Essex Partnership University
NHS Foundation Trust

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

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POLICY SUMMARY

This policy sets out the arrangements for the reporting of Medical Device Adverse Incidents to the Medicines and Healthcare products Regulating Agency and the handling and dissemination of Safety Notices from NHS England, NHS Protect, Field Notices and Medical Device Alerts through the Central Alerting System.

This policy and accompanying procedural guidance relates to the notification of Medical Device Adverse Incidents occurring within the Trust to the MHRA via the Central Alert System and encompasses all Safety Alerts sent to the Trust via the MHRA, Central Alert System. It also relates to other types of alert received from the Central Alerting System or directly from manufacturers.

This policy applies to all Medical Equipment owned by EPUT their employees (specifically Clinical Staff) including temporary staff, patients and / or their carers, visitors and contractors whilst on Trust premises or who in the course of their duties may be required to use medical devices.

The Trust monitors the implementation of and compliance with this policy in the following ways;
This Policy and its attached Procedures will be monitored by the Health Safety and Security Committee via the Risk Management Department and the incident reporting system (Datix). Any amendments to this policy and procedural guideline will be submitted to the Medical Devices Group, Health Safety and Security Committee. In consequence of the frequency of guidance provided by the Medicines and Healthcare products Regulatory Agency (MHRA); this policy and procedural guidelines will updated annually and reviewed every three years.

Services	Applicable	Comments
Trust-wide	✓	
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 POLICY

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

1.0 INTRODUCTION

1.1 The Central Alerting System (CAS), launched in September 2018 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.

1.2 This policy sets out the process to ensure a consistent approach for dealing with the management of alerts received through the Central Alert System (CAS). It is important that all Trust personnel are aware of their roles and responsibilities with regard to dissemination and actions required in complying with alerts.

1.3 The policy also sets out the process required for the reporting of Adverse Incidents involving Medical Devices and details individual responsibilities. System.

1.4 Successful implementation of the Central Alert System is an integral aspect of the assurance mechanisms the Trust Board utilises to ensure that advice given by National bodies is disseminated, acted upon and becomes part of the risk learning process for the organisation. This policy is adjacent to and supplements the contents of the Trust's General Workplace Risk Assessment Policy RM11.

2.0 DUTIES

2.1 The Trust Board has overall responsibility for ensuring the principles of this policy and procedures and other associated policies are implemented across the organisation. The duty of ensuring all measures needed to ensure safe working with medical devices is delegated to Directors within their areas of responsibility.

2.2 The Board of Directors is fully committed to a safety culture within the organisation and will ensure that Safety Alerts are acted upon as appropriate.

2.3 The Executive Nurse will ensure that there is an effective system in place to report all Medical Device Adverse Incidents and disseminate all safety alerts and that these are acted on.

2.4 Directors and Senior Management will:

- Monitor the operational implementation of this policy and ensure that where reporting and responses are required that they are sent to the Medical Device Safety Officer (MDSO)/ Associate Director for Risk & Compliance via the Datix alert system.
- Monitor the progress of any remedial action required as a result of all safety alerts.
- Ensure that the Risk Management department is notified of all relevant staff changes.

2.5 The Medical Device Safety Officer (MDSO) will**:**

- Be the contact point for the Central Alert System and will manage all Medical Device Alerts and safety notices
- Carry out the required responsibilities of contact to and from the Central Alert System. The primary role of the MDSO is to encourage, promote and co-ordinate adverse incident reporting through awareness raising, training of healthcare and support staff and medical device users; manage the dissemination of all alerts and provide feedback via the CAS.
- In conjunction with the Executive Nurse ensure completion of the MHRA on-line notification form and inform the MHRA of Medical Device Adverse Incidents if required.
- Ensure other staff are identified who can deputise in the absence of the MDSO who are competent and available to undertake all duties related to safety alerts;
- Manage the system on a day by day basis and be responsible for the receipt and handling of safety alerts via the Central Alert System;
- Ensure incoming alerts are monitored throughout the day Monday to Friday by the risk team and out of hours by the contact centre as required. Once received, an alert is acknowledged immediately;
- Ensure the timely dissemination of relevant alerts to the key individuals in the Trust;
- Ensure that the feedback information is collated and the Central Alert System web site updated as appropriate. When all required actions have been taken the notice will be closed.

2.6 The Health Safety and Security Committee will review H&S safety alerts on a monthly basis via the Risk Management Report and disseminate findings to directorate Health and Safety meetings.

