echogenicity

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Incident Reporting & Management Policy and Procedure

Scanning Cornwall's Hearts

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1 Introduction

1.1. Echogenicity is committed to the delivery of safe and effective high quality care to its patients and high standards of safety to its employees, visitors, and contractors.

1.2. In order to enable learning and minimise loss it is essential to have in place an effective system for reporting, investigating and learning from adverse incidents and near misses and to ensure that any incident that has the potential to involve Echogenicity in either litigation or adverse publicity is promptly reported to appropriate personnel so that it may be effectively managed.

1.3. All members of staff are required to report incidents as part of their responsibility to their patients and colleagues. Echogenicity has therefore produced this Incident Reporting and Management Policy and Procedure which provides a framework for incident reporting and management across the organisation.

1.4. There are a number of benefits of reporting:

- Resources targeted more effectively: reported incidents provide evidence to better target resources. They identify areas for change and improvement in patient care and patient / staff / public safety.
- Increased responsiveness: timely reporting can help increase responsiveness, particularly when undertaking investigations. It also enables staff to be open with patients and their carers at an earlier stage.
- Pre-empting complaints: Echogenicity can prepare proactively for potential complaints and litigation cases. More detailed information on an incident when given to patients and /or their carers at an earlier stage may lead to fewer complaints and litigation claims, saving time and resources.
- Reducing costs: financial benefits arise from reduced severity of incidents, e.g. reduced costs of treatment, reduced length of stay
- Statutory responsibilities: The Trust must also fulfil its statutory responsibilities under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) 1995. The regulations impose a duty to report serious incidents to the Health and Safety Executive (HSE) without delay; and for certain diseases and over-three-day injuries to staff within ten days.

2. Purpose of this Policy/Procedure

The purpose of this policy is to ensure that all incidents are reported, managed and investigated in accordance with national standards.

3. Scope

This policy applies to all Echogenicity staff members.

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4. Definitions / Glossary

Incident: any unexpected or unintended, event or circumstance that leads to or could have led to harm, loss or damage to people, property or reputation.

Harm: injury (physical or psychological), disease, suffering, disability or death.

Near miss: an incident that had the potential to cause harm but was prevented; resulting in no harm.

Serious Incident (SI): an incident that results in one of the following:

- Unexpected or avoidable death
- Serious harm or where the outcome requires life-saving intervention, major surgical/medical intervention, permanent harm, will shorten life expectancy or will result in prolonged pain or psychological harm.
- Allegations of abuse
- Adverse media coverage
- One of the core set of Never Events
- Safeguarding Incident

Critical Incident (CI): an incident graded as major or catastrophic that does not fit the criteria for a Serious Incident.

Serial Incident: an adverse event, clinical or otherwise in nature, which leads to multiple requests for information and/or guidance being made to the Trust from patients, staff or the public at large.

RIDDOR: Reporting of Injuries, Diseases and Dangerous Occurrences Regulations.

5. Ownership and Responsibilities

5.1. Role of the All Employees

All employees have a responsibility to:

- Ensure that they have read and understood Echogenicity policy and local arrangements and will report and respond to incidents accordingly.
- Ensure that an incident report form is completed for any contractor, visitor or other person involved in an incident.

5.2. Role of the Line Managers

The Chief Executive / Clinicians will be responsible for ensuring that:

- Effective incident reporting, investigation and management arrangements exist in all their areas of responsibility.
- Management arrangements meet the requirements of this policy and procedure.
- Open communication exists to enable organisational learning to take place.
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5.3. Role of the Risk Co-ordinators

The Chief Executive is also the Risk Co-ordinators are responsible for:

- Monitoring and reviewing the management of all incidents.
- Assisting in the development of local risk management policies.
- The provision of tools, advice and support for staff in the processes of risk management, incident reporting and investigation.
- Alerting the complaints and claims teams of incidents that are likely to lead to a formal complaint or claim.

5.4. Role of the Quality Improvement Manager

The Chief Executive is also the Quality Improvement Manager is responsible for:

- Ensuring the administration and management of Echogenicity's incident reporting system in relation to all incidents.
- Ensuring that the incident reporting system is analysed and interrogated for trends relating to clinical risk/patient incidents and for reporting these to the relevant managers to support the joint analysis reporting process.
- Ensuring that support is provided to Investigating Officers when undertaking Root Cause Analysis (RCA) investigation of all Serious Incidents.

