

Memorandum on the Islamic Republic of Pakistan Stock Management Audit report

The attached Gavi Audit and Investigations report sets out the conclusions on the stock management audit of the Islamic Republic of Pakistan's Expanded Programme of Immunisation, managed by the Ministry of National Health Services, Regulation and Coordination. The audit was conducted between July and August 2016 and covered the management of stock and immunisation supplies for the period 1 January 2014 until 31 July 2016.

This audit was undertaken in response to an incident in February 2015, when 1.3 million doses of pentavalent vaccine were damaged and temperature expired while in the custody of Federal Expanded Programme on Immunisation (EPI). Following the incident, the Federal and Provincial EPI teams strengthened their warehouse systems and processes to improve vaccine management.

The objective of the audit was to assess the vaccine management practices within the new improved environment across primary warehouses at the Federal and provincial level, including a review of stock records and an assessment of storage practices.

The audit scope did not include Gavi's cash grant support, which since 2011 has been exclusively channelled through WHO and UNICEF in Pakistan.

The report Executive Summary (pages 1 to 2) sets out the key conclusions (the details of which are set out in the body of the report).

1. No other significant incidents of shelf-expired or damaged vaccines after the incident of February 2015 were identified.
2. The holding and movements of the stocks were recorded and tracked by the stock records and the vast majority of vaccines were properly accounted for.
3. Notwithstanding recent progress obtained in the stock management processes and systems since the 2015 incident, additional opportunities for improvement were identified in the following areas: stock record keeping; stock count and reconciliation; the use of standardised forms; and the physical storage environment.

The results of this audit have been discussed and agreed with the Pakistan Ministry of National Health Services, Regulation and Coordination and they agreed to the overall audit findings.

Gavi will follow through with the Ministry to validate further upgrades in the provincial warehouses and to review any further improvements, to assess whether these are responsive to the issues identified in the audit.

Geneva, July 2017

ISLAMIC REPUBLIC OF PAKISTAN

Stock Management Audit of the Ministry of National Health Services, Regulation and Coordination (MONHSR&C) and Provincial EPI stores in Pakistan

Gavi Secretariat, Geneva, Switzerland

Final Report – 26 June 2017



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1. Executive Summary

1.1. Context

This audit was scheduled following an incident in February 2015, when 1.3 million doses of pentavalent vaccine were damaged after reaching Vaccine Vial Monitor (VVM) stage 3 or 4.¹ At the time the vaccines were stored at the premise of National Institute of Health in Islamabad on behalf of the Federal Expanded Programme on Immunisation (EPI).

Shortly after the incident, the Ministry of National Health Services, Regulation and Coordination (MONHSR&C) set up a committee to investigate the incident. In its report of 19 March 2015, the committee stated that the damage was largely due to poor storage, handling and supervision practices that did not comply with Standard Operating Procedures (SOP) of the time.

At the store level, the pentavalent vaccines were overstocked in a cold room by more than 100% of the recommended capacity, and the boxes containing the vaccines were poorly stacked with insufficient space for air circulation. In addition different batches of pentavalent vaccines and their respective expiry dates were commingled, the temperature of the cold room was not monitored, power back up was not deployed when required, stock ledgers for the type of vaccines were not maintained, and the vaccines were not issued following EEFO principles.

Supervision and monitoring activities were ineffective. According to the investigation committee's report, a senior Federal EPI official, responsible for the store operations, was found not to have the right set of management skills to oversee an operation of that magnitude. The management had failed to implement the necessary supervision and monitoring checks as required by the SOPs. For a prolonged duration leading up to the incident, the overall management of the store was relegated to a few junior store staff.

As a consequence of the incident, the MONHSR&C, with the help of in-country development partners, improved its cold chain infrastructure and stock recording systems, and recruited additional staff for the Federal EPI team.

Due to Gavi continuing to provide significant support to Pakistan's immunisation programme, Gavi decided to audit the measures introduced after the incident, to ensure that the likelihood of any such future incidents was better mitigated.

1.2. Conclusion

Based on the Audit Team's analysis stock records and physical stock counts, no other significant incidents of shelf-expired or damaged vaccines were identified after the incident of February 2015. The holding and movements of the stocks were recorded and tracked by the stock records and the vast majority of vaccines were properly accounted for.

