Internal Audit

Medicines Management on Wards

July 2018

Internal Audit Assurance assessment:

Objective One	Objective Two	Objective Three	Objective Four	Objective Five	Objective Six
Significant Assurance	Significant Assurance	Moderate Assurance	Significant Assurance	Moderate Assurance	Moderate Assurance

Timetable

Date closing meeting held: No meeting held, client responded directly to draft report

Date draft report issued: 8 June 2018

Date management comments received: 25 June 2018

Date Final report issued: 3 July 2018

Date presented to Audit and Risk Committee: 27 August 2018

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1. Introduction

1.1 All areas where medicines are handled must have a system of procedures that meet legal requirements, in line with national guidance, and that ensures that risks to patients and staff are managed effectively.

1.2 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 Policy & Procedures covers topics such as stock-ordering, storage of medicines, record-keeping and physical security. Specific sections within the Policy & Procedures stipulate additional requirements for managing Controlled Drugs, with Charge Nurses having overall responsibility for medicines held on wards.

1.3 NHS Lothian's Clinical Medicines Management Group (CMMG) supports compliance with the NHS Lothian Safe Use of Medicines Policy & Procedures and other relevant policy / legislative requirements. Although not mandatory, the CMMG encourages wards to complete annually a Safe Handling and Security of Medicines self assessment.

1.4 Clinical governance and oversight is provided by the Lothian Area Drug and Therapeutics Committee (ADTC). Its purpose is to ensure that adequate systems and processes relating to medicines governance are in place in local NHS Boards. The ADTC is supported in its role by several subcommittees, including the University Hospitals Division Drug & Therapeutics Committee (UHD D&TC) and Hospital & Specialist Services Medicines Committee (HSSMC).

Scope

1.5 This review assessed the adequacy and effectiveness of internal controls on medicines management in wards within an acute setting, including stock control, monitoring arrangements and physical security. This included the controls governing both controlled and other medicines.

1.6 Fieldwork was carried out at the Royal Infirmary, Royal Hospital for Sick Children, St, John's and the Western General hospital sites, across nine wards.

Acknowledgements

1.7 We would like to thank all staff consulted during this review, for their assistance and cooperation.

2. Executive Summary

Summary of Findings

2.1 The table below summarises our assessment of the risks and the adequacy and effectiveness of the controls in place to meet each of the risk areas agreed for this audit. Definitions of the ratings applied to each action are set out in Appendix 1.

No.	Control Objectives	Assurance Level	Number of findings			
			Critical	High	Medium	Low
1	Medicines are available at the time they are needed.	Significant Assurance	-	-	1	-
2	Medicine stocks are kept at an appropriate range and level to minimise wastage.	Significant Assurance	-	-	-	1
3	Medicine stock ordering is suitably authorised and receipted.	Moderate Assurance	-	1	-	-
4	Stocks of controlled drugs held on wards are managed through regular checking and upkeep of records.	Significant Assurance	-	-	-	1
5	The security and quality of medicines is maintained in all areas where medicines are stored or administered.	Moderate Assurance	-	1	-	1
6	Unwanted and out-of-date medicines are identified and disposed of safely and securely.	Moderate Assurance	-	1	-	-
TOTAL			**-**	**3**	**1**	**3**

Conclusion

2.2 While the Safe Use of Medicines Policy & Procedures sets out clear instructions for managing medicines, the requirements of the Policy & Procedures are not always being followed across wards.

Main Findings

2.3 The Safe Use of Medicines Policy & Procedures sets out clear requirements for managing medicines across wards and other clinical areas. In particular, the Policy & Procedures has specific sections covering ordering, stock control, storage and security, with dedicated sections for controlled drugs.

2.4 Each year, Charge Nurses and Pharmacists review stock lists for individual wards. Stock lists are used to order drugs and help maintain adequate stock holdings. Amendments to the stock lists can also be carried out during the year if necessary. Ward staff are also using appropriate stationary when requesting on-off or emergency medicines out with the normal ordering schedule. The Policy & Procedures also allows wards to borrow medicines from each other.

2.6 The Policy & Procedures directs that stock must be rotated according to expiry dates, so that oldest stock is used first. Wards visited appeared to be following this guidance.

2.7 Requirements for the security of drugs are set out in the Safe Use of Medicines Policy & Procedures. This has ensured that drugs cupboards are appropriate for the safe and secure storage of medicines, including the additional storage requirements for Controlled Drugs. Keys for accessing the drugs cupboards are also subject to appropriate controls, with keys to the Controlled Drugs and 'other' medicines held separately in accordance with the Policy & Procedures.

