University Hospitals of Leicester NHS
NHS Trust

UHL Policy for the Management of Safety Notices and Alerts

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REVIEW DATES AND DETAILS OF CHANGES MADE DURING THE REVIEW

March 2024 – V7 changes include:

- Inclusion of reference to the UHL Patient Safety Team managing National Patient Safety Alerts (NatPSAs) and CMOs.
- Removal of reference to NHS EFAs, EFNs, Drug Alerts – noting these types of alerts have been accredited to be issued as National Patient Safety Alerts (NatPSAs).
- Change to policy title to UHL Policy for the Management of Safety Notices and Alerts (formerly the Central Alerting System Policy).

Key Words:

- Safety Alerts
- Safety Notices
- Internal alerts
- Field Safety Notices
- National Patient Safety Alerts
- Chief Medical Officer Alerts / Letters
- Alerts Triage Team
- Central Alerting System (CAS)

1 INTRODUCTION AND OVERVIEW

1.1 This document sets out the University Hospitals of Leicester (UHL) NHS Trust Policy for management of Safety Notices and Alerts.

1.2 Healthcare organisations are required to develop, implement and maintain processes for dissemination and review of Safety Notices and Alerts in accordance with the Medicines and Healthcare products Regulatory Agency (MHRA) publication *'Reporting adverse incidents and Disseminating Safety Alerts'- DB2011(01)*.

1.3 Regulation 12(2)(b) of the Health and Social care Act 2008 (Regulated Activities) Regulations 2014 concerning the Safe Care and Treatment of people who use our services, requires the Trust to do "all that is reasonably practicable to mitigate risks". The guidance, issued by the Care Quality Commission (CQC) on meeting this legal requirement which providers must take account of states:

'Providers must comply with relevant Patient Safety Alerts, recalls and rapid response reports issued from the Medicines and Healthcare products Regulatory Agency (MHRA) and through the Central Alerting System (CAS).'

1.4 The 2024 policy review includes changes to the management of National Patient Safety Alerts (NatPSA), in line with NHS England 'Supporting information for Providers' (CHT/2023/002). NatPSAs are managed by the UHL Patient Safety Team under the leadership of the Head of Patient Safety.

2 POLICY SCOPE

2.1 This policy applies to all members of staff employed within UHL who are involved in the management, dissemination, action, response or review of Safety Notices and Alerts.

2.2 The aim of this policy is to ensure that all Safety Notices and Alerts are communicated promptly and effectively to relevant members of staff and that appropriate action is taken in a timely manner.

3 DEFINITIONS AND ABBREVIATIONS

3.1 Central Alerting System (CAS)

CAS is a national database for issuing National Patient Safety Alerts, important public health messages and other safety critical information and guidance to the NHS and others. The CAS system is managed by the UHL Patient Safety Team and include National Patient Safety Alerts (NatPSA) and Chief Medical Officer (CMO) Alerts / Letters.

3.2 Safety Notices and Alerts

Safety Notices and Alerts include:

I. **Chief Medical Officer (CMO) Alerts / Letters** - Issued by the DoHSC to the NHS and healthcare organisations to advise on key public health and clinical quality issues. These alerts will be received via the CAS database and managed by the UHL Patient Safety Team. The process to manage this type of alert is described in appendix 3.

II. **Field Safety Notices (FSN)** - Issued by medical device manufacturers, or their representatives, in connection with a field safety corrective action (FSCA) these are the prime means of communicating safety information to the wider healthcare environment in relation to medical devices and medical equipment for information and action. Corrective Action is an action taken by a manufacturer to reduce the risk of death or serious deterioration in the state of health associated with the use of a medical device that is already available on the market. There may be certain FSNs that require corporate oversight and implementation and they will not be distributed using Datix, however evidence will be uploaded onto Datix following closure of the FSN as good

governance. These alerts will be received via the Medical Devices Safety Officer (MDSO) and managed by the UHL Risk Management Team. The process to manage this type of FSN is described in appendices 4 and 5 (Flowchart for FSNs requiring corporate oversight and implementation).

