University Hospitals of Derby and Burton NHS Foundation Trust

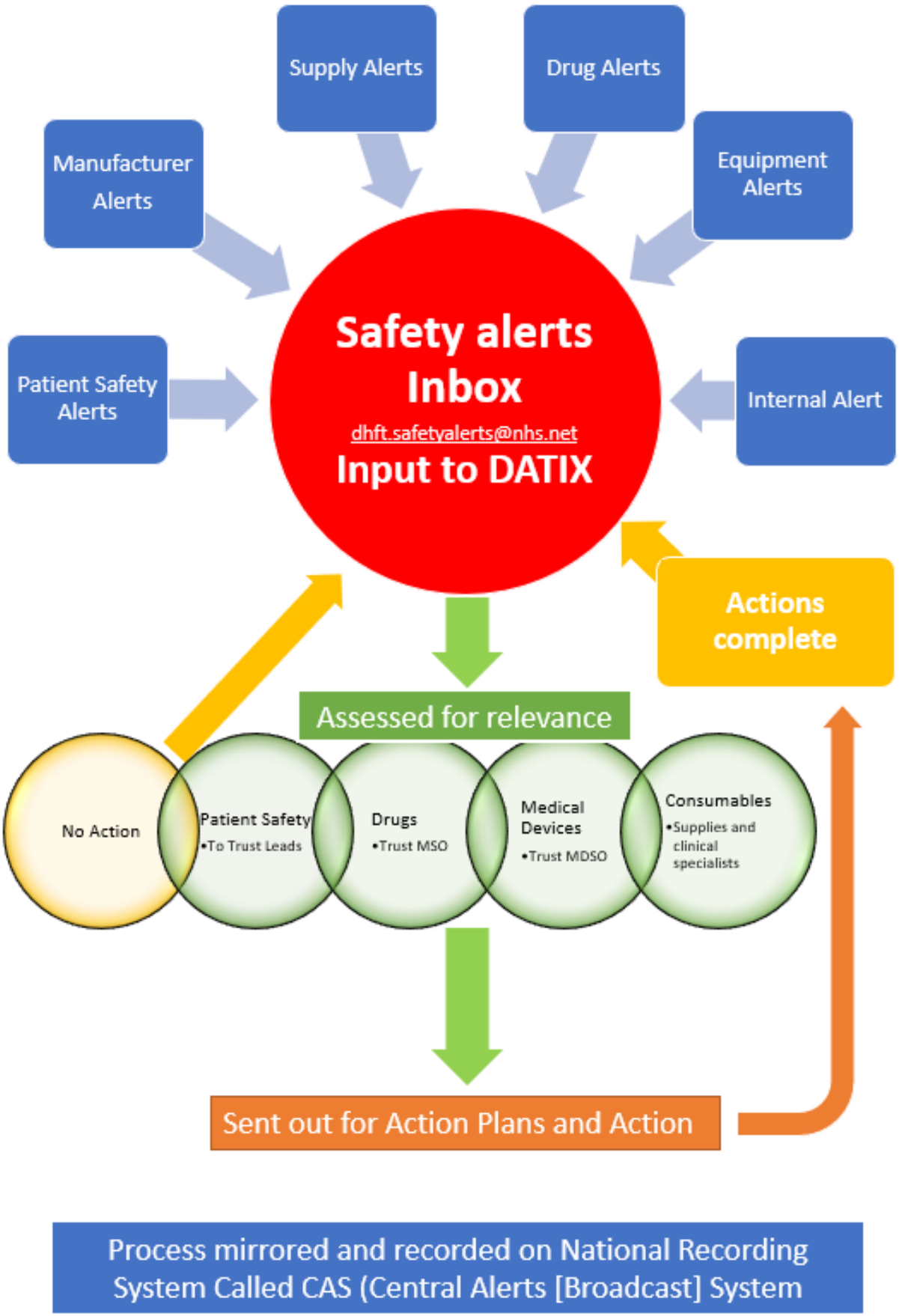
TRUST POLICY AND PROCEDURES FOR THE MANAGEMENT OF SAFETY ALERTS

Reference Number RKM 2014 036	**Version:** V5	**Status:** Draft	**Author:** Mark Cannell **Job Title:** Clinical Specialist and Equipment Library Manager	
Version / Amendment History	Version	Date	Author	Reason
	V1	Dec 2007	Kay Fawcett	Original Policy
	V2	January 2011	B.J. Youson	Policy Reformatted to NHSLA Standard
	V3	July 2014	L Fryatt	Updated in line with NHS England Patient Safety Alerting System and organisational changes.
	V4	Nov 2016	Mark Cannell	Updated to reflect Scan4Safety procedures
	V5	Feb 2022	Mark Cannell	Post-Merger policy
Intended Recipients: All Staff				
Training and Dissemination: Dissemination via Trust Intranet. It is anticipated that there will be no specific training requirements associated with this policy/procedure.				
To be read in conjunction with: Trust Policy & Procedures for Management of Medical Devices, Incident Reporting, Analysing, Investigating andLearning and Trust Policy for the Assessment and Management of Risk.				
In consultation with and Date: Medical Devices Group, and Quality Improvement/Review Group.				
EIRA stage One Completed Yes**Stage Two Completed** N/A				

