



Public – To be published on the Trust external website

Procedure for the Management of Safety Alerts, Rapid Response Reporting, Field Safety Notices and Trust Safety Notices

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1 Introduction

This document sets out the Tees, Esk and Wear Valleys NHS Foundation Trust (TEVV) Procedure for the management of Central Alerting System (CAS) Safety Alerts and other external and internal safety alerts as needed.

The Central Alerting System is a national web-based cascading system for issuing 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 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 the Central Alerting System – those that require an external response (on the CAS website) and those that do not.

Alerts issued on behalf of MHRA Medical Devices, NHS England & Improvement and Department of Health Estates & Facilities, have set deadlines for acknowledgement and completion of actions. NHS Trusts are 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.

MHRA Drug Alerts and CMO Messaging do not require an external response. These are managed via the alerts process in the same way.

Internal safety alerts are managed by the Patient Safety Team. On receipt of a request for an urgent Patient Safety Briefing/SBARD to be distributed, the Patient Safety Team will confirm if a previous briefing or other form of communication has been circulated to determine if a different form of action is required. Once the need for a Patient Safety Briefing has been confirmed, this will be developed between Patient Safety and other relevant persons to ensure the content and requested action as well as the timeframe for assurances to be returned is appropriate. The Patient Safety Team will then circulate the briefing by email to the relevant services via the Business Managers. Internal safety alerts are stored in the Learning Library. Any assurance requested is stored in the PST Learning Database.

Healthcare organisations are required to develop, implement, and maintain processes for dissemination and review of Safety Alerts in accordance with the Medicines and Healthcare products Regulatory Agency (MHRA) publication 'Reporting adverse incidents and Disseminating Safety Alerts'- DB2011(01).

The Trust is committed to protecting patients, staff, and visitors by ensuring that safety alerts and other safety notices are acted upon within the required timescales. The Trust's nominated CAS Liaison Officer (within the Patient Safety Team) is responsible for

acknowledging, disseminating, closing off safety alerts and providing feedback to relevant committees within designated timescales.

This procedure is critical to the delivery of [Our Journey To Change \(OJTC\)](#), supporting our ambition to co-create safe care for our patients by ensuring safety concerns are addressed. This in turn enables co-creating of a great experience for colleagues



IMPORTANT: To ensure that the Trust processes for management and distribution of Central Alerting System Safety Alerts is effective all new Safety Alerts or Field Safety Notices received through any other route must be emailed to the following mailbox to ensure appropriate action can be taken tewv.safetyalerts@nhs.net

2 Purpose

The application of the procedure will help to ensure a consistent approach throughout the Trust for 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.

3 Who this Procedure applies to

This procedure applies to all staff.

Management of safety alerts received will take place centrally within the Patient Safety Team. Specialist Leads, as well as staff in management roles across all areas will have a key part to play in ensuring actions needed are completed and all staff are made aware of alerts that may affect them in their area of work.

4 Related documents

This procedure links to:-

- ✓ [Medical Devices Policy](#)
- ✓ [Incident Reporting and Serious Incident Review Policy](#)
- ✓ [Medicines – management of alerts, recalls, reporting](#) (procedure)

5 Procedure for Safety Alerts

The aim of this procedure is to ensure that all Safety Alerts are communicated promptly and effectively to relevant members of staff and that appropriate action is taken in a timely manner.

