States of Jersey

The States of Jersey Department for
Health & Social Services

Patient Safety Learning Event Policy

March 2019

DOCUMENT PROFILE

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Approval Forum	Quality and Safety Assurance Committee
Review Date	1 year from approval
Contact Details	Patient Safety Officer E.O'Connor@health.gov.je

CONTENTS LIST:

1. INTRODUCTION

1.1 Rationale

Patient safety is the avoidance of unintended or unexpected harm to people during the provision of health care. Health and Community Services (HCS) is committed to providing an environment where people are free from unnecessary or potential harm arising from healthcare and driving improvements in safety and quality. People must be treated in a safe environment and protected from avoidable harm[1].

When things go wrong, it is vital events are recorded to ensure learning can take place. By learning, we mean people working out what has gone wrong and why it has gone wrong, so that effective and sustainable actions are then taken locally to reduce the risk of similar events occurring again.

HCS uses Datix, a risk management system, to manage all patient safety data. This system facilitates the review and analysis of all patient safety data, providing the organization with a greater understanding of priorities for safety improvement. It also helps us to identify emerging risks and issues that might not be recognized at departmental level.

Where appropriate, patient safety events will be reported to external organizations so that learning of national significance is shared and to meet legislative or best practice requirements.

1.2 Scope

This policy applies to all staff employed within HCS; the reporting of patient safety events and near misses is the responsibility of all staff.

1.3 Principles

A patient safety learning event, however serious, is rarely caused wilfully. It is not, in itself, evidence of carelessness, neglect or a failure to carry out a duty of care. Errors are often caused by a number of factors including process problems, human error, individual behaviour and lack of knowledge or skills. Learning from events can only take place when they are reported and investigated in a positive, open and structured way.

HCS upholds the creation of a just safety culture where wider systemic issues are considered when things go wrong, enabling care practitioners and those operating the system to learn without fear of retribution. Supporting staff to be open and feel confident to speak up when things go wrong allows valuable lessons to be learnt so the same errors can be prevented from being repeated.

In the majority of cases, investigations show that system failure is the cause of the vast majority of events, however, it is impossible to completely remove the possibility that the fault may lie with an individual. A ‘no blame’ culture, is neither feasible nor desirable and failing to recognise unsafe acts would undermine the culture and credibility of HCS. All

patient safety events will be properly analysed before the organisation concludes what caused it to occur. The Incident Decision Tree will assist this process and provide a standardised approach for all employees.

Disciplinary procedures are only likely to apply in the following circumstances for staff personally involved:

- Where the Incident Decision Tree's deliberate harm test indicates a staff member may be culpable for the event.
- Failure to report a serious incident.
- Failure to co-operate with an investigation or root cause analysis.
- Criminal actions.
- Actions so far removed from reasonable practice that any competent practitioner would have been able to predict the adverse outcome.

2. POLICY PURPOSE

This policy defines the roles and responsibilities of staff in relation to the process for reporting, managing and investigating events and the approach to learning lessons and preventing recurrence.

This policy provides guidance that ensures:

- Events are managed effectively and immediate action/learning takes place.
- Staff follow the correct procedures when an event occurs.
- Investigations are conducted in a timely manner and are of high quality.
- HCS learns from events to improve the safety and quality of services.
- Any person affected by an adverse event are provided with appropriate support throughout the process.

3. DEFINITIONS

Patient safety event (incident)

An event is any unexpected or untoward event that has a short or long term detrimental effect on any person.

Near-miss

A near miss is any event that could have had a short or long term detrimental effect had it been allowed to reach its natural conclusion.

The reporting of a near miss on Datix is important as these are 'free lessons' for HCS and a proactive approach can be taken.

Serious incident

Serious Incidents (SI) in health care are adverse events, where the consequences to any person(s) or the organisation are so significant or the potential for learning is so great, that a heightened level of response is justified. SI's include acts or omissions in care that result in; unexpected or avoidable death, unexpected or avoidable injury resulting in serious harm - including those where the injury required treatment to prevent death or serious harm, abuse.

