NHS Lothian

# Medicines Management

Internal Audit Report

March 2026

| Level of assurance: | |
|---|---|
| Design | Moderate |
| Effectiveness | Limited |

IDEAS | PEOPLE | TRUST

# Contents





| Distribution List | | |
|---|---|---|
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| Report Status | |
|---|---|
| IA delivery team: | Claire Robertson, Gemma Macleod |
| Fieldwork performed: | 19 January 2026 |
| Initial findings shared: | 17 March 2026 |
| Draft report issued: | 19 March 2026 |
| Management responses received: | 30 March 2026 |
| Final report issued: | 30 March 2026 |

# Executive Summary

| Level of assurance: (see appendix II for definitions) | | |
|---|---|---|
| Design | Moderate | Generally, a sound system of internal control designed to achieve system objectives with some exceptions. |
| Effectiveness | Limited | Non-compliance with key procedures and controls places the system objectives at risk. |

| Summary of findings | | # of agreed actions |
|---|---|---|
| H | 2 | 6 |
| M | 2 | 4 |
| L | 4 | 5 |
| Total number of findings: 8 | | |

## Background

It was agreed as part of the 2025/26 Internal Audit Plan that Internal Audit would conduct a review of the arrangements around Medicines Management at NHS Lothian.

A Medicines Management audit was carried out by NHS Lothian's previous internal auditors in 2023/24 which resulted in limited assurance and a follow up review was carried out in 2024/25, also resulting in limited assurance. It was noted by Management that the follow up review commenced only eight months after the initial review and that there has also been some turnover of action owners from the original recommendation which has impacted their delivery.

Following on from the previous reviews, an Improvement Plan has been developed and progress against this will be overseen by the Medicines Safety and Risk Group (MSRG) which was established in November 2023 and meets quarterly. A Short Life Working Group has also been established with each of the action owners coming together to review progress.

It is intended that the key measure of improvement in the area of Medicines Management will be through the Lothian Accredited Care Assurance Standard (LACAS); this is a review undertaken biannually by the Charge Nurse and Clinical Nurse Manager. 11 medicines management related questions are now included. LACAS results are scrutinised by the Nursing and Midwifery Care Assurance Board. Assurance will also come through four monthly controlled drug checks carried out by Pharmacists and Pharmacy Technicians.

It was agreed with Management that Internal Audit would focus the 2025/26 review on the governance around improvement activity whilst progress against the previous review recommendations would continue to be tracked through the quarterly internal audit follow up process; with a view to completing a further full Medicines Management Follow Up review in 2026/27.

## Purpose

The objective of this audit was to provide independent assurance over the effectiveness of the governance arrangements in place to drive and monitor improvements in Medicines Management within NHS Lothian. This included assessing whether the newly implemented processes (e.g., revised LACAS questions, training provision, four-monthly pharmacy audits, and overall improvement plan governance) are robust and address the issues identified in previous internal audits.

## Conclusion

As part of our work, we have identified eight findings, two high, two medium and four assessed as low significance.

Following on from the previous Medicines Management audits, NHS Lothian have made efforts to improve performance through several initiatives and have addressed all of the recommendations due at the time of this audit. Questions were incorporated into the existing LACAS reviews to gain assurance over the areas of weakness identified, and the Four Monthly Controlled Drug Checks were also redesigned to help target these areas.

There are structures in place to provide oversight of performance with regular Medicines Safety and Risk Group meetings and newly established Site-Based Medicine Safety and Risk Groups. There is also a Medicines Safety Working Group which reports into the MSRG and focusses on driving activity on audit recommendations assigned to the MSRG; however it was noted that there have been difficulties in this group meeting regularly to date.

Although the above structures have been put in place, there have been issues in the consistency of their application; the LACAS review is currently on a three month pause at it is being redesigned following recent external SPSO reviews, and our testing found that the Four Monthly Controlled Drug Checks are not consistently completed in line with the schedule. These issues create gaps in the assurance available over medicines management performance.

Although staff report a perceived improvement in medicine management awareness and a drive for improvement, it was noted that availability of resource and estates condition continue to be seen as blockers to progress.

As a result of our audit, we are able to provide moderate assurance over the design and limited assurance over the operational effectiveness of NHS Lothian's arrangements in place in relation to governance of improvement activity in relation to medicines management.

# Executive Summary

## SUMMARY OF GOOD PRACTICE

We noted a number of areas of good practice being demonstrated at the organisation in relation to medicines management improvement activity. These include:

LACAS Reviews

- The Medicines Management questions which have been developed for inclusion in LACAS effectively align with the areas of weakness identified as part of the previous Medicines Management reviews.
- In developing the LACAS questions, previous data on Medicines Management compliance was reviewed to identify themes which should be addressed by the new questions.
- LACAS incorporates both a self-assessment and an external peer assessment process.
- The Senior Charge Nurse (SCN), Clinical Nurse Manager (CNM), Chief Nurse and the Lead Nurse for Quality Improvement and Standards meet to review the completed LACAS cycle and complete an improvement plan – we observed examples of this for the most recent cycle.
- There is an intranet page dedicated to LACAS which includes a copy of the Framework, a link to the MEG system for completion of the self-assessment, and a copy of the schedule for LACAS cycles. There is a message on the page which explains the current pause in LACAS and provides an FAQ document with more information.
- Staff advised that they have been reaching in to local universities to ensure student nurses are aware of the LACAS process.
- We were provided with evidence that the most recent LACAS cycle output was shared with the Diagnostic, Anaesthetic and Critical Care (DATCC) Senior Management Team. The report was produced by the Lead Nurse Quality Improvement and Standards, and was approved by the Head of Nursing for Quality Improvement & Standards, the Associate Nurse Director (Corporate Nursing), and the Associate Nurse Director for DATCC.

