Family Nursing & Home Care

# Standard Operating Procedure

## Safety Alerts Procedure

July 2021

## Document Profile

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| **Author(s)** | Mo de Gruchy |
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## Version Control / Changes Made

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## 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.

### 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, 2016).

**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 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 patient safety incident data from the National Reporting and Learning System (NRLS). There are three stages of patient safety alerts

- Stage one – a "warning" alert to make healthcare staff aware early of emerging concerns
- Stage two – this is a "resource" alert which follows if the stage one alert requires further action. It contains more information and advice
- Stage three – This type of alert is a "directive" and UK healthcare organisations are mandated to respond to confirm that they have undertaken the necessary action to reduce the risk. There is no requirement for FNHC to send confirmation, however, the organisation should complete the requirements of the 'directive' where this is relevant.

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

In most instances the Operational Leads and Home Care Manager will be the first line recipients of safety alerts. It is their responsibility to manage the alert process within their areas and this includes:

- Assessing the relevance of alerts received to their areas
- 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 spreadsheet on central filing within 7 days of receiving the alert or within any other required timeframe.
- Providing an update to the Clinical Effectiveness Facilitator where requested.
- Ensuring a deputy is appointed when required and communicating this person's name to the Clinical Effectiveness Facilitator.

**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 time lines
- 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 time lines
- Providing feedback as requested

## 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*

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

The Clinical Effectiveness Facilitator and their nominated deputy will be signed up to receive automatic alerts from both CAS and the MHRA. The Clinical Effectiveness Facilitator will monitor their emails daily (Monday to Friday with the exception of bank/public holidays) for safety alert notices.

The Clinical Effectiveness Facilitator will inform their deputy when they will be away from work

When alerts are received, the Clinical Effectiveness Facilitator/deputy will determine which alerts are likely to be relevant to FNHC.

The Clinical Effectiveness Facilitator 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 Clinical Effectiveness Facilitator 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 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 spreadsheet should be kept updated.

The Clinical Effectiveness Facilitator 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 Clinical Effectiveness Facilitator will provide a quarterly report to the Director of Governance, Regulation 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 Regulation 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*

FNHC expect all staff who receive an alert to respond within the timeframes identified as failure to do this may compromise patient safety.

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 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 patient safety incident and escalated to the Senior Management Team, who will consider further action as appropriate.

## Safety Alerts Procedure Flowchart