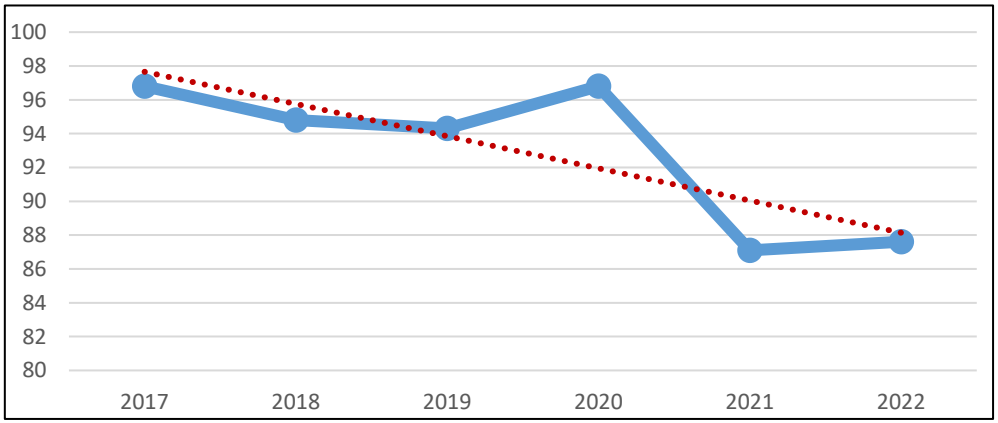
Context and Criteria

The equity goal of Gavi's 5.0 strategy is, *"Health systems sustainably reach all zero-dose and under-immunised children and their communities with the full range of vaccines as the first step towards providing integrated Primary Health Care (PHC) services"*. Gavi defines zero-dose children as those who lack the first dose of diphtheria-pertussis- tetanus containing vaccine (DPT1).

Condition

Over the period 2017 to 2022, overall full immunisation coverage dropped from 96.8% in 2017 to 87.6% in 2022, a net reduction of 9% as illustrated below:

Figure 2: Full immunisation coverage over 2017 to 2022



Recommendation 14

NIHE (NEPI) should develop a plan to catch up on missed routine immunisations.

Recommendation 15

WHO and UNICEF have published guidance on considerations for integrating Covid-19 vaccination into immunisation programmes and primary health care for 2022 and beyond. The MoH should review, document and develop a national strategy for transitioning its Covid-19 vaccination response and integrating this into its routine immunisation, highlighting the: relevant delivery strategies, resources required and timeframe to complete this transition

Root Cause

- Impact of Covid-19 during 2020-21 with some localities suspending the implementation of routine immunisation.
- The massive floods in 2019 also affected routine immunisation in certain parts of Viet Nam.
- Key demand generation activities within the post transition engagement grant were not executed. See section 4.5.1

Management comments

See detailed management responses on Annex 8

Risk / Impact / Implications

Based on the country's average annual birth cohort of 1.2 million children, approximately 110,000 children per year may have missed vaccinations. A comparison between targeted coverage and actual immunisations yields a variance of 640,513 children over the audit period.

Responsibility	Deadline / Timetable
NIHE(NEPI) and MoH	Action 14: Q4 2025 Action 15: Q4 2024

4.4.2 Gaps in the quality of administrative immunisation coverage data

Context and Criteria

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

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

Condition

Differences between reported number of children vaccinated with pentavalent vaccine and the vaccines distributed- The audit team compared the reported pentavalent vaccinations with the number of vaccines doses distributed and noted that the number of children reported as vaccinated was higher than the quantities of vaccines issued to the provinces ranging from 7% to 125% in three of eight sampled provinces over the period 2017 to 2022.

Table 11: Comparison of pentavalent distributed and reported immunisation coverage

Year	Thai Binh province			Phu Tho province			Dong Nai province		
	Vaccines dispatched	Immunisation reported	% difference	Vaccines dispatched	Immunisation reported	% difference	Vaccines dispatched	Immunisation reported	% difference
2017	87,000	85,256	-2%	79,500	78,748	-1%	167,050	147,661	-12%
2018	71,260	68,748	-4%	42,280	55,954	32%	91,770	111,110	21%
2019	87,165	81,478	-7%	64,136	71,643	12%	110,791	131,164	18%
2020	85,656	80,967	-5%	50,564	71,425	41%	130,399	139,361	7%
2021	82,520	79,637	-3%	49,008	65,702	34%	72,000	62,858	-13%
2022	35,231	77,736	121%	25,000	56,205	125%	68,560	114,239	67%
Total	**448,832**	**473,822**	**6%**	**310,488**	**399,677**	**29%**	**640,570**	**706,393**	**10%**

Inconsistences in the recorded number of children receiving pentavalent and OPV vaccinations administered at the same time: The audit team compared the reported vaccinations for vaccines administered at the same time based on the Viet Nam immunisation schedule (See Annex 5) and noted variances for ranging from -45% to 19% all the sampled eight provinces in the period 2017 to 2022. See Annex 7a.

Recommendation 16

NIHE (NEPI) should:

- Perform a Data Quality Audit to routinely triangulate available data, including an assessment of immunisation coverage data and vaccine availability/ utilisation to check the accuracy of data reported. Such analyses should be undertaken at national and sub-national levels and any data inconsistencies noted should be validated and explained.
- Ensure an adequate supervision is conducted at sub-national level covering data collection and data management elements, including a follow-up of recommendations addressing data management gaps, as identified from routine supervision visits.
- Amend the reporting template to disaggregate immunisations in both the public and private health facilities to aid accurate reporting.

<table>
<tr><td>Root Cause
• Data reviews carried out at national level only focus on data timeliness and completeness of reporting without emphasis on data quality aspects like triangulation of coverage data to logistics/distribution data. In addition, the audit team noted that Districts and communes 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 commune self-assessments were synthesised and analysed by NIHE (NEPI) for decision making and follow up.
• The template utilised to report on administration coverage includes children immunised at both public and private facilities while the vaccine dispatches data only includes vaccines dispatched to the public facilities. The reporting template was not disaggregated between immunisations in the public and private facilities.
• NIIS which would have aided data triangulation is not fully utilised.</td><td colspan="2">Management comments
See detailed management responses on Annex 8</td></tr>
<tr><td>Risk / Impact / Implications
Unexplained data anomalies undermine the credibility of the reported immunisation administrative coverage. Reporting inaccurate coverage via Gavi's performance framework is not compliant with the Partnership Framework Agreement. Lack of reliable vaccination coverage compromises the immunisation programme's ability to identify under immunised children.</td><td>Responsibility