5.5. Role of the Health and Safety Manager

The Chief Executive is also the Health & Safety Advisor who is responsible for:

- The development of local health and safety policies.
- The provision of advice and support to staff on health and safety related incidents.
- Reviewing incidents relating to Health & Safety issues and report to the HSE under RIDDOR.

5.6. Role of the Chief Executive

The Chief Executive is kept fully informed of any serious incident (SI) and the results of investigations into such incidents, to ensure that the policy is being followed and organisational learning is taking place.

6. Standards and Practice

6.1. An Open and Fair Culture

6.2. Echogenicity seeks to promote an open and fair culture within the organisation. Incidents are more often than not the result of system s failure not the result of one individual's actions. Blaming individuals can result in defensive behaviour, resentment, closed communication and disciplinary problems. This can also prove to be extremely damaging as people become reluctant to report incidents or report the true facts and can result in a distorted view of the actual cause. It seldom prevents recurrence of an incident as it changes nothing about the system. Reviewing the way things are done rather than individuals' involved assists us

in establishing what corrective action can be taken in order to modify systems and processes, as opposed to apportioning blame.

6.3. It is important to recognise that there may be cases where an individual violates systems or processes that result in an incident. In such cases appropriate disciplinary procedures will be followed.

6.4. Being Open when Patients are Harmed

6.5. Being open means apologising and explaining what happened to patients and/or their carers who have been involved in a patient safety incident.

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Communicating effectively with patients and/or their carers is a vital part of the process of dealing with errors or problems in their treatment and a prerequisite to improving patient safety and the quality of healthcare systems. In doing so, Echogenicity can mitigate the trauma suffered by patients and potentially reduce incidents and complaints arising.

6.6. An individual who has suffered harm as a result of the care they have received must receive an apology. This applies to all patients, employees, visitors, contractors and volunteers etc. who use the service of Echogenicity

6.7. The principles of Being Open are fully supported by a wide range of Royal colleges and professional organisations including the Medical Protection Society (MPS), the Medical Defence Union and the General Medical Council (GMC).

6.8. For more information refer to the Policy and Procedure for Being Open.

6.9. Staff Support

6.10. Individual members of staff, teams and departments involved in incidents may suffer the effects of stress. Appropriate levels of support should be given to staff, including counselling, team debriefs and feedback.

6.11. Support can be formal or informal and an assessment of individual need should be made to ensure the appropriate response. It is important that staff should not feel vulnerable or isolated when involved in an incident.

6.12. Providers of Specialist Information

6.13. Staff Support Officer

6.14. Assist in the management of incident relating to security and provides assurance/support to staff and departments as necessary.

6.15. Staff are responsible and accountable for maintaining their competencies. If incidences arise as a result of poor practice, managers may wish to implement staff supervision / clinical competencies. This is not a disciplinary measure but one to support staff and ensure quality and effective care is maintained.

6.16. The Chief Executive will ensure that where repeated violation of policies and procedures by staff occur they will advise managers on employment policy and the legal context to ensure appropriate disciplinary action is taken. In other cases where competency is an issue, they will advise managers on training opportunities and performance monitoring methods.

6.17. Incident Management Process

6.18. The first objective is to minimise harm and to attend to the immediate health needs of the individual(s) affected. Where an incident has occurred to a patient in the ward environment a doctor must be contacted to formally review the patient's condition, according to their immediate needs. The area should be made safe and staff involved should ensure that potential hazards are removed.

6.19. All incidents and near-misses should be brought to the attention of the Chief Executive immediately, or as soon as practicably possible. The Chief Executive will take any immediate actions necessary following an incident. This will include:

- Ensuring an area has been made safe.
- Determining appropriate further action.
- Isolating and/or retaining equipment and medicines if necessary.
- Providing support to staff

6.20. All Serious Incidents must be reported immediately to the Chief Executive. For further information refer to the Serious Incident Management Policy and Procedure.

6.21. GE medical should be notified of any incident that relates directly to suspect/defective medical devices or equipment. In all cases such equipment should be retained and isolated to support further investigation.

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6.22. Reference should always be made to other appropriate policies dependent upon the nature of the incident i.e the inoculation policy, manual handling, slips trips falls and violence and aggression.