III. **Internal Alerts** – Issued by the UHL Risk Management Team in response to an incident, near miss or issue where there is critical learning to be shared. This may occur at any stage of the investigation process in order to share learning which may prevent future harm. Internal alerts must be given the same priority as alerts from external sources. Any area can request an internal alert to be issued and in order to do so must complete an internal alert template, which is available from the UHL Risk Management Team. The internal alert will be issued following approval by the UHL Safety Notices and Alerts Triage Team. These alerts will be received via the MDSO and managed by the UHL Risk Management Team. The process to manage this type of alert is described in appendix 6.

IV. **National Patient Safety Alerts (NatPSA)** - Issued by NHS England to the NHS and wider healthcare environment in relation to patient safety matters. Typically a NatPSA will require action to be centrally coordinated on behalf of the whole organisation, rather than by multiple individual teams. All NatPSAs need Board Director level oversight of governance systems that provide evidence that the required actions have been completed before any NatPSA is recorded as 'action completed' on the CAS. Failure to take the actions required under any NatPSA may lead to the Care Quality Commission (CQC) taking regulatory action. NatPSAs are managed by the UHL Patient Safety Team under the leadership of the Head of Patient Safety. The process to manage this type of alert is described in appendix 2.

4 ROLES

4.1 Executive Lead

4.1.1 The Medical Director and Chief Nurse are the Board level leads and have accountability for ensuring effective arrangements are in place for managing Safety Notices and Alerts.

4.2 UHL Medical Device Safety Officer (under the leadership of the Head of Risk Assurance and the Head of Clinical Engineering) is responsible for administering the systems and processes for monitoring, overseeing and auditing Field Safety Notices (FSNs), and Internal Safety Notices and Alerts. The MDSO will support local medical device incident reporting and learning, act as the main contact for NHS England and the MHRA and medical device manufacturers and be a member of the National Medical Devices Safety Network. The MDSO will chair a monthly multi professional group to regularly review medical device incident reports, improve reporting and learning and take local action to improve the safety of medical devices. The multi professional group will consist of the Head of Patient Safety, CMG HoN representative, Point of Care Testing Manager and Medical Device Trainer (or nominated deputies in their absence).

4.3 UHL Risk Management Team

4.3.1 Under the leadership of the Head of Risk Assurance, the UHL Risk Management Team is responsible for administering the systems and processes for monitoring, overseeing and auditing Field Safety Notices and Internal Alerts. The administration procedure to receive, process and manage Safety Notices and Alerts is outlined in appendix 1.

4.4 UHL Patient Safety Team

4.4.1 Under the leadership of the Head of Patient Safety, the UHL Patient Safety Team is responsible for accessing the national CAS database and for administering the systems and processes for monitoring, overseeing and auditing (NatPSAs).

4.5 CMG / Directorate Leads

4.5.1 **Heads of Nursing (HoN) or Directorate Head of Profession (Band 7 and above)**, are responsible for:

i. Ensuring effective arrangements are in place to manage Safety Notices and Alerts in their CMG / Directorate.
ii. Ensuring the CMG / Directorate is appropriately resourced including trained administrator(s) to facilitate with administration functions.
iii. Appointing a CMG / Directorate Deputy.
iv. Implementing business resilience to ensure continued operation of Safety Notices and Alerts at a local level in the event of absences of the CMG / Directorate Lead and CMG / Directorate administrator(s).
v. Informing the UHL Risk Management team about any changes to CMG / Directorate Safety Notices and Alerts management arrangements.
vi. Accessing the Safety Notices and Alerts documents on the Datix Safety Alerts module using the link provided in the notification email or via any other direct route.
vii. Saving a copy of the Safety Notice/Alert in a designated folder on a shared network drive and collating evidence in relation to actions taken to comply with the Safety Notice/Alert, including responses received from Specialty / Department & Directorate Officer(s).
viii. Assessing relevance of Safety Notices and Alerts for their areas of responsibility.
ix. Distributing Safety Notices and Alerts to Specialty / Department & Directorate Officer(s) to take forward actions or for information.
x. Assessing the evidence provided for sign-off from Directorate / Specialties / Departments.
xi. Uploading evidence of actions taken to comply with the Safety Notices and Alerts from the network drive to the Datix Safety Alerts module.
xii. Completing the 'Final Response' form on the Datix Safety Alerts module to confirm closure of Safety Notices and Alerts.
xiii. Monitoring and overseeing Specialty / Department & Directorate Safety Notice / Alert responses.
xiv. Completing and returning 'missed Safety Notices and Alerts deadline' template to the UHL Risk Management team in instances where actions have not been completed within the specified timescales.
xv. Monitoring and reporting to CMG / Trust forums on the Safety Notices and Alerts performance of the CMG / Directorate / Specialties / Departments.
xvi. Reviewing and auditing actions taken at Specialty / Department level to comply with Safety Notices and Alerts.
xvii. Providing support and guidance to Specialties / Departments in relation to Safety Notices and Alerts.
xviii. Ensuring this policy is brought to the attention of all Specialty / Department managers.