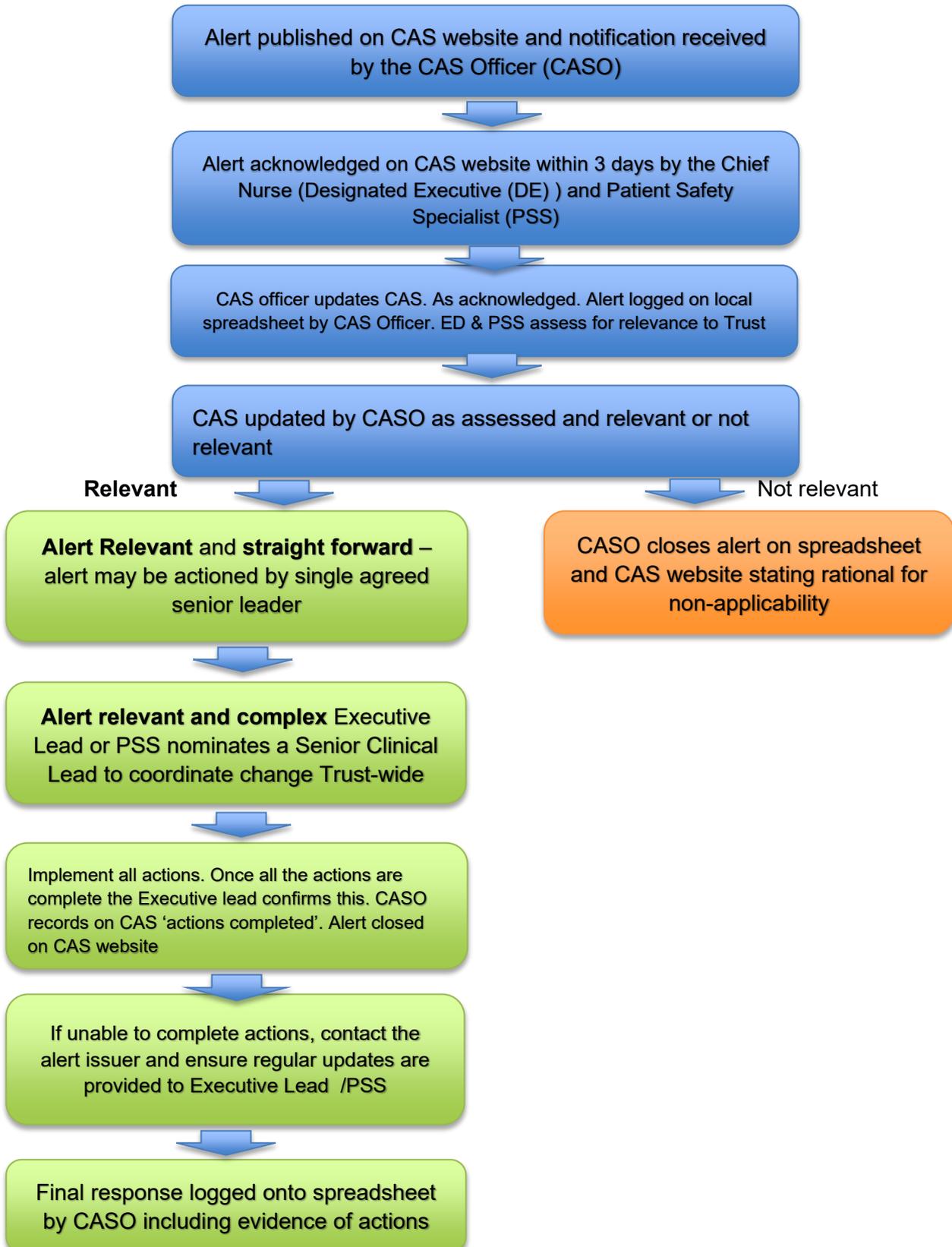
This procedure describes the processes and responsibilities that ensure that:

- Safety alerts are circulated appropriately,
- All appropriate staff are aware of safety alerts,

-
- The relevant leads are identified and forward safety alerts to the relevant people within their area,
 - Appropriate corrective action is identified and implemented in response to safety alerts, and
 - Assurance is given that safety alerts risks are being appropriately controlled.

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.

5.1 Provider Process flow for National Patient safety Alerts



5.2 Types of Alert

There are 8 types of alert notices

5.2.1 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.

5.2.2 NHS England National Patient Safety Alerting System

These Patient Safety Alerts are prepared by NHS England Patient Safety Domain and requires 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.

5.2.3 NHS Estates Notices

Estates and Facilities Alerts relate to all non-medical equipment, engineering plant installed services and building fabric in the NHS

5.2.4 MHRA Drug Alerts

MHRA alerts are defined within [Medicines – management of alerts, recalls, reporting \(procedure\)](#).

5.2.5 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.