6.23. Following an incident to an individual, steps should be taken by staff to ensure that the patient and/or next of kin are advised as soon as possible. In the event of a Serious Incident (SI) the patient and/or next of kin must be contacted as a matter of priority and always prior to any media involvement. It should be remembered that a person-to-person meeting may be more appropriate in these circumstances. For more information please refer to the Policy and Procedure for Being Open.

6.24. For incidents that may impact on a large scale the public would be informed by the Chief Executive. All media involvement must be agreed and co -ordinated by them.

6.25. Reporting Incidents

6.26. The Trust recognises its responsibility to report, record, investigate and learn from all incidents. Research has shown that the more incidents are reported, the more information is available about what is going wrong, and the more action can be taken to improve safety in healthcare. This procedure should be followed for all incidents.

6.27. All incidents and near miss incidents including those involving safeguarding and Depravation of Liberty (DoL's) must be reported as soon as practicably possible following the event

6.28. When reporting an incident please ensure that all details recorded are accurate, factual (i.e no opinions or hearsay) and complete. Mandatory fields are highlighted on screen by a red asterix and these fields must be completed together with all other relevant information.

6.29. Every incident is graded by the reporter for its 'actual' severity as it appears at the time of the incident. For incidents involving a person(s), the severity grading is broken down into five categories: No apparent injury or minor injury not requiring first aid; minor injury or illness first aid treatment needed; moderate injury/ RIDDOR / Agency reportable; major injury or long term incapacity; death or major permanent incapacity. In some circumstances incidents may be reported which affect the Trust i.e. have the potential for a complaint, litigation claim, damage to property, loss of a facility etc. These incidents should also be graded for their „actual severity as outlined above.

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6.30. Investigating Incidents

6.31. The Chief Executive must investigate every incident assigned to them to establish what, if any, lessons can be learned, shared and incorporated into future practice to ensure that the risk of similar incidents occurring in the future is minimised. The degree of investigation should be commensurate with the severity of outcome; likelihood of recurrence and/ or the potential future risk/loss to the organisation see Appendix 2.

6.32. As part of any investigation, Chief Executive should establish:

- When, where, to whom the incident happened and the outcome.
- How and why the incident happened, giving the immediate cause of injury or loss and the secondary/ contributory causes.

6.33. Incident investigations must be completed within 14 working days of the incident occurring. Should any investigation be ongoing for more than 14 working days the record must be updated every 7 working days. However, incident investigations should rarely be ongoing in excess of 30 days.

6.34. Results of the investigation must be recorded in the incident file and should include:

- findings and outcome(s) of the investigation including causes
- corrective action taken
- changes to systems or procedures necessary to prevent recurrence
- lessons learned for sharing across the organisation
- any identified risk(s) and their risk grading

6.35. Where a significant risk is identified a full risk assessment should be undertaken. All risks should be supported by an action plan (with timescales) and should be monitored on a continual basis with amendments made as appropriate. For further information refer to the Policy & Guidance for Risk Assessment.

6.36. All incidents graded as „Serious Incidents must be investigated in accordance with the Echogenicity's Investigation Policy and the Serious Incident Management Policy & Procedure and subjected to a root cause analysis. It may be appropriate for other incidents to be similarly investigated especially where:

- The consequence was of a moderate, severe or catastrophic nature
- A significant trend has been identified
- Where clinical practice or judgment is in question.

6.37. See flowchart Appendix 3 for guidance on when to undertake a RCA investigation.

6.38. Enforcement / NHS Agencies

6.39. Echogenicity recognises the role and responsibilities of the enforcement agencies. In most cases these agencies have a statutory duty to investigate. Every facility should be extended to them in their work. It should be noted that in some instances non co-operation is in itself a criminal offence.

6.40. The enforcement agencies below have the following statutory powers:

- Police: All cases of reported suspected criminal activities.
- Health & Safety Executive: All reportable accidents, also power of entry at all times.
- Fire Brigade: All fires, also power of entry to inspect/ check safety standards.
- Coroner's Office: All reportable deaths or deaths in suspicious circumstances.
- Local Counter Fraud Service: All incidents involving actual or suspected fraud.