For further detail please see HCS Management of Serious Incidents.

Never events

Never Events are serious incidents that are entirely preventable because guidance or safety recommendations providing strong systemic protective barriers are available at a national level, and should have been implemented by all healthcare providers[2]. For further detail please see Revised Never Events policy and framework.

Appendix 1 details examples of learning events which must be reported on the Datix system.

4. EVENT (INCIDENT) MANAGEMENT

4.1 Immediate management

The immediate management of any patient safety event is the responsibility of the most senior person on duty in the area at the time the event occurs or is reported for the first time.

That individual is responsible for:

- Ensuring those directly involved in the event receive the immediate care and assistance required to minimise any injury, or psychological trauma.
- Assessing the situation and deciding on the appropriate response.

The following factors should be taken into account to determine necessary action:

- The extent of harm caused and the immediate first aid and support needed to the injured or traumatised.
- The adequacy of the immediate nursing, medical and management response, and the need for specialist advice/support, for example, Quality and Safety team and / or Health and Safety team.
- The safety of the situation and the potential for further harm.
- The need to inform service users, carers and relatives in accordance with the Duty of Candour (Being Open) Policy and Procedure (January 2016).

- The need to inform external agencies (i.e. Police).
- The need to escalate the response to senior management.
- The need to support service users, staff and others affected by the event.

When the event is an actual or suspected SI, the manager should liaise with senior management and senior members of the Quality and Safety team to:

- Ensure any additional immediate or remedial action required is taken.
- Secure all relevant records.
- Advise all staff involved to write a reflective account of the event to aid recall if asked to participate in an investigation. A reflective piece will also facilitate personal learning.
- Ensure that arrangements are in place for additional support (including de-briefing and counselling) and communication

4.2 Management of events or near-misses involving medical devices / equipment

If you believe a medical device/equipment adverse event has occurred, you must, if practicable, isolate the equipment immediately and clearly mark the item 'defective do not use'. If the item has an asset number/unique identifier number/batch number, you must record this on the Datix form. You must not interfere with, or change, any settings or memory data and all readings must be documented. Unless this would destroy evidence, the device should be decontaminated according to the policy Decontamination of Hospital Equipment Including Medical Devices. The gathering of photographic evidence and eye witness reports should be considered.

If device(s) are required to be kept in use, it may be possible to remove defective part(s) so that the equipment may be repaired for re-use. Any parts so removed must be isolated and securely stored pending investigation.

If it is not possible to remove defective parts or withdraw the machine / equipment / medical device from use, staff should be made aware of the need for increased vigilance and extra caution during use. A risk assessment concerning the continued use of the equipment must be performed, documented and communicated.

In the case of a suspected or actual serious untoward incident, any data recorded should be witnessed and the witness should also make a personal written record that is signed, dated and timed.

For single use devices or consumables, all material evidence, including wrapping and containers should be preserved and suitably labelled. The manufacturer of the device/equipment (or their agents) must not, unless they are authorised to do so by the Medicines and Healthcare Regulatory Agency (MHRA), interfere with or remove any part; an inspection may be allowed in the presence of the person in charge of the ward / department (refer to the engineering department for advice).

If the equipment involved is maintained by the HCS Engineering Department, you should contact them as soon as possible. The engineer will advise on what local action should be taken as an interim measure to ensure the safety of service-users and others.

In the case of equipment not maintained by the HCS engineering department, an external assessment by the appropriate provider should be undertaken.

If the equipment/medical device event or near-miss involves infection prevention and control (IPaC) issues, a member of the IPaC team should be contacted for advice on further management.

If the event or near-miss involves a substance hazardous to health a member of the Health and Safety team must be contacted. For further detail please see Policy for the Control of Substances Hazardous to health (COSHH).

5. REPORTING A PATIENT SAFETY LEARNING EVENT

5.1 Internal reporting

Once the urgency of the event has been addressed, it is the responsibility of all members of staff to bring the event to the attention of their line manager or the most senior person on duty in the area.

