Policy

Worcestershire Acute Hospitals NHS Trust

Management of Safety Alerts

Department / Service:	Operations
Originator:	Patient Safety & Risk Manager Health & Safety Manager
Accountable Director:	Chief Nursing Officer Chief Operating Officer
Approved by:	Trust Management Executive
Date of Approval:	6th April 2021
Review Date: This is the most current document and should be used until a revised version is in place	6th April 2024
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:
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
July 2017	Review in light of new Governance structure	Paul Graham, Katherine Leach
October 2016	Documents extended for 12 months as per TMC paper approved on 22nd July 2015	TMC

Sep 2016	Reword of 5.2 as per Trust Medicines Policy Inclusion of MSO role	Alison Smith
Aug 2017	Changes made in line with Patient Safety Alert NHS/PSA/RE/2016/003	P Graham
20/10/14	Changes to meet the requirements of new guidance from MHRA and NHS England	P Graham C Rawlings
1/10/2012	Minor changes	P Graham C Rawlings
23/8/10	New process for National Patient Safety Alerts (NPSA) and introduction of Datix Safety Alert module to manage responses.	C. Rawlings P. Graham
1/4/09	Policy reviewed by H&S Manager and HR Policy Working Group. Minor amendments made as a result of system changes i.e. SABS to CAS.	H&S Manager
1/7/09	Minor changes made to reflect new management structure and responsibilities	H&S Manager

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- Equality Impact Assessment Tool
- Financial Risk Assessment

1. Introduction

This document sets out Worcestershire Acute Hospitals NHS Trust's system for Safety Alerts Management. It provides a robust framework to ensure a consistent approach across the whole organisation 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 the appointed Medical Devices Safety Officer (MDSO). Supported by the Corporate Patient Safety Team, the CAS Liaison Officer will also complete an electronic feedback form to confirm that action has been taken in response to each alert, with supporting evidence and audit trail, located centrally. 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. To include Medical Device Alerts, Internal Alerts, Estates and Facilities Notifications, Patient Safety Alerts, Drug Alerts, Chief Medical Officer Alerts, Field Safety Notices and Supply Disruption Alerts via the Central Alerting System.

The policy applies to all Trust staff.

3. Definitions

The Central Alerting System (CAS) is an NHS web-based cascading system 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; it combines the former Chief Medical Officers' Public Health Link (PHL) and the Safety Alert Broadcast System (SABS 2008). It enables alerts and urgent patient safety specific guidance to be accessed at any time.

Patient Safety Alerts

NHS Improvement will publish an Alert on patient safety issues that are important and have a specific timeline 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.

Medicines Recalls/Notifications

These are issued by the Medicines and Healthcare Produces Regulatory Agency (MHRA). Medicines Recalls/Notifications are carried out to protect patients from the harm that may be caused to them by defective medicines.

Medical Devices Alerts
These are issued by the Medicines and Healthcare Products Regulatory Agency (MHRA); they are an executive agency of the Department of Health in the United Kingdom which is responsible for ensuring that medicines and medical devices work and are safe for use.

Estates Alerts
These are issued by NHS Improvement ensuring provision of a safe environment and reducing risk to patients, staff and visitors in the NHS.

Chief Medical Officer Alerts
These are circulated to the Medical Director for sharing with relevant Clinical Directors. 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. However, the alert will be cascaded to relevant staff, where applicable.

Supply Disruption Alerts
Alerts issued by the Department of Health Supply Disruption to notify of potential shortages in medical equipment.

Medical Devices Safety Officer (MDSO) – The Trust's Health and Safety Manager is the appointed MDSO.

Medicines Safety Officer (MSO) – The Trust has a designated Officer for receipt of these alerts as identified as part of safety alert NHS/PSA/D/2014/005.

Primary Recipients - A nominated senior member of staff within Directorates, who receive the relevant notices and ensure that the recommended actions are completed, reported internally to the division on a monthly basis, and by the appropriate deadlines.

4. Responsibility and Duties

Role of Chief Executive
The Duty of Care placed on the Trust rests ultimately with the Chief Executive who 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 process.

The Medical Devices Safety Officer (MDSO)
The Trust's MDSO will be primarily responsible for distribution of alerts/notices to the relevant areas for action, supported by the Patient Safety Team. Where

appropriate, any incidents involving medical devices that affect a patient will be reported to the National Learning and Reporting System (NRLS).

