NHS
Cumbria Partnership
NHS Foundation Trust

Policy Title: Alerts Policy & Procedure

Reference	POL/002/053
Version	2
Date Ratified	26/02/2019
Next Review Date	28/02/2022
Accountable Director	Executive Chief Nurse
Policy Author	Clinical Risk and Patient Safety Manager

Please note that the Intranet / internet Policy web page version of this document is the only version that is maintained.

Any printed copies or copies held on any other web page should therefore be viewed as "uncontrolled" and as such, may not necessarily contain the latest updates and amendments.

Policy On A Page

SUMMARY & AIM

This policy applies to all members of staff employed within the Trust who are involved in any aspect of internal/ external alert dissemination, action, and/or review. The purpose of this document is to define the systems to be used for the dissemination of internal/external safety alerts, field safety notices, emergency alerts, drug alerts and medical device alerts.

It is the aim of CPFT 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 DoH timescales in order to safeguard patients, visitors, and staff from harm. The Risk Management Team will action the receipt of an alert within 2 working days of its issue.

Cumbria Partnership NHS Foundation Trust recognises and accepts its duty to distribute and action safety alert notices received via the Central Alerting System (CAS). The Trust will apply the procedures outlined in this document to distribute and action alerts received from external agencies via the Central Alerting System (CAS) as well as any internally generated alerts.

TARGET AUDIENCE:

- Attendance at training is managed in accordance with the Learning and Development Policy.
- All current and newly appointed staff that hold responsibility for actioning alerts must complete incident, risk and CAS alert training with the Risk Management Team.

TRAINING:

- Training is available via the risk team in the form off face to face training and also via webinar. Please contact the team for further details on: incidentteam@cumbria.nhs.uk

KEY REQUIREMENTS

1. All recipients of a safety alert (for action) have the duty to respond within 2 working days with details of how they have, or will, action the requirements of the safety alert via Ulysses.
2. All staff who are in receipt of an alert will have the understanding of how to action an alert and will attend training to ensure they know how to use all aspects of the alerts module
3. On receipt of an Alert the Care Group and Support Service Leads should cascade the alert via Ulysses to all relevant parties.
4. Care Group and Support Service Leads have responsibility to monitor responses, coordinate and collate the overall reply for their area within allocated timescales.
5. The System (through Ulysses) will send reminders to the Care Group and Support Service Leads to remind staff of deadlines to ensure actions are carried out within timescales.
6. The Accountable Officer and Administrator will audit the quality of the process as per the monitoring table within the policy to ensure they are appropriate and provide sufficient details and evidence that actions have been taken.
7. Non-compliance with the alert(s) is discussed in the first instance with the Head of Patient Safety and they will liaise with the Care Group and Support Service Leads to request compliance with the alert.
8. The Head of Patient Safety will be responsible for areas of non-compliance, delay or difficulties with alerts and they will escalate risks and concerns to the Director of Nursing immediately.

TABLE OF CONTENTS

SCOPE

This policy applies to all members of staff employed within the Trust who are involved in any aspect of internal/external alert dissemination, action, and/or review. The purpose of this document is to define the systems to be used for the dissemination of internal/external safety alerts, field safety notices, emergency alerts, drug alerts and me e alerts.

1 INTRODUCTION

The Central Alert System (CAS) is an electronic cascade system developed by the Department of Health and is the key route to communicate and disseminate important patient safety and device alerts information within the NHS.

The CAS facilitates distribution of safety, emergency, medical device, drug and estates alerts, field safety notices, Chief Medical Officer messages and Dear doctor letters issued by;

- The Medicines and Healthcare products Regulatory Authority (MHRA)
- NHS England
- Department of Health (DoH)
- NHS Department of Estates and Facilities

Internal alerts by the Trust may also be issued. These alerts will be used to provide rapid dissemination of information.

CAS also provides an electronic feedback form that has to be completed to confirm that, where Trusts have received a safety alert notice, their response and compliance to it are actioned.

