SAFETY ALERTS PROCEDURE

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Consultation	Patient Safety & Medical Devices Group
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Name of approving group/Committee **Date of approval**	Physical Health and Medical Devices Group 19 April 2023

VALIDITY – Policies should be accessed via the Trust intranet to ensure the current version is used.

CHANGE RECORD

Version	Date	Change details
1.0	*13/08/2018*	*New procedure*
1.1	*21/12/2020*	*Minor changes to incorporate Medical Device Safety Bulletins (section 5)*
1.2	*14/12/2022*	*Added in named roles and detailed the alert types and who is responsible, with deputies. Updated flow charts accordingly. Approved by PHMD Group (14/12/22).*
1.3	*19/04/23*	*Review (minor amends) - Changes only to ensure the procedure mirrors the NHS 'Provider process flow for National Patient Safety Alerts' published March 2023 and to incorporate "NHS England Estates and Facilities Alerts" and "UKHSA Urgent Public Health Messages". Approved by PHMD Group (19/04/22).*

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1. INTRODUCTION

National Patient Safety Alerting Committee (NaPSAC) requires healthcare providers to have robust systems in place for planning and coordinating the actions required by any National Patient Safety Alert across their organisation, and this must include executive oversight. This is essential for effective delivery of systematic actions to protect staff from error and protect patients from risk of death or disability. **NHS England: Introducing National Patient Safety Alerts**

"Failure to take the actions required under any National Patient Safety Alert may lead to CQC taking regulatory action. Declared compliance with alerts is a key safety indicator, and compliance with National Patient Safety Alerts is a focus of CQC inspection" (NHS England)

This procedure details Humber Teaching NHS Foundation Trust's arrangements for the safe and effective management of national patient safety alerts. It also outlines the procedure for other safety notification and drug alerts.

Safety alerts are issued via the Central Alerting System (CAS) and outline actions that must be taken to address potential safety risks to service users, visitors and staff. Failure to implement alert requirements in a timely and appropriate manner can lead to significant impact to safety and reputational consequences for the Trust.

The following alert and notifications are covered by this procedure:

- National Patient Safety Alerts (Nat/PSA)
- Medicine Defect Information
- Medicine Recall
- Chief Medical Officer Alerts (CEM/CMOs)
- Device Safety Information (DSI)
- Serious Hazards of Transfusion (SHOT)

2. SCOPE

This procedure applies to all employees of Humber Teaching NHS Foundation Trust but specifically to individuals and teams involved in the review and organisational response of safety alerts namely:

- Executive Director of Nursing, Allied Health and Social Care Professionals
- Patient Safety Specialist.
- Nominated CAS officer
- Medicines Safety Team
- Medical Devices Safety Officer

3. PROCEDURE STATEMENT

This procedure seeks to establish a safe consistent approach to the management of safety alerts to:

- Provide assurance on the implementation of safety alerts within the organisation and the processes that support delivery.
- To ensure appropriate clinical leadership and co-ordination in response to safety alerts
- Ensure that staff members receive adequate notification of relevant safety alerts in a timely manner for actions to be taken and changes in practice to be fully embedded.
- Minimise risk to service users, visitors or staff through the implementation of safety alerts.
- Ensure that the correct teams/staff members are notified of the right alerts at the right time to effective management.

4. DUTIES AND RESPONSIBILITIES

Chief Executive has overall accountability for having effective management systems and internal controls in place relating to alerts issued by the Central Alerting System (CAS) and for meeting statutory requirements. The chief executive delegates responsibility to the Trust's Executive Director of Nursing, Allied Health and Social Care professionals for executing the Trust's response.

Executive Director of Nursing, Allied Health and Social Care Professionals:

- Is the designated member of the executive team with overall responsibility for executing the Trust's response to patient safety alerts ensuring appropriate clinical leadership and action implementation.
- They will provide authorisation for recording Nat/PSAs as 'action completed' on CAS once all actions have been completed.
- In the absence of the Executive Director of Nursing this responsibility will be delegated to the Medical Director or Deputy Director of Nursing.