5.2.6 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)

5.2.7 Internal Alerts

Any information, from within the Trust 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 Business managers or a designated admin member for the Care Groups.

5.2.8 Security Alerts

The Local Security Management Specialist (LSMS) is responsible for assessing the relevance of the Alert once received. Not all alerts will need to be cascaded throughout the Trust. The decision to cascade will be based upon the threat to Staff, the likelihood and possible consequences. For example, some alerts may only be relevant to NHS acute hospitals with A&E departments. If the Alert requires a cascade this will be distributed by the LSMS via the Health and Safety Co-ordinator who will log responses accordingly.

5.3 Acknowledgement, Distribution & Management of Safety Alerts

5.3.1 Receipt and Acknowledgement of alerts

Alerts issued through the Central Alerting System are emailed to a central email box within the Trust.

Alert receipt to be acknowledged, in accordance with the category of the alert, or within 2 (3 for NPSA) working days at the CAS Web Interface is to be updated to status “Acknowledged”; On CASO the alert, in accordance with the category of the alert, or within 2 (3 for NPSA) working days at the latest; this is done by:

- Accessing the [CAS Web Interface](#) (using the login)
- Navigating to the alerts by clicking “View my Alerts” to display the received alerts list
- Clicking the alert title of the relevant alert to display full details of the alert
- Selecting the appropriate response status and clicking save

Upon receipt the CASO;

- Forward the alert to the weekly alert review huddle members and or designated executive and Patient Safety Specialist for NPSA within 1 working day of receipt.
- Contact procurement and seek confirmation of whether the item has been purchased, advising the weekly alert review huddle of the response.

5.3.2 Assessment of relevance and distribution of alerts

Alerts (unless NPSA (see appendix 3) or urgent) will be reviewed and assessed for relevance and distribution in the weekly alert review huddle. The huddle consists of specialist in Patient Safety, Health & Safety, Infection Control, Medical Devices, Physical Healthcare, Back Care Advisory, Risk Management, Pharmacy, and other relevant professionals as required. The huddle will determine the area the alert its relevant to.

The patient safety team will then distribute alerts accordingly, to the nominated Alert Leads within the Care Group and other services who will cascade to the appropriate people within their speciality.

National Patient Safety Alerts will be brought to the attention of both the Chief Nurse who is the Designated Executive) and the Patient Safety Specialist for executive oversight and co-ordination. A work plan will be created for the required actions .

CMO alerts are issued directly to the Medical Director and/or Chief Executive. These should be assessed for relevance and distribution. If it is determined that distribution is necessary, a copy of the alert should be sent to the CASO for distribution, as identified by the Medical Director/Chief Executive.

5.3.3 Management and Action of Alerts

The Patient Safety Team will distribute a CAS notification of each alert to the relevant Nominated Lead detailing the response date and the date for action completion. This will be as advised by the Designated Executive and Patient Safety Specialist for any NPSA (See Appendix 3).

The Nominated Alert Leads will distribute to the relevant staff from whom a response is required. The Nominated Alert Leads will ensure responses are completed within their specialty, from those whom they sent the alert for action and will complete a final response, to the CASO by the initial response deadline.

Where an action plan is required, the Nominated Alert Leads will work with the Lead Officer for the alert and are responsible for ensuring the action plan is developed, monitored, and completed by those identified as being responsible by the actions completed deadline. The action plan will be monitored by the most appropriate governance route.

The Lead Officer and/or Nominated Leads will forward the agreed action plan to the CASO by the initial response deadline, provide updates accordingly and confirm that all actions have been completed prior to the action's completion deadline. Progress of which is monitored by the weekly huddle.

If responses are not received and/or deadlines are missed the CASO will escalate this to the Care Group Directors. Any deadlines missed will be reported into the relevant governance/assurance meetings.

5.3.4 Closure of Alerts

Alerts will be closed by the Patient Safety Team/CASO following review and agreement by the weekly alert review group following confirmations from the Lead Officer and/or each of the relevant Nominated Alert Leads that:

- No action is required, and the reason why clearly stated.
- Actions completed, matter resolved with details of actions taken as required by the alert and/or supporting action plan attached where appropriate.