Four Monthly Controlled Drug Reviews

- The Four Monthly Controlled Drug reviews were updated significantly following the previous Medicines Management reviews to address known areas of non-compliance. The checks have also been digitised and are now completed using MS Forms.
- The audit cycle includes a full balance check; directly linked to the findings of the previous Medicines Management reviews. Additionally, a full stock balance is required to be completed if there are more than 20 missing/incomplete/incorrect entries since the previous pharmacy check.
- There is a SOP in place which is up to date and provides clear instructions on the process to be followed for completing the checks.
- There is a separate document linked within the SOP which is a crib sheet for the Safe Use of Medicines Procedures (SUMP) and Support Tools relevant to the questions included in the audit - this can be used by the person carrying out the audit to ensure they are aware of the relevant criteria/guidance for each question and to signpost nursing teams where an action is identified.
- The Admin Support Officer within the Controlled Drug Governance Team performs a monthly download of all completed forms and completes a sense check of these; including a check of whether a DATIX has been raised for any issues identified during the checks.

Improvement Activity Oversight

- We found that Management have implemented all of the due recommendations from the previous Medicines Management reviews. An improvement plan was developed to track implementation of the recommendations.
- Site based Medicine Safety Groups have recently been established and will have oversight of improvement activity.
- The Controlled Drug Accountable Officer issues an annual report which goes to the Area Drug and Therapeutics Committee, Area Pharmaceutical Committee, Pharmacy Senior Leadership Team, and the Healthcare Governance Committee. The 2023/24 report included an update on the actions taken in response to the Grant Thornton audit. The 2024/25 report acknowledges under procedures that one of the key areas of focus was recommendations from the 2023 Medicines Management Audit and that additional recommendations from the 2024 follow up audit had been incorporated in the four-monthly CD checks and the Controlled Drug Governance Team (CDGT) workplan.
- We reviewed minutes from three meetings of the Medicines Safety and Risk Group (MSRG) and observed a meeting during audit fieldwork. We found that there was suitable engagement and attendance at these meetings. Discussion was relevant and challenged performance, and suitable follow up actions were monitored (and are reviewed at each meeting). There was discussion of the medicines management audits and implementation of recommendations at each meeting as well as reports on relevant subjects such as SAERs, alerts, Medicines Safety Programme updates, Scottish Patient Safety Programme, Opioids prescribing, and GLP-1.

# Executive Summary

## SUMMARY OF HIGH AND MEDIUM SIGNIFICANCE FINDINGS

Notwithstanding the areas of good practice, we have noted areas where further improvements can be made, the most significant of which are summarised below:

- **LACAS Pause -** Management noted that at the time of this audit, the performance of LACAS had been put on a three month pause until the end of March 2026 as a result of 4 SPSO reports which have been received in quick succession. Only one cycle of LACAS had been completed which incorporated the new medicines management questions prior to the pause taking hold. There are ongoing discussions about hosting the medicines management questions separately from LACAS with their own dashboard and undertaking these checks more frequently.
- **Completion of Four Monthly Controlled Drug Checks** – We found that the Four Monthly Controlled Drug Checks are not being completed consistently and that there is a lack of regular, formal oversight of completion of these checks. Staff reported difficulties in scheduling these checks due to availability of staff to support.
- **Resource Issues Impacting Performance** – Staff interviewed flagged resourcing concerns including the availability of nursing staff and aged estates as the main barriers to progress in improvement activity.
- **Consistency of LACAS Improvement Plan Completion** - During our review, we were provided with two Improvement Plans which were produced as part of the most recent LACAS round (July 2025). We reviewed these plans and observed that the priority column wasn't consistently completed for the medicines management related improvements, and that the review meeting column was absent of dates of review meetings. Management noted that these plans are live, dynamic documents and therefore completion is ongoing.

# Detailed Findings

# Detailed Findings

**Risk: If the revised Lothian Accredited Care Assurance Standards (LACAS) questions fail to effectively address known risk areas from previous audits, NHS Lothian could face continued vulnerabilities in Medicines Management, potentially leading to patient safety issues and regulatory non-compliance.**

| Finding 1 - LACAS Pause | Type |
|---|---|
| It is important that there are regular medicines management performance reviews carried out, particularly focussed on known areas of risk based on previous audits. One of the key sources of assurance identified following the previous limited assurance medicines management audits was the Lothian Accredited Care Assurance Standards (LACAS), for which the questions were updated to include areas where findings had been identified in the medicines management audits.<br><br>Management noted that at the time of this audit, the performance of LACAS had been put on a three month pause until the end of March 2026 - this is as a result of 4 SPSO reports which have been received in quick succession; the findings of which necessitated a review of the LACAS content. Only one cycle of LACAS had been completed which incorporated the new medicines management questions prior to the pause taking hold.<br><br>The Consultant Nurse Urgent/Unscheduled Care noted in the Medicines Safety and Risk Group (observed by Internal Audit) on 25/02/26 that there were limitations to the use of LACAS for provision of assurance over Medicines Management as not all sites/wards complete LACAS. It was also noted that it is very difficult to extract only the Medicines Management related data from LACAS for analysis/reporting purposes. The Consultant Nurse Urgent/Unscheduled Care also noted that there are ongoing discussions whether it would be more appropriate for the Medicines Management checks to be done on a quarterly basis, rather than six monthly which is the current LACAS schedule; and whether it should be hosted separately to LACAS with its own MEG dashboard. | Design and Effectiveness |
| **Implication** | **Significance** |
| The temporary pause in LACAS performance reviews could lead to gaps in assurance over medicines management. Without regular reviews, there is a risk that issues or areas of concern may go unnoticed, potentially compromising patient safety and care quality. | High |

| Recommendations | Action owner | Management response | Completion date |
|---|---|---|---|
| 1. We recommend that, as under current consideration, NHS Lothian moves to hosting the medicines management checks separately from LACAS with their own MEG dashboard. This would help to ensure that medicines management checks are not disrupted by any LACAS redesigns required in the future. We also agree with Management's suggestion that the medicines management checks be carried out on a quarterly basis rather than six-monthly. | VM | Alternative options for hosting medicine management questions to be discussed with Pharmacy and Nursing leaders<br><br>Once platform established frequency of checks to be increased too quarterly<br><br>**Oversight by Medicine Management WG** | Q3 (Oct - Dec) |