Approving Body and Date Approved	Trust Delivery Group - 28 November 2022
Date of Issue	April 2022
Review Date and Frequency	April 2025 (then every 3 years)
Contact for Review	Clinical Specialist and Equipment Library Manager
Executive Lead Signature	Executive Medical Director
Approving Executive Signature	 Dr James Crampton, Interim Executive Medical Director

Contents

Simplified General Flowchart



TRUST POLICY AND PROCEDURES FOR THE MANAGEMENT OF SAFETY ALERTS

1. Introduction

It is essential that all alerts are communicated promptly to all relevant members of staff employed within the Trust, so that relevant actions can be promptly initiated to safeguard patients, visitors, and staff from harm. For this process to work, it needs to be known (what to do), it needs to be easy to do, and coordinated so that these responses are measured, effective and evaluated (demonstrate governance).

All Alerts at UHDB will be directed to the Safety Alerts inbox for evaluation and dissemination to the most appropriate Trust Staff.

Plans and responses will be received back in the Safety Alerts team and managed via the Safety Alerts Module in DATIX

2. Purpose and Outcomes

The purpose of the Alert System, and this policy reflecting its use, is to support Patient and Staff Safety within the influence of UHDB Trust.

This policy applies to **ALL** members of staff employed within the Trust.

This policy identifies specific responsibilities to those who are involved in any aspect of Alert dissemination, action, and/or review of these Alerts.

The Trust shall provide adequate management of external safety advice to ensure that:

- Responsibility and accountability for the receipt, recording, dissemination and follow-up of safety information is sufficiently explicit
- All Divisions, Business Units, Departments and Staff are made aware of safety information that may be relevant to their areas of work and responsibility
- The organisation responds appropriately and records evidence of its responses to external safety information on how the alerts have been implemented as well as provide details of any remedial actions taken / planned along with timescalesfor completion.
- Process for monitoring compliance with the above are in place and active.

3. Alerts and Definitions Used

NHS England » Introducing National Patient Safety Alerts is a document explaining many of the national structures and designs on the processes before they reach the Trust

Table 1: Abbreviations and definitions

NHS	National Health Service
DHSC	Department of Health and Social Care (formerly the Department of Health)
UHDB	University Hospitals of Derby and Burton NHS Foundation Trust
CQC	Care Quality Commission

CAS	The **Central Alerting System** is a Department of Health web-based cascading system for issuing patient safety alerts, important public health messages and other safety critical information and guidance to the NHS and others, including independent providers of health and social care (https://www.cas.dh.gov.uk/Home.aspx)
NaPSAC	The **National Patient Safety Alerting Committee** (NaPSAC) has been established to improve the effectiveness of these safety critical communications and to support providers to better implement the required actions. They provide and monitor the National Patient Safety Alerts Accreditation. Organisations that have achieved National Patient Safety Alert accreditation: NHS England and NHS Improvement Patient Safety Team Medicines and Healthcare products Regulatory Agency Public Health England ***The NatPSA prefix Alerts are monitored Nationally, with timescales and the CQC often request full communication logs and action plans as part of their assessments***

New and modified alerts are evolving so further NaPSAC approved alerts are expected.

Please see Appendix 1 for alert types

4. Key Responsibilities/Duties

Executive Chief Nurse

The Executive responsibility for Safety Alerts is within the portfolio of the Executive Chief Nurse's Team. There are direct managerial and professional links to the Safety Alerts team, and Patient Safety Specialists within the Trust.

Medical Director of Safety and Quality

The Physician Lead for safety and quality is one of the Trust's nominated Patient Safety Specialists and has direct links into the Board via the Executive Medical Director. Their role includes special interests in National and Local Safety Standard setting.

Head of Patient Safety

The Head of Patient Safety plays a key role in the development of a patient safety culture, safety systems and improvement activity. They are also one of the Trust's Patient Safety Specialists and provides expert safety advice and support to the Trust. Access to the executive team is to The Chief Nurse, which facilitates the escalation of patient safety issues or concerns.

