Avon and Wiltshire NHS
Mental Health Partnership NHS Trust

Managing Safety Alerts and Other Safety Communications Policy

Board library reference	Document author	Assured by	Review cycle
P018	Medical Device Liaison Officer	Quality and standards committee	3 years

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1. Introduction

1.1 CAS System

The Central Alerting System (CAS) is a web-based system for issuing patient safety alerts and other safety critical guidance to NHS Trusts, Primary CareTrusts, Ambulance Service Trusts, Health Authorities and Social Services for information and / or action.

The system was introduced in September 2008 and brings together the Public Health Link (PHL) and Safety Alert Broadcast System (SABS). The Chief Medical Officer led the merging of the existing systems to provide a robust and streamlined means of distributing safety alerts to the NHS and other Health and Social Care providers, with the potential to expand as needs arise.

Safety alerts, emergency alerts, drug alerts, Dear Doctor letters and medical device alerts are sent through the CAS system on behalf of the following originators:-

- National Patient Safety Agency
- MHRA Drug Alerts
- CMO Messaging
- NHS Blood and Transplant
- DH Estates and Facilities
- Department of Health
- MHRA Medical Device Alerts
- National Institute for Health and Clinical Excellence
- NHS Estates
- MHRA Dear Doctor Letters

1.2 Field Safety Corrective Action (FSCA) and Field Safety Notices (FSN)

The policy also identifies a formalised process for managing Field Safety Notices.

A Field Safety Notice is communication regarding a specific device to customers and/or users sent out by a manufacturer or its representative in relation to a Field Safety Corrective Action.

A Field Safety Corrective Action (FSCA) is an action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. Such actions should be notified via a Field Safety Notice. The Manufacturer is obliged to notify the MHRA of any FSCA.

The FSCA may include:

- The return of a medical device to the supplier
- Device modification
- Device exchange
- Device destruction.
- Retrofit by purchaser of manufacturer’s modification or design change.

The manufacturer or their representative asks the purchaser to respond to the FSN. However, if they consider there is insufficient response, they will inform the MHRA and the FSN may then be issued as a CAS alert that requires a formal response. The MHRA may also issue supplementary advice to FSN’s

1.3 Internal Safety Alerts

As well as managing externally created alerts, the Trust has a developed its own system for issuing internal safety alerts to make staff aware of particular issues. The concerns may arise from learning from incidents that should be shared with a wider audience or require a practice change or may be used to alert staff to a changed policy or procedure requirement.

Internal alerts may also be generated in response to a CAS alert or FSN tailored to make the required actions more Trust specific.

1.4 Reporting incidents involving Medical Devices

The information from adverse incident reports can help identify faults with medical devices and may prevent similar incidents happening again. If there is an adverse incident involving a medical device it should be reported via the Adverse Incident process. It may also require reporting externally.

2. Policy Statement

The implementation of this policy will provide assurance to the Trust and the Department of Health that alerts have been acted upon appropriately.

The Trust places great importance on the distribution and administration of alerts received through the Central Alerting System (CAS) and other communications. The Trust is committed to putting in place all reasonable measures to ensure the health and safety of Trust staff and service users and anyone else who may be affected by the activities of the Trust.

Our Internal Alerting System provides an effective process to ensure that there is a proactive approach to managing risks. In addition to this, lessons learned from incidents in the Trust are identified and acted upon. It is also a platform for sharing important information.

3. Purpose or Aim

The purpose of this policy is:

To ensure that Safety Alerts issued by the Department of Health are received at one point of contact and are acted upon and disseminated to relevant areas and individuals throughout the Trust.

To ensure necessary local action is taken on safety alerts and field safety notices to protect the safety of patients, staff, and others. That internal processes exist to monitor feedback and provide an audit trail of actions.

To be compliant The Care Quality Commissions (CQC) Outcome 11D. ‘Ensure relevant alerts from an expert, professional body or manufacturer are acted.

To ensure incidents involving medical devices that are reportable to the MHRA are actioned appropriately.

To ensure regular monitoring of compliance with MHRA requirements.

To ensure other notices issued via the Central Alerting System are appropriately distributed and actioned.

4. Scope

The policy encompasses the processes required for the management of alerts issued via CAS and other communications This is a Trust-wide policy which applies to all Directorates and services without any exceptions. This policy also applies to staff that work in AWP Trust services but are not employed by the Trust.

5. Content

5.1 CAS Alerts

There are two ranges of alerts received by the Trust via the CAS system these are:

Non Emergency Alerts - Alerts that were formerly SABS alerts. E.g.