2.8 We identified seven issues / improvement opportunities during this review:

<u>High Rating</u>

- When drugs are delivered to wards, nurses are required to sign for deliveries and check and store drugs as soon as possible. Reviewing documents and visiting wards identified a number of instances where checking for drugs received is not being documented. Management should remind ward staff of the importance of keeping complete records around the receipt and handling of medicines.

- Where drugs are held in fridges or freezers, the Safe Use of Medicines Policy & Procedures requires that temperatures are regularly monitored and recorded daily. However this is not always being done by wards, therefore staff should be reminded of the importance of maintaining a complete and up-to-date record of fridge temperature checks.

- The Safe Use of Medicines Policy & Procedures directs that medicines that are expired or no longer required must be returned to Pharmacy with itemised lists. However the use of an itemised list by wards is inconsistent. Wards should be reminded of the requirement of maintaining an itemised list of all medicines removed from cabinets for return to Pharmacy.

Medium Rating

- The review has identified inconsistencies across wards on the use of control documentation when borrowing medicines. Management should remind ward staff of the requirement under the Policy & Procedures to use the appropriate stationery when borrowing drugs between wards.

Low Rating

- All stock lists reviewed for this audit have recorded maximum stock levels; however none have minimum stock levels included, which is a requirement of the Policy & Procedures. Management should consult with Pharmacy the requirement to include minimum stock levels within the ward stock lists. Any decision to maintain the current layout and content of the lists should be reflected in updated Policy & Procedures.

- In addition to 3-monthly checks by Pharmacy, the policy & Procedures requires holding of Controlled Drugs to be checked at least once each day. While 3-monthlyl checks are taking place, one ward visited had not fully complied with the requirement for daily checks.

- Some wards are writing the date liquid medicines are opened on their labels as a means of monitoring when this should be removed and disposed off if unfinished. Ward staff should be reminded to apply reasonable monitoring controls around the use of liquid medicines. This should include recommending that the date after which the medicine should be disposed off be written on bottles in the first instance.

3. Management Action Plan

Finding 1	
Control objective 1: Medicines are available at the time they are needed. **Associated risk of not achieving the control objective: Charges associated with the use of medicines are incorrect.**	**Medium**

Background

According to the Safe Use of Medicines Policy & Procedures, medicines may only be borrowed between wards, theatres and departments when the pharmacy is closed or in a clinical emergency.

The Procedures also advise that a pharmacy order form or medicines transfer record book must be completed for all medicines borrowed whether full packs or single doses, clearly stating the issuing and receiving wards, theatres or departments, and signed by the nurses issuing and receiving. A copy of the form must be retained in the borrowing area and lending area, so that replacement or further supplies may be ordered when the pharmacy opens. A copy must also be sent to the pharmacy so that the medicine can be reissued and costed to the borrowing ward and sent to the ward it was borrowed from to replace the stock (as per instructions on documentation from ward); and a record held.

Observation and Risk

The review has identified inconsistencies across wards on the use of control documentation when borrowing medicines. While two wards of nine visited are completing the ward transfer book, one ward of the two was not routinely passing copies to pharmacy. Elsewhere it was noted that ward transfer record book is not being completed each time medicines are borrowed between wards. Some ward's most recent entries in their books dates from 2015, although charge nurses at these wards have indicated that medicines have been borrowed more recently than that.

Also, one ward visited was unable to locate their record book for review.

Without appropriate use of documentation when borrowing medicines between wards, there is a risk that charges associated with the use of medicines are incorrect, or pharmacy are not provided with an accurate record of the use and requirement of medicines of specific wards, to support review of the ward stock lists.

Also, patient safety on wards may be compromised where there is no adequate audit trail in case of drugs recalls or alerts; or adverse incident investigations where patients have been harmed.

