Memorandum on the Arab Republic of Egypt
COVAX Programme Audit report

The attached Gavi Audit and Investigations report sets out the conclusions of the COVAX programme audit of the Arab Republic of Egypt's Expanded Programme of Immunisation, managed by the Ministry of Health and Population (MOHP). The audit was conducted in September 2022 and covered the management of COVAX stock and immunisation supplies for the period 1 January 2021 until 30 June 2022.

This audit covered Gavi's COVAX support provided to Egypt up until 30 June 2022, and the resultant activities conducted at national and sub-national levels using this support..

The objective of the audit was to assess the adequacy and effectiveness of systems, processes, and controls over the approved Covid-19 vaccines and ancillary support. This was done by reviewing: governance and programme management; the monitoring and evaluation of immunisation data; vaccine supply chain management and cold chain management.

The audit scope did not include Gavi's cash grant support, as only a modest amount of COVAX delivery support totalling USD 0.25m was directly implemented by the MOHP.

The report Executive Summary (page 4) sets out the key conclusions (the details of which are set out in the body of the report).

1. There is an overall audit rating of "Effective" which means that "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."
2. In total, three medium importance issues were identified in the monitoring and evaluation area. To address all of the risks associated with the findings identified, the audit team raised seven recommendations, none of which were rated as high risk.
3. Key findings were that:
    a. In general, the programme's controls and processes over vaccines and stocks were adequately designed, minimising the risks presented by the operation of Egypt's COVID-19 immunisation activities. No significant incidents of shelf-expired or damaged COVAX vaccines were identified.
    b. The government is encouraged to establish a plan for the transition of its COVID-19 emergency response over to its routine immunisation programme.
    c. There was some scope of improving the quality and timeliness of maintaining immunisation coverage and vaccine stock data.

The results of this audit have been discussed and agreed with the Ministry of Health and Population. They accepted the audit findings, acknowledged the weaknesses identified, and committed to implement a detailed management action plan.

The Gavi Secretariat continues to work with the Ministry of Health and Population to ensure that their commitments are met.

Geneva, November 2023

COVAX programme audit report

The Arab Republic of Egypt

July 2023

Gavi
The Vaccine Alliance

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1. Executive Summary

1.1. Audit findings by section

1.2. Overall audit opinion

The audit team has assessed the Ministry of Health and Population's management of COVAX Facility support and COVID-19 immunisation as **Effective – No issues or few minor issues noted**, meaning 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.

This summative rating is based on the audit team's assessment of the comprehensive picture of the above audit findings, as well as the good practices noted, which were conducive to the overall performance of the COVID-19 programme.

The audit team proposes **7 recommendations** throughout section 4 of the audit report, which form the basis of the Audit recommendations action plan under Annex 6.

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

1.3. Executive summary

The programme's controls and processes were generally adequately designed, which minimise the risks presented by the operation of Egypt's COVID-19 immunisation activities.

Our review demonstrated that the country was able to meet the challenge of promptly responding to the pandemic, including setting up appropriate governance structures and adequately resourcing its public health measures to mitigate the impact of COVID-19.

Some weaknesses and areas for improvement were identified, as summarised in section 4 of this audit report which, if addressed, could assist the MOHP in progressively transitioning and integrating its COVID-19 efforts into a more standardised routine immunisation management approach.

Governance and programme management

The Higher Committee for the Management of the COVID-19 Pandemic would meet regularly but the process for following up on its decisions, resulting actions, and monitoring their status, was not well defined or documented, including unclear ownership and accountability.

The government is encouraged to establish a plan for the transition of its COVID-19 emergency response to the routine immunisation programme under the EPI's stewardship. This transition should seek to appropriately scale the COVID-19 resources and infrastructure, and in accordance with WHO and UNICEF's guidance for incorporating COVID-19 vaccination programmes into national immunisation programmes and primary care.

Monitoring and evaluation

Vaccine logistics are managed by way of a live, nationwide Integrated Vaccine Management System (IVMS), able to match the demand for COVID-19 doses with supply. Data quality and the validation of inputs into this IVMS could be strengthened.

Periodic audits of the vaccine information and immunisation activities recorded in IVMS identified some discrepancies and anomalies. The roles and responsibilities for the various units involved in investigating, reconciling, documenting, and reporting corrective action, including amendments to IVMS, were not fully articulated. Additionally, the audit reports were not sufficiently specific on the location of where the data discrepancies or anomalies had occurred.

A national online system is in place to monitor for any adverse effects from COVID-19 vaccination. Incidents were primarily recorded at the point of vaccine delivery, however access to the system thereafter was not readily available to other health practitioners.

Vaccine supply chain management

A review of paper-based primary stock records identified missing information, notably batch numbers and expiry dates which are essential to managing stock in accordance with Earliest Expiry First Out principles. In those sites visited by the audit team, the IVMS was being updated routinely but retroactively, even though real-time visibility over stocks requires that the IVMS be kept up to date.

Cold chain management

The roll-out of the COVID-19 vaccine created periods when additional cold chain storage and surge capacity was needed, some of which was acquired with COVAX funding. There is currently no plan in place for how any excess cold chain equipment will be repurposed. Also, no exhaustive national inventory of supply chain assets was available during the audit.

2. Audit scope and objectives

2.1. Audit scope

Established in 2020, the COVAX Facility (COVAX) is administered by the Gavi Alliance, a Swiss-based non-profit foundation. The COVAX Facility's goal is to accelerate access to COVID-19 vaccines, which is complimentary to Gavi's mission and goals of leaving no-one behind with immunisation and saving lives and protect people's health by increasing equitable and sustainable use of vaccines.

Since 2021, the Arab Republic of Egypt (Egypt), through the Emergency Outbreak Support and COVID-19 Vaccine support, received vaccines and other ancillary support from Gavi COVAX.

Countries receiving such support may be audited by Gavi to ensure the accountability of funds, approved vaccines, equipment, and supplies disbursed to the country, in accordance with the "Gavi grant terms and conditions for COVAX AMC Group participants."

This audit covered the support provided to Egypt up until 30 June 2022, and the resultant activities conducted at national and sub-national levels using this support. Specifically, the audit assessed the adequacy and effectiveness of systems, processes, and controls over approved vaccines and ancillary support. This was done by reviewing: programme management governance, and oversight; immunisation data systems; vaccine supply chain management and cold chain infrastructure.

