

<b>DOCUMENT CONTROL</b>	
<b>Title:</b>	<b>Central Alerts System</b>
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<b>Scope:</b>	
The Central Alerting System will be the key means to communicate the important safety information to all staff of Pennine Care NHS Foundation Trust. The alert system has an associated web site, which holds copies of all alert notices, together with statistics on responses from Trust and Strategic Health Authority	
<b>Purpose:</b>	
CAS is an electronic system operated by the Department of Health, and provides a mechanism for the swift despatch of a number of safety related alerts and information, comprising of: <ul style="list-style-type: none"> <li>• Medical Devices Alerts from Medicines and Healthcare Products Regulatory Agency (MHRA)</li> <li>• Safety Notices and Safety Bulletins from NHS Estates</li> <li>• Patient Safety Alerts from the National Patient Safety Agency (NPSA)</li> <li>• Guidelines and bulletins on specific subjects from the Department of Health</li> </ul>	
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This document has been developed in collaboration with the following interested parties: <ul style="list-style-type: none"> <li>• None</li> </ul>	

<b>Individual(s) &amp; group(s) involved in the Consultation:</b>	
The document has been circulated for consultation and comments have been taken into consideration and the document amended accordingly:	
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<b>Responsibility of:</b>	Health, Safety & Emergency Planning Lead
<b>Other Trust documentation to which this guideline relates (and when appropriate should be read in conjunction with):</b>	
CO022	Risk Management Policy
CO016	Medical Devices Policy
CL015	Medicines Policy
<b>Other external documentation/resources to which this guideline relates:</b>	
<b>CQC Regulations</b>	
<b>This guideline supports the following CQC regulations:</b>	

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## 1. INTRODUCTION

### Central Alerting System (CAS)

The Central Alerting System will be the key means to communicate the important safety information throughout Pennine Care NHS Foundation Trust. The alert system has an associated web site, which holds copies of all alert notices, together with statistics on responses from Trust and Strategic Health Authority.

CAS is an electronic system operated by the Department of Health, and provides a mechanism for the swift despatch of a number of safety related alerts and information, comprising of:

- Medical Devices Alerts from Medicines and Healthcare Products Regulatory Agency (MHRA)
- Safety Notices and Safety Bulletins from NHS Estates
- Patient Safety Alerts from the National Patient Safety Agency (NPSA)
- Guidelines and bulletins on specific subjects from the department of health

## 2. PURPOSE

CAS is an electronic system operated by the Department of Health, and provides a mechanism for the swift despatch of a number of safety related alerts and information, comprising of:

- Medical Devices Alerts from Medicines and Healthcare Products Regulatory Agency (MHRA)
- Safety Notices and Safety Bulletins from NHS Estates
- Patient Safety Alerts from the National Patient Safety Agency (NPSA)
- Guidelines and bulletins on specific subjects from the Department of Health

## 3. RESPONSIBILITIES, ACCOUNTABILITIES AND DUTIES

### **Responsibilities of all staff and non-executive Directors:**

All staff and non-executive directors are obliged to adhere to this policy. Managers at all levels are responsible for ensuring that the staff for whom they are responsible are aware of and adhere to this Policy. They are also responsible for ensuring staff are updated in regard to any changes in this Policy

### **Responsibilities of Departmental / Service Managers**

A named person will be identified for each department from where the Trust delivers services. The Department / Service Managers will ensure that this policy is available to staff for access and any updates are brought to staff attention at the earliest opportunity.

## **Chief Executive Officer (CEO)**

The CEO carries ultimate responsibility for the management of medical devices. Reports and Medical Devices Committee minutes will be communicated to the Trust Board through the approved committee structure.

## **Medical Director**

The Medical Director is the Chair to the Medical Devices Committee.

## **Trust Committees and Groups**

The following committees will have responsibility to review and action any CAS alerts deemed relevant to any Trust service provision or activity

The Medical Devices Committee will act as a dedicated review group comprising of clinical and non-clinical leads to review CAS alerts and make recommendations to the Trust via various committees and groups such as; the Borough / Divisional Integrated Governance Groups on how to proceed in responding to the requirements of any CAS alert deemed relevant to the Trust services and activities

## **Health, Safety and Emergency Planning Manager / CASLO**

The Health, Safety and Emergency Planning Lead acts as the CASLO and is responsible to update the CAS website, disseminate CAS medical device / equipment, Estates and Drug alerts and to archive the responses for audit.