There is also a risk that without the application of appropriate controls, medicines may be illegally diverted by NHS staff, or administered to patients with intent to harm

Recommendation Using advice from Pharmacy, management should review the requirements of the Safe Use of Medicines Policy & Procedures and establish actions to address the use of relevant documentation when wards borrow medicines from each other. Once done, management should obtain regular assurances that wards under their supervision are complying with requirements.	
Management Response Agree that actions need to be put into place to rectify non-adherence to policy. The Management Action The documentation for wards to complete will be discussed at the Pharmacy Operations Group for agreement of consistency of process across sites. Once done, Site Lead Pharmacists and their teams will implement this and instruct ward areas of the correct process for the transfer of medicines. Clinical Pharmacy Service and Associate Nurse Directors and their teams will undertake reviews of ward transfer documentation as part of their regular ward checks.	
Responsibility: Nurse Director - Acute Services Associate Nurse Directors Clinical Nurse Managers Associate Director of Pharmacy (Acute & SCAN) Lead Clinical Pharmacists and Clinical Technicians	Target date: 30 December 2018

Finding 2	
Control objective 2: Medicine stocks are kept at an appropriate range and level to minimise wastage. **Associated risk of not achieving the control objective: Wards are unable to provide drugs when they are required.**	**Low**

Background

Charge Nurses and their responsible pharmacists have agreed medicine stock lists which reflect the needs of the parent group in clinical areas, and are in line with agreed formularies. The ward stock lists are used to order a number of medicines to an agreed schedule.

The Safe Use of Medicines Policy & Procedures (SUMPP) advises that stock lists must be reviewed and updated regularly, and contain the list of the names an forms of all medicines required, including the minimum stock level that must be held.

Observation and risk

While it has been confirmed that ward stock lists are subject to review throughout the year, all stock lists reviewed for this audit have recorded maximum stock levels, however none have minimum stock levels included.

The inclusion of minimum levels in medicines stock ordering is to prevent stock from running out and the submission of emergency pharmacy order forms.

Recommendation

Management should confirm with Pharmacy the requirement to include minimum stock levels within the ward stock lists. Any decision to maintain the current layout and content of the lists should be reflected in updated Policy & Procedures.

Management Response

This recommendation will be referred to the Medicines Policy Group (who maintain the Policy & Procedures) to consider if the inclusion of minimum quantities would be the desired way forward or whether it introduces more risk to the system. Once a decision has been made, this will be communicated to the Associate Director of Pharmacy (Acute & SCAN) who will take any appropriate actions needed with the pharmacy team.

Pharmacy Medicines Management Team (Acute) is currently updating a stock review report to facilitates the annual stock-list review and simplify the process. This will be shared with clinical pharmacists when available.

The Management Action

The Chair of Medicines Policy Subgroup will discuss the inclusion of minimum quantities at its July 2018 meeting, with feedback provided to the Associate Director of Pharmacy (Acute &

SCAN). The Pharmacy Medicines Management Team (Acute) will share updated stock review report with clinical pharmacists to support the annual stock list review.	
Responsibility: Chair of the Medicines Policy Group Associate Director of Pharmacy (Acute & SCAN) Site Lead Pharmacists/ Pharmacy Medicines Management Team (Acute)	Target date: 30 September 2018

Finding 3	
Control objective 3: Stock ordering is suitably authorised and receipted. **Associated risk of not achieving the control objective: Discrepancies of drugs held at the ward may not be identified and followed-up.**	**High**

Background

When drugs are delivered to wards by Pharmacy, the Safe Use of Medicines Policy & Procedures requires that nurses sign for deliveries and check and store drugs immediately. If deliveries cannot be checked immediately, they must be stored securely.

Observation and risk

Generally drugs awaiting storage are held in secure areas within wards, however this review has identified inconsistencies around how drugs are being signed for and checked at ward level. Twenty one orders were reviewed across a small sample of wards visited; with three orders (14%) demonstrating that checks had been carried out on the medicines delivered and signed off using the documentation generated by Pharmacy and accompanying the medicine delivery. For the remaining 18 orders (86%), documentation had either been left entirely blank or showed evidence of checking, but no sign-off. Testing was suspended at 5 wards (of nine visited) where staff advised that the checking and sign-off of order documentation was not carried out at all.

Individuals responsible for the receipt, checking and storage of medicine orders should be easily identified in the event of identifying any discrepancies on the quantity of drugs held. Also, wards are expected to present for audit purposes documentation that clearly demonstrates that delivered medicines have been checked by an identifiable member of staff.

Recommendation

Using advice from Pharmacy, management should review the requirements of the Safe Use of Medicines Policy & Procedures and establish actions to address the completion of relevant documentation when receiving medicines through pharmacy orders.

Once done, management should obtain regular assurances that wards under their supervision are complying with requirements.