# Detailed Findings

**Risk: If the pharmacy-led controlled drug audits fail to address risk areas from previous audits, NHS Lothian could face ongoing vulnerabilities in drug management, potentially leading to compliance issues and compromised patient safety.**

| Finding 2 - Completion of Four Monthly Controlled Drug Checks | Type |
|---|---|
| Each site maintains a tracker which is to be used to record the due and completion dates of Four Monthly Controlled Drug Checks for each ward or clinical area on that site.<br><br>We obtained the trackers for four sites (WGH, RIE, RHCYP & REH) and reviewed these for the level of completion of checks between April 2025 (when the new forms were introduced) and February 2026. We noted that the due dates for 2026 have not yet been consistently completed in the trackers. We also found that there was a significant number of wards with either overdue checks, or with no checks scheduled in the tracker. We have noted below the total percentage of wards with either overdue checks or no checks scheduled, see Appendix I for a full breakdown.<br><br>• RIE – 34% of checks overdue, 25% of wards with no checks scheduled<br>• REH – 33.5% of checks overdue, 3.5% of wards with no checks scheduled<br>• RHCYP – 90% of checks overdue<br>• WGH – 34% of checks overdue, 12% of wards with no checks scheduled<br><br>Our interviews with staff found that scheduling checks can be challenging, primarily owing to lack of availability of nursing staff to support. The trackers currently don't reflect where attempts have been made to schedule checks, or the reasons why checks have not been completed; the tracker could be made more useful by adding a comment section where reasons for delays or attempts to schedule can be recorded to make it easier to identify themes or issues in completing the checks.<br><br>We requested a sample of 12 forms to support checks that had been marked as completed on the tracker and noted the following:<br><br>• Two forms were unavailable; staff noted it was most likely that these were completed on paper and not uploaded to MS Forms as required by the SOP.<br>• For four of the forms, the date the form was completed did not align with the date that the check was recorded as completed in the tracker. In two of these cases, the form date was later than the tracker date (one by two months, and one by 27 days), in the other two cases the form date was earlier than the tracker date (one by 45 days and one by 56 days).<br><br>One of the Site Lead Pharmacists we interviewed noted that once the check has been completed, they do not get sight of the completed form, which they would find useful, though they do get Datix notifications where non-conformities are identified. Our discussions with Management found that this can be provided on request. At present, there is a lack of formal oversight of completion of DA2s; Site Lead Pharmacists interviewed mentioned that they may discuss completion of the checks at team meetings but this is not a formal agenda item and there is no set regularity for checks on progress. DA1 | Design and Effectiveness |

**Slide 8**

**DA1** Include in report that Site Lead Pharmacists do receive notifications from Datix submissions where non-conformities have been noted during the checks

Alexander, Debbie, 2026-03-27T13:22:56.164

**DA2** The pharmacist or technician completing the report has a access and sends a copy to the ward therefore this could be requested by the Site Lead.

Alexander, Debbie, 2026-03-27T13:24:14.525

# Detailed Findings

**Risk: If the pharmacy-led controlled drug audits fail to address risk areas from previous audits, NHS Lothian could face ongoing vulnerabilities in drug management, potentially leading to compliance issues and compromised patient safety.**

| Finding 2 - Completion of Four Monthly Controlled Drug Checks | | | Type |
|---|---|---|---|
| Implication | | | Significance |
| The inconsistency in completing due dates for 2026 and the high percentage of overdue checks or unscheduled checks across various wards indicate potential lapses in compliance and patient safety. The lack of availability of nursing staff to support these checks further exacerbates the problem, suggesting resource constraints that need addressing. Additionally, discrepancies between the completion dates on forms and trackers, along with missing forms, point to weaknesses in record-keeping and adherence to standard operating procedures. | | | High |
| Recommendations | Action owner | Management response | Completion date |
| 1. We recommend that oversight of level of completion of the Four Monthly Controlled Drug Checks is formalised and that this is reported into the Site Based Medicine Safety Groups at each meeting with an opportunity for discussion around any persistent themes or blockers to progress and a clear escalation route if required. | Site Lead Pharmacists / DA | Introduce a KPI on completion rate of checks within Pharmacy Assurance Framework (PAF, reporting to PSLT<br>Data provided to MSRG by Site Lead Ph for oversight | April 2026 |
| 2. Each site should prioritise mapping out the scheduled checks for 2026. | Site Lead Pharmacists | Plan completion dates for all of 2026 | April 2026 |
| 3. A comment section should be added to trackers and utilised to record attempts to schedule checks and any issues in completing checks. | Jenny Scott / DA | Update Clinical Pharmacy SOP<br>- Add commentary box to tracker | April 2026 |
| 4. A copy of any completed checks should be shared with the relevant Site Lead Pharmacist, this can then be cross checked to the tracker to confirm correct completion dates have been recorded and will also flag instances where forms have not been uploaded to MS Forms for checks recorded as completed on the tracker. | Jenny Scott / DA | Update Clinical Pharmacy SOP<br>- include copy sent to Site Lead Pharmacist<br>- Site Lead Pharmacist to confirm tracker reflects completion and dates accurately<br>Monthly PAF reporting will provide assurance to PSLT | April 2026 |
| 5. Staff responsible for completing checks should be reminded of the need to upload forms completed on paper to MS Forms and also of recording the correct completion date in the tracker. | Site Lead Pharmacists | Brief updated SOP requirements and remind of requirements to update tracker promptly and accurately | May 2026 |

