NHS Lothian

Internal Audit 2023/24

Medicines Management Review

January 2024

Final report

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- Craig Stenhouse – Deputy Chief Nurse for the Royal Edinburgh Hospital

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- Calum Campbell - Chief Executive
- Craig Marriott – Director of Finance
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Executive summary

Background

Meticulous medicines management is vital to the performance of every health and social care organisation. Mistakes with medication can cause dangerous side effects that render the medication ineffective, or even result in the death of patients. Effective medicines management reduces illness and provides safer and more reliable healthcare services.

All health and social care organisations that deal with patient medication are required to have appropriate medicine management processes and policies in place that are aligned to national guidance to support and guide staff in the safe management of medicines.

Healthcare professionals who handle medication are required to understand the importance of medicine management and the systems and processes they need to follow to ensure the safe use of medicines to deliver the best outcomes for both the organisation and its patients.

NHS Lothian's Safe Use of Medicines Policy & Procedures has been developed to establish, document, and maintain an effective system to manage medicines safely and securely to meet patients' clinical needs. The NHS Lothian Accreditation and Care Assurance Standards (LACAS) provides a framework to give organisational and service user assurance that quality person-centred care is being delivered consistently across all NHS Lothian's services.

The Area Drug and Therapeutics Committee (ADTC) provides professional clinical advice and leadership to each NHS board to support the safe, clinically effective and patient-centred use of medicines in all care settings.

This audit has evaluated the adequacy of internal controls in place around the ordering, receipt, and storage and security of medicines in wards.

Executive summary

Objectives

Our review focussed on the following key risks:

- Are staff complying with the Board's policies in the safe and secure handling, storage, disposal, ordering and receipt of medicines and stationary , including that related to Controlled Drugs?
- Are Board's staff appropriately trained in the safe management of medication and recognise their individual responsibilities to ensure medication is securely stored and safely administered; and
- Does the Board have adequate arrangements in place to monitor compliance with its medicines management policy and take action where compliance is sub-standard?

Limitations in scope

Our findings and conclusions will be limited to the risks identified above. The scope of this audit does not allow us to provide an independent assessment of all risks and controls linked to the Medicines Management review.

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.

This report does not constitute an assurance engagement as set out under ISAE 3000.

Acknowledgement

We would like to take this opportunity to thank your staff for their co-operation during this internal audit.

Headline messages

Conclusion

Limited Assurance

We have reviewed the processes and controls around medicines management and have concluded that the processes have provided a rating of **LIMITED ASSURANCE.** This was confirmed through testing in specific areas of the organisation and through discussions with management.

The objectives reviewed are set out on the following page with the assurance rating we have assessed for each one and the number of recommendations raised. We have reported by exception against the areas where we consider that Management and the Audit Committee should focus their attention.

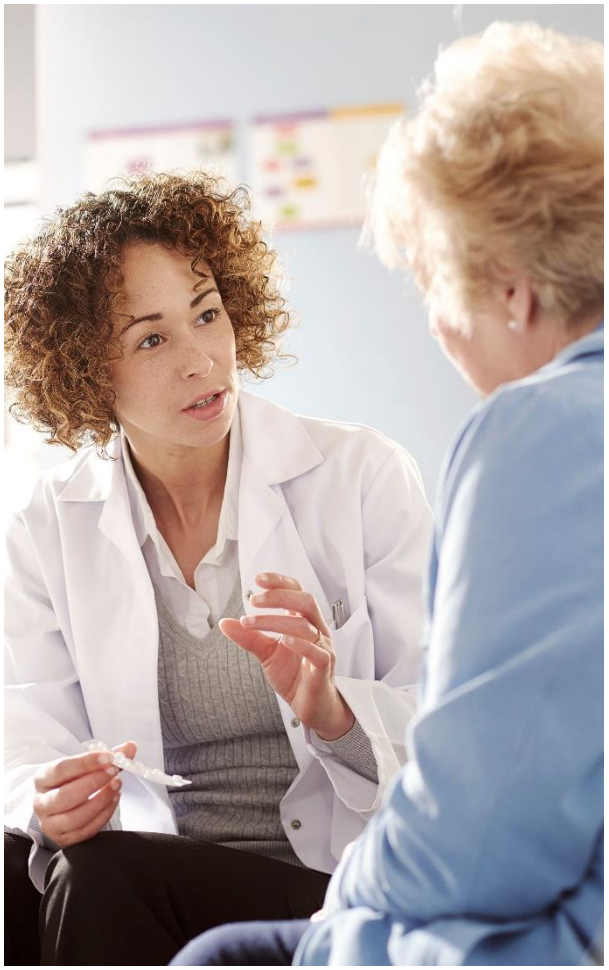
We have undertaken visits to 9 areas previously selected by Lothian NHS Board. The visits were spread across three sites: Western General, the Royal Infirmary and the Royal Edinburgh Hospital. At the clients request these visits had previously been announced to the Ward Managers in the areas that were to be visited and in all the areas we visited staff were expecting us.

At the time of the review, it was evident by the number of reported vacancies and the reported use of Bank and Agency staff in the areas we visited that the organisation is experiencing significant challenges with their workforce and it is recognised this may have influenced some of the findings within this report.

However, the effectiveness in the safe and secure management of medicines is an area of significant risk to the performance of health and social care providers and requires prioritising to ensure clear oversight of areas of risk is provided and that staff are sufficiently aware of their role and responsibilities in the safe management of medicines.

While we identified areas of good practice associated with the completion of daily CD monitoring, the secure storage of CD stationary and the management of medical gases. There was noted to be variable compliance with Lothian NHS Board's policies and procedures relating to the safe and secure storage of medication in many of the areas we reviewed.

Furthermore, the oversight and monitoring of compliance with the Boards policies and procedures related to the safe and secure storage of medicines requires formalising and processes to gain assurance actions to address identified gaps in compliance are appropriately completed need establishing. Additional development is also required in ensuring that identified learning associated with the safe and secure storage of medicines is effectively shared, allowing staff to understand and take ownership of medicines management arrangements.



Headline messages

Conclusion

We have raised 8 recommendations and 2 improvement points. The grading of these recommendations, based on risk, is summarised in the table below.

