

Internal Audit



Medicines Management on Wards

March 2014

Overall Opinion	Requires Improvement
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Executive Summary

Overall opinion	Requires improvement
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Risks	Control Opinion
Medicines are not available when required	Satisfactory
Excessive stock levels are held	Satisfactory
Drugs are lost or stolen	Requires improvement

Overall opinion

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

To promote the holding of adequate stock levels, Charge Nurses and Pharmacy review the requirements of wards and other clinical areas individually each year. Pharmacy has pre-agreed schedules for receiving and delivering routine orders, as well as clinical areas being able to place one-off orders or borrow stock from each other.

The Safe Use of Medicines Policy & Procedures stipulates minimum requirements for drug cupboards, as well as security over keys and controlled stationery. During the audit, examples were found of drugs not being held as securely as expected and staff not fully complying with the Safe Use of Medicines Policy & Procedures.

Stock-holdings and availability

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 stock-control, storage and security, with dedicated sections for Controlled Drugs.

Each year, Charge Nurses and Pharmacists aim to review stock-lists for individual wards and clinical areas. Stock-lists are used to order drugs and help maintain adequate stock-holdings. As at October 2013, figures reported by Pharmacy indicate some slippage in keeping the review of stock-lists up to date, with Pharmacists explaining that work associated with implementing a new IT system has taken priority (issue 4).

Pharmacy has pre-agreed schedules for receiving and delivering routine orders for wards and clinical areas. Where necessary, wards and other areas can place one-off orders. Also, the Safe Use of Medicines Policy & Procedures allows wards to borrow medicines from each other. However, wards are generally not completing the correct paperwork (issue 2).

The Safe Use of Medicines Policy & Procedures directs that stock must be rotated according to expiry dates, so that oldest stock is used first. Wards and clinical areas visited during the audit appeared to be following the practice. However, records were not kept by nearly all areas with fridges or freezers to confirm that temperatures were being monitored (issue 2).

Physical security

Requirements for the security of drugs are set out in the Safe Use of Medicines Policy & Procedures. For example, the Policy & Procedures requires drug cupboards to comply with British Standards, with additional requirements where large amounts of Controlled Drugs are held. During the audit, neither Pharmacy nor Estates could confirm that cupboards meet the British Standard, with none of the cupboards inspected marked to confirm compliance. Also, the Policy & Procedures sets out clear requirements for the holding of keys to drug

cupboards, as well as controls over duplicate keys. Only in about a third of areas were keys generally managed in compliance with the Policy & Procedures (issue 1).

When drugs are delivered to wards or clinical areas, nurses are required to sign for deliveries and check and store drugs immediately. If deliveries cannot be checked immediately, deliveries must be stored securely. Reviewing documents and visiting wards raised concerns that about half of wards are not adequately checking and securing drug deliveries (issue 1).

In addition to 3-monthly checks by Pharmacy, the Policy & Procedures requires holdings of Controlled Drugs to be checked at least once each day. While 3-monthly checks are taking place, nearly all areas visited had failed over the past 3 months to carry out daily checks (issue 2).

The Policy & Procedures states that all stationery used to order drugs is classified as controlled stationery. In almost a quarter of areas, stationery and records were not being held securely (issue 2).

Following an internal audit report issued in June 2010, Nursing agreed to risk-assess the practice whereby wards do not keep records of drugs received, issued or held (other than Controlled Drugs). However, the risk-assessment does not appear to have taken place, potentially leaving residual risks that may exceed what is considered acceptable (issue 3).

The Controlled Drugs Governance Team monitors trends in the ordering of Controlled Drugs. Any anomalies found with Controlled Drugs are advised to Site Leads to follow up with Clinical Pharmacists. The Controlled Drugs Governance Team investigates any significant concerns. (The functions performed by the Controlled Drugs Governance Team were outside the scope of the audit.)

Background, Objective & Scope

Background

Stocks of medicines held by wards and clinical areas are supplied by the pharmacy departments at the main hospital sites.

As well as other aspects, the Safe Use of Medicines Policy & Procedures sets out the framework for managing medicines held by wards. The policy covers topics such as stock-ordering, storage of medicines, record-keeping and physical security. Specific sections within the Safe Use of Medicines Policy & Procedures stipulate additional requirements for managing Controlled Drugs. Responsibility for medicines held on wards lies with Charge Nurses.

As well as wards, stocks of medicines can be maintained by areas such as theatres, clinics and outpatient departments. Again, the management of medicines is covered by the Safe use of Medicines Policy & Procedures.

Objective

The objective of the audit was to evaluate the adequacy and effectiveness of internal controls over medicines held by wards and clinical areas.

The audit focused on specific risks.