In the case of National Patient Safety Alerts as detailed in appendix 3 the Executive Lead will confirm that all actions have been completed. This will then be updated on the CAS by the CASO to ensure the alert is closed on CAS.

If the Trust is unable to complete actions, this should be reported to the alert issuer. This should be escalated to the Executive Lead of the Trust’s Patient Safety Specialist.

6 Roles and Responsibilities

Role	Responsibility
Chief Executive	The Chief Executive is accountable for the Trust having the necessary management systems in place for CAS alerts, including the nomination of a responsible Executive Director and a nominated Patient Safety Specialist.
Chief Nurse	The Chief Nurse is the designated Executive Director responsible for the implementation and monitoring of the CAS procedure.
Director of Quality Governance Associate Director of Patient Safety Patient Safety Specialist	The Director of Quality Governance, Associate Director of Patient Safety and the Patient Safety Specialist will support the Director of Nursing & Governance in ensuring the procedure is robust and effective.
Care Group Directors	Care Group Directors are responsible for: <ul style="list-style-type: none"> • The implementation of CAS Alerts within their service • Following up and managing the occasions when the Nominated Manager fails to respond to an alert notification within the given time frame.
Nominated CAS Officer	A nominated CAS Officer (CASO) will be responsible for: <ul style="list-style-type: none"> • Ensuring the relevance of alerts is appropriately assessed • Ensuring appropriate steps are taken and actions created and completed to comply with the alert requirement. • Arranging the addition of relevant alerts to the risk register. • Share any learning from alerts. • Reporting any incident associated with non-compliance with alerts. • In the event of responses not being received/ deadlines outstanding, escalate to Care Group Directors

<p>Patient Safety Team Administrator(s)/CASO</p>	<ul style="list-style-type: none"> • Receives the CAS alerts into the central mailbox. • Acknowledges receipt of all alerts received via CAS, within two working days (or other relevant timescale) • Adds alerts to the safety alert spreadsheet for tracking. • Maintain appropriate distribution groups and monitor responses. • Distributing alerts via email to the weekly alert review group members and adding to next meeting agenda. • Distributing alerts to Lead managers and wider circulation as required. • Adds responses and updates received to the next weekly alert review group agenda. • Updating alerts on spreadsheet and CAS as required. • In the event of responses not being received/ deadlines outstanding, escalate to Designated Director and/or Patient Safety Specialist. • For Health and Safety Alerts for dangerous people and NHS Protect Alerts, the Local Security Management Specialist will email these to the PST administrator if distribution is required. • If it is agreed that an alert needs to be distributed, the PST administrator will send an email to any staff that need to take action, with a deadline date. The alert should be sent to other appropriate staff, for information purposes. • Maintain a database of all safety notices disseminated throughout the Trust and any resulting action • Maintain a database of all local safety briefings, and any assurance required with dates obtained • Ensure that local patient safety briefings and SBARDS are placed in the Learning Library on the Trust’s intranet. • In terms of National Patient Safety Alerts, the Provider Process for National Patient Safety Alerts’ (flow chart issued March 2023 in appendix 3) should be followed
<p>Nominated Alert Leads</p>	<p>This role may vary between care groups and services and different types of alerts (this role could include Business Managers/ General Managers/ Service Managers/ Matrons) however there should be an identified lead within each service line for the co-ordination of alerts.</p> <p>Nominated managers are key recipients of safety alerts.</p>

