Policy Document

Reference: RM13

University Hospitals of North Midlands NHS Trust

Dissemination and Implementation of Safety Alerts

Version:	**5**
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Policy Author:	**Head of Quality, Safety and Compliance**
Executive Lead:	**Medical Director**

Version Control Schedule

Version	Issue Date	Comments
1	October 2006	
2	July 2008	
3	November 2011	
4	February 2014	Policy ratified by Quality and Safety Forum following review
5	April 2019	Responsibilities clarified re Medical Device Alerts; UHNM Safety Alerts; Estates and Facilities Alerts; Supplies and Distribution Alerts; Expanded Recall Notices to include Field Safety Notices; SOPS updated; UHNM Safety Alert template added; Out of date appendices removed

Statement on Trust Policies

The latest version of 'Statement on Trust Policies' applies to this policy and can be accessed here

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1. INTRODUCTION

The University Hospitals of North Midlands NHS Trust aims to provide, so far as reasonably practicable, an environment which is free from risks to health and safety.

Safety Alerts, issued in response to incident reports, either on a national or local level, are designed to ensure that action required is alerted to the appropriate areas and promote sharing of lessons learned.

Therefore it is policy of the Trust to ensure that robust systems and process are in place to ensure that any information relating to patient safety is received, distributed, acted upon and recorded appropriately in accordance with agreed timescales. In order to achieve this, roles and responsibilities are clearly identified within this policy.

An "Equality Impact Assessment" has been undertaken and no actual or potential discriminatory impact has been identified relating to this document.

2. SCOPE

All members of staff at The University Hospitals of North Midlands NHS Trust (UHNM) have responsibility for ensuring the health and safety of patients and staff through minimisation of risk.

This policy addresses the process, roles and responsibilities for ensuring that risks identified within safety alerts and recall notices are acted upon in relation to the following:

- MHRA Medical Device Alerts
- NHS Patient Safety Alerts
- Estates and Facilities Notifications
- NHS Estates Alerts
- Product Recall Notices/Field Safety Notices
- Supplies Distribution Alerts
- Pharmacy Safety Alerts
- UHNM Internal Safety Alerts

3. DEFINITIONS

Term	Definition
CAS	Central Alert System (web based tracking system)
Recall Notice/Field Safety Notice	A notice issued by a manufacturer to customers when a problem with a product has been identified.
Compliance Form	A form that may be issued with Medical Device Alerts to record action taken in response to the alert – *see suggested template in Appendix One (this may be amended depending on the nature of alert)*
NHS Patient Safety Alert	National Patient Safety Agency; an Executive Agency of the Department of Health whose remit aims to improve the safety and quality of care through reporting, analysing and learning from adverse incidents and 'near misses' involving NHS patients via CAS
Estates and Facilities Alerts/Notifications	An alert or notice issued via CAS which relates to equipment managed/maintained by Estates and/or where Estates & Facilities have the overall responsibility in addressing recommendations made in the notice
Supplies and Distribution Alerts	An alert issued via CAS when a problem has become apparent with the supply of a specific product e.g. a specific medicine
Medical Device Alert	An alert issued via CAS in relation to a specific problem pertaining to a Medical Device (can refer to associated FSNs which may or may not have been received by the Trust)

Term	Definition
UHNM Safety Alert	An alert that has been created and circulated internally by the Trust to make staff aware of issues affecting patient safety and the actions they need to take

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4. ROLES AND RESPONSIBILITIES

4.1 Medical Device Related Safety Alerts Issued through CAS

The **Head of Quality, Safety and Compliance**, who acts as CAS Liaison Officer on behalf of the Trust is responsible for:

- Acknowledging receipt of safety alerts issued via CAS through the online system.
- In liaison with the Supplies Department and the Medical Devices Safety Officer, ascertain the locations, where applicable, of affected products to determine the appropriate circulation route for the alert
- Disseminating safety alerts to the relevant teams/locations to obtain responses ***or*** disseminating the alert to the Divisional Governance & Quality Managers (DGQM), where the CAS Liaison Officer deems the nature of the alert to be Trust-wide e.g. where a device is used across the Trust
- Issuing 'Compliance Forms' to the appropriate Divisional Governance & Quality Managers (DGQM) for circulation to their individual areas with the alert notice, where alerts are felt to be Trust-wide in nature so that responses can be collated
- Updating the electronic CAS database to reflect the Trust position against each safety alert issued.
- Informing the Compliance Steering Group of issues with regard to failure or delay in compliance with safety alerts.
- Maintaining an internal tracking log of all Medical Device Alerts; Recall/Field Safety Notices; Estates and Facilities Alerts/Notifications; Patient Safety Alerts etc to record the status of all alerts/notices
- Providing updates to appropriate meetings/forums when requested
- Escalating non-responses to alerts appropriately