Objectives	Assurance rating	Number of recommendations			
		High	Medium	Low	Imp
Are staff complying with the NHS Board's policies in the safe and secure handling, storage, disposal, ordering and receipt of medicines and stationery , including that related to Controlled Drugs?	Limited Assurance	1	4	0	1
Are the Board's staff appropriately trained in the safe management of medication and recognise their individual responsibilities to ensure medication is securely stored and safely administered ?	Moderate Assurance	0	1	1	0
Does the Board have adequate arrangements in place to monitor compliance with its medicines management policy and take action where compliance is sub-standard?	Moderate Assurance	0	1	0	1

Summary of findings

Examples of where recommended practices are being applied

- There is good compliance with the completion and recording of the daily CD checks and CD stationary was generally stored securely in the CD cabinets.
- There is good compliance with the monitoring and recording of emergency equipment and resuscitation drugs.
- There are effective arrangements in place to ensure medical gases are monitored and replaced in a timely manner.
- The is good separation of medicines in accordance with the route of administration and
- There is evidence of good stock rotation processes in place and that the review of stock if generally being undertaken bi annually

Areas requiring improvement

- Access to the clinical room in some areas was not restricted to registered and authorised staff, and in some instances, this resulted in medication and intravenous fluids being accessible to unauthorised staff.
- Staff require greater clarity on the safe management of elixirs and eye drops to ensure these drugs are not used beyond intended disposal dates.
- Further work is required to raise awareness and improve compliance with the documentation of the CD order books and to ensure effective action is taken to address the outcome of CD Audits.
- Processes to gain assurance that medication is safely and securely stored require strengthening and should include the ability to monitor that areas requiring improvement are appropriately addressed in a timely manner.
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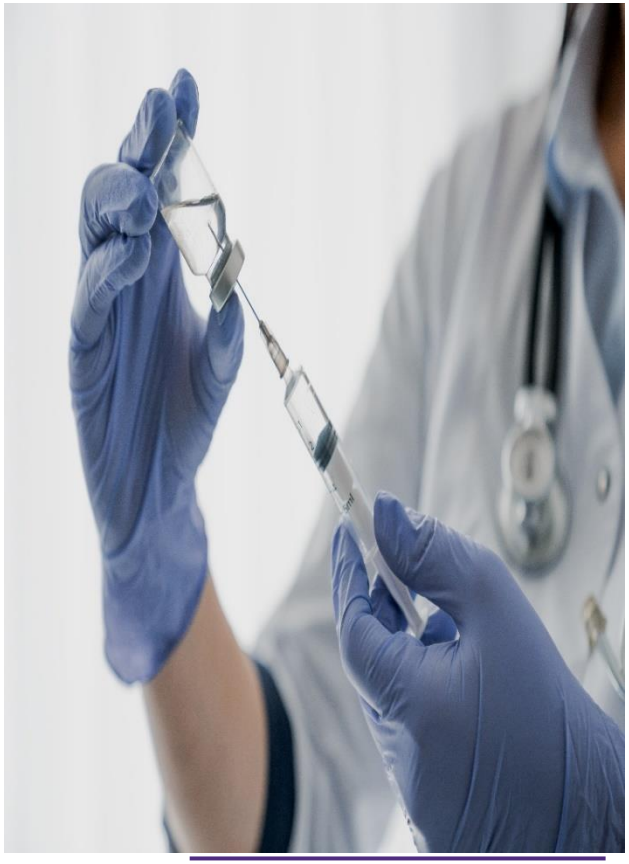


Detailed findings

Objective 1.	Are staff complying with the Board's policies in the safe and secure handling, storage, disposal, ordering and receipt of medicines and stationery , including that related to Controlled Drugs?	Limited Assurance

Finding and implications	Audit recommendation	Management response, including actions
There is variable staff compliance with the Board's 'Safe Use of Medicines' procedure. Access to the Clinical Rooms is generally secure. However, in two areas we identified access to the clinical room doors was not secured or restricted and in both these areas we noted medication was accessible due to Unlocked cupboards Unlocked fridges Medicines left out in the clinical room. In addition, in one area we found 4 Computer on wheel trollies with unsecured drawers containing a variety of medication being routinely stored in communal areas . We requested the drawers to be secured after the risk was raised with the nurse in charge and staff were advised to move the CoWs to the Clinical room. This information was reported to the Ward Pharmacist who was on the ward at the time of our visit. **Recommendation 1** In several areas we noted the cupboards storing topical preparations were routinely left unlocked and staff were not always aware this was a requirement. **Recommendation 5** In three areas we identified the drug fridges did not have integrated locks that allowed them to be secured. We were told fridges were the wrong specification for drug fridges. Until the fridges can be replaced staff in those areas must ensure mitigations are put in place to ensure medicines requiring fridge storage are appropriately restricted to authorised personnel. **Recommendation 1** The Board's 'Safe Use of Medicines' procedure. states a Master set of keys for individual cabinets are held in each ward. Master keys should be stored in a locked cupboard when not in use. A check to account for all master keys should be made at least once in 24 hours . However, staff were generally unaware of a master set of keys and there is no process to routinely check them. Furthermore, on Ward 23 after looking in key safes the master set of keys the spare POD locker key was located inside a folder on the Nurses station. We were told this save staff time locating keys. These findings all potentially allow access to medication by unauthorised personnel and indicates non-compliance with the Boards policy. **Recommendation 1**	**Recommendation 1** To improve compliance with the secure storage of medicines Lothian NHS Board should : • Review access rights to clinical rooms where medication is stored across all the sites and restrict access to non-clinical staff and those not involved in the care of patients • Introduce regular spot checks of areas used to store medicines to monitor the security and ensure duplicate set of medicines keys are securely stored and routinely checked in line with the organisation procedures. • Ensure that when areas replace a drug fridges, the fridge adheres to pharmaceutical specification. In areas where the drug fridges staff should be aware of the need to implement mitigation to restrict the access to the drug fridge by unauthorised personnel.	**Actions:** Meeting held with key stakeholders took place on 6th December 2023 and agreed that immediate critical actions would be taken forward. Compiled immediate actions aligned to Objective 1 and recommendation 1 , 2, 4 into a single communication with key messages for all staff across all hospital sites sent to Site Associate Nurse Directors on 15th December 2023 to share and ensure actioned within all clinical areas with medicines stored. **Due Date:** Completed December 2023 Future compliance will be monitored via integrated LACAS / PCAT audits, 4monthly Pharmacist led Controlled Drug checks and Controlled Drug Governance Team support visits. **Due Date** September 2025 **Responsible Officer:** Gillian McAuley – Director of Nursing & Craig Stenhouse – Deputy Chief Nurse with Site Associate Nurse Directors **Executive Lead:** Alison MacDonald – Executive Director of Nursing, Midwifery & Allied Health Professionals.