Primary Recipients

Primary recipients are nominated personnel within Divisions who will be responsible for receiving alerts/notices 'for action' and circulating the information to all relevant staff within their area of responsibility, asking them to take appropriate action as indicated by the alert/notice. Progress will be monitored by the Divisional Governance Committee meetings, via a monthly report, with supporting evidence. Consideration should be given to the timing of audit to ensure the revised process is embedded. Primary Recipients who receive an alert/notice 'for information only' should note the content but not take any action.

Patient Safety Team

The Patient Safety Team will receive notifications for all patient safety alerts issued by NHS Improvement, with oversight from the Deputy Chief Nurse. 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 monthly.

The Patient Safety Team will produce a quarterly assurance report to the Clinical Governance Group, reporting on process compliance and action. Divisions will provide updates as required, to support the reporting timetable.

Medicines Safety Officer

The Medicines Safety Officer is responsible for the oversight and management of actions related to medicines recalls and notifications. Updates are provided to the Patient Safety Team for quarterly reporting to CGG, with oversight on progress with actions overseen by the Medicines Safety Committee.

Staff Duties

Staff receiving an alert/notice should take appropriate action as indicated by the contents and confirm in writing to their Primary Recipient that this has been completed, including populated action plans and evidence of completion.

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, Estates and Facilities and Trust MDSO who will provide updates

on all alerts, including identification of, and management plans created for, alerts that are not progressing as expected. Oversight for this will be provided by the DCNO.

Responsibilities for safety alert types are:

- **Pharmacy** – Medicines Recalls and Notifications
- **Estates and Facilities** – Medical Device Alerts, Estates and Facilities Alerts, Estates and Facilities Notifications and Field Safety Notices
- **Patient Safety Team** – National Patient Safety Alerts

The Trust's MDSO will receive all alerts either via the CAS website, or directly from the manufacturer. He/she will then confirm receipt, indicate the type of action required and liaise with the DCNO before distributing to the appropriate work areas for action. Appendix B sets out the local action required for staff receiving safety alerts.

When all actions are complete the Trust's MDSO will close the alert on the CAS website or arrange for the manufacturer to be notified of actions taken.

Where the recommended actions are not achieved by the deadline date then 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.

All safety alerts are notified to the DCNO and shared with the Patient Safety Team, where the details of the alert and deadlines are added to the safety alerts tracker. The DCNO confirms the distribution of the safety alert, to ensure all parties are correctly informed.

Each individual team will track their own safety alerts and the use of a central safety alert database will allow close management of the safety alerts, the recording of actions and subsequent evidence required to implement the alert and links to any risk assessment associated with the alert.

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 below.

5.1 Non-Patient Safety Alerts (Appendix A)

The Trust's MDSO will liaise with the DCNO to confirm which trust staff should receive a copy of the alert/notice, based on its content and recommended distribution list.

Where the alert involves medical equipment or products involved in direct patient care, the Trust's MDSO will liaise with the relevant staff to determine whether the equipment or product is held by the Trust and ensure the Patient Safety Team is kept informed.

The Trust's MDSO will issue alerts/notices electronically either 'for information only' or 'for action'. The period of time for action is determined by the issuing body and is conveyed to the Primary Recipients.

The Trust's MDSO will receive written responses from all Primary Recipients who were issued with the alert/notice (Appendix C) and following this will inform CAS that the Trust has acted in accordance with the information contained within.

The Trust's MDSO will monitor the CAS website and ensure that all alerts/notices are acted upon before the deadline dates. Any outstanding actions will be placed on the risk register.

Primary Recipients must ensure that all staff to whom they copy the alert/notice have responded to them in writing and they must ensure that all appropriate actions have been taken and evidence collated to support compliance.

Primary Recipients will confirm in writing to the Trust's MDSO that all their staff to whom the alert/notice was issued have taken appropriate action and that written responses from their staff are electronically filed and available for audit.

Primary Recipients who receive an alert/notice 'for information only' should note the content but not take any action.

Hard copies of safety alerts/notices issued by manufacturers will be delivered to the appropriate work areas for action. On completion the Primary Recipient will arrange for the manufacturer to be informed of the actions taken. A copy of any returns will be forwarded to the MDSO for retention.