NIHE(NEPI)</td><td>Deadline / Timetable

Q4 2025</td></tr>
</table>

4.4.3 Immunisation data in NIIS is incomplete

Context and Criteria

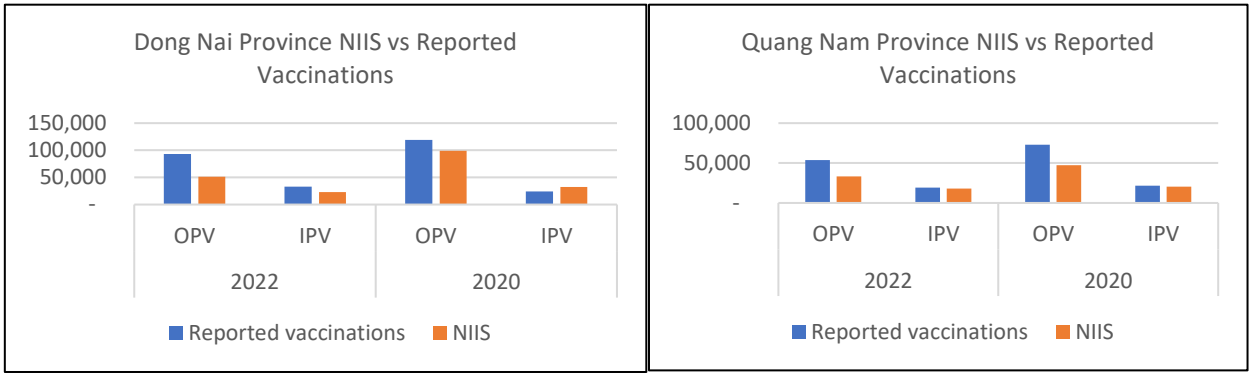
As already noted on section 3.4, The NIIS software application was rolled out nationwide in 2017 to tracks women's and children's immunisation status, generate short message service (text) reminders for caregivers when immunisation is due, provides real-time data access, and allow health workers to easily generate reports at the local and district levels.

In 2020, NEPI and PATH requested and received support from Gavi to enhance adoption of the NIIS nationwide.

Condition

The audit team compared the administrative coverage data in NIIS for two provinces (which had rolled out NIIS in 2017) with the reported immunisation (based on excel spreadsheets) and noted that the immunisation data in NIIS was incomplete.

Figure 3: Comparison of reported immunisations with NISS records at provincial level



See details on Annex 7b

Recommendation 17

Once the recommendations on 4.2.1 and 4.2.2 have been addressed, NIHE (NEPI) should work with provinces to develop and execute:

- A revised comprehensive plan to complete the deployment of NIIS including the training of users, provision of tools i.e., computers, inclusion of the remaining fee-based facilities etc.
- A mechanism to track the completeness of reporting on NIIS by each province.

Root Cause

- Challenges in the design of the NIIS system. These have been discussed on 4.2.2
- NIIS is not utilised at all communes in the provinces.
- There was no system in place to track completeness of reporting in NIIS.

Management comments

See detailed management responses on Annex 8

Risk / Impact / Implications

Incomplete data limits the utility of NIIS and impacts its sustainability.

Responsibility

NIHE(NEPI)

Deadline / Timetable

Q4 2025

4.4.4 Inconsistences between the Vietnamese national vaccine registration portal and aggregate vaccination data maintained by NEPI

Context and Criteria

In July 2021, the Viet Nam Ministry of Health government launched on online register for Covid-19 vaccines where Vietnamese nationals and foreigners could register online for vaccinations, look up vaccination history and results. This system is also utilised for all recipients of Covid-19 vaccines to capture details including name, sex, age, priority group etc.

Section 10.6 (b) and (c) of the National Deployment and Vaccination Plan (NDVP) for Covid-19 required Vaccination facilities to complete a daily report, routine report and unscheduled report as guided by MOH and the National expanded immunisation project to track, monitor COVID-19 vaccination activities. To this end, the National expanded immunisation program disseminated google sheets to provinces which are utilised to report aggregate numbers of vaccinations completed.

Data Quality Assessments (DQA) conducted by immunisation programmes provide a self-assessment opportunity to identify their data challenges and develop improvement plans.

Condition

The audit team compared the reported Covid-19 vaccination data (based off google sheets) and the Ministry of health (MoH) database (Vietnamese National Vaccine Registration Portal) which includes vaccine recipient details as of 9th June 2023 and noted unexplained variance of 13.3 million doses as follows:

Table 12: Comparison of reported vaccination data and database

	Vaccination as per MoH database (doses)	Vaccination as per google sheet (doses)	Variance (doses)
Overall vaccination	251,680,004	265,005,537	-13,325,533

Recommendation 18

NIHE (NEPI) should perform a Data Quality Audit to routinely triangulate available data, to compare the Covid-19 coverage against the volume of vaccines consumed/available and validate the accuracy of data reported. The triangulation analyses should be done at both the national and sub-national levels, and any inconsistencies in the data should be followed up and explained.

Root Cause

- Immunisation details shared by the NEPI (google sheets data) might include private immunisation which may not have been shared with the MoH.
- No triangulation of data to help NEPI to identify the data anomalies, offering the possibility for data correction.

Management comments

See detailed management responses on Annex 8

Risk / Impact / Implications

- Inaccurate and incomplete data recorded at facility, sub-national and national level may impact on the overall results reported.
- Data in the Vietnamese National Vaccine Registration Portal cannot be used to accurately assess local Covid-19 vaccination coverage levels or coverage of key populations as defined by the NDVP.

Responsibility

NIHE(NEPI)

Deadline / Timetable

Closed

4.5 Budgeting and Financial Management

4.5.1 Delays in the implementation of grants leading to low absorption

Context and Criteria

The government of Viet Nam issued decree No. 114/2021/ND-CP dated 16 December 2021 on the management and use of official development assistance (ODA) and concessional loans provided by foreign donors.

Article 8 of the decree provides Order and procedures for management and use of ODA and concessional loans:

1. For programs/projects funded by ODA and concessional loans:

a) Draft, select and approve the program/project proposal.
b) Send an official notice of the approved program/project proposal to the foreign donor.
c) Draft, appraise and decide on the investment policy for the program/project.
d) Officially notify the foreign donor of the investment policy decision of the program or project and the sponsoring request.
e) Draft, appraise and decide on investment in the program/project.
f) Depending on donor regulations, one of the following procedures shall be performed:
   - Sign international treaties, agreements on ODA and concessional loans.
   - Carry out the performance management and financial management.
   - Complete and transfer the results.

Article 12 provides guidance on decision making authority on investment policy for the programs/projects funded by ODA and concessional loans vesting authority to approve on investment policy within the Prime Minister's office.