	<p>For each safety alert that they (or their nominated deputy) receive, they must follow instructions on the accompanying email for example, they may be asked to:</p> <ul style="list-style-type: none"> • Send a return email acknowledging receipt of email within 2 days; • Consider if they use the equipment/if the alert applies to their area – if it is relevant staff • Send one response within the timescale stated on the alert for their area of responsibility stating one of the following responses: <ul style="list-style-type: none"> ○ Action not required; ○ Action required and will confirm action completed before the deadline date. <p>Depending on the type of alert, if action is required they will also:</p> <ul style="list-style-type: none"> • Formulate an action plan. • Ensure their respective Quality Assurance & Improvement Group is kept informed of progress, which in turn reports to the Quality and Assurance Committee. • Ensure the Patient Safety Team/CASO are notified when action has been completed. <p>If there is a delay in completing the action, the Patient Safety Team/CASO should be informed as soon as possible.</p>
<p>All other staff in receipt of safety alerts from the Patient Safety Team or local manager</p>	<p>Where applicable, ensure all relevant staff are aware of the safety alert.</p> <p>Ensure that any relevant action resulting from a safety alert is completed within the required timescale and that nominated manager is kept up to date</p>
<p>Estates and Facilities Management</p>	<p>The Patient Safety Team forwards the alert to the Associate Director of Estates, who determines the relevance of alert to the Trust and if appropriate, this is to be added to the risk register.</p> <ul style="list-style-type: none"> • If not relevant to the Trust, they will advise the Patient Safety Team that it does not need to be distributed to Trust staff.

	<ul style="list-style-type: none"> • If estates confirm that the alert should be distributed to TEWV staff, alert will be sent to the Business Managers or nominated deputies for onward distribution. • If relevant to the Trust, a lead will be identified to action the alert. • The lead will prepare an action plan with target dates to action the alert. Monthly updates will be provided to the Directorate Management Team. • On completing identified actions, the PST administrator/CASO will be informed to ensure the appropriate actions are taken to close the alert down
Lead Pharmacist	<ul style="list-style-type: none"> • The Lead Pharmacist is the point of contact for CAS Safety alerts in relation to Medicines. They will identify the appropriate person to manage these alerts and ensure all actions are completed. They are also to act as the essential link between local actions to improve medication safety and implementation of national initiatives. • Specific actions for medicines alerts are defined in Medicines – management of alerts, recalls, reporting (procedure)
The Associate Director of Procurement at County Durham and Darlington Foundation Trust	Will within 5 working days of a Medical Device Alert being released, inform the Trust Patient Safety team admin/CASO if the Trust has purchased the subject of the alert through procurement.
The Trust IPC, Medical Devices, Physical Healthcare and Back Care Advisory Service, Medical Devices, Safety Officer (MDSO) and Patient Safety Leads	<p>After receiving the response from the Associate Director of Procurement at County Durham and Darlington Foundation Trust, regarding whether the Trust has purchased the subject of the alert through procurement; the Patient Safety Team will forward the alert to the Trust IPC, Medical Devices, Physical Healthcare Team, Back Care Advisory Service and MDSO to determine if the product may have been purchased through other means.</p> <p>The Patient Safety team will also forward any Field Safety Notices.</p> <p>The IPC, Medical Devices, Physical Healthcare and Back Care Advisory Service access the Approved Medical Device Templates on Cardea to ensure the product is not listed. A secondary safety check is also performed through a search of the Medical Device email account to identify if this has been purchased through a non-catalogued request.</p>

The IPC, Medical Devices, Physical Healthcare and Back Care Advisory Service also consider whether the product may be utilised in the community through an external non-Trust procurement route as this may have a direct effect on patient care delivery and staff usage. Examples include patients own equipment, day services and private care providers.

If not relevant to the Trust they will advise the PST administrator that it does not need to be distributed to Trust staff.

If the IPC, Medical Devices, Physical Healthcare and Back Care Advisory Service confirm that the alert will be circulated to TEWV staff, the PST administrator will circulate this.

The IPC, Medical Devices, Physical Health and Back Care Advisory Service will respond to and follow up adverse incidents involving medical devices. Where appropriate, this will be done in conjunction with relevant clinical staff or Trust staff and reported through the Medical Devices Group.

7 Terms and definitions

Term	Definition
Central Alerting System (CAS)	<ul style="list-style-type: none"> Electronic broadcast system where key safety alerts will be emailed to the Trust.
Medical Device	<p>Any instrument, apparatus, appliance, material or health care product, excluding drugs, used for a patient for the purpose of:</p> <ul style="list-style-type: none"> Diagnosis, prevention, monitoring, or treatment of disease or disability. Diagnosis, monitoring, treatment, or alleviation of, or compensation for, an injury or handicap. Investigation, replacement or modification of the anatomy or of a physiological process. The testing of alcohol and illicit drugs Walking aids, continence aids, contact lenses, commodes, hospital beds and wheelchairs are also medical devices. A more extensive list of products that fall within the definition of medical device can be found at www.mhra.gov.uk
Adverse Incident	<ul style="list-style-type: none"> An event that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of patients, users or other persons.