The **Medical Devices Safety Officer** is responsible for:

- Advising the CAS Liaison Officer on the suitable locations/specialities/departments etc that the alerts should be issued to (with input from Supplies & Procurement where necessary)
- Confirming if they are satisfied that the appropriate action(s) have been taken to address the recommendations in the alerts so that the CAS Liaison Officer can update the CAS system and internal tracking log and close off notices appropriately

The **Divisional Governance and Quality Managers** are responsible for:

- Collating completed Compliance Forms from each applicable area within their Division within agreed timescales (where the CAS Liaison Officer has deemed this as the way in which the alert should be coordinated e.g. where a device is used across the Trust)
- Ensuring that Compliance Forms are completed accurately before submitting to the Head of Quality, Safety and Compliance, i.e. the form needs to record either 'not applicable' or the action taken in response to the alert for each area

All Staff who have been issued notices to act upon are responsible for:

- Having appropriate mechanisms in place for receiving and acting upon any safety alert applicable to their area within the agreed timescales.
- Accurately recording action taken in response to safety alerts (this may be on the Compliance Form if provided as part of the alert)
- Confirming if the affected product is not used (this may be on the Compliance Form if provided as part of the alert)

- Returning the completed Compliance Form to their Divisional Governance & Quality Managers (DGQM) within the agreed timescales (where the CAS Liaison Officer has deemed this as they way in which the alert should be coordinated)

4.2 NHS Patient Safety Alerts issued via CAS

The **Head of Quality, Safety and Compliance** is responsible for:

- Acknowledging receipt of safety alerts issued via the CAS through the online system.
- Agreeing with colleagues an appropriate lead/s to undertake the actions required.
- Disseminating safety alerts to the appropriate lead/s for action and aligning the alert with any relevant corporate groups
- Maintaining a record of action taken or progress in line with the CAS online system.
- Providing updates to the MHRA on implementation of Patient Safety Alerts when requested
- Maintaining an internal tracking log of all Medical Device Alerts; Recall/Field Safety Notices; Estates and Facilities Alerts/Notifications; Patient Safety Alerts etc. to record the status of all alerts/notices
- Providing updates to appropriate meetings/forums when requested
- Escalating non-responses to alerts appropriately

The **appropriate clinical lead/s** is responsible for:

- Ensuring that the action is implemented within the agreed timescales.
- Reporting back progress as required to any relevant corporate groups
- Providing updates to the CAS Liaison Officer when requests for progress have been made by the MHRA

4.3 NHS Estates Alerts and Estates and Facilities Notifications issued via CAS

The **Head of Quality, Safety and Compliance** is responsible for:

- Acknowledging receipt of safety alerts issued via the CAS through the online system.
- Forwarding safety alerts to the Estates, Facilities and PFI Division for action.
- Maintaining a record of action taken or progress in line with the CAS online system.
- Maintaining an internal tracking log of all Medical Device Alerts; Recall/Field Safety Notices; Estates and Facilities Alerts/Notifications; Patient Safety Alerts etc to record the status of all alerts/notices
- Providing updates to appropriate meetings/forums when requested
- Escalating non-responses to alerts appropriately

The **Estates, Facilities and PFI** Division is responsible for:

- Ensuring that Estates and Facilities Alerts are disseminated appropriately within their division as described in NHS Improvement Notice NHSI/2018/001
- Ensuring that the actions are implemented within the agreed timescales
- Reporting back progress to the CAS Liaison Officer as requested so that the CAS system can be updated

4.4 Recall Notices/Field Safety Notices

Under European legislation, manufacturers are obliged to inform all relevant Authorities (the MHRA in the UK), of any Field Safety Corrective Action (FSCA) that they are undertaking. A manufacturer undertakes a FSCA for technical or medical reasons connected with the characteristics or performance of a device, where death or serious injury might result. Manufacturers use a Field Safety Notice (FSN) to inform their customers about any FSCA that they are undertaking.

