1 Introduction

The Central Alert System (CAS) is an electronic cascade system developed by the Department of Health and is a key means by which to communicate and disseminate important safety and device alerts information within the NHS. The CAS supersedes the SABS (Safety Alert Broadcast System) and Public Health Link (PHL). The CAS facilitates distribution of safety alerts, emergency alerts, NPSA Alerts, Medical Device alerts (MDAs), Drug alerts, Estates alerts, field safety notices, Chief Medical Officer messages and Dear doctor letters.

Trusts are required to implement and maintain systems for alert dissemination and review in accordance with Care Quality Commission Outcomes: Outcome 16 “Assessing and monitoring the quality of service provision” and the DB2011(01) “Reporting Adverse Incidents and Disseminating Medical Device Alerts”.

This policy is designed to ensure a consistent approach for dealing with the management of alerts received through the Central Alert System (CAS). It is important that all Trust personnel are aware of their roles and responsibilities with regard to dissemination and actions required in complying with alerts.

Alerts originate from the following organisations:

- a) Medicines and Healthcare products Regulatory Agency (MHRA);
- b) NHS Commissioning Board Special Health Authority
- c) Department of Health Estates and Facilities (DHEF)
- d) Department of Health (DH)

It may also be necessary for the Trust to distribute “internal alerts”. These alerts will be used to provide rapid dissemination of information, e.g. medical device/equipment recall.

It is the aim of the Trust to ensure that all alerts are communicated promptly to all relevant members of staff employed within the Trust and that action to comply with alerts is taken within Department of Health timescales in order to safeguard patients, visitors, and staff from harm.
2 Scope

The policy applies to all members of staff employed within the Trust who are involved in any aspect of alert dissemination, action, and/or review.

3 Aims

It is the Trust's intention that there is a robust system for disseminating and providing feedback on the implementation of the Safety Alerts, which may be issued by the MHRA, NPSA and DHEF, in conjunction with the Department of Health. This policy will ensure that the Trust has a:

- Clearly defined identified alert communications system
- System for distributing alerts and obtaining responses from identified Directorate Liaison Officers (DLO)
- System for monitoring that actions identified in the alerts have been taken, to ensure the safety of all those who deliver and receive services from the Trust.

4 Duties (Roles and responsibilities)

The success of the system in reducing the risks of adverse incidents and litigation relies upon all relevant staff being aware of and acting on alerts and ensuring appropriate documentation is maintained to provide evidence of actions taken.

4.1 The Chief Executive has overall responsibility for Patient Safety, with operational management delegated to the Medical Director and Director of Nursing and Patient Services.

4.2 Trust Executive members (or nominated deputies) will at certain times undertake alert reviews and determine who should receive copies of the alert and/or who should be asked to lead on actions arising from the alert:

- Director of Pharmacy/Procurement Pharmacist for drug alerts and other pharmaceutical notices
- EME Manager for alerts relating to medical devices
- Director of Estates for Estates related alerts
- Supplies Manager for alerts relating to non-electronic medical devices and other stock items
- Director of Quality and Effectiveness and/or Patient Safety and Risk Lead for NPSA related alerts.

4.3 The Patient Safety and Risk Lead is responsible for the management of safety alerts, on behalf of the Chief Executive. The role of CAS Liaison Officer (CLO) for the Trust is integrated within the role of Patient Safety and Risk Lead, and this role has responsibilities including;
• Formulating and reviewing policy guidance for the alert process
• In association with the Directorate Liaison Officer, perform an annual review to assess directorates’ compliance with this policy
• To provide support and guidance to directorates regarding alerts, medical device adverse incident reporting, and any other related issues.
• To identify the appropriate lead(s) to lead on NPSA alerts actions
• Providing training regarding alert processes for relevant members of staff
• Providing a bi-monthly report of the status of all alerts received to the Corporate Governance Committee (CGC)
• Providing quarterly reports on progress of all alerts (ongoing and closed) to the Clinical Risk Group
• Sharing relevant information with the Medical Devices Committee
• Notifying the MHRA of any changes to the CAS Liaison Officer