Information regarding the recall of products will be received by or forwarded to the Supplies Department for the appropriate action to be taken. Appendix D sets out the process in the Supplies Department.

5.2 Medicines Recalls and Notifications

All Medicines Recalls and Notifications are received and managed by the Pharmacy Department including, if necessary, outside of pharmacy opening hours via a regional on call cascade system.

Wards, departments and clinical staff will be advised by pharmacy of any necessary action that needs to be taken following a Medicines recall or notification, in accordance with internal pharmacy procedures. An audit trail of action taken by pharmacy is retained in pharmacy and will be shared with the Trust patient safety team.

Medicines Recalls have different classifications, some of which require immediate action taken, therefore a 24 hour process should be in place. There

is a separate process for the administration and cascade of Medicines Recalls/Notifications which have a classification that denote the timescale for action:

Medicines Recall/Notification Classification	Defect risk classification	Action
Class 1 Medicines Recalls (Patient Safety Alert)	The defect presents a risk of death or disability.	Immediate Action
Class 2 Medicines Recall	The defect may cause mistreatment or harm to the patient, but it is not life-threatening or serious	Action within 48 hours
Class 3 Medicines Recall	The defect is unlikely to cause harm to the patient, and the recall is carried out for other reasons, such as noncompliance with the marketing authorisation or specification.	Action within 5 days
Class 4 Medicines Notification	The MHRA also issues "Caution in Use" notices, where there is no threat to patients or no serious defect likely to impair product use or efficacy.	Medicines defect information but product removal from circulation is not required
Company-led Medicines Recall/Notification	These are generally used for minor defects in packaging or other printed materials. "Caution in Use" notices may also be issued where a defect has been identified but due to supply concerns product cannot be recalled, in these instances the alert will be used to provide advice to healthcare professionals.	

N.B. A NatPSA may be issued for any type of medicines defect that presents a risk of death or disability.

All Supply Disruption Alerts (via CAS) are forwarded to the Medicines Safety Officer and Responsible Manager for management by the Pharmacy Department by the MDSO.

Wards, departments and clinical staff will be advised by Pharmacy of any necessary action to be taken following receipt of a Supply Disruption Alert in accordance with internal pharmacy procedures.

Pharmacy will confirm in writing to the Trust's MDSO that appropriate action has been taken and written responses are electronically filed within Pharmacy and available for audit.

5.3 Patient Safety Alerts (Appendix A)

The responsibility of reviewing all patient safety alerts will be the corporate patient safety and risk team. All new alerts will be sent to the DCNO as the agreed lead for senior oversight and cascaded to an agreed list of responsible

persons (including the executive team, where applicable) for information. A lead will be identified by the DCNO, who will ensure appropriate people who are responsible for ensuring completion of the actions within the alert are aware of their roles and responsibilities. The responsibility of monitoring the completion of actions will be the patient safety team.

Stage One Alert: Warning (W)
This stage will warn organisations of an emerging risk. It will encourage the Trust to:

- Consider if the risk issue could happen/has happened locally
- Consider if action can be taken locally to reduce risk
- Disseminate the warning to relevant staff, departments and organisations as directed by individual alert.

Stage Two Alert: Resource (Re)
This may be issued some weeks or months after a Stage One alert and may include:

- Sharing of relevant information provided by organisations in Stage One
- Sharing examples of good practice
- Access to tools/resources that will help organisations implement solutions to the stage one alert
- Access to learning resources

The alert will contain guidance as to what actions should be completed before sign-off. A timeframe will be set to complete this process.

Stage Three Alert: Directive (D)
At this stage the Trust will be required to confirm that it has implemented specific solutions or actions within the given timeframes.

On receipt of a new Patient Safety Alert:

- The alert will be sent to the 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.
- The alert will be placed on the internal tracker by the Patient Safety and Risk Management 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 and Divisional Governance Teams in accordance with timescales
- The alert will be tabled for information at the next Clinical Governance Group, providing action progress and response trajectory.

