



STANDING OPERATING PROCEDURE

Subject	Safety Alerts (SOP010)
Applicable to	All Care Services staff in the Hospice
Date issued	20 June 2023
Next review date	20 June 2026
Lead responsible for Policy	Director of Care
Policy Reviewed by	Governance Lead
Notified to	Quality and Safety Group 20 June 2023
Authorised by	Quality and Safety Group 20 June 2023
CQC Standard	SAFE
Links to other Policies/Procedures	Risk Assessment Policy OP004 Reporting of Accidents and Incidents Policy OP002 (under review) Administration of Medication – Hospice in Your Home Policy CS008 (under review) Administration of Medication – GRACE Unit Policy CS014 (under review)
Summary	The purpose of this procedure is to give comprehensive and clear guidance in the effective distribution and action requirements of safety alerts, notices and other communication concerning safety.
Target Audience	All Care Staff

IMPORTANT NOTICE

Staff should refer to the Hospice website or Policies and Procedures folder on the 'N' drive for the most up to date Policy. If the review date of this document has expired it is still valid for 3 months. After that staff should seek advice from their clinical lead or manager.

1.	<p>Aim</p> <p>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), NICE and any other patient safety organisations (e.g. HSE).</p>
2.	<p>Definitions</p> <p>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. It distributes alerts from the agencies below.</p> <p>National Patient Safety Committee issue all safety-critical alerts for medicines and medical devices that require action to be taken by healthcare organisations.</p> <p>The Medicines and Healthcare products Regulatory Agency (MHRA) are the regulator of medicines, medical devices and blood components for transfusion in the UK.</p> <p>The Hospice is required to action these alerts in accordance with the following:</p> <p>Medical Devices: - Medical devices and equipment are items used for the diagnosis and/or treatment of disease, for monitoring patients, and assistive technology.</p> <p>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</p>

	<p>in health and social care. This includes products purchased through procurement systems.</p> <p>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.</p> <p>There are four types of Drug Alerts:</p> <ul style="list-style-type: none"> • 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 <p>Field Safety Notices: Actions identified by the manufacturers or distributors of medical devices or consumables relevant to the safety performance of the product.</p> <p>Yellow Card Scheme</p> <p>The Yellow Card Scheme is the system for recording adverse incidents with medicines and medical devices in the UK.</p> <p>Reports can be made online, by email or by post. Cards can be downloaded and printed off.</p> <p>Reports can be made by professionals and patients.</p>
3.	<p>Responsibilities</p> <p>Chief Executive</p> <p>The Chief Executive has overall responsibility for ensuring effective arrangements are in place for managing risk.</p>

Director of Care (Controlled Drugs Accountable Officer)

Responsible for ensuring appropriate systems are in place to enable the effective management of safety alerts. Overall responsibility for ensuring the reporting process for safety alerts is managed and reported to the Quality & Safety Committee.

Governance Lead

Responsibilities include:

- Receiving and reporting on alerts via CAS on behalf of the Hospice
- Distributing alerts to appropriate persons
- Maintaining a central record of alerts acted upon

Managers

Responsible for ensuring that staff understand their role in responding to safety alerts in the areas they are responsible for and, when appropriate, communicating the nature and seriousness of an alert.

Responsibilities include:

- Providing support and guidance to staff regarding alerts
- Reporting medical events to the MHRA via yellow card scheme
- Ensuring staff respond to alerts in the time frames set out in the alert.

All staff

This procedure applies to all care staff employed by the Hospice, whether on a permanent or temporary basis, contracted or bank staff. Staff are 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.

	<p>They should raise any queries with their line manager.</p> <p>Disciplinary action may be taken for failure to follow this procedure.</p>
4.	<p>Monitoring of Alerts</p> <p>A quarterly status report of Safety Alerts actioned will be provided by the Director of Care to the Quality & Safety Committee for review.</p>

Process for Cascading Alerts Received via CAS (Central Alert System)