Article 13 provides guidance on Proposal for programs/projects funded by ODA and concessional loans vesting authority to approve program/project proposals within the Prime Minister's office. It also provides Order and procedures for approval of a program/project proposal involving Ministry of Planning and Investment, the Ministry of Finance and concerned agencies (could include other Ministries including Ministry of Foreign affairs) in accordance with law.

The decree also introduced the following key changes to the way the government managed foreign grants within the immunisation sector (including Gavi funds):

a) All grants require a project management unit (PMU) at the MoH
b) For implementation at provincial level, there is a need he need for a project document for every province where interventions were being held. This was because the legal establishing NEPI as a national programme had lapsed at the end of 2020.
c) Project budgets must be confirmed as opposed to utilising estimates.
d) The Project Management Unit at the MoH takes on a more active financial management role including approval of payment transactions.
e) Contracts/MoUs would be signed between donors (i.e., Gavi fund recipients) and implementing partners but the funding would be received and managed by a project PMU established at the MoH.

Condition

NEPI submitted a Post Transition Engagement (PTE) proposal in October 2019 in coordination with WHO, UNICEF, PATH and CHAI. Gavi approved PTE grants in February 2020 for a total amount of USD 1,993,094, split between WHO, UNICEF, CHAI and PATH. Disbursements of USD 1,691,988 were made by end of 2021. The overarching programmatic areas for the PTE support included: data strengthening; new approaches to demand generation; evidence generation for policy advocacy for a sustainable EPI programme; vaccination in emergencies; vaccine hesitancy communications; and supply chain strengthening.

Since the PTE plan and implementation took during the Covid-19 outbreak with strict restrictions implemented by the MoH, programme fund absorption rate was low, approximately 25% in 2021. Many activities were delayed or deferred in order to focus on implementing the Covid-19 deployment plan. In 2021, Gavi agreed to one year no cost extension until end of 2022 to provide the MoH and the Gavi Alliance partners (as implementers) time to undertake all planned activities.

In 2021, Gavi also approved additional Covid-19 delivery support (CDS) amounting to USD 3,000,000 with an implementation timeframe of one year.

Low absorption of PTE and CDS grants – As of June 2023, the audit team noted that the rate of fund absorption for both the PTE and the CDS grants remains low at 51% and 38% respectively.

Table 13: Post transition engagement grant absorption

Implementer	Budget (in USD)	Actual (in USD)	% fund absorption
UNICEF	*272,160*	*272,160*	100%
WHO	*791,800*	*202,718*	26%
PATH	*750,769*	*418,237*	56%
CHAI	*178,365*	*124,855*	70%
TOTAL	***1,993,094***	***1,017,970***	**51%**

Table 14: Covid-19 delivery support grant absorption

Implementer	Budget (in USD)	Actual - Dec 22 (in USD)	% fund absorption
MoH	*1,827,803*	*0*	0%
UNICEF	*822,197*	*853,787*	104%
WHO	*350,000*	*273,698*	78%
Total	***3,000,000***	***1,127,485***	**38%**

Recommendation 19

NIHE (NEPI) and the implementing partners should comprehensively review the requirements of Decree 114, including the practical implications for grant implementation, so that in-country immunisation stakeholders can begin planning and entering into a dialogue with Gavi regarding “MICs grant”.

<table>
<tr><td>Root Cause
• PTE activities had to be delayed and some deferred to focus on the implementation of the Covid-19 deployment plan.
• PTE and CDS activities were impacted by delays in the application and implementation of Decree No. 114/2021/ND-CP. An example is the CDS grant to the Ministry of Health which accounts for 61% of the entire CDS grant.
○ 4 October 2021 – Gavi issued Decision Letter;
○ 28 December 2021 (approximately three months later)– GDPM obtained MoH grant approval;
○ February 2022 – The grant is revised and submitted to Gavi for reapproval.
○ August 2022 – Gavi approves the revised proposal, and reverts to MoH for its consent (six months later)
• As of June 2023, no formal MoH approval has been obtained to proceed with implementation (approximately 8 months after Gavi's approval)</td><td colspan="2">Management comments
See detailed management responses on Annex 8</td></tr>
<tr><td>Risk / Impact / Implications
Key immunisation interventions related to new approaches to demand generation, evidence generation for policy advocacy for sustainable EPI and vaccine hesitancy communication have not been fully implemented</td><td>Responsibility
NIHE(NEPI)</td><td>Deadline / Timetable
Q4 2024</td></tr>
</table>

4.5.2 Inconsistencies in reported grant expenditures

Context and Criteria

Annex 2, Section C, Article 16 of the PFA states that: "*The Government's use of Gavi's vaccine and cash support is subject to strict performance monitoring. Gavi seeks to use the Government reports and existing country-level mechanisms to monitor performance. The Government shall monitor and report on the use of vaccines and related supplies and the funds provided by Gavi stating the progress made towards achieving the objectives of the Programmers) during the preceding year by submitting the Annual Progress Report(s). The Government shall also share their internal management reports on the use of funds on a quarterly or periodic basis with Gavi. The Government shall also submit all documents and reports that are required to be submitted as part of the Annual Progress Reports and country applications. For certain cash support, Gavi shall monitor and review annually the progress made in the Country towards the funded objectives of the Programmers) by participating in the annual health sector review through existing country-level mechanisms. The Government shall submit all documents relevant to annual health sector reviews as requested by Gavi*".

Section 4.3.2 of the grant agreement between the Gavi and UNICEF states that, "*UNICEF shall maintain accurate accounting records documenting how Grant funds are used and disbursed. UNICEF will remain solely responsible for disbursing Grant funds for budgeted Activities*."

Section 4.3.2 of the grant agreement between the Gavi and WHO states that, "*WHO shall maintain accurate accounting records documenting how Grant funds are used and disbursed. WHO will remain solely responsible for disbursing Grant funds for budgeted Activities*".

Condition

The audit team noted that 23% (USD 888,823) of Gavi cash grant funding received and managed by UNICEF was sub-contracted to NEPI and 45% (USD 1,041,122) of Gavi cash grants received and managed by WHO were similarly sub-granted.

Some national expenditures reported by the UN partners was not traceable to NEPI's records - The audit team noted that expenditures reported by the United Nations partners could not be accurately traced to NEPI's underlying records as illustrated in the table below:

Table 15: Variances between partner reported expenditure and NEPI records in USD

Grants	WHO (in USD)	UNICEF (in USD)
Graduation/Transition	*791,895*	*815,133*
COVAX CDS (CDS)	*201,312*	*17,166*
PTE	*47,915*	*0*
Engagement With Countries Post Transition	*0*	*56,525*
Total national expenditures reported by WHO and UNICEF as having used sub-contracted Gavi funding	***1,041,122***	***888,824***
NEPI reported expenditure traced to the NEPI General Ledger	*945,309*	*924,249*
Unexplained difference	*95,813*	*(35,425)*

Recommendation 20

- NEPI should prepare detailed reconciliations of funds received from Gavi alliance partners. These reconciliations should include source of funding.