An electronic Datix form must be completed as soon as possible using this link, http://datix/Datix/Live/index.php, or access via the Apps page on clinical desktop. As much factual information about the event as possible should be recorded, avoiding opinion; depending upon the type of event, supplementary documentation may be required, for example, photographs. Guidance for staff on how to complete a Datix report can be found here.

The completion of a Datix form is not a substitute for documenting in a person's notes (where applicable). Any event affecting service-users must be documented in their record with any action taken and / or consequence noted. A printed copy of the completed Datix must not be printed or placed in the patient's medical records.

Where there are two or more teams involved in a person's care, the team identifying the event will be responsible for reporting on Datix.

The Datix system facilitates reporting using an internal alerting cascade. The Datix email notifications include,

- The reporter's line manager.
- The HCS operational management team.
- The senior managers of the location where the event occurred.
- The senior managers of the speciality team / department.
- The event classification team i.e. infection prevention control team are notified when any event is classified as a needle-stick injury irrespective of location.

5.2 External reporting

5.2.1 Health and Safety Inspectorate (HSI)

At times, HCS may be required to notify the HSI of any events that occur. These situations will be assessed by the Health and Safety Manager / Officers and where appropriate, the Health and Safety team will notify the HSI.

Notifications to the HSI must not be made by any employee other than those from the Health and Safety team.

5.2.2 Medicine and Healthcare Regulatory Authority (MHRA)

The MHRA is the executive agency of the Department of Health (DH) charged with protecting and promoting public health and patient safety by ensuring that medicines, healthcare products and medical equipment meet appropriate standards of safety, quality, performance and effectiveness, and that they are used safely.

Where a medical equipment or device has not met this product standard or is deemed faulty, senior members of the Quality and Safety or the Health and Safety Manger in conjunction with the reporting manager will notify MHRA via the online Adverse Incident Centre (AIC) reporting database, https://www.gov.uk/report-problem-medicine-medical-device.

The MHRA's Adverse Incident Centre will provide advice where necessary, particularly on whether arrangements should be made for the item to be examined prior to any decontamination. Where decontamination / cleaning would destroy vital evidence, the items should be placed in protective containment, labelled and placed in isolation. The MHRA and the manufacturer/supplier should be contacted for advice prior to any further action being taken.

IT IS ILLEGAL TO SEND CONTAMINATED ITEMS THROUGH THE POST

MHRA will sometimes issue a Medical Device Alert (MDA) follow their initial investigation warning of hazardous products, potential safety issues or unsafe procedures, and providing relevant advice.

A record of the notification will be kept on Datix. In some circumstances, HCS may find it appropriate to carry out a serious incident review, and put in place corrective actions to reduce the risk of recurrence.

5.2.3 Radiation protection advisor

In any event resulting in an unnecessary radiation exposure to any person, the relevant Radiation Protection Supervisor must be informed (in addition to completing a Datix form). The Radiation Protection Supervisor shall immediately report to the head of the appropriate department and, if necessary, to the Radiation Protection Advisor in accordance with the local rules. The Radiation Protection Advisor will then notify the

Radiation Protection Supervisor/Manager if the event is reportable to the Jersey Health and Safety Inspectorate (HSI) under the following Approved Code of Practice: Health & Safety at Work (Jersey) Law 1989 (ACOP 2 revised 2002).

6 INVESTIGATING A PATIENT SAFETY LEARNING EVENT

6.1 Grading of an event

The level of any investigation depends on the grading of the event.

The event is graded by the severity and likelihood of reoccurrence of the event within HCS. The event potential severity and likelihood of reoccurrence, is rated on a scale of 1 to 5. The risk rating is the multiplication of potential severity and the likelihood of reoccurrence at that severity, with a total of 25 being the highest risk rating possible.

Refer to the table below and Appendix 2.

