Management of Safety Alerts

Department / Service:	Corporate Division	
Originator:	Patient Safety Team	Health & Safety Manager
Accountable Director:	Chief Nursing Officer	Chief Operating Officer
Approved by:	Improving Safety Action	on Group
Date of Approval:	4 th February 2025	
Review Date: This is the most current document and should be used until a revised version is in place	4 th February 2028	
Target Organisation(s)	Worcestershire Acute	Hospitals NHS Trust
Target Departments	All	
Target staff categories	All	

Policy Overview:

This document outlines the way in which the Worcestershire Acute Hospitals NHS Trust receives, acknowledges and responds to safety information issued by the Medicines and Healthcare Products Regulatory Agency and NHS Improvement via the Central Alerting and Safety Alert Broadcast Systems. It also includes how safety information received directly from manufacturers is managed.

Key amendments to this Document:

Date	Amendment	By:
January 2025	Revised process for the receiving, recording and dissemination of Field Safety Notices.	Allan Bailey
June 2023	Revised policy in-line with changes to reporting process	K. Apps and J. Noble
March 2021	Change to classifications for alerts related to medicines in line with CH/2021/001: Changes to MHRA Drug Alerts. Addition of Supplies Department process flowchart	D. Johnson
December 2019	Clarification of committees for reviewing safety alerts and addition of nominated lead for safety alert oversight.	D. Johnson
October 2019	Biennial review	H&S Manager
Aug 2018	Review of process and timescales	Samantha Trigg, Lisa Wood

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1.1.2.0017	Deview in light of new Covernence structure	Daul Craham
July 2017	Review in light of new Governance structure	Paul Graham,
		Katherine Leach
October	Documents extended for 12 months as per TMC paper	TMC
2016	approved on 22 nd July 2015	
Sep 2016	Reword of 5.2 as per Trust Medicines Policy	Alison Smith
·	Inclusion of MSO role	
Aug 2017	Changes made in line with Patient Safety Alert	P Graham
Ū	NHS/PSA/RE/2016/003	
20/10/14	Changes to meet the requirements of new guidance from	P Graham
	MHRA and NHS England	C Rawlings
1/10/2012	Minor changes	P Graham
		C Rawlings
23/8/10	New process for National Patient Safety Alerts (NPSA)	C. Rawlings
	and introduction of Datix Safety Alert module to manage	P. Graham
	responses.	
1/4/09	Policy reviewed by H&S Manager and HR Policy Working	H&S Manager
	Group. Minor amendments made as a result of system	
	changes i.e. SABS to CAS.	
1/7/09	Minor changes made to reflect new management structure	H&S Manager
	and responsibilities	

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1. Introduction

This document sets out Worcestershire Acute Hospitals NHS Trust's process for Safety Alerts Management. It provides a robust framework to ensure a consistent approach across the whole organisation for the management of all safety alerts received within the Trust, and supports our statutory duties as set out in the NHS Constitution.

The Department of Health directive requires a nominated local lead that is responsible for cascading alerts within an organisation. The CAS Liaison Officer for Worcestershire Acute Hospitals Trust is appointed by the Medical Devices Safety Officer (MDSO). The CAS liaison Officer receives alerts via two separate systems: Central Alerting System (CAS) and Safety Alert Broadcast System (SABS)

These systems provide a consistent and easily accessible source of data to enable NHS Trusts to assure themselves how effectively they are managing important safety issues.

2. Scope of this document

The scope and purpose of this document is to ensure adherence to the management of Safety Alerts received within the Trust. Types of safety alerts received include; National Patient Safety Alerts (NPSA), Chief Medical Officer (CMO) Alerts and Field Safety Notices (FSN). NPSA alerts and CMO alerts are received via the Central Alerting System (CAS) other alerts (e.g. FSN, product recall requests) are received through the Trust Safety Alert Broadcast System (SABS) mailbox.

The policy applies to all Trust staff.