8 How this procedure will be implemented

- This procedure will be published on the Trust’s intranet, and external website
- Line managers will disseminate this procedure to all Trust employees through a line management briefing.

8.1 Training needs analysis

The training needs analysis remains on-going as the corporate team managing safety alerts is merging with the patient safety team. The process for dissemination of internal briefings also remains on-going. The QI team are working with representatives from operational services including business managers from both Care Groups and the Patient Safety Team to streamline dissemination of all safety alerts. Training will then be

identified; this procedure may then need further revision. This procedure includes the new Provider Process Flow for National Patient Safety Alerts (see appendix 3). This CAS alert issued in March 2023 will be circulated Trust-wide for information purposes.

9 How the implementation of this procedure will be monitored

Number	Auditable Standard/Key Performance Indicators	Frequency/Method/Person Responsible	Where results and any Associate Action Plan will be reported to, implemented and monitored; (this will usually be via the relevant Governance Group).
1	This procedure will be audited to monitor whether the process is being followed, to see if it needs updating, and to monitor whether it is working effectively.	This procedure will be audited annually.	Any results will be monitored by the Director of Quality Governance and the Associate Director of Patient Safety and discussed in the appropriate corporate governance group and the governance groups of both care groups

10 References

Medicines and Healthcare Products Regulatory Agency (MHRA) publication ‘Reporting adverse incidents and Disseminating Safety Alerts’- DB2011(01).

11 Document control (external)

To be recorded on the policy register by Policy Coordinator

Date of approval	26 April 2023
Next review date	26 April 2026
This document replaces	CORP-0039-v4 Safety alerts - procedure for the Distribution of Safety Alert Broadcasts and Trust Safety Notices
This document was approved by	EQAIG
This document was approved	25 April 2023

This document was ratified by	Executive Directors Group
This document was ratified	26 April 2023
An equality analysis was completed on this policy on	14 Dec 2022
Document type	Public
FOI Clause (Private documents only)	N/A

Change record

Version	Date	Amendment details	Status
v5	26 Apr 2023	<p>Full review:</p> <p>1/ Responsibilities and process flow charts updated to reflect the inclusion of patient safety briefings and restructure of the responsible team for oversight and management of the processes set out in this procedure.</p> <p>2/ It also reflects the Provider process flow for National Patient Safety Alerts issued in March 2023.</p> <p>3/ Section 5.2.4 MHRA Drug Alerts amended to signpost to procedure.</p> <p>4/ Section 6 Roles and Responsibilities – Lead Pharmacist responsibility amended for medicines alert actions to signpost to procedure.</p>	Ratified

Appendix 1 - Equality Analysis Screening Form

Please note: The Equality Analysis Policy and Equality Analysis Guidance can be found on the policy pages of the intranet

Section 1	Scope
Name of service area/directorate/department	Corporate – Nursing and Governance
Title	Procedure for the Management of Safety Alerts, Rapid Response Reporting, Field Safety Notices and Trust Safety Notices
Type	Procedure
Geographical area covered	Trust wide
Aims and objectives	The application of the procedure will help to ensure a consistent approach throughout the Trust for 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 have been generated as a result of an adverse incident.
Start date of Equality Analysis Screening	12 December 2022
End date of Equality Analysis Screening	20 December 2022

Section 2	Impacts
Who does the Policy, Service, Function, Strategy, Code of practice, Guidance, Project or Business plan benefit?	Staff and Patients
Will the Policy, Service, Function, Strategy, Code of practice, Guidance, Project or	<ul style="list-style-type: none"> • Race (including Gypsy and Traveller) <u>NO</u>