	Consequence				
Likelihood of recurrence	1 Negligible	2 Minor	3 Moderate	4 Major	5 Catastrophic
5 Almost Certain					
4 Likely					
3 Possible					
2 Unlikely					
1 Rare					

6.2 Level of investigation

The investigation process depends on the level of investigation that is required. The levels of investigation used within HCS are as follows;

1. Departmental investigation
2. Mini Root Cause Analysis (RCA): Pressure sores
3. Concise internal investigation: more in-depth than a departmental investigation and is stored within Datix.
4. Level 2 SI: Comprehensive internal investigation
5. Level 3 SI: External / Independent investigation

Appendix 3 details the protocol for conducting a departmental investigation. For all other level of investigations, please refer to the HCS Management of Serious Incidents.

‘Handler’

The handler of an investigation is generated automatically by Datix and is usually the manager of the person that reported the event. An email notification is sent to individuals with a direct link to the WEB form.

The handler is responsible for;

1. The general overview of the report
2. Ensuring all the details are factual and correct, including date, time, location, and speciality (where appropriate).
3. The allocation of an investigator(s).
4. Ensuring the event is managed within the specified timescales.
5. The risk grading of the event (prior to any mitigation).

The handler of an event must not be changed without prior discussion with the Quality and Safety team.

‘Investigator’

The investigator is responsible for finding out why an event occurred, the action(s) taken to minimise recurrence and the lessons learnt for dissemination. An appropriate investigator is nominated by the handler and an email notification is sent to individuals with a direct link to the WEB form.

The investigator responsibilities include;

1. Checking all the information is correct and factual (avoiding opinion).
2. Completing an investigation as per protocol.
3. Completing the risk grading following the implementation of action and controls.
4. Contact approval.
5. Up-dating the handler through the communication and feedback section as to the progress of the investigation.

6.3 Final approval

An event can be finally approved once the investigation has been completed and any mitigating actions are in place.

The final approver is usually the handler or the handler’s line manager. Responsibilities include;

- Ensuring a high standard of investigation including root causes and contributory factors.
- Ensuring the risk grading and the level of harm are correct.
- Ensuring that the depth of investigation is proportionate to the event.
- Requesting additional information from the hander and / or investigator if not satisfied.
- Changing the approval status to ‘finally approved’ which will close of the event.

6.4 Feedback

Following the final approval of an event, the reporter will receive an email notifying them of the lessons learnt and actions taken as part of the investigation.

7 REJECTING A PATIENT SAFETY EVENT

A completed Datix form can be rejected by the Quality and Safety team only and under the following circumstances;

1. The event is in fact not an adverse event.
2. Reported in error.

If the same event has been reported by two or more different people, these will be linked rather than rejected.

8 LEARNING FROM A PATIENT SAFETY EVENT

The sharing of the lessons learnt following an investigation is a crucial part of patient safety learning event management. Learning from patient safety events is a collaborative, decentralised and reflective process that draws on experience, knowledge and evidence from a variety of sources. The learning process is a process of change evidenced by demonstrable, measurable and sustainable change in knowledge, skills, behaviour and attitude.

Learning can be demonstrated at an organisational level by changes and improvements in process, policy, systems and procedures relating to patient safety within healthcare organisations. Individual learning can be demonstrated by changes and improvements in behaviour, beliefs, attitudes and knowledge of staff at the front line of healthcare delivery.

Where appropriate, information should also be communicated to external stakeholders to ensure appropriate involvement in the investigation and to share lessons learnt from events, for example, Family Nursing and Home Care (FNHC), Jersey Hospice and Private Care Providers. It may also be necessary, if an event occurs across a number of organisational boundaries, to work together in a joint investigation.

Learning from an event should be linked to safety related policy, practice and process issues raised by the event. Examples of learning are given below:

- Solutions to address event root causes which may be relevant to other teams and services.
- Identification of the components of good practice which reduced the potential impact of the event and how they were developed and supported.

- Systems and processes that allowed early detection or intervention which reduced the potential impact of the event.
- Lessons from conducting the investigation which may improve the management of investigations in future.
- Documentation of identification of the risks, the extent to which the risks have been reduced, identified and how this is measured and monitored.

The Quality and Safety team has overall responsibility for ensuring that learning from patient safety events takes place.