Patient Safety Nurse

The role directly supports the Head of Patient Safety, and monitors compliance on Key and Strategic Alerts as part of their Role.

The Safety Alerts Team

The roles of the safety alerts team currently sit within the “Patient Safety” and the “Medical Equipment Library” Teams. This team receive, record, evaluate and distribute (appropriately) all alerts received in the Trust, they hold the following Nationally recognised roles: CAS Officer, MSO, MDSO, and SALO within the team. Trust Responses are recorded on the Trust DATIX system, and responses to all alerts are Co-ordinated by this team.

For clarity, the process for dissemination and Handling of “National Safety Alerts” is the same in principle as the other non - NaPSAC recognised alerts and notices.

Please consider all of these to be collectively labelled under the term “Alerts” for this policy, despite the majority of these being handled within Procurement, Pharmacy and Clinical/Medical Engineering.

The CAS Officer

This role is within the Safety Alerts team and is the senior member who ensures receipt and appropriate dissemination of all alerts via most apt routes. They initiate the Baton system of hand over to the SALO role. This individual has Clinical and Managerial credentials and authority to allow decision making, and for any required escalations. At this point any alerts are assessed for collateral involvement of other threads of Trust Activity that would require specialised input (IT, IG, Engineering Specialities, Clinical Specialities or Joint Care providers/Contractors)

Medical Devices Safety Officer (MDSO)

This is a nominated role, and identified in their Job description, they are the Medical Devices lead for Safety, and an active member of the MHRA’s MDSO Network, they advise the Trust for Yellow Card reporting relating to Medical Devices, and application of the Medical Devices Regulations. They manage any alert processes relating to Medical Devices.

Safety Alerts Liaison Officer (SALO)

This is one of the administrative roles within the Safety Alerts Team, the SALO is a nominated administrator responsible for:

- Receiving and acknowledging receipt of CAS notices on CAS system
- Flagging “Alerts” promptly with appropriate Trust lead
- Registering and maintaining the Trust database of alerts received, and actions taken (Currently DATIX)
- Distribution of “alerts” across UHDB (to nominated leads – recorded within “Distribution Lists” in DATIX)
- Following internal SOPs on “alerts”, chase nominated/identified staff for compliance data and evidence.
- Under the instruction of the CAS Officer - updating the CAS web site on alert status

Supplies and E-Procurement Team

The Team act on receipt and instruction of the CAS officer on “Alerts”.

For FSN’s and SDA’s (NB: these are occasionally received directly, so need to flag the receipt with SALO), the team accept the alert “Baton” and commence a check on relevant systems for evidence of the items involved (Unit4/Agresso, “hTrak - Pospitalia”, NHS “Supply Chain”) to see if the product has been used in the Trust and if so where it is currently located.

The Alert “Baton” is then forwarded by the Supplies and E-Procurement team to the “user” for action. This is recorded in DATIX.

Medicines Safety Officer (MSO)

This is the Pharmacy lead for safety and a member of MHRA MSO network, advisor for Medicines Yellow Card reporting, often a recipient of the Baton from the Safety Alerts Team. They manage any alert processes relating to Drugs/Medicines.

Division / Business Unit Coordinator

Each division/business unit has local processes for the receipt and distribution of alerts as necessary. Whilst this is often unnecessary for the less global alerts (as either supplies or the safety alerts team will communicate directly with affected services), nominated individuals/teams responsible for local dissemination of “Alert’s” collating the responses and all action plans and responding centrally to Risk Services (Via DATIX). see Appendix 4). The wider action plans and evidence of action taken will have been processed via the relevant “Divisional Risk and Governance teams” processes and recorded on DATIX (see Appendix 3).

All staff given an alert for action

Will take appropriate action for safety alerts and report back to their Division/Business Unit Coordinators (Advising their managers (Via DATIX) where action is required beyond their sphere of control.

Patient Safety Reporting

The Trust receives reports for assurance of process and for escalation via the Quality Review Group (QRG), this committee will receive reports from the Safety Alerts Team, Issues of non-compliance will be addressed through this arena and will be escalated as appropriate. Escalations will be to GIG/QPC

Medical Devices Group

This committee and its subgroups have responsibility for the effective management (use and purchasing) of Medical Equipment for the Trust. As part of this remit, it also requires sight and assurance of any relevant Alerts, and assurance of compliance. The same Quarterly report and escalations will be shared with these Groups.

5. Implementing the Policy and Procedures Receipt of Alerts

Alerts are sent to the Safety Alerts mailbox. The SALO will acknowledge receipt to CAS within 2 working days. In times of the SALO being absent, access to the e-mail address box will be assigned to another member of the Patient Safety Team.