4.4 CAS Support Officer (CSO) - Clinical Governance and Risk Department – Responsible for the practical application of the alerts process on behalf of the CLO, in particular:
• Receiving alerts via CAS on behalf of the Trust
• Liaise with Electronic and Medical Engineering (EME), Supplies and Estates to ascertain the relevance of received alerts.
• Maintaining a central record of alerts
• Distributing alerts to Directorate Liaison Officers,
• Maintaining records confirming dissemination and actions completed within directorates
• Regularly reviewing actions taken with Directorate Liaison Officers
• Maintaining an up to date list of directorate leads and nominated deputies
• Closing alerts on the CAS when actions have been completed.

4.5 Specialist Procurement Pharmacist/Chief Pharmacist have responsibility for:
• Reviewing and acting upon all drug alerts received via the CAS system.
• Providing summary of action taken to CSO
• Providing reports to the Medicines Management Committee on alerts received and action taken.

4.6 Directorate Managers/ Clinical Directors have responsibility to ensure arrangements are in place for the dissemination, action, and review of alerts within directorates. This will include the nomination of a Directorate Liaison Officer for the alerts process. In addition all staff with responsibility for managing alerts must be appropriately resourced and provided with support and training in relation to the management of alerts.

4.7 Directorate Liaison Officer (DLO)
The DLO will be designated to manage alerts and notices that are received into the Directorate via the CLO. The DLO will be an appropriate person with the necessary experience and authority to implement the actions identified within
each alert or notice and ensures the sustainability of the actions on an ongoing basis. This individual will usually be a Directorate Manager or Head of Department, and the role may be delegated to specialists such as Matrons, Technical Officers or Specialist Nurses.

Responsibilities include:
- Maintaining a robust system for distribution of alerts to appropriate departments within the directorate
- Maintaining records confirming distribution and actions taken within related departments
- In association with the CAS Liaison Officer (CLO) perform an annual review of the directorate’s compliance with the Safety Alerts policy / process
- Maintain a directorate reference file for alerts
- To provide the CLO with confirmation of actions by the timely completion of alert response forms
- Notifying the CLO of changes to Directorate Liaison Officer or deputy
- Ensuring a named deputy is available to manage alerts in the absence of the Directorate Liaison Officer
- Providing guidance to departments within own Directorate with regard to alerts
- Reporting medical device adverse incidents through Datix to the MHRA via the CLO (CSO)
- Log any risks detailing areas in non-compliance against alerts or notices, on the Directorate Risk Register.

4.8 Supplies Department / EME / Estates will, upon the request of the CLO provide information to confirm whether or not the Trust has any products and/or devices affected by alerts. Nominated officers of these areas are also responsible for passing on any Field Safety Notices, Manufacturer Notices or Supplier Notices that they directly receive from external sources, to the CLO for action/coordination.

4.9 The Clinical Risk Group (CRG) is responsible for receiving progress reports, assessing compliance with alerts and disseminating this information where necessary.

4.10 The Corporate Governance Committee (CGC) has overall responsibility for the performance management of the alerts process and is the Committee responsible for receiving evidence in ensuring compliance under the Care Quality Commission standards.

5 Definitions

CAS- Central Alert System (CAS) is an electronic cascade system developed by the Department of Health
6 Management of Alerts

6.1 MHRA Medical Device Alerts

All alerts are received via the CAS, and the CSO (or deputy, in the absence of the CSO) should access the CAS and provide acknowledgement no later than 48 hours since the release of the alert.

All alerts received via the CAS relating to medical devices and equipment will be assessed, and advice sought from the Supplies Manager and/or Medical Electronics Manager in relation to usage, stock levels and location of devices and equipment in order to assess the relevance of the alert for the Trust.

The alert is then disseminated via email to the appropriate Directorate Liaison Officer and he/she must cascade the alert to all relevant wards/departments within the Directorate, to ensure that all areas of the Directorate are reviewed in accordance with the alert. (See Appendix 1 for process flowchart).