3. Definitions

The Central Alerting System (CAS) is an NHS web-based cascading system used for issuing National 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

The Safety Alert Broadcast System (SABS) is the system where Field Safety Notices and Product recalls are cascaded to and received to the Trust by a SABS mail box.

National Patient Safety Alerts

NHS England are responsible for NPSA alerts. The NHS England 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

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ensure alerts provide clear, effective actions to reduce the risk of death or disability.

To support this, NPSA alerts are developed with input, advice and guidance from the 'National Patient Safety Response Advisory Panel'. All NPSA Alerts focus on patient safety issues that are important / of concern and have specific timelines for implementation. They are typically issued in response to a new or under-recognised patient safety issue which has the potential to cause death or severe harm.

Chief Medical Officer Alerts

These are circulated to the Chief Medical Officer (CMO) by the CASLO. The CMO is required to share relevant / applicable CMO Alerts with relevant Clinical Directors for their information / action. As these are for **cascade only** and often sent out of hours, the CAS system does not request the status of these alerts to be changed, therefore closure is not required.

Medical Devices Safety Officer (MDSO) – The Chief Operating Officer is the appointed MDSO. The Health and Safety Team has delegated responsibility to manage the CAS alert system.

Medicines Safety Officer (MSO) – The Trust has identified a medication safety officer (MSO) to link with other nominated safety medicine's officer's/safety specialists.

4. Responsibility and Duties

Role of Chief Executive

The Duty of Care placed on the Trust rests ultimately with the Chief Executive however this is delegated to the Trust Managing Director to ensure they are satisfied that measures are in place to convey such alerts using a correct and timely process.

Deputy Chief Nursing Officer for Patient Safety (DCNO)

The Deputy Chief Nursing Officer for Patient Safety (DCNO) has delegated authority for the oversight and management of the safety alerts and field safety alerts process.

The Medical Devices Safety Officer (MDSO)

The Trust's MDSO will be responsible for distribution of alerts/notices to the relevant areas for action. They will manage the non-patient safety alerts.

The CAS liaison Officer

The Health and Safety Officer will act on behalf of the MDSO as the CAS liaison officer (CASLO). The CASLO receives all national patient safety alerts and CMO alerts (via the CAS system) and Field Safety Notices (via SABS mail box). From this the CASLO distributes the alert to the appropriate team/person (as described within the alert) who is/are responsible for addressing the alert. The CASLO will monitor deadline dates to assist teams

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in completing alerts in a timely manner (where applicable). Once the required action from the alert has been completed and signed off (e.g. by the DCNO) the CASLO is provided with the evidence. The CASLO then closes the alert on the CAS system and retains evidence for assurance purposes.

Patient Safety Team

The Patient Safety Team (PST) will receive notifications for all National Patient Safety Alerts issued to the CAS system by the CASLO. Once received the PST will then liaise with the DCNO to assess the requirements and urgency of the alert. The Team will be responsible for ensuring that all patient safety alerts are collated centrally on a designated system, store all supporting evidence of progress against each alert and monitor the progress of actions

The Patient Safety Team (PST)will produce a quarterly assurance report to the Quality Governance Committee reporting on process compliance and action. The patient safety team will provide updates to the CASLO to ensure the CAS system is up to date. The PST are also required to provide information to the Medical Devices committee on any NatPSA which involve Medical Devices and Report to the Risk Management Committee.

Medicines Safety Officer

The Medicines Safety Officer is an essential link for the identification and implementation of (local and national) medication safety initiatives, supports the dissemination of medication safety communications from NHS England and the MHRA, and has oversight of actions taken by Pharmacy related to medicines recalls and notifications. The Medicines Safety Officer receives has oversight of the MRHA website and receives notifications of any NatPSA relevant to Medicines via the Clinical Risk Manager and PST.

Staff Duties

Any Staff member receiving an alert/notice not sent from either the MDSO, CASLO or the PST should not commence managing the process themselves without direct request from the DCNO, MDSO, CASLO, MSO or the PST as this creates confusion. Staff must actively engage with e.g. DCNO to prevent delays.