# Detailed Findings

**Risk: If the revised Lothian Accredited Care Assurance Standards (LACAS) questions fail to effectively address known risk areas from previous audits, NHS Lothian could face continued vulnerabilities in Medicines Management, potentially leading to patient safety issues and regulatory non-compliance.**

| Finding 3 - Resource Issues Impacting Performance | Type |
|---|---|
| We interviewed a sample of Site Lead Pharmacists and Chairs of the newly formed Site Based Medicine Safety and Risk Groups and noted the following themes:<br>• The prevailing barrier to the work of the Site Based Medicine Safety and Risk Groups was reported to be time/availability of staff - there is no lack of desire to be involved in medicine safety initiatives, and it was unanimous that there is good buy in and people want to improve, but staff have competing priorities and are often unable to commit time - particularly nursing staff and it was emphasised that the involvement of clinical staff in this initiative is crucial to success.<br>• It was flagged in several meetings that estates issues are a big barrier to improvement in medicines management - investment in equipment would make a difference e.g. fingerprint access to cabinets instead of relying on a key held by a nurse, it was acknowledged that some areas where medicines are stored do not have doors. An example was given that assurance at RHCYP tends to be much better as it is a new hospital with improved facilities.<br>Management noted that they are currently recruiting Medicine Management Nurses; there is one currently in post and NHS Lothian are looking to recruit a further three posts. A Job Description has been drafted, and these specialist nurses will largely focus on education and training in this area. | Design and Effectiveness |
| **Implication** | **Significance** |
| There is a risk that these identified resource issues are hindering progress in improving medicines management performance across the Health Board. | Medium |

| Recommendations | Action owner | Management response | Completion date |
|---|---|---|---|
| 1. We recommend that clear attendance expectations are set for the Site Based Medicine Safety and Risk Groups for Nursing, Pharmacy and Medical Leads. Meetings should be kept short and focused and scheduled around handovers to make it easier for nursing staff to join. In order to make it easier to contribute outside meetings, a simple template for pre read updates and decisions needed should be circulated one week in advance of the meetings and views of any who are unable to attend can be collected via email. | SG | MSRG will review how best to support and strengthen the medicine safety governance structure, ensure appropriate membership of site safety groups and best use of time to drive improvement. | May 2026 |

# Detailed Findings

**Risk: If the revised Lothian Accredited Care Assurance Standards (LACAS) questions fail to effectively address known risk areas from previous audits, NHS Lothian could face continued vulnerabilities in Medicines Management, potentially leading to patient safety issues and regulatory non-compliance.**

| Finding 3 - Resource Issues Impacting Performance | | | Type |
|---|---|---|---|
| Recommendations | Action owner | Management response | Completion date |
| 2. NHS Lothian should continue to prioritise recruiting to the Medicines Management Nurse posts. They could also consider the feasibility of appointing ward-based "Medicines Safety Champions" who are asked to support local fixes, brief colleagues at huddles, and escalate risks to the site group. | DA<br><br>VM / DA | Finalise Job Description and commence recruitment of Medicine Management Nurses<br>Medicine Safety Champions active within wards (AND and WG support) | May 2026<br><br>Q3 (Oct-Dec) |
| 3. We recommend that NHS Lothian consider carrying out a standardised survey of medicines storage areas to map gaps e.g. doors, cabinets, access control, temperature monitoring, lighting and signage. Issues identified should be ranked by risk and patient impact and a site-level remediation plan should be agreed with Estates and Facilities. | Site ANDs and Estate Leads | Outputs of Medicine Management questions and 4 monthly CD checks to identify gaps<br>Work with estates to understand areas of risk. Complete risk assessments and mitigation for high-risk areas | Sept 2026 |

# Detailed Findings

**Risk: If governance and reporting mechanisms for Lothian Accredited Care Assurance Standards (LACAS) and Pharmacy Audit results are inadequate, NHS Lothian risks insufficient scrutiny and follow-up on identified issues, potentially leading to unresolved risks and missed opportunities for improvement in patient care and compliance.**

| Finding 4 - Consistency of LACAS Improvement Plan Completion | TYPE |
|---|---|
| As part of the LACAS cycle, there is a requirement for an Improvement Plan to be established to address any areas of shortfall identified. This is an important step to ensure ongoing improvement as a result of the LACAS reviews.<br><br>During our review, we were provided with two Improvement Plans which were produced as part of the most recent LACAS round (July 2025). We reviewed these plans and observed that the priority column wasn't consistently completed for the medicines management related improvements, and that the review meeting column was absent of dates of review meetings. Management noted that these plans are live, dynamic documents and therefore completion is ongoing. | DESIGN & EFFECTIVENESS |
| **IMPLICATION** | **SIGNIFICANCE** |
| The inconsistency in completing the priority column for medicines management-related improvements suggests that there may be a lack of clarity on which issues need immediate attention. This can lead to delays in addressing critical areas, potentially impacting patient safety and the effectiveness of medicines management. Without clear records of when reviews are conducted, it becomes challenging to monitor the implementation of improvements and ensure timely follow-up | Medium |

| RECOMMENDATIONS | ACTION OWNER | MANAGEMENT RESPONSE | COMPLETION DATE |
|---|---|---|---|
| 1. Staff should be reminded of the importance of fully completing the Improvement Plan template; particularly the priority and review meeting fields. | VM | Nursing will provide ongoing support and training to reinforce expectations on record keeping and mandatory completion of the priority and review meeting fields for all improvement actions. | May 2026 |