Detailed findings

Objective 1.	Are staff complying with the Board's policies in the safe and secure handling, storage, disposal, ordering and receipt of medicines and stationery , including that related to Controlled Drugs?	Limited Assurance

Finding and implication	Audit recommendation	Management response, including actions
There was generally clear separation of IV fluids that contain potassium, and one area had labelled the shelf with red signage. Access to IV fluids was not consistently restricted to registered staff and in two areas visited we identified the overflow stock of IV fluids were being stored in unsecured rooms that allowed unrestricted access to unauthorised personnel. **(Recommendation 2)** In addition, we observed that IV fluids are sometimes decanted from original packaging due to the existing storage arrangements. However, this is not in-line with best practice and storage arrangements should allow IV fluids to be contained within their original boxes. **(Recommendation 2)**	**Recommendation 2** To improve compliance with the safe management and storage of IV fluids the Board should: ▪ Ward and Department Managers and Matrons should ensure all IV fluids are securely stored and undertake frequent random spot checks of cupboards storing IV fluids to monitor the security, and storage arrangements.	**Actions:** Meeting held with key stakeholders took place on 6th December 2023 and agreed that immediate critical actions would be taken forward. Compiled immediate actions aligned to Objective 1 and recommendation 1 , 2, 4 into a single communication with key messages for all staff across all hospital sites sent to Site Associate Nurse Directors on 15th December 2023 to share and ensure actioned within all clinical areas with medicines stored. **Due Date:** December 2023 Work will be undertaken to develop the informal local monitoring processes routinely undertaken in clinical areas. **Due Date:** Ongoing Future compliance will be monitored via integrate LACAS / PCAT audits. **Due Date** September 2025 **Responsible Officer:** Gillian McAuley Director of Nursing & Craig Stenhouse Deputy Chief Nurse with Site Associate Nurse Directors **Executive Lead:** Alison MacDonald – Executive Director of Nursing, Midwifery & Allied Health Professionals.

Detailed findings

Objective 1.	Are staff complying with the Board's policies in the safe and secure handling, storage, disposal, ordering and receipt of medicines and stationery , including that related to Controlled Drugs?	Limited Assurance

Finding and implication	Audit recommendation	Management response, including actions
There is good compliance with the completion and recording of the daily CD checks and CD stationary was generally stored securely in the CD cabinets. Lothian Board has recently introduced theatre style CD registers and we found the wastage of CDs was routinely documented in the CD register. However, we did note in one area the index page of the CD register had not been completed and a review of the previous register also had no documented index. This suggests limited oversight of CD governance in this area. Staff told us they checked the CD against the page number recorded on each CD box. This is not in line with required practice. We undertook a check of CD stock to confirm there was nothing missing, **(Recommendation 3)** This was immediately escalated to the Ward Pharmacist to follow up. We observed the CD keys are routinely held by the nurse in charge and are held separately from other drug keys in line with best practice. However, there is variable compliance with staff signing the CD order book on receipt of a CD order and in several areas, we noted on occasion that the same member who ordered the CD also signed to say it had been received and this is not in line with best practice as documented in Lothian's 'Safe Us of Medicines' procedure. **(Recommendation 3)** However not all staff were aware of this. **(Recommendation 5)**	**Recommendation 3** To improve governance arrangements in the management of controlled drugs The Director of Pharmacy should: • Review and report compliance with the completion of the quarterly CD audits and incorporate a review of the CD order book to monitor compliance with the CD policy. • Include an action to the quarterly CD audit to gain assurance that areas of previous limited compliance have been sufficiently addressed. • Embed a feedback process to allow the outcome of CD audits to be cascaded.	**Actions:** Centralised collation of completed 4 monthly Controlled Drug Check for Schedule 2 Controlled Drugs completed by the pharmacy teams will support a review of common themes and identify area where these checks have not been completed within the expected timeframe. A review of the questions within this check will also be completed to ensure this supports the updates to the controlled drug section within the SUMP which is due to be launched March/April 2024. A data will be located in a digital library and reviewed and reported monthly by the CD Governance Team to the Accountable Officer for Controlled Drugs. There will be support and follow up from the controlled drug governance team and wider thematic issues will be progressed through the Medicines Governance committees specifically the Medicines Safety and Risk Group. **Responsible Officer:** Debbie Alexander _ Lead Pharmacist CD Governance **Executive Lead:** Scott Garden – Director of Pharmacy **Due Date:** April 2024

Detailed findings

Objective 1	Are staff complying with the Board's policies in the safe and secure handling, storage, disposal, ordering and receipt of medicines and stationery , including that related to Controlled Drugs?	Limited Assurance

Finding and implications	Audit recommendation	Management response, including actions
Generally, we observed there is good separation of medication aligned to the route of administration. However, in one area we visited we found acetone solution was routinely being stored with oral medications. This was removed at the time of our visit. Our review identified variable compliance in the safe storage of medication. We noted in 8 out of the 9 areas visited the routine recording of the opening dates on bottles of elixirs and eye drops to ensure staff have clear guidance when the medication requires discarding was inconsistently followed. **(Recommendation 4)** Furthermore, in one area (109) we found multiple blister packets of two different schedule three medications being stored in a single container. Staff were advised to place back in the original packaging to reduce the risk of the wrong medication being administered. We also found in two of the POD lockers we examined in different wards unidentified medication dispensed and left unadministered in medicine pots. The contents of the medicine's pots were disposed of at the time of our visit It was also identified in two areas (202 & 70) that completion of the daily drug fridge temperature recordings was variable. **(Recommendation 4)** There is evidence of stock reviews taking place and stock rotation is recognised as good practice. However, in three areas we found out-of-date medication available for staff to use. The out-of-date items were removed from circulation at the time of our visit. The wards visited generally used a standardised monitoring form to record the twice daily drug fridge temperature checks. However, this form could not be located on the Margaret Duguid Unit and in three other areas it was noted compliance with recording drug fridge temperatures was variable. **(Recommendation 4)** We also noted several of the clinical rooms were very warm however, staff reported there was no requirement for them to routinely monitor and record the clinical room temperature as we have observed as standard practice at other hospitals reviewed.	**Recommendation 4** To improve compliance with Lothians' 'Safe Use of Medicines' procedures ' The Board should introduce a process that allows formal spot checks of medicine management arrangements: ▪ Monitoring the completion of drug fridge temperature checks, appropriate storage and timely disposal of expired and unused medication and compliance with appropriate labelling on elixir bottles , insulin and eye drops with the date of opening. ▪ Monitoring compliance with the recording of drug fridge temperature checks. ▪ To improve staff awareness of Lothian's 'Safe Us of Medicines' procedure. The Clinical Skills Team should develop mandatory medicine safety update training that can be updated to address themes from incidents and audit findings.	**Actions:** Meeting held with key stakeholders took place on 6th December 2023 and agreed that immediate critical actions would be taken forward. Compiled immediate actions aligned to Objective 1 and recommendation 1 , 2, 4 into a single communication with key messages for all staff across all hospital sites sent to Site Associate Nurse Directors on 15th December 2023 to share and ensure actioned within all clinical areas with medicines stored. **Responsible Officer:** Gillian McAuley Director of Nursing & Craig Stenhouse Deputy Chief Nurse with Site Associate Nurse Directors **Due Date:** December 2023 Work will be undertaken to develop an informal local monitoring processes routinely undertaken in clinical areas and to develop a sub -Committee of the Medicines Policy Committee . This will be attended by nurse leadership to gain oversight on progress to address actions **Due Date:** Ongoing Future compliance will be monitored via integrated LACAS / PCAT audits **Due Date:** December 2025 **Actions:** The clinical education team will add cold chain management to RNRM induction and to the medicines management session with reference to the storage of elixirs, eye drops, insulin and other cold chain medicines. The clinical education team will promote further awareness of the safe use of medicines policy and procedures on the intranet on ALL clinical skills and education courses involving medicines. **Responsible Officer:** Fiona Pollock – Clinical Skills Team Leader **Executive Lead:** Alison MacDonald – Executive Director of Nursing, Midwifery & Allied Health Professionals. **Due Date:** January 2024

