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Safety Alerts Policy

Regulated by Care Quality Commission

BANQUO
Part of Prospero Group

Safety Alerts: Standard Operating Procedure

Lead Clinician for Guideline:	Samantha Norgate - Registered Manager
Discipline:	Governance
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Approved By:	Registered Manager
Audit Date:	N/A
Guideline Review Date:	October 2025

Rationale for Development:

This policy sets out an Organisational process to be followed to ensure appropriate acknowledgement and actions are carried out upon receipt of Safety Alerts and Medicines and Healthcare Products Regulatory Authority (MHRA) alerts are received.

The application of the procedure will help to ensure a consistent approach throughout Banquo Limited with the distribution of safety alerts received from the Department of Health, NHS Improvement, Medicines, and Healthcare Products Agency (MHRA) as well as in-house safety notices such as Patient Safety Briefings and SBARDS which may have been generated as a result of an adverse incident.

Aims and Objectives:

Staff are expected to comply with the principles and processes outlined in this document and are encouraged to note their duties and responsibilities regarding safety alerts.

Method of Guideline Development:

In accordance with national guidance and local practice

Roles & Responsibilities

All Staff to be aware and comply with the guidelines.

Implementation:

Policies will be accessible on our website at the bottom of the page. Internal staff policies will be held on our internal staff/HR platform Employment Hero

Monitoring: Quarterly / Annual report.

Procedure

The Management Team must ensure they are familiar with Medicines and Healthcare Products Regulatory Agency (MHRA) safety alerting systems.

Receipt of Alerts

Electronic alerts are received via the MHRA safety alerting system which Banquo Limited have subscribed to fully.

The Registered Manager is responsible for triaging alerts and disseminating information to the appropriate members of the team for action where appropriate and necessary.

Field Safety Notices (FSN's), issued by GOV.UK, are for information only. If an FSN is received, this MUST be triaged within 48 hours of receipt by a member of the senior management team. The information is to then be disseminated electronically for action as necessary. The senior management team must receive feedback of FSN actions.

Issued alerts are available on the CAS website, and include safety alerts, Estates and Facilities notifications, CMO messages, drug alerts, Dear Doctor letters and Medical Device Alerts issued on behalf of the Medicines and Healthcare Products Regulatory Agency, NHS England, and the Department of Health and Social Care. In addition, the organisation receives Alerts from NHS Protect providing information about high-risk incidents/individuals.

Types of Alert

There are 8 types of alert notices:

MHRA Medical Device Alerts (MDA)

Medical Devices Alerts contain information including Hazard Notices, Safety Notices, Device Alerts, Advice Notices and Safety Notices for and relating to all medical devices.

NHS England National Patient Safety Alerting System.
These Patient Safety Alerts are prepared by NHS England Patient Safety Domain and require prompt action to address high risk safety problems within a specific timeframe. The three stages of National Patient Safety Alerting System (NPSAS) alerts are:
Stage One Alert: Warning This stage 'warns' organisations of emerging risk. It can be issued very quickly once a new risk has been identified to allow rapid dissemination of information.
Typical actions required of organisations in a stage one alert would include:

- Consider if this (the risk issue) could happen/has happened locally.
- Consider if action can be taken locally to reduce the risk.
- Disseminate the warning to relevant staff, departments, and organisations.

Stage Two Alert: Resource This alert may be issued some weeks or months after the stage one alert, and could consist of:

- sharing of relevant local information identified by providers following a stage one alert;
- sharing of examples of local good practice that mitigates the risk identified in the stage one alert.

- access to tools and resources that help providers implement solutions to the stage one alert: and access to learning resources that are relevant to all healthcare workers and can be used as evidence of continued professional development.

Stage Three Alert: Directive

- When this stage of alert is issued, organisations will be required to confirm they have implemented specific solutions or actions to mitigate the risk. A checklist will be issued of required actions to be signed-off in a set timeframe. These actions will be tailored to the patient safety issues.

MHRA Drug Alerts MHRA alerts are defined within Medicines – management of alerts, recalls, reporting (procedure).

Chief Medical Officer (CMO) messages These are classified into four categories: Immediate: to be cascaded within approximately 6 hours.

- Urgent: to be cascaded within 24 hours
- Non-Urgent: to be cascaded within 48 hours For Information.
- *All of the above to be sent for information.

Suspicious Drug Requests

This can be received from any NHS England Local Area Team or the Integrated Care System (ICS). If a request is made from a member of public to a member of Trust staff, this must be reported as an incident and sent directly to the Local Security Management Specialist (LSMS)
Internal Alerts

Any information, from within the Organisation that needs wider circulation, can be done so via an Internal Alert, examples include SBARDs or a Patient Safety Briefing. These are currently circulated to appropriate recipients by either the Registered Manager or a designated individual.

Storage of Alert

All alerts and related documents are stored in a folder on the shared hard drive.

The safety alerts folder contains an EXCEL spread sheet in which details of all alerts that are recorded along with actions taken.

There are also ‘Relevant’ and ‘Not Relevant’ sub folders in which all related PDF files are saved.

The Registered Manager must:

1. triage all alerts deciphering between; relevant / not relevant but urgent / non-urgent alerts.
2. record all alerts on the EXCEL spread sheet held in the MHRA Safety Alerts folder on the shared hard drive
3. take relevant action for all urgent alerts

Actions are monitored and reviewed against timescales and amendments are made where necessary.

Information is reported to relevant external professionals as required.

The Registered Manager is responsible for ensuring annual audits occur to ensure alerts have been triaged correctly and appropriate action taken as required.

Evidence

Evidence base	Health and Social Care Act (2008) Regulated activities regulations (2014) Care Quality Commission Fundamental Standards (2015) https://improvement.nhs.uk/resources/patient-safety-alerts/ https://www.cas.mhra.gov.uk/Home.aspx
Identified Risks	Risk of harm to patients Non-compliance with Care Quality Commission Fundamental Standards 2015
Monitoring	The procedure is monitored via annual audit