Table 1 hereafter summarises the COVAX support received by Egypt's Ministry of Health and Population (MOHP) up to 30 June 2022.

Table 1 - COVAX support up to 30 June 2022 disbursed to the MOHP:

Type of support	Support disbursed	Administered by MOHP
COVID-19 vaccines shipped	~65.2 million doses	~65.2 million doses
Early access CDS funding[1]	USD 100,000	USD 100,000
Needs-based CDS funding	USD 286,000	USD 154,117
Total COVAX cash implemented by MOHP =		USD 254,117

Vaccine support was accompanied by ancillary items – including syringes and safety boxes.

Given that only a modest amount of CDS funding totalling USD 254,117 was directly implemented by the MOHP, this cash amount was excluded from the audit scope.

Additional grant funding totalling nearly USD 6 million was disbursed and implemented by the local WHO and UNICEF country offices in Egypt. These amounts were excluded from the scope of this audit, in conformity with the "United Nations single audit principle" which gives their Board of Auditors, the exclusive right to audit the accounts and statements of its agencies.

Approximately USD 4 million of this funding was managed by the UN, related to the procurement and supply of cold and ultra-cold chain equipment, whose purchase was facilitated by the UNICEF Supply Division (Copenhagen), in benefit and support for Egypt's national supply chain and COVID-19 vaccine deployment.

The audit was undertaken at both the central level, as well as across a representative sample of governorates, districts, and Primary Health Care (PHC) units. See Annex 4 for a list of sites visited by the audit team.

2.2. Audit objectives

The primary objective of such an audit is to ensure any and all Gavi COVAX support are used and applied for the sole purpose of fulfilling the programme(s) described in the country's application. In accordance with the Gavi grant terms and conditions for COVAX AMC group participants and Article 13 of the COVID-19 Vaccine support decision letter between Gavi and the MOHP, the MOHP is responsible for:

- maintaining accurate records documenting how doses of approved vaccine, equipment and supplies are managed and distributed, as relevant; and
- where funding was provided by Gavi COVAX for the programme, maintaining accurate accounting records documenting how such funds were used. Such accounting records are to be maintained in accordance with its government-approved accounting standards for at least three years after the date of last disbursement of Gavi funds.

This report makes recommendations to remedy any deficiencies identified, with the purpose of strengthening the management of any subsequent Gavi support.

It has been prepared, based on the information and documentation made available to the team during their audit of Gavi COVAX support received up until 30 June 2022. As such, this audit report is limited to the processes and systems reviewed and does not provide an opinion over the broader COVID-19 vaccination programme in Egypt or its management.

[1] CDS funding = COVID-19 vaccine Delivery Support.

2.3. Audit phases

This audit was conducted in two phases in-country:

- An initial one-week scoping visit between 24 to 28 July 2022.
- Two weeks fieldwork undertaken between 18 to 29 September 2022.

2.4. Applicable exchange rates

Gavi's support is initially measured in US dollars (USD). The use of cash grants and expenditures incurred in Egypt by the MOHP were mostly incurred in Egyptian Pounds (EGP).

For the purposes of this report, the average monthly rate of exchange per http://www.oanda.com is applied to convert any expenditures incurred in EGP into USD-equivalents.

3. Context

3.1. Introduction

Overall context

Egypt covers an area of over 1 million km², of which the inhabited area is estimated at some 77,000 km², less than 8%. It is divided into 27 governorates (see Annex 3 of this audit report) and shares its international borders with Libya to the west, the Sudan to the south, and the Gaza Strip and Israel to the east.

The last population census was conducted in 2017 and, with 95 million inhabitants, placed Egypt as the most populous country in the Arab world and the third most populous on the African continent. Medical advances and improved agricultural productivity contributed to the country's rapid population growth between 1970 and 2010. Today's population is estimated at over 103 million with a fairly even ratio between male and female inhabitants[2]:

Approximately 30 million inhabitants are aged twelve and under. This tranche falls outside of Egypt's target population for COVID-19 immunisation (see footnote 5 on page 8 of this audit report).

Purchasing Power Parity GDP per capita at USD 14,226 [3] is roughly double the average annual wage, and is primarily sourced by tourism, remittances from Egyptians working abroad and Suez Canal revenues.

The 2014 constitution requires the government to allocate at least 3 percent of GDP to health but, according to a study by the Egyptian Initiative for Personal Rights, the government in 2019-2020 allocated 1.19 percent and, following the COVID-19 pandemic, allocated 1.37 percent of the 2020-2021 GDP.

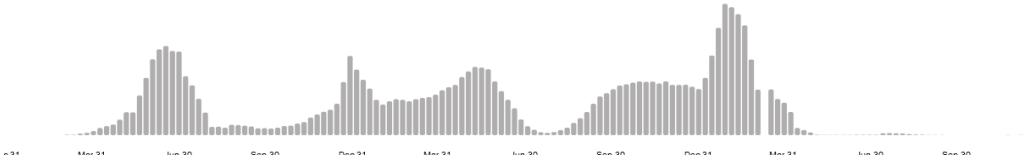
The Expanded Programme on Immunisation (EPI) was established in 1984 and is a cornerstone of Egypt's widespread establishment of basic health services. Immunisation is free of charge and compulsory in Egypt for all children. MOHP boasts national coverage of 95% or more on all routine vaccinations. Consequently, non-communicable diseases account for 84% of all deaths in Egypt, with a 28% risk of premature death between 30 and 70 years. Cardiovascular disease and cancer are the leading cause of death, accounting for 40% and 13% respectively[4].

Immunisation coverage disparity remains a challenge, with rates as low as 20% among the poorest and hardest to reach populations of Egypt, in particular among nomadic, internally displaced, and migrant populations, as well as those living in vast sparsely populated areas, and in the Sinai Peninsula which has endured nearly 40 years of insurgencies and insecurity.