## **Chief Pharmacist**

The Chief Pharmacist will be responsible for all drug related CAS alerts to be disseminated and actioned as appropriate

## **Procurement Department**

The Procurement Department will be consulted by the CASLO where alerts maybe relevant to purchased equipment, devices or accessories.

## **Responsible Recipients (Borough / Division)**

- The CASLO has a dedicated responsible recipient list (CASRR) which will be used to disseminate CAS alerts, as received, for consideration by service managers as to their relevance and action as required
- The CASRR are responsible to circulate the alerts to all departments within their respective boroughs / divisions including medical staff and community venues.
- They will then receive from the individual departments; information indicating the action taken this will be entered onto a CAS Alert Assurance document sheet and forwarded to the CASLO.
- It is the responsibility of the Responsible Recipients to ensure that timescales are met. The Responsible Recipients must appoint a deputy so that the system will run smoothly in their absence.

## **Departmental / Service Managers**

Are responsible for implementing the alert locally and informing all staff within their area of responsibility, including: clinicians and non-clinicians, occupational therapist, physiotherapists, medical staff etc. Managers are responsible for completing the paperwork and returning it to the CASRR within the timescales indicated on the alert.

## **All Staff**

Are responsible to be aware of issues raised by the alerts and work within guidelines

## **NHS Estates Central Alerts and Hazard Notices.**

On receipt of these notices the CASLO will consult with the Estates Department to determine the relevance and distribution of the alert notice.

## **National Patient Safety Agency – Patient Safety Alerts and Medical Devices Alerts (MDA)**

On receipt of an alert, the CASLO will, if necessary, consult the Medical Director / MDS Medical Devices Safety Officer (MDSO) (as appointed) to determine the relevance and distribution of the alert notice.

## **Department of Health Guidance Bulletins/Documents.**

The Medicines and Healthcare Products Regulatory Agency issue information bulletins on specific subjects (“One Liners”). These bulletins are a very useful and informative means of expanding knowledge on a myriad of related subjects relating to the use of medical devices.

## **4. CAS LIAISON OFFICER (CASLO)**

The Health, Safety and Emergency Planning Manager is the Trust nominated CASLO and is responsible for the prompt dissemination of all relevant safety alerts and notices throughout Pennine Care NHS Foundation Trust and for completing the feedback form to the department of Health confirming what action, if any is required, has been taken in response to the notices

When the CAS Liaison Officer is unavailable, the CASLO will nominate a suitable deputy as cover.

The CASLO will monitor the procedures to ensure that they are effective and being followed.

## **5. MANAGEMENT OF ALERTS**

The CASLO has identified nominated Responsible Recipients (CAS RR) in each service area of the Trust and has set up an internal distribution system to ensure alerts are reaching them. Returns to the CASLO must be made as directed by a CAS Alert or within 14 days of receipt of the CAS alert.

In cases where there is not a risk of death, serious injury or requiring an immediate action for the Trust, this timeframe can be extended and will be communicated by the CASLO on dissemination of an individual CAS Alert.

Returns will not be accepted from any source other than the nominated recipients, or on forms other than those approved by this policy

<b>CAS Responsible Recipient</b>	<b>Area of Alert</b>
Head of Operational Estate Services	Estates Alerts
Patient Safety Lead	Medical Device alerts DH Advisory
Medical Equipment Management Services (MEMS) Manager	Medical Device alerts DH Advisory
Chief Pharmacist	Drug / Medicines alerts
Borough (CS) / Divisional (MH) Governance Managers and nominated deputies and administrative recipients	MH Tameside and Glossop MH Stockport MH Oldham MH Bury MH Rochdale MH Specialist services CS Heywood Middleton & Rochdale CS Bury CS Oldham CS Trafford Dental Directorate

## **6. DISSEMINATION PROCEDURE**

### **Medical Device Alert.**

On receipt of Medical Devices Alerts, via the CAS system, the alert message accompanied with a response form will be forwarded by e-mail to the responsible recipient for:

- Further dissemination and action through their area of responsibility, or representation
- Notify the CASLO of the actions taken, where applicable and within the timescales on the accompanying response form
- Notify the CASLO where there is no action required, or that the areas concerned does not hold or operate any of the equipment any of the equipment

Divisional / Borough Governance Managers will retain copies. When appropriate, alerts are forwarded by the CASLO to the Executive / Divisional Director teams.