Detailed findings

Objective 1.	Are staff complying with the Board's policies in the safe and secure handling, storage, disposal, ordering and receipt of medicines and stationery , including that related to Controlled Drugs?	Limited Assurance

Finding and implication	Audit recommendation	Management response, including actions
Staff could generally locate the Medicines management policies and procedures on Lothian's intranet , although one member of staff had difficulties navigating the system and had initially suggested there was a hard copy of the Medicines Policy. In addition, we noted variable awareness in regard to : • the requirement to sign the CD order book on receipt of a CD • how the wasted part does of CD should be disposed of e.g sink , blue bins or small denaturing kit . • the outcome of CD audits • the need to keep pharmacy boxes with medicines for turn to pharmacy secure • The need to keep topical preparations secure and in one area at the Royal Edinburgh infirmary staff were unfamiliar with the intranet and unable to locate Lothian policies.	**Recommendation 5** To improve staff awareness of Lothian NHS Board's 'Safe Use of Medicines' procedure the Clinical Skills Team should develop mandatory medicines management refresher training. The emergency tray on Margaret Duguid should clearly display the location of the emergency drugs.	**Actions:** There are three overarching medicines management Learnpro modules relevant to different nursing and midwifery specialist areas. These modules will be regularly updated by the medicines management nurses . Regular themes from incidents and audits will be added to the modules following review at the medicine's safety and governance forum. The three medicines modules will now be included in the relevant categories of the 2 yearly essential learning list for nurses and midwives. In addition, the key medicine management messages will be incorporated into future medical staff medicine updates and their induction. **Responsible Officer:** Fiona Pollock – Clinical Skills Team Leader & Melinda Cuthbert- Associate Director of Pharmacy **Executive Lead:** Alison MacDonald – Executive Director of Nursing, Midwifery & Allied Health Professionals. **Due Date:** March 2024 and ongoing following medicines safety and governance meetings.
One area at the Western General were storing a significant backlog of patients CD medication after the Patient had left the ward. This resulted in significant additional time being taken to complete the daily check of CDs. We were advised there were arrangements in place for Pharmacy to regularly dispose of CDs, but Pharmacy was also experiencing challenges with its workforce and capacity that impacted on their availability.	**Improvement point 1** We identified there was a backlog of patients own CD medication awaiting collection by Pharmacy for disposal. Pharmacist should prioritise the collection of patients own CD medication to allow timely disposal.	**Action :** This action is specific to WGH. Actions: Briefing to nursing teams to ensure timely requests for destruction of patients own controlled drug medicines are made to the pharmacy team to ensure that this task is prioritised **Responsible Officer:** Jin Hah Lead Pharmacist WGH Site **Executive Lead:** Scott Garden _ Director of Pharmacy **Due Date:** January 2024

Detailed findings

Objective 2.	Are Board's staff appropriately trained in the safe management of medication and recognise their individual responsibilities to ensure medication is securely stored and safely administered ?	Moderate Assurance

Finding and implication	Audit recommendation	Management response, including actions
Medicine management procedures are incorporated as part of the new staff induction programme and there is medicine competency document used in some areas , however we were told this has not regularly reviewed and there is no requirement to complete refresher training of competencies unless staff are involved in an incident. Furthermore, there is no requirement to complete a mandatory medicines management update periodically which we have frequently seen in other similar organisation. **(Recommendation 5)** All nurses new to NHS Lothian are expected to complete a competency document. This is used in capability assessments and is completed locally by Charge Nurses or local educators. In the clinical areas we visited Charge Nurses reported new staff are supported by Clinical Educators and Preceptors to achieve competency in the management of medicines and are not required to taken on the responsibility of medicines until the competencies have been signed off by a senior member of the team and the new staff member is confident. However, some staff told us there has been pressure to pass the competencies to reduce the reliance on Bank and Agency staff. In one area a ward induction checklist had been developed for new staff who are recruited. This document includes the ordering of medication and CDs, the borrowing of medication from other wards. However, this remains a challenge when there the ward experiences high reliance on the use of Agency and Bank staff. Centrally a Newly Qualified Nurses and Midwives Program (NQNM)has been developed. We were told this course is not only for NQNM and sometimes includes staff who are invited back due to capability assessment. There is also extended training provided for any registered nurse required to administer Intravenous Therapy. This training was reported to be readily accessible by Charge Nurses and is supported by comprehensive pre learning that reinforces the key principles of professional. However, bookings for this training is reliant on the Charge Nurses booking staff on the study days as it's not mandatory. This may result in staff not accessing training as all area Charges Nurses we spoke to acknowledged it has been a challenge to release staff to complete non mandatory training. **(Recommendation 6)**	**Recommendation 6** To improve attendance at the Newly Qualified Nurses and Midwives Program and at bespoke training developed in response to incidents the Trainer should be provided with a list of all staff who are eligible or required to complete the training to allow assurance it is being appropriately cascaded.	**Action:** All newly qualified practitioners will attend medicines management as part of induction and will have access to attend additional sessions open to all NMC registrants. This will be in addition to their essential medicines management e-learning. Compliance will be monitored and escalated as appropriate by the Clinical Skills Team. **Responsible Officer:** Kirsten Hood – Strategic Lead of Practice Learning and Fiona Pollock - Clinical Sills Team Leader **Executive Lead:** Alison MacDonald – Executive Director of Nursing, Midwifery & Allied Health Professionals. **Due Date:** January 2024

Detailed findings

Objective 2.	Are Board's staff appropriately trained in the safe management of medication and recognise their individual responsibilities to ensure medication is securely stored and safely administered ?	Moderate Assurance