Dissemination of all internal / external alerts, supplementary information, responses and actions etc. are managed and stored on the Alert Module within Ulysses Safeguard System.

2 STATEMENT OF INTENT

It is the aim of CPFT 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 DoH timescales in order to safeguard patients, visitors, and staff from harm. The Risk Management Team will action the receipt of an alert within 2 working days of its issue.

Cumbria Partnership NHS Foundation Trust recognises and accepts its duty to distribute and action safety alert notices received via the Central Alerting System (CAS). The Trust will apply the procedures outlined in this document to distribute and action alerts received from external agencies via the Central Alerting System (CAS) as well as any internally generated alerts.

3 DEFINITIONS

4.1 Central Alerts System (CAS) is the electronic system developed by the DoH for sending important safety and device alerts to NHS organisations

4.2 Safety Alert Bulletins is a generic term for alerts issued relating to medical devices, NHS Estates and NHS England alerts

4.3 Medicines and Health Regulatory Authority (MHRA). They are the DoH body who regulates medicines, medical devices and blood components for transfusion in the UK. They are recognised globally as an authority in its field; the agency plays a leading role in protecting and improving public health and supports innovation through scientific research and development?

4.4 DoH Estates and Facilities alerts (EFA) are issued by NHS Estates. They are a means of communicating safety information relating to engineering, installed services and building fabric.

4.5 NPSA Alerts are issued by NHS England on various patient safety and governance issues. There are three levels of alerts as identified below;

Stage One - A "warning" alert is issued to ensure healthcare staff are made aware of the potential issue at the earliest opportunity.

Stage Two - If a Stage One alert requires further action, a Stage Two "resource" alert will follow, with more in-depth information and advice allowing the recording of schedules and evidence of action taken to mitigate risks locally.

Stage Three - A Stage Three "directive" alert will be issued to Senior Staff within the Trust, requiring them to confirm that they have undertaken specific actions and introduced specific controls and assurances to mitigate the against risk. The allocation of the alert will be dependent on the topic of the directive, and this decision will be made by the designated accountable officer for the trust.

4.6 Internal Alert Notices (IANs) are internally generated alert notices which are issued at the request of a Quality and Safety Lead or Senior Support Services Manager / Lead in order to share learning or raise awareness. Depending on the nature of the IAN, actions may or may not be required from recipients. IANs will be issued and monitored in the same manner as alerts received via the CAS system.

Drug Alerts are managed by the pharmacy team but will occasionally involve asking each ward/team to perform requested actions. The monitoring of these alerts will be undertaken by the Lead Pharmacist and reported to the Medicines Management Committee, which is a sub group of the Trust Wide Clinical Governance Meeting.

4.7 Field Safety Notices (FSNs) are issued by the MHRA and published on the MHRA website. These arise directly from the Manufacturer when problems are identified. They involve recalls or warnings regarding medical devices.

4.8 Dear Doctor Letters are issued by the Chief Medical Officer and usually concern emergency or international/national key messages.

5 DUTIES

5.1 Chief Executive

The Chief Executive will assume overall responsibility for ensuring the Trust has appropriate arrangements in place for the management and response to safety alerts. The Chief Executive delegates responsibility for the management of safety alerts to the Executive Chief Nurse.

Executive Chief Nurse

The Executive Chief Nurse has delegated responsibility for ensuring the Trust has in place appropriate policies and procedures for the management and response to all safety alerts.

5.2 Head of Patient Safety

The Head of **Head of Patient Safety**, with the Clinical Risk and Patient Safety Manager, identify appropriate staff to lead on specific alerts. Additionally this post holder chairs the monthly Quality and Safe Systems Group.

5.3 Clinical Risk and Patient Safety Manager

The Clinical Risk and Patient Safety Manager is the designated Accountable Officer for CAS in CPFT and is responsible for the management of safety alerts via the Alerts Module on Ulysses Safeguard System.