5. Overall Management of Safety Alerts

This policy is about receiving, assessing and responding to safety alerts/notices in an appropriate and timely fashion. Internal distribution to the nominated leads enables the relevant members of staff to ensure that the necessary steps to ensure that the Trust meet the recommended actions. Appendix A illustrates out the overarching process.

The management process is supported by the Patient Safety Team, Pharmacy (including MSO), Trust MDSO and CASLO who will provide updates on all alerts, including identification of and management plans

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created for alerts that are not progressing as expected. Oversight for this will be provided by the PST and DCNO.

Responsibilities for safety alert types are:

- **Pharmacy** Medicines Recalls and Notifications
- **Department relevant to the notice** Field Safety Notices
- **Patient Safety Team** National Patient Safety Alerts

The Trust's MDSO (COO) has delegated the H&S officer to act as the CASLO; the CASLO will receive all alerts either via the CAS website / or SABS or directly from the manufacturer. The CASLO will forward to the appropriate lead and DCNO for the alert – they will then confirm receipt, indicate the type of action required and liaise with the PST / DCNO Appendix B sets out the local action required for staff receiving safety alerts.

Handling of Patient Safety alerts

The CASLO will inform the PST and DCNO when a National Patient Safety Alert has been received via the CAS website. The PST must acknowledge receipt of the alert and then liaise with the DCNO to identify a nominated lead for managing the alert. The PST will then co-ordinate with the nominated lead for that alert to support, monitor and assist the actions being completed within the allocated time frame, ensuring all evidence is captured (and electronically stored within the PST) and able to support completion to close. The PST will present to the DCNO how the actions have been achieved and request approval to close the alert. This will be recorded on the agreed proforma (see appendix) and forwarded to the CASLO.

Upon receipt of the completed proforma confirming agreement for closure the Trust's CASLO will close the alert on the CAS website.

Where the recommended actions are not able to be achieved patients and/or staff may be put at risk. As a result, a risk assessment will be carried out to determine the level of residual risk and where necessary this risk will be added to the Risk Register for further monitoring and action.

This process will be overseen and managed by the Head of Patient Safety, the Patient Safety Team and the Medical Devices Safety Officer as described.

Handling of Field Safety Notices (FSN) and Product Recall Requests

The CASLO will receive Field Safety Notices (FSN) and Product Recall Requests (PRR) directly from a manufacturer or via the Safety Broadcast system (SABs). All FSN / PRR's include a description of who is the target team / person for addressing the alert e.g. procurement teams). If a FSN is received into the organisation from any other route, i.e. directly to a team or a division, then the receiving team MUST alert the HS manager (CASLO) and the (MDSO). The CASLO distributes the FSN / PRR's to the appropriate

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team/person and request it is addressed. The DCNO is copied into all distribution emails. Once the required action from the alert has been completed the lead for the alert (e.g. Siemens, Materials Management, Procurement, Tech Services) will complete a Company memo documenting the alert, action taken and information for assurance purposes that the required action has been completed. This evidence is retained by the CASLO for assurance purposes and should be in a format that can be retrieved and shared with the DCNO upon request.

Handling of Chief Medical Officer Alerts (CMO)

The CASLO will receive Chief Medical Officer Alerts (CMO) via the CAS Alert system. The CASLO sends all CMO Alerts to the Trust CMO; the CMO must acknowledge receipt to the CASLO for assurance purposes. The CMO assesses alerts and then distributes to the relevant staff as listed within the alert. Currently CMO Alerts are for information only therefore there isn't a requirement to complete any further action (e.g. submit evidence / sign off).

5.2 Medicines Recalls and Notifications

Only those medicines related alerts, with safety-critical issues (risk of death or disability), are published and/or issued via the CAS website as a National Patient safety alert.

