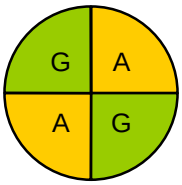
Internal Audit

Pharmacy Stores

August 2015

Report Assessment



Contents

Introduction

The pharmacy stores purchase, store and then dispense medicines to patients within all the acute and community hospitals within the organisation. Purchases must reflect current stock levels and expected demands, and must also conform to the requirements of the Lothian Joint Formulary. Drugs must be stored according to individual requirements (e.g. some require refrigeration), and pharmacy stores staff must ensure that there is effective stock rotation. Drugs are dispensed to patients and wards only after approval by clinicians.

Pharmacy operates from six main stores: four for acute hospitals (including the area store at St John's Hospital) and two for primary care and community hospitals. During the year to March 2015, costs of medicines within NHS Lothian pharmacies totalled approximately £85 million. The Director of Pharmacy is supported by two Associate Directors: one for managed acute services, and one for primary care and contracted services.

Pharmacy stocks for all hospitals within the organisation are recorded on the electronic system JAC, which replaced the Ascribe and Pharmiss systems in June 2014.

Scope

This audit reviewed the controls that are in place to manage pharmacy stores; particularly the controls over stock levels, usage forecasts, processes for ordering and issuing stock, the maintenance of stock records, and the safe disposal of stock.

Acknowledgements

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

Executive Summary

Conclusion

We have identified that stock management controls are not operating consistently across each pharmacy site, particularly those relating to standard operating procedures, stock checks and exception reports. We have also identified some areas where agreed procedures have not been followed, including supplies ordering and regular changes to access codes.

Summary of Findings

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

No.	Control Objective	Control objective assessment	Number of actions by action rating			
			Critical	Significant	Important	Minor
1	Stock movements are valid, authorised, correctly processed, and accurately accounted for.	**Amber**	-	1	2	-
2	Stocks are securely and safely stored, transported and disposed of in order to prevent loss, theft, deterioration or misappropriation of stock items.	**Green**	-	-	2	-
3	Stock levels are monitored in order to detect and react to replenishment requirements, and obsolete and slow-moving items.	**Amber**	-	1	3	-
4	Stocks are adequately stored in order to facilitate complete, accurate and timely fulfilling of orders.	**Green**	-	-	-	-

Control Objective Ratings

Action Ratings	Definition
Red	Fundamental absence or failure of controls requiring immediate attention (60 points and above).
Amber	Control objective not achieved - controls in place are inadequate or ineffective (21 – 59 points).
Green	Control objective achieved – no major weaknesses in controls but may be scope for improvement (20 points or less).

Main Findings

We noted a number of areas of good practice during the review.

Stocks are adequately stored in order to facilitate complete, accurate and timely fulfilling of orders. All stock lines held by the pharmacy have a unique location code which corresponds with JAC. When JAC produces a picking list for distribution the list clearly states the location code and the picking list is printed in such a way to enable efficient picking of stock items.

There is adequate segregation of duties between ordering, receiving and administering drugs. However, there is insufficient segregation of roles within the ordering process for the raising, authorising and issuing of purchase orders. Generally, one member of staff has responsibility for the entire process. The goods are received from the supplier by a member of the pharmacy team and checked to the delivery note and the original order, before JAC is updated by another member of staff to record the new stock received. The drugs are then distributed to the wards by porters and administered to patients by clinicians.

Physical security is robust. All external doors can only be opened from the inside and internal doors can only be accessed via an access code or a swipe card. Access to the JAC system is also secure; each user requires a unique username and password and users are assigned different levels of access depending on their requirements. There is also a dedicated JAC System Manager who ensures the system is operating efficiently and effectively.

All staff we met with were aware of good practice in terms of stock control. Staff were aware that more recent orders should be stored at the back of the shelves and older items at the front. When staff are picking items for distribution they also check the expiry dates to ensure items have not breached their expiry date.

We identified two significant areas for improvement during the review:

- There is an Authorised Signatory Database (ASD) in place. The ASD sets out delegated authority limits for different staff and should be followed when approving pharmacy orders, prior to the order being sent to the supplier. We tested this and found three instances where an individual had approved orders that were outwith their delegated authority. We found a further 20 instances where the individual who approved the order was either not included in the ASD or was included in the ASD but did not have any delegated authority limit.