The SALO in conjunction with (acting CAS officer) others in the Patient Safety team, will undertake an initial review to determine which staff should be involved with taking actions in respect of the alert. This will usually involve communication with the Procurement Manager, Equipment Library Manager, Facilities Management or Pharmacy Manager to confirm whether products affected by alerts are in use within the Trust (using the various systems – see Appendix 5)The following table details the initial review process and subsequent action for each type of alert (see appendix 2).

6. Internal Alerts

In addition to the CAS alerts this procedure also allows for the generation of Internal Trust alerts that may need to be issued by the Trust to provide rapid and effective distribution of information, e.g., following a Serious Incident (SI), incident or accident.

The distribution process will follow the CAS procedure with the exception that progress of actions will not be reported to the Department of Health. An internal alert will only be distributed following the agreement of the Director of Patient Experience and Chief Nurse and/or the Medical Director.

7. Dissemination of the Alert

Following assessment (section 5: Implementing the Policy and Procedures Receipt of Alerts)

Once identified the alert is relevant, the actions required as identified on the alert will become live and this will be communicated out to the relevant areas of the Trust.

The correspondence from the Safety Alerts Team will include the Local DATIX reference, this reference as on this Single document all subsequent/supplemental information will be recorded and copied to.

All further information and action plans will be recorded on this DATIX file and this includes all Actions (see Appendix 3)

The SALO maintains the CAS safety alerts database, recording distribution, deadlines for action and actions taken, and reports compliance using the following Central Alerting System definitions for returns:

- Acknowledged
- Assessing Relevance
- Action Not Started
- Action Required: Ongoing
- Action Not Required*
- Action Complete

If the alert is not relevant to the Trust the SALO will make a record to this effect on the CAS web site (*fifth selection from above).

8. Division / Business Unit Action

It is a fundamental facet of this procedure that the Division / Business Unit coordinators ensure that they have a robust system in place to action all Alerts in a timely manner, including arranging for a prompt and consolidated reply to the SALO. Arrangements for cover for periods of absence should be factored into local arrangements. Division/Business Unit coordinators should note the response timescales on individual Alerts and ensure that actions taken are commensurate with the timeframe specified.

All Actions to be completed in DATIX on the action section of the Alert

All Related files to be kept on the DATIX alert for governance purposes.

9. Follow-Up Procedures

DATIX time stamps all interactions, and the sheets all have response times that enable the SALO to monitor the Alert's progress, and issue reminders/requests for "progress notes" to be updated if any Division/Business Unit coordinators or other addressee fails to reply to the Alert.

The SALO will send a reminder to the Division/Business Unit coordinators to ensure the timescales for responses are met and will escalate to Divisional Directors and the Patient

Safety Committee any issues/concerns.

The Safety Alerts Team meet weekly to monitor all "Alerts" and review responses. An alert can only be recommended for closure once **ALL** returns have been received and the action taken fulfils the terms and wording of the alert. Once the action taken is agreed as sufficient to close the alert this will be signed off by the CAS officer role and the SALO will sign off on the National CAS database.

Issues of concern or escalations will be flagged at all relevant Trust arenas by the CAS officer, or directly to Board level through the Patient Safety Specialists.

10. Monitoring Compliance and Effectiveness

The key requirements will be monitored in a composite report presented on the Trusts Monitoring Report Template: See Appendix 6

Monitoring Requirement:	The Trust can demonstrate compliance in relation to responding to the Department of Health and NHSEngland within appropriate timeframes
Monitoring Method:	To analyse and to operationally monitor the state of play of all alerts. Reviewing with Patient Safety Specialists on a regular basis. Using CAS information to provide a 3 monthly report of Alerts Activity, this is submitted to the Patient Safety Group and Derbyshire's Clinical Commissioning Group National Patient Safety Concerns and action plans made available on Request
Report Prepared by:	MDSO, CAS Officer and SALO
Monitoring Report presented to:	Quality Review Group, NatPSA's on Monthly agenda, Activity Report 3monthly.
Frequency of Report	3 Monthly.