For other information see <u>CAS – Other Safety Information (mhra.gov.uk)</u>

MHRA Drug Safety Update is managed and disseminated by Medicines Safety Committee

Medicines Recalls/Notifications, and Medicines Supply and Shortages are managed by Pharmacy according to pharmacy procedures

A quarterly assurance report of actions taken in response to Drug Recall Alerts, Medicines Supply Notices and Patient Safety Alerts is provided to Medicines Safety Committee and included in the Director of Pharmacy's quarterly report to CGG.

On receipt of a new National Patient Safety Alert:

- The alert will be sent to the DCNO and Patient Safety Team Executive Team, the Divisional Management Teams, Divisional Governance Teams and any relevant Corporate Management Teams, depending on the nature of the alert.
- A lead (or leads) will be identified by the Deputy Chief Nurse (with assistance where required) to ensure completion of the actions within the alert. The nominated lead will work closely with the Divisional Governance Teams.

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- The alert will be placed on the internal tracker by the Patient Safety Team, identifying the lead and timescales for actions.
- Dependant on the type of alert actions required, a round table meeting, where appropriate, will be arranged by the nominated lead or Departments/Divisional Governance Teams in accordance with timescales
- The alert action plan will be tabled for information at the next Improving Safety Action Group (ISAG) providing action progress and response trajectory.
- The patient safety team will assist the nominated lead where required, to set up meetings and support the lead(s) in monitoring the actions within the alert where necessary.
- Upon completion of the actions, the proforma will be compiled by the Clinical Risk Manager or PST; all supporting documentation will be attached to the proforma for assurance, once completed, the proforma will be forwarded to the DCNO for approval
- Any overdue actions will be presented/fed into ISAG, via the tracker for any support required, also to be discussed at the Clinical Governance Group and placed on the risk register if deemed appropriate.
- When the DCNO agrees closure of the Patient Safety Alert, the Patient Safety Team will record this on the proforma, update the tracker system and alert the Trust's CAS Liaison Officer who will close the alert on CAS.

6. Safety Alert Governance and Reporting Arrangements

The safety alerts issued by the Central Alerting System (CAS) will follow the governance arrangements set out in Appendix E.

The NHS Central Alert System will issue notifications of a new alert to the CASLO (as designated by the Medical Devices Safety Officer (MDSO) and the Medicines Safety Officer (MSO)

Safety Alerts will be tabled at the specialist meetings applicable to the alert where action plans (Appendix F) and sources of evidence will be agreed.

A Safety Alert report will be compiled by the Clinical Risk Manager / patient safety team quarterly, and presented to the Improving Action Safety Group.

The MDSO will report as required via health and safety committee

7. Implementation of policy

Implementation of this policy will ensure that:

• Safety Alerts and urgent patient safety specific guidance are disseminated to the appropriate staff and departments.

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- Monitoring, implementation and closure of Safety Alerts are within the specified time frame.
- Centralised recording, monitoring, follow-up and outcome of all Safety Alerts received and implemented.
- Provides a reporting and response mechanism to the Regulatory agencies via the web-based system.

7.1 Plan for implementation

Monitoring of compliance as described in Section 7 and remedial action by the MDSO, DCNO and Patient Safety Team with escalation of issues and unmet alert timescales to the Executive Directors will further embed the policy.

7.2 Dissemination

This policy will be communicated to all staff-side safety representatives and Trust managers and made available to all staff via the Trust's intranet site.

All Primary Recipients will be informed of the policy and process to ensure that they can effectively carry out their functions.

7.3 Training and awareness

The Clinical Risk Manager and Patient Safety Team will inform staff about this policy during corporate and local induction training and during their three yearly risk management update training.

Clinical and other leads for alerts will be supported through the process as described in Section 5.

The Clinical Risk Manager will discuss learning and sharing of the alert with the Head of Patient Safety; where there is value in sharing the information of new alerts agreed to be published on the Trust intranet site via the weekly briefing or other means should this briefing change.