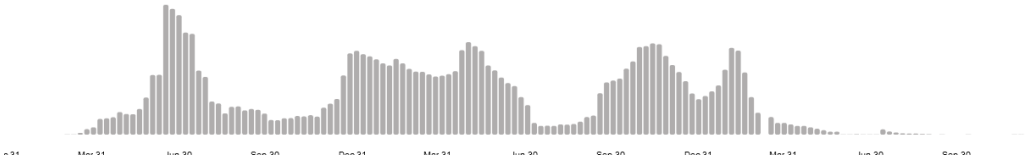
COVID-19 context and response

Being heavily reliant on tourism and trade, and with much of its population living in densely populated urban centres, as early as March 2020, the government of Egypt established a dedicated *COVID-19 coordination platform* managed out of the Office of the President (see section 3.2 of this audit report). This platform engaged several government ministries and fostered broad consensus on an emergency response to COVID-19, naturally transcending the EPI mandate given that vaccines were not brought to market until approximately one year into the pandemic (see section *3.2.* of this audit report for further details on the organisational structure).

Egypt has experienced three waves of the COVID-19 pandemic, with peaks in May-June 2020, April 2021, and November-December 2021. Up to 30 September 2022, Egypt had recorded just over 515'000 confirmed cases of COVID-19[5]:



Up to 30 September 2022, Egypt had also recorded fewer than 24'800 COVID-19 related deaths[6]:



Egypt first announced its vaccine rollout on 24 January 2021 with online registration for health workers, the elderly, and those with pre-existing risk factors starting 28 February 2021. Within the first week, over 150,000 people had motioned for registration. Before they were dealt the vaccine, registration was then announced to the general public on 6 March 2021, leaving little time for vulnerable communities to be prioritised for vaccination.

Up to 30 September 2022, Egypt had administered more than 100 million COVID-19 vaccine doses, enabling it to fully vaccinate approximately 40 million persons, some 42% of its target population[7]. While falling short of MOHPs stated target of 70% coverage, immunity, testing and other precautions have resulted in virtually no new confirmed cases or deaths due to COVID-19 since the end of May 2022.

[2] Source : Demographics of Egypt (2020)
[3] Source : *World Economic Outlook Database: October 2021"*
[4] WHO, 2018, Noncommunicable diseases country profiles 2018: Egypt.
[5] Source: Egypt: WHO COVID-19 dashboard : since October 2022, there continue to be virtually no new cases. This includes the period during which Egypt hosted UN Climate Change Conference - COP27 in Sharm el-Sheikh.
[6] Source: WHO Covid-19 dashboard for Egypt: since October 2022, there continue to be virtually no new cases. This includes the period during which Egypt hosted UN Climate Change Conference - COP27 in Sharm el-Sheikh.
[7] Target population in Egypt is defined as all citizens aged 12 years and above.

ACT and COVAX

The Access to COVID-19 Tools (ACT) Accelerator is a global collaboration mandated to accelerate the development, production, and equitable access to COVID-19 tests, treatments, and vaccines. Within ACT-A, COVAX is the vaccines pillar.

COVAX is co-led by the Coalition for Epidemic Preparedness Innovations (CEPI), Gavi and the World Health Organization (WHO), alongside key delivery partner UNICEF. In the Americas, the PAHO Revolving Fund is the recognized procurement agent for COVAX. It aims to accelerate the development and manufacture of COVID-19 vaccines and to guarantee fair and equitable access for every country in the world.

92 low- and middle-income economies, including Egypt, are eligible to have their participation in the COVAX Facility supported by Gavi's COVID-19 Vaccines Advance Market Commitment (COVAX AMC), enabling access to donor-funded doses of safe and effective COVID-19 vaccines.

The AMC, combined with additional support for country readiness and delivery, helped ensure the most vulnerable in all countries could be protected in the short term against COVID-19, regardless of income level.

During the period under audit, Egypt received and implemented 65.2 million doses of COVID-19 vaccines via the COVAX Facility, roughly 65% of the total number of doses administered. The remaining COVID-19 vaccines were donated by or acquired from other sources or manufactured locally[8].

3.2. Government institutions involved in COVID-19 and COVAX grant management[9]

Office of the President - Higher Committee for the Management of the COVID-19 Pandemic

Responsible for overall leadership and oversight of the COVID-19 response activities, including vaccine deployment.

High-Level Oversight Committee *(Cabinet's emergency operating centre)*

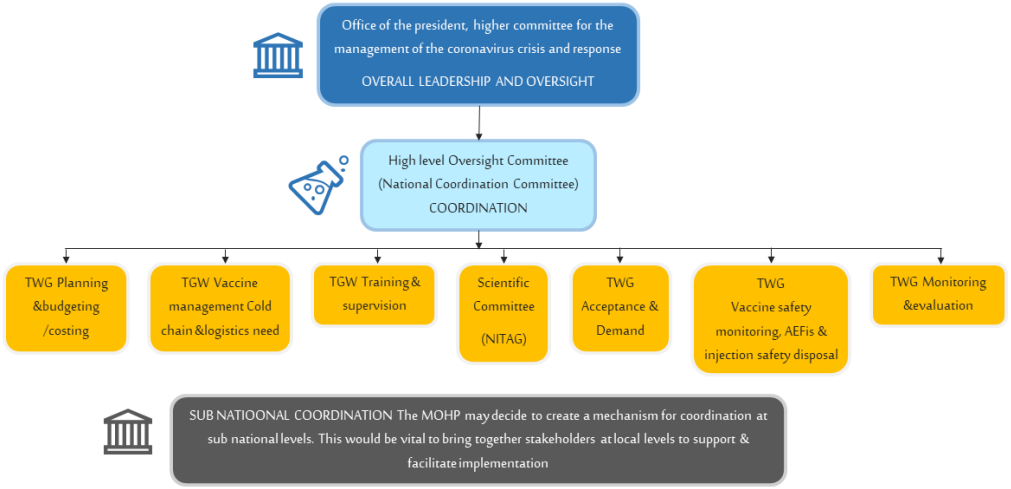
Chaired by the MOHP, its responsibilities include planning, coordination, and implementation of the plan. It is comprised of senior-level officials from MOHP, relevant ministries, UN agencies, and representatives from the private sector and civil society organizations.

Technical Working Groups

Each Technical Working Group comprised several technical experts from the government and development agencies and would meet regularly to ensure country readiness for the COVID-19 vaccine roll-out, and reports to the High-Level Oversight Committee. The seven Technical Working Groups are:

1. Planning and budgeting.
2. Vaccine management, cold and logistic needs.
3. Training and supervision.
4. Scientific Committee.
5. Acceptance and demand.
6. Vaccine safety monitoring, AEFIs, and injection safety disposal.
7. Monitoring and evaluation. Ministry Of Health and Population.