11. References

NHS England (2019) Introducing National Patient Safety Alerts
(https://www.england.nhs.uk/patient-safety/national-patient-safety-alerting-committee/)

NHS Improvement (2019) Summary criteria for the management and creation of National Patient Safety Alerts
(https://webarchive.nationalarchives.gov.uk/ukgwa/20200706210047/https:/improvement.nhs.uk/documents/6027/Credentialing_Criteria_Confirmed_May_2019_.pdf)

Live Central Alerting System website (https://www.cas.mhra.gov.uk/Home.aspx)

MHRA (2022) Medical devices regulation and safety: detailed information
(https://www.gov.uk/topic/medicines-medical-devices-blood/medical-devices-regulation-safety)

Medical Devices and Software Applications (2021)

(https://www.gov.uk/government/publications/medical-devices-software-applications-apps)

Alerts, recalls and safety information: drugs and medical devices (All UK Registered

Safety Notices)
(https://www.gov.uk/drug-device-alerts)

Patient Safety Incident Investigation (PSII) 2022
(https://www.england.nhs.uk/patient-safety/patient-safety-investigation/)

Patient Safety Incident Response Framework 2022
(https://www.england.nhs.uk/patient-safety/incident-response-framework/)

12. Appendix 1 Types of Alerts

Central Alert System

The Government and UHDB Central Alerting System currently operates Monday – Friday, 0900 – 1700 hours, excluding Bank Holidays.

Alerts reach the Trust in 3 main ways: National Alerts, Manufacturer advisory notices (Field Safety Notices), or internal alerts

National Alerts: As of November 2019, Safety Alerts were brought under the NHS England Banner, and they began issuing accredited 'National Patient Safety Alerts'. Their own patient safety team was the first national body accredited to issue National Patient Safety Alerts by the National Patient Safety Alerting Committee (NaPSAC).

All National Patient Safety Alerts are required to meet NaPSAC's thresholds and standards, which include working with patients, frontline staff and experts to ensure alerts provide clear, effective actions to reduce the risk of death or disability.

These alerts are an evolving list. Full details available via the CAS web site.

NatPSA/…/NHSPS	Alerts issued by NHS England and NHS Improvement Patient Safety Team, follow this identifier format, e.g., NatPSA/2021/009/NHSPS. Which was the 9th National alert issued by them in 2021. The Suffix indicates the origin of the alert.
NatPSA/…/MHRA	Alerts issued by the UK Medicines and Healthcare products Regulatory Agency, follow this identifier format, e.g., NatPSA/2021/005/MHRA. The Suffix indicates the origin of the alert.
NatPSA/.../UKHSA	Public Health England has been superseded by UK Health Security Agency, they follow the NatPSA format, the Suffix indicates the origin of the alert, e.g., NatPSA/2021/010/UKHSA
EL(year)…	Drug Alerts (with an EL prefix) are specific drug-based issues, issued by the MHRA. Drug Safety updates are also issued.
CEM/CMO/…	**Chief Medical officer** Communications, shared immediately with the Trust's Senior Medical Team for cascade to clinical teams, e.g., CEM/CMO/2021/022.
SDA/…	DHSC & NHS England and Improvement: **Supply disruption alerts**, e.g., SDA/2021/014
MHRA	The **Medicines and Healthcare products Regulatory Agency** is responsible for the regulation of medicines and medical devices and equipment used in healthcare and the investigation of harmful incidents.The MHRA also looks after blood and blood products in the UK.
FSN	**Field Safety Notices** are product notices that are sent directly from Manufacturers

EFA/EFN	**Estates and Facilities Alerts:** These now appear superseded by other processes outside this Policy and system.

These alerts and their responses are recorded centrally and in the public domain on the MHRA Central Alerting System (CAS), a web-based cascading system for issuing/coordinating alerts, important public health messages and other safety critical information and guidance to the NHS and social care (including other organisations and independent providers of health).

NHS England publish monthly data on their website for any Trusts who fail to declare compliance with any stages of the alerts by their set due date. Failure to comply is likely to be used by the Care Quality Commission in their Intelligent Monitoring System and as an integral part of commissioners' responsibilities for improving quality.

Locally the alerts are managed through the Trusts DATIX Risk System, using response tracking and the network of Risk links throughout the Trust to ensure the information is effectively communicated and actions coordinated, this department is also responsible for recording the acknowledgements and outcomes on CAS. To further add a degree of granularity and security to our processes the introduction of the Scan4Safety project adds a system that will facilitate the immediate identification of where a product is, and if/which patient a product has been used on. Traceability through Prospitalia's 'hTrak' system is currently available (April 2022) in Radiology, Cath Lab, and all theatres areas at RDH, with similar areas at Burton to follow.