8. Failure to comply with an alert within the published deadline

- Deadlines are set by the alert originator after consultation with external bodies (e.g. Royal Colleges) and manufacturers. Originators aim to make deadlines realistic based on the complexity of the actions required and the degree of risk to patients and staff.
- Where alerts require an on-going programme such as training or regular inspections, the alert may be signed off complete once processes are in place to manage these requirements.
- If actions are not completed; the Clinical Risk Manager will continually monitor the alert and discuss/update the Head of Patient Safety progress of those uncompleted actions.
- If an alert has not been fully implemented because replacement equipment is not yet available from the supplier, the alert may be signed off complete provided this is entered onto the Trust's risk register with a plan in place to review on a regular basis; if after

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carrying out a risk assessment, the Trust has very strong reasons for not implementing any part of an alert, evidence to support the decision should be obtained before marking the action as completed

 If an alert or part of alert will not be completed by the published deadline; progress of the NatPSA which has become overdue due to uncompleted actions will be discussed at the next ISAG meeting and barriers to completion will be escalated to the Quality Governance Committee. If a risk identified, this should be added to the risk register as necessary. In the meantime, work must be continued to mitigate the risks.

9. Monitoring and compliance

This policy will assist the Trust to provide safe and effective care for its patients and ensure ongoing compliance with the Care Quality Commission's Fundamental Standards of Quality and Safety. Compliance reports will be provided to the Trust's commissioners to an agreed schedule.

Section	Key Control	Evidence of compliance	By whom	Reported to	Frequency
Section 5	Risks associated with non-compliance are placed on risk register if deemed appropriate	Datix Risk ID	Clinical Risk Manager	Risk Management Committee or Clinical Governance Group	Quarterly
Section 5.1	Completion of CAS Website	Records of receipt, distribution and actions (for clinical alerts)	H Clinical Risk Manager	Medical Devices Safety Committee	Quarterly
Section 5.2	Pharmacy Procedures	Assurance report of Drug Recall Alerts, Medicines Supply Notices and Patient Safety Alerts	Director of Pharmacy	Medicines Safety Committee	Quarterly
Section 5.3	Completion of CAS Website	Records of receipt, distribution and actions (for clinical alerts)	Clinical Risk Manager	Clinical Governance Group	Quarterly

10. Policy Review

The Trust Risk Management Committee, Clinical Governance Group and Medical Devices Committee will review this policy every two years or upon any significant change to working practice or relevant legislation.

11.References

F	Risk Management Strategy	WAH	T-CG-007			
Risk Management Handbook				T-CG-007a		
	Patient Safety Alert– Improving medication error incident reporting and learning (March 2014)			PSA/D/2014/005		
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Patient Safety Alert– Improving medical device incident	NHS/PSA/D/2014/006
reporting and learning (March 2014)	
Patient Safety Alert- Patient safety incident reporting and	NHS/PSA/RE/2016/003
responding to Patient Safety Alerts (April 2016)	
Managing Medical Devices – Guidance for Healthcare	
and Social Services Organisations April 2021	
Alert from the Central Alerting System Helpdesk Team:	CHT/2019/001
The introduction of National Patient Safety Alerts (Alert	
ref: (September 2019)	
Changes To MHRA Drug Alerts	CH/2021/001
https://www.cas.dh.gov.uk/Home.aspx CAS website	
http://www.nrls.npsa.nhs.uk/alerts NPSA Alerts website	
+ NHSE Enduring Standards	

12. Background

12.1 Equality requirements

There are no equality issues associated with this policy.

12.2 Financial risk assessment

There may be financial implications associated with this policy in terms of complying with a particular safety notice. These will be addressed as necessary on an individual basis through the Trust's business planning process.

12.3 Consultation process

This policy will be reviewed by the Risk Management Committee as part of the health and safety consultation process and the Clinical Governance Group.