Finding and implication	Audit recommendation	Management response, including actions
The staff also required to complete a learn pro module on the electronic medicines administration system. This is mandatory for all staff using HEPMA. The organisations electronic prescribing system. Before staff are given access to the system, they are required to provide proof that the HEPMA learn pro has been completed to IT services. This provides a level assurance the system cannot be accessed by unauthorised personnel. Additional specialised training has been developed in response to incidents such as the safe use of Clozapine and CD drug training and we heard examples of how learning has been shared between sites where appropriate and this reduces the duplication of work. However, there is a lack of clarity if all the required staff have accessed the training and concerns were raised that staff may not be released for training due to staffing challenges, **(Recommendation 6)** In some areas we visited staff told us that the allocated Pharmacists have provided some ad hoc medicines training in response to a new drug being added to the Ward stock or following an incident or near miss and at the Royal Edinburgh Hospital a Medicines Management Update has been produced to share learning. However, there was limited awareness of these updates among the staff we spoke to at the Royal Edinburgh, and this is not a standardised practice in all areas. The identification of medication training requirements are driven by the review of adverse incidents reported on Datix the Boards incident reporting system. All incidents involving medicines are reviewed by the Medicine Management Nurses who identifies themes and develops and delivers appropriate training resources to raise staff awareness e.g. Clozapine and CD training. However, the Medicines Management Nurses are not routinely sighted on audit findings related to medicines and the CD Governance Team are not sighted on the compliance and outcome of quarterly CD audits and this would improve oversight of compliance and identify any areas that require targeted training. **(Recommendation 7)**	**Recommendation 7** To improve oversight and compliance with the safe and secure management of medicines the Lothian NHS Board should: ▪ Strengthen their process for sharing the outcome of audits related to medicines and the associated learning with staff and Pharmacy services. ▪ Incorporate a medicines storage module into the PCAT and LACAS audit tool . This would provide a regular oversight of compliance with medicines management. To strengthen the quality of the audits Lothian Board should consider the implementation of a peer review process to gain improved objectivity of an areas medicine management arrangements. ▪ Develop a formalised spot check template that can be completed on any environment walk around by Pharmacists and Clinical Ward Managers . To provide increased formal oversight of compliance with medicines management arrangements.	**Actions:** National Acute Pharmacy Service (NAPS) Group have an existing Task & Finish Group developing the core actions related to medicines governance and management that are routinely identified from HIS visits to acute hospital sites into a checklist for audit. This check list of required elements will be delivered April 2024 to NAPS and Directors of Pharmacy for approval and engagement with SEND/ Acute Nurse Leads of how to best implement in Health Boards. In NHS Lothian, the preferred option is to integrate into LACAS ad PCAT for a single approach to governance and assurance. Any necessary themes and improvements can then be managed through the same single process. **Responsible Officer:** Laura Inglis- Head of Nursing Quality Improvement and Standards Gillian McAuley -Director of Nursing , Craig Stenhouse - Deputy Director of Nursing Melinda Cuthbert- Associate Director of Pharmacy **Executive Lead:** Scott Garden Director of Pharmacy and Alison MacDonald – Executive Director of Nursing, Midwifery & Allied Health Professionals. **Due Date:** September 2025

Detailed findings

Objective 3.	Does the Board have adequate arrangements in place to monitor compliance with its medicines management policy and take action where compliance is sub-standard?	Moderate Assurance

Finding and implication	Audit recommendation	Management response, including actions
NHS Lothian has two embedded monitoring tools that provide some level of oversight medicine management compliance. Reviewing compliance with medicine review , reconciliation and staff awareness of administration processes. However, these tool contain limited formal monitoring of the safe and secure storage arrangements for medication. **(Recommendation 7)** The Patient Care Assurance Tool (PCAT) is completed monthly by the Charge Nurse and recorded on MEG the organisations electronic quality and risk system and informs the Quality managers of areas of general risk. In addition, the Lothian Accredited Care Assurance Standard (LACAS) is completed biannually. This review is undertaken by the Charge Nurse and the Clinical Nurse Manager, and the outcome is presented to the monthly Clinical Managers Group where themes and trends are reviewed. We were told the LACAS review will also incorporate the Clinical Nurse Manger undertaking a walk round of the clinical area and would include feedback on any identified medicines management arrangements. However, the staff we spoke to were unclear of any process to monitor the completion of actions identified by the PCAT and LACAS and this may limit sustainable progress in addressing gaps in compliance. **(Recommendation 8)** There is also a quarterly audit of CD in line with national guidance undertaken by Ward Pharmacists and Charge Nurses. However, staff reported the frequency of the audits was variable, and this was attributed to workforce challenges in Pharmacy. This may explain the delay in identifying the non-complaint process for monitoring CDs on ward 202.	**Recommendation 8** To improve awareness and ownership of areas of poor compliance with medicines management the Quality Lead should develop a process to monitor the completion, sustainability and effectiveness of actions implemented to address areas of non-compliance. In addition, further improvement is required to establish a formal process to allow the learning and outcome of audits to be effectively shared.	**Actions:** This will be incorporated into the LACAS and PCAT tools with responsibility sitting with the Quality Improvement Resource allocated to these programmes. The responsibility for monitoring through PCAT and LACAS sits with the professional nursing teams on the site, the quality leads take a role in leading the process, validating data, collating reports making recommendations and supporting improvement, but the results and actions are owned by the teams. **Responsible Officer:** Laura Inglis- Head of Nursing Quality Improvement and Standards Gillian McAuley -Director of Nursing , Craig Stenhouse - Deputy Chief Nurse & Professional nursing teams on each hospital site **Executive Lead:** Alison MacDonald - Executive Director of Nursing, Midwifery & Allied Health Professionals. **Due Date** September 2025

Detailed findings

Objective 3.	Does the Board have adequate arrangements in place to monitor compliance with its medicines management policy and take action where compliance is sub-standard?	Moderate Assurance

Finding and implication	Audit recommendation	Management response, including actions
There is also a CD Governance Team who undertake visits across the Lothian Board sites in response to incident or identified concern. Two of the areas we visited reported they had been visited by the CD Governance Team and one had developed an action plan to address the CD Governance Teams findings. Progress and evidence to demonstrate progress with these actions is followed up directly with the CD Governance Team. However, we note that it was at the visit by the CD Team in July 2023 the unsecured access to the clinical room was noted and that it remained unaddressed in September may indicate a need for a more timely follow up. **(Recommendation 8)** In addition, there is a limited oversight of compliance with the quarterly CD audits by the CD Governance Team to allow transparency in areas with limited oversight. **(Improvement point 2)** The Charge Nurses who accompanied our visits to each area were aware of the outcome of audits however the outcome of audits had not always been cascaded to the ward staff and it was reported this was a challenge due to the frequent use of Bank and Agency staff. **(Recommendation 8)**	Improvement Point 2 To improve the oversight of compliance with the quarterly CD audits the CD Governance Team should receive a quarterly report to allow the identification of themes to inform future training, and any areas with limited oversight.	**Action:** Pharmacy 4 monthly checks – CD Governance team awareness (as per Objective 1, recommendation 3). Centalised collation of completed 4 monthly Controlled Drug Check for Schedule 2 Controlled Drugs completed by the pharmacy teams will support a review of common themes and identify area where these checks have not been completed within the expected timeframe. A review of the questions within this check will also be completed to ensure this supports the updates to the controlled drug section within the SUMP which is due to be launched March/April 2024. **Responsible Officer:** Debbie Alexander- Lead Pharmacist CD Governance **Executive Lead:** Scott Garden – Director of Pharmacy **Due Date:** April 2024

Appendices

Appendix 1 Sample testing – medicine management compliance – Western General

We have undertaken visits to 3 nominated areas at the Western General Site. We have RAG rated the compliance with the Board's medicines management policy and best practice using our RAG rating definitions below. We saw variable compliance with the management of medicines in all areas visited.