- Medicines and Healthcare products Regulatory Agency (MHRA) Medical Device Alerts
- National Patient Safety Agency (NPSA)
- Department of Health (eg. Estates and Facilities)

These alerts are received and managed by the Trusts designated CAS Liaison Officer who is also the Medical Device Liaison Officer. These alerts require feedback within specific timescales set by CAS and performance against the criteria set is monitored externally.

The Distribution and Action of Non- Emergency Alerts Received by the CAS Liasion Officer Procedure can be accessed here. This procedure describes how alerts (formerly SABS alerts are received, cascaded and actioned in the Trust.

Emergency Alerts - CAS is also used to send out emergency alerts (important public health messages – 'CMO messaging' and MHRA drug alerts). These alerts can be issued out of normal office hours if required, but they do not require trusts to make a response on CAS. These alerts are not the responsibility of CAS Liaison Officer but are instead emailed directly to the Executive Medical Director onward cascade.

The Distribution and Action of Emergency Alerts received by the Executive Medical Director Procedure can by access here. This procedure describes how these alerts received by the Executive Medical Director are handled by the Trust.

5.2 Field Safety Notices (FSN) and Field Safety Corrective Action (FSCA)

The manner in which the Trust receives field Safety Notices is not as controlled as those via the CAS system. Manufacturers may target different individuals in the Trust.

The Management of Field Safety Notice (FSN) and Field Safety Corrective Action (FSCA) Procedure can be accessed here. This procedure describes how field safety notices are dealt with within the Trust to ensure that there is a formalised process.

5.3 Internal Safety Alerts

Internal Safety Alerts are generated by a variety of sources:

- Alerts which arise from risks or issues identified within the Trust.
- Red Top Alerts - Red top alerts are issued by the Trust following the investigation of very serious adverse incidents.
- Alerts which arise in response to new guidance.
- Alerts which flag the publication of new Safety Matters Bulletins (which summarize the findings of the Trust's themed reviews).
- Alerts requesting information.

The Generating, Distribution and Action of Internal Safety Alerts Procedure can be accessed here. This procedure describes the mechanisms for ensuring that internal alerts are cascaded and responded to appropriately.

These procedures are of relevance to all those who have designated responsibilities in this policy.

6. Roles and Responsibilities

6.1 Executive Responsibilities

The Chief Executive has overall accountability for having effective management systems and internal controls in place relating to alerts issued by the Central Alerting System and for meeting statutory requirements.

The Director of Nursing, Compliance, Assurance and Standards is the Executive Director for medical device and safety alert management and is responsible for ensuring the Trust's overall duty for safety alert management is discharged appropriately.

The Medical Director has responsibility for all communications issued to them by the Central Alerting System and for systems and processes to exist to ensure that such alerts are appropriately responded to.

The Director of Operations has responsibility for ensuring that safety and other alerts are appropriately actioned by localities and estates staff, contractors or SLA providers in accordance with stipulated timescales. They are responsible for ensuring that a suitably accountable lead is identified to take the actions for the alert forward.

The Head of Risk & Compliance has responsibility for supporting the Medical Device Liaison Officer (who is the CAS Liaison Officer) and for ensuring that other members of the risk management team can manage the alerts in the MDLO's absence. This individual will provide evidence and assurance to the organisation with regard to the efficacy of its arrangements for managing alerts.

The Clinical Risk Manager, supported by the Head of Risk and Compliance has responsibility for generating internal safety alerts in conjunction with other relevant professionals.

The Medical Device Liaison Officer is the Trusts CAS Liaison Officer and has responsibility for receiving all allocated safety alerts and performing an important risk management role by ensuring that they are disseminated and targeted appropriately within the Trust and adhering to timescales (e.g. immediate action notices should be distributed without delay, those designated action could take a less immediate route). She also has responsibly for completing feedback electronically on the CAS system to indicate what action has been taken. The CAS Liaison Officer also manages field safety notices and the internal alerting system and has responsibility for jointly creating alerts that arise from the physical health / infection control / medical device group.

The Chief Pharmacist has responsibility for ensuring that all medication related alerts and other alerts are distributed throughout the organisation and that systems and processes exist to provide an audit trail to show actions taken. She is supported in this task by the PA to the Medical Director.

Locality and speciality Managing Directors are responsible for ensuring that the safety alerts are disseminated to all wards, teams and departments, and for ensuring that Safety Alerts are actioned and responded to within the specified timescale, communicating action taken to the Medical Device Liaison Officer. They are responsible for ensuring that systems and processes exist within teams to receive, handle and respond to safety alerts and that cascading lists are kept current so that alerts reach all relevant people. They are also responsible for ensuring that department Managers follow the correct process for replying to alerts

6Modern Matrons, Department Managers, Equipment Controllers and Team Leaders have responsibility for ensuring that relevant alerts are acted upon in a timely manner, that a safety alert file is kept in each area with a clear audit trail and staff signatures to show that they have been made aware of the alerts. How to access safety alerts and staff responsibilities should be discussed regularly at team meetings and explained to new staff as part of their induction.