Patient Safety Specialist:

- Holds the overall responsibility for ensuring CAS alerts have been escalated by the CAS officer to the Executive Director of Nursing and other relevant senior leaders.
- In the absence of the Trust's nominated CAS officer, they will act as interim CAS officer.
- They will support and oversee the delivery of actions by the appropriate clinical leaders and escalate concerns directly to the Executive Director of Nursing.
- They will review the CAS system and HealthAssure monthly to ensure responses and updates have been applied. In the absence of the CAS officer this will be done daily (Mon-Friday).
- If wider communication of an alert is required for example through a practice note, the Patient Safety Specialist will co-ordinate this through the communication teams.

Nominated CAS officer:

- Is responsible for acknowledging receipt of safety alerts through the Central Alerting System (CAS) and is responsible for updating the CAS system around the organisation's progress in implementing an alert's required actions.
- The CAS officer is required to ensure Nat/PSAs rapidly reach the designated executive lead and other senior leaders who will co-ordinate the delivery of an alert's required action.
- They should only be recording NatPSAs as 'action completed' on CAS once all actions have been completed and they have the authorisation of the designated member of the executive team (Executive Director of Nursing, Allied Health and Social Care Professionals).
- For all other alerts and notification, the CAS officer is responsible for ensuring timely dissemination and review by relevant senior leaders including were relevant the Patient Safety Team, Chief Pharmacist, Medical Devices Safety Officer, Medicines Safety Officer, Infection Prevention and Control Lead Nurse, Procurement Manager, Estates and Facilities Manager.
- CAS recommend that Trusts "acknowledge alerts as soon as possible after receipt, even if you do not know at that point whether the actions will be relevant to your organisation". The CAS officer (or deputy) will therefore acknowledge receipt and cascade of alerts within 3 working days on the CAS system.
- They will complete monthly reports for QPaS and Physical Health and Medical Devices meetings to monitor compliance with required actions.
- They will support and co-ordinate a gap analysis and develop an action plan to ensure all actions on National Patient Safety Alerts (if relevant to HTFT) have been addressed.

Medicines Safety Team

- All National Patient Safety Alerts involving medicines or medicine safety will be reviewed by the Chief Pharmacist or in their absence The Deputy Chief Pharmacist.
- The Chief Pharmacist will co-ordinate responses from the wider medicine's safety team, medicines safety officer (MSO), community pharmacist and/or pharmacy technician as required in relation to confirmation of applicability and co-ordination of any actions required.
- These will be feedback to the CAS officer and Patient Safety Specialist.
- All other medicines related alerts i.e., medicine recalls, medicine notifications will be reviewed by the MSO who will be responsible for co-ordinating responses from pharmacy technicians, community pharmacist or relevant others as appropriate.
- The MSO will review and update all such alerts on HealthAssure and will feedback to the CAS Officer and Patient Safety Specialist. Concerns will be escalated to the Chief Pharmacist.
- The CAS officer, as with any national patient safety alert, will be responsible for closing the alert on both the CAS system and HealthAssure.
- In the absence of the MSO, the responsible staff will be the Medicines Optimisation Nurse and Medicines Optimisation Technician

Medical Devices Safety Officer (MDSO)

- Any alert relating to medical devices will be reviewed by the Trust's nominated Medical Devices Safety Officer who will work with the appropriate teams to determine if the device is used or held within HTFT. This will require the review of the asset register and confirmation through the procurement team as to whether any such devices has been purchased by any of our services.
- The Medical Devices Safety Officer will be registered with the MHRA and will act as a point of contact for manufacturers for Field Safety Notices.
- They will be responsible for working with the relevant teams in response to any relevant field safety notices.
- Action taken in relation to Field Safety Notices will be reported to the Physical Health and Medical Devices group.
- The MDSO will review and feedback to the CAS officer and Patient Safety Specialist.
- Concerns will be escalated to the Patient Safety Specialist and the Physical Health and Medical Devices Group.
- Approval for closure of all medical device related national patient safety alerts will be obtained from the Executive Director of Nursing.
- In the absence of the MDSO the Patient Safety Specialist. will act as the Interim MDSO.