- The patient safety and risk team will assist the Divisional Governance Teams, where required, to set up meetings and support the lead(s) in monitoring the actions within the alert where necessary.
- A response will be sent by the nominated lead to the MDSO in accordance with alert timescales.
- Upon completion of the actions, a report will be compiled by the lead and approved at relevant Divisional meetings prior to final approval at the Clinical Governance Group.
- Any overdue actions will be presented by the lead, via an exception report and discussed at the Clinical Governance Group and placed on the risk register if deemed appropriate.
- When the Clinical Governance Group agrees closure of the Patient Safety Alert, the Patient Safety Team will record this in the relevant spreadsheet and alert the MDSO 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 Medical Devices Safety Officer (MDSO), the Medicines Safety Officer (MSO) and the Patient Safety Team inbox.

To facilitate continuity of service the patient safety team inbox will act as a reserve recipient of alerts should the MDSO and MSO be absent.

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

A joint Safety Alert report will be compiled by the Clinical Risk Manager, Medicines Safety Officer and the Medical Devices Safety Officer quarterly to be presented at the Clinical Governance Group.

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.
- 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 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 MDSO 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.

When required i.e. where there is value in sharing the information new alerts will 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 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 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 complete.
- If an alert or part of alert will not be completed by the published deadline, it must be discussed at the Clinical Governance Group and the risk added to the risk register if necessary. Work must be carried out in the meantime to mitigate the risks of not completing the actions in time.
- Data will be published monthly on the NHS England website regarding any Trusts that have failed to declare compliance with stage one, two or three alerts by their due date. This information is likely to be used by the CQC in their monitoring of overall quality improvement.

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	H&S Committee or Clinical Governance Group	Quarterly
Section 5.1	Completion of CAS Website	Records of receipt, distribution and actions (for non-clinical alerts)	H&S Manager	Medical Devices Safety Committee	Quarterly
Section 5.2	Pharmacy Procedures	Records of receipt, distribution and actions (for drug alerts)	Medicines Safety Officer	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 Health and Safety 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

Risk Management Strategy	WAHT-CG-007
Risk Management Handbook	WAHT-CG-007a
Patient Safety Alert– Improving medication error incident reporting and learning (March 2014)	NHS/PSA/D/2014/005
Patient Safety Alert– Improving medical device incident reporting and learning (March 2014)	NHS/PSA/D/2014/006
Patient Safety Alert– Patient safety incident reporting and responding to Patient Safety Alerts (April 2016)	NHS/PSA/RE/2016/003
Managing Medical Devices – Guidance for Healthcare and Social Services Organisations April 2014	
Alert from the Central Alerting System Helpdesk Team: The introduction of National Patient Safety Alerts (Alert ref: (September 2019)	CHT/2019/001
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	

12. Background

12.1 Equality requirements

There is 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.