<table>
<tr><td>Root Cause
• There were no periodic reconciliations of NEPI records to Alliance Partner reported expenditure.
• NEPI reported expenditure for UNICEF included expenditure from other sources of funding beyond Gavi.</td><td colspan="2">Management comments
See detailed management responses on Annex 8</td></tr>
<tr><td>Risk / Impact / Implications
Financial reports submitted to Gavi by Alliance Partners are inaccurate</td><td>Responsibility
NIHE(NEPI)</td><td>Deadline / Timetable
Q4 2024</td></tr>
</table>

4.5.3 NIHE (NEPI) used Gavi funds to pay VAT

Context and Criteria

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

Condition

The audit team noted that Gavi funds received by NIHE (NEPI) were used to pay taxes (VAT) in contravention of article 15 of the Partnership Framework Agreement (PFA) between Gavi and Government of Viet Nam. Grants amounting to USD 1,308,845 received directly from Gavi and USD 1,041,122 received from Gavi through WHO were utilised to pay VAT. The current accounting records at NEPI do not support the extraction and reporting of VAT paid. Based off the total expenditure incurred (i.e., USD 2,045,573) from these two sources, the audit team estimated USD 185,961[38] as VAT paid utilising Gavi funds.

The audit team noted that the VAT related to UNICEF sub-grants was separately reported and claimed by UNICEF

Recommendation 21

NIHE (NEPI) and partners should review Gavi's budgeting and financial guidelines including the PFA requirements and apply these in future as applicable.

Recommendation 22

In future, all expenditures including VAT payments using Gavi grant funding should be identified and tagged, so that VAT amounts can be reclaimed from the revenue authority and paid back into the immunisation programme.

Root Cause

NIHE (NEPI) finance and accounting staff were not aware of the PFA requirements.

Management comments

See detailed management responses on Annex 8

Risk / Impact / Implications

Non-compliance with the PFA.

Responsibility

NIHE(NEPI)

Deadline / Timetable

Action 21: Q4 2024

Action 22: Q4 2025

[38] VAT rate in the period of audit was 10%

5. Annexes

Annex 1 : Acronyms

AEFI	Adverse Events Following Immunisation
CCE	Cold Chain Equipment
CCEOP	Cold Chain Equipment Optimisation Platform
CDC	Centers for Disease Control
CHAI	Clinton Health Access Initiative
cMYP	Comprehensive Multi-Year Plan
DQA	Data Quality Audit
DVS	District Vaccine Store
FIF	Fee-based Immunisation Facilities
GDP	Gross Domestic Product
GDPM	General Department of Preventive Medicine
HR	Human Resources
HSS	Health System Strengthening
HMIS	Health Management Information Systems
LMIS	Logistics Management Information System
MoH	Ministry of Health
NEPI	National Expanded Programme for Immunisation
NIIS	National Immunisation Information System
NIHE	National Institute of Hygiene and Epidemiology
NVS	National Vaccine Store
PHD	Provincial Health Departments
PFA	Partnership Framework Agreement
PHEIC	Public Health Emergency of International Concern
PVS	Provincial Vaccine Store
RVS	Regional Vaccine Store
UNICEF	United Nations Children's Fund
USD	United States Dollars
VAT	Value Added Tax
VIG	Vaccine Introduction Grant
VND	Vietnamese Dong
WIC	Walk in Cold room
WIF	Walk in freezer
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 Gavi Secretariat but also to the programmes and activities carried out by Gavi's grant recipients and partners. More specifically, its scope encompasses the examination and evaluation of the adequacy and effectiveness of Gavi's governance, risk management processes, system of internal control, and the quality of performance in carrying out assigned responsibilities to achieve stated goals and objectives.

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

A. Overall Audit Opinion

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

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

B. Issue Rating

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

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

Annex 4 : List of Facilities Visited

National Vaccine Store	Regional Vaccine Store	Provincial Vaccine Store	District Vaccine Store	Health Facility/Commune
National Vaccine Store (Hai Ba Trung)	Northern (Northern EPI- Hanoi)	Langson CDC	TP Langson Health Center	Vinh trai Ward
				Dong Kinh Ward
		Phu tho CDC	Lam thao Health Center	Son vi Commune
		Thai Binh CDC	Dong Hung Health Center	Phong Chau Commune
	Central (Pasteur Institue Nha Trang-Khanh Hoa)	Quang tri CDC	Dong Ha Health Center	Ward 4
				Dong Phuong Ward
		Quang Nam CDC	Hiep Duc Health Center	Thang Phuoc Commune
	Highlands (Tây Nguyên Institute of Hygiene and Epidemiology-Dac Lak)	Kon Tum CDC	Kon Tum City Health Center	Hoa Binh Commune
				Duy Tan Commune
	Southern (The Pasteur Institute-Ho Chi Minh)	Dong Nai CDC	Long Thanh Health Center	Long Duc
				Phuoc Thai Commune
		Kien Giang CDC	An Bien Health Center	Tay Yen A Commune
				Thu Ba town Health Facility

Annex 5 : Viet Nam immunisation schedule

Vaccine	Schedule	Nationwide
Hepatitis B (HepB)	birth;	Yes
Bacillus Calmette–Guérin (BCG)	1 month;	Yes
Diphtheria, Pertussis, Tetanus, Hepatitis B and Haemophilus influenzae type B (DPT-HepB-Hib)	2, 3, 4 months;	Yes
Oral poliovirus vaccines (OPV	2, 3, 4 months;	Yes
Inactivated poliovirus vaccine (IPV)	5 months;	Yes
Measles	9 months;	Yes
Japanese encephalitis (JE)	12 months; +2 weeks; 2 years;	Yes
Measles Rubella	18 months;	Yes
Diphtheria, Pertussis, Tetanus (DPT)	18 months;	Yes
Tetanus (Td)	7 years;	No
Tetanus Toxoid (TT)	1st contact; +1, +6 months; +1 year;	Yes

Annex 6: Gaps in Vaccine Supply Chain Management

Annex 6a: Stock Outs of Vaccines at NVS

	Name of Vaccine	Stockout 1 (Days)	Stockout 2 (Days)	Stockout 3 (Days)	Stockout 4 (Days)	Stockout 5 (Days)	Stockout 6 (Days)	Total
National Vaccine Store	Pentavalent vaccine	3	355	0	0	0	0	**358**
	Inactivated Polio vaccine (IPV)	0	0	0	0	0	0	**0**
	DPT	176	83	288	55	168	38	**808**
	Pfizer Vaccine	50	0	0	0	0	0	**50**
	AstraZeneca AB AZD1222	0	0	0	0	0	0	**0**
	Moderna Switzerland GMBH mRNA-1273	143	0	0	0	0	0	**143**