4.6 CMG Specialty / Department & Directorate Officers

4.6.1 CMG Specialty / Department & Directorate Officer(s) are responsible for:

i. Ensuring effective arrangements are in place to manage Safety Notices and Alerts in their Specialty / Department & Directorate.
ii. Ensuring the Specialty / Department & Directorate is appropriately resourced to facilitate with administration functions.
iii. Ensuring appropriate resilience arrangements are in place with a named deputy appointed.
iv. Notifying the CMG / Directorate Lead of any changes to Specialty / Department & Directorate Safety Notices and Alerts arrangements.
v. Assessing relevance of Safety Notices and Alerts for their areas of responsibility.
vi. Disseminating information contained in Safety Notices and Alerts to appropriate staff within the Specialty / Department & Directorate.
vii. Ensuring actions are taken forward within specified timescales to comply with Safety Notices and Alerts.
viii. Maintaining documented evidence of actions taken at a Specialty / Department & Directorate level for audit purposes.

ix. Providing updates (within specified timescales) to the CMG / Directorate Leads about progress with Safety Notices and Alerts and to confirm actions taken.
x. Provide evidence and assurance that appropriate actions have been taken in line with the requirements detailed in the Safety Notices and Alerts to the CMG / Directorate Lead / Administrator.
xi. Ensuring this policy is brought to the attention of all Specialty / Department & Directorate staff involved in any aspect of the Safety Notices and Alerts process.

4.7 All staff

4.7.1 All staff who receive a Safety Notices and Alerts must ensure it is read and understood and appropriate actions are taken forward to comply.

4.8 UHL Safety Notices and Alerts Triage Team

4.8.1 As the DoHSC priority is to alert all Trusts of issues *potentially* relevant to them, it targets the whole of the NHS so there will be occasions when Safety Notices and Alerts may not be relevant to this Trust.

4.8.2 In the interests of patient safety it is important that Safety Notices and Alerts received are checked and acted upon as necessary. The Trust will triage all Safety Notices and Alerts through an identified process. The UHL Safety Notices and Alerts Triage Team will be responsible for the investigation of relevance and provision of information within a timely manner to the UHL Risk Management team. The UHL Safety Notices and Alerts Triage Team will consist of:

i. Risk Management Team
ii. Chief Pharmacist / Medication Safety Lead Pharmacist (Medication Safety Officer)
iii. Clinical Procurement Advisor / Procurement Advisor
iv. Health and Safety Team
v. Medical Physics Team
vi. Medical Device Safety Officer (MDSO)
vii. Patient Safety Team (including Patient Safety Specialist)

4.8.3 After seeking suitable advice, where it is determined Safety Notices and Alerts are not relevant to the Trust, they will not be distributed for action and will be closed with the reasons why it is not relevant to the Trust. Safety Notices and Alerts will be entered on Datix uploading all relevant correspondence for audit and assurance purposes. All relevant Safety Notices and Alerts will be distributed as per the processes set out in this policy.

5. POLICY IMPLEMENTATION AND ASSOCIATED DOCUMENTS

5.1 Implementation and Dissemination

5.1.1 The implementation and dissemination process for managing different types of Safety Notices and Alerts, by role and responsibilities, are outlined in the flowcharts referred to in sections 5.1.2 - 5.1.6:

5.1.2 National Patient Safety Alerts (NatPSA) – appendix 2.
5.1.3 Chief Medical Officer (CMO) Alerts / Letters – appendix 3.
5.1.4 Field Safety Notices (FSN) – appendix 4.
5.1.5 FSN's requiring corporate oversight and implementation – appendix 5.
5.1.6 Internal Alerts – appendix 6.