# Detailed Findings

**Risk: If training and guidance for completing the new Lothian Accredited Care Assurance Standards (LACAS) questions are inadequate, NHS Lothian risks inconsistent and inaccurate responses, undermining the quality assurance process and potentially leading to flawed data that fails to support ongoing improvements in Medicines Management.**

| Finding 5 - Document Governance | Type |
|---|---|
| Clear and up to date guidance on the LACAS approach will help to ensure that reviews are completed consistently and in line with expected quality standards.<br><br>There is a Framework in place to provide guidance on the LACAS approach, The Framework is dated 2023 and although it is currently under review, this was prompted by the external investigations which have taken place; there is no documented version control/review cycle within the Framework. The document contains outdated references/links to the NHS Lothian Strategic Plan 2014 and the NHS Lothian Quality Strategy 2015. | Design |
| **Implication** | **Significance** |
| The presence of outdated references and links to older strategic documents (such as the NHS Lothian Strategic Plan 2014 and the NHS Lothian Quality Strategy 2015) suggests that the framework may not align with current organisational goals and standards. This misalignment can result in reviews that do not fully support or reflect the current strategic direction and quality expectations. The absence of a documented version control or review cycle means there is no formal process to ensure the framework is regularly updated and maintained. This can lead to the use of obsolete practices and guidance, reducing the framework's relevance and effectiveness over time. | Low |

| Recommendations | Action owner | Management response | Completion date |
|---|---|---|---|
| 1. We recommend that, as part of the ongoing review of LACAS, the Framework is updated to remove any outdated references. Version control should be added to the Framework which clearly displays the date of last review and then next required review date. If Management decides to separate medicines management reviews from the LACAS process; separate guidance should be developed for the new process, and this should be subject to a regular review cycle. | VM | In line with Finding 1 recommendation to host questions on MEG, this will be explored, and separate guidance will be developed.<br><br>The LACAS team will be informed of this recommendation to incorporate into their current Rapid Review of LACAS. | Q3 (Oct-Dec)<br><br>April 2026 |

# Detailed Findings

**Risk: If the pharmacy-led controlled drug audits fail to address risk areas from previous audits, NHS Lothian could face ongoing vulnerabilities in drug management, potentially leading to compliance issues and compromised patient safety.**

| Finding 6 - Training Completion Oversight | TYPE |
|---|---|
| The SOP for the Four Monthly Controlled Drug Checks requires that those who are responsible for carrying out the checks have completed training.<br>Our interviews with a sample of Site Lead Pharmacists found that there is no clear oversight of training completion at a local level; it is assumed that those who are completing the checks will have completed training. | DESIGN & EFFECTIVENESS |
| **IMPLICATION** | **SIGNIFICANCE** |
| There is a risk that those completing the Four Monthly Controlled Drug Checks may not have completed the required training and therefore may not conduct the reviews in line with expectations. | Low |

| RECOMMENDATIONS | ACTION OWNER | MANAGEMENT RESPONSE | COMPLETION DATE |
|---|---|---|---|
| 1. We recommend that a tab is added to the CD Check tracker for each site to record the members of staff who have completed training and are therefore qualified to complete the checks – this should be signed off by an appropriately senior member of staff. | Site Lead Ph | Training logs for SOPs to be reviewed by Site Lead Pharmacists and list of those signed off uploaded into the tracker folder | April 2026 |

# Detailed Findings

**Risk: If the pharmacy-led controlled drug audits fail to address risk areas from previous audits, NHS Lothian could face ongoing vulnerabilities in drug management, potentially leading to compliance issues and compromised patient safety.**

| Finding 7 - CD Checks SLT Reporting | | | TYPE |
|---|---|---|---|
| The Controlled Drug Accountable Officer's annual report for 2023/24 noted that themes from the Four Monthly Controlled Drug Checks would be shared with Senior Leadership Teams to highlight trends, areas of best practice and areas on non-compliance.<br>Management advised that this thematic reporting has not yet commenced but that it is still intended that this will be done. | | | DESIGN |
| IMPLICATION | | | SIGNIFICANCE |
| There is an opportunity to improve the oversight of medicines management performance by implementing the action outlined in the Annual Report. | | | Low |
| RECOMMENDATIONS | ACTION OWNER | MANAGEMENT RESPONSE | COMPLETION DATE |
| 1. We recommend that, as stated in the 2023/24 Controlled Drug Accountable Officer's annual report; NHS Lothian commence reporting on themes from the Four Monthly Controlled Drug Checks to Senior Leadership Teams. | DA | Themes from controlled drug audit to be shared with pharmacy and nursing teams through briefing pharmacy and nursing leader via MRSG and N&W CAOB meetings | May 2026 |

# Detailed Findings

**Risk: If governance and reporting mechanisms for Lothian Accredited Care Assurance Standards (LACAS) and Pharmacy Audit results are inadequate, NHS Lothian risks insufficient scrutiny and follow-up on identified issues, potentially leading to unresolved risks and missed opportunities for improvement in patient care and compliance.**

| Finding 8 - Group ToRs | TYPE |
|---|---|
| It is important that any governance groups involved in medicines management have a clear and up to date remit to guide their work.<br><br>During our review, we found that the ToR for the Medicine Management Audit Working Group was in the process of being drafted. This group was set up to drive implementation of the recommendations from the previous medicines management audits, and it is intended that it will remain in operation to oversee improvement activity until the site based Medicine Safety and Risk Groups are more established.<br><br>The Working Group has not met formally since August 2025 (although Management noted that there have been virtual discussions in the interim period and also there have been meetings between the Director of Pharmacy, the Lead Pharmacist, the Executive Nurse Director and the Nurse Director – Acute Services to discuss progress); the original intention was for this group to meet monthly to drive improvement activity, but it was noted that it has been challenging for nursing staff to engage due to the ongoing reviews. | DESIGN |
| **IMPLICATION** | **SIGNIFICANCE** |
| There is a risk that if ToRs are not in place or are not subject to regular review, that groups may become unclear on their role or objectives and may therefore operate less effectively. | Low |

| RECOMMENDATIONS | ACTION OWNER | MANAGEMENT RESPONSE | COMPLETION DATE |
|---|---|---|---|
| 1. We recommend that the ToR for the Medicine Management Audit Working Group is finalised and implemented with a regular review date scheduled. | DA / VM | ToR for Medicine Management Working Group confirmed MSRG Feb 2026 | Feb 2026 |
| 2. We recommend that NHS Lothian establish a calendar of dates for the Medicine Management Audit Working Group in advance, they should agree the required quorum for meetings to take place. | DA / VM | Plan meetings for Medicine Management Working Group for 2026/2027 | April 2026 |

# Observations

# Observations

### 1. LACAS Performance

Within the singular LACAS cycle (July 2025) which has taken place since the new questions were introduced and before the pause:

- The Acute In-patient hospitals (RIE/WGH/SJH) obtained an average of 75% compliance for medicines management, resulting in silver assurance. In the Clinical Nurse Manager observation, averaged out for all three sites, all questions were rated green with the exception of the question on medicines refrigeration which had 70% compliance.
- Critical Care obtained an average of 94% for medicines management and therefore resulted in gold assurance.
- OPD Acute obtained an average of 99% for medicines management and therefore resulted in gold assurance.