	Name of Vaccine	Total Number of Stock out Days	Maximum number of Stock Out Days
National Vaccine Store	Pentavalent vaccine	358	355
	Inactivated Polio vaccine (IPV)	0	0
	DPT	808	288
	Pfizer Vaccine	50	50
	AstraZeneca AB AZD1222	0	0
	Moderna Switzerland GMBH mRNA-1273	143	143

Annex 6b: Stock Outs of Vaccines at RVS

Regional Vaccine Store	Name of Vaccine	Stockout 1 (Days)	Stockout 2 (Days)	Stockout 3 (Days)	Stockout 4 (Days)	Stockout 5 (Days)	Stockout 6 (Days)	Stockout 7 (Days)	Stockout 8 (Days)	Cumulative # of Stockout Days	Maximum # of Stockout Days
Northern	Pentavalent vaccine	136	0	0	0	0	0	0	0	136	136
Northern	Inactivated Polio vaccine (IPV)	0	27	22	54	2	30	0	0	195	60
Northern	Inactivated Polio vaccine (IPV)	60	0	0	0	0	0	0	0		
Central	Pentavalent vaccine -	21	14	53	0	0	0	0	0	88	53
Central	Inactivated Polio vaccine (IPV)	56	126	35	0	0	0	0	0	217	126
Highland	Pentavalent vaccine	9	46	22	0	31	0	0	0	108	46
Highland	Inactivated Polio vaccine (IPV)	23	61	12	120	34	39	30	0	289	120

Store	Vaccine	Average # of stockout days	Max # of stockout days
RVS	Pentavalent vaccine	111	136
	Inactivated Polio vaccine (IPV)	234	126

Annex 6c: Stock Outs of Vaccines at PVS

Provincial Vaccine Store	Name of Vaccine	Stockout 1 (Days)	Stockout 2 (Days)	Stockout 3 (Days)	Stockout 4 (Days)	Stockout 5 (Days)	Stockout 6 (Days)	Cumulative # of Stockout Days	Maximum # of Stockout Days
Langson	Pentavalent vaccine	1	2	3	0	0	0	6	3
Langson	Inactivated Polio vaccine (IPV)	12	6	46	43	22	27	156	46
Langson	Inactivated Polio vaccine (IPV)	34	21	60	0	0	0	115	60
Phu Tho	Inactivated Polio vaccine (IPV)	36	55	66	57	54	36	304	66
Thai Binh	Pentavalent vaccine	52	45	55	53	0	0	205	55
Thai Binh	Inactivated Polio vaccine (IPV)	12	76	63	39	53	21	264	76
Thai Binh	Inactivated Polio vaccine (IPV)	29	0	15	51	21	7	123	51
Thai Binh	Inactivated Polio vaccine (IPV)	34	0	0	0	0	0	34	34
Quảng Trị	Pentavalent vaccine	18	12	0	0	0	0	30	18
Quảng Trị	Inactivated Polio vaccine (IPV)	38	27	22	0	0	0	87	38
Quang Nam	Inactivated Polio vaccine (IPV)	52	11	6	0	0	0	69	52
Dong Nai	Pentavalent vaccine	7	30	0	0	0	0	37	30
Dong Nai	Inactivated Polio vaccine (IPV)	26	25	41	0	0	0	92	41
Kien Giang	Pentavalent vaccine	35	33	56	43	25	0	192	56
Kien Giang	Inactivated Polio vaccine (IPV)	27	42	34	9	0	0	112	42

Store	Vaccine	Average # of Stockout days	Max # of Stockout days
PVS	Pentavalent vaccine	94	56
	Inactivated Polio vaccine (IPV)	136	76

Annex 6d: Stock Outs of Vaccines at DVS

District Vaccine Store	Name of Vaccine	Stockout 1 (Days)	Stockout 2 (Days)	Stockout 3 (Days)	Stockout 4 (Days)	Stockout 5 (Days)	Stockout 6 (Days)	Cumulative # of Stockout Days	Maximum # of Stockout Days
Lam Thao	Pentavalent vaccine	7	18	4	55	62	57	203	62
Lam Thao	Inactivated Polio vaccine (IPV)	3	8	37	3	23	2	477	97
Lam Thao	Inactivated Polio vaccine (IPV)	20	1	31	32	97	59		
Lam Thao	Inactivated Polio vaccine (IPV)	31	57	3	14	54	2		
Dong Hung	Pentavalent vaccine	26	28	23	26	0	0	103	28
Dong Hung	Inactivated Polio vaccine (IPV)	22	26	26	14	28	28	539	33
Dong Hung	Inactivated Polio vaccine (IPV)	33	1	32	28	32	29		
Dong Hung	Inactivated Polio vaccine (IPV)	25	31	29	33	31	32		
Dong Hung	Inactivated Polio vaccine (IPV)	31	28	0	0	0	0		
Dong Ha	Inactivated Polio vaccine (IPV)	25	28	27	25	14	0	119	28
Hiep Duc	Inactivated Polio vaccine (IPV)	3	20	5	2	27	2	228	50
Hiep Duc	Inactivated Polio vaccine (IPV)	3	50	3	22	26	14		
Hiep Duc	Inactivated Polio vaccine (IPV)	14	16	21	0	0	0		
Kon Tum	Pentavalent vaccine	92	0	0	0	0	0	92	92
Long Thanh	Pentavalent vaccine	22	27	60	0	0	0	109	60
Long Thanh	Inactivated Polio vaccine (IPV)	29	26	0	0	0	0	55	29
An Bien	Pentavalent vaccine	23	57	57	15	2	1	372	161
An Bien	Inactivated Polio vaccine (IPV)	28	57	31	55	32	28	374	57

Store	Vaccine	N	Average # of stockout days	Max # of stockout days
DVS	Pentavalent vaccine	7	176	161
	Inactivated Polio vaccine (IPV)	7	299	97