5.2 Record Keeping

5.2.1 Records relating to the Safety Notices and Alerts must be retained for a minimum period of five years following the completion of actions. This will enable UHL to provide evidence for external assessments / audits (e.g. Internal Audit, CQC, etc.) or if required to support incident investigation / inquest and / or associated litigation. Records can be maintained

as electronic copies or hard copies. The minimum dataset of information to be retained is listed below:-

Trust wide (held on Datix Web Safety Alerts Module – since October 2020)

i. Copy of the Safety Notices and Alerts.
ii. Date received.
iii. Date of distribution.
iv. Area of distribution.
v. Date when actions were completed and a copy of completed response.
vi. Date of any reminder notice issued and a copy of reminder, where necessary.
vii. Current status of Safety Notices and Alerts (e.g. Action required: on-going or Action completed).

CMG / Corporate Level (held by CMG / Directorate Lead)

i. Copy of the Safety Notices and Alerts.
ii. Date received.
iii. Date of distribution.
iv. Area of distribution.
v. Date when actions were completed and a copy of completed response.
vi. Date of any reminder notice issued and a copy of reminder, where necessary.
vii. Record of actions taken in line with the requirements detailed in the Safety Notice/Alert.

5.3 Missed Deadlines

5.3.1 If actions to comply with deadlines for Safety Notices and Alerts have not been completed a reminder will be sent to the Lead Officer (including CMG / Directorate Lead(s) as required) two weeks before the deadline. If actions remain outstanding a final reminder will be issued one week before the deadline and copied to the Medical Director, Chief Nurse and where applicable to the CMG Head of Nursing / Corporate Directorate Head of Department. On occasions where Safety Notices and Alerts have short deadlines (i.e. two weeks or less) then the two reminders will be issued outside of the normal guidance above.

5.3.2 Where there is non-compliance with Safety Notices and Alerts and completion of actions will be later than the stipulated deadline, the Lead Officer should assess the level of risk(s) to the Trust (including CMG / Specialty / Directorate and / or the Trust-wide) and, where necessary, raise a risk entry onto the Trust risk register detailing the risk due to non-compliance against Safety Notices and Alerts. The information included on the risk register must include recommendations of how the areas of non-compliance will be met, any patient safety and financial implications associated with implementing the recommendations and the consequences of failing to implement the identified actions.

5.3.3 The Lead Officer must set out the reasons for missed deadlines via the *'missed Safety Notices and Alerts deadline'* template which will be sent out when a deadline date has been missed. The Lead Officer must provide a report, including a completed missed deadline template, immediately to the Patient Safety Committee.

5.4 Business Continuity

5.4.1 In the event of significant Datix downtime (i.e. more than one working day) Safety Notices and Alerts will be distributed via the UHL email system. Once Datix is restored any Safety Notices and Alerts distributed via the UHL email system will be entered onto Datix. All relevant correspondence will be uploaded onto Datix following closure of Safety Notices and Alerts.

5.4.2 In the event of significant e-mail downtime (i.e. more than two working days) Safety Notices and Alerts will be distributed via the UHL internal mail system.

6 EDUCATION AND TRAINING REQUIREMENTS

6.1 There are no formal education requirements; however it is recommended that CMG / Directorate Leads and Administrators and Specialty / Department Officers and Administrators receive training from the UHL Risk Management team as part of a new starter's induction. Awareness (and refresher) training can be requested at any time and will be delivered by the UHL Risk Management team.

7 PROCESS FOR MONITORING COMPLIANCE

7.1 The audit criteria for this policy and the process to be used for monitoring compliance are given in the table below:

Element to be monitored	Lead	Tool	Frequency	Reporting arrangements
Retention of minimum dataset at Trust, CMG / Corporate / and Specialty / Department & Directorate level	Head of Risk Assurance / Head of Patient Safety / CMG / Directorate Lead	Datix web Safety Alerts module - Review documentation at corporate and local level	Monthly	CMG Quality & Safety Boards (or equivalent) / Patient Safety Committee (for NatPSAs)
The number of Safety Notices and Alerts received.	Head of Risk Assurance / Head of Patient Safety / CMG / Directorate Lead	Datix web Safety Alerts module Monitoring Key Performance Indicators (KPIs)	Monthly	CMG Quality & Safety Boards (or equivalent) / Patient Safety Committee (for NatPSAs)
The number of Safety Notices and Alerts completed within specified deadline.	Head of Risk Assurance / Head of Patient Safety / CMG / Directorate Lead	Datix web Safety Alerts module Monitoring Key Performance Indicators (KPIs)	Monthly	CMG Quality & Safety Boards (or equivalent) / Patient Safety Committee (for NatPSAs)
Actions recorded on Datix web to comply with Safety Notices and Alerts.	Head of Risk Assurance / Head of Patient Safety / CMG / Directorate Lead	Audit review Datix web Safety Alerts module and visits to clinical / non-clinical areas.	Annually	CMG Quality & Safety Boards (or equivalent) / Patient Safety Committee (for NatPSAs) Quality Account (for NatPSAs)
Completion of missed Safety Notices and Alerts deadline template.	Head of Risk Assurance / Head of Patient Safety / CMG / Directorate Lead	Monitoring KPIs in Quality & Safety (Q&S) report	Monthly	CMG Quality & Safety Boards (or equivalent) / Patient Safety Committee (for NatPSAs)