Illustration 1: COVID-19 coordination platform



[8] Since July 2021, state-run Holding Company for Biological Products and Vaccines (VACSERA) has manufactured COVID-19 vaccines under license from Sinovac China.

[9] Some of the content in this section is sourced from Egypt's COVID-19 vaccine deployment plan.

Office of the Minister's Assistant for Public Health Projects and Initiatives (PHPI)

Gavi's COVAX financial and vaccine support directly to the MOHP is under the stewardship of the PHPI, which also oversees other sources of bilateral cooperation in support of public health.

COVID-19 Vaccine Scientific Committee

The key tasks of this committee include the development of the vaccine plan with a clear framework of functions and responsibilities assigned to different stakeholders. It is also responsible for sharing vaccine coordination, information with different stakeholders, and for communication with partners and the media on vaccine deployment.

This committee is also responsible for making key decisions that address strategically important issues, monitoring vaccine deployment progress across Egypt, and reporting thereon to the Minister of Health and Population.

VACSERA

State-run holding company VACSERA is an established producer of vaccines and serums in Egypt and is one of the country's main blood banks. In May 2021, VACSERA was granted a license by Chinese manufacturer Sinovac Biotech to manufacture COVID-19 vaccines. In late June 2021, the first batch of 1 million doses were distributed to some of Egypt 's 650+ vaccination centres. By February 2022, VACSERA had manufactured approximately 28 million doses of Sinovac/VACSERA COVID-19 vaccines, including exporting some doses to neighbouring countries.

3.3. Other institutions met during Gavi's COVAX audit

World Health Organisation[10]

In addition to hosting the WHO Country Office, Cairo also hosts WHOs Regional Office for the Eastern Mediterranean. WHOs programmes in and support to Egypt include health systems strengthening, the Expanded Programme on Immunization, Pandemic influenza, and the COVID-19 response.

United Nations International Children's Emergency Fund[11]

The procurement of Gavi COVAX's doses was facilitated by UNICEF supply division in Copenhagen. This resulted in COVID-19 vaccines being purchased by UNICEF Supply Division, and air freighted to Cairo International Airport, where they were received by the government of Egypt.

Using COVAX funding, UNICEF also procured and delivered essential COVID-19 medical supplies, personal protective equipment, hygiene kits and respiratory ventilators, on behalf and in benefit of the government.

WHO and UNICEF, are organisations within the Gavi Alliance, as well as members of the COVAX Facility, in coordination with the Coalition for Epidemic Preparedness Innovations (CEPI) and Gavi.

[10] Source: WHO Egypt website

[11] Source: UNICEF Egypt website

4. Detailed results

In addition to the Gavi grant terms and conditions applicable to all COVAX AMC Group participants, implementing partners are expected to uphold applicable local legislation, international standards of transparency and anti-corruption, and relevant standard operating procedures. This section 4 reports on any such matters or other weaknesses as identified during the audit of Gavi's COVAX support, related to potential risks and impacts. Audit findings and any related recommendations are grouped by thematic under sub-sections 4.1 through 4.4.

The "**Egypt Deployment and Vaccination Plan for COVID-19 vaccine"** (EDVP) is the health authorities' action plan for managing the deployment of the COVID-19 vaccines.

4.1. Governance and programme management

4.1.1. COVID-19 pandemic management

Context

A Higher Committee for the Management of the COVID-19 Pandemic (the "Higher Committee") within the Office of the President was established in March 2020. The Higher Committee comprises the Minister of Health, Governorate Health Directors, as well as other appointed members.

According to meeting minutes reviewed by the audit team, the Higher Committee met at least once per month during the height of the pandemic and throughout 2021. The frequency of its meetings reduced from early 2022, in response to a reduction in the reporting of COVID-19 cases and deaths.

Description

A review of the Higher Committee's minutes and deliberations suggested that resulting actions were not always well-defined. Key elements not always indicated were action owners, an assessment of human and/or financial resources required for successful implementation, and a deadline by which actions should be implemented.

The Committee's minutes also made no reference to an update and the status of actions minuted in previous meetings. No dashboard or monitoring tool for these actions was in place.

Recommendation

- Minutes and resulting actions should be clearly documented. For the purposes of accountability, actions should be assigned to a designated individual responsible for implementation, the necessary resources identified, and a deadline by which time the action is to be completed.
- It is further suggested that a dashboard or monitoring tool be put in place to facilitate regular follow-up and implementation of the Higher Committee's actions.

Management response / action

See Annex 6 to this audit report

Risks / Implications

- Insufficient clarity of actions to be taken.
- Insufficient appreciation of the timeline or resources required to implement actions assigned by the Higher Committee.
- Inadequate follow-up on actions to be implemented or their post-implementation effectiveness.
- Ineffective oversight on ownership and accountability and delivering on Higher Committee expectations.

Owner(s)

See Annex 6 to this audit report

Due date

See Annex 6 to this audit report

4.1.2. COVID-19 vaccination integration into routine immunisation

Context

As described under section 3.2 of this audit report, Gavi's COVAX financial and vaccine support to the MOHP is under the stewardship of the Office of the Minister's Assistant for Public Health Projects and Initiatives (PHPI), in conjunction with other sources of bilateral support for public health. PHPI helped place COVAX support front and centre in MOHPs vaccination response to the COVID-19 pandemic.

The MOHP is also home to the Expanded Programme on Immunization (EPI) which, since 1984, has been responsible for all routine and non-routine vaccination services in Egypt, with the exception of the COVID-19 immunisation programme which, to date, is part of the government's *COVID-19 coordination platform*.

WHO and UNICEF are developing guidance outlining considerations for incorporating COVID-19 vaccination programmes into national immunization programmes and primary care. Among priorities is helping countries shift from the mass vaccination campaigns required during the pandemic's initial emergency response to more sustainable, integrated approaches that continue to make COVID vaccines available while better balancing attention and resources to other health services.[12]

Description

The country's response to the pandemic extended beyond both the MOHP and the EPI's mandate, requiring a whole of government engagement. This response resulted in managing and subsequently reducing the incidence of COVID-19 cases, which currently remain under control over the past few months.

