Essex Partnership University
NHS Foundation Trust

REPORTING AND DISSEMINATING MEDICAL DEVICE ALERTS AND SAFETY ALERT BULLETINS TO AND FROM THE CENTRAL ALERTING SYSTEM PROCEDURE

POLICY REFERENCE NUMBER:	RMPG10
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REPLACES SEPT DOCUMENT	RM10
REPLACES NEP DOCUMENT	CP6/Medical devices Policy/03/16
KEY CHANGES FROM PREVIOUS VERSION	Inclusion of the introduction of the National Patient Safety Alerts. Change in the main Medical Device Contractor. Inclusion of actions to follow re consumable devices.
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PROCEDURE SUMMARY

The purpose of this procedural guideline is to set out the processes for the reporting of Medical Device Adverse Incidents and arrangements for the receipt, handling and response to all Patient Safety Alerts from NHS England, Field Notices and Medical Device Alerts from the Medicines and Healthcare Products Regulatory Agency (MHRA) via the Central Alert System.

The Trust monitors the implementation of and compliance with this procedure in the following ways;

This Policy will be monitored by the Health Safety and Security Committee via the Risk Management Department. Amendments to this policy and procedural guideline will be submitted to the Medical Devices Group and the Health Safety and Security Committee. In consequence of the frequency of guidance provided by the MHRA; this policy and procedural guidelines will be updated annually and reviewed every three years.

Services	Applicable	Comments
Trustwide	✓	
Essex MH&LD		
CHS		

The Director responsible for monitoring and reviewing this policy is the Chief Executive Officer

ESSEX PARTNERSHIP UNIVERSITY NHS FOUNDATION TRUST

SAFETY ALERT BULLETINS PROCEDURE

CONTENTS

1.0 INTRODUCTION

1.1 The Central Alerting System (CAS), launched in September 2008 is a web-based cascading system for issuing patient safety alerts, important public health messages and other safety critical information and guidance to the NHS and others, including independent providers of health and social care. Alerts available on the CAS website include NHS Improvement Patient Safety Alerts (PSA) and Estates Alerts, MHRA Dear Doctor letters, Medical Device Alerts (MDA) and Drug Alerts, Chief Medical Officer (CMO) Alerts, and Department of Health & Social Care Supply Disruption alerts. The Policy has been reviewed in line with the recommendations of this alert.

1.2 It is imperative that all safety alert bulletins are reported and that notices are disseminated promptly throughout the Trust and the necessary action identified within them, is taken by identified individuals as necessary to ensure patient, staff and visitor safety.

1.3 The Trust Medical Devices Safety Officer is the contact point for the Central Alert System and will manage all alerts received.

2.0 ALERT TYPES

2.1 Medical Device Alert (MDA)

An MDA is a notice issued by the MHRA via the Central Alerting System each MDA is given one of the following categories:

- Immediate Action; Used in cases where there is a risk of death or serious injury and where the recipient is expected to take immediate action on the advice.
- Action: Used where the recipient is expected to take action on the advice, where it is necessary to repeat warnings on long standing problems or to support or follow-up manufacturers field modifications.
- Updated: Used to update the recipient about previously reported incidents or series of incidents possibly on a topical or device group basis and where further follow-up safety information is judged to be beneficial.
- Information request: Used to alert recipients about a specific issue that may become a problem and where DoH is requesting feedback. These alerts will be sent out with additional questions to be completed.

The MDAs give guidance on the issue identified, what action is expected and by whom, and gives specific deadlines for when actions need to begin and when they should be completed; these vary depending on the seriousness of the issue. All MDAs will be presented to the Medical Devices Group with an overview of actions and outcomes.

2.2. NHS Improvement Patient Safety Alerts

Alerts from the National Patient Safety Alerting Committee (NaPSAC) relate to a variety of issues and are usually as a result of adverse incidents that have occurred elsewhere in the health or social care environments.

Alerts have clear, effective actions and require senior oversight. All National Patient Safety Alerts will be presented and agreed at the Clinical Governance and Quality Committee and a senior lead identified.

Patient Safety Alerts will be monitored and signed off by the Clinical Governance Sub Committee until completion.

2.3 NHS Estates & Facilities Alerts

NHS Estates & Facilities Alerts relate to the physical environment and It gives guidance on the issue identified, what action is expected and by whom, and specific deadlines for when actions need to begin and when they should be completed; these vary depending on the seriousness of the issue. These alerts will be sent to the Director of Estates for action as required, action plans will be monitored through to completion and sign off at the Health Safety & Security Committee.

2.4 Drug Alerts

These alerts are distributed by the MHRA and are sent to the Trust's Chief Pharmacists who liaise with the organisations pharmacists and reports on alerts to the Medicine Management Committees. The Chief Pharmacist and MDSO will liaise in regard to Drug Alerts and actions required. Alerts will be monitored via the Medicine Management Committees.

2.5 Field Safety Notices

This notice will usually come directly from the manufacturers. While it may not contain expected timescales they will, nonetheless, be dealt with in the same way as the other alerts, using the system described above. All MDAs will be presented to the Medical Devices Group with an overview of actions and outcomes.