Management Response

Agreement that the policy was found not to be complied with and is essential for the safe storage of medicines.

The Management Action

Establish and implement the correct procedure and process for the receipt, checking and

storage of medicines. Improved compliance will be monitored with regular ward visits by the Clinical Nurse Manager's and incorporated into the Clinical Medicines Management Group education programme.	
Responsibility: Nurse Director - Acute Services Associate Nurse Directors Clinical Nurse Managers	Target date: 30 December 2018

Finding 4	
Control objective 4: Stocks of controlled drugs held on wards are managed through regular checking and upkeep of records. **Associated risk of not achieving the control objective: The loss of controlled drugs is not identified promptly.**	**Low**
Background In addition to 3-monthly checks by Pharmacy, the Safe Use of Medicines Policy & Procedures requires holdings of Controlled Drugs to be checked against Controlled Drugs Record Books at least once each day, with checks recorded and witnessed. Observation and risk While the 3-monthly checks are taking place, one ward visited had not fully complied with the requirement for daily checks, with one day missed across a three month period. Reconciliation checks are a useful means of identifying discrepancies and the potential loss of Controlled Drugs.	
Recommendation With advice from Pharmacy, management should request that senior ward staff regularly review their controlled drugs records. Where gaps or discrepancies are identified through review of the daily reconciliation checks, this should be raised immediately with ward staff and Pharmacy informed.	
Management Response The audit evidenced overall good compliance with this element. The Management Action Reinforce the correct process and procedure as part of the ongoing training and education programme associated with the Clinical Medicines Management Group. Spot checks will be periodically undertaken by the Clinical Pharmacists and Clinical Technicians for the given specialist area(s).	
Responsibility: Lead Clinical Pharmacists and Clinical Technicians Associate Nurse Directors Clinical Nurse Managers	Target date: 30 December 2018

Finding 5	
Control objective 5: The security and quality of medicines is maintained in all areas where medicines are stored or administered. **Associated risk of not achieving the control objective: Liquid medicines held at wards may not be used appropriately.**	**Low**

Background

Good practice from the Safe Use of Medicines Policy & Procedures advises that stock must be rotated according to the expiry date so that oldest stock is used first.

Observation and risk

While this is being done, it was noted that staff are writing on the labels the date that liquid medicines are opened, as opened medicine will have a shorter shelf life.

However, the adding of the date the medicine was opened requires staff to calculate the date in the future when the medicine should be removed each time it is used. It has also been noted that two of the nine wards visited were not writing the date opened on the labels.

If the staff member opening a liquid bottle in the first instance writes the calculated date the medicine should be removed from storage, this would avoid having to do this each time the medicine is used and prevent potential errors in the calculation.

Recommendation

Ward staff should be instructed to apply reasonable monitoring controls around the use of liquid medicines. It is further recommended that the date after which the medicine should be disposed off be written on bottles when used in the first instance.

Management Response

Can see the rationale for this recommendation but consideration will need to be given to how this might be best achieved due to the intervariability of expiration periods for medicines.

The Management Action

This recommendation will be considered by the Pharmacy Dispensary Managers Group and communicated back to Pharmacy Operations Group for final decision. Once approved by the Pharmacy Operations Group it will then be communicated to the Nurse Director - Acute Services to advise nursing teams accordingly; and for implementation on sites.

Responsibility:	Target date:
Nurse Director – Acute Services	30 November 2018

Associate Nurse Directors Clinical Nurse Managers Associate Director of Pharmacy (Acute & SCAN) Pharmacy Dispensary Managers Group Pharmacy Operations Group	December 2018

Finding 6	
Control objective 5: The security and quality of medicines is maintained in all areas where medicines are stored or administered. **Associated risk of not achieving the control objective: Medicines may become spoiled and require disposal.**	**High**

Background

Where drugs are held in fridges or freezers, the Safe Use of Medicines Policy & Procedures requires that temperatures are regularly monitored and recorded daily. Documentation provided through the Policy & Procedures is designed to allow staff to enter date and initials to confirm checks twice each day.

Observation and risk

Of the nine wards visited that used fridges to store medicines, four had complete records. Of the other five wards, the completeness of records varied. For example, some wards were completing documentation only once each day, where others had no information entered at all. Also, one ward is using an old style form which required one check each day.