The Audit Team recognised the MONHSR&C's efforts to strengthen the cold chain supply for stores at the Federal EPI and select provinces, including improvements in the vaccine storage, handling and recording practices. However, the team concluded that across the Federal and the provincial EPI, there remain certain areas which needed to be strengthened including: parts of inventory management and record keeping; periodic stock counts and stock reconciliation; the use of standardised forms; and the physical storage environment. Further, the MONHSR&C should give

¹ (VVM) is a label on vaccine vial which registers cumulative heat exposure over time. Exposure to the high temperature and duration of the heat causes the inner square of the VVM to darken, gradually and irreversibly; also known as the discard point (stage 3 or 4).

priority to complete the rollout of its web based Vaccine Logistic Management System (vLMIS); and ensure that the system is fully operational in all provinces and their respective districts.

In September 2016, the Gavi Audit Team shared these conclusions in its debrief with the MONHSR&C, and EPI representatives from the Federal level and provinces. At this debrief, the government participants indicated their agreement with the audit findings and validated the individual provincial, Federal and summary reports, as well as the overall conclusions. In April 2017, the MONHSR&C provided its management response, which is included in the individual provincial audit reports.

Section 0 of this report provides three key recommendations aimed at improving respective EPI vaccine management practices and to mitigate the residual risks identified by the Audit Team. The MONHSR&C agrees with these recommendations.

2. Audit Scope & Objective

2.1. Objectives

The audit's primary objective was to assess whether the vaccine management improvements made by the MONHSR&C post the February 2015 incident, would mitigate further occurrences of damage or expired vaccines. The scope included an assessment of the existence and accuracy of the stocks including a review of: the stock records; the associated supporting documents; and storage and handling practices.

The audit scope did not include Gavi's cash grant support, which since 2011 has been channelled through the World Health Organisation (WHO) and United Nations International Children's Emergency Fund (UNICEF). The total direct financial support provided for the immunisation programme in Pakistan for the period 2003 - 2016 is USD 145,880,207. In 2016, an additional USD 84 million HSS grant (based upon a grant ceiling of \$100M) was approved by Gavi's Independent Review Committee and will be channelled through a World Bank administrated multi-donor trust fund.²

Gavi contracted A. F. Fergusons & Co, a local audit firm, to undertake the stock management review of the Federal EPI and provincial processes. This took place from August to September 2016. The audit covered the 2.6 year period from 1 January 2014 to 31 July 2016, and focused on the Federal and provincial level vaccine stores, excluding lower delivery levels. The Audit Team visited the following stores:

Table 1: Federal, Provincial and FATA EPI vaccine stores visited by the Audit Team

Location visited by Audit Team	Province/ Area
Vaccine store - Federal	Federal Capital Territory
Vaccine store - Karachi	Sindh
Vaccine store - Lahore	Punjab
Vaccine store - Quetta	Baluchistan
Vaccine store - Peshawar	Khyber Pakhtunkhwa
Vaccine store - FATA	Federally Administered Tribal Areas

² Source: Gavi Joint Appraisal report August 2016.

2.2. Vaccine financing provided by Gavi in benefit of the MONHSR&C

Gavi's support to Pakistan's National Expanded Programme of Immunisation (EPI) began in 2001. The accumulated value of the vaccines support provided by Gavi over the past 15 years totalled USD 762 million. The vaccines were procured by UNICEF as a procurement agent. During the audit scope period, i.e. from January 2014 to June 2016, Gavi's vaccine support totalled USD 237 million.

Table 2: Gavi's vaccine support to Pakistan MONHSR&C for the period 2001-2016 in USD

Vaccine support in USD	2001 - 2013	2014 - 2016 (Jun)
Hepatitis B	24,953,324	-
Measles – Supplementary Immunisation Activities	10,029,548	-
Pentavalent (Penta)	267,744,784	75,418,514
Pneumococcal (PCV)	190,511,622	155,794,498
Tetra Diphtheria, Tetanus, Pertussis- Hepatitis B (DTP-HepB)	31,387,734	-
Inactivated Polio Vaccine (IPV)	-	6,187,971
Total	524,627,012	237,400,983

The vaccines and related immunisation supplies (hereafter referred to as “stock”) provided to Pakistan are procured by Gavi through UNICEF, its procurement agent. The Federal EPI received custody of the stock upon delivery at Islamabad International airport by the manufacturers. After custom clearance, the stock were received at the central vaccines stores in Islamabad.