We noted that the LACAS process results in provision of a level of assurance (gold [moderate]/silver [limited]/bronze [no assurance]) based on the RAG rating of the standards. We queried with Management whether it was appropriate to assign no assurance as “bronze” as this may be misleading; Management noted that these ratings are being revisited as part of the ongoing review of LACAS.

### 2. LACAS Governance Route

The next level of governance to which the LACAS output was due to be shared with following the DATCC SMT was the Acute Clinical Management Group – DATCC were scheduled to present their quarterly site report in December 2025; however, at the time the LACAS November 2025 cycle report was still in preparation. As such, the previous LACAS cycle report (May 2025) was used for the December submission.

### 3. Four Monthly Controlled Drug Checks Dashboards

There are two Data Analysts in the Pharmacy and Medicines Directorate who are currently assessing how best to use the data from the reviews with a view to developing dashboards for performance monitoring.

### 4. Use of Spreadsheets for Controlled Drug Checks

All sites currently use a spreadsheet tracker to schedule/record completion of the checks. Some sites trialled using an electronic calendar system for scheduling but found that this didn't work well so they have reverted to the spreadsheet approach.  They found that the electronic system was sending alerts to some members of staff but not to others, and that it was difficult to monitor who had completed what checks.

### 5. Interviewee Views on Improvement Activity

Interviewees felt that there has been an improvement since the last audit, anecdotally, they reported that awareness is better amongst staff on governance and responsibilities, medicines management is often a topic of conversation amongst senior staff, and there is better reporting of errors.

# Observations

### 6. Hospital Adverse Events Related to CDs

The Controlled Drug Accountable Officer Annual Reports from 2022/23 to 2024/25 showed an overall increase in hospital adverse events related to CDs (see table below for breakdown). Although overall number of reported adverse events has increased, it was noted that this should not be seen as a bad thing in itself, as NHSL wants to promote a culture in which events are recorded without fear of blame and changes to CD procedures launched in April 2024 confirmed reporting requirements and are thought to have contributed to increased reporting.

| *Adverse Event Category* | *2022/23* | *2023/24* | *Movement in Year* | *2024/25* | *Movement in Year* |
|---|---|---|---|---|---|
| *Administration Incident* | *312* | *418* | *+34%* | *494* | *+18%* |
| *Record Keeping* | *144* | *221* | *+53%* | *200* | *-11%* |
| *Spillage/Breakage* | *N/A* | *192* | *N/A* | *160* | *-17%* |
| *CD Register Discrepancy* | *96* | *183* | *+91%* | *319* | *+74%* |
| *Missing CDs* | *84* | *144* | *+71%* | *151* | *+5%* |
| *Prescribing Incident* | *68* | *117* | *+72%* | *182* | *+56%* |
| *Dispensing/Supply Incident* | *85* | *67* | *-21%* | *61* | *-9%* |
| *Security* | *50* | *32* | *-36%* | *40* | *+25%* |
| *Suspected Fraud or Criminality* | *5* | *9* | *+80%* | *12* | *+33%* |
| *Other* | *182* | *140* | *-23%* | *132* | *-6%* |
| *TOTAL* | *1026* | *1523* | *+48%* | *1751* | *+15%* |

# Appendices

# Appendix I - Overdue Controlled Drug Checks

| Site | Total Wards | Wards with a check completed in last 4 months | Wards overdue by 1 month | Wards overdue by 1-3 months | Wards overdue by 3-6 months | Wards overdue by 6-9 months | Wards with checks scheduled but no checks completed since April | Wards with no checks scheduled |
|---|---|---|---|---|---|---|---|---|
| RIE | 59 | 24 (41%) | 9 (15%) | 0 | 7 (12%) | 1 (2%) | 3 (5%) | 15 (25%) |
| REH | 27 | 17 (63%) | 2 (8%) | 0 | 1 (3.5%) | 4 (14%) | 2 (8%) | 1 (3.5%) |
| RHCYP | 10 | 1 (10%) | 0 | 0 | 9 (90%) | 0 | 0 | 0 |
| WGH | 43 | 23 (54%) | 4 (9%) | 2 (4.5%) | 7 (16%) | 2 (4.5%) | 0 | 5 (12%) |

# Appendix II - Background

It was agreed as part of the 2025-26 Internal Audit Plan that Internal Audit would conduct a review of medicines management at NHS Lothian, focussing on the governance of improvement activity in this area following previous audits.

NHS Lothian's previous internal auditors conducted two audits of medicines management, both which resulted in a limited assurance opinion; and it was therefore agreed that internal audit would revisit this area to provide assurance that improvements have been made.

LACAS

Off the back of the previous audits in this area, there was a set of 11 questions specific to Medicines Management incorporated into the Lothian Accredited Care Assurance Standards (LACAS)reviews, to provide a greater degree of assurance over medicines management performance.

Management noted that at the time of this audit, the performance of LACAS has been put on a three month pause until the end of March 2026 - this is as a result of 4 SPSO reports which have been received in quick succession, the findings of which necessitate a review of the LACAS content. There has only been one LACAS cycle since the Medicines Management content was incorporated; this took place in July 2025.