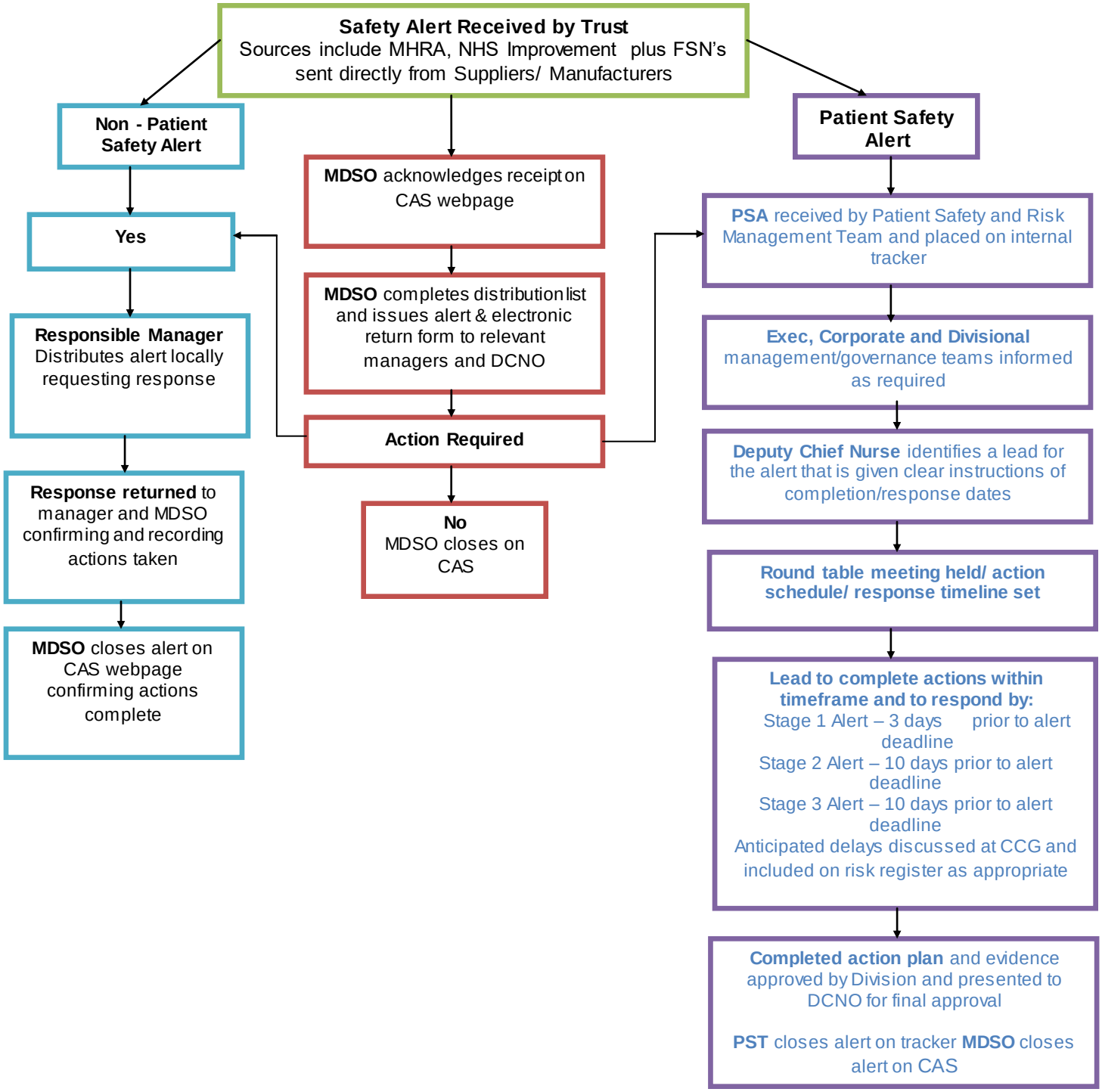
12.3 Consultation process

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

12.4 Approval process

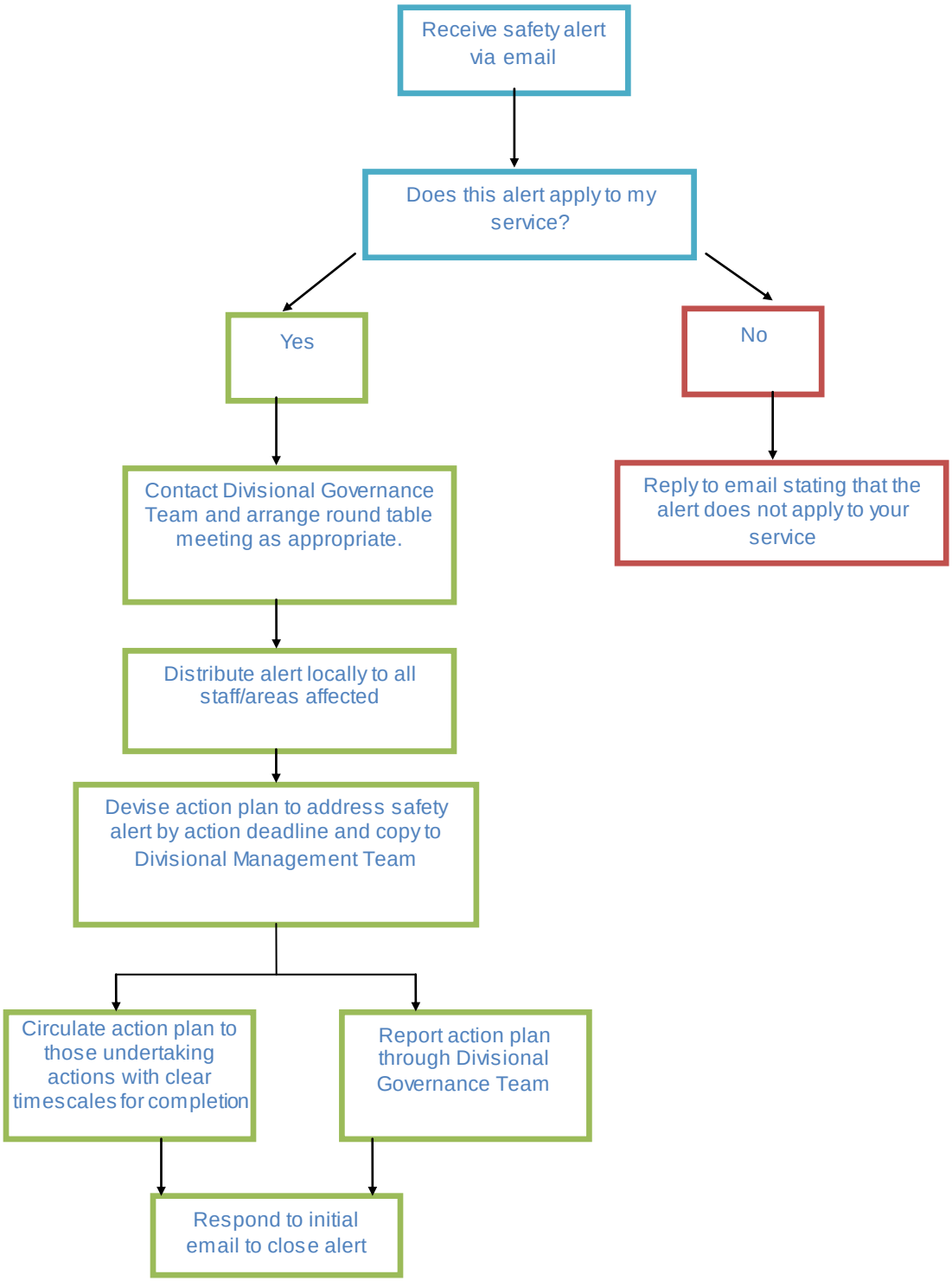
This policy will receive final approval from the Clinical Governance Group and the Joint Negotiation Consulting Committee.

