Family Nursing & Home Care

Standard Operating Procedures

Safety Alerts Procedure

December 2024

Document Profile

Type	Standard Operating Procedures
Title	Safety Alerts
Author(s)	Updated by Head of Quality and Safety in consultation with the Quality and Performance Development Nurse
Category	Organisational
Version	3
Approval Route	Organisational Governance Approval Group (OGAG)
Date approved	5th December 2024
Review date	5 years from approval
Document Status	This is a controlled document. Whilst it may be printed, the electronic version posted on the intranet is the controlled copy. Any printed copies of this document are not controlled. As a controlled document, it should not be saved onto local or network drives but should always be accessed from the intranet.

Version Control

Date	Version	Summary of changes made
April 2018	1	Renamed Safety Alerts Procedure (formerly the Central Alerting System Procedure) Sharing an alert with another organisation may be an appropriate response to an alert. 'Appointed person from the Quality and Governance Team' now defined as the Clinical Effectiveness Facilitator Safety Alerts Spreadsheet now being updated by first line recipients New Home Care Manager role acknowledged

Date	Version	Summary of changes made
		Safety Alerts Spreadsheet to be completed initially by first line recipients within 7 days. Flow chart updated to reflect above changes
May 2021	2	Previous 'Safety Alerts Procedure' document transferred to SOP template Content reviewed and updated, as per changes to MHRA Drug Alert categories and classifications Changes to MHRA Drug alert titles and classification - GOV.UK (www.gov.uk)
December 2024	3	Transferred to current Standard Operating Procedures template. General updating including title changes. SOP reflects that the Quality and Performance Development Nurse now leads on the monitoring the dissemination of safety alerts. 'Definitions and Explanations' section moved from the 'Introduction' to 'Appendix 1'. Information regarding National Patient Safety alerts updated with link to website added.

Contents

Introduction

This Standard Operating Procedure (SOP) relates to all types of safety alerts and updates issued by the Central Alerting System (CAS), Medicines and Healthcare Regulatory Authority (MHRA), internally generated or from any other source.

The type of alerts on the CAS website include:

- Safety Alerts
- Chief Medical Officer messages
- Medicines Recalls/Notifications
- Dear Doctor Letters
- Medical Device Alerts (MDAs)

This procedure must be followed in the event of receiving any safety alert or update which has been disseminated by the appointed person from the Quality and Governance Team or their deputy.

The organisation seeks to have a pro-active culture; working with staff and other healthcare providers to prevent and manage potential safety hazards. Other local healthcare providers may also be signed up to receive alerts from CAS and the MHRA. Whilst it is not the responsibility of Family Nursing & Home Care (FNHC) to keep other organisations appraised of alerts, this may be an appropriate action to take when responding to an alert.

In the event of an alert being pertinent, FNHC will take any immediate or remedial action and review the issues highlighted to minimise the chance of hazardous incidents occurring in the future.

If the organisation cannot take action itself it will, where appropriate, make other agencies aware of issues which they may need to address.

For definitions and explanations see Appendix 1.

SOP 1 Process to prevent and manage potential safety hazards

Purpose

This SOP provides a risk management process to prevent and manage potential safety hazards. It is designed to protect patients, clients, staff and the organisation.

Scope

This SOP applies to all staff working for FNHC or seconded to work within the organisation.

Core Requirements/Procedure

The particular circumstances of the safety alert/update will influence the immediate actions to be taken.

The Head of Quality and Safety and the Quality and Performance Development Nurse will be signed up to receive automatic alerts from the Central Alerting System (CAS), the Medicines and Healthcare Products Regulatory Agency (MHRA) and the Food Standards Agency (FSA).

The Quality and Performance Development Nurse will monitor their emails daily (Monday to Friday with the exception of bank/public holidays) for safety alert notices.

The Head of Quality and Safety will deputise when the Quality and Performance Development Nurse is absent.

Where neither the Quality and Performance Development Nurse nor Head of Quality and Safety are available, the Director of Governance and Care will monitor the safety alerts.

When alerts are received, the Quality and Performance Development Nurse/deputy will determine which alerts are likely to be relevant to FNHC.

The Quality and Performance Development Nurse will respond on behalf of FNHC to any Field Safety Notices received directly from a manufacturer.

All alerts thought to be relevant/possibly relevant will be entered onto a centrally held Safety Alert database.

The Quality and Performance Development Nurse will email safety alerts/updates, thought to be relevant/possibly relevant, to first-line recipients or their deputy (as appropriate to the alert). Where there is uncertainty about the relevance of any alert, it should be sent anyway to the relevant people.

Emails sent will be flagged for the recipient indicating that a response is required within one week (or earlier if indicated).

On receipt of the email, the recipient will assess the safety alert and make a decision on whether it is relevant/potentially relevant for their area and the action they need to take, such as dissemination to relevant staff.

The action taken must be recorded on the safety alert database (spreadsheet) within one week (or earlier if indicated) of the alert being sent to them.

Some alerts will only require dissemination to relevant staff for information whilst others may involve the withdrawal of equipment, a change in practice or other appropriate action.