The Head of Estates is responsible for ensuring that all estates related alerts are handled appropriately by SLA, other providers or internal staff.

The Head of Procurement is responsible for ensuring the procurement team provide where possible information items purchased that relate to any Safety Alerts or Field Safety Notices

6.2 Employee Responsibilities

All individuals can contribute to a positive risk management environment by working safely. Positive measures include:

- abiding by safety alerts and responding appropriately
- reporting incidents and near misses in accordance with the Trust's Incident Policy
- working within professional codes of conduct

All Trust employees must adhere to advice received from their department managers as a result of CAS alerts. Staff also have responsibility to bring any problems / faults / defects that have the potential to cause unexpected or unwanted effects involving the safety of patients, users, or other persons to the attention of their line manager.

They also have the responsibility for taking unsafe equipment out of service immediately, appropriately labelling, safely storing it, and reporting to their line manager in accordance with the Serious Untoward Incident Policy.

6.3 Committee Responsibilities

The Infection Control and Physical Healthcare Group, reporting to the Executive Management Team has overall responsibility for assuring the organisation of the Trust's arrangements for safety alerts and monitoring the implementation of this policy.

7. Standards

Care Quality Commission Outcome 11. Safety and Suitability of Equipment.

National Patient Safety Agency (NPSA)

Health and Safety at Work Act 1974

8. Training

The CAS Liaison Officer will attend annual conferences hosted by the MHRA where there is always an emphasis on reporting, current trends and managing the CAS system. There are also online training manuals which can be accessed via the CAS system.

The CAS Liaison officer will keep the PA to the Medical Director appraised of any CAS system developments and cascade training where appropriate.

Statutory, mandatory and other training will be revised as necessary and as indicated by any safety alerts to ensure that the Trust is always teaching to the latest guidance.

Any safety alerts identifying a new training requirement will be discussed in the first instance with the Assistant Director of Learning and Development to agree an appropriate implementation strategy.

9. Definitions

CAS - Central Alerting System - A system for issuing patient safety alerts and other safety critical guidance to Healthcare organisations.

SABS - Safety Alert Broadcast System - was the email system used to send safety alerts to healthcare organisations. It was active from April 2004 to Sept 2008. It has now been superseded by the CAS system.

PHL - Public Health Link. - Important safety messages were formerly issued via this system. E.g. Dear Doctor letters, CMO messages and Drug alerts. These are now issued via the CAS system.

Emergency Alerts - Important Public Health Messages issued by CAS and received by the Executive Medical Director. Formerly PHL messages.

Non - Emergency Alerts – Range of Alerts that CAS Liaison Officers need to respond to formerly SABS

NPSA - National Patient Safety Agency.

MRHA - Medicines and Healthcare Products Regulatory Agency.

MDA - Medical Device Alert.

SLA's - Service Level Agreements.

CQC - Care Quality Commission.

CMO - Chief Medical Officer.

RRR - Rapid Response Report

EFA - Estates and Facilities Alert.

FSN - Field Safety Notice .- A notice issued by a manufacturer or supplier in relation to a FSCA

FSCA - Field Safety Corrective Action – Action that is required to reduce risk of harm from a device already on the market.

F2 asset register - Electronic asset management system for AWP Medical Devices.

CAS Liaison Officer - The person in the Trust who manages the CAS system in relation to alerts that require feedback.

10. Associated and Related Procedural Documents

- Incident Reporting Procedure Appendix B1- Adverse Incident Reporting Procedure.
- External Agency Reporting - Appendix B2 - External Agency Reporting.
- Adverse incident reporting system
- Medical Equipment Policy
- The Medicines and Healthcare products Regulatory Agency: http://www.mhra.gov.uk
- Patient safety website: http://www.nrls.npsa.nhs.uk/
- The Chief Medical Officer (for England): http://www.dh.gov.uk/health/category/cpo/chief-medical-officer
- CAS - Home

Version History

Version	Date	Revision description	Editor	Status
1.0	10 Dec 2008	Final approved by Integrated Governance in December	LDH	Approved
2.0	01 Dec 2009	Approved by Quality and Healthcare Governance Committee	LDH	Approved
3.0	9 May 2103	Approved by Quality and Standards Committee	LDH	Approved
4.0	11 May 2016	Policy extension until 30/112016 approved by Quality and Standards committee	Head of patient safety systems	Approved