- There was an inconsistent approach to stock checks across the three sites we visited. Different stock checks were carried out across each site with varying frequencies. In addition, the documentation used to record the stock checks was inconsistent.

Further details of each of these points, as well as some less significant issues, are set out in the Management Action Plan.

Management Action Plan

Control objective 1: Stock movements are valid, authorised, correctly processed, and accurately accounted for.	
1.1: Pharmacy orders have not been approved in line with the authorised signatory database.	**Significant**

Observation and risk

There are segregation controls in place for the raising of purchase orders, receiving goods and booking them into JAC. No formal controls are in place to ensure that the responsibility for raising, approving and issuing of purchase orders is also segregated. Currently a single member of staff can raise, authorise and issue purchase orders to suppliers, increasing the risk of incorrect orders being issued.

Meanwhile, Pharmacy Assistants and Technicians use JAC to generate pharmacy orders. All orders must be approved in line with the agreed Authorised Signatory Database (ASD) for pharmacy orders, prior to the order being sent to the supplier. The ASD is maintained by Finance and it sets out the authorisation limits for each individual. We tested a sample of purchase orders across each site to ensure they had been authorised in line with the ASD. We found:

- Three of ten orders (30%) at the REH were approved by an individual who did not possess the required delegated authority limit. In all three instances the authoriser's limit was £2,000 but the purchase orders were for between £3,794 and £7,203.

- In 20 of 30 (67%) instances at SJH and RIE, the staff member who authorised the order was either not in the ASD or was in the ASD, but had no delegated authority limit.

The ASD is not being adhered to in all instances. There is a risk that, where orders are not approved in line with the agreed scheme of delegation, NHSL could incur unnecessary or inappropriate expenditure.

Recommendation

Controls should be introduced at each site that provide adequate segregation during the purchase order process. Ideally, the members of staff responsible for raising the purchase order in the first instance should not be the same individual who authorises the order.

The ASD should be reviewed and updated to confirm whether it is a complete and accurate list of authorisers and associated limits. The ASD should be reviewed at least annually to ensure it remains up-to-date.

Upon receiving an approved order for sending to the supplier, pharmacy staff should check that the order has been approved in line with the ASD. If an order has not been approved in

line with the ASD then it should be rejected and held until it has been approved in line with the ASD.

NHSL could consider implementing additional controls where a large order is raised but there is nobody physically present with the relevant authority to authorise the order. For example, authorisation could be obtained via email or alternatively authorisation from two members of staff may be deemed sufficient.

Where individuals are found to be authorising orders outwith their delegated authority levels, this should be raised with the individual and continued occurrences should be reported to their line manager.

Management Response and Action

We are satisfied that in all instances the order had been authorised by the correct individual. However, we recognise that the ASD has not been kept up-to-date. We recognise the need to have segregation of duties in place over pharmacy orders, but there are a small number of occasions where this is not possible. Where senior staff are not available to authorise orders we would rather the medicine is ordered and received timeously as opposed to there being delays to an order. Therefore, it is neither practical nor feasible to ask that segregation of duties are in place for 100% of orders.

We will reiterate to staff the need to strive for segregation of duties in the purchase order process. Where senior staff are not available to approve orders and there is a clinical need for the order to be placed immediately, the order will be retrospectively authorised by a senior member of staff. This will avoid staff authorising their own orders where senior staff are not available.

We will also ensure that the ASD is updated and it will be formally reviewed by site leads on an annual basis going forward to ensure it is up-to-date. This will be added to the action plan for the Pharmacy Stores Managers Group to review and reemphasise segregation of tasks where possible and review delegated authority levels.

Responsibility: Site Leads/Store Managers on each site, Chair of Stores Managers Group	Target date: 31/10/2015

1.2: Standard operating procedures are not consistent across each site.	**Important**
Observation and risk The introduction of JAC allows pharmacy staff to manage the ordering, receipt and distribution of medicines across all sites using one system, resulting in a consistent way of working within acute and community pharmacy distribution services. The Pharmacy Site Leads Operational Group agreed that, following the implementation of JAC, a suite of standard operating procedures (SOPs) to instruct staff on new ways of working should be developed. However, at the time of our audit not all of the required SOPs had been developed. Sites are currently using SOPs that have been produced locally to guide staff on various activities, though a number of these have passed their review dates. There is a risk of inconsistent practice across sites, which may not be aligned with best practice or the expectations of the pharmacy management team.	
Recommendation We recommend that a complete suite of SOPs, which are applicable to all sites, are developed and made available to all relevant sites and staff.	
Management Response and Action Work on developing and embedding the suite of SOPs has progressed since the implementation of JAC and this work will continue until completion. The Pharmacy Stores Managers Group will ensure that appropriate SOPs are completed and implemented across each site.	
Responsibility: NHSL JAC System Manager/Store Managers on each site	Target date: 31/01/2016