Where appropriate, safety information about equipment/medicines that might potentially be in use by patients on the caseload but are not used/administered by FNHC staff, should be disseminated to relevant staff in case they identify the equipment/drug in use by a patient.

Where an alert requires ongoing action, progress will be discussed at the monthly Operational Management meetings and the Safety Alerts database kept updated.

The Head of Quality and Safety will monitor the database and close the alerts when all areas have completed their response to them and all practicable remedial action to reduce risk has been undertaken.

The Head of Quality and Safety will provide a quarterly report to the Director of Governance and Care that includes categories of safety alerts and 'exceptional reporting'. This information is shared with the Governance Sub Committee and Main Committee.

Where specific issues have been identified as likely to be of significant risk to FNHC (for whatever reason) and may require financial, legal or other action, the Chief Executive Officer (CEO) and the Director of Finance will be appraised by the Director of Governance and Care and added to the organisational risk register if appropriate.

SOP 2 Process to follow in the event of non-compliance

Purpose

This SOP provides a process to follow in the event of non-compliance. It is designed to protect patients, clients, staff and the organisation.

Scope

This SOP applies to all staff working for FNHC or seconded to work within the organisation.

Core Requirements/Procedure

Family Nursing & Home Care expect all staff who receive an alert to respond within the timeframes identified, as failure to do this may compromise the safety of others.

At any stage of the process, where there is a failure to respond to the alert in the appropriate timeframe the staff member should be contacted by telephone to request an immediate reply.

Should no response then be received within two working days, a final reminder will be sent by email flagged 'important'.

If still no response within two working days, the situation should be logged on Assure as a safety incident and escalated to the relevant member of the Senior Management Team, who will consider further action as appropriate.

References

Central Alerting System (date unknown) Central Alerting System Homepage, available at CAS - Home (mhra.gov.uk) (accessed 14.10.24)

Appendices

Appendix 1

Definitions and Explanations

Central Alerting System (CAS) - "The Central Alerting System (CAS) is a web-based cascading system for issuing patient safety alerts, important public health messages and other safety critical information and guidance to the NHS and others, including independent providers of health and social care." (Central Alerting System, date unknown).

Dear Doctor Letters – these come from the Chief Medical Officer and generally convey emergency or international/national key messages

Estates and Facilities Alerts (EFA) – These are issued by NHS Estates to communicate safety information about engineering, installed services and building fabric. These alerts are unlikely to be relevant to Family Nursing & Home Care (FNHC).

Field Safety Corrective Action (FSCA) – this is undertaken by a manufacturer when there are technical or medical concerns about the characteristics or performance of their product which could cause death or serious injury. The Medicines and Healthcare Regulatory Authority assesses all FSCA and if required issues a Medical Device Alert (MDA).

Field Safety Notices (FSN) – These are used by manufacturers to communicate with their customers about FSCA providing advice or action that needs to be undertaken. The MHRA publishes manufacturers' FSNs on their website however, the majority of these will not be relevant to FNHC. Those that are relevant may need to be disseminated to staff for information/awareness and action if required. If contacted directly by the manufacturer a FSN would need to be actioned. Not all FSNs result in a Medical Device Alert (MDA).

Internally Generated Alerts – These are issued to share local learning or raise awareness about safety issues. They will be managed in the same way as alerts from the Central Alerting System and the Medicines and Healthcare Regulatory Authority.

Medicines and Healthcare Regulatory Authority (MHRA) – A UK Department of Health (DH) executive agency, it regulates medicines, medical devices and blood components for transfusion to ensure their safety, quality and effectiveness.

Medicines Recalls/Notifications – These are generated by the Medicines and Healthcare Regulatory Authority (MHRA) as per MHRA Medicines Recall and Notification classifications

National Patient Safety Alerts – These are issued by NHS England and are derived from reviewing and analysing information sources on patient safety events e.g. Learn from patient safety events (LFPSE) service and other sources. Further information can be found in the following link NHS England » Introducing National Patient Safety Alerts

First Line Recipients of Alerts (Operational Leads, Home Care Manager and other relevant Managers/Personnel)

In most instances Registered Managers will be the first line recipients of safety alerts however, other senior managers or Heads of Service may be the first line recipient depending on the alert. It is their responsibility to manage the alert process within their areas and this includes:

- assessing the relevance to their area of alerts received
- disseminating alerts to the appropriate personnel
- ensuring that there are processes in place within their areas of responsibility for actioning alerts and monitoring that agreed actions have been completed
- recording the action they have taken regarding alerts on the safety alert database within 7 days of receiving the alert or within any other required timeframe
- providing updates on the alert where requested
- ensuring a deputy is appointed when required and communicating this person's name to the Quality and Performance Development Nurse and Head of Quality and Safety

Second Line Recipients of Alerts (staff receiving an alert from a 'first line' recipient)

Responsibilities include:

- dissemination to other team members if appropriate
- taking the appropriate action as per the alert and/or as requested by the first line recipient
- adhering to timelines
- providing feedback as requested

Third Line Recipients of Alerts (staff receiving an alert from a 'second line' recipient).

Responsibilities include:

- taking the appropriate action as per the alert and as requested by the sender
- adhering to timelines
- providing feedback as requested