This role has responsibilities including;

- Receiving alerts via CAS on behalf of CPFT
- Updating CAS on progress with alerts and closing the alerts when actions are completed.
- Co-ordination and leading the Trust action plan on specific alerts.
- Evaluating the evidence to determine if appropriate actions have been taken.
- Where non-compliance, delay or difficulties with alerts occur, they will escalate risks and concerns to the Head of Patient Safety / Executive Chief Nurse immediately
- Formulating and reviewing policy guidance for alerts biannually or more regularly if required.
- In association with each Care Group's Quality and Safety Lead (Or equivalent), undertake a review of performance with the policy standards (including audits re alert compliance).
- Providing support and guidance to Care groups regarding alerts.
- Maintain a central record of alerts received, disseminated and actions taken.
- Providing training and support regarding alert processes for relevant members of staff.
- Liaise with the Head of Clinical Governance; identify appropriate staff to lead on specific alerts.
- Provide a highlight report at the Monthly Quality and Safe Systems Group systems group meeting and act as vice-chair for the meeting.
- Provide a quarterly report to the relevant associated groups / meetings for internal

review and evaluation.

5.4 The CAS Support Officers

The CAS Support Officers role is to deputise for the Accountable Officer to receive alerts. The nominated post holders are, the Risk Systems Lead and Risk Systems officers / or Head of Patient Safety.

5.5 Associate Directors of Nursing

Have responsibility to ensure arrangements are in place for effective dissemination, action and enabling the provision of evidence of compliance with the alert. This will include the nomination of Care Group Quality and Safety Lead(s) / Leads and Heads of Support Services for the alerts process and that arrangements are in place to provide cover when the liaison officer is on annual leave or sickness.

5.6 Care Group and Support Service Leads

The Care Group and Support Service Leads responsibility is to manage the alerts process within their Care Group. They also have a duty to attend the quarterly Ulysses Systems Group meeting. They will be individuals with the necessary experience and authority to implement the actions identified within each alert and respond in a timely manner.

Responsibilities include;

- Use of the Ulysses System for distribution of alerts to relevant departments within the Care Group.
- Acknowledgement of an alert within 2 working days of distribution
- Maintaining records confirming distribution and detail actions taken with related departments.
- To provide the Accountable Officer with confirmation of actions by the timely completion of alert response on the Ulysses System.
- Notify the Accountable Officer of changes to individuals performing the Care Group Liaison role by contacting the Incident Reporting Team via IncidentTeam@cumbria.nhs.uk.
- Ensure a named deputy is available to manage alerts in the absence of the Care Group and Support Service Leads.
- Provide guidance to departments within own Care Group with regard to alerts.
- Provide the Care Group governance meeting with regular reports on progress and risks and attend the monthly Quality Safe systems Group Meeting.
- Log and manage any risks identified on the Care Group Risk Register via the Ulysses System.
- Attend training provided by the Risk Management Team in regard to the management of Alerts

5.7 Purchasing/Supplies/Estates Department

The Department will, upon the request of the Accountable Officer provide information, via the Ulysses System, to confirm whether or not CPFT has any products and/or devices affected by MDA alerts. The same process will also apply to field safety notices. The Accountable Officer will forward field safety notices to the relevant teams' Care Group / Support Service.

6 Management of alerts

All alerts are received via CAS from DoH, and the CAS Accountable Officer should provide acknowledgement within 2 working days of its receipt within the organisation. (No acknowledgement is required for drug alerts and CMO messaging). Both internal and external alerts will be managed via the Ulysses Alerts Module. These will be entered onto Ulysses by the Risk Systems Officers and cascaded to the relevant parties for action.

6.1 Medical Device Alerts

All alerts are disseminated via the Ulysses Safeguard System relating to medical devices and equipment. The Purchasing Manager and/or Medical Engineering Manager will action and provide information via Ulysses.