1.3: The generic password for stock adjustments has not been changed since JAC was introduced.	**Important**
Observation and risk The functionality within JAC to allow posting of stock adjustments over £100 can only be accessed by entering an additional password. Only certain staff are aware of the password. However, we were informed that the password is the same password across each site and it has not been changed since JAC was implemented in June 2014. There is a risk that the password is known by staff who should not know it and stock balances are adjusted inappropriately.	
Recommendation The stock adjustment password should be changed at least every six months to ensure only relevant staff know the password.	
Management Response and Action We acknowledge the importance of security controls regarding stock adjustment passwords. The password was only issued to appropriate member of staff with this in mind. We will set up a process to ensure that the password is changed every six months and e-mail evidence is available regarding this change.	
Responsibility: NHSL JAC Systems Manager on each site	Target date: 30/09/2015

Control Objective 2: Stocks are securely and safely stored, transported and disposed of in order to prevent loss, theft, deterioration or misappropriation of stock items.	
2.1 The code to access the REH pharmacy has not been changed every six months.	**Important**
Observation and Risk Doors to access the pharmacy area are controlled through either a keypad (SJH and REH) or proximity access cards (RIE). The access codes to the keypad doors are only known by relevant staff and doors are locked at all times. We confirmed that these security arrangements appear to be operating effectively at the time of our visits to each of the three sites. However, the formal procedure covering security arrangements for the REH pharmacy states that the access code for the keypad doors should be changed every six months or when there is a change in staff (whichever is sooner). We were informed that the access codes at REH had not been changed within the past year. There is a risk of unauthorised access to the REH pharmacy, which may increase the risk of theft.	
Recommendation The procedure for security arrangements at REH should be followed by ensuring that the access codes are changed at least every six months or whenever there is staff turnover.	
Management Response and Action We are aware of the importance of password security and at the REH only pharmacy staff have access to this. The password was changed in July 2015. We will review the current procedure and ensure that adherence to the six monthly change is implemented. Adherence to this control will be evidenced via email.	
Responsibility: Office staff REH	Target date: 30/9/2015 (Completed)

2.2: Ward profiles are not agreed to picking lists and ward staff do not confirm receipt of medicines.	**Important**

Observation and risk

Ward profiles are normally submitted to the pharmacy between one and three times per week. The ward profile is input to JAC by pharmacy staff and JAC produces a picking list to assist staff with locating the stock for delivery to the ward. Once the required stock has been picked, a second member of staff will check that the items physically picked correspond with the picking list. The items are then sealed with a delivery note ready for collection by a porter for delivery to the ward.

However, we noted inconsistencies in practices across the three sites we visited. At SJH, distribution staff perform a check between the ward profile and picking list produced by JAC to confirm that the ward profile has been input to JAC correctly. However, this check is not performed by distribution staff at REH or RIE. In addition, ward staff at RIE and REH are required to sign documentation to confirm receipt of medicines at the ward. However, no similar control is in place at SJH (excluding the receipt of controlled drugs).

There are inconsistent practices in operation across sites. There is a risk that the picking lists are not accurate at REH or RIE, leading to wards not receiving exactly what they selected on their ward profile. There is also a risk at SJH that stock is not delivered to the ward and this is not picked up as wards are not required to sign to confirm receipt of stock.

Recommendation

Pharmacy staff at all sites should be required to perform a check to confirm that the picking list agrees to the ward profile, as well as to the physical stock actually picked. This should be evidenced through signing the picking list. Ward staff at each site should be required to sign documentation to confirm receipt of medicines at the ward. The documentation should be returned to the pharmacy and retained for a set period of time as evidence of the delivery.

Management Response and Action

NHS Pharmacy management agree with a standardised and consistent approach across sites where feasible regarding the checking of picking lists. However, we plan to introduce a risk assessment to determine the level of checking required across each site. Where issues are identified the level of checking will be increased. The risk assessment will be regularly reviewed by the Pharmacy Stores Managers Group to ensure it remains correct. The risk assessment is there to recognise that not all sites are the same and different controls are required for different sites. A separate risk assessment will be undertaken regarding checking receipt of stock by ward staff.