Thereafter, the stocks are distributed to the provincial vaccine stores based on a distribution schedule. Thereupon, distribution to districts and health facilities is managed by the provinces. However, depending on the proximity of sub-national stores along the delivery route, some stock is delivered directly from the Federal EPI to the respective district stores. Some provinces also procured additional vaccines directly from UNICEF with their own provincial funds.

3. Audit Findings

For the management of the vaccines in Pakistan, a web-based management information system known as Vaccine Logistic Management Information System (vLMIS) is in use. The vLMIS is designed to be a comprehensive logistic management system encompassing modules for forecasting, inventory and logistics management, distribution, consumption (i.e. vaccination coverage) and monitoring. The system was developed with financial support from USAID, John Snow International, as well as other partners. The Federal and the various provincial EPIs are the primary users of the tool.

However, except for EPI at the Federal level and in Sindh, which both actively use the vLMIS, the other provinces continued to maintain their manual registers as a primary stock record.

3.1. Incomplete implementation and underutilisation of the web-based stock recording tool

The rollout of the vLMIS and the transition to this management information system remains incomplete. At the time of the audit in August 2016, in Punjab province, the vLMIS was rolled out in

only 13 of 36 districts. Similarly in early 2014³, although the tool was rolled out to most of the other provinces including Punjab, KPK and FATA, two years later in August 2016, only the Federal and Sindh province EPI units were using the tool for inventory management and decision making.

Table 3: Status of the vLMIS rollout at the locations audited as at September 2016

Province / Federal	Districts with vLMIS	Districts without vLMIS	Total number of districts
Federal Capital Territory	1	-	1
Sindh	41	-	41
Punjab	13	23	36
Baluchistan	09	23	32
Khyber Pakhtunkhwa	05	20	25
Federally Administered Tribal Areas	14 agencies	-	14 agencies

Source: National Program Manager, EPI, July 2016. Error! Bookmark not defined.

3.2. Data migration from manual registers to the web-based tool not effectively planned

The transition of data from manual stock registers to the vLMIS was not managed effectively. Little or no controls were established for the transition, and the majority of the steps involved in the transition were not documented. Moreover, the provinces recognised the flaws in the data migration process, and had no confidence in the accuracy of the data input into the vLMIS since the system was first installed in early 2014. Therefore except for Sindh and the Federal EPI, as at August 2016, the vLMIS databases in all of the sites where the system was introduced, was not accurate.

Key weaknesses which occurred in the migration of data into the vLMIS were:

- A lack of planning including defining the role and responsibilities for the system users, so that each member understood their role during the migration process. Also data migration policy documents were not developed. These documents would have ensured that the data was handled securely and verified by appropriate authority for quality, completeness and accuracy prior to migration.
- There was no communication plan which kept the stakeholders informed regarding the frequency, format and duration of the data migration exercise. In the absence of a defined cut-off date, and because of a flawed stock count process at transition, there were multiple attempts to migrate and clean the data in the vLMIS, including several times for the same sites. For example, in Punjab, a stock count was carried out at the provincial vaccine store in April 2014, October 2014 and October 2015. Similarly, the data transferred into the system was not reconciled back to the manual closing balances. During the migration process across all provinces, there was no official validation of the data that was migrated to the vLMIS.
- As at August 2016, it was not yet known by the EPI team when Pakistan would complete its vLMIS scale up and move all of its stock management and record keeping to the system. Deadlines for the validation of data and completion of migration to the vLMIS were not yet set. No procedural guidelines were in place if the country wanted to continue maintaining both systems in parallel. Several EPI provincial representatives stated the need for both systems to

³ The vLMIS was first rolled out to the provinces at different dates, ranging from January 2014 to September 2015.

continue to be run in parallel as their respective auditor general would require that manual stock registers be maintained. However, no decision was made regarding adoption of the vLMIS as the primary tool or maintaining it in parallel with the manual registers. The Audit Team questions the value of maintaining two set of records.