The alert will also be disseminated via email through the Ulysses Safeguard System to the appropriate Care Group and Support Services. Care Group Quality and Safety Lead(s) / Leads and Heads of Support Services will then cascade the alert to all relevant wards/departments within the Care Group, to ensure that all areas within the Care Group are reviewed in accordance with the alert.

Ulysses Safeguard System is used to send the alert for completion indicating relevance and appropriate actions. All alerts must be acknowledged within 2 working days of distribution. The Care Group and Support Service Leads will coordinate the Care Group response for action within the specified timescales. In the event of The Ulysses Safeguard System being unavailable the Business Continuity Plan will commence and all relevant staff will be informed.

6.2 Field Safety Notices

A Field Safety Notice (FSN) is a communication sent by medical device manufacturers, or their representatives, in connection with a Field Safety Corrective Action (FSCA).

If anyone within CPFT is sent a Field Safety Notice (FSN) this must be sent with immediate effect to the Accountable Officer to ensure action is taken to issue an internal alert notice (IAN)

A manufacturer undertakes a FSCA for technical or medical reasons connected with the characteristics or performance of a device, where death or serious injury may result. Manufacturers use a field safety notice (FSN) to tell their customers about a FSCA that they are undertaking and provide instructions or advice on what action is needed and by whom.

The MHRA assesses each FSCA received and decides whether to issue further advice, this is usually via a Medical Device Alert. The MHRA places manufacturers'

FSNs on their website for information and these will not normally require further action by users unless contacted directly by the manufacturer or if supplementary advice has been issued.

Field Safety Notices may be issued but not all FSNs result in a Medical Device Alert.
All FSNs must be forwarded to the Accountable Officer who will issue an IAN via the Ulysses Safeguard system.

6.3 NHS England Alerts

When a new alert is received, the Accountable Officer will assess the alert, and may liaise with the Head of Patient Safety, to identify a Trust Lead(s) for the alert. The Accountable Officer will make contact with the identified lead and discuss the relevance of the alert, and required actions. The Accountable Officer will continue to monitor progress of the alert and provide regular progress reports. All NHS England Alerts must be forwarded to the Accountable Officer who will add the notice to Ulysses.

6.4 Estates and Facilities Alerts

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

6.5 Drug Alerts

Drug alerts are published by the MHRA. The pharmacy department will action all drug alerts as received, and in accordance with, the national cascade system. This will often be undertaken by the pharmacy department supplying the medicines. A report detailing all the drug alerts is provided to the Medicines Management Committee which includes alert information. All Drug Alerts must be managed by the pharmacy department who will add the notice to Ulysses.

6.6 Internal Alerts

Internal alerts are issued via Ulysses within CPFT to provide rapid and effective distribution of information, e.g. following failure of a procedure, piece of equipment or other serious patient safety incident. The distribution will follow that of the alerts procedure. The Care Group and Support Service Leads will coordinate the Care Group response for action within the specified timescales. In the event of Ulysses Safeguard System being unavailable the Business Continuity Plan will commence and all relevant staff will be informed.

6.7 Emergency Alerts

Emergency alerts are currently sent by the following originators – MHRA Drug Alerts, MHRA Dear Doctor Letter and CMO Messaging. Although these alerts do have deadlines, these relate to how quickly the information contained should be cascaded onwards and do not require a response. As a matter of course they are sent to all Medical Directors and Chief Executives of NHS Trusts.

The Trust's nominated Accountable Officer is responsible for cascading such alerts to the relevant groups and individuals and support the nominees in entering responses into

CAS.

6.8 Compliance with Alerts

All recipients of a safety alert (for action) have the duty to respond within 2 working days with details of how they have, or will, implement the requirements of the safety alert via Ulysses. They must also respond to indicate if they consider no action is necessary. On receipt of an Action Alert the Care Group and Support Service Leads should cascade the alert via Ulysses to all relevant parties. It is their responsibility to monitor responses, coordinate and collate the overall reply for their area. The Safety Alert System (through Ulysses) will send reminders to the Care Group and Support Service Lead to remind of deadlines. They in turn should use Ulysses to remind the alert recipients. Overall responses will also be monitored and acted upon by the Accountable Officer to ensure they are appropriate and provide sufficient details and evidence that actions have been taken.

