

HANDLING DRUG RECALLS

— an audit scheme to assess systems in place

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Effective handling of drug recalls is an important part of supply chain management. This article presents an audit scheme developed to evaluate pharmacy systems for handling these situations



Systems should be in place for handling drug recalls, including those that are received outside normal working hours

Drug recalls issued by the Medicines and Healthcare products Regulatory Agency (MHRA) are not an uncommon occurrence — there were 20 in 2002 and 18 in 2003. During normal working hours, such recalls are usually handled in many hospital pharmacy departments by a small number of pharmacists or pharmacy technicians, usually based in the stores or quality assurance departments. However, recalls received out-of-hours may be handled by staff who are not familiar with the process and consequently may be unable to respond to such a recall correctly.

To help rectify this problem, systems and procedures put in place for handling drug and device recalls in secondary care must be robust. They should also be known and made available to all key personnel, including those providing out-of-hours services. For pharmacists working out-of-hours, there should be clear and concise standard operating procedures available, for example in an on-call bag, which provide simple, step-by-step guidance on the action to be taken in the event of an urgent drug or device recall being issued.

So how robust are your systems for handling drug and device recalls? This article sets out an audit scheme for assessing how drug and device recalls are handled. Full compliance with all the points in the

scheme is not necessary to demonstrate that a robust system is in place. However, the audit scheme can be used as a tool to drive quality improvement towards “best practice”. The article also covers the background to the audit scheme.

BACKGROUND

The document “Controls assurance standard for medicines management (safe and secure handling)” was first introduced by the Department of Health (DoH) in February 2000.¹ Criterion 10 of the standard deals with the reporting of adverse incidents involving medicinal products and devices, as well as the appropriate management of any subsequent required action, such as a recall. Under the information section of this criterion, the DoH states that: “An auditable procedure is in place in primary and secondary care relating to the management of drug recalls”. Although trusts are no longer required to report compliance with the standard to the DoH, as of 1 August 2004, one example of verification given by which a trust can demonstrate compliance is to have a “policy covering drug alerts, including out-of-hours, with a named lead professional and annual audit results from the system”.

In July this year, following a period of consultation, the DoH published “Standards for better health”.² This document details 24 core health care standards for the National Health Service (NHS) that will be audited by the Healthcare Commission (formerly the Commission for Healthcare

Audit and Inspection). The purpose of the core standards is to establish “a level of quality of care which can be expected by all NHS patients, regardless of where they are treated”. The first group of core standards relates to safety and the first of these standards (C1b) states: “Health care organisations have systems in place to ensure that patient safety notices, alerts and other communications concerning patient safety which require action, are acted upon within required time scales.”

This core standard is augmented by a further developmental standard, D1a (developmental standards are designed to improve the overall quality of NHS care). D1a states: “Health care organisations continuously and systematically review and improve all aspects of their activities that directly affect patient safety.”

With these requirements in mind, I designed an audit scheme to enable trust chief pharmacists to demonstrate the effectiveness of their recall systems within a secondary care setting. The audit scheme is set out in Panel 1 (p384). Anyone wishing to use this audit scheme to assess how compliant and robust their recall system is can do so by using it as a tool to check current documentation (eg, procedures or protocols already in place) and records of any previous recalls that have been dealt with.

It should be noted that if a hospital pharmacy department holds a wholesaler dealer’s licence issued by the MHRA, the provisions for drug recalls, as stated in the guidelines on good distribution practice of medicinal products for human use, also apply.³

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Panel 1: Audit scheme

Management

- A policy, protocol or standard operating procedure on the handling of drug and device alerts (including out-of-hours provision) is in place and readily available
- A named senior pharmacist or technician is responsible for handling all drug and device alerts (including the provision of cover in the absence of a named responsible person)
- Records of the response to all alerts, including those for which no action was required, are kept on file

Receipt

- A system is in place to ensure that all relevant alerts are received. This may include: having all alerts directed to a "manned" fax line; checking relevant websites daily (eg, MHRA, DrugInfoZone); checking the current alert number against the previous number to ensure the alerts are consecutive; and participating in duplicate alert systems, eg, regional quality control cascade and e-mail alerts via Public Health Link
- There is a robust system in place to ensure that alerts requiring immediate action can be received out of hours. This should be subject to periodic assessment
- If necessary, a system is in place to cascade alerts locally when required
- The effectiveness of any local onward cascade is regularly audited or routinely verified by the use of feedback loops at the end of the cascade chain
- A system is in place to identify whether the affected batch(es) of stock were received. If a manual system is used, a system is in place to identify the locations of where all such stock would be kept, both within and outside the pharmacy department. If batch numbers are recorded on receipt on a computer system, there is a random manual double-check of stock locations to ensure the computer record is accurate
- A system is in place to identify how much stock may have been received. If a manual search of purchase orders is required, the procedure includes directions to check outstanding paperwork, eg, incomplete orders, "to follows", returns, queries, etc. This may also be relevant if a computerised system is used
- A system is in place to remove affected stock from all locations and quarantine it, clearly marked as defective or recalled stock. The system should also include the booking out of such stock from the computer system
- A system is in place to ensure prompt reordering of replacement stock if necessary (this may be triggered by booking the affected stock off the computer system). The procedure should address the actions to be taken if the recalled item is a critical or emergency list product (eg, arrangements with nearby trusts, emergency orders to wholesalers [including out-of-hours], consultations with appropriate clinicians to determine what alternative products can be given, etc)
- A system is in place to ensure that recalled stock is returned to the manufacturer and that free replacement stock is received

Follow-up

- A system is in place to identify how much affected stock may have been used or administered to patients, eg, by reconciliation of stock ordered versus the quantity quarantined. (It is not expected that individual patients who received the affected stock can be identified in most cases)
- Based on the seriousness of the alert, a risk assessment of the likely clinical consequences of any such patient administration or use is made by the responsible pharmacist or technician
- Such risk assessments are recorded
- Based on the seriousness of such risk assessments, a system is in place to alert the appropriate clinicians that their patients have received affected stock and may require monitoring for a lack of clinical effectiveness or any adverse reaction. Where possible, this should include a system for contacting any outpatients to ask them to return affected stock and receive appropriate care

SCOPE OF AUDIT

The use of this audit scheme will allow the auditor to establish whether there are systems and procedures in place that enable the following points to be dealt with:

- Determine whether or not affected batch(es) have been received into stock
- Determine exact quantities and locations of where any affected stock has been distributed
- Determine how much of the affected batch(es) has been administered to patients and how much can be recovered (or is unaccounted for)
- Carry out a risk assessment of the hazard to patients who may have received some of the affected stock

- Maintain essential supply by either reordering or agreeing with clinicians which alternative products can be used

CONCLUSION

The audit scheme outlined has been tested in a successful trial in the pharmacy department at Ipswich Hospital. The auditors discovered that the scheme was simple to use and the audit relatively quick to undertake. Use of the audit scheme identified a number of areas where procedures could be improved and documentation clarified, in particular with regard to follow-up actions such as patient risk assessment and restocking of critical or emergency list drugs.

REFERENCES

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3. Medicines Control Agency (MCA). Guidelines on good distribution practice (GDP) of medicinal products for human use. In: MCA. Rules and guidance for pharmaceutical manufacturers and distributors. London:The Stationery Office; 2002. p. 329–30.

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