Responsibility: Store Managers on each site	Target date: 31/01/2016

Control Objective 3: Stock levels are monitored in order to detect and react to replenishment requirements, and obsolete and slow-moving items.	
3.1 Inconsistent approach to stock checks.	**Significant**

Observation and Risk

Year-end stock counts are carried out on pharmacy stock across NHSL. In addition, further stock checks are carried out throughout the year to provide assurance over stock levels and values. However, we noted inconsistencies in stock checks across each site we visited:

- At REH and SJH, daily stock checks are carried out on 25 random stock lines through checking that the physical stock balance agrees to JAC. Similar daily stock checks are not carried out at RIE.

- At RIE, daily stock checks are carried out for all desirable items (security check). This check is conducted twice per week at SJH and REH.

- At RIE, periodic stock counts are carried out on high value items. This check is conducted once per month at REH and not at all at SJH.

Our audit testing also highlighted that each site was using different documentation to record the stock checks. The most comprehensive documentation appeared to be that used at REH. Staff at this site used documentation appended to the relevant SOPs, which required signatures to confirm counts, stock adjustment and review by senior staff. These checks were not being clearly recorded at RIE or SJH.

The inconsistent approach to stock checks may lead to stock discrepancies not being identified and rectified in a timely manner. Current stock check practices within each site may not be aligned with the expectations of the pharmacy management team.

Recommendation

As part of developing an overall SOP for stock checks, the pharmacy management team should agree which stock checks should be carried out at each site and how often they should be carried out. If it is decided that stock checks at some sites will differ from others this should be clearly set out within the relevant SOP.

Pharmacy management should develop standard forms for the different stock checks and ensure these are embedded across each site. The standard forms should also be included within the relevant SOP.

Management Response and Action

Prior to the implementation of JAC, SJH carried out monthly checks of high value items.

However, after JAC was implemented SJH captured high value items at the transfer of stock levels onto JAC and at the annual stock check. Prior to the audit, SJH carried out a high value check using the PRICE report. The SOP does allow for stock checks to be carried out more frequently at different sites. For example, it states that security checks should be carried out at least twice per week, but the RIE has elected to increase these checks to daily. However, we recognise that some sites are not carrying out stock checks in line with the SOP i.e. continuous stock checks and high value. We will review the SOPs regarding stock checks to ensure a consistent approach across all sites. A KPI will also be introduced to ensure compliance. Where performance is not in line with expectations then additional action will be taken to address any issues.	
Responsibility: Site Leads/Store Managers on each site	Target date: 30/11/2015

3.2 Inconsistent approach to stock checks.	**Important**
Observation and Risk Our testing of the stock checks identified the following issues: • The daily security checks on desirable items at RIE had not taken place in eight of 15 instances (53%). • The twice weekly security checks on desirable items at SJH had not taken place in one of six instances (17%). Stock checks have not been carried out in line with agreed procedures. There is a risk that issues or discrepancies are not identified, investigated and resolved.	
Recommendation Staff should be reminded of the importance of carrying out the different stock checks at the agreed intervals. The Stores Manager should take ownership for ensuring the stock checks have been completed. This could be achieved through the introduction across all sites of the monthly checklist in place at the REH to confirm that the stock checks have been carried out at the different intervals as required. The Pharmacy Management Team could monitor completion of stock checks as a standard KPI.	
Management Response and Action Stock checks are an important part of the stores role. We recognise that this requires monitoring and it will be included as a pharmacy store KPI and monitored regularly. Where performance is not in line with expectations then additional action will be taken to address any issues.	
Responsibility: Site Leads/Store Managers on each site	Target date: 30/11/2015

3.3 Fixed flags on JAC are not routinely reviewed and ward profiles have not been reviewed annually across all sites.	**Important**

Observation and Risk

JAC records a minimum stock level for each stock item. Once the minimum stock level has been reached, JAC will notify staff so that an order can be placed. JAC has the functionality to utilise historic usage trends and purchase levels to adjust the minimum stock balance and suggested order quantities.