In future, the management of the COVID-19 response could be assigned to the EPI as soon as public health needs are commensurate.

No plan has been established regarding the integration of the COVID-19 response. Such a plan would need to consider:

- Realigning health workers' roles and responsibilities.
- Decommissioning or reassignment of COVID-19 service delivery points; and
- The redeployment of CCE.

Recommendation

- Develop a plan, to facilitate the transition from COVID-19 response, in accordance with WHO and UNICEF guidance and considerations for incorporating COVID-19 vaccination programmes into national immunization programmes and primary care.

Management response / action

See Annex 6 to this audit report

Risks / Implications

- Delayed or hasty transition from pandemic response to seasonal virus response.
- Lessons learned and best practices are inadequately captured and rolled forward into the EPI programmes at large.
- Suboptimal allocation of human and financial resources between EPI and PHPI.

Owner(s)

See Annex 6 to this audit report

Due date

See Annex 6 to this audit report

[12] Source: COVID GAP article by Nellie Bristol published on 18 August 2022

4.2. Monitoring and evaluation

4.2.1. Data quality

Context

The EDVP contains no explicit guidance on data quality assurance, other than stating on page 39: "Regular feedback on the findings of the M&E system with concerned stakeholders at each level, this can be a powerful intervention to improve performance, staff morale and engagement, through sharing progress information and improve data quality by encouraging ownership."

Description

There is an absence of standardised procedures around data input and subsequent control and validation. This is in part mitigated by the existence of a e-LMIS Logistics Management Information System (named IVMS). The system has been tailored to manage the COVID-19 vaccine supply chain and vaccination scheduling.

In addition to gaining an understanding of the tools in use and procedures and controls around data input, the audit team also assessed during each site visit the completeness and reliability of data contained in a sample of daily vaccination registers, vaccination consumption reports, and in the IVMS:

- In five of the vaccination sites visited, discrepancies between IVMS and vaccination consumption reports were identified. For four of these five sites, these discrepancies were subsequently clarified by reconciling supporting documentation. For the remaining site, it was concluded that the discrepancy related to human error.
- Supervision logbooks were in place at the sites visited by the team, in a range of formats. Some recorded the date, person and title of the supervisor(s), others were more complete including hand-written or electronic supervision reports highlighting positive practices, suggestions for improvements, action taken during the visit/supervision, and recommendations for future follow-up.

Some supervision reports were found to be incomplete or unfinished, which could not be explained by local management who are recipients of these reports and custodians for change.

Recommendation

- Formalise and harmonise data quality assurance procedures at the time of data input, during post input verification and for any subsequent supervisions.
- Develop and implement standard supervision forms or reports to be completed at all levels of the supply chain.

Management response / action

See Annex 6 to this audit report

Risks / Implications

- Data input (human) errors can and do occur from time to time.
- The current control environment might fail to identify or report data errors.
- Supervisions and their documentation vary in quality and completeness.

Owner(s)

See Annex 6 to this audit report

Due date

See Annex 6 to this audit report

4.2.2. Data quality assurance mechanisms within the MOHP

Context

Data on the COVID-19 vaccines received by the supply chain, is input into IVMS by the Technical Officer's team within the Preventive Sector of MOHP. The movement of vaccines is subsequently tracked via IVMS. When vaccines are administered at the PHCs and vaccination centres, the batch numbers and the number of doses administered are also input into IVMS.

Thereafter, the MOHP's IT team routinely analysed the IVMS data for any anomalies or inconsistencies. Their findings are summarised by governorate in an audit report, which is sent to the Technical Officer, who disseminates and forwards these reports to the governorate for further investigation and reconciliation, respectively.

Only the Technical Officer's team is authorised to edit IVMS data, thus adjustments need to be sent to them for review and input.

Description

The audit team reviewed the COVID-19 IVMS data verification audit reports and noted that these identified discrepancies – mostly minor - between the number of vaccines administered and vaccine doses consumed.

The Technical Officer stated his view that the minor data discrepancies could have resulted from the possibility that more doses per vial could be administered than the manufacturer's stated allocation. No evidence was available to corroborate this view.

These audit reports were governate specific, but the exact origin of data anomalies and inconsistencies were not identified, hampering the governate's ability to follow-up and resolve issues.

The governates' following up and investigating the audit report findings was not evidenced. Further, no record was available of any correction being made in IVMS by the Technical Officer or their team.

The IT team's personnel involved in the IVMS data analysis confirmed to the audit team that they were not informed of any remedial action undertaken.

Recommendation

- Request more specific audit reports from the MOHP IT team in order to identify the exact origin of a data anomalies and inconsistencies.
- Clarify the roles and responsibilities for: following-up, investigating, and reconciling data anomalies and inconsistencies, reporting on the follow-up, and documenting the corrective input in IVMS.
- Review MOHPs IT teams' follow-up of actions taken according to the audit reports' findings.

Management response / action

See Annex 6 to this audit report

Risks / Implications

- There is scope for interpretation as to which data anomalies and inconsistencies require follow-up.
- Most data anomalies or inconsistencies in IVMS remain unresolved, undermining the reliability of its content.

Owner(s)

See Annex 6 to this audit report

Due date

See Annex 6 to this audit report

4.2.3. Pharmacovigilance

Context

The EDVP contains guidance on pharmacovigilance activities to be implemented at all PHCs offering COVID-19 vaccination and dedicated vaccination centres. The guidance outlines the need for:

Pre-vaccination activities:

Information posters on centre walls explaining possible vaccination side effects, how to react and who to contact if effects worsened or persisted.

During registration, two examples of a consent form are signed by the citizen (or legal guardian for persons under the age of 18) in the presence of a physician who orally advises of possible side effects and provides the citizen with an information flyer explaining possible vaccination side effects, how to react and who to contact if effects worsened or persisted.

Post-vaccination activities:

Citizens are advised to remain on site for a 15-minute observation period.

Adverse Events Following Immunization (AEFI) arising during that observation period are referred to the pharmacovigilance focal point on site who, depending on the side effects, will either offer advice or immediately refer the citizen to an immunisation specialist or emergency ward.