The Ulysses Alerts Module, maintained by the Clinical Governance team, will be used to collate information regarding actions taken and to monitor whether recipients have responded.

Non-compliance with the alert(s) is discussed in the first instance with the Head of Patient Safety. The Accountable officer will liaise with the Care Group and Support Service Lead to request compliance with the alert, and this will also be discussed at the Quality and Safe Systems Group. The Head of Clinical Governance will be responsible for areas of non-compliance, delay or difficulties with alerts and they will escalate risks and concerns to the Director of Nursing immediately. The Accountable Officer /Risk Systems Lead will enter the details on the Trust risk register detailing the area and specific concerns regarding non- compliance.

7 Training

Attendance at training is managed in accordance with the Learning and Development Policy. All current and newly appointed staff that hold responsibility for actioning alerts must complete incident, risk and CAS alert training with the Risk Management Team.

8 Monitoring Compliance with This Policy

The table below outlines the Trusts' monitoring arrangements for this policy/document. The Trust reserves the right to commission additional work or change the monitoring arrangements to meet organisational needs.

The Accountable Officer/ Lead Incident and Risk Co-ordinator will provide regular reports regarding the timescales and also arrange random audits of the whole process by testing a sample of alerts in some services.

Aspect being monitored	Monitoring Methodology	Reporting		
		Presented by	Committee	Frequency
Alerts are responded to within CAS within 2 working days	Review of CAS via National system	Accountable Officer and CAS support officer	Quality and Safety Leads Group	Quarterly
Alerts are reviewed and appropriate actions are completed within the alert	Review within Ulysses Module	Accountable Officer and CAS support officer	Quality and Safety Leads Group	Quarterly
Alerts are reviewed, actioned and completed within allocated timescales	Review within Ulysses Module	Accountable Officer and CAS support officer	Quality and Safety Leads Group	Quarterly
Quarterly paper written for CMG in regard to the management of Alerts	Data acquired via Ulysses system Full process review by Accountable officer	Accountable Officer and CAS support officer	CMG	Quarterly

Wherever the above monitoring has identified deficiencies, the following must be in place:

- Action plan
- Progress of action plan monitored by the *name of relevant committee* minutes
- Risks will be considered for inclusion in the appropriate risk registers

REFERENCES/ BIBLIOGRAPHY

An introduction to the NHS England National Patient Safety Alerting System

9 RELATED TRUST POLICY/PROCEDURES

Medical Devices Policy

Business Continuity Plan

DOCUMENT CONTROL

Equality Impact Assessment Date	
Sub-Committee & Approval Date	*TWCGG 19/3/19*

History of previous published versions of this document:

Trust	Version	Ratified Date	Review Date	Date Published	Disposal Date
CPFT	1.0	February 2017	March 2019	March 2017	

Statement of changes made from previous version 1.0

Version	Date	Section & Description of change
1	12.02.2019	• Changes of Job titles throughout document in line with organisational changes • Monitoring table reviewed and updated (figure 1 page 13) • The inclusion of : 1. Policy on a page 2. Document control
1.1	01/03/2019	Policy Management Group amendments • Headers and footers to be formatted as per the current policy template • References to 'joint' to be removed

List of Stakeholders who have reviewed the document

Name	Job Title	Date
Jemma Barton	Head of Clinical Governance	12.02.2019
Maureen Gordon	Head of Patient Safety	12.02.2019
Helen Boit	Senior Quality and Safety Lead Community Care Group	12.02.2019
Jayne Walls	Risk Systems Officer Alerts Administrator	12.02.2019
Jane Weatherill	Clinical Risk and Patient Safety Manager - Accountable Officer	12.02.2019