8 EQUALITY IMPACT ASSESSMENT

8.1 The Trust recognises the diversity of the local community it serves. Our aim therefore is to provide a safe environment free from discrimination and treat all individuals fairly with dignity and appropriately according to their needs.

8.2 As part of its development, this policy and its impact on equality have been reviewed and no detriment was identified.

9 SUPPORTING REFERENCES, EVIDENCE BASE AND RELATED POLICIES

9.1 MHRA publication *'Reporting Adverse Incidents and Disseminating Safety Alerts'- DB2011 (01)* (March 2011).

9.2 Regulation 12(2)(b) of the Health and Social care Act 2008 (Regulated Activities) Regulations 2014 concerning the Safe Care and Treatment of people who use our services.

9.3 MHRA Central Alerting System Helpdesk Team – CHT/2019/001 (17/09/2019) - The Introduction of National Patient Safety Alerts.

9.4 MHRA Central Alerting System Helpdesk Team - CHT/2022/001 (17/02/2022) – The Medicines Supply Team at the Department of Health and Social Care (DHSC) and the Commercial Medicines Unit at NHS England and Improvement (NHSEI) accredited to issue National Patient Safety Alerts for medicine supply issues.

9.5 NHS England - CHT/2023/001 (20/02/2023) - The NHS England Estates and Facilities Team accredited to issue National Patient Safety Alerts for Estates issues.

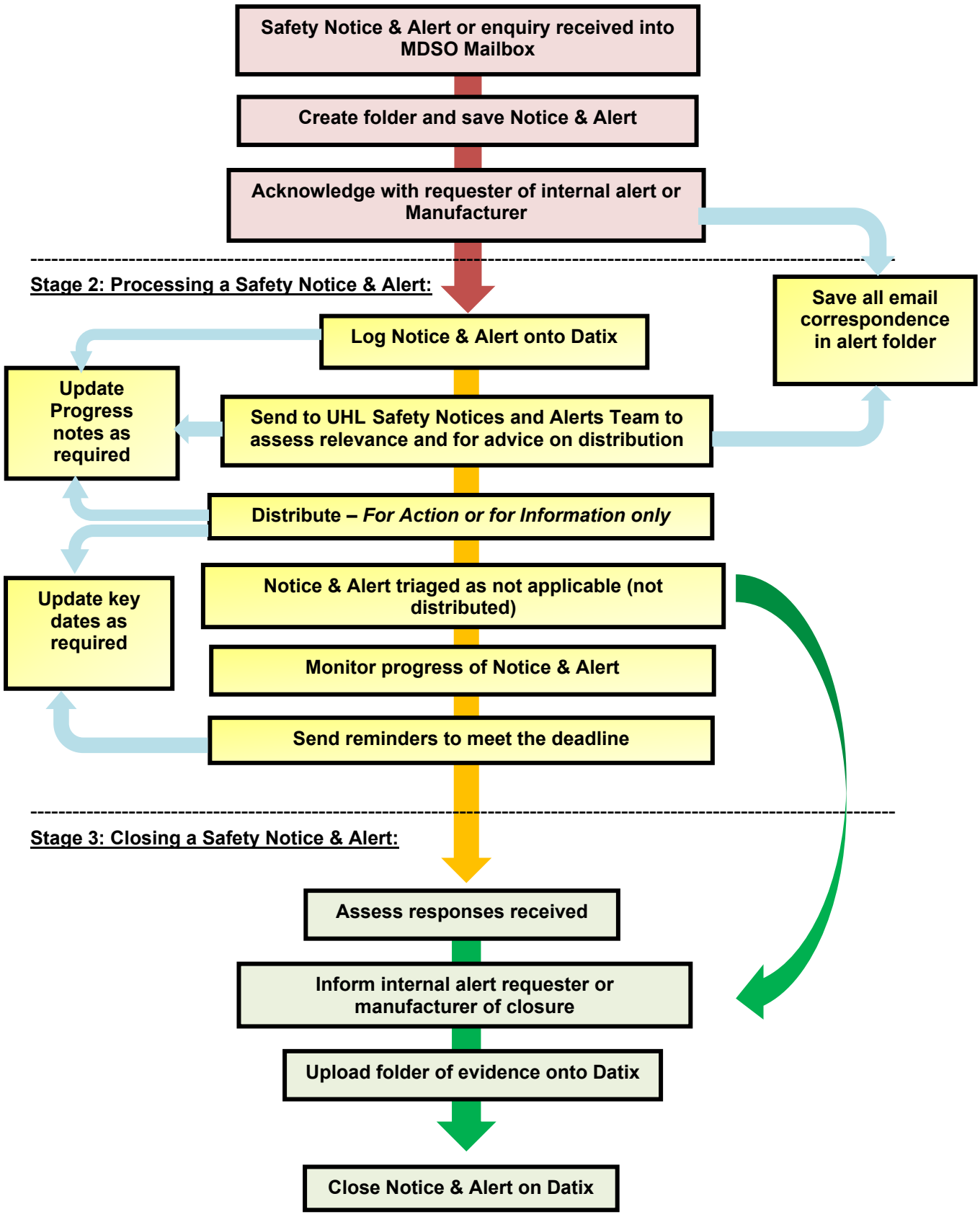
9.6 NHS England – CHT/2023/002 (24/03/2023) – Supporting information for Providers to manage National Patient Safety Alerts.