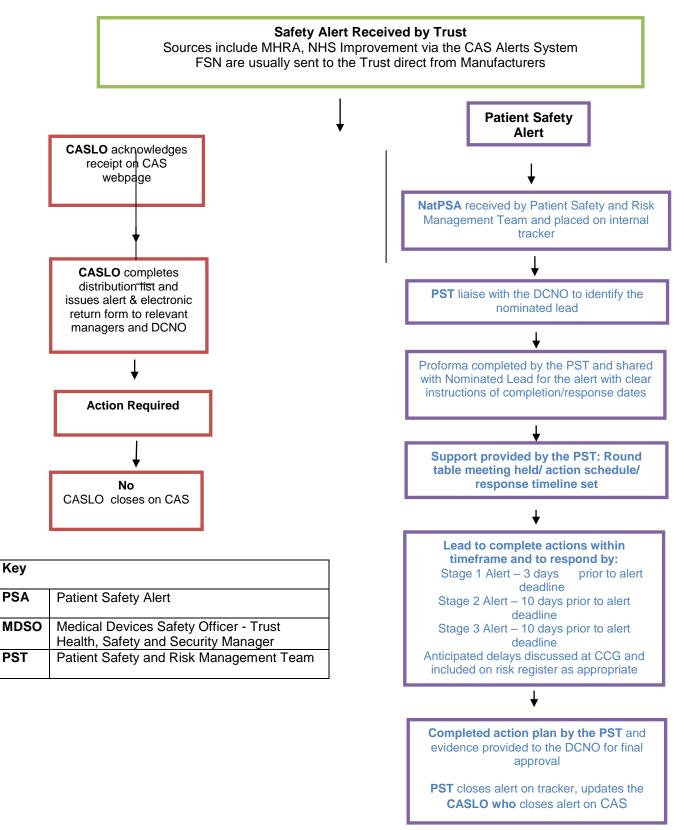
12.4 Approval process

This policy will receive final approval from the Risk Management Committee, Clinical Governance Group and the Joint Negotiation Consulting Committee.

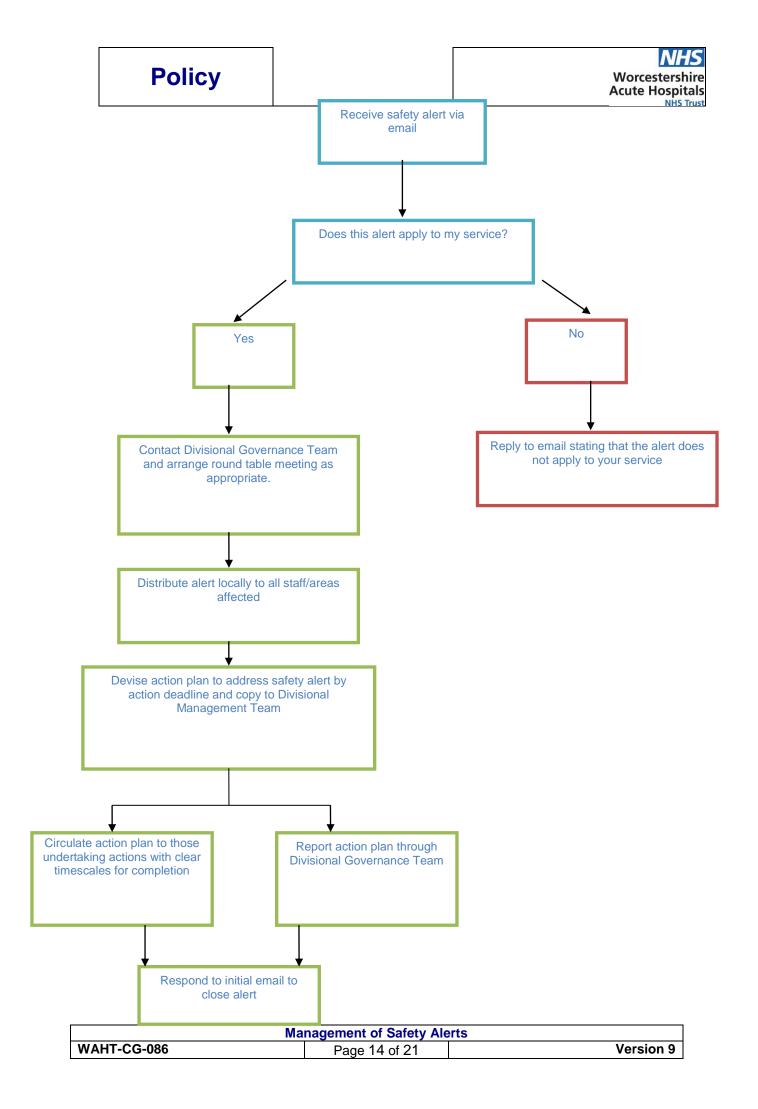
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Appendix A: Flowchart for Patient Safety Alerts