Area visited	Secure Storage	Safe Storage	CD Management	Storage of IV fluid	Cold Chain management	POD Arrangement	Emergency Equipment	Medical Gases	Stationary storage	Drug disposal	Stock levels displayed	Staff knowledge
Ward 23												
Medical Assessment Unit												
Ward 70 (MOE)												

Appendix 1 Sample testing – medicine management compliance – Western General

We visited 3 pre-selected areas within the Boards Western General Hospital Site. Our key finds are listed below.

- Compliance with the management of medicines policy at the Western General Hospital was variable . Staff reported they felt well supported by the pharmacy service and in the areas with an allocated Pharmacy Support worker staff recognised this had assisted in improving the effective management of medicines.
- In one area it was noted the Clinical room had no door to secure access due to estates issues. The Clinical rooms in the other two areas was restricted by the use of digi - locks. However, all staff on the wards registered and non-registered have unrestricted access to the Clinical room including Band, Agency and domestic staff and staff were unaware if the key codes required regular changing as we have seen in other hospitals we have reviewed. In two of the wards, we identified cupboards containing medication had broken locks that had not been reported. In addition, on ward 23 the box containing drugs for return to pharmacy was not securely stored. This resulted in medicines being accessible to unauthorised personnel. **(Recommendation 1)**
- There was good separation of medication aligned to the required route of administration and strength. Medication stock lists were displayed, and medicines are generally stored in the original packaging. However, we did note some unidentified medication in a medicine pot within a POD on ward MAU which we disposed of at the time of our review.
- In all areas there were medication stock lists displayed and had been recently updated. We were told stock levels are reviewed on a regular basis by ward and pharmacy staff.
- IV fluids were well separated however, in two areas (23 & 70) excess stock of IV fluids were stored in unsecured rooms allowing potential access to unauthorised personnel. Furthermore, on ward 70 we identified some out of date IV fluids still available for use. **(Recommendation 2)**
- In two areas (MAU & ward 23) we identified that opened bottles of elixirs did not consistently have the date of opening recorded on them and this results in staff not being aware of when the contents of the bottle should be discarded. **(Recommendation 4)**
- The drug fridges on (MAU & 23) were not locked at the time of our review and we noted there was variable compliance with the monitoring and recording of drug fridge temperatures in these areas. Furthermore, staff told us there was no requirement to record the temperature of the clinical room as we have observed at other Organisations although we noted the clinical rooms were very warm on (23 & 70).**(Recommendation 1)**
- CD and Medication stationary was securely stored in all the areas we reviewed at the Western General however we noted in the CD order book that the receipt of CD medication was not consistently recorded (MAU & 70) and there were occasions that a CD had been ordered and received by the same individual. This is not in line with best practice as outlined in Lothian's Safe Use of Medicines Procedures. This was something staff were not all aware of.
- We noted there was good compliance with the completion of the daily CD checks and the recording of CD disposals in the CD register . However, there was variance in the way staff reported a part does of a CD would be disposed of with some staff saying it would be put in a denaturing pot, some squirted down he sink, and some put into the sharp's container. In addition, on MAU we noted there was a significant backlog of CD awaiting disposal which is reported by staff to take a lot of time to check each day. **(Improvement point 1)**
- Individual POD lockers were all secured although on Ward 23 we identified the duplicate key for the POD lockers was routinely stored in an unsecured folder at the nurse's station. **(Recommendation 1)**
- There is good separation of medicines aligned to the designated route of administration. However, on ward 23 we located a bottle of acetone being stored in a cupboard with oral elixirs. This was removed at the time of our visit. **(Recommendation 4)**
- There was generally good compliance with the completion of the emergency trolley checks.

Appendix 1 Sample testing – medicine management compliance – Royal Infirmary

We have undertaken visits to 3 nominated areas at the Royal Infirmary Site. We have RAG rated the compliance with the Board's medicines management policy and best practice using our RAG rating definitions below

Area visited	Secure Storage	Safe Storage	CD Management	Storage of IV fluid	Cold Chain management	POD Arrangement	Emergency Equipment	Medical Gases	Stationary storage	Drug disposal	Stock levels displayed	Staff knowledge
Ward 109												
Ward 204												
Ward 202 (MOE)												

Appendix 1 Sample testing – medicine management compliance – Royal Infirmary

We visited 3 pre-selected areas within the Royal Infirmary Hospital site. Our key finds are listed below.

- Compliance with the management of medicines policy at the Royal Infirmary Hospital was variable and, staff generally felt supported by the pharmacy services. Although we were told Pharmacy currently had a lot of vacancies.
- There was evidence of medication stock lists being displayed and we were told they would be regularly reviewed although the Pharmacist on 202 reported it was only reviewed every 18 months due to staff levels.
- The access to all clinical rooms we reviewed were secured by Digi -locks and the access was given to all staff registered and non-registered who worked on the ward. However, at the time of the review the digi-lock on 109 was broken. The digi lock breakage had been reported on July 7th, 2023, but remained unresolved at the time of our visit and resulted in unrestricted access to the Clinical room. **(Recommendation 1 & 8)**
- In all areas we noted further work was needed to ensure the secure storage of medicines as cupboards containing medicines on 109 & 204 had been unlocked and on 202 & 109 the drug fridges were not locked. **(Recommendation 1)**
- There was clear separation of medication aligned route of administration and strength on ward 204 and stock levels were displayed. However, there appeared to be less organisation of medicines and clarity of stock levels on 109 & 202 and medication was frequently observed not to be stored within its original package. Which may increase the risk of a medication error. Furthermore, we witnessed steps had been introduced to maintain tighter oversight of schedule 3 drugs by storing them separately. However, we noted on ward 109 multiple blister packs of both gabapentin and pregabalin were found stored together in a separate cupboard to allow increased oversight. However, the multiple blister packs were loose and not in the original packaging. This may make it more difficult to identify if a blister of medication had been diverted and potentially increase the risk of the wrong medicine being administered. **(Recommendation 4)**
- In all the areas visited at the Royal Infirmary we identified that opened bottles of elixirs did not consistently have the date of opening recorded on them and this may result in staff not being aware of when the contents of the bottle should be discarded. **(Recommendation 4)**
- POD lockers at the patient bedside that we inspected were all secured. In the majority of Acute areas, we visited staff reported the drug drawers on the Computer on wheels (CoW)had been removed to prevent staff leaving medications in the drawers . However, this action had not been taken on ward 202 and we found 4 out of the 6 CoWs had drawer containing medication that had been left unsecured in a patient area. This allows unrestricted access to a variety of medicines. Where possible we secured the drawers or moved the CoWs to the clinical room. The nurse in charge was aware this was not in line with Board guidance and reported staffing shortages contributed to the challenge. **(Recommendation 1)**
- IV fluids were separated however, in one areas (204) excess stock of IV fluids was being stored in an unsecured rooms. This allowed unrestricted access to unauthorised personnel. **(Recommendation 2)**
- Drug fridge temperatures were generally completed in line with Board guidance . However, on ward 202 compliance with temperature monitoring was limited . Although the temperature monitoring template requires a signature to indicate the fridge has been cleaned and tidied, we noted this was not routinely documented and on ward 204 we noted the fridge contained out of date medication and 3 vials of insulin that we disposed of. This may indicate the frequent review of drug fridges is not being undertaken. **(Recommendation 4)**
- There was good compliance with the completion of the daily CD count and CD and medication stationary was generally securely stored in the areas we reviewed at the Royal Infirmary. However, on ward 109 & 202 we noted the medication stationary was not securely stored an on 202 the CD register had also been left out on the side in the Clinical room. A review of the CD register showed that the index page had not been completed and staff were checking the drugs against page numbers in the CD register. This is not in line with national guidance and was escalated to the ward Pharmacist at the time of the review. **(Recommendation 3)**
- A review of the CD order books in all the areas we visited at the Royal Infirmary demonstrated that the receipt of CD medication were not consistently signed for and there were examples in the ward 202 order book that indicated a CD had been ordered and received by the same individual. **(Recommendation 3)**