- Medicines are not available when required.
- Excessive stock levels are held.
- Drugs are lost or stolen.

Scope

The scope of the audit included:

- wards, clinics, theatres and outpatient departments;
- stock ordering and receipts;
- storage of medicines;
- record keeping;
- stock checks;
- destruction of medicines on wards; and
- physical security.

The scope excluded:

- issuing medicines from pharmacies;
- administering medicines to patients;
- monitoring done by the Controlled Drugs Governance Team; and
- budgets and finance.

Audit Issues & Recommendations

<p>Issue 1 Significant</p>	<p>Drugs are not being held as securely as required under the Safe Use of Medicines Policy & Procedures</p>
<p>During the audit, 17 wards or clinical areas were visited to review the management of medicines. Across that sample, important security aspects set out in the Safe Use of Medicines Policy & Procedures were not being applied consistently.</p> <p><u>Compliance with British Standards</u></p> <ul style="list-style-type: none"> • The Policy & Procedures requires drugs cupboards to comply with British Standard BS2881, with cupboards to be marked with the security level category. During the audit, neither Pharmacy nor Estates could confirm that cupboards meet the British Standard, with none of the cupboards inspected marked to confirm compliance. Although not necessarily breaching BS2881, 7 out of 17 cabinets for non-Controlled Drugs were wooden rather than metal, and one out of 16 cupboards for Controlled Drugs was wooden. • For Controlled Drugs, the Policy & Procedures advises that compliance with BS2881 may not be sufficient where large amounts of drugs are held or staff are not present 24 hours every day. In such cases, drugs cupboards require to be evaluated against Sold Secure Standard SS304. However, areas that fall into the high-risk category have not been specifically identified for evaluations to be done. <p><u>Control over keys</u></p> <ul style="list-style-type: none"> • Under the Policy & Procedures, duplicate keys to drugs cupboards require to be stored in a locked cabinet. At least once a day, the location and safety of duplicate keys require to be checked. From 15 areas, 7 areas reported that no duplicate keys exist. From the other 8 areas, 3 areas did not know where the duplicate keys were, and the others could not confirm that the location and safety of duplicate keys was checked each day. For one area with 2 wards, duplicate keys to the drugs cupboards are held by a third-party facilities management company, thereby potentially allowing access by staff not employed by NHS Lothian. • Rather than keys, access to drugs cupboards within 2 areas was restricted by use of key-pads. The access codes were apparently known by all nurses, and the codes have not been changed for some time. • With Controlled Drugs requiring to be held in separate cupboards from other drugs, the Policy & Procedures directs that keys for Controlled Drugs cupboards must be kept separate from other keys. From sampling 16 areas that hold Controlled Drugs, 7 areas were not complying with the requirement. • As a separate requirement, duplicate keys for Controlled Drugs cupboards require to be held securely, with records kept of access to keys. Out of 16 areas, 8 areas advised that duplicate keys have never been held, while another 2 areas did not know where the duplicate keys were. From the remaining 6 areas, the duplicate keys for one location are held by the third-party company already mentioned. <p><u>Deliveries to wards</u></p> <ul style="list-style-type: none"> • When drugs are delivered to wards or clinical areas by Pharmacy, the Policy & Procedures requires that nurses sign for deliveries and check and store drugs immediately. If deliveries cannot be checked immediately, deliveries must be stored securely. Reviewing 145 delivery notes held by wards or clinical areas found that 78 	

notes (54%) were not signed to confirm delivery, and 68 notes (47%) were not ticked to indicate that deliveries had been checked. From visiting 53 wards which had recently received deliveries, 25 wards (47%) had not checked deliveries immediately nor adequately secured deliveries waiting to be put away.

Security over medicines trolleys

- According to the Policy & Procedures, medicines trolleys must be locked and immobilised when not in use. Usually, trolleys are secured by being chained to the wall. From inspecting 4 trolleys that held drugs, one trolley which was positioned beside a wall-chain and padlock had not been secured.

Marking of cupboards

- The Policy & Procedures states that drugs cupboards must not be marked to indicate their contents. In 7 out of 17 areas, drugs cupboards were clearly identifiable with signs or lists of drugs attached to cupboard doors.

Without adequate security, the risk is increased that drugs may be lost or stolen.

Recommendation

The Nurse Director should oversee a review of security measures against the requirements of the Safe Use of Medicines Policy & Procedures, with the results reported to the Healthcare Governance Committee. In particular, the review should report on the adequacy of drugs cupboards across NHS Lothian, including arrangements for original and duplicate keys.

Meanwhile, the Nurse Director should reinforce the requirement for drugs to be held securely, including following deliveries from Pharmacy.

Management Response

The issues identified require prompt action and review of practices across NHS Lothian.