5. DEFINITIONS

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. The system can be accessed via the following web link www.cas.mhra.gov.uk

National Patient Safety Alerts
As per NHS England » Introducing National Patient Safety Alerts National Patient Safety Alerts typically require action to be centrally coordinated on behalf of the whole organisation, rather than by multiple individual teams, divisions or directorates. All National Patient Safety Alerts need executive level oversight of governance systems that provide evidence that the required actions have been fully completed before any National Patient Safety Alert is recorded as 'action completed' on the Central Alerting System (CAS).

Complex and straightforward alerts:
Each National Patient Safety Alert is designated as either 'complex' or 'straightforward', and providers are required to take a different response to each:

- 'Complex' alerts require actions that cannot be delivered by any single division or professional group within an organisation and will require the organisation's executive leader to nominate a senior clinical leader relevant to the alert to coordinate delivery
- 'Straightforward' alerts may be actioned on behalf of the whole organisation by agreed senior leaders (for example, an agreement that the chief pharmacist will ensure all stocks throughout the organisation are checked for a National Patient Safety Alert requiring removal of a specific drug batch), or may be directed at a specific senior leader relevant to the alert

Medicine Recalls and Medicine Notifications

All Class 1 Medicines Recalls will meet the National Patient Safety Alert criteria and will be issued as National Patient Safety Alerts (NatPSA). Responses will be collected via the CAS website. Any Recalls and Notifications that do not meet the National Patient Safety Alert criteria will not be published on the CAS website but will be published on Health Assure and via Alerts, recalls and safety information: drugs and medical devices - GOV.UK (www.gov.uk)

Field Safety Notice

A Field Safety Notice (FSN) is a communication sent by a medical devices manufacturer, or their representatives, in connection with a Field Safety Corrective Action (FSCA).

A 'field safety notice' (FSN) is an important communication about the safety of a medical device that is sent by a device manufacturer, or their representative.

FSNs outline the actions needed to do to reduce the specified risks of using the medical device. The actions are referred to as 'field safety corrective actions' (FSCAs).

FSN are also published on Alerts, recalls and safety information: drugs and medical devices - GOV.UK (www.gov.uk)

Chief Medical Officer (CMO) and UKHSA Public Health Messages alerts are issued to provide up-to-date information key public health and clinical quality issues. The patient safety team will review and assess the applicability of these communications and distribute accordingly, following consultation with the Medical Director or designated other as appropriate"

6. ALERT RESPONSES

All responses to safety alerts (including a summary of actions taken) by the Trust are communicated and recorded through the HealthAssure system CAS portal were applicable.

7. GOVERNANCE AND REPORTING

Responses and actions taken are monitored through internal assurance processes linked to the Physical Health and Medical Devices Group (PHMD), the Clinical Risk Management Group (CRMG). The Trust's Drugs and Therapeutics Group (DTG) meets on a bi-monthly basis and reviews all drug alerts issued via the Central Alerting System as well as the status of any required actions and also seeks assurance around completion.

A report detailing all alerts received and actions taken by the Trust is submitted 6 weekly to Quality and Patient Safety Group (QPaS). Where applicable to the alert being cascaded, alerts will also be monitored by and reported to Health and Safety Group, or any group deemed relevant.

8. DUE DILIGENCE

Upon the acquisition of new Trust services, CRMG will commission a look-back exercise to determine all patient safety alerts applicable to the newly-acquired service, to seek assurance that all required actions have been addressed and to identify any further actions to be taken to ensure full compliance.

Any commissioned look-back exercises will also be reported into QPaS on a quarterly basis to enable further oversight of outcome of the exercise and to provide assurance around any actions taken.