- New Standard Operating Procedures (SOPs) were finalised by the vLMIS implementation team in August 2015, and available in the public domain. However, except for the Sindh and Federal EPI stores, these SOPs were not fully complied with. According to the EPI representatives of some provinces, no consideration was given to align the resources needed to meet the SOP requirements. At the provincial level, the practical implementation of the new SOPs was also not defined, i.e. in the context of day to day vaccine management, the practical detail of what was to be done and who was responsible was not defined.

3.3. Non-compliance with “Early Expiry First Out” (EEFO) principles

Web-based tool - The Audit Team’s analysis of the vLMIS data related to the Federal and Sindh province EPI revealed instances of the vaccines with later expiry dates being issued before vaccines with earlier expiry dates. No documents were on file to justify these transactions. Although the vLMIS has the possibility of generating priority “picking lists” identifying which vaccines should be issued first, the warehouse staff responsible for physically issuing the vaccines from the cold stores occasionally selected vaccine doses and batches other than those suggested by the vLMIS.

Manual register - The manual stock records on which most of the provinces relied were incomplete with respect to key vaccine details. Details including vaccine expiry dates and the respective Vaccine Vial Monitor (VVM) stage, which is necessary to ensure that vaccines are issued in compliance with the principle of EEFO, were not indicated in the records. There were no other compensating controls to ensure EEFO compliance.

3.4. Discrepancy between the stock records maintained in manual registers and the web-based tool

Though the vLMIS was rolled out at the Federal as well as in all of the provincial EPI stores, the introduction was incomplete. Except for Sindh as of August 2016 all of the provinces continued to rely on their manual records. These same provinces accepted that their vLMIS data was unreliable and could not be used for planning and decision making. Comparing stock data between provinces’ manual records and their vLMIS, the Audit Team identified a range of data discrepancies.

For example, the Audit Team noted material differences between both the KPK and the FATA EPI manuals and the vLMIS stock records. In KPK, the Measles vaccines stock was overstated in the vLMIS by 16,100 vials and syringes by 4,388,843 units. Similarly, in FATA, PCV-10 vaccines were overstated by 22,694 vials, syringes by 637,267 units and safety boxes by 28,433 units.

In addition, the Audit Team identified mathematical errors in the manual stock records maintained by the Punjab, FATA and Baluchistan provincial stores. All three provinces solely relied on these manual records. Had a periodic stock count been performed, the errors could have been timely identified, explained and corrected.

3.5. Discrepancy between the quantities of stocks physically found in the vaccine stores and the stock records

Web-based tool – While the physical quantities of vaccines generally agreed with the vLMIS records (Federal and Sindh), there were mismatches between the batch numbers of the vaccines in the vLMIS and in the stores.

Manual register - There were discrepancies between the actual stock available at the stores and the running stock balances as per the manual records. Except for the Federal EPI and Sindh EPI where the vLMIS was deemed to be operational, the Audit Team used manual records for comparison. Discrepancies particularly in KPK were material where its manual records understated Pentavalent by 26,390 vials and PCV by 40,077 vials.

In addition, the stock counts were not routinely performed by the staff at the Federal level and all of the provincial EPI stores even though it was an important control activity. As a result any shrinkage, expiry and discrepancy in inventory was not effectively monitored or identified.

3.6. Transactions in stock records were inadequately supported

Web-based tool - the vLMIS allowed for the passing of adjustments to amend stock balance or rectify erroneous data entries. However the Audit Team identified multiple instances where there was no supporting document or justification for such "adjustment" entries. This finding applied to both the Federal EPI and to all of the provinces audited.

Manual register - Vaccine stores' key support documents such as "goods issue notes/ issue voucher", "goods received notes" and "demand forms" were not available on file. These documents are an integral part of the stock records and are required to be retained on file to validate the completeness and traceability of the movements of stock. Further, the Audit Team found instances where the transactions were not recorded in the stock manual ledgers. For example, in Punjab, for the period Nov 2014 to Dec 2015, significant quantities of vaccines were issued to districts that were not recorded in the manual stock ledger, including 39,700 vials of PCV-10 and 166,900 vials of Pentavalent. Also in Punjab, there were differences in the quantities of vaccines issued between manual register and vaccine issue notes, the manual register was usually understated.

In addition, the vaccine requisition notes, on the basis of which vaccines were issued, i.e. from district to province and province to Federal, varied in format. Some of these notes contained manual serial numbers while others were not numbered at all. Several requisition notes were hand written on blank stationery paper. As a result, the Audit Team could not verify the completeness and authenticity of some of the requisition forms. This finding was applicable to both the Federal EPI and the provinces.

