Tees, Esk and Wear Valleys
NHS Foundation Trust

Medicines – management of alerts, recalls, reporting

PHARM-0002-008-v3

Status: Approved
Document type: Procedure

Contents

1 Purpose

Following this procedure will help the Trust to:

- Maintain systems to ensure that patient safety alerts, rapid response reports and patient safety recommendations disseminated by the NPSA and supplier-led defective medicine alerts and recalls which require action are acted upon within required time-scales

2 Related documents

This procedure describes what you need to do to implement the Management of untoward incidents section of the Medicines Overarching Framework and the trust guidance for managing staff involved in medicine incidents or errors (excluding prescribing errors)

This procedure should also be read in conjunction with the Incident reporting and serious incident review policy

The Medicines Overarching Framework defines the compliance requirements for safe, secure and appropriate handling of medicines which you must read, understand and be trained in before carrying out the procedures described in this document.

3 Medication incidents

Definition: A medication incident is a preventable incident associated with the use of medicines which may put a patient at risk. Such incidents may be related to any of the steps relating to the use of medicine. This includes prescribing, dispensing and administration of the medicine and the transfer of information. All medication incidents should be reported via Datix.

Review of Medication Incidents: The multidisciplinary Safe Medication Practice Group meets quarterly to review medication incident reports, establish trends and to take action in order to prevent further incidents. Action may involve system redesign and improvement and/or education, training and competency assessment of employees on any aspect of medicine use.

4 Adverse Drug Reaction (ADR) reporting

Any medicine may produce unwanted or unexpected adverse reactions.

If a patient suffers a suspected adverse reaction to a prescribed, over-the-counter or herbal medicine, the adverse reaction should be reported via the Yellow Card Scheme. Further information from www.yellowcard.gov.uk

5 Defective medicines reporting

Adverse events must not be confused with effects caused by a defective medicine.

During manufacture or distribution of a medicine, an incident may occur which results in the medicine not conforming to its specification. Such a defect may impair the therapeutic effect of the medicine and could adversely affect the patient's health. Examples of defects are:

- Mislabelling
- Mix up of products in a container
- Faulty closures or packaging
- Wrong product
- Unusual appearance

If a defective medicine is found or suspected the following action must be taken:-

- If the product has been administered to a patient inform the doctor responsible for the patient as soon as possible and record the defects in the patient's notes.
- Report the incident to the Appointed or Designated Practitioner in Charge of the ward or department.
- Inform the Medication Safety Officer / Lead Pharmacist for Patient Safety who will advise on all reporting, recording and investigating of the defect. If a medicine defect is detected outside of normal working hours the on-call pharmacist should be informed.
- Inform the ward pharmacy technician/pharmacist or a member of the Trust pharmacy team who will inform the supplying dispensary of the suspected defect and arrange an alternative supply of medicine if necessary.
- Retain any remaining product and any associated products or equipment (e.g. other containers with the same batch number, administration sets, etc.). Store securely on the ward/department ensuring that it is isolated from medicines in use.
- Record the details of the product and the defect.
- Do not administer further doses of the suspected defective batch.
- A report of the defective medicine must be made on Datix.

6 Drug alerts

Drug alerts relating to medicines are widely distributed via a cascade system within the Trust, following a pharmacy specific procedure. Staff in receipt of a drug alert notice must take the appropriate action as outlined in the alert.

Information on specific drug alerts and the action taken can be obtained from the Trust Pharmacy Department. For assurance purposes, the pharmacy processes in response to alerts and recalls are shown in appendices 1-3.

7 Loss or theft of prescriptions/controlled stationery

Actual or suspected loss or theft of prescription stationery must be reported to the Chief Pharmacist and the Appointed Practitioner in Charge immediately so that appropriate action can be taken to reduce the potential for fraudulent access to medicines. If the incident is noted on a weekend or Bank holiday the on-call pharmacist must be informed - this can be done during daytime hours after 9am.

8 Document control

Date of approval:	26th September 2019	
Next review date:	1st October 2022	
This document replaces:	V2	
Lead:	Name	Title
	Emma Kettle	Lead Pharmacist for Patient Safety
Members of working party:	Name	Title
	Amanda Metcalf Chris Williams	Lead Pharmacy Technician Chief Pharmacist
This document has been agreed and accepted by: (Director)	Name	Title
	Ruth Hill	Chief Operating Officer
This document was approved by:	Name of committee/group	Date
	Drug and Therapeutics Committee	26th September 2019
An equality analysis was completed on this document on:	Part of overarching medicines documents EIA	
Amendment details:	September 2017: minor changes throughout with flow charts added into appendices. Title change. V3: September 2019 – minor changes due to move from Lloyds to internal dispensary.	