LACAS cycles happen twice a year in adult inpatient areas, critical care, outpatient departments, endoscopy suites, and children's services. They are all done at different times throughout the year. According to the intranet, LACAS standards are in development for a range of other service areas including Maternity, Mental Health & Learning Disabilities, Theatres & Recovery and Same Day Emergency Care.

Senior Charge Nurses (SCN)/Department Charge Nurses are responsible for carrying out the reviews; data is collected and uploaded on the MEG system. There is also a Clinical Nurse Manager walk around and a section of the checks that pulls data from other NHS systems and looks at establishments/rosters.

Training for those completing LACAS is managed at a local level and Lead Nurses would be responsible for ensuring that those responsible for completing the reviews (SCNs) have access to the MEG system and understand their roles and responsibilities. Clinical Nurse Managers (CNMs) would be the relevant direct line managers so would also have a hand in overseeing this. There is a Framework in place which provides guidance on the LACAS approach.

LACAS incorporates a self assessment and external peer assessment process. The expectation is that clinical teams will undertake a review of their clinical areas every six months with an external peer assessment for every fourth review. The decision on when a service is ready for peer review is to be made at the Patient Outcome Programme Board.

The LACAS cycle includes the following steps:

1. Department Profile Data - The SCN completes a baseline profile which captures KPIs including workforce data, training, appraisal, harm data, finance, feedback, department activity, and HAI. This data comes from various NHSL dashboards and systems.

2. Department Observation - The CNM or external peer assessor completes an observation which looks at environment, culture, medicines management, meal times and Ward/Department Systems.

3. Episodes of Care - The SCN/Team Leader or peer reviewer selects 5 patients who have care needs aligned to the standard being assessed e.g. patients who have fallen for the falls standard

4. Validation - The Lead Nurses for Quality Improvement & Standards check profile data, observations and episodes of care and work with the SCN/CNM teams to ensure they have fully submitted and selected the most appropriate patients to assess. Data is combined and weighted to generate a score for each standard. These scores are RAG rated (red <60%, amber 60%-79%, green >80%).

5. Level of Assurance - The Head of Nursing Quality Improvement and Standards will award each ward/team with their level of assurance (gold [moderate]/silver [limited]/bronze [no assurance]) based on the RAG rating of the standards.

6. Quality Planning - The SCN, CNM, Chief Nurse and the Lead Nurse for Quality Improvement and Standards meet to review the cycle and complete an improvement plan. A prioritisation matrix is used to identify priority areas for improvement activity/risk mitigation.

The Lead Nurse for Quality Improvement and Standards, along with Quality Improvement teams, will support wards/teams to drive improvement activity. Where common theme are identified, the Quality Improvement function will establish and support collaborative/pan-Lothian improvement workstreams.

# Appendix II - Background

Four Monthly Controlled Drug (CD) Checks

There were significant changes made to the CD reviews following the previous audits. Previously these reviews mostly focussed on checking the accuracy of running balances of CDs. During the update to the process, known areas of non-compliance were included. It was noted that there were too many areas to cover in one go, so the review was split into three cycles with the third cycle covering a full balance check (although a full balance check can be carried out at any time if there are concerns). Medicines are also balance checked daily by nursing staff. It is the intention to make sure all areas are visited three times in the financial year.

There is a SOP in place which outlines the process for completing checks – this was issued in December 2024 and is scheduled to be reviewed every two years. The SOP notes that the Charge Nurse of registered practitioner in charge of the ward or clinical area has responsibility for medicine safety. A member of the registered pharmacy staff (pharmacist or pharmacy technician) must conduct a controlled drug check with a registered nurse every 4 months in any areas that hold Schedule 2 Controlled Drugs (CDs).

Pharmacy staff must complete training before completing the audits, this includes carrying out a supervised audit with another member of the team. There is a form appended to the SOP to record training completion.

There is a separate document linked within the SOP which is a crib sheet for the Safe Use of Medicines Procedures (SUMP) and Support Tools relevant to the questions included in the audit- this can be used by the person carrying out the audit to ensure they are aware of the relevant criteria/guidance for each question and to signpost nursing teams where an action is identified.

All sites use a spreadsheet tracker to schedule/record completion of the checks. A further change that was made to the process was that all checks are now required to be submitted on MS Forms, the MS form automatically directs to the appropriate questions depending on the current cycle.

Where there are any issues identified during checks, these are raised on DATIX. Generally the nursing staff are responsible for acting on the DATIX and the Pharmacist or Pharmacy Technician will follow up to ensure it has been closed off, if there are any issues the Site Lead Pharmacist will intervene as they have oversight of the DATIXs raised. The CD Governance Team are also automatically notified on the submission of a DATIX report.

The Admin Support Officer within the Controlled Drug Governance Team performs a monthly download of all completed forms from MS Forms and completes a check of these. During her checks, she will seek to confirm that a DATIX has been raised for any issues identified during the checks. If a DATIX has not been raised, she will follow this up with the person who completed the check. She maintains a tracker to ensure that any queries she has raised are resolved.

# Appendix III: Definitions

| Level of assurance | Design of internal control framework | | Operational effectiveness of controls | |
|---|---|---|---|---|
| | Findings from review | Design opinion | Findings from review | Effectiveness opinion |
| Substantial | Appropriate procedures and controls in place to mitigate the key risks. | There is a sound system of internal control designed to achieve system objectives. | No, or only minor, exceptions found in testing of the procedures and controls. | The controls that are in place are being consistently applied. |
| Moderate | In the main there are appropriate procedures and controls in place to mitigate the key risks reviewed albeit with some that are not fully effective. | Generally a sound system of internal control designed to achieve system objectives with some exceptions. | A small number of exceptions found in testing of the procedures and controls. | Evidence of non compliance with some controls, that may put some of the system objectives at risk. |
| Limited | A number of significant gaps identified in the procedures and controls in key areas. Where practical, efforts should be made to address in-year. | System of internal controls is weakened with system objectives at risk of not being achieved. | A number of reoccurring exceptions found in testing of the procedures and controls. Where practical, efforts should be made to address in-year. | Non-compliance with key procedures and controls places the system objectives at risk. |
| No | For all risk areas there are significant gaps in the procedures and controls. Failure to address in-year affects the quality of the organisation's overall internal control framework. | Poor system of internal control. | Due to absence of effective controls and procedures, no reliance can be placed on their operation. Failure to address in-year affects the quality of the organisation's overall internal control framework. | Non compliance and/or compliance with inadequate controls. |