Appendix 1 Sample testing – medicine management compliance – Edinburgh Royal

We have undertaken visits to 3 nominated areas at the Edinburgh Royal Hospital. We have RAG rated the compliance with the Board's medicines management policy and best practice using our RAG rating definitions below

Area visited	Secure Storage	Safe Storage	CD management	Storage of IV fluid	Cold Chain management	Key Arrangement	Emergency Equipment	Medical Gases	Stationary storage	Drug disposal	Stock levels displayed	Staff knowledge
Margaret Duguid Unit				N/A								
Balcarres Ward				N/A								
Mercaston Ward				N/A								

Appendix 1 Sample testing – medicine management compliance – Royal Edinburgh

We visited 3 pre-selected areas within the Royal Edinburgh site. Our key finds are listed below.

- The access to the clinical rooms we reviewed at the Royal Edinburgh site were all secure at the time of the review. Each area reported that all staff , registered and non - registered required access to the Clinical room. On the Margaret Duguid Unit we found medication (GTN and Ibuprofen gel) left unsecured on the side in the clinical room. **(Recommendation 1)**
- The drug fridges in all areas visited were unsecured as they did not have integrated locks. This allowed access to all staff with access to the Clinical room. We were told that the fridges were of the incorrect specification. **(Recommendation 1)**
- In addition, we identified that opened bottles of elixirs and eye drops were not consistently dated with the date of opening and this may result in staff not being aware of when the contents of the bottle should be discarded. **(Recommendation 4)**
- There was generally good compliance with the monitoring of drug fridge temperatures. However, on the Margaret Duguid Unit compliance with recording the temperature was variable. We were told this may be due to the frequent reliance of Bank and Agency staff to cover night shifts when the temperature checks are completed. In addition, we found an expired GTN spray in a patient's own tray and there were three bottles of expired eye drops that had not been discarded from the drug fridge. We disposed of the expired medicines at the time of the review. This may indicate insufficient oversight of the drug fridge contents. **(Recommendation 4)**
- The stock list for the ward medications were displayed in all the areas we visited and had all been updated within 6 months of this visit. Staff told us that pharmacy service were responsive and stock levels were frequently reviewed. However, on Balcarress and Mercaston wards we identified a significant quantity of expired or no longer required medicines being stored that we were told were waiting for collection by Pharmacy. It was reported the backlog was due to shortages in Pharmacy staff.
- On Balcarres ward we were told extra monitoring and oversight of Temazepam, Morphine Sulphate and Codiene Phosphate tablets had been put in place following concerns of possible drug divergence . Additional measures had also been put in place on the Margaret Duguid Unit, where the benzodiazepines were stored separately and counted at the handover of shifts to maintain timely oversight of their use. There was variance in the level of monitoring and staff were unclear if there was a standardised process **(Recommendation 5)**
- There was consistent compliance across the 3 areas we visited with the daily monitoring and recording of CD medication reviews and the CD stationary was securely stored in line with The Boards 'Safe Use of Medicines' procedure. However, routine medicine order books were kept in an unsecured drawer in the Clinical room of Margaret Duguid which is not in line with the Board procedures. In addition, a review of the CD order books demonstrated that the receipt of CD medication was not consistently being recorded by ward staff and on occasion we noted on both Margaret Duguid and Mercaston that a CD had been ordered and received by the same individual. This is not in line with best practice as outlined in Lothian's Safe Use of Medicines Procedures. **(Recommendation 3)**
- On Margaret Duguid there was limited oversight of the daily checks of the emergency tray in the Clinical room and staff were not clear where to locate the emergency drug box that was established later to be routinely stored with the defibrillator on a neighbouring ward . Furthermore, staff were not familiar with the Medicines homepage on the intranet. **(Recommendation 5)**

Appendix 2: Areas visited

Western General site

- Ward 23
- Medical Assessment Unit
- Ward 70 (MOE)

Royal Infirmary site

- Ward 109
- Ward 204
- Ward 202 (MOE)