Recall notices/Field Safety Notices are usually received via the Supplies Department. Any Recall notice/Field Safety Notice received elsewhere within the Trust should be immediately forwarded to the Supplies Department and the Medical Devices Safety Officer

The **Supplies & Procurement Department** is responsible for:

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- Assisting in ascertaining the location, where applicable, of affected products.
- Ascertaining whether or not the affected product has been purchased by the Trust

The **Head of Quality, Safety and Compliance** is responsible for:

- Disseminating the recall notice to the relevant location, with clear instructions of the action required.
- Maintaining an internal tracking log of all Medical Device Alerts; Recall/Field Safety Notices; Estates and Facilities Alerts/Notifications; Patient Safety Alerts etc to record the status of all alerts/notices
- Reporting or escalating any issues relating to Recall/Field Safety Notices as appropriate.
- Providing updates to appropriate meetings/forums when requested
- Escalating non-responses to alerts appropriately

The **Medical Devices Safety Officer** is responsible for:

- Forwarding any recall/field safety notices they recieve to the CAS Liaison Officer
- Advising the CAS Liaison Officer on the suitable locations/specialities/departments etc that the notices should be issued to (with input from Supplies & Procurement where necessary)
- Confirming if they are satisfied that the appropriate action(s) have been taken to address the recommendations in the notices so that the CAS Liaison Officer can update the CAS system and internal tracking log and close off notices appropriately

All Staff who have been issued notices to act upon are responsible for:

- Having appropriate mechanisms in place for receiving and acting upon any recall notices applicable to their area within the agreed timescales.
- Ensuring effective communication is delivered to all staff within their ward or department in relation to every applicable recall received.
- Ensure that any issues with the actions required are bought to the attention of the CAS Liaison Officer
- Notifying the CAS Liaison Officer when actions have been completed

4.5 Medicines Safety Notices

Medicines related safety or recall notices are received via the Pharmacy Department. Any recall notice received elsewhere within the Trust should be immediately forwarded to the Director of Pharmacy.

The **Pharmacy Stores and Procurement Manager (Pharmacy Department)** is responsible for:

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- Ascertaining the location, where applicable, of affected products.
- Disseminating the recall notice to the relevant location, with clear instructions of the action required.
- Maintaining records of recall notices received and subsequent action taken for future reference.
- Reporting or escalating any issues relating to recall notices as appropriate.

Designated **ward or department staff (i.e. ward/theatre manager)** are responsible for:

- Having appropriate mechanisms in place for receiving and acting upon any recall notices applicable to their area within the agreed timescales.
- Ensuring effective communication is delivered to all staff within their ward or department in relation to every applicable safety alert received.

4.6 Supplies Distribution Alerts

The **Supplies & Procurement Department** is responsible for:

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- Assisting in ascertaining the location, where applicable, of affected products.
- Ascertaining whether or not the affected product has been purchased by the Trust

The **Head of Quality, Safety and Compliance** is responsible for:

- Disseminating the alert to the relevant locations/departments etc, with clear instructions of the action required.
- Maintaining an internal tracking log of all Medical Device Alerts; Recall/Field Safety Notices; Estates and Facilities Alerts/Notifications; Patient Safety Alerts etc to record the status of all alerts/notices
- Reporting or escalating any issues relating to alerts as appropriate.
- Providing updates to appropriate meetings/forums when requested

All Staff who have been issued alerts to act upon are responsible for:

- Having appropriate mechanisms in place for receiving and acting upon any recall notices applicable to their area within the agreed timescales.
- Ensuring effective communication is delivered to all staff within their ward or department in relation to every applicable recall received.
- Ensure that any issues with the actions required are bought to the attention of the CAS Liaison Officer
- Notifying the CAS Liaison Officer when actions have been completed

4.7 UHNM Safety Alerts

The Quality, Safety and Compliance Department may circulate an internal safety alert following an adverse incident, or receipt of a safety notice, which has Trust wide implications. The safety alerts provide a brief summary of the background to the incident and give key recommendations for action.