10 PROCESS FOR VERSION CONTROL, DOCUMENT ARCHIVING AND REVIEW

10.1 The updated version of the Policy will then be uploaded and available on INsite and the Trust's externally-accessible Freedom of Information publication scheme. It will be archived through the Trusts Policies and Guidelines Library (PAGL) system.

10.2 This policy will be reviewed every three years and it is the responsibility of the Trust Lead for this policy to commission the review.

APPENDIX 1 - UHL Risk Management Team – Flowchart for managing Safety Notices and Alerts



APPENDIX 2 - UHL Management of Safety Notices and Alerts Flowchart for managing National Patient Safety Alerts (NatPSAs)

National Patient Safety Alert (NatPSA) alert received via UHL NatPSA email system

UHL Patient Safety Team to:

- **Acknowledge NatPSA** on CAS website within two working days of receipt
- **Save NatPSA** document in designated folder on shared network drive and collate evidence in relation to actions taken to comply with NatPSA
- **Enter NatPSA** alert details onto Datix Safety Alerts module
- **Assess relevance**
- **Investigate NatPSA** via email to relevant members of UHL Safety Notices and Alerts Triage Team for assessment of relevance and response
- **Distribute NatPSA** using Microsoft Outlook to Medical Director / Chief Nurse

Medical Director / Chief Nurse to:

- **Assess relevance of NatPSA** document and where necessary **appoint senior officer(s**) to take the lead on actions required
- **Notify** UHL Patient Safety Team of the appointed senior officer(s) and actions required

UHL Patient Safety Team to:

- **Issue NatPSA** alert to appointed senior officer(s) to take forward actions using Microsoft Outlook

Senior Officer(s) to:

- **Take forward actions** to sign-off the closure of NatPSA
- *If the NatPSA requires local actions (i.e. within CMGs) then to liaise with the UHL Patient Safety team to disseminate relevant details for action / information (usually via the Internal Alert process to ensure appropriate assurance is received)*
- **Provide evidence** and assurance via Microsoft Outlook that appropriate actions have been taken in line with requirements detailed in NatPSA to Medical Director / Chief Nurse & UHL Patient Safety Team via final response

Medical Director / Chief Nurse to:

(Following receipt of all final responses)

- **Assess evidence** provided by senior officer(s) to sign-off closure of the NatPSA
- **Confirm closure** of NatPSA to UHL Patient Safety Team via final response