Business plan impact negatively on any of the protected characteristic groups?	<ul style="list-style-type: none"> • Disability (includes physical, learning, mental health, sensory and medical disabilities) <u>NO</u> • Sex (Men, women and gender neutral etc.) <u>NO</u> • Gender reassignment (Transgender and gender identity) <u>NO</u> • Sexual Orientation (Lesbian, Gay, Bisexual, Heterosexual, Pansexual and Asexual etc.) <u>NO</u> • Age (includes, young people, older people – people of all ages) <u>NO</u> • Religion or Belief (includes faith groups, atheism and philosophical beliefs) <u>NO</u> • Pregnancy and Maternity (includes pregnancy, women who are breastfeeding and women on maternity leave) <u>NO</u> • Marriage and Civil Partnership (includes opposite and same sex couples who are married or civil partners) <u>NO</u> • Armed Forces (includes serving armed forces personnel, reservists, veterans and their families) <u>NO</u>
Describe any negative impacts	None
Describe any positive impacts	None

Section 3	Research and involvement
What sources of information have you considered? (e.g. legislation, codes of practice, best practice, nice guidelines, CQC reports or feedback etc.)	Feedback from audit one CAS alerts guidance National patient Safety Alerts guidance
Have you engaged or consulted with service users, carers, staff and other stakeholders including people from the protected groups?	<u>Yes</u>

If you answered Yes above, describe the engagement and involvement that has taken place	Work operational services/Senior representation from both Care Groups, Business Managers the QI team and Patient Safety, Pharmacy.
If you answered No above, describe future plans that you may have to engage and involve people from different groups	The above work is on-going

Section 4	Training needs
As part of this equality analysis have any training needs/service needs been identified?	No
Describe any training needs for Trust staff	n/a
Describe any training needs for patients	n/a
Describe any training needs for contractors or other outside agencies	n/a

Check the information you have provided and ensure additional evidence can be provided if asked

Appendix 2 – Approval checklist

	Title of document being reviewed:	Yes / No / Not applicable	Comments
1.	Title		
	Is the title clear and unambiguous?	Yes	
	Is it clear whether the document is a guideline, policy, protocol or standard?	Yes	procedure
2.	Rationale		
	Are reasons for development of the document stated?	Yes	
3.	Development Process		
	Are people involved in the development identified?	Yes	Remains ongoing due to merging of Patient Safety teams, introduction of Care Groups, Governance Review and ongoing QI work with operational and corporate services
	Has relevant expertise has been sought/used?	Yes	
	Is there evidence of consultation with stakeholders and users?	Yes	Teams involved with the management of this process have been fully involved with the review of and changes to this procedure. Ongoing - QI team are working with representatives from operational services including business managers from both Care Groups and the Patient Safety Team to streamline dissemination of all safety alerts.
	Have any related documents or documents that are impacted by this change been identified and updated?	Yes	
4.	Content		
	Is the objective of the document clear?	Yes	

	Title of document being reviewed:	Yes / No / Not applicable	Comments
	Is the target population clear and unambiguous?	Yes	
	Are the intended outcomes described?	yes	
	Are the statements clear and unambiguous?	yes	
5.	Evidence Base		
	Is the type of evidence to support the document identified explicitly?	Yes	
	Are key references cited?	yes	
	Are supporting documents referenced?	yes	
6.	Training		
	Have training needs been considered?	Yes	
	Are training needs included in the document?	TBC	Ongoing development of training needs – see Training Needs Analysis.
7.	Implementation and monitoring		
	Does the document identify how it will be implemented and monitored?	Yes	
8.	Equality analysis		
	Has an equality analysis been completed for the document?	Yes	
	Have Equality and Diversity reviewed and approved the equality analysis?	yes	14 Dec 2022 approved by HR EDI team
9.	Approval		
	Does the document identify which committee/group will approve it?	yes	EQAIG
10.	Publication		
	Has the policy been reviewed for harm?	Yes	No harm
	Does the document identify whether it is private or public?	Yes	public
	If private, does the document identify which clause of the Freedom of Information Act 2000 applies?	N/A	

Appendix 3- Process Flow for National Patient Safety Alerts