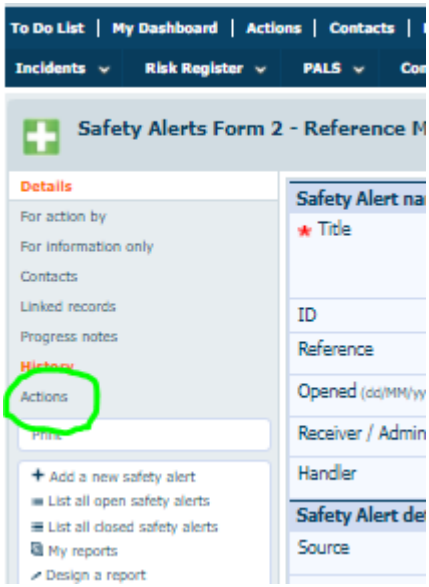
For most recent alerts, very focused actions, relating to only a concise few areas have been the requirement, these are managed through the Patient Safety Leads. A more general approach, if required would require triggering of the Divisional co-ordinators (see appendix 4)

Manufacturers Advisory Notices: Or Field Safety Notices (FSN) are issued not by Government but by the manufacturers. These are produced reactionary to product issues and issued directly to customers, whilst notifying NHS England and the MHRA in the process (as part of their regulatory requirements). Trust Medical Device Safety Officers (MDSO) and Medicines Safety Officers (MSO) must register with the MHRA to keep a master list of contacts, these are intended to be the recipients of all relevant FSN's. This does not often occur, and these alerts are received quite haphazardly. All FSN's are funnelled into the Trust Process and dealt with as per General Flow chart.

Internal Alerts: are identified by our own Risk and Incident analysis, issued via our internal Patient Safety teams and via the Trust Learning Review Group (LRG) or Trust Quality Review Group (QRG), to provide rapid and effective distribution of information e.g., following an Incident and its following investigation (using the Patient Safety Incident Response Framework, or PSIRF tools). The distribution process will follow the CAS procedure with the exception that progress of actions will not be reported out of Trust.