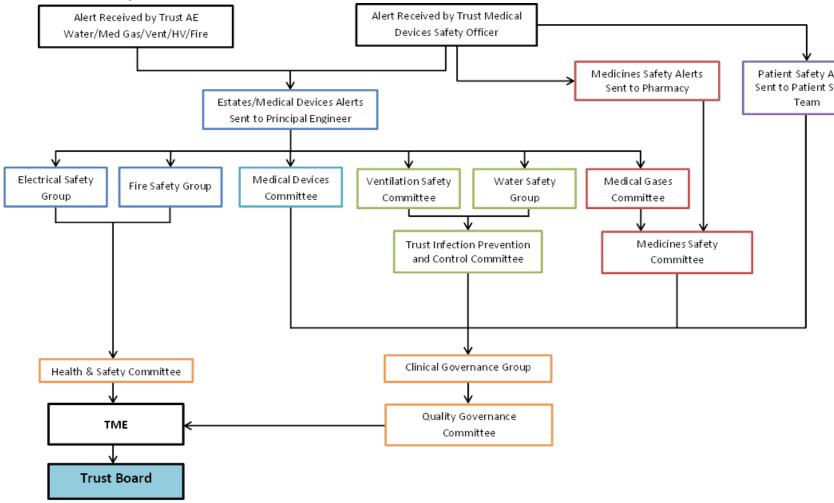


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Appendix B: Safety Alerts Governance Map

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Appendix C: action tracker

NATPSA Number	Date Issued	Action Issue	Departments Affected	Action Owner	Actions Required	Due date	Date submitted/closed 🔻	Progress
2023/001	10/01/2023		All			20/01/2023	27/01/2023	

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Supporting Document 1 – Equality Impact Assessment form

To be completed by the key document author and included as an appendix to key document when submitted to the appropriate committee for consideration and approval.

Please complete assessment form on next page;

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Herefordshire & Worcestershire STP - Equality Impact Assessment (EIA) Form Please read EIA guidelines when completing this form

Section 1 - Name of Organisation (please tick)

Herefordshire & Worcestershire STP		Herefordshire Council	Herefordshire CCG
Worcestershire Acute Hospitals NHS Trust	~	Worcestershire County Council	Worcestershire CCGs
Worcestershire Health and Care NHS Trust		Wye Valley NHS Trust	Other (please state)

Name of Lead for Activity

Details of individuals completing this assessment	Name Allan Bailey	Job title Associate Director of Clinical Governance and Risk	e-mail contact wah- tr.PatientSafety@nhs.net
Date assessment completed	19/08/2024		

Section 2

Activity being assessed (e.g. policy/procedure, document, service redesign, policy, strategy etc.)	Title: Policy/Procedure				
What is the aim, purpose and/or intended outcomes of this Activity?	To provide guidance on the management of safety alerts				
Who will be affected by the development & implementation of this activity?	□ Service User ✓ Staff □ Patient □ Communities □ Carers □ Other □ Visitors □				
Is this:	 ✓ Review of an existing activity □ New activity □ Planning to withdraw or reduce a service, activity or presence? 				
What information and evidence have you reviewed to help inform this assessment? (Please name sources, eg demographic information for patients / services / staff	Not applicable				

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groups affected, complaints etc.