2.6 MHRA Dear Doctor Letters

Dear Doctor letters are correspondence that alerts doctors and other healthcare providers about important new or updated information regarding a marketed medicine or biologic, the letter will include identified risks.

2.7 Chief Medical Officer (CMO) Messaging

These notices advise of important information and updates from Public Health England about health related topics.

2.8 Internal Alerts

Alert information will be gathered from the Datix incident reporting system, internal intelligence and other Trusts.

3.0 ALERT PROCESS

3.1 Medical Devices Safety Officer (MDSO) and Central Alerting System

The trust has a designated Medical Devices Safety Officer (MDSO) who is the Central Alerting System contact. The MDSO manage the dissemination of alerts and provide feedback as well as promote and co-ordinate adverse incident reporting through encouragement and training of healthcare and support staff and medical device users.

3.2 Receiving Alerts

Alerts will be received via:

- The Central Alerting System
- Other Trusts
- EPUTs Incident Reporting System

The MDSO or their nominated deputy will be responsible for monitoring the content of their email box to identify safety alerts on a daily basis (Monday – Friday 9-5).

Out of hours - alerts are received by the Contact Centre and actioned on the advice of the manager/director on call. The Contact Centre will advise risk management of alerts received and actioned. Risk will update the CAS accordingly.

When an alert arrives the MDSO or nominated deputy will acknowledge receipt within 1 working day.

All forms of alerts received are recorded onto the Datix Safety Alert system and are managed by the Risk Management Department. Datix is used to cascade all alerts to the relevant leads that are required to action as appropriate and respond for their respective areas.

3.3 Assessing Alerts

The level of response for each Alert is dependent upon the specific issues raised in each alert, which will be assessed on receipt by the nominated Medical Device Safety Officer (MDSO) and a cohort of nominated leads from Community Health Services, Mental Health, Procurement, Quality and Clinical Governance and Compliance. It is imperative notices are disseminated promptly throughout the Trust with the necessary action(s) identified undertaken by relevant individuals as necessary.

The MDSO in discussion with the Head of Assurance will determine dependent on the risk assessment of the Alert received the inclusion of the Alert on the Trust's risk register.

3.4 Disseminating Alerts

- Alerts will be distributed via the Datix alert system.
- The Alert will be sent out to identified leads and it is their responsibility to action/ cascade the alerts to the team leaders/nominated staff in their areas of responsibility as directed on the alert.

3.5 Actioning Alerts

- Each contacted lead has the responsibility to cascade, action and sign off the alert on Datix and to provide written confirmation that the action described within the alert has been complied with. Details of any local plans with associated implementation timescales must be included where relevant.

- Should no action be required then a negative return must be recorded on Datix.
- Timescales for alerts are given when sent via datix.
- A reminder will be sent to recipients, compliance will be reported via the risk management report presented to the Health Safety and Security Committee.
- Patient Safety Alerts will be presented to the Clinical Governance and Quality Committee and assessed for relevance. If relevant an action plan will be put in place, leads identified and monitored through to completion. Once completed the alert will be audited for implementation within one year.
- Estates and facilities Alerts will be presented to the Health Safety and Security Committee and assessed for relevance. If relevant an action plan will be put in place, leads identified and monitored through to completion.

3.6 Reporting on Notified Alerts

- The MDSO will procedure produce a monthly report on activity to varies governance committees as appropriate and commissioners where requested.
- An annual report will be provided.

4.0 INCIDENT REPORTING

4.1 Medical device near miss and incidents including no harm events must be reported via Datix as per Trust Policy CPG 3 Adverse Incident Reporting Including SIs and where appropriate identify that a clinical risk has occurred.

4.1.1 Where an incident involves a medical device consideration needs to be given if it needs reporting to the MHRA by the Trust appointed Medical Device Safety Officer (MDSO); if the incident has led to or if it were to occur again could lead to:-

a) Death, life-threatening illness or injury;
b) Deterioration in health or permanent impairment of the body structure or function;
c) The necessity for medical or surgical intervention;
d) Unreliable test results leading to inappropriate diagnosis or therapy;
e) Inpatient hospitalisation or prolongation of existing hospitalisation;
f) Foetal distress, foetal death or a congenital abnormality of birth defect.

4.1.2 The MHRA also need to be informed of any other minor safety or quality problems, minor faults or discrepancies, as they may take on a greater significance when aggregated with other similar events in demonstrating trends or may be indicators of inadequate quality assurance on the part of the manufacturing or supply systems.

4.1.3 The MHRA must be informed of adverse incidents even if they appear to be caused by human error as:

- The error may be partly (or wholly) due to deficiencies in the design of the device or instructions for use.

- They may prompt promulgating of advice or device design improvements that will help prevent repetition of mistakes.

4.1.4 Incidents relating to medical devices must be reported to the MHRA as soon as possible via the MHRA website (www.mhra.gov.uk) reporting forms.

4.1.5 Reporting to the MHRA will be completed by the Medical Device Safety Officer or nominated deputy in conjunction with the Executive Nurse via the MHRA website.