13. Appendix 2 Alert Dissemination Flowchart

14. Appendix 3 Action Plan Image from DATIX

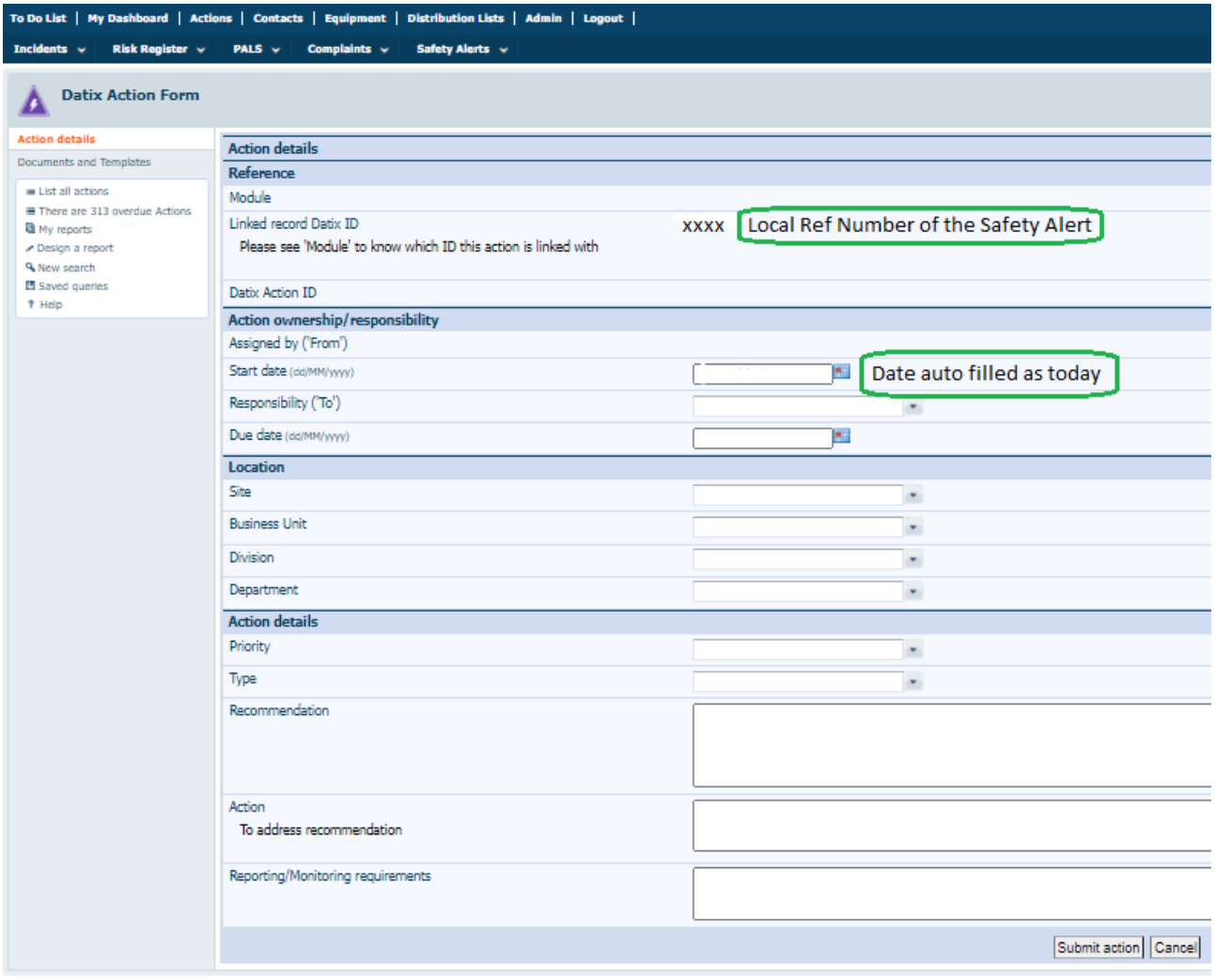


Action Plans Accessed by using the Upper left menu options on the main page of each Safety Alert.

The “Actions” Menu option is Orange if there are Actions existent on this alert

The DATIX Actions Form: Note the actions are linked to this Safety Alert, the date when the form was started will automatically complete although is editable.

The name of the responsibility is for the Action not the Alert



15. Appendix 4 Division Coordinators

Division	Speciality	Designation
Corporate Services	Infection Control	Infection Prevention and Control Specialist Nurses
	Facilities	Deputy Head of Facilities Management
	Medical Devices	Clinical Specialist & Equipment Library Manager/MDSO
	Clinical/Medical Engineering	Manager
MEDICINE (Covers DME and Rehab) – uhdb.clinicalgovernancemedicine@nhs.net	All Medicine	Clinical Governance Advisor/Facilitator
SURGERY (Covers Anaesthetics) – uhdb.surgerygovernanceteam@nhs.net	All Surgery	Clinical Governance Advisor/Facilitator
CANCER,DIAGNOSTICS & CLINICAL SUPPORT (Covers Dietetics / Pathology / Pharmacy / OT / Physio / Radiology / Therapies) – uhdb.cdcsgovernanceteam@nhs.net	All	Clinical Governance Advisor/Facilitator. Quality Manager Superintendent Radiographer MSO
WOMEN & CHILDREN'S SERVICES (includes Gynae and GUM) Children's Services – uhdb.paedsgovernanceteam@nhs.net (Mon-Wed only)	Maternity & Gynaecology	Audit Assistant & Clinical Governance Facilitator
	Children's Services	Governance Facilitator Patient Safety Coordinator

16. Appendix 5 Overview of Related National and Trust Data Systems

System	Processes	Description
Central Alerting System	Supplies (CAS), Medical Devices (CAS), Pharmacy (CAS)	National system for the dissemination and reporting ofnational safety alerts
Agresso	Supplies (CAS), Supplies (FSN), Medical Devices (FSN)	Finance system used for processing payments to suppliers
NHS Supply Chain	Supplies (CAS), Supplies (FSN), Medical Devices (FSN)	National NHS Supply Chaincatalogue
hTrak - Pospitalia	Supplies (CAS), Supplies (FSN)	Stock and usage solution to automate inventory and provide functionality for product traceability
JAC	Pharmacy (via CAS), Pharmacy (via LRI)	Pharmacy inventory management system. Used for ordering drugs, recording batch number of unlicensed drugs, recalling drugs dispatched to clinical areas
AIMS/E-Quip (2022 transition)	Medical Devices (CAS), Medical Devices (FSN), Medical Devices (Datix)	Clinical Engineering inventory management system. Includes a record of the last known location of medical equipment
Datix	Medical Devices (Datix)	Patient safety and risk management software for incident reporting and adverse events

17. Appendix 6 Reporting Template

NHS
University Hospitals of Derby and Burton
NHS Foundation Trust

Clinical Quality Review Group	Date:	Item:	Enc:

Title of Report:	**Quarterly Central Alerting System (CAS) Assurance Report**
Lead Executive:	
Title:	Executive Chief Nurse
Author(s):	
Purpose:	To provide update on the Central Alerting System (CAS) compliance within UHDB for Quarter

Executive Summary:
The paper is to provide update on UHDB's compliance with alerts via the Central Alerting System. There has been the following Alerts published in this Quarter: ➢ [enter number] reportable alerts published this last quarter ➢ Of these [enter number] New NatPSA,

Primary PRIDE Objective(s):	
☒	**Putting Our Patients and Our Communities First**
☒	**Right First Time**
☐	**Invest Our Resources Wisely**
☐	**Develop and Nurture Our Colleagues**
☐	**Ensure Improvement Through Effective Partnerships**

Key Risks (including those on BAF):

Report previously received by (Committee/Group):

Has the final report been approved by the Executive Director?	☐

Recommendation:
The report is to provide update on alerts received within the trust and to provide assurance on actions taken.