AEFI incidents are to be entered into a nationwide online system by the pharmacovigilance focal point on site using the *Electronic Medical Report.* The AEFI system is monitored 24/7 by pharmacovigilance specialists at the central level whose role it is to a) contact and advise the citizen and monitor their recovery; b) provide further details to the *Electronic Medical Report*; and c) categorise the AEFI case according to the severity (mild, intermediate, serious) of the side effects and document the outcome.

Description

The audit team's visits to 13 PHCs and 1 dedicated vaccination centre, review the procedures in place on site, relating to pre- and post-vaccination activities, as well as a sample of AEFI reports that were raised during the period under review. Overall, the EDVP guidelines were largely followed at the majority of sites. It was noted that:

- One PHC did not dispose of a post-vaccination waiting area.
- One PHC was using a hand-written AEFI report due to unstable internet access from that location.
- Hard copies of COVID-19 AEFI guidelines were available at each location but did not appear to have been regularly consulted (new or nearly new).
- Based on the AEFI incidents reviewed, cases arose infrequently and were mostly categorised as mild. More AEFI incidents were reported in 2021 than in 2022.

The AEFI reporting tool is not accessible to health practitioners other than the pharmacovigilance focal points at PHCs and vaccination centres and central level specialists monitoring the content of the tool. This means that, after the individual vaccinated has left the vaccination centre, the ability of other health practitioners to record any subsequent adverse effects is not clearly defined or supported.

Recommendation

- Explore establishing a process which facilitates access to the online AEFI reporting tool for health practitioners – other than the focal point on site – so as to record adverse effects occurring subsequent to vaccinated individuals leaving PHCs and vaccination centres.

Management response / action

See Annex 6 to this audit report

Risks / Implications

- AEFI reporting are likely incomplete, notably for any adverse effects occurring subsequent to a vaccinated individual leaving the PHC or vaccination centre.

Owner(s)

See Annex 6 to this audit report

Due date

See Annex 6 to this audit report

4.3. Vaccine supply chain management

4.3.1. Stock management tools

Context

The EDVP does not provide explicit guidance on COVID-19 vaccine stock management tools, but it does refer on several occasions, including screenshots, to stock management using the IVMS. Additionally, government agencies, including the MOHP, are required to maintain paper-based records.

Paper-based stock registers are the unified, primary stock management tool across all government agencies, and subject to inspection and monitoring by national regulatory authorities such as the Central Auditing Organization.

These paper-based stock registers are supplemented by IVMS, which has the advantage of being online, updated nationwide and thus providing up to date information on vaccine and dry goods stock levels at each depot across the country.

Description

During the site visits, the audit team identified occasions when vaccine batch numbers and expiry dates had not been recorded in the paper-based stock registers. Conversely, no missing batch numbers or expiry dates were found in IVMS (section 4.2.2 of this audit report describes that this, and other information, are entered just once at the central level when vaccines first enter the EDVPs vaccine supply chain).

In eight of the 13 PHCs visited by the audit team, IVMS was being updated at the end of a working day, or when time permitted, using the information recorded in the primary stock registers. In the remaining five PHCs visited, staff updated both the primary stock registers and the IVMS at the same time.

Non-standard stock management tools, such as locally developed computer spreadsheets or off-the-shelf paper notebooks, were identified in three of the 13 PHCs visited by the audit team.

Recommendation

Amend EDVP guidance to encourage standard practices, notably:

- Compulsory stock management tools to have in place.
- Recording batch numbers and expiry dates in the paper-based stock registers.

Request that government:

- Accept IVMS as the sole stock register for vaccines and dry goods.
- Authorise MOHP to discontinue paper-based stock registers.

Management response / action

See Annex 6 to this audit report

Risks / Implications

- Incomplete vaccine information in paper-based stock registers also falls short of established standard practices.
- IVMS data is not 100% up to date in those PHCs who update IVMS retroactively, which could adversely impact vaccine availability in PHCs that rely on just-in-time vaccine delivery in response to limited cold chain storage capacity.
- In those PHC whose primary stock management tool are paper-based registers, Earliest Expiry First Out management could be impeded by missing expiry dates.

The declining movement in COVID-19 vaccines over the period under audit inherently reduces the above risks and impacts.

Owner(s)

See Annex 6 to this audit report

Due date

See Annex 6 to this audit report

4.4. Cold chain management

4.4.1. Available cold chain capacity

Context

In order to scale up cold-chain capacity and manage the surge COVID-19 doses, a number of PHC and vaccination centres with domestic refrigerators and freezers (CCE) to manage the increase in product volume. Those domestic CCE observed by the audit team, which were not acquired with Gavi COVAX support, were not compliant with WHOs Performance, Quality and Safety (PQS) Standards for the storage of vaccines. Nevertheless, temperature monitoring records and routine maintenance records available at all sites visited by the audit team evidenced that the domestic CCE had been reliable to date.

Some of the COVAX funding managed by the UN was for the procurement and supply of CCE and ultra-cold chain equipment (UCCE), facilitated by the UNICEF Supply Division (Copenhagen), in benefit and support for Egypt's national supply chain and COVID-19 vaccine deployment, including UCCE storage capacity for Pfizer-BioNTech vaccines. UCCE items procured with Gavi COVAX resources included: 17 large, 8 medium and 7 small freezers, and 30 mobile units.

The MOHP established UCC storage hubs in six of the 27 governorates: Cairo (VACSERA), ElBehera, Port Said, Luxor, Assiut and El-Dakahlia[13]

Description

A national comprehensive inventory of supply chain assets was not available, to provide overall visibility of the current vaccine supply chain management infrastructure. In addition, no local asset inventories were maintained for any of the sites visited.

The audit visits undertaken in July and September 2022 found that existing cold-chain capacity exceeded current needs for COVID-19 vaccine storage. Some PHCs and vaccination centres were equipped with spare refrigerators and freezers that were either operating empty or were switched off.

Progressively, as dedicated COVID-19 vaccination areas are reassigned to public health service delivery and the COVID-19 vaccination programme is scaled back, select CCE units will be available for repurposing.