2.7 The Clinical Quality and Governance Committee will review all Patient Safety alerts and where required medical device alerts.

2.8 The Medicine Management Committees will review all Drug alerts issued.

2.9 Managers and Persons in Charge / Team Leaders will ensure that staff who receive a copy of an alert take the appropriate action, including:

- Providing feedback to the MDSO via the Datix Alert system;
- Provide where appropriate an Annual Report on Safety Notifications which is included in the Health and Safety Annual Report;
- Maintain an effective system for receiving, analysing, cascading and following up alerts to ensure compliance with the action and recommendations within them;
- Where "No Action" in their area for the alert is required, they will provide a negative response return to the MDSO via Datix.
- It is the responsibility of all staff to ensure on receipt of a safety alert from the MDSO, that it is opened and read, cascaded as appropriate and where necessary actions taken. For the system to work effectively it is imperative that quality feedback is given to the MDSO via Datix in a timely manner, enabling the timetable for reporting back to the Central Alert System on actions taken to address the issues identified.

2.10 Workforce Development and Training will ensure training is provided at induction for all staff on the relevant aspects of this policy and accompanying procedural guidance.

2.11 Individuals must ensure that the principles contained within this policy and associated guidelines are followed, and that all actions in relation to MDA's and safety alerts are co-ordinated through the MDSO.

3.0 DEFINITIONS

3.1 Central Alerting System

The Central Alert System is a web based system administered by the Department of Health that distributes safety alerts by email. It provides a feedback mechanism whereby all Trusts are required to confirm that action has been taken in response to an alert. This feedback element provides evidence that a Trust can demonstrate that safety alerts have been received and acted on.

3.2 Incident Definitions

Definitions of the following terms are contained under Section 3 of Trust Policy CP3 (Adverse Incidents, including Serious Incidents SI's):

- All Incidents;
- Grading of incidents (No harm, low, moderate incident, severe incident, death);
- Risk (Clinical, Financial, Organisational).

3.3 Medical Device Definition

The definition of a medical device is any instrument apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper action intended by the manufacturer to be used for human beings for the purpose of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease;
- Diagnosis, monitoring, treatment or alleviation of, or compensation for an injury or disability;
- Investigation, replacement or modification of the anatomy or of a physiological process;
- Control of conception.

And which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

3.4 Medical Device Adverse Incident

Within this document the Trust considers that an Adverse Incident regarding a Medical Device is an event that causes, or has the potential to cause, unexpected or unwanted effect involving the safety of patients, device users or other persons. Adverse incidents in medical devices may arise due to:

a) Shortcomings in the design or maintenance of the device itself:
b) Inadequate instructions for use:
c) Inadequate servicing and maintenance;
d) Locally initiated modifications or adjustments;
e) Inappropriate user practices, (which in turn may result from inadequate training);
f) Inappropriate management procedures;
g) The environment in which it is used or stored;
h) Selection of the incorrect devices for the purpose.

Conditions of use may also give rise to adverse incidents, e.g.
a) Location (e.g. devices designed for hospitals may not be suitable for use in the Community or ambulances);
b) Environmental conditions (e.g. electromagnetic interference).

4.0 PRINCIPLES

4.1 The detailed processes contained within this policy and accompanying procedural guidance aim to reduce the risk of incidents occurring thereby ensuring the safety of care and treatment for patients, employees and other individuals (visitors, contractors, etc.); within the operational area of EPUT by:

- the prompt reporting of Medical Device Adverse Incidents to the MHRA through Central Alert System and
- the receipt, dissemination and robust management of all safety alerts received from the Central Alert System; (for all types of safety alerts see section 4.0 of the accompanying procedural guidance).

4.2 The structures for the implementation of this policy are given in the Procedural Guidelines RMPG10

5.0 POLICY REFERENCES / ASSOCIATED DOCUMENTATION

5.1 There are a range of local policies and national guidelines that have been considered in the development of this policy and procedural guideline:

- Health and Safety at Work Act 1974;
- Health and Social Care Act 2008 (Regulated Activities) Regulations 2010.
- Management of Health and Safety at Work Regulations 1999

5.2 There are a number of guidelines from external organisations that have been considered in the development of this policy and procedural guideline, principally, the guidance provided by the MHRA.

6.0 REFERENCE TO OTHER TRUST POLICIES/PROCEDURES

- Trust Policy and procedure CLP17 and CLPG17 Medical Devices and Equipment Management;
- CP3 and CPG3 (Adverse Incidents including Serious Incident Reporting)
- General Workplace Risk Assessment Policy RM11

END