UHL Patient Safety Team to:

(Following receipt of final response)

- **Assess evidence** provided via Microsoft Outlook to sign-off closure of NatPSA
- **Upload evidence** of actions taken and correspondence from designated folder to Datix Safety Alerts module
- *Where necessary, send out 'missed Safety Alert deadline' pro forma*
- **Close NatPSA** on Datix Safety Alerts module
- **Close NatPSA** on CAS website

UHL Patient Safety Team to:
As appropriate monitor progress of alert, allocate relevant senior patient safety team member to support progressing alert actions, request progress updates and send reminders to Senior Officer(s) to meet the deadline.

APPENDIX 3 - UHL Management of Safety Notices and Alerts Flowchart for managing Chief Medical Officer (CMO) Alerts / Letters

Chief Medical Officer (CMO) Alert / Letter received via UHL NatPSA email system

UHL Patient Safety Team to:

- **Acknowledge CMO Alert / Letter** on CAS website within two working days of receipt
- **Save CMO Alert / Letter** document in designated folder on shared network drive and collate evidence in relation to actions taken to comply with CMO Alert / Letter
- **Assess relevance**
- **Investigate CMO Alert / Letter** via email to relevant members of UHL Safety Notices and Alerts Triage Team for assessment of relevance and response
- **Enter CMO Alert / Letter** details onto Datix Safety Alerts module
- **Distribute CMO Alert / Letter** using Microsoft Outlook to Medical Director / Chief Nurse to seek advice

UHL Patient Safety Team to:
As appropriate, request progress updates

Medical Director / Chief Nurse to:

- **Assess relevance** of CMO Alert / Letter
- **Advise UHL Patient Safety Team** on actions required to comply with CMO Alert / Letter

UHL Patient Safety Team to:

- **Issue CMO Alert / Letter** using Microsoft Outlook to relevant personnel to take forward actions as advised by the Medical Director / Chief Nurse. *(There is usually no requirement to submit a response to the CAS website for these Alerts / Letters)*

UHL Patient Safety Team to:

- **Upload evidence** of actions taken and correspondence from designated folder to Datix Safety Alerts module
- **Close CMO Alert / Letter** on Datix Safety Alerts module
- **Close CMO Alert / Letter** on CAS website (*if required*)

APPENDIX 4 - UHL Management of Safety Notices and Alerts Flowchart for managing Field Safety Notices (FSN)

Field Safety Notice (FSN) received via postal system, MDSO email, or other route

UHL Risk Management Team to:

- **Acknowledge FSN** with manufacturer
- **Save FSN** document in designated folder on shared network drive and collate evidence in relation to actions taken to comply with FSN
- **Assess relevance / Investigate FSN** via email to relevant members of UHL Safety Notices and Alerts Triage Team for assessment of relevance and response
- **Enter FSN** details onto Datix Safety Alerts module
- **Issue FSN** using Datix Safety Alerts module to CMG / Directorate Lead(s) / Administrator(s)

CMG / Directorate Lead(s) and Administrator(s) to:

- **Access FSN** document on Datix Safety Alerts module using link provided in notification email
- **Save FSN** document in designated folder on shared network drive and collate evidence in relation to actions taken to comply with FSN
- **Assess relevance** and **appoint** Specialty / Department & Directorate Officer(s) to take forward actions
- **Issue FSN** to CMG Specialty / Department & Directorate Officer(s) to take forward actions or for information only

CMG Specialty / Department & Directorate Officer(s) to:

- **Assess relevance** and **take forward actions** to sign-off FSN
- **Provide evidence** and assurance that appropriate actions have been taken in line with the requirements detailed in FSN to CMG / Directorate Lead(s) / Administrator(s) via final response

CMG / Directorate Lead(s) and Administrator(s) to:

(Following receipt of all final responses)

- **Assess evidence** provided for sign-off from CMG Specialty / Department & Directorate Officer(s)
- **Upload evidence** of actions taken to comply with FSN from designated folder to Datix Safety Alerts module
- **Complete 'Final Response' form** on Datix Safety Alerts module

UHL Risk Management Team to:

(Following receipt of all final response forms)