4.2 Other incidents which detail potential and actual risks must be reported via Datix as per Trust Policy CPG 3 Adverse Incident Reporting Including SIs. Information contained within these incident reports provide the organisation with valuable information and where assessed as appropriate will be shared via the Datix Safety Alert System as internal alerts for information or action.

5.0 DEFECTIVE OR CONTAMINATED ITEMS AND EVIDENCE

5.1 Evidence

5.1.1 Medical devices that have been involved in an incident must be "quarantined". All items that have been involved in incidents must initially be withdrawn from use secured and clearly labelled in red "not for use". Until the MHRA has been given the opportunity to carry out an investigation, they should not be;

- Discarded;
- Repaired;
- Returned to the manufacturer.

5.1.2. All material evidence, i.e. devices, parts removed, replaced or withdrawn from use following an incident, instructions for use, records of use, repair and maintenance records, packaging materials or other means of batch identification must be:

- Clearly identified and labelled;
- Stored securely.

5.1.3 Evidence must not be interfered with in any way except for safety reasons or to prevent its loss. Where appropriate a record must be made of all readings, settings and positions of switches, valves, dials, gauges and indicators, together with any photographic evidence and eyewitness reports.

5.1.4 If you think an urgent examination of the device (and or related items) is needed, contact the MHRA Adverse Incident centre. An MHRA device specialist will decide whether to inspect the item urgently on site (or at other appropriate facilities), or may request that the device is sent to the MHRA.

5.1.5. **If you are in any doubt about what to do with a device, contact the Risk Management Department on 01268 739731**

5.2. Contaminated Items

5.2.1 All equipment must be cleaned before being sent to or collected for examination, repair or checking. A decontamination label must be attached to the equipment to show that it has been cleaned properly.

5.2.2 Advice on decontamination of Medical Devices / Healthcare Equipment is contained in the Trust ICPG - Infection Control in Clinical Practice, Procedural Guidelines (Section 3).

5.2.3 MHRA Device Specialists can provide additional advice, particularly if the item requires examination prior to any decontamination.

5.2.4 Where decontamination / cleaning would destroy vital evidence the item should be placed in protective containment, labelled and placed in quarantine. The MHRA and the manufacturer / supplier will be contacted by the Medical Device Safety Officer (MDSO) or nominated deputy for advice prior to any further action being taken.

5.3 Defective Medical Devices / Equipment and Disposal

5.3.1 Where a Medical Device / Equipment has been involved in an adverse incident then the manufacturer or supplier must be informed promptly, and allowed to inspect the items if accompanied by an appropriate person. To facilitate an investigation, it may be possible to provide the manufacturer with a sample of unused stock from a large batch. However, until advised to the contrary by the MHRA, the manufacturer must not be allowed to exchange, interfere with, or remove any part of the product implicated in the incident as this might prejudice the investigation(s) of the MHRA, or investigations of other official bodies.

5.3.2 Once the MHRA has indicated that an item may be returned to the manufacturer, the manufacturer must be contacted to ensure that the correct forms of documentation and carriage are arranged.

5.3.3 Medical equipment will be disposed of and replaced when beyond economic repair or obsolete. This decision will be made by the Director of Service or nominated Deputy for the affected directorate taking advice from Head of Operations. The Medical Device Contractor will update the inventory to reflect the change.

5.3.4 Medical equipment that is no longer required or has passed its serviceable life should be disposed of in discussion the Medical Device Contractor Althea UK using the Disposal Form in accordance with the disposal procedure under Waste Management Procedural Guidelines RM13 (c) Disposal of Surplus/Redundant Equipment procedure Appendix 1. This is to ensure equipment is removed from the medical equipment database and that necessary questions are answered prior to disposal. Althea UK will provide a condemnation notice for sign off by the service and this will be logged with the MDSO.

5.4 Defective Medical Consumable Devices

5.4.1 Where a there has been an incident due to a defective medical consumable it must be reported on Datix and the following carried out.

5.4.2 Establish if the defect has not been caused locally by incorrect storage/handling. If it has please check the remaining stock to ensure that this is not defective and take corrective action to stop the issue occurring again.

5.4.3 If the defect is due to a manufacturing fault or another factor outside of our control please check the remaining stock to see if other stock has the same defect. Quarantine the defective stock so that it cannot be used. Do not dispose of it at this time unless it is hazardous to store.

5.4.4 Report the defect via Datix, listing the description of the product along with the manufactures name and part number and the batch of the products affected (if known).

5.4.5 Procurement will then take the necessary steps and feedback to the supplier/manufacturer.

5.4.6 Once procurement receive a response from the supplier/manufacturer we will advise what should be done with the defective stock.

6.0 REFERENCE TO OTHER TRUST POLICIES

6.1 The Trust has a number of policies and procedural guidelines that deal in detail with specific incidents. These policies should always be consulted. In particular:

- CLP17 – Medical Devices Policy & Procedure
- CP3 Adverse Incidents and SI's.
- ICP1 Infection Control in Clinical Practice, Procedural Guidelines (Section 3).

END