An Action Response form (see Appendix 2) is sent with the alert for completion indicating relevance of alert and appropriate actions. The DLO will coordinate the Directorate response for action within specified timescales.

6.2 NPSA Alerts

When a new alert is received, the CLO will assess the alert, and escalate to the Director of Quality and Effectiveness where necessary, to identify a Trust lead(s) for the alert. The CLO will make contact with the identified lead and discuss the relevance of the alert, and required actions. The CLO will continue to monitor progress of the alert and provide regular updates to the CGC and CRG as per the reporting schedule.

6.3 Estates & Facilities Alerts

All alerts received via the CAS relating to Estates and Facilities will be forwarded to the DLO for Estates and the Director of Estates, who will assess relevance of the alert and any implications for the Trust. The DLO will coordinate the response for action within specified timescales.

6.3.1 PFI Build

The Building Manager responsible for the PFI build will receive a copy of the Estates & Facilities Alert(s) to assess relevance to the new build and will coordinate the response for action within specified timescales.
6.4 Management of 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. The Specialist Procurement Pharmacist / Chief Pharmacist will action all drug alerts as received, and in accordance with, the national cascade system.

There are four types of Drug Alerts:
- **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

The Drug Alert feedback proforma will be completed for each alert and forwarded to the CSO upon completion of actions arising out of each alert. The CSO will cross reference each response against the drug alerts received via the CAS route to ensure all actions have been completed and the alerts database updated. The Procurement Pharmacist will report regularly to the Medicines Management Committee on the status of drug alerts.

6.5 Internal Alerts

On occasions, internal alerts may need to be issued within the Trust to provide rapid and effective distribution of information, e.g. following failure of a piece of equipment or other serious adverse event. The distribution process will follow that of the alerts procedure with the exception of progress of actions, which will be fed back to the CLO. An internal alert will only be distributed following consultation with necessary parties i.e. supplies, EME. The CSO will be responsible for coordinating the internal alerts and dissemination of the recall information will be done using the appropriate form.

6.6 Pharmaceutical product internal recalls

Internal alerts may have to be issued by Pharmacy to recall products that may be defective, either through a manufacturer alert or via the Trust internal recall system for defective products.

If a decision is made that any products should be recalled, the manufacturer should be informed and the following decisions need to be made:

Consider if the MHRA needs to be informed about the defective product. Classification of recall in terms of urgency as follows:
- **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
If the product has been administered to patients and there is a possibility that administration of the defective product may result in harm to patients, a decision must be made by the Specialist Procurement Pharmacist (SPP) on who else needs to be informed.

The recall will be carried as per Pharmacy’s procedure on completing drug alerts.

6.7 Reporting of adverse incidents to external agencies

Adverse events will initially be reported by members of staff in accordance with the Trust’s Management and Reporting of Accidents and Incidents Policy. In addition, in certain circumstances, incidents may require reporting to external agencies as detailed below:

- The CLO (or EME if the device is electronic) will be responsible for reporting adverse incidents involving medical devices in accordance with the published MHRA guidance.

- Director of Estates will be responsible for reporting defects and failures involving non-medical devices to the Department of Health Estates and Facilities Division.

- The Clinical Director – Laboratory Medicine will ensure that adverse blood safety incidents are reported to the MHRA via the online reporting system - Serious Adverse Blood Reactions and Events (SABRE) in accordance with guidance issued by the MHRA.

- The Trust Chief Pharmacist will ensure that adverse medication incidents are reported to the MHRA in line with the guidance issued by the MHRA.

6.8 Non-compliance with alerts

Where there is non-compliance with the alert(s) and completion of actions will be past the stipulated deadline, the Directorate Liaison Officer / alert lead / CLO will raise a risk entry into the Trust risk register detailing areas of non-compliance against the alerts or notices. The information included on the risk registers must include recommendations of how the areas of non compliance will be met, any financial implications associated with implementing the recommendations and the consequences of failing to implement the identified actions.