3.7. Poor stock handling and storage practices at some vaccine stores

Storage and handling conditions have significantly improved in recent years. However, at the time of the audit fieldwork in August and September 2016, the storage conditions in the Punjab, FATA and Baluchistan provincial stores were poor. There were insufficient or else a lack of racks and shelves, stock handling equipment, safety tools for employees, and fire safety equipment.

3.8. Absence of effective segregation of duties

Except for Sindh EPI store, there were no appropriate segregation of duties, such as those between the conflicting tasks of stock handling and stock recording. Furthermore, key controls such as the supervisor's validation of amendments made to stock records were not in place to compensate for the lack of segregation of duties.

4. Key recommendations

4.1. Early Expiry First Out compliance

The vaccine stores at the Federal and provincials levels should ensure strict compliance with Early Expiry First Out (EEFO) principles stipulated in the EPI's Vaccine Logistic Manual. Store managers should ensure that all the stock movements (receipts and issuance) are recorded in the web-based stock record tool (vLMIS). An up-to-date stock record enables the vLMIS to propose priority list of vaccine to be issued based on the expiry date and VVM status. Therefore the issuance of the vaccines should be guided by an issue voucher generated by the vLMIS. In other words, vaccines must not leave the store without the issue voucher.

4.2. Periodic physical stock counts

The Federal and provincial stores should comply with the WHO recommendation with regards to conducting a periodic stock count. A national (Federal) vaccine store is recommended to conduct stock count every three months and the subnational (provinces) stores are recommended to conduct stock count at the time of ordering vaccines from the Federal level. In the event of insufficient staff capacity, particularly at larger stores, consideration should be given to hiring temporary workers.

The result of the stock count should be documented. Stock records must be corrected immediately after the stock count has been completed. A valid reason for every adjustment must be recorded in the stock record tool.

During the stock count, stocks with a limited shelf life should be identified and segregated from the rest of the stock so they can easily be located and prioritised for distribution.

4.3. Optimise the use of web-based stock recording tool

The maintenance of complete and accurate stock records is a pre-requisite for effective management of the stocks. The recommendations above also highlight the importance of an effective automated stock recording tool. Therefore, as a priority, the MONHSR&C should ensure that the vLMIS is rolled-out – at least down to district level for all provinces. Based on prior experience, it is recommended that the transition to the vLMIS is effected in a phased manner and with suitable checks and balances incorporated into the migration processes. The following elements are suggested:

Preparatory/ Pre-migration phase

- Involve vaccine management committees at the national and provincial levels to undertake oversight role during the vLMIS roll-out;
- Identify critical roles, primary users, and end users for data input and authorisation roles;
- Train all users on their role vis-à-vis the usage of the vLMIS;
- Ensure the availability of appropriate hardware (e.g. computers, uninterrupted power supply, internet connection etc.) and software (e.g. an up-to-date anti-virus and malware packages) at all levels;
- Communicate a clear cut-off date for migration from manual stock management registers to vLMIS so that all stakeholders can coordinate resources effectively;
- Respective EPI heads should sign-off on all data migration documents such as roles and responsibilities, training modules, hardware/software requirements and cut-off date;

Migration to the vLMIS phase

- Complete physical stock count should be conducted on the cut-off date, and ideally these counts should be undertaken simultaneously at all stores where the vLMIS is being rolled out;
- Determine the opening balance for the stock after reconciling stock count results with the manual stock registers;
- Validate the opening balances to ensure completeness and accuracy of data to be migrated;

Post implementation phase

- Test and ensure that users' access to the vLMIS is determined according to their respective roles and responsibilities;
- Perform periodic stock count and reconcile with the vLMIS records and update any change in VVM status;
- Maintain strict compliance with EEFO. In the case of any need to deviate from that standard, obtain the necessary authorisation and document that;
- Configure the vLMIS to record noncompliance with EEFO. In the event that a justification is not filed in the system within a week, the system should generate a notification to the Federal EPI for further inquiry; and
- Continue to ensure strict compliance with EPI's Standard Operating Procedures for the warehouse and EPI's Vaccine Logistic Manual.