- **Assess evidence** provided on the Datix Safety Alerts module to sign-off closure of FSN
- **Upload evidence** of actions taken and correspondence from designated folder to Datix Safety Alerts module
- *Where necessary, send out ''missed Safety Notice/Alert deadline' pro forma*
- **Close FSN** on Datix Safety Alerts module
- **Close FSN** with manufacturer

UHL Risk Management Team to:
As appropriate monitor progress of alert, request progress updates and send reminders to the CMG / Directorate Lead(s) / Administrator(s) to meet the required deadline

APPENDIX 5 - UHL Management of Safety Notices and Alerts Flowchart for managing Field Safety Notices (FSNs) requiring corporate oversight and implementation

Field Safety Notice (FSN) (requiring corporate oversight and implementation) received via postal system, MDSO email, UHL email system, or other route

UHL Risk Management Team to:

- **Acknowledge FSN** with manufacturer
- **Save FSN** document in designated folder on shared network drive and collate evidence in relation to actions taken to comply with FSN
- **Assess relevance / Investigate FSN** via email to relevant members of UHL Safety Notices and Alerts Triage Team for assessment of relevance and response
- **Enter FSN** details onto Datix Safety Alerts module
- **Issue FSN** using Microsoft Outlook to Senior Officer(s)

Senior Officer(s):

- **Take forward actions** to sign-off FSN
- **Provide evidence** and assurance that appropriate actions have been taken in line with requirements detailed in FSN via final response

UHL Risk Management Team to:

(Following receipt of all final responses)

- **Assess evidence** provided via Microsoft Outlook to sign-off closure of FSN
- **Upload evidence** of actions taken and correspondence from designated folder to Datix Safety Alerts module
- *Where necessary, send out 'missed Safety Notices and Alerts deadline' pro forma*
- **Close FSN** on Datix Safety Alerts module
- **Close FSN** with manufacturer

UHL Risk Management Team to:
As appropriate monitor progress of alert, request progress updates and send reminders to the Senior Officer(s) to meet the required deadline

APPENDIX 6 - UHL Management of Safety Notices and Alerts Flowchart for managing Internal Alerts

Internal Alert request received via UHL email system or other route

UHL Risk Management Team to:

- **Acknowledge Internal Alert** request with requester within two working days of receipt
- **Investigate Internal Alert** request via email to UHL Safety Notices and Alerts Triage Team to check relevance and approve Internal Alert document
- **Save Internal Alert** document in designated folder on shared network drive and collate evidence in relation to actions taken to comply with Internal Alert
- **Enter Internal Alert** details onto Datix Safety Alerts module
- **Issue Internal Alert** using Datix Safety Alerts module to CMG / Directorate Lead(s) / Administrator(s)

CMG / Directorate Lead(s) and Administrator(s) to:

- **Access Internal Alert** document on the Datix Safety Alerts module using link provided in notification email
- **Save Internal Alert** document in designated folder on shared network drive and collate evidence in relation to actions taken to comply with the Internal Alert
- **Assess relevance** and **appoint** Specialty / Department & Directorate Officer(s) to take forward actions
- **Issue Internal Alert** to Specialty / Department & Directorate Officer(s) to take forward actions or for information

CMG Specialty / Department & Directorate Officer(s) to:

- **Assess relevance** and **take forward actions** to sign-off Internal Alert
- **Provide evidence** and assurance that appropriate actions have been taken in line with requirements detailed in Internal Alert to CMG / Directorate Lead / Administrator via final response

CMG / Directorate Lead(s) and Administrator(s) to:

(Following receipt of all final responses)

- **Assess evidence** provided for sign-off from the CMG Specialty / Department & Directorate Officer(s)
- **Upload evidence** of actions taken to comply with Internal Alert from designated folder to Datix Safety Alerts module
- **Complete 'Final Response' form** on Datix Safety Alerts module

UHL Risk Management Team to:

(Following receipt of all final response forms)

- **Assess evidence** provided on Datix Safety Alerts module to sign-off closure of Internal Alert
- **Upload evidence** of actions taken and correspondence from designated folder to Datix Safety Alerts module
- *Where necessary, send out a ''missed Safety Notice & Alert deadline' pro forma*
- **Close Internal Alert** on Datix Safety Alerts module
- **Close Internal Alert** with requestor

UHL Risk Management Team to:
As appropriate monitor progress of alert, request progress updates and send reminders to the CMG / Directorate Lead(s) / Administrator(s) to meet the required deadline