The whole system of reporting and investigating patient safety events is designed to improve the quality and safety of services. To do this, it is important that learning is well defined and understood and capable of being measured. HCS categorises learning in four levels and defines it as follows:

Level	How learning takes place	Examples
Individual	Reflective practice Email feedback through Datix	Improved individual knowledge, skill, performance and development.
Team / Department	Reflective practice. Case-study discussion. Local department mechanisms (e.g.) newsletters. Promoting learning from other areas. Datix dashboards. Feedback sessions following SI investigations.	Improved team performance indicators. Changes to environment, practice. Systems review to improve safety for patients and staff and the introduction of safer system of work.
Service / directorate	Feeding event themes into specific groups (e.g.) falls group, tissue viability, transfusion committee. Governance committee(s) review of events and SI's ((e.g.) medicines governance) and monitoring of progress against action plans. Datix dashboards.	Changes to functioning and management of services. Improved service / directorate performance indicators.
Organisational	Quality and Safety Committee review of all events. Dissemination of Safety Alerts.	Changes to HCS policy and training.

	Development of clinical audit programmes to support safety priorities.	Commissioning of service reviews and additional resources. Improved HCS performance indicators.

8.1 Thematic review

A thematic review may be commissioned when HCS identifies common features to a number of patient safety events. Common features may include location, department or task specific. The goal of a thematic review is to enable wider systemic learning from events and to ensure that commonalities between individual events and investigations are identified and addressed.

The aim of the formal thematic review meeting is to identify common themes, make recommendations as to future actions to address risks identified and to ensure learning can take place.

A thematic review may be undertaken when:

- Three similar events occur in one division (to be groups).
- A cluster of similar events are identified.
- Three rare occurrences of an event happen across several divisions (groups).

A thematic review will be identified and commissioned by the Head of Quality and Safety, the Associate Medical Director for Quality and Safety and / or Serous Incident Review Panel (SIRP). The review will be undertaken by a reviewer or a panel identified by the commissioner(s). The commissioner(s) will oversee the Terms of Reference (TOR) and methodology.

The findings of any thematic review will be shared with the appropriate panel and the Quality and Safety Assurance Committee before wider dissemination.

9 TRIGGER LISTS

The use of ‘triggers’ to identify patient safety learning events is an effective method for measuring the overall level of harm experienced by patients in a healthcare organisation. Traditional efforts rely on voluntary reporting of events; public health researchers have established that only 10-20 per cent of errors are ever reported. A more effective way to identify events that cause harm to patients is needed[4.]

A trigger is not necessarily an event; rather it provides a prompt to investigate whether or not there was an event and if so, was this avoidable. Not all reported triggers will have resulted in harm or found to have been avoidable.

Each department / speciality are now encouraged to develop their own trigger lists. See Appendix 4 for the trigger lists already used within HCS.

10 RESPONDING TO DEATHS

Learning from deaths of people in their care can help providers improve the quality of the care they provide to patients and their families by identifying common themes and problems associated with poor outcomes, and working to understand how and why these occur so meaningful action can be taken[3].

Mechanisms for learning from deaths must be robust and effective to identify learning from death and to further identify changes in practice that would, in the future, prevent a death or reduce morbidity. The process of learning from deaths is mandatory in the United Kingdom (UK), HCS will follow this best practice. The expectation is that learning from deaths data will be reviewed as a matter of routine and learning shared within the specialty and where appropriate, the wider organisation.

HCS will use the structured judgment review (SJR) methodology developed by the Royal College of Physicians (RCP).

11 TRAINING

All staff will receive Health and Safety training which includes event awareness and the reporting of events.

Training for the management and investigation of the events on the Datix system is provided in a variety of ways;

- User guide
- Individual training.
- Group training.

Training dates are available,

1. On the Datix page
2. By request to the Datix Administration Team.

12. STANDARDS AND QUALITY ASSURANCE

Measurement and key performance indicators,

1. The event should be reviewed by the appropriate manager within 72 hours working hours of the event reported on Datix.

2. All departmental events should be processed to final approval within 4 weeks and closed on Datix by the appropriate manager.