- The CASLO will determine whether the safety alerts are relevant to the Trust. If there is any doubt the CAS alert will be sent out as usual.
- CAS alerts will be distributed individually and not accumulated and distributed together
- The CASLO will receive feed-back via the response form from the responsible recipients in the Trust within agreed timescales.

- CASLO will provide feedback to the DH via the CAS when action is in hand to implement recommendations contained in the alert.
- The CASLO will maintain a spreadsheet, which will highlight the pattern of responses in order to verify the efficacy of the system and assist in the reminder process to responsible recipients.
- When CAS alerts are not relevant to the Trust e.g. alerts about hip replacements, the CASLO will provide the DH via CAS the reason why.
- To ensure that CAS alerts are not missed a report of all alerts received will be provided for the Medical Devices Committee.

## 7. ALERT CATEGORIES

- **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 support or follow-up manufacturers' field modifications.
- **Update:** Used to update the recipient about previously reported incidents, possibly on a topical or device group basis and where further follow-up safety information is judged to be beneficial.
- **Information Requested:** Used to alert users about specific issues that may become a problem and where CAS are requesting feedback. These alerts will be sent out with additional questions to be completed.

## 8. CONSULTATION AND COMMUNICATION WITH EXTERNAL STAKEHOLDERS

Where CAS alerts may effect or be relevant to services which are shared with partner stakeholders such as; Clinical Commissioning Groups (CCG), Acute Hospitals and Community Services or directly with service users, it is the responsibility of receiving CASRR / Service management teams to liaise with these groups to ensure that relevant information, guidance and any actions required are clearly communicated and actioned and that any such actions are noted on the CAS cover sheet and returned to the CASLO for audit and reporting procedures.

## 9. EQUALITY IMPACT ANALYSIS

As part of its development, this document was analysed to consider / challenge and address any detrimental impact the policy may have on individuals and or groups protected by the Equality Act 2010. This analysis has been undertaken and recorded using the Trust's analysis tool, and appropriate measures will be taken to remove barriers and advance equality of opportunity in the delivery of this policy / procedure.

## **10. FREEDOM OF INFORMATION EXEMPTION ASSESSMENT**

Under the Freedom of Information Act (2000) we are obliged to publish our policies on the Trust's website, unless an exemption from disclosure applies. As part of its development, this policy was assessed to establish if it was suitable for publication under this legislation. The assessment aims to establish if disclosure of the policy could cause prejudice or harm to the Trust, or its staff, patients, or partners. This assessment has been undertaken using the Trust's Freedom of Information Exemption Guide, and will be reviewed upon each policy review.

## **11. INFORMATION GOVERNANCE ASSESSMENT**

This Policy has been analysed to ensure it is compliant with relevant information law and standards as in place at the time of approval, and are consistent with the Trust's interpretation and implementation of information governance components such as data protection, confidentiality, consent, information risk, and records management.

Compliance will be reviewed against any changes to legislation / standards or at the next review of this document.

## **12. SAFEGUARDING**

All staff have a responsibility to promote the welfare of any child, young person or vulnerable adult they come into contact with and in cases where there are safeguarding concerns, to act upon them and protect the individual from harm.

All staff should refer any safeguarding issues to their manager and escalate accordingly in line with the Trust Safeguarding Families Policy and Local Safeguarding Children/Adult Board processes.

## **13. MONITORING**

- The compliance with this policy will be monitored by the Medical Devices Committee as part of their agenda as appropriate.
- The Committee meets every 2 months or sooner should the Trust, the Department of Health or circumstances require an earlier meeting.
- The Medical Devices Committee reports to the QGAC, where minutes are submitted for review.

The effective application of this policy / guideline, including adherence to any standards identified within will be subject to monitoring using an appropriate methodology and design, such as clinical audit.

Monitoring will take place on a biannual basis and will be reportable to the Quality Group via the Clinical Effectiveness and Quality Improvement Team.

## **14. REVIEW**

This policy will be reviewed three-yearly unless there is a need to do so prior to this; e.g. change in national guidance.

## **15. GLOSSERY OF TERMS**

CAS	Central Alerting System
CASLO	Central Alerting System Liaison Officer
CASRR	Central Alerting System Responsible Recipient
MDSO	Medical Devices Safety Officer
MEMS	Medical Equipment Management Services
MHRA	Medicines and Healthcare Products Regulatory Agency
NPSA	National Patient Safety Agency