Appendix 1: Process for the Internal Management of Drug Alerts and Drug Recalls

Receipt

- Alert/Recall is received by email to TEWV Pharmacy Team
- Lead Pharmacy Technician - Medication Safety - **LPT (alerts)**
- Lead Pharmacy Technician - Procurement **- LPTP (recalls)**
- Lead Pharmacist for Patient Safety - **LPPS**
- Deputy Chief Pharmacist - **DCP**
- Chief Pharmacist - **CP**

Internal communication

- **TEWV** LPT will action drug alerts and LPTP will action drug recalls who will then contact and confirm status with, the locality lead technician at each of the dispensaries.
- LPT & LPTP will complete a record of actions form, and add the alert/recall detail to weekly conference call for information.
- **Locality leads:** to respond to LPT with implications for all dispensaries and actions

Recording

- All documents mentioned in this section can be found on the shared drive under Pharmacy / Governance/ Patient Safety / Drug Alerts & Recalls
- LPT & LPTP or deputy to complete columns 1-4 of the Action Log for Drug Alerts and Drug Recalls on receipt of any Drug Alert / Drug Recall.
- LPT & LPTP (or deputy) to create new folder in 'Record of Actions - Active Alerts' folder. This should be titled 'Record of Actions - Drug Name - Class - Date'.
- All email responses received from the dispensaries to be saved in the appropriate 'Record of Actions - Active Alerts' folder
- LPT & LPTP to initiate Record of Actions Template' and store electronically in the designated 'Active alerts' folder for all to access.
- LPT to take overall responsibility for completion of the action log

Sharing with Trust

- **For Patient/clinic level drug alert/recall only: LPT to email tewv.safetyalerts@nhs.net** to inform appropriate Trust wide practitioners as required (see Drug Recalls and Critical Medicine Shortages - Checklist) . Email pharnacyadmin to request team email be distributed.
- **For ALL alerts/recalls:** Discuss during weekly or scheduled conference call and agree to disseminate information and actions via approprate medium e.g. e-bulletin, targeted email distribution etc.
- All above actions should be logged on the appropriate 'Record of Actions' form.

Sharing with Pharmacy Team

- CP to inform pharmacy staff as required (see Drug Recalls and Critical Medicine Shortage Framework) .
- LPT to update details on Action Log for Drug Alerts and Drug Recalls
- L PPS or LPT to add a quarterly extract from the 'Action Log' to the Safe Medication Practice Group Agenda to ensure that alert details are recorded in the minutes.

Closing the alert

- All actions to be recorded on the designated 'Record of Actions' document.
- Overview of all actions taken to be noted on weekly conference call, including the agreement to close the alert.
- Closed 'record of actions' folder to be moved to the 'Record of Actions - Closed Alerts' folder and filed under the relevant year.

Appendix 2: Drug Alert / Drug Recall – Record of Actions

Quick title:			Initials
Alert No.		Hyperlink:	
Is the alert relevant to TEWV? Yes ☐ No ☐ If no, why:			Choose an item.
Contacted Roseberry Park, York and Westpark locality leads and are actioning alert? Yes ☐ No ☐ N/A ☐			Choose an item.
Level of recall: Patient ☐Pharmacy ☐Clinic☐ Other (state):			
Is a specific conference call required: Yes ☐ No ☐			Choose an item.
Date and time of conference call: Or state weekly conference call date: Click here to enter a date.			
State wards that may have had affected stock:			Choose an item.
State batch numbers (if appropriate):			
Agreed actions: • Trust wide email alert / fax: Yes ☐No ☐ • Targeted email / fax: Yes ☐No ☐ • Pharmacy Bulletin: Yes ☐No ☐ • Alert to Pharmacy Staff: Yes ☐No ☐ • Wards that Pharmacy have visited and collected stock from: • Clinics / wards phoned (state contacts): • For patient/clinic level drug alert/recall only: LPT to email tewv.safetyalerts@nhs.net • Other actions:			Choose an item.
Date closed: Click here to enter a date.			Choose an item.

Appendix 3: Process for the Internal Management of Patient Safety Alerts

Receipt

- Patient Safety Alert received into pharmacy department by Chief Pharmacist (CP), Deputy Chief Pharmacist (DCP) and/or Medication Safety Officer (MSO)
- CP / DCP to inform MSO of alert received to ensure they are aware.

Recording

- MSO to save a PDF copy of the alert in the Alerts folder (hyperlink below) on the shared drive. The title of the document should be the as per the alert title.
- MSO to add the alert to the TEWV Pharmacy patient safety alert log (hyperlink below).
- Hyperlink to The saved PDF to be included in the title column of the TEWV Pharmacy Patient Safety Alert Log.

Actions and Sharing

- If applicable to TEWV Pharmacy, add to weekly conference call to ensure PLT are aware.
- Allocate a lead for TEWV (default to MSO) unless the lead is likely to be external to the pharmacy department e.g. Head of Nursing
- Identify potential actions to be taken and agree with PLT
- Add to SMPG agenda to discuss and identify potential further actions at next meeting. If timing does not allow this, add to SMPG agenda to inform group members of actions taken .

Immediate Communication of Alert

- Choose one or more of the following to disseminate the alert:
  - Cascade alert to pertinent staff immediately
  - Share with pharmacy staff via weekly update
  - Disseminate via trust patient safety team
  - Disseminate via pharmacy bulletin
  - Disseminate via weekly e-bulletin

Closing the Alert

- When all actions are complete, add these to the TEWV Pharmacy Patient Safety Alert Log including hyperlinks to evidence e.g. Any communication disseminated or resources created & circulated.
- Advise the trust patient safety team that the alert has been actioned and closed from a pharmacy perspective.