The Quality and Safety team will review the content of all Datix event forms and quality assure the risk grading and level of harm applied to any reports. The Quality and Safety

team will sample events as part of a Quality Assurance process to ensure that the appropriate level of investigation has been undertaken to establish the root cause(s) and any action points / learning.

Senior managers will be provided with a monthly report detailing any outstanding investigations. In addition, feedback on the quality of reports will be given to individuals involved and also the appropriate senior managers to identify training needs.

Reports of specific events are accessible by pre-determined individuals / groups on the basis of event-coding, for example, medication events to the medicines Governance Committee allowing them the opportunity to request further information and assist in the investigation process.

13. DEVELOPMENT AND CONSULTATION PROCESS

13.1 Consultation Schedule

The previous policy and procedure was widely consulted and this policy draws together both the policy and procedure document but there are no changes to the previous processes.

This documents reflects the change in terminology, incidents are now referred to as events.

14. REFERENCE DOCUMENTS

1.NHS Improvement, Patient Safety, https://improvement.nhs.uk/improvement-hub/patient-safety/, Last accessed, 22nd February 2019.

2. NHS Improvement, Revised Never Events policy and framework, https://improvement.nhs.uk/resources/never-events-policy-and-framework/, Last accessed 22nd February 2019.

3. Learning from deaths in the NHS, https://improvement.nhs.uk/resources/learning-deaths-nhs/, Last accessed 22nd February 2019.

4. Institute for Healthcare Improvement, Introduction to Trigger Tools for Identifying Adverse Events, http://www.ihi.org/resources/Pages/Tools/IntrotoTriggerToolsforIdentifyingAEs.aspx, Last accessed, 1 March 2019.

15. IMPLEMENTATION PLAN

Once ratified, this will be uploaded to the Policy Publishing Centre. A link is available to the relevant policy on the Datix event form.

The policy will be incorporated into all the Datix and investigator training.

Action	Responsible Officer	Timeframe
Circulate via communication to all managers and consultants.	Emma O'Connor	As soon as ratified
Managers to ensure their staff are aware of the new policy through, for example, team briefing and staff meetings. Managers must ensure staff have read the policy.	All managers	End March 2019

16. APPENDICES

Appendix 1 Examples of patient safety events

The following list contains examples of events which must be reported on the Datix system, irrespective of whether harm occurred or not. The list and range of examples presented is by no means exhaustive.

Clinical event	Any event directly related to care and treatment which did or could have resulted in harm.
Ill-health (work related)	Any case of known or suspected work-related ill-health.
Health & Safety event	Any event resulting in injury, ill health, loss or damage which in the case of service-users is not due to treatment or care, includes any events impacting upon staff / visitor safety.
Operational event	Any event whereby the ability of HCS to continue to deliver one or more aspects of its service(s) is compromised.
Fire Event	Any event involving fire, firefighting equipment or fire warning systems (including false alarms).
Information Governance	Any event where there is a suspected breach of one of the data principles, including breach of confidentiality, misfiled medical records.
Behaviour, violence, aggression	Any event involving verbal abuse, unsociable behaviour, racial or sexual harassment, physical assault.
Infection control	Failure to decontaminate hands / equipment, to dispose of sharp instruments, use of personal protective equipment (PPI), breaches of IPAC policy.
Security event	Any event involving theft, loss or other damage to HCS or personal property, intrusions.
Non-intentional property loss or damage	Any event where equipment, buildings or other property is damaged.
Loss of patients property	Any loss of patient's property.
ICT security event	Any intentional or non-intentional event that damages HCS's information assets, reputation.
Screening events	Any event where the integrity of a screening programme is compromised.