Recommendation

- A national comprehensive inventory of supply chain assets should be conducted to provide overall visibility of the current vaccine supply chain management infrastructure and spare capacity in order to inform repurposing decisions.
- Plan and execute a redeployment of CCE assets, in accordance with vaccine capacity requirements and public health needs, and in compliance with the Gavi COVAX requirements.[14]

Management response / action

See Annex 6 to this audit report

Risks / Implications

- There is no strategy or plan in place to repurpose excess CCE capacity.
- Some of the domestic refrigerators and freezers currently in place might not be PQS certified for vaccine storage, which may restrict repurposing options.
- Without a comprehensive inventory of CCE, it is unclear how the repurposing of equipment dedicated to COVID-19 vaccine storage or transportation will be managed effectively.

Owner(s)

See Annex 6 to this audit report

Due date

See Annex 6 to this audit report

[13] Source: Table 12 on page 42 of the EDVP.
Of the six UCC storage hubs, Gavi's audit team visited Cairo (VACSERA), ElBehera and El-Dakahlia

[14] Source: COVAX CCE Support Application Consolidated Application Form: Part E: Performance Framework: "In addition to reporting on progress against targets, applicants will be required to submit a report detailing how any equipment procured through this platform will be repurposed in the coming years. Participants will be required to redeploy this equipment in support of immunisation programs, unless they can demonstrate that all routine immunisation needs (e.g., CCE retirement, cold chain expansion, etc) have been met. A template for this report will be made available to applicants in 2021, and the report will be due 12 months from the start of support."

Annexes

Annex 1 – Acronyms

AEFI	Adverse Events Following Immunization
CCE	Cold Chain Equipment
EDVP	Egypt Deployment and Vaccination Plan for COVID-19 vaccine
EGP	Egyptian Pound
EPI	Expanded Programme on Immunisation
Gavi	Gavi, the Vaccine Alliance
GDP	Gross Domestic Productivity
HR	Human Resources
HSS	Health Systems Strengthening
IVMS	Integrated Vaccine Management System
MOHP	Minister of Health and Population
PHC	Primary Health Care units
PHPI	Office of the Minister's Assistant for Public Health Projects and Initiatives
SOP	Standard Operating Procedures
UCC	Ultra Cold Chain
UCCE	Ultra Cold Chain Equipment
UNICEF	United Nations International Children's Emergency Fund
USD	United States Dollar

Annex 2 – Definitions: audit opinion, audit ratings et prioritisation

A. AUDIT RATINGS AND OVERALL 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. RISK RATING OF AUDIT FINDINGS

The audit ratings and overall opinion, defined in section A above, are the result of Gavi auditors' assessment of the number and severity of the audit findings for each thematic/section. The risk rating for each audit finding combines the probability of a risk materialising and its impact (financial and/or operational). The following levels of rating are given:

Low

Moderate

High

Annex 3 – Governorates of Egypt

Governorate	No Of Districts
Cairo	41
Giza	22
Sharqia	19
Dakahlia	18
ElBehera	16
Assuit	13
Kafr Elsheikh	11
Sohag	11
Qalubya	11
Menofia	10
Gharbia	10
Qena	9
Menia	9
Matrouh	8
South Sinai	8
Alexandria	8
Beni-suef	7
Fayoum	7
Luxor	7
Ismailia	7
Red Sea	6
Aswan	6
North Sinai	5
Demitta	5
New Valley	5
Suez	5
Portsaid	1
27	**285**

Egypt is divided into 27 governorates which are themselves sub-divided into districts. Public health and the vaccine supply chain are organised along this same structure.

Annex 4 – List of facilities visited, and work performed

Facilities visited in each governorate

Governorate	Facility
Alexandria	PHC St Stefano PHC Family Health El Amrawy PHC Sidi Bichr
Beheira	Beheira Directorate vaccine storage facility PHC Nasser
Cairo	VACSERA manufacturing and storage facility Helwan District vaccine storage facility Madinet Nasr Mega Vaccination Centre PHC Al-Qatamia PHC 1st Settlement New Cairo PHC 6th District Madinet Nasr PHC Sheraton PHC Al-Asmarat PHC Masr Al-Qadimah PHC Saraya El-Koppa PHC Al Khaleej PHC Ahalina PHC Al-Andalus
Dakahlia	Dakahlia Directorate vaccine storage facility

PHC = Primary Health Care units.

In addition to Madinet Nasr Mega Vaccination Centre, each of the 13 PHC selected and visited by the audit team offered COVID-19 vaccination. Other facilities were part of the COVID-19 vaccine storage and supply chain.

Work performed

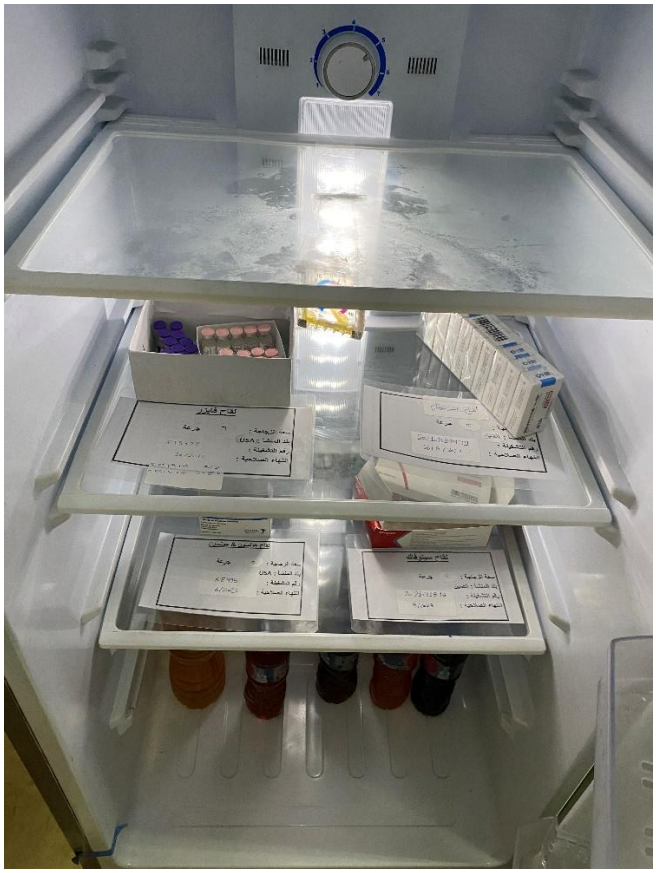
Dependent on the nature of each facility, audit procedures were conducted to assess operational effectiveness and compliance with documented policies and operating procedures in the following areas of COVID-19 immunisation: pharmacovigilance; cold chain management; vaccine stock management; vaccination waste management; facility and stock safety and security; immunisation tools and processes; and vaccination data quality assurance.