Appendix A: Flowchart for Safety Alerts (including Patient Safety Alerts)



Key	
PSA	Patient Safety Alert
MDSO	Medical Devices Safety Officer - Trust Health, Safety and Security Manager
PSRT	Patient Safety and Risk Management Team

Appendix B: Local Action for Staff Receiving Alerts (Leads)



Appendix C: CAS Electronic Return Form

Worcestershire NHS
Acute Hospitals NHS Trust

Health &Safety Manager
Kings Court 1st Floor
Worcestershire Royal Hospital
Charles Hastings Way
Worcester
WR5 1DD
Tel: 01905 768946

CAS Electronic Return Form

To: **Responsible Manager**

From: Medical Devices Safety Officer

Date:

Re: Central Alerting System (CAS):

Dear Colleague

The attached Safety Notice was issued by on

As the responsible manager for your area I would be grateful if you would note the actions required by the notice and respond accordingly.

The following questions 1- 4 should be completed as appropriate and returned to me by the

1. No action is required as the equipment referred to is not used in my area of responsibility □
2. The following action(s) have been taken

Action(s) taken	By Whom	Date Completed

3. In order that the risks identified in the notice are effectively managed it will be necessary to implement further actions as detailed below

Further Action(s)	By Whom	Target Date

4. Return completed by:

Name of Respondent:……

Position……

Ward/Department:……

Date:……

NOTE: Please return this form via email

Thank you for your co-operation in this matter.