Summary of engagement or consultation undertaken (e.g. who and how have you engaged with, or why do you believe this is not required)	Representatives from Health and Safety, Pharmacy, Estates & Facilities, Corporate Nursing and Patient Safety Team received copies of the changes to the procedure for comment via email.
Summary of relevant findings	Clarification of some terminology and governance structure provided.

Section 3 Please consider the potential impact of this activity (during development & implementation) on each of the equality groups outlined below. Please tick one or more impact box below for each Equality Group and explain your rationale. Please note it is possible for the potential impact to be both positive and negative within the same equality group and this should be recorded. Remember to consider the impact on e.g. staff, public, patients, carers etc. in these equality groups.

Equality Group	Potential <u>positive</u> impact	Potential <u>neutral</u> impact	Potential <u>negative</u> impact	Please explain your reasons for any potential positive, neutral or negative impact identified
Age		~		
Disability		~		
Gender Reassignment		~		
Marriage & Civil Partnerships		~		
Pregnancy & Maternity		~		
Race including Traveling Communities		~		
Religion & Belief		✓		
Sex		✓		
Sexual Orientation		~		
Other Vulnerable and Disadvantaged Groups (e.g. carers; care leavers; homeless; Social/Economic deprivation, travelling communities etc.)		~		
Health Inequalities (any preventable, unfair & unjust differences in health status between groups, populations or individuals that arise from the unequal distribution of social, environmental & economic conditions within societies)		~		

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Section 4

What actions will you take to mitigate any potential negative impacts?	Risk identified	Actions required to reduce / eliminate negative impact	Who will lead on the action?	Timeframe
How will you monitor these actions?				
When will you review this EIA? (e.g in a service redesign, this EIA should be revisited regularly throughout the design & implementation)	In line with Trust policy for review.			

<u>Section 5</u> - Please read and agree to the following Equality Statement

1. Equality Statement

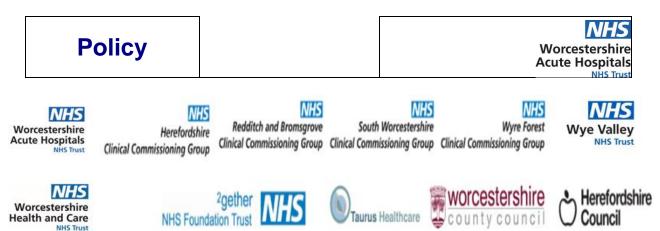
1.1. All public bodies have a statutory duty under the Equality Act 2010 to set out arrangements to assess and consult on how their policies and functions impact on the 9 protected characteristics: Age; Disability; Gender Reassignment; Marriage & Civil Partnership; Pregnancy & Maternity; Race; Religion & Belief; Sex; Sexual Orientation.

1.2. Our Organisations will challenge discrimination, promote equality, respect human rights, and aims to design and implement services, policies and measures that meet the diverse needs of our service, and population, ensuring that none are placed at a disadvantage over others.

1.3. All staff are expected to deliver services and provide services and care in a manner which respects the individuality of service users, patients, carer's etc, and as such treat them and members of the workforce respectfully, paying due regard to the 9 protected characteristics.

Signature of person completing EIA	Alben Benling
Date signed	19/02/2025
Comments:	
Signature of person the Leader Person for	
this activity	
Date signed	
Comments:	

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Financial Risk Assessment

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

	Title of document:	Yes/No
1.	Does the implementation of this document require any additional Capital resources	No
2.	Does the implementation of this document require additional revenue	No
3.	Does the implementation of this document require additional manpower	No
4.	Does the implementation of this document release any manpower costs through a change in practice	No
5.	Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programmes or allocated training times for staff	No

If the response to any of the above is yes, please complete a business case and which is signed by your Finance Manager and Directorate Manager for consideration by the Executive Team before progressing to the relevant committee for approval.

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