Annex 6e: Comparison of UNICEF reference prices and Viet Nam procurement prices

#	Vaccine	Year	Quantity Procured	Unit price of dose	Note	Unit price of dose (VND)	USD-VND Exchange Rate*	UNICEF Reference Prices (US$)	Viet Nam Procurement Prices (US$)	UNICEF Procurement Prices (US$)	Viet Nam Procurement Prices (US$)	Potential savings (US$)
1	Quinvaxem - Janssen	2017	4,296,300	21.838,59 VND/dose	Via UNICEF	21,838.59	22,765	0.80				
				19.446,4 VND/dose		19,446.40	22,765	0.80				
2	ComBE Five – Biological E	2018	4,646.50	28.966,11 VND/dose	Via UNICEF	28,966.11	22,602	1.15				
3	Penta (SII – India)	2018	5,085,700	31.960 VND/dose	open tender	31,960	22,602	1.1	1.41	5,594,270	7,191,338	1,597,068
4	Penta (SII – India)	2019	2,000,000	31.960 VND/dose	open tender	31,960	23,050	1.2	1.39	2,400,000	2,773,073	373,073
5	Penta (SII – India)	2020	2,000,000	34.172 VND/dose	open tender	34,172	23,208	1.2	1.47	2,400,000	2,944,800	544,800
6	Penta (SII – India)	2021	2,000,000	34.172 VND/dose	open tender	34,172	23,208	1.15	1.47	2,300,000	2,944,800	644,800
	TOTAL											**3,159,741**

**Source for Exchange Rate: World Bank*

Annex 6f: Domestic refrigerators used to store vaccines at the commune

Annex 7: Gaps in Data Management

Annex 7a: Inconsistencies in reported vaccinations for vaccines administered at the same time

Sample Province	Year	DPT-Vgb-Hib (5 in 1)			bOPV			Inconsistency noted		
		Dose 1 (A)	Dose 2 (B)	Dose 3 (C)	bOPV 1 (D)	bOPV 2 (E)	bOPV 3 (F)	% dose 1 (A-D)/A	% dose 2 (B-E)/B	% dose 3 (C-F)/C
Thái Bình	2018	26,773	20,325	21,650	27,958	27,611	27,524	-4%	-36%	-27%
Phú Thọ	2018	18,187	18,645	19,122	24,498	24,312	24,230	-35%	-30%	-27%
Lạng Sơn	2018	10,350	10,959	11,373	13,520	13,611	13,817	-31%	-24%	-21%
	2020	13,324	13,296	13,495	12,298	12,010	11,956	8%	10%	11%
	2022	9,500	9,335	9,323	8,088	8,007	7,799	15%	14%	16%
Quảng Trị	2018	8,388	8,682	8,695	11,436	11,632	11,445	-36%	-34%	-32%
Quảng Nam	2022	20,617	20,031	20,412	17,525	17,800	18,259	15%	11%	11%
Kon Tum	2018	10,339	8,289	7,664	12,203	11,997	11,692	-18%	-45%	-53%
	2022	10,790	10,592	10,444	9,366	9,230	9,113	13%	13%	13%
Đồng Nai	2018	36,433	36,940	37,737	44,846	44,717	45,621	-23%	-21%	-21%
	2020	47,345	46,455	45,561	39,453	39,671	39,895	17%	15%	12%
	2021	21,943	20,899	20,016	26,847	26,220	25,246	-22%	-25%	-26%
	2022	38,242	37,892	38,105	30,848	31,005	31,435	19%	18%	18%
Kiên Giang	2018	21,866	19,046	17,981	24,664	23,203	22,497	-13%	-22%	-25%
	2022	20,874	20,891	20,494	17,886	18,093	17,848	14%	13%	13%

Annex 7b: Incomplete data in NIIS

Province	Document	Year 2022				Year 2020			
		OPV 1	OPV 2	OPV 3	IPV1	OPV 1	OPV 2	OPV 3	IPV1
Dong Nai	As per Manual report	30,848	31,005	31,435	33,092	39,453	39,671	39,895	24,114
	As per NIIS	18,590	17,387	15,549	22,846	38,574	31,104	29,451	32,125
	Variance	**12,258**	**13,618**	**15,886**	**10,246**	**879**	**8,567**	**10,444**	**- 8,011**
Quang Nam	As per Manual report	17,525	17,800	18,259	19,106	25,109	24,145	23,731	21,652
	As per NIIS	11,847	11,443	10,000	17,966	19,681	17,635	10,000	20,288
	Variance	**5,678**	**6,357**	**8,259**	**1,140**	**5,428**	**6,510**	**13,731**	**1,364**

Annex 8: Detailed Management responses

Finding	Audit Recommendations	Management Action	Action Owner	Deadline for execution
There were gaps in the EPI governance arrangements	**Recommendation 1** NIHE (NEPI) should revise and update its governance arrangements to oversee EPI activities, ongoing grants and future support from the Gavi Middle Income Countries (MICs) approach. The governance arrangements should include as a minimum: • The scope of oversight within the immunisation programme to include all immunisation activities in addition to Gavi grants. • Requirement for members to adhere to conflict-of-interest declarations best practice. • Broad representation from a variety of stakeholders that implement the immunisation programme including provincial focal points. • Designate the frequency of meetings. • Definition of key oversight areas covered including programmatic, operational, and financial management.	On Feb 5, 2024, the Government issued Decree 13/2024/ND-CP indicating allocation of the State Budget for vaccine procurement, transportation and storage. Local budgets are to be utilised for operational costs. On the basis of Decree 13, the MOH will strengthen the EPI and NEPI will keep Gavi informed. **Action 1** A stakeholder governance body/committee will be set up at national level to oversee the immunisation programme. NIHE(NEPI) will keep Gavi informed of any changes.	NIHE (NEPI)	Q2 2024
Gaps in sustainability planning for the National Immunisation Information System	**Recommendation 2** The MOH should: • Establish a formal contract or agreement with a suitable service provider to support NIIS maintenance and upgrades. • Migrate NIIS data over to government ownership in order to safeguard the system's sustainability beyond donor support.	**Action 2** • The MOH will negotiate with Viettel to establish a formal arrangement or Memorandum of Understanding to support the NIIS. • The MOH will work on modalities to transfer data ownership once a formal arrangement has been established.	MoH	Q4 2025

Finding	Audit Recommendations	Management Action	Action Owner	Deadline for execution
	Recommendation 3 The MoH should work with Viettel to: • prepare comprehensive quantification of all fixed and recurring operational costs for NIIS maintenance. • Develop a comprehensive transition plan detailing all associated costs required to operate and maintain NIIS at Provincial and national level; and • perform a data growth projection to anticipate the current and future storage and processing requirements for NIIS. This will facilitate adequate planning for the necessary resources, such as disk space, memory, and processing power, to ensure optimal performance and avoid capacity constraints and slow system performance as the data volume exceeds server capacities. The plan could be used as resource mobilisation tool with the MoH to ensure NIIS operational costs are budgeted for and fully financed.	**Action 3** Following these recommendations, the MoH will collaborate with international organisations to accelerate implementation. Within the framework of MICs TA, NEPI will develop plans for deploying electronic reporting at intervention localities and share experiences with other localities to expand the scope of implementation.	MOH and NIHE(NEPI)	Q4 2025