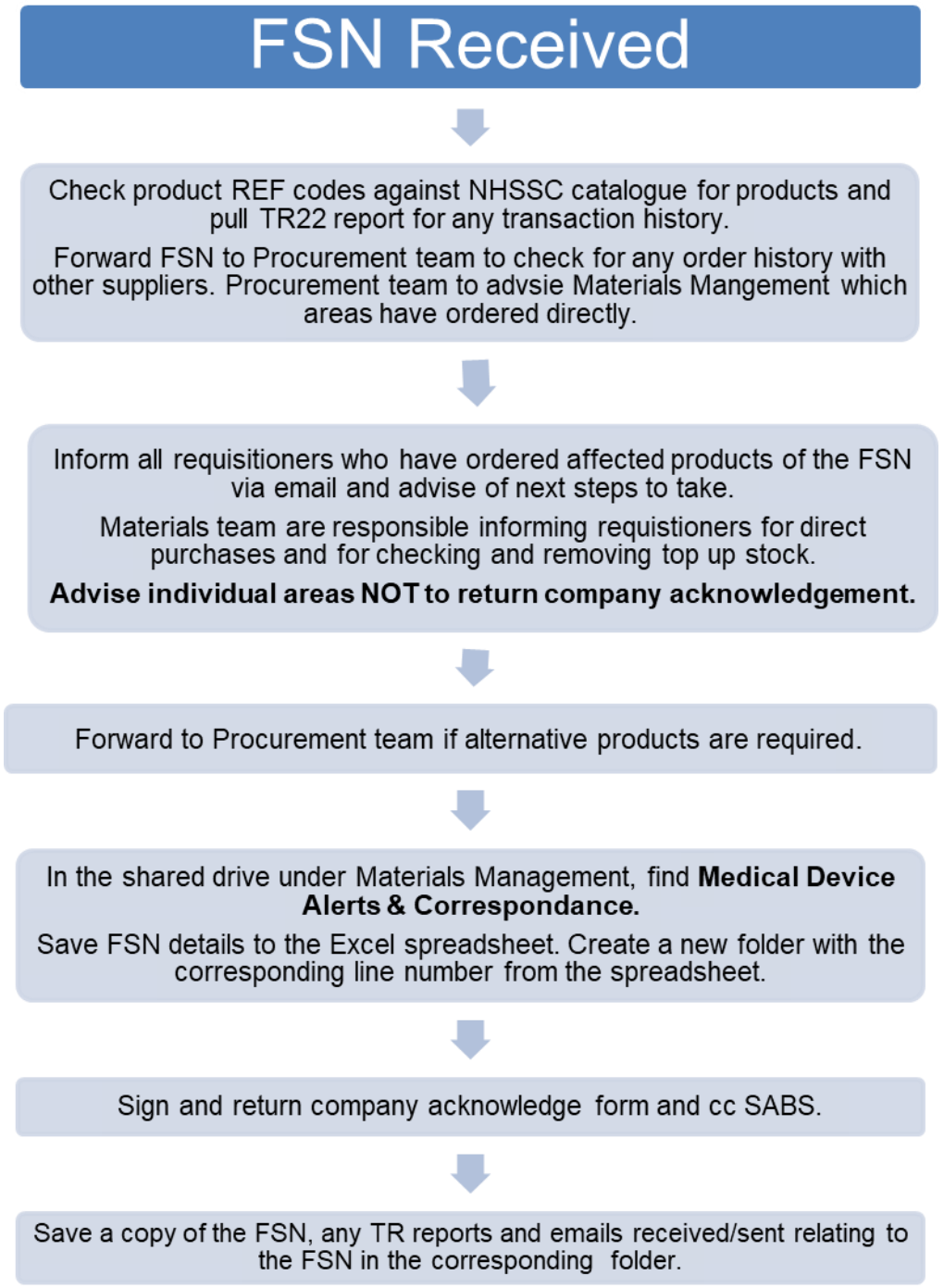
Yours sincerely,

[NAME]