Management Action

- 1) The Nurse Director will reinforce, in a letter to nursing staff, the necessity for all drugs to be held securely and in line with the Safe Use of Medicines Policy & Procedure.
- 2) The Director of Pharmacy will write to Estates regarding the compliance of cupboards with the relevant standard and pursue compliance.
- 3) The Nurse Director will commission an action plan to ensure better compliance.

Responsibility:
Nurse Director
&
Director of Pharmacy

Target date:
1) 31 March 2014
2) 31 March 2014
3) 30 September 2014

<p>Issue 2 Significant</p>	<p>Staff are not fully complying with the requirements of the Safe Use of Medicines Policy & Procedures</p>
<p>As well as anomalies regarding security (refer to Issue 1), reviewing practices within 17 wards or clinical areas found examples where staff are not following the Safe Use of Medicines Policy & Procedures.</p> <p><u>Checking of Controlled Drugs</u></p> <ul style="list-style-type: none"> In addition to 3-monthly checks by Pharmacy, the 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. While the 3-monthly checks take place, 14 out of 16 areas have not been fully complying with the requirement for daily checks. Controlled Drugs in one clinic are not checked daily as the clinic does not run each day, and any checks that do take place are not witnessed. For the other 13 areas, checks missed range from one day to 36 days across a 3-month period, with an average of 6 checks missed. At one location, Controlled Drugs are ordered, recorded, administered, checked and destroyed by the same Pharmacist. While entered into the Controlled Drugs Record Book, entries are not always witnessed to confirm what actions have taken place. Also, mistakes made in the Controlled Drugs Records Book are not always being double-signed. Because of costs, the Pharmacist advises that the appropriate crystals are not always used to denature methadone before the drug is flushed down the sink. <p><u>Borrowing medicines</u></p> <ul style="list-style-type: none"> When pharmacies are closed, wards are allowed to borrow medicines from other wards. Despite being a requirement of the Policy & Procedures, only one out of 17 areas completes the correct stationery. While 3 wards have devised their own alternatives, the remaining 13 areas advised that borrowing drugs would not be recorded. (While volumes vary, one ward that keeps records lent drugs to other wards on 38 occasions over a 10-week period.) <p><u>Controlled stationery</u></p> <ul style="list-style-type: none"> The Policy & Procedures states that all stationery used to order drugs is classified as controlled stationery and must be kept securely. From 17 areas, stationery within 4 areas was not locked away, with stationery observed lying on worktops. Also, one area does not lock away the Controlled Drugs Record Book as the book is too large to fit in the cabinet. <p><u>Records of drugs</u></p> <ul style="list-style-type: none"> Although a requirement of the Policy & Procedures, 15 out of 16 areas do not record the number of units of each drug in words. Instead, units are being recorded in figures. (After this point was raised during the audit, the Area Drugs & Therapeutics Committee decided that figures are acceptable.) Under the Policy & Procedures, records relating to Controlled Drugs require to be kept for at least 2 years. From 16 areas, one area only keeps order forms and delivery notes for one year, while another area could not confirm where old documents are kept. A third area had a large pile of documents that had not been sorted or filed. 	

Checking temperatures

- Where drugs are held in fridges or freezers, the Policy & Procedures requires that temperatures are regularly monitored and recorded daily. From 15 areas visited that had fridges or freezers, 13 areas did not keep adequate records.

Return of drugs

- The Policy & Procedures directs that medicines that are expired or no longer required must be returned to Pharmacy with itemised lists. From 10 areas that return drugs, 4 areas advised that Pharmacists collect drugs with no records kept of what has been returned.

Organisation of drugs

- According to the Policy & Procedures, medicines must be stored alphabetically in their original packaging. While drugs in all cupboards inspected were still in their original packaging, drugs in 2 cupboards were not stored alphabetically.

By not complying with the Safe Use of Medicines Policy & Procedures, the overall control framework is weakened and could result in errors, loss or theft.

Recommendation

With advice from Pharmacy, the Nurse Director should review the requirements of the Safe Use of Medicines Policy & Procedures and consider actions to address each of the points raised above.

The Nurse Director's action plan should be presented to the Healthcare Governance Committee, with regular updates to the Healthcare Governance Committee until actions are complete. In particular, the Healthcare Governance Committee may require the Nurse Director to obtain regular assurances from Chief Nurses that wards and clinical areas under their supervision are fully complying with requirements.

Management Response

Agree that the issues highlighted are of concern and action will be taken to improve practice and compliance.

Management Action

- 1) The Nurse Director will reinforce, in a letter to nursing staff, the necessity for all drugs to be held securely and in line with the Safe Use of Medicines Policy & Procedure.
- 2) With the support of the Director of Pharmacy, a review of the issues identified in this section will inform an action plan.
- 3) The Nurse Director will commission an action plan to ensure better compliance.

