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Standard Operating Procedure (SOP010) for: Safety Alerts	
Staff groups SOP applies to:	All Care Services staff in the Hospice
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Content

1. AIM

Nottinghamshire Hospice is committed to protecting patients, staff, and service users, ensuring that safety alerts are acted upon within the required timescales. The purpose of this document is to give comprehensive and clear guidance in the effective, distribution and action requirements of safety alerts, notices and other communication concerning safety that have been issued via the Central Alerting System (CAS).

This procedural document supports the Risk Assessment Policy OP004, Reporting of Incidents and Accidents Policy OP002, Administration of Medication Policy CS008 and CS014.

2. DEFINITIONS

2.1 **Central Alerting System (CAS)**: - 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.

2.2 **The Medicines and Healthcare products Regulatory Agency (MHRA)**: - The MHRA is the executive agency of the Department of Health charged with protecting and promoting public health and patient safety by ensuring that medicines, healthcare products and medical equipment meet appropriate standards of safety, quality, performance and effectiveness, and that they are used safely.

2.3 **National Patient Safety Alerting System (NPSAS)**: - NHS England through NPSAS issues 3 stages of alerting and reporting that the Hospice is required to action in accordance with the following:

2.4 **Categories of Alerts**: - As well as those alerts issued through the NPSAS under the 3 stage process there are a number of categories that an alert might fall into under CAS which require a response:

- **Immediate Action**: Used in cases where there is a risk of death or serious injury and where the recipient is expected to take immediate action on the advice.
- **Action**: Used where the recipient is expected to take action on the advice, where it is necessary to repeat warnings on long standing problems, or to follow up manufacturers Field Safety Notices.
- **Update**: Used to update the recipient about previously reported incidents or series of incidents, possibly on a topical or device group basis, and where further follow up safety information is judged beneficial.
- **Information Request**: Used to alert users about a specific issue that may become a problem and where feedback is required. These alerts may be sent out with additional questions to be completed.

2.5 **Executive Assistant**: - They are the point of reporting for the hospice and recording actions taken.

2.6 **Medical Devices**: - Medical devices and equipment are items used for the diagnosis and/or treatment of disease, for monitoring patients, and as assistive technology.

2.7 **Medical Device Alerts (MDAs)**: - Medical Device Alerts (MDAs) are the Medicines Healthcare products Regulatory Agency (MHRA) prime means of communicating safety information to medical device users in health and social care. This includes products purchased through procurement systems.

2.8 **MHRA Drug Alerts**: - Drug alerts are published by the Defective Medicines Reporting Centre at the MHRA with the resulting alerts distributed via a national cascade system.

There are four types of Drug Alerts:

Class 1 - Action now (including out of hours)
Class 2 - Action within 48 hours
Class 3 - Action within 5 days
Class 4 - Caution in use

2.9 **Field Safety Notices**: - Actions identified by the manufacturers or distributors of medical devices or consumables relevant to the safety performance of the product. These come through sources outside CAS and may be distributed through hospice internal communications.

3. RESPONSIBILITIES

3.1 Chief Executive

The Chief Executive has overall responsibility for ensuring effective arrangements are in place for managing risk.

3.2 Director of Care

Responsible for ensuring appropriate systems are in place to enable the effective management of safety alerts including receiving and reporting on alerts via CAS on behalf of the hospice. Overall responsibility for ensuring the reporting process for safety alerts is managed and reported to the Quality & Safety committee.
Responsibilities include:

- Distributing alerts to responsible persons
- Liaising with the care managers to monitor status of alerts
- Confirming action to the Executive assistant for recording
- Updating the status of alerts within the Hospice
- Providing support and guidance to staff regarding alerts
- Reporting medical events to the MHRA.

3.3 Executive Assistant

Responsibilities include:

- Maintaining a central record of alerts.
- Maintaining records and confirming action
- Maintaining a monthly summary of alerts to the monitoring committee.

3.4 Care Managers

Responsible for ensuring that safety alerts are acted upon as notified through internal communications, in the areas they are responsible for and for communicating the nature and seriousness of the alert as appropriate.

Responsibilities include:

- Responding to alerts in the time frames set out in the alert.
- Ensure the distribution of alerts to appropriate departments / teams.
- Providing confirmation of actions taken to the DOC/Executive Assistant relevant to the alert issued.

3.5 All staff

Responsible for acting upon alerts notified to them in accordance with the alert issued. On receipt of an alert, they will take the necessary actions within the required timeframes and submit response as required to their line manager who will report to the Executive Assistant through the alert reporting procedure.

4. MANAGEMENT OF SAFETY ALERTS

4.1 Types of Safety Alerts issued through CAS

CAS is a key means to communicate important safety information to the NHS, requiring action to address risks to patient safety. There is a distinction between the two types of alerts sent via CAS:

- **NON-EMERGENCY ALERTS** – issued on behalf of MHRA, Medical Devices, NHS England and DH Estates and Facilities alerts have set deadlines for acknowledgment and completion of actions. Nottinghamshire Hospices is required to submit responses on the action they have taken on alerts and are monitored on their compliance with completing such alerts within agreed deadlines.

- **EMERGENCY ALERTS** - are currently sent by the following originators – MHRA Drug Alerts, MHRA Dear Doctor Letter and CMO Messaging. These alerts can be sent out of office hours (24/7) and are issued directly by the alert originator. Although these alerts do have deadlines, these relate to how quickly the information contained should be cascaded onwards and do not require a response through CAS. As a matter of course these will be monitored through the Hospices reporting process.

5. MONITORING OF ALERTS

A quarterly status report will be provided by the Executive Assistant to the monitoring committee to identify the status of alerts and actions required to close down the alerts. Outstanding actions must be followed up through care managers.

6. APPLICABILITY

This policy applies to all staff employed by the Hospice, whether on a permanent or temporary basis, contracted or bank staff. Failure to action alerts will mean that the safety issues may not be implemented and put the Hospice in breach of its license to safeguard patients. Disciplinary action may be taken for failure to follow this procedure.

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APPENDIX A – PATHWAY FOR CENTRAL ALERTING SYSTEM CASCADES/UPDATES