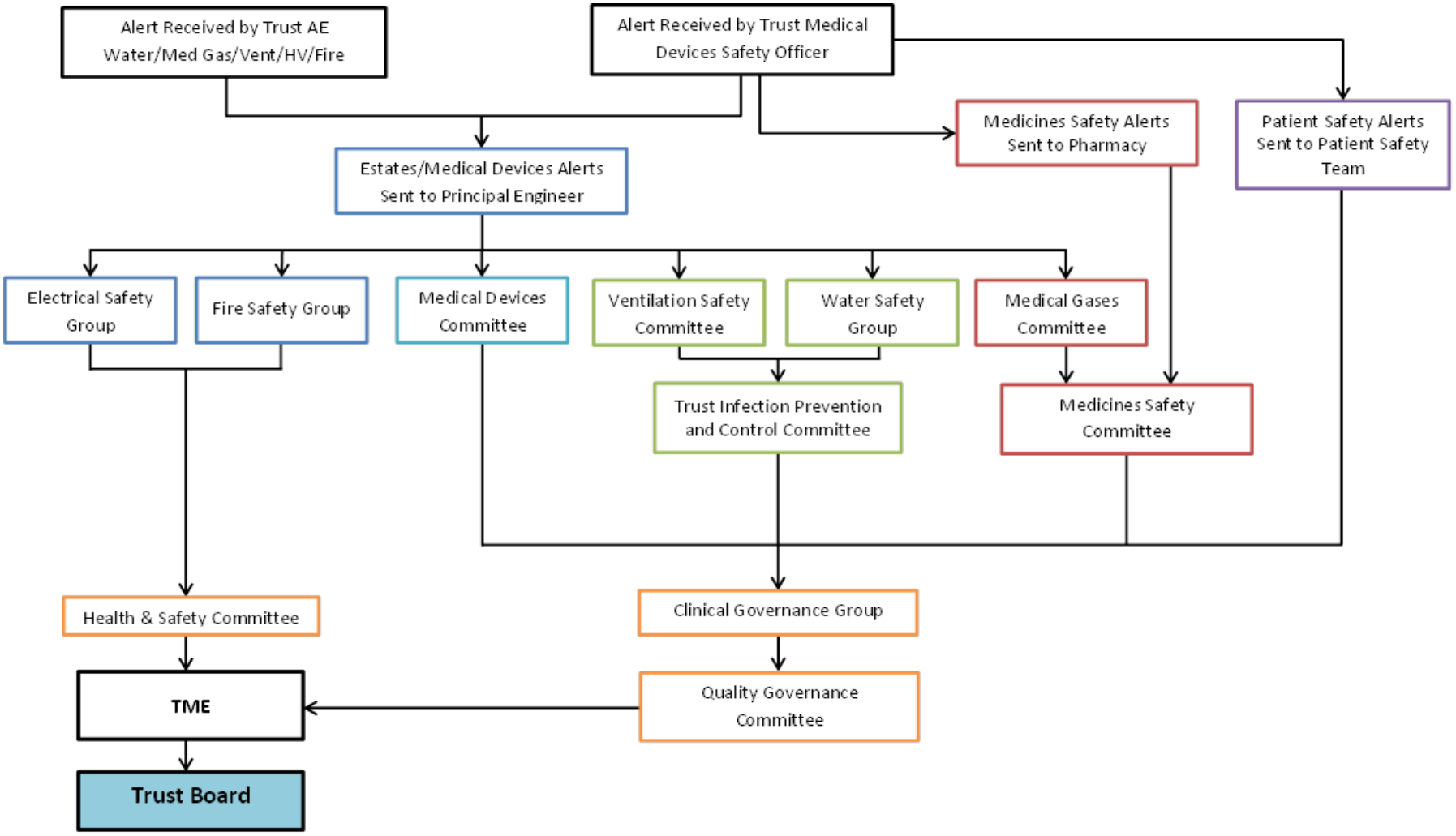
Medical Devices Safety Officer

Ext 36786

Appendix D: Supplies Department Process Flowchart



Appendix E: Safety Alerts Governance Map



Appendix F: Patient Safety Alert Action Plan Template

PATIENT SAFETY ALERT ACTION PLAN

TITLE OF ALERT:
ALERT REFERENCE NUMBER: NHS/PSA/….
DATE ALERT ISSUED: 27TH September 2017
DATE ACTIONS TO BE COMPLETED BY:
LEAD FOR ALERT:

ACTION	LEAD	COMPLETION DATE	RESPONSE/PROGRESS UPDATE	STATUS

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;

NHS Worcestershire Acute Hospitals NHS Trust

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**	**Job title**	**e-mail contact**
	D Johnson	**Head of Patient Safety**	**wah-tr.PatientSafety@nhs.net**
Date assessment completed	**25/03/2021**		

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 ❑ Patient ❑ Carers ❑ Visitors		✓ Staff ❑ Communities ❑ Other _____ ❑	
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 groups affected, complaints etc.	Not applicable			

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 positive impact	Potential neutral impact	Potential negative 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)		✓		

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
	Not applicable	.		
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.**			

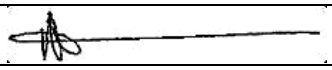
Section 5 - Please read and agree to the following Equality Statement

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	
Date signed	25/03/2021
Comments:	
Signature of person the Leader Person for this activity	
Date signed	
Comments:	

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.