Responsibility:
Nurse Director

Target date:

- 1) 31 March 2014
- 2) 30 September 2014
- 3) 30 September 2014

<p>Issue 3 Significant</p>	<p>Wards and clinical areas do not keep stock records of drugs received, issued or held</p>
<p>In June 2010, Internal Audit issued a report on Pharmacy Dispensing & Medicines Management on Wards. Within the report, an issue was raised that wards do not keep records of drugs received, issued or held (other than Controlled Drugs). The audit recommended that a formal risk-assessment be done to confirm whether or not the practice reflects an acceptable level of risk.</p> <p>While the recommendation was agreed, the risk-assessment does not appear to have taken place.</p> <p>During the current audit, 16 out of 17 Charge Nurses reported instances of drugs going missing or other irregularities. Although contrary to the Safe Use of Medicines Policy & Procedures, several Charge Nurses advised that they keep certain desirable drugs (eg ketamine, diazepam, mifepristone) in Controlled Drugs cupboards for extra security.</p> <p>As such, the underlying risks may exceed what is considered acceptable.</p>	
<p><u>Recommendation</u></p> <p>The Nurse Director should oversee a formal assessment of the underlying risks associated with wards and other clinical areas not keeping records of non-Controlled Drugs. In particular, the assessment should consider the risks associated with desirable drugs.</p> <p>The risk-assessment along with recommendations should be presented to the Area Drugs & Therapeutics Committee and Healthcare Governance Committee, outlining the level of residual risk.</p> <p><u>Management Response</u></p> <p>Agree with the recommendation.</p> <p><u>Management Action</u></p> <p>The Nurse Director will commission a risk-assessment to establish the risk of such practices and, if the risk is unacceptable, actions to mitigate the risk.</p>	
<p>Responsibility: Nurse Director</p>	<p>Target date: 30 September 2014</p>

<p>Issue 4 Important</p>	<p>Stock-list reviews by Charge Nurses and Pharmacy have fallen behind schedule</p>
<p>Each year, Charge Nurses and Pharmacists aim to review stock-lists for each ward or clinical area. The stock-lists record the names and forms of medicines required, as well as appropriate minimum stock-levels. Pharmacists review the stock-lists on a rolling basis throughout the year, with the number of stock-lists varying across Pharmacy sites. Wards and clinical areas use the stock-lists to order drugs and help maintain adequate stock holdings.</p> <p>As at October 2013, figures reported by Pharmacy indicate some slippage in the schedule of expected reviews. For example, during the preceding 12-month period Pharmacists had reviewed:</p> <ul style="list-style-type: none"> • Royal Infirmary of Edinburgh – 71% of 84 stock-lists; • Royal Edinburgh Hospital – 100% of 96 stock-lists; • St John's Hospital – 87% of 30 stock-lists; • Royal Hospital for Sick Children – 51% of 63 stock-lists; and • Western General Hospital – 66% of 87 stock-lists. <p>At present, Pharmacy is preparing to replace Ascribe and Pharmed with the JAC system. Pharmacists explain that work associated with the change of system has taken priority, resulting in a lower level of stock-list reviews than normal.</p> <p>Nevertheless, keeping stock-lists up to date is an important element in helping to reduce the number of one-off orders placed by wards and clinical areas.</p>	
<p><u>Recommendation</u></p> <p>The Director of Pharmacy and Nurse Director should monitor annually the level of stock-reviews taking place. Especially once JAC is operational, any untoward decrease in the level of reviews should be investigated.</p> <p><u>Management Response</u></p> <p>Agree with the recommendation.</p> <p><u>Management Action</u></p> <p>The Director of Pharmacy and Nurse Director will jointly monitor, on an annual basis, the schedule for reviews and support a rolling programme to ensure progress.</p>	
<p>Responsibility: Director of Pharmacy & Nurse Director</p>	<p>Target date: 30 September 2014</p>

Definition of Ratings

Audit Opinions

- Fully satisfactory - the control framework is fully adequate and effective to manage the main risks within acceptable limits.
- Satisfactory - although improvement is possible, controls are adequate and effective to manage the main risks within acceptable limits.
- Requires improvement - significant issues exist with the adequacy or effectiveness of controls which could result in disruption, loss or reputational damage.
- Unsatisfactory - the control framework is generally inadequate or ineffective with issues that require immediate attention to prevent disruption, loss or reputational damage.

Issue Ratings

- Critical - the issue has a material effect upon the wider organisation.
- Significant - the issue is material for the subject under review.
- Important - the issue is relevant for the subject under review.

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