The **Head of Quality, Safety and Compliance** is responsible for:

- Ensuring that internal safety alerts are developed in response to adverse incidents that have Trust wide implications (as recommended by the Risk Management Panel or following team discussion and in liaison with divisional/speciality experts).
- Ensuring that internal safety alerts are disseminated Trust wide to ensure sharing and learning from adverse incidents.
- Maintaining a register of internal safety alerts that have been issued
- Uploading internal safety alerts that have been issued to http://uhnm/clinicians/clinical-guidance/quality,-safety-and-compliance/safety-alerts/

The **author** of the alert is responsible for:

- Consulting relevant individuals/teams/groups in the formulation of the alert as appropriate
- Forwarding the draft alert to the Quality, Safety and Compliance Team for checking prior to issue

The **designated Contact Lead/Team** detailed on the alert is responsible for:

- Providing additional guidance/advice to staff on the contents of the alert if required

All Trust Staff are responsible for:

- Ensuring safe working practices in accordance with advice from safety alerts.
- Keeping themselves up to date with safety issues and maintaining awareness of relevant safety alerts at all times.
- Reporting any issues in relation to safety alerts via the Trust's Adverse Incident Reporting System – see Trust Policy RM07 Policy for Reporting and Management of Incidents including SIRI and STEIS Reportable Incidents
- Contacting the designated contact/team on UHNM Safety Alerts if they require guidance/advice

5. EDUCATION/TRAINING AND PLAN OF IMPLEMENTATION

It is recognised that the systems and processes outlined within this policy are embedded across the Trust. However, advice can be sought from the Quality, Safety and Compliance Team if needed.

No formal education or training is required for the implementation of this policy.

6. MONITORING AND REVIEW ARRANGEMENTS

6.1 Monitoring Arrangements

- This policy will be monitored through ongoing implementation and delivery of the process outlined whereby action will be undertaken, documented and where necessary, approved.

- The policy will also be monitored via the adverse incident reporting system and where necessary, the appropriate investigation process and action will be undertaken.

- A summary of CAS alerts will also be included in the Quarterly Compliance, Information Governance and Effectiveness Report.

- A summary of open CAS alerts is reported at the weekly Quality Panel

6.2 Review

This policy will be reviewed by the Head of Quality, Safety and Compliance, every three years unless legislation or national guidance indicates the need for earlier review.

7. REFERENCES

- MDM02 Trust Policy for the use of Medical Devices/Equipment
- MDM04 Trust Policy for Managing the Maintenance and Inventories of Medical Devices
- RM07 Trust Policy for Reporting and Management of Incidents including SIRI and STEIS Reportable Incidents
- HS01 Trust Policy for Health and Safety
- MM02 Trust Policy for the Prescription, Safe Handling and Storage, Supply and Administration of Cytotoxic Agents and Cytotoxic Monoclonal Antibodies
- MM04 Policy for the Prescribing, Use and Supply of Unlicensed Medicines
- MM05 Use of PGD's for the Supply/Administration of Medicines by Registered Non-Medical Healthcare Professionals (C32)
- MM06 Policy for the Prescribing, Supply and Administration of Controlled Drugs
- EF23 Operational Policy for Estates Management

APPENDIX 1: COMPLIANCE FORM TEMPLATE

CENTRAL ALERTING SYSTEM	
MHRA Regulating Medicines and Medical Devices	MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY (MHRA)

COMPLIANCE FORM			
Reference:		**Date Issued:**	
Device:			
Problem:			

1.	**Is this device in use within your Division?**	**Yes**		**No**	

If you have answered 'no' to question 1: Please ensure that the contact details and assurance statement have been completed and return this form electronically to your divisional governance and quality manager: -

Medicine
Surgery
Support Services

If you have answered 'yes' to question 1: Please record the action taken, within the relevant areas of your Division in accordance with the Device Alert in section 3 below:

2.	**Action required:**
•	
3.	**Action taken within the clinical area/s:**

4.	Assurance Statement		
Completion and return of this form confirms that the Clinical Division are confident that where applicable, the necessary action has been taken and would be happy to provide further evidence for audit purposes in the future.			
Division:		Date:	

5.	**Approval**		
I confirm that I am satisfied sufficient action has been taken in response to the above named MDA.			
Signature:		**Date:**	
Designation:			

APPENDIX 2: UHNM INTERNAL SAFETY ALERT TEMPLATE

For an editable copy please contact Quality, Safety & Compliance 01782 676438

University Hospitals of North Midlands NHS
NHS Trust

PROUD TO CARE

SAFETY ALERT

Quality Safety & Compliance

UHNM/2018
000
2018

Background:

Issue:

Risk/Implications to patients/staff:

Action required:

Deadline for action

Contact details:
For further information or advice regarding this alert, please contact:
☎: ext