NHSL decided not to use this facility and instead minimum stock levels ("fixed flags") were set up during the implementation of JAC. However, the minimum stock levels have not been reviewed since the implementation of JAC in June 2014. There is a risk that the minimum stock levels in JAC are inaccurate, leading to inadequate stock levels.

In addition, each ward has a ward profile, which is a list of drugs required by that ward and suggested stock levels that should be held in the ward. The ward profile assists staff in placing orders to replenish ward stock. Each ward profile must be reviewed at least annually, with sites reporting against this as part of their KPIs. We reviewed the KPI reports and found that SJH reported that 100% of all ward profiles were reviewed during 2014/15, REH reported 88% compliance. RIE had not reported against this KPI since May 2014.

There is a risk that ward profiles are not accurate. This could lead to excessive or insufficient stock being held on wards. In addition, this may lead to an increase in ad hoc orders being received by the pharmacy, which will increase the workloads of pharmacy staff.

Recommendation

The minimum stock levels within JAC and all ward profiles should be reviewed at least annually. It may be more efficient to undertake this on a rolling basis with a sample of fixed flags and ward profiles being reviewed each quarter, whilst ensuring each fixed flag and ward profile is reviewed at least once during the year.

Management Response and Action

Reorder level reviews require the Crystal reporting tool. This is currently being addressed by the Systems Manager. Once reports are available, process can be defined and a consistent approach implemented. This will also be part of the stores KPIs.

Ward profile reviews at the REH are not up to date because pre-JAC preparation meant they were all done at once; we are in the process of catching-up on this. This will be reflected in an improvement in the KPI. Other sites will review their process to produce a similar outcome.

Responsibility: Site Leads/Store Managers on each site	Target date: 31/01/2016

3.4: JAC reports are not run consistently for each site.	**Important**
Observation and risk The JAC system has an exception reporting facility to assist with fulfilling orders. For example, the follow-on report identifies instances where an order is received by the pharmacy but it cannot be fulfilled due to insufficient stock levels. In addition, a KLEVEL report is run which lists all drugs that are out of stock, low in stock or slow moving stock. During our audit we found that the follow-on report is run twice daily at SJH and REH, but not run at all at RIE. In addition, the KLEVEL report is run weekly at REH, but not run at all at SJH or RIE. Pharmacy took the decision to install Crystal Reports to operate alongside JAC. Crystal Reports allow bespoke reports to be created and run for each site based on its own specific needs. However, the Crystal Report system is not yet embedded. The Pharmacy System Manager has been testing the Crystal Report system and is working with the JAC Reporting Structure Group to build the relevant reports. There is a risk that sites are not making best use of the exception reports available within JAC. This may lead to low stock levels not being identified and rectified.	
Recommendation Until the bespoke reports are available from the Crystal Report system, each site should run the follow-on and KLEVEL reports on a consistent basis. Once the Crystal Report system is in place and tested, an agreed suite of reports should be produced across all sites.	
Management Response and Action There was a delay in implementing Crystal Reports for a variety of reasons. The Systems Manager and others are currently working through a prioritised list to develop reports for operational pharmacy requirements. The reports will be defined and will be incorporated into the core SOPs.	
Responsibility: NHSL JAC system manager/Store Managers on each site	Target date: 31/01/2016

Control Objective 4: Stocks are adequately stored in order to facilitate complete, accurate and timely fulfilling of orders.
We identified no significant issues in relation to this control objective. All stock lines held by the pharmacy have a unique location code which corresponds with JAC. When JAC produces a picking list for a ward order the list clearly states the location code and the picking list is printed in such a way to enable efficient picking of stock items. At each site, similar stocks (such as liquids) are kept together and the stock rooms we visited were tidy and free from clutter to allow efficient picking of items. At the end of each shelving unit there was a list showing the specific location of each item located in that area.

Appendix 1 - Definition of Ratings

Management Action Ratings

Action Ratings	Definition
Critical	The issue has a material effect upon the wider organisation – 60 points
Significant	The issue is material for the subject under review – 20 points
Important	The issue is relevant for the subject under review – 10 points
Minor	This issue is a housekeeping point for the subject under review – 5 points

Control Objective Ratings

Action Ratings	Definition
Red	Fundamental absence or failure of controls requiring immediate attention (60 points and above)
Amber	Control objective not achieved - controls in place are inadequate or ineffective (21 – 59 points)
Green	Control objective achieved – no major weaknesses in controls but may be scope for improvement (20 points or less)