Finding	Audit Recommendations	Management Action	Action Owner	Deadline for execution
Challenges in design of the National Immunisation Information System impacting the system's operating effectiveness	**Recommendation 4** To address the challenges and ensure the successful adoption of a unique identifier system, the MoH should ensure that the following considerations are met during the selection process of a unique identifier: • Uniqueness: The chosen identifier must be inherently unique to avoid any potential confusion or duplication within the system. • Consistency: Consistent usage of the identifier across all healthcare facilities and vaccination centres is paramount to ensure seamless data integration and accuracy. • Standardisation: Adherence to international standards for identifier formats and coding systems will facilitate interoperability and smooth data exchange among different health systems. • Security: Robust security measures must be in place to safeguard the confidentiality and privacy of patient information associated with the unique ID. • Compatibility: Compatibility with existing health information systems and electronic health record platforms is vital to ensure smooth integration and data sharing. • Accessibility: The ID system should be user-friendly and easily accessible for healthcare providers, enabling efficient data capture and retrieval processes. • Scalability: The selected identifier system should have the capacity to scale effectively to accommodate the growing needs of vaccinations and the increasing population.	**Action 4** The MoH will work with NIHE/NEPI and Viettel to implement a unique identifier as recommended.	MoH	Q4 2024

Finding	Audit Recommendations	Management Action	Action Owner	Deadline for execution
	Recommendation 5 The MoH should perform a comprehensive systems vulnerability and functionality audit to: • identify and correct errors and bugs in the system including data validation checks; • Identify and remove dummy data in the production environment; • Update end-user manuals and TOT guides; • Incorporate policies related to Decree 13 on personally identifiable information; • Establish a policy on data backup and restoration testing; • Enhance performance of system dashboards and reports The review should aim to support the new vaccine introductions under the MICs strategy and include lessons learned from the parallel systems run for Covid19 vaccination data.	**Action 5** The MoH will work with NIHE/NEPI, PATH and Viettel to implement the recommendation of conducting a comprehensive systems review.	MoH	Q2 2025
	Recommendation 6 NIHE (NEPI) and PATH should perform a comprehensive review of the e-Learning module in NIIS to: • Rectify security issues identified. • Ensure SCORM standards are incorporated in the design. • Complete the development of the ~~29~~ outstanding modules.	**Action 6** NEPI will collaborate with PATH, CHAI to translate this recommendation into action	NIHE(NEPI)	Q4 2025
Limited interoperability of NIIS with digital health tools utilised by the Ministry of Health	**Recommendation 7** NIHE (NEPI) should consider establishing a process to integrate its systems containing vaccine and logistics data, by establishing a singular data warehouse to improve visibility and reduce cases of duplication of data points.	**Action 7** Paper-based reporting system on vaccine and logistic is essential to manage State Investment for EPI according to State Budget Law. NEPI will gradually expand the e-reporting system on vaccines and logistics in parallel from year to year and ultimately build a Datawarehouse.	NIHE(NEPI)	Q4 2025

Finding	Audit Recommendations	Management Action	Action Owner	Deadline for execution
Nationwide vaccine stock outs may limit the achievement of zero dose and hinder the plans for routinisation of Covid-19 vaccination	**Recommendation 8** NIHE (NEPI) should finalise the current consultation processes on vaccine procurement with MoH, MoF and National Assembly to develop a long-term solution on vaccine procurement arrangements.	**Action 8** On February 5, 2024, the Government issued Decree No. 13/2024/ND-CP, amending and supplementing some articles of Decree 104/2016/ND-CP dated July 1, 2016, on vaccination activities, including provisions on ensuring funding for vaccine purchases in the Expanded Immunisation Program, specifically: • The Ministry of Health will guide localities in planning, determining vaccine needs by type and organizing the procurement of EPI vaccines. • The Ministry of Finance will be responsible for presenting to competent authorities the arrangement of funds for the Expanded Immunisation Program and epidemic vaccination according to the regulations of the State Budget Law. • Operational costs will be covered by the local governments	MoH	Q1 2024
Variances exist between the UNICEF reference and the NIHE negotiated prices for pentavalent vaccines	**Recommendation 9** In accordance with UNICEF and Gavi's advice, the MoH should consider putting in place a suitable mechanism in order to access the UNICEF negotiated prices for its future procurements where there is a comparative advantage in price.	**Action 9** Vaccine procurements are guided by the procurement laws of the country. MoH and NIHE(NEPI) will explore ways of accessing UNICEF negotiated prices.	MoH, NIHE(NEPI)	Q4 2024
	Recommendation 10 NIHE/MOH should include a provision for price market surveys in the bid solicitation process.	**Action 10** NIHE(NEPI) and MOH have now included a provision for price market surveys in the bid solicitation process.	MoH, NIHE(NEPI)	Q1 2024
Challenges in forecasting and supply planning resulted in stock wastage	**Recommendation 11** NIHE (NEPI) should institute mechanisms to carry out: • Periodic review of its stock levels at the NVS and other peripheral stores • Regular monitoring of stock and the supply plan	**Action 11** NIHE(NEPI) will implement strict management of vaccines and supplies by: • Managing vaccine inventory and completing monthly vaccine usage reports, quarterly vaccine needs reports accurately and promptly. • Obtaining regular feedback on vaccine usage, including usage progress, utilization rate, vaccine demand proposals and inventory of vaccines in the EPI by lower levels. • Adjusting the annual vaccine purchase plan according to inventory and usage capacity.	NIHE(NEPI)	Q4 2024