6.41. Reporting to External Agencies

6.42. Care Quality Commission (CQC)

6.43. The CQC is the independent regulator of health and adult social care in England. They register and licence providers of care services if they meet

6.44. essential standards of quality and safety and monitor them to ensure they continue to meet the standards. Echogenicity is required to report specific incidents to the CQC such as serious injury to a patient, an event that stops or may stop Echogenicity from running the service safely and properly, applications to Supervisory Bodies or the Court of Protection to deprive a person of their liberty (DoL's), allegations of abuse or incidents reported to or investigated by the police. The Risk Team review all reported incidents to assist in the identification of those for further action and ongoing reporting to the CQC.

6.61. NHS England

6.62. NHS England was established in April 2013 to continue the work of the NPSA to co-ordinate the efforts of all those involved in healthcare and more importantly to learn from patient safety incidents occurring in the NHS. It helps the NHS learn from things that go wrong and develops solutions to prevent harm in the future. This is done by working with staff and patients both locally and nationally to foster a culture where errors can be investigated and innovative solutions developed.

6.64.Health and Safety Executive (HSE)

6.65. Echogenicity has a legal duty to formally notify the HSE with details of certain incidents that occur in the course of work activities. The Health and Safety Advisors are responsible for ensuring that the Trust complies with the requirements of the regulations

and the time limits for reporting. This is immediate for serious injuries and dangerous occurrences and within 10 days for over 3-day absence from work for staff injured in a work related incident.

6.66. National Health Service Litigation Authority (NHSLA)

6.67. The NHSLA provides indemnity for the majority of Trust activities through the NHSLA Risk Management Standards. All claims will be handled in accordance with the Trust Claims Policy by the Legal Services Department. The NHSLA also requires information on incidents that may generate claims and this information is routed to the NHSLA by Legal Services. Certain specific liabilities are indemnifies through commercial insurance and managed through Legal Services and the Finance Department. Legal Services will direct claims and notifiable incidents eligible for cover under the commercial schemes accordingly.

6.68.Medicines and Health Care Products Regulatory Agency (MHRA)

6.69. The Trust is required to report adverse incidents that involve medical devices to the MHRA. Where medical equipment is involved in an incident and there has been or is the potential for harm to occur to the patient or the user of the equipment, the MHRA must be notified before any repairs / modifications are made to the medical device. Manufacturers should not be allowed to inspect such equipment until permission has been granted by the MHRA. Where circumstances allow, medical devices should be removed from the department and taken to the Medical Physics Department.

6.70. If equipment cannot be moved due to size, fixtures etc., it must be clearly labelled (i.e do not use) and staff notified of the problem. The Medical Physics Department is responsible for MHRA reporting.

6.71.Committee on Safety of Medicines.

6.84. Echogenicity Liability

6.85. Echogenicity is vicariously liable for acts/omissions of its employees. Where it is considered that staff have acted in the course of their employment, Echogenicity will take full responsibility in the event of legal action arising from a Serious Incident. The prompt and accurate reporting of serious incidents is essential so that Echogenicity may support its staff in dealing with the incident itself and any subsequent developments, such as legal action.

6.86. Should a member of staff wish to raise any matters of concern where the interests of others or of the organisation itself are at risk then the process is explained fully in the Raising Concerns in the Public Interest (Whistleblowing) Policy.

7. Dissemination and Implementation

This policy and procedure will be kept in Echogenicity's head office, it will be made available to all staff.

8. Monitoring compliance and effectiveness Element to be monitored Duties of all staff to report all types of incidents as per the procedure and of managers to investigate incidents assigned to them as appropriate.

Incidents are reviewed by the appropriate staff.

Incidents are reported to external agencies as appropriate.

Review of the processes for staff to raise concerns

Acting on recommendations and Lead(s) Recommendations as a result of any shortfalls identified to be actioned by the Chief Executive.

Change in practice and lessons to be shared

Required changes to practice will be identified and actioned within the time frame agreed by the Chief Executive

9. Updating and Review

This policy and procedure will be reviewed and updated every three years or in accordance with any legislative or statutory developments as they occur.

10. Equality and Diversity

10.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement.

10.2. Equality Impact Assessment

10.3. The Initial Equality Impact Assessment Screening Form is at Appendix 1.

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Appendix 1. Stakeholders

Internal Stakeholders will include:

- Executive Management Team
- Professional / Clinical Staff
- Support Staff (Administration and reception teams;.)
- Shared Services (Cornwall IT Services; Education and Training;)