Appendix 2 Risk grading matrix

Domain	Consequence Score and Descriptor				
	1	2	3	4	5
	Negligible	Minor	Moderate	Major	Catastrophic
Injury or Harm Physical or Psychological	No/minimal injury requiring no/minimal intervention or treatment No time off work required	Minor injury or illness, requiring intervention Requiring time off work for <4 days Increase in length of hospital stay by 1-3 days	Moderate injury requiring intervention Requiring time off work for 4 -14 days Increase in length of hospital stay by 4-14 days RIDDOR / agency reportable incident	Major injury leading to long term incapacity/disability Requiring time off work for >14 days Increase in length of hospital stay by >14 days	Incident leading to death Multiple permanent injuries or irreversible health effects
Quality of the patient experience outcome	Unsatisfactory patient experience not directly related to the delivery of clinical care	Unsatisfactory patient experience directly related to clinical care – readily resolvable	Mismanagement of patient care, short term effects <7 days	Mismanagement of patient care, long term effects >7days	Totally unsatisfactory patient outcome or experience
Statutory **(Locally coroners give a narrative verdict)**	Coroners verdict of natural causes accidental death, open No or minimal impact of statutory guidance	Coroners verdict of misadventure Breach of statutory legislation	Police criminal Investigation Prosecution resulting in fine >50k Issue of a statutory notice	Coroners verdict of neglect/system neglect Prosecution resulting in fine >500k	Coroners verdict of unlawful killing Criminal prosecution (inc Corporate manslaughter) > imprisonment or director/executive
Business/Finance & Service Continuity	Minor loss of non-critical service Financial loss <£10k	Service loss in a number of non-critical areas <2 hours or 1 area or <6 hours Financial loss £10-£50k	Loss of services in any critical area Financial loss £50 - £500K	Extended loss of essential service in more than one critical area Financial loss £500K to £1m	Loss of multiple essential services in critical areas Financial loss >£1m
Potential for complaint or litigation / claims	Unlikely to cause complaint or litigation	Complaint possible Litigation unlikely Claim(s) <£10k	Complaint expected Litigation possible but not certain Claim(s) £10-£100K	Multiple complaints / Ombudsmen inquiry Litigation expected Claim(s) £100k - £1m	High profile complaint(s) with national interest Multiple claims or high value single claim >£1m
Staffing and competency	Short-term low level that temporarily reduces patient care / service quality (<1 day) Concerns about competency / skill mix	Ongoing low staffing level that reduces patient care / service quality Minor error(s) due to levels of competency (individual/team)	Ongoing problems with levels of staffing that result in late delivery of key objective/service Moderate error(s) due to levels of competency (individual/team)	Uncertain delivery of key objectives/service due to lack of staff Major error(s) due to levels of competency (individual/team)	Non-delivery of key objective/service due to lack of staff/loss of key staff Critical error(s) due to levels of competency (idividual/team)
Reputation or Adverse Publicity	Within the organisation Local media 1 day e.g. inside pages, limited report	Local media <7 day coverage e.g. front page, headline Regulator concern	National media <3 day coverage. Regulator action	National Media >3 day coverage. Minister concern. High Profile coroners inquest	Full public enquiry Public investigation by regulator
Compliance Inspection / Audit	Non significant / temporary lapses in compliance/targets	Minor non-compliance with standards/targets. Minor recommendations from report.	Significant non-compliance with standards/targets. Challenging report	Low Rating. Enforcement action. Critical report	Loss of accreditation/registration. Prosecution. Severely critical report.

Appendix 3 Departmental Investigation Protocol

Departmental Investigation Protocol

Departmental events are low level events that have been reported on Datix that do not meet the criteria for a serious incident review or concise review; these are resolved within the team/service.

Review Procedures

1. Departmental reviews are undertaken at a departmental / team level and documented on Datix.

2. All managers responsible for a team or a department have a Datix login which enables them to access and view event reports relating to their area of responsibility.

3. The Datix system will send an email notification to the manager's inbox when a member of their staff has submitted a Datix report.

4. The manager will review events with the team, identify any root causes, undertake any necessary remedial action and record these on Datix as part of the signing off process.

5. Where serious issues are identified, immediate escalation to relevant senior managers must take place.

6. The manager is responsible for making sure that the staff, patient, and relatives are supported in accordance with the Duty of Candour (Being