Any issues and suggested improvements arising from each facility visit were documented in facility-related working papers, discussed, and agreed with relevant facility personnel in the presence of national MOHP representatives accompanying the visits. Local facility management committed to implementing appropriate corrective action under the direction of national MOHP.

By their very nature and content, these working papers are internal to Gavi Secretariat and not disclosed in this audit report. In lieu, any significant issues and concerns, particularly those identified at more than one facility, are reported under section 4 of this audit report.

Annex 5 – Illustrations of audit findings

Illustration 1: Madinet Nasr Mega Vaccination Centre (July 2022).



Illustrations 2 & 3: respectively PHC Family Health El Amrawy and PHC Al Khaleej (September 2022).

These three illustrations exemplify the opportunity to adjust COVID-19 vaccination services to current levels of demand.

Illustration 4: Beheira Directorate vaccine storage facility: ultra-cold chain equipment purchased through UNICEF with COVAX CDS funding (July 2022).

Illustration 5: PHC Sidi Bichr: one example of COVID-19 vaccine waste disposal management (September 2022).

Illustration 6: PHC Ahalina: public information on navigating the COVID-19 vaccination centre and reporting adverse effects (September 2022).

Illustrations 7 & 8: Dakahlia Governorate: vehicles recently acquired for the delivery of COVID-19 vaccines to the district level (July 2022).

Annex 6 – Audit recommendations action plan

Ref.	Finding	Recommendation	Management response / action	Owner(s)	Due date
4.1.	**Governance and programme management**				
4.1.1.	COVID-19 pandemic management	Minutes and resulting actions should be clearly documented. For the purposes of accountability, actions should be assigned to a designated individual responsible for implementation, the necessary resources identified, and a deadline by which time the action is to be completed.	Noted for future Higher Committee meetings and their related minutes.	Higher Committee	Going forward
		It is further suggested that a dashboard or monitoring tool be put in place to facilitate regular follow-up and implementation of the Higher Committee's actions.	Noted.	Higher Committee	Going forward
4.1.2.	COVID-19 vaccination integration into routine immunisation	Develop a plan, to facilitate the transition from COVID-19 response, in accordance with WHO and UNICEF guidance and considerations for incorporating COVID-19 vaccination programmes into national immunization programmes and primary care.	• Egypt has provided sufficient vaccine stock to enhance the sustainability of the national covid vaccination program after the initial emergency response to the pandemic • The Covid vaccination program is currently under direct supervision of EPI. • According to the EPI plan, primary care centers have been relied upon as essential centers for Covid vaccination. • As for the cold chain equipment, EPI depends on the CCE available in the primary care centers designated for vaccines used in all vaccination programs, in addition to the cold chain equipment that was provided specifically for Covid vaccine during the pandemic.	EPI	Ongoing
4.2.	**Monitoring and evaluation**				
4.2.1.	Data quality	Formalise and harmonise data quality assurance procedures at the time of data input, during post input verification and for any subsequent supervisions.	Already in place and working on strengthening it through continuous training and extensive supervisory visits.	IT; Vaccine management unit	Ongoing
		Develop and implement standard supervision forms or reports to be completed at all levels of the supply chain.	There are extensive supervisory visits to ensure that only standardized reporting forms are relied upon.	Vaccine management unit	Ongoing
4.2.2.	Data quality assurance mechanisms within the MOHP	Request more specific audit reports from the MOHP IT team in order to identify the exact origin of a data anomalies and inconsistencies.	EPI believes most, if not all, discrepancies between the higher number of vaccines administered and the lower number of doses consumed according to stock records can be explained by it being possible to administer one or two doses more per vial than stipulated by the vaccine manufacturers. In light of the above explanation, no further follow-up is deemed necessary.	N/A	N/A
		Clarify the roles and responsibilities for: following-up, investigating, and reconciling data anomalies and inconsistencies, reporting on the follow-up, and documenting the corrective input in IVMS.			
		Review MOHPs IT teams' follow-up of actions taken according to the audit reports' findings.			

Ref.	Finding	Recommendation	Management response / action	Owner(s)	Due date
4.2.3	Pharmacovigilance	Explore establishing a process which facilitates access to the online AEFI reporting tool for health practitioners – other than the focal point on site – so as to record adverse effects occurring subsequent to vaccinated individuals leaving PHCs and vaccination centres.	Given that side effects of each antigen are now well documented, and that Covid-19 vaccination is now being administered to less vulnerable tranches of the population (students, international travellers), health practitioners have reverted to routine immunisation AEFI reporting mechanisms.	EPI	Ongoing
4.3.	**Vaccine supply chain management**				
4.3.1.	Stock management tools	Amend EDVP guidance to encourage standard practices, notably: • Compulsory stock management tools to have in place. • Recording batch numbers and expiry dates in the paper-based stock registers.	• Considered as part of Covid-19 vaccination being incorporated into national routine immunisation. • Continuous supervisory visits place emphasis on the need to adhere to recording the expiry date and batch number for each movement in vaccine stock.	EPI	Ongoing
		Request that government: • Accept IVMS as the sole stock register for vaccines and dry goods. • Authorise MOHP to discontinue paper-based stock registers.	Will be considered as part of a broader shift to digital health records for all Egyptian citizens and digital record-keeping across all government institutions.	EPI	Dependent on government-wide shift to digital records
4.4.	**Cold chain management**				
4.4.1.	Available cold chain capacity	A national comprehensive inventory of supply chain assets should be conducted to provide overall visibility of the current vaccine supply chain management infrastructure and spare capacity in order to inform repurposing decisions.	Routine comprehensive inventories of cold chain capacity are carried out. The frequency at which these are carried out is deemed sufficient in view of declining demand for Covid-19 vaccines and the resultant excess cold chain capacity.	EPI	Ongoing
		Plan and execute a redeployment of CCE assets, in accordance with vaccine capacity requirements and public health needs, and in compliance with the Gavi COVAX requirements.	Redeployment of cold chain equipment has been carried out and has taken account of Gavi COVAX requirement.	EPI	Done