There is a risk that without regular checks of the fridge temperatures, medicines must be stored within the recommended temperature range to prevent decrease in efficacy of the medicine or premature expiration of the product resulting in destruction and wastage. Prompt identification of a fault or unintended temperature excursion reduces the risk to the medicine and ensures remedial action can be taken to address the cause (e.g. faulty fridge; overfilling causing poor temperature circulation; thermometer not reset after door left open for extended period to place new stock).

Recommendation

Ward staff should be instructed of the importance of maintaining a complete and up-to-date record of fridge temperature checks. The current form used for this should be redistributed for wards to replace any older versions that they are using. Management should request confirmation from senior ward staff that the daily checks are occurring in accordance with the Policy & Procedure's requirements.

Management Response

Incomplete record keeping is an omission and the importance of maintaining a stable drug fridge temperature is recognised as important.

The Management Action

The checking of drug fridge temperature charts to be part of the Clinical Nurse Managers' checklist. Charge Nurses will be advised of the correct form to use when recording fridge

temperature checks.	
Responsibility: Nurse Director – Acute Services Associate Nurse Directors Clinical Nurse Managers	Target date: 30 December 2018

Finding 7	
Control objective 6: Unwanted and out-of-date medicines are identified and disposed of safely and securely. **Associated risk of not achieving the control objective: drugs may be removed or lost.**	**High**

Background

The Safe Use of Medicines Policy & Procedures directs that medicines that are expired or no longer required must be returned to Pharmacy with itemised lists accompanying them.

Observation and risk

Of the eight wards visited that are likely to return medicines to Pharmacy the use of an itemised list is inconsistent. While all will occasionally return medicines to pharmacy, only one ward visited confirming that itemised lists are provided along with the returned medicines. Also, one ward advised that the box used to hold medicines awaiting return to the pharmacy is not stored securely in a lockable cupboard.

Without reasonable controls over the security and content of unwanted medicines, there is a risk that drugs may be removed or lost.

Recommendation

With advice from Pharmacy, management should request that senior ward staff maintain itemised lists of all medicines removed from cabinets for return to Pharmacy. Where the secure storage of these medicines cannot be assured until uplift, appropriate steps should be taken to prevent unauthorised or inappropriate access.

Management Response

Agreement that the policy was found not to be complied with and is essential for the safe storage and destruction of medicines.

The process for return of out-of-date medicines from clinical areas to pharmacy for destruction is outlined in the Policy & Procedures under Section 15.1.6 and states: *"An itemised list, using the appropriate paperwork, containing the name, strength and form of the medicine, and the quantity being returned, must accompany all medicines returned to the pharmacy. If this is patients' own medication then only the name of the individual patient is required."*

If nursing staff are uncertain what paperwork to complete they should check with their clinical pharmacy team member.

Ward areas normally have a dedicated container/cupboard in their clean rooms for to store these medicines until they can be returned to pharmacy. If the security of the outer door is

<table>
<tr><td colspan="2">maintained to the rooms containing these medicines then there should not be inappropriate or unauthorised access to these medicines.

The Management Action

Reinforce correct process for the safe disposal and security of expired medicines; and ensure that wards are aware of the appropriate documentation to be completed each time these medicines need to be returned to pharmacy for destruction.

The security of the outer doors for the clean room containing medicines cupboards must be maintained at all times (i.e. doors should be closed and locked (if not keypad entry) at all times when there is not a member of staff present in the room.

Clinical Pharmacy Service and Associate Nurse Directors and their teams, undertake reviews as part of their regular ward checks.</td></tr>
<tr><td>Responsibility:

Nurse Director – Acute Services

Associate Nurse Directors

Clinical Nurse Managers

Clinical Pharmacy Service</td><td>Target date:

30 December 2018</td></tr>
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Appendix 1 - Definition of Ratings

Findings and management actions ratings

Finding Ratings	Definition
Critical	A fundamental failure or absence in the design or operating effectiveness of controls, which requires immediate attention
High	A key control failure has been identified which could be either due to a failure in the design or operating effectiveness. There are no compensating controls in place, and management should aim to implement controls within a calendar month of the review.
Medium	A control failure has been identified which could be either due to a failure in the design or operating effectiveness. Other controls in place partially mitigate the risk to the organisation, however management should look to implement controls to fully cover the risk identified.
Low	Minor non-compliance has been identified with the operating effectiveness of a control, however the design of the control is effective

Report ratings and overall assurance provided

Report Ratings	Definition	When Internal Audit will award this level
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 one Critical finding or a number of High 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)
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)
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)