7 Training

There are no training requirements for this policy however the staff who are designated as Directorate Liaison Officers are provided with a standard operating procedure as guidance.
8 Equality and Diversity

The Trust is committed to ensuring that, as far as is reasonably practicable, the way we provide services to the public and the way we treat our staff reflects their individual needs and does not discriminate against individuals or groups on any grounds. This document has been appropriately assessed.

9 Monitoring compliance

<table>
<thead>
<tr>
<th>Standard / process / issue</th>
<th>Monitoring and audit</th>
<th>Method</th>
<th>By</th>
<th>Committee</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monitor the status of alerts received and ensure compliance with all alerts issued</td>
<td>Regular report of status of alerts received</td>
<td>CLO (Patient Safety and Risk Lead)</td>
<td>Corporate Governance Committee</td>
<td>Bi-monthly</td>
<td></td>
</tr>
<tr>
<td>Monitoring the status of alerts both closed and ongoing and ensuring compliance with actions arising out of NPSA alerts</td>
<td>Regular report on progress of alerts, both ongoing and closed</td>
<td>CLO (Patient Safety and Risk Lead)</td>
<td>Clinical Risk Group</td>
<td>Quarterly</td>
<td></td>
</tr>
<tr>
<td>Ensure involvement and input where necessary from medical devices experts</td>
<td>Sharing relevant alert information</td>
<td>Patient Safety and Risk Lead</td>
<td>Medical Devices Steering Group</td>
<td>Bi-monthly</td>
<td></td>
</tr>
</tbody>
</table>

Actions taken by the Trust on alerts are reported nationally, and progress against actions can be benchmarked with other Trusts via the Central Alert System (CAS) website.

10 Consultation and review

As part of the review of this policy it has been presented at the Medical Devices Steering Group and Pharmacy to ensure involvement of the relevant leads. The policy will be ratified by the Corporate Governance Committee.

11 Implementation (including raising awareness)

This policy will be disseminated by the CGARD team as part of the monthly Trust Policy newsletter. All policies are available to staff through the Trust intranet.

12 Associated documentation

- Management and Reporting of Accidents and Incidents Policy
- Medical Device Management Policy
Appendix 1

Central Alerts System (CAS) Flowchart

Alert received via CAS system (SABS@nuth.nhs.uk)

Acknowledged and initial assessment

- NPSA
- Estates
- MDA

CLO to assess/identify alert lead and disseminate

Disseminated to Head of Estates/Estates DLO/Interserve (PFI)

Advice sought from supplies EME/other expert advice

Distribution of alert to Directorate Liaison Officers.

Alert Applicable/Not applicable

Response of action taken

CSO

Any action taken/action plan development which takes place following receipt of an alert.

Monitor action plans ALL – CGC/CRG

Response to CAS via electronic feedback form (except drug alerts)

LEGEND
CLO – CAS Liaison Officer
CSO – CAS Support Officer
DLO – Directorate Liaison Officer
SPP – Specialist Procurement Pharmacist
CPI – Chief Pharmacist
CGC – Corporate Governance Committee
CRG – Clinical Risk Group

Drug Alerts received via cascade system

Disseminated via drug alert cascade to SPP/CP procedure.

Copy of all drugs alerts and actions to be sent to CSO to cross reference and file

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Appendix 2

**CAS (SABS) Response/Action Form**

<table>
<thead>
<tr>
<th>MDA</th>
<th>EFA</th>
<th>NPSA</th>
<th>Manufacturers Alerts</th>
<th>Field Safety Notices</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Title of Alert:**

**Action Immediately** and return to the CAS Liaison Officer at, [SABS@nuth.nhs.uk](mailto:SABS@nuth.nhs.uk) no later than (    )

<table>
<thead>
<tr>
<th>I acknowledge that I have received and read the attached Safety Alert</th>
<th>YES/NO</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Is any action required?</th>
<th>YES/NO</th>
</tr>
</thead>
</table>

If no action is required, please state a reason(s):

If action is required please state what action is necessary:

*(Please enter lot numbers/batch numbers and quantity to be returned when identified, do not contact manufacturer/company direct)*

<table>
<thead>
<tr>
<th>Do you need to follow up any actions for this alert to be completed?</th>
<th>YES/NO</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>If “YES” please state date you will be following up to confirm action required has been completed (please ensure this meets the DH timescales for completion)</th>
<th></th>
</tr>
</thead>
</table>

**Directorate:**

**Named Lead:**

**Job Title:**

**Date:**
### IMPACT ASSESSMENT – SCREENING FORM A

This form must be completed and attached to any procedural document when submitted to the appropriate committee for consideration and approval.

<table>
<thead>
<tr>
<th>Policy Title: Central Alert System (CAS) Policy and procedure</th>
<th>Policy Author: Jackie Moon, Patient Safety and Risk Lead</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Does the policy/guidance affect one group less or more favourably than another on the basis of the following: (* denotes protected characteristics under the Equality Act 2010)</td>
<td></td>
</tr>
<tr>
<td>Race *</td>
<td>No</td>
</tr>
<tr>
<td>Ethnic origins (including gypsies and travellers)</td>
<td>No</td>
</tr>
<tr>
<td>Nationality</td>
<td>No</td>
</tr>
<tr>
<td>Gender *</td>
<td>No</td>
</tr>
<tr>
<td>Culture</td>
<td>No</td>
</tr>
<tr>
<td>Religion or belief *</td>
<td>No</td>
</tr>
<tr>
<td>Sexual orientation including lesbian, gay and bisexual people *</td>
<td>No</td>
</tr>
<tr>
<td>Age *</td>
<td>No</td>
</tr>
<tr>
<td>Disability – learning difficulties, physical disability, sensory impairment and mental health problems *</td>
<td>No</td>
</tr>
<tr>
<td>Gender reassignment *</td>
<td>No</td>
</tr>
<tr>
<td>Marriage and civil partnership *</td>
<td>No</td>
</tr>
<tr>
<td>2. Is there any evidence that some groups are affected differently?</td>
<td>No</td>
</tr>
<tr>
<td>3. If you have identified potential discrimination which can include associative discrimination i.e. direct discrimination against someone because they associate with another person who possesses a protected characteristic, are any exceptions valid, legal and/or justifiable?</td>
<td>n/a</td>
</tr>
<tr>
<td>4(a). Is the impact of the policy/guidance likely to be negative? (If &quot;yes&quot;, please answer sections 4(b) to 4(d)).</td>
<td>No</td>
</tr>
<tr>
<td>4(b). If so can the impact be avoided?</td>
<td></td>
</tr>
<tr>
<td>4(c). What alternatives are there to achieving the policy/guidance without the impact?</td>
<td></td>
</tr>
<tr>
<td>4(d) Can we reduce the impact by taking different action?</td>
<td></td>
</tr>
</tbody>
</table>

Comments:  

Name and Designation of Person responsible for completion of this form: Jackie Moon, Patient Safety and Risk Lead  
Date: 01/08/13  
Names & Designations of those involved in the impact assessment screening process: Jackie Moon, Patient Safety and Risk Lead

(If any reader of this procedural document identifies a potential discriminatory impact that has not been identified on this form, please refer to the Policy Author identified above, together with any suggestions for the actions required to avoid/reduce this impact.)

For advice on answering the above questions please contact Frances Blackburn, Head of Nursing, Freeman/Walkergate, or, Christine Holland, Senior HR Manager. On completion this form must be forwarded electronically to Steven Stoker, Clinical Effectiveness Manager, (Ext. 24963) steven.stoker@nuth.nhs.uk together with the procedural document. If you have identified a potential discriminatory impact of this procedural document, please ensure that you arrange for a full consultation, with relevant stakeholders, to complete a Full Impact Assessment (Form B) and to develop an Action Plan to avoid/reduce this impact; both Form B and the Action Plan should also be sent electronically to Steven Stoker within six weeks of the completion of this form.