Finding	Audit Recommendations	Management Action	Action Owner	Deadline for execution
Large quantities of obsolete stock are taking up storage space	**Recommendation 12** NIHE (NEPI) should work with the MoH to escalate the disposal process for the existing expired vaccines. In addition, the MoH should establish timeframes and standards of service, so that all future disposals of obsolete stocks are promptly scheduled, initiated and executed.	**Action 12** The EPI program has reported to the Ministry of Health the situation of expired vaccines in the Expanded Immunisation Program and will proceed with the disposal of expired vaccines. Urging all levels to implement the disposal process of expired vaccines in the Expanded Immunisation Program according to the current guidelines of the Ministry of Health.	MoH, NIHE(NEPI)	Q3 2024
Gaps in management of cold chain equipment at subnational level	**Recommendation 13** NIHE (NEPI) should work with provinces to ensure that: • The cold chain contingency plans are circulated nationwide, and that appropriate on-the-job mentorship is provided. • Cold chain equipment used to store vaccines are WHO PQS compliant.	**Action 13** Implementing this recommendation, NEPI will report the Ministry of Health (MoH) to send official document to the Provincial People's Committees to allocate funds for activities of cold chain contingency plans and cold chain equipment maintenance (According to Section 4, Article 1 of Decree 13/2024 /ND-CP dated February 5, 2024 on ensuring local government budget for EPI Program activities). In 2021-2023, NEPI has trained and guided provincial and district staff to develop vaccine storage standard procedures, including contingency plans in case of cold chain emergencies. In 2024, NEPI will continue to guide units with cold chain equipment to complete the standard procedures on vaccine storage and managements, updating the supportive supervision checklist on monitoring vaccine storage management to include the contents of cold chain contingency plans. Currently, NEPI is replacing and equipping cold chain equipment for provincial, district and commune levels with WHO PQS equipment. From this Gavi recommendation, NEPI would like to request WHO and UNICEF to send an official document to MOH on recommendation the use of WHO PQS cold chain equipment for vaccine storage.	MoH, NIHE(NEPI)	Q4 2024
Decline in routine immunisation coverage over last five years	**Recommendation 14** NIHE (NEPI) should develop a plan to catch up on missed routine immunisations.	**Action 14** NEPI (NIHE) has developed the EPI action Plan 2024 including catching-up the missed doses and amount of vaccines purchased for the year 2024 and early 2025, and submitted it to the Ministry of Health for their review and approval. The Ministry of Health was also presented with the MICs plan, which includes reaching ZDC in routine immunisation. NEPI (NIHE) will collaborate with international organizations to develop guidelines for localities on identifying, catching ZDC and conducting activities within the MICs framework.	NIHE(NEPI)	Q4 2025

Finding	Audit Recommendations	Management Action	Action Owner	Deadline for execution
	Recommendation 15 WHO and UNICEF have published guidance on considerations for integrating Covid-19 vaccination into immunisation programmes and primary health care for 2022 and beyond. NIHE (NEPI) should review, document and develop a national strategy for transitioning its Covid-19 vaccination response and integrating this into its routine immunisation, highlighting the: relevant delivery strategies, resources required and timeframe to complete this transition	**Action 15** MoH stated that COVID-19 was classified as a B category of infectious disease. The Ministry of Health is working on the 2024 plan on COVID-19 vaccination. Currently, a dose will be provided to high-risk individuals.	MoH	Q4 2024
Gaps in the quality of administrative immunisation coverage data	**Recommendation 16** NIHE (NEPI) should: • Perform a Data Quality Audit to routinely triangulate available data, including an assessment of immunisation coverage data and vaccine availability/ utilisation to check the accuracy of data reported. Such analyses should be undertaken at national and sub-national levels and any data inconsistencies noted should be validated and explained. • Ensure an adequate supervision is conducted at sub-national level covering data collection and data management elements, including a follow-up of recommendations addressing data management gaps, as identified from routine supervision visits.	**Action 16** NEPI (NIHE) will develop plans on assessment of data quality, monitor, and support various levels in the coming period. NEPI requests technical and financial supports from international community on DQA.	NIHE(NEPI)	Q4 2025
Immunisation data in NIIS is incomplete	**Recommendation 17** Once the recommendations on 4.2.1 and 4.2.2 have been addressed, NIHE (NEPI) should work with provinces to develop and execute: • a revised comprehensive plan to complete the deployment of NIIS including the training of users, provision of tools i.e., computers, inclusion of the remaining fee-based facilities etc. • a mechanism to track the completeness of reporting on NIIS by each province.	**Action 17** • The MoH will prepare a plan to comprehensively deploy NIIS. • NEPI (NIHE) will work with PATH to conduct training of users and provide technical supports including tools to track the completeness of reporting on NIIS.	MoH, NIHE(NEPI)	Q4 2025
Inconsistences between the Vietnamese national vaccine registration portal and aggregate vaccination data maintained by NEPI	**Recommendation 18** NIHE (NEPI) should perform a Data Quality Audit to routinely triangulate available data, to compare the Covid-19 coverage against the volume of vaccines consumed/available and validate the accuracy of data reported. The triangulation analyses should be done at both the national and sub-national levels, and any inconsistencies in the data should be followed up and explained.	**Action 18** The Ministry of Health has temporarily suspended the COVID-19 Vaccine Data Management System. Currently, the implementation of COVID-19 vaccination is slowing down. EPI will manage aggregate data and perform Data Quality Checks on this.	NIHE(NEPI)	Closed

Finding	Audit Recommendations	Management Action	Action Owner	Deadline for execution
Delays in the implementation of grants leading to low absorption	**Recommendation 19** NIHE (NEPI) and the implementing partners should comprehensively review the requirements of Decree 114, including the practical implications for grant implementation, so that in-country immunisation stakeholders can begin planning and entering into a dialogue with Gavi regarding "MICs grant".	**Action 19** EPI experienced the submission of project proposals recently that may help to shorten the preparatory phase. EPI and in-country partners will discuss on planning for MICs TI soon once we get a greenlight from Gavi. EPI requests Gavi's guidance on next steps and its requirements.	MoH, NIHE(NEPI)	Q4 2024
Inconsistencies in reported grant expenditures	**Recommendation 20** NEPI should prepare detailed reconciliations of funds received from Gavi alliance partners. These reconciliations should include source of funding.	**Action 20** All reconciliations of grant directly funded by GAVI to NEPI (NIHE) were marked by funding source. NEPI (NIHE) also prepared detailed reconciliations of funds received from Gavi alliance partners, but these were not marked by funding source. For future grants, NEPI (NIHE) will prepare detailed reconciliations including source of funding if any TA is provided and grant is indirectly funded through the partners.	MoH, NIHE(NEPI)	Q4 2024
NIHE (NEPI) used Gavi funds to pay VAT	**Recommendation 21** NIHE (NEPI) and partners should review Gavi's budgeting and financial guidelines including the PFA requirements and apply these in future as applicable.	**Action 21** NEPI will review and apply Gavi's budgeting and financial guidelines in the future.	MoH, NIHE(NEPI)	Q4 2024
	Recommendation 22 In future, all expenditures including VAT payments using Gavi grant funding should be identified and tagged, so that VAT amounts can be reclaimed from the revenue authority and paid back into the immunisation programme.	**Action 22** In reality, the budget allocated for VAT payments constitutes a small portion of the funds provided by GAVI during the 2017-2022 period. In the upcoming phase, NEPI will report to the Ministry of Health regarding the allocation of state budget funds to cover VAT for activities supported by GAVI. NEPI (NIHE) requests Gavi to address this policy in the sponsorship notification letter. A report will be made to the Ministry of Health on the allocation of state budget funds to cover VAT payments for activities funded by GAVI.	NIHE(NEPI)	Q4 2025