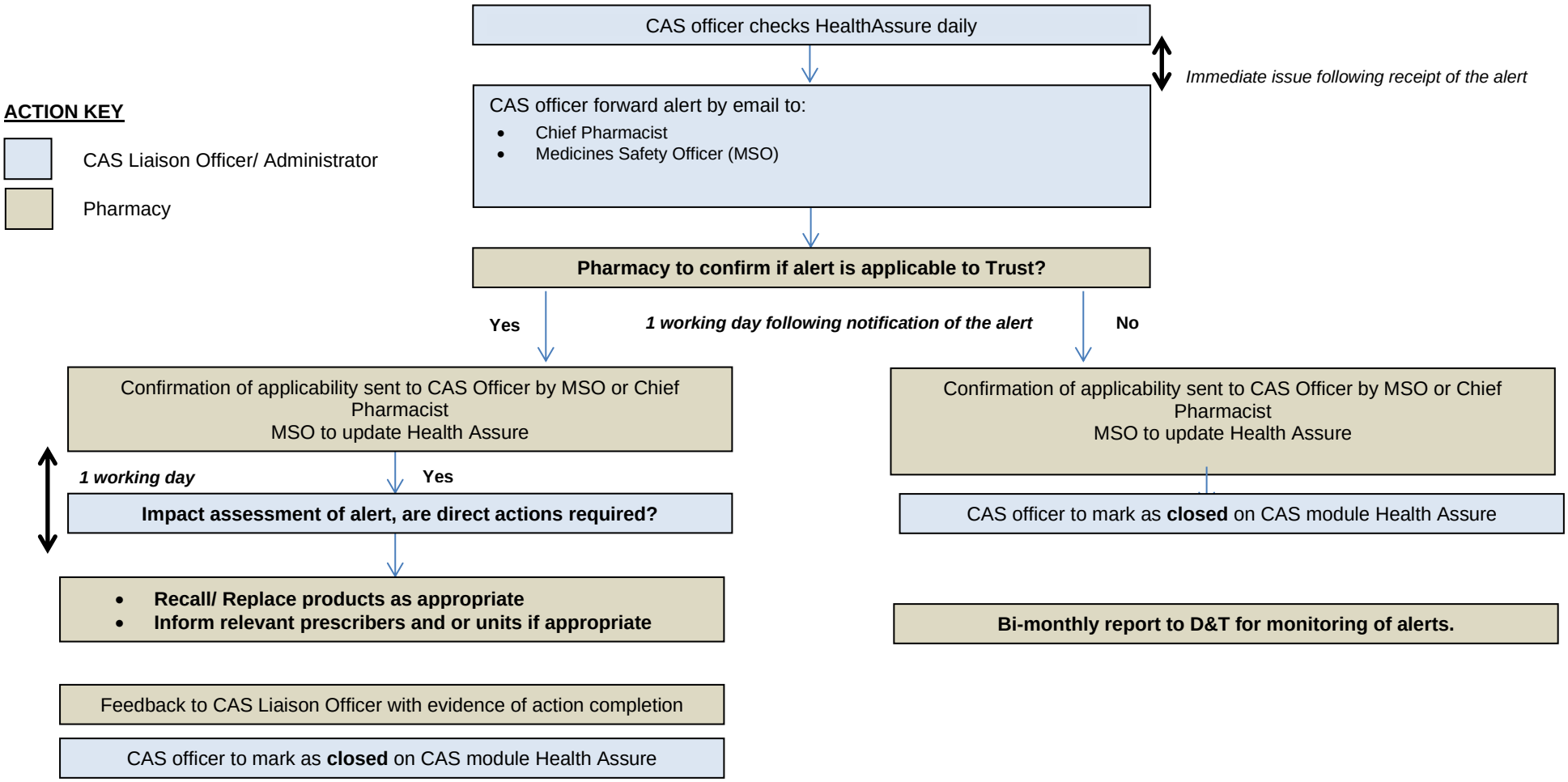
9. MONITORING AND AUDIT

Compliance and monitoring of patient safety alerts is overseen by the Quality and Patient Safety Group (QPAS).

A 6 weekly report will be submitted to QPaS outlining a position statement against each alert that has been deemed as applicable to our organisation.

As directed by QPAS the Quality Governance and Patient Safety team will audit changes in practice resulting from patient safety alerts in order to provide assurance to QPaS that improvement actions have been adopted and embedded. This will be undertaken as appropriate to the PSA, e.g. audit, peer review or monitoring against specific KPIs.

10. MHRA MEDICINES ALERTS CLASS 2- 4 – PROCESS FLOW



Note:
Class 2 medicine recalls require action within 48 hours

11. NATIONAL PATIENT SAFETY ALERTS – PROCESS FLOW