| Recommendation significance | |
|---|---|
| High | A weakness where there is substantial risk of loss, fraud, impropriety, poor value for money, or failure to achieve organisational objectives. Such risk could lead to an adverse impact on the business. Remedial action must be taken urgently. |
| Medium | A weakness in control which, although not fundamental, relates to shortcomings which expose individual business systems to a less immediate level of threatening risk or poor value for money. Such a risk could impact on operational objectives and should be of concern to senior management and requires prompt specific action. |
| Low | Areas that individually have no significant impact, but where management would benefit from improved controls and/or have the opportunity to achieve greater effectiveness and/or efficiency. |

# Appendix IV: Terms of reference

| Extract from terms of reference |
|---|
| **Purpose** |
| The objective of this audit is to provide independent assurance over the effectiveness of the governance arrangements in place to drive and monitor improvements in Medicines Management within NHS Lothian. This will include assessing whether the newly implemented processes (e.g., revised LACAS questions, training provision, four-monthly pharmacy audits, and overall improvement plan governance) are robust and address the issues identified in previous internal audits. |
| **Key risks** |
| • If the revised LACAS questions fail to effectively address known risk areas from previous audits, NHS Lothian could face continued vulnerabilities in Medicines Management, potentially leading to patient safety issues and regulatory non-compliance.<br>• If training and guidance for completing the new LACAS questions are inadequate, NHS Lothian risks inconsistent and inaccurate responses, undermining the quality assurance process and potentially leading to flawed data that fails to support ongoing improvements in Medicines Management.<br>• If the pharmacy-led controlled drug audits fail to address risk areas from previous audits, NHS Lothian could face ongoing vulnerabilities in drug management, potentially leading to compliance issues and compromised patient safety.<br>• If governance and reporting mechanisms for LACAS and Pharmacy Audit results are inadequate, NHS Lothian risks insufficient scrutiny and follow-up on identified issues, potentially leading to unresolved risks and missed opportunities for improvement in patient care and compliance.<br>• If the Improvement Plan lacks comprehensive coverage of previous audit issues and the oversight groups are ineffective, NHS Lothian risks failing to implement necessary changes in Medicines Management, potentially leading to ongoing safety risks and accountability gaps. |
| **Exclusions** |
| The scope of the review is limited to the areas documented under the scope and approach. All other areas are considered outside of the scope of this review. Our review will not provide assurance over all aspects of medicines management.<br><br>Where sample testing is undertaken, our findings and conclusions will be limited to the sample tested only. Please note that there is a risk that our findings and conclusions based on the sample may differ from the findings and conclusions we would reach if we tested the entire population from which the sample is taken. |

# Appendix V: Staff interviewed

| BDO LLP appreciates the time provided by all the individuals involved in this review and would like to thank them for their assistance and cooperation. | |
|---|---|
| Scott Garden | Director of Pharmacy |
| Debbie Alexander | Lead Pharmacist CD Governance and Medicine Safety |
| Victoria Mulholland | Consultant Nurse Urgent/ Unscheduled Care |
| Linda Conway | Lead Nurse Quality Improvement and Standards |
| Lorna Turner | Lead Nurse Quality Improvement and Standards |
| Emma Morrison | Consultant Clinical Pharmacologist |
| Jin Hah Werne | Site Lead Pharmacist WGH |
| Ommar Ahmed | Lead Pharmacist Orthopaedics |
| Patrick Downie | Site Lead Pharmacist SJH |
| Ewan McLean | Site Lead Pharmacist RIE/RHCYP |

# Appendix VI: Responsibilities, limitations and conformance with the Global Internal Audit Standards

### Management responsibilities

The Board is responsible for determining the scope of internal audit work, and for deciding the action to be taken on the outcome of our findings from our work.

The Board is responsible for ensuring the internal audit function has:

- The support of the Company's management team.
- Direct access and freedom to report to senior management, including the Chair of the Audit Committee.
- The Board is responsible for the establishment and proper operation of a system of internal control, including proper accounting records and other management information suitable for running the Company.

Internal controls covers the whole system of controls, financial and otherwise, established by the Board in order to carry on the business of the Company in an orderly and efficient manner, ensure adherence to management policies, safeguard the assets and secure as far as possible the completeness and accuracy of the records. The individual components of an internal control system are known as 'controls' or 'internal controls'.

The Board is responsible for risk management in the organisation, and for deciding the action to be taken on the outcome of any findings from our work. The identification of risks and the strategies put in place to deal with identified risks remain the sole responsibility of the Board.

### Limitations

The scope of the review is limited to the areas documented under Appendix II - Terms of reference. All other areas are considered outside of the scope of this review.

Our work is inherently limited by the honest representation of those interviewed as part of colleagues interviewed as part of the review. Our work and conclusion is subject to sampling risk, which means that our work may not be representative of the full population.

Internal control systems, no matter how well designed and operated, are affected by inherent limitations. These include the possibility of poor judgment in decision-making, human error, control processes being deliberately circumvented by employees and others, management overriding controls and the occurrence of unforeseeable circumstances.

Our assessment of controls is for the period specified only. Historic evaluation of effectiveness may not be relevant to future periods due to the risk that: the design of controls may become inadequate because of changes in operating environment, law, regulation or other; or the degree of compliance with policies and procedures may deteriorate.

**Conformance with the Global Internal Audit Standards** This engagement has been conducted in accordance with the Institute of Internal Auditors' Global Internal Audit Standards.

FOR MORE INFORMATION:

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