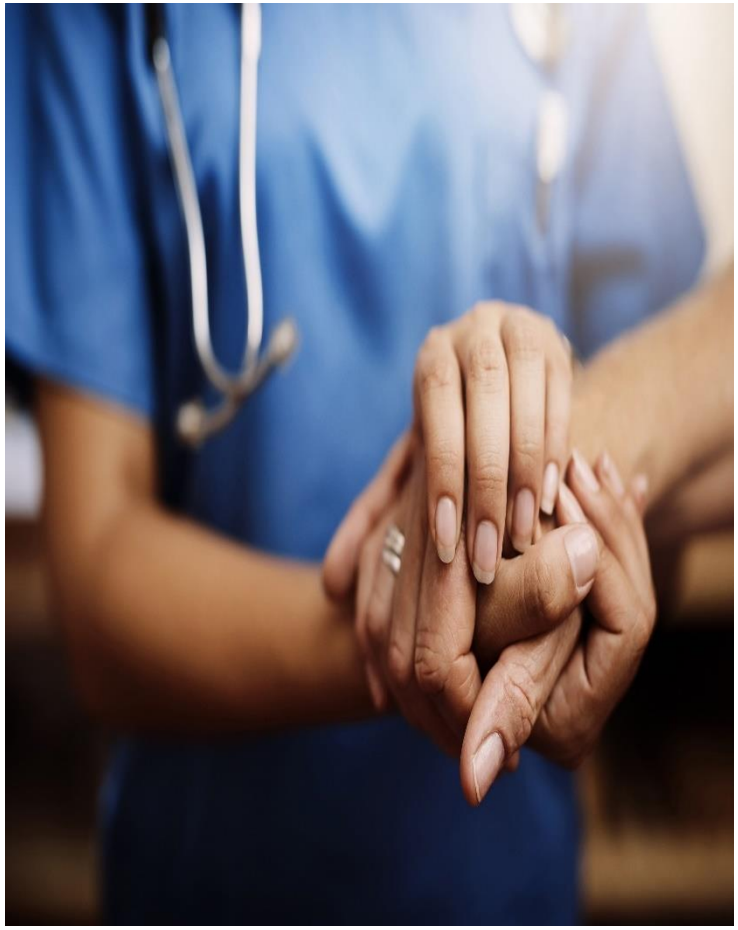
Royal Edinburgh site

- Balcarres Ward
- Margaret Duguid Unit
- Mercaston Ward

Appendix 2:
Staff involved

Staff involved

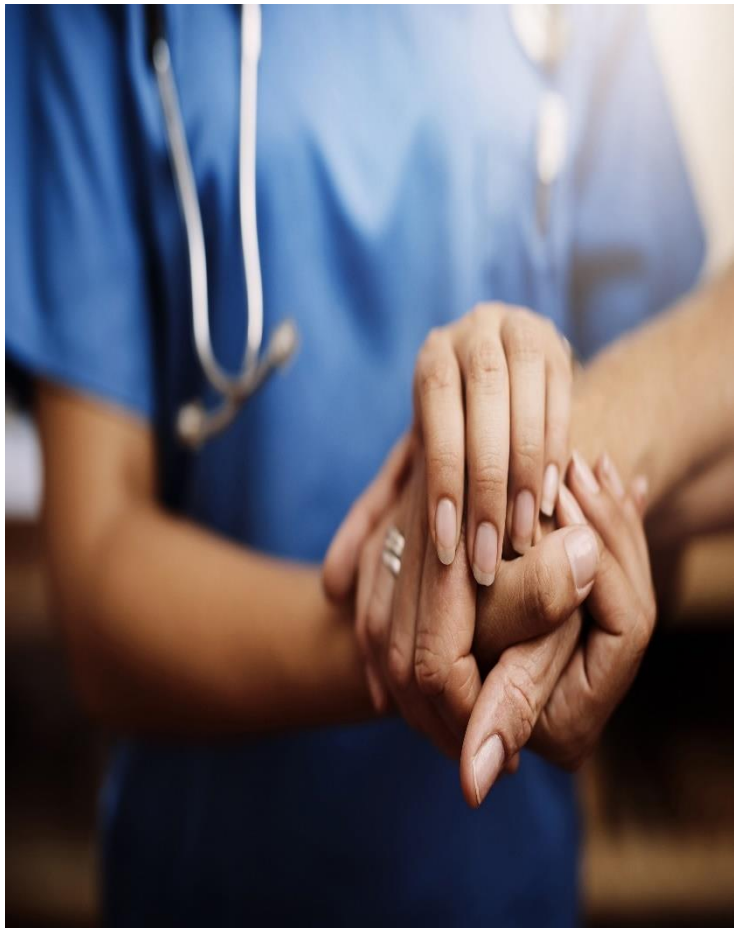
- Scott Garden – Director of Pharmacy
- Melinda Cuthbert – Associate Director of Pharmacy
- Gillian McAuley – Director of Nursing -Acute
- Craig Stenhouse – Deputy Chief Nurse for the Royal Edinburgh Hospital
- Stuart Currie – Medicines Management Nurse (REAS)
- Fiona Pollack – Clinical Skills Team Leader
- Christine Austin- Medicines Management Nurse – St John's Hospital
- Debbie Alexander – Lead Pharmacist Controlled Drug Governance and Medicine Safety | Deputy Controlled Drug Accountable Officer



Appendix 3:
Documents reviewed

Documents reviewed

- Safe Use of Medicines Procedures 2022
- Safe Use of Medicines Policy 2019
- Professional Guidance on the Administration of Medicines in Healthcare Settings (Jan 2023)
- Pharmacy Support worker Job Description
- Administration of Prescribed Medicines By Registered Nurse/ Midwife - Clinical Competency
- Examples of Medicine Management Updates from the Royal Edinburgh Hospital - 2022/23
- Clozapine training presentation
- Controlled Drug Awareness presentation
- PCAT –Medicines template
- LACAS – Medicines template
- Medicines Management induction for newly qualified practitioners' presentation



Appendix 4:
Our assurance levels

The table below shows the levels of assurance we provide and guidelines for how these are arrived at. We always exercise professional judgement in determining assignment assurance levels, reflective of the circumstances of each individual assignment.

Rating*	Description
Significant Assurance	The Board can take reasonable assurance that the system(s) of control achieves or will achieve the control objective. There may be an insignificant amount of residual risk or none at all. There is little evidence of system failure and the system appears to be robust and sustainable. The controls adequately mitigate the risk, or weaknesses are only minor (for instance a low number of findings which are all rated as 'low' or no findings)
Moderate Assurance	The Board can take reasonable assurance that controls upon which the organisation relies to achieve the control objective are in the main suitably designed and effectively applied. There remains a moderate amount of residual risk. In most respects the "purpose" is being achieved. There are some areas where further action is required, and the residual risk is greater than "insignificant". The controls are largely effective and in most respects achieve their purpose with a limited number of findings which require management action (for instance a mix of 'medium' findings and 'low' findings)
Limited Assurance	The Board can take some assurance from the systems of control in place to achieve the control objective, but there remains a significant amount of residual risk which requires action to be taken. This may be used when: • There are known material weaknesses in key control areas. • It is known that there will have to be changes that are relevant to the control objective (e.g. due to a change in the law) and the impact has not been assessed and planned for. The controls are deficient in some aspects and require management action (for instance one 'high' finding and a number of other lower rated findings)
No assurance	The Board cannot take any assurance from the audit findings. There remains a significant amount of residual risk. The controls are not adequately designed and / or operating effectively and immediate management action is required as there remains a significant amount of residual risk (for instance a number of HIGH rated recommendations)

Appendix 4:
Our recommendation ratings

The table below describes how we grade our audit recommendations based on risks:

Rating	Description	Possible features
High	Findings that are fundamental to the management of risk in the business area, representing a weakness in the design or application of activities or control that requires the immediate attention of management	• Key activity or control not designed or operating effectively • Potential for fraud identified • Non-compliance with key procedures/standards • Non-compliance with regulation
Medium	Findings that are important to the management of risk in the business area, representing a moderate weakness in the design or application of activities or control that requires the immediate attention of management	• Important activity or control not designed or operating effectively • Impact is contained within the department and compensating controls would detect errors • Possibility for fraud exists • Control failures identified but not in key controls • Non-compliance with procedures/standards (but not resulting in key control failure)
Low	Findings that identify non-compliance with established procedures, or which identify changes that could improve the efficiency and/or effectiveness of the activity or control but which are not vital to the management of risk in the business area.	• Minor control design or operational weakness • Minor non-compliance with procedures/standards
Improvement	Items requiring no action but which may be of interest to management or which represent best practice advice	• Information for management • Control operating but not necessarily in accordance with best practice