For:					
Approval:	☐	**Discussion:**	☐	**Information:**	☒

1 - Background/Introduction

As of November 2019, Safety Alerts were brought under the NHS England Banner, and they began issuing accredited 'National Patient Safety Alerts'. Their own patient safety team was the first national body accredited to issue National Patient Safety Alerts by the National Patient Safety Alerting Committee (NaPSAC).

All National Patient Safety Alerts are required to meet NaPSAC's thresholds and standards, which include working with patients, frontline staff and experts to ensure alerts provide clear, effective actions to reduce the risk of death or disability.

These alerts and their responses are recorded centrally and in the public domain on the MHRA Central Alerting System (CAS), a web-based cascading system for issuing/coordinating alerts, important public health messages and other safety critical information and guidance to the NHS and social care (including other organisations and independent providers of health).

In this report we identify the formal alerts, their responses and outline relevant action plans.

There is a new notification – this is not recorded on CAS system. DSI (Device safety Information) looks to be replacing the Medical Devices Safety Bulletin; these would be shared through internal processes much like the CMO Notices.

Main Abbreviations:	In Full	Issue By
DHSC	Department of Health and Social Care	
CAS	Central Alerting System	The Medicines and Healthcare products Regulatory Agency
MHRA	Medicines and Healthcare products Regulatory Agency	Department of Health
NatPSA/…/NHSPS	National Patient Safety Alert	NHS England
NatPSA/.../MHRA	Medical Devices Alert	MHRA
NatPSA/…/UKHSA	Public Health Alerts	UK Health Security Agency (formerly PHE)
SDA	DHSC & NHS England and Improvement: Supply disruption alert	DHSC & NHS England and Improvement
EL	Drug Alert	MHRA Drug Alerts
EFA/EFN	Estates and Facilities Alert/Notice	DH Estates and Facilities/Health and Safety Executive
CMO/CEM	Chief Medical Officer Message	DHSC

NatPSA's are managed by the Lead Nurse - Patient Safety

Device Alerts are managed by the Trust MDSO (Medical Devices Safety Officer)

Medicines are managed by the Trust MSO (Medicines Safety Officer)

Estates Alerts are managed through Estates Management

CMO Notices are published by the Trust Executive Medical Director

Internally this process is managed Via DATIX

2 - Main Report - Central Alerting System Compliance report (Q4 2021/22)

10 alerts received in total broken down as below *(example)*

Issue Date	Response	CAS Helpdesk Team	CMO Messaging	National Patient Safety Alert - MHRA	National Patient Safety Alert - UKHSA	SHOT - Serious Hazards of Transfusion	Grand Total
[month]	Action Required: Ongoing					1	1
	Response Not Required		4				4
[month]	Response Not Required	1	2				3
[month]	Action Completed				1		1
	Action Required: Ongoing			1			1
Grand Total		**1**	**6**	**1**	**1**	**1**	**10**

None of the above were late in response or deadline.

2.1 *Patient Safety alerts issued and **in progress** (please note Blue highlighted are the alerts from the National Patient Safety Agency)*

Reference	Alert Title	Originated By	Issue Date	Status	Response	Deadline
					Action Required: Ongoing	

The 1 alert is led by the Trust Patient Safety Lead and Managed by the Trust MDSO, this is on target for completion within deadline.
Two opened this quarter

Full Listing of this quarter's Published Alerts

Reference	Alert Title	Originated By	Issue Date	Status	Response	Deadline

*2.2 Patient Safety alerts **closed this quarter***

Alert reference	Alert Title	Issue date	Date Acknow	Completion deadline date	Completed Date	Completed Within Deadline	Current status
							COMPLETED

2.3 On-going Patient Safety Alerts

As indicated by point 2.1 NatPSA/2022/002/MHRA currently active and managed by Trust MDSO, on target for closure within deadline.

The SHOT alert is technically not yet an Alert – but is being manged as such, again due for closure within deadlines.

3 – Recommendation

The report is to provide update on alerts received within the trust and to provide assurance on actions taken.

Escalation Regarding Field Safety Notices: these are documents generated by manufacturers to inform customers of concerns or issues, these have significantly increased since beginning of Q1. Issue is the delivery of these is haphazard and often less effective. MHRA are publishing these as regularly as possible but to a site for public access not for a notification process.

The increase in Supply Disruptions, due to mix of BREXIT, COVID and other Supply disruptions continue internationally, the information on these is reaching the Trust Via multiple routes, this has caused problems with SDA/2021/12U as an example, as this was received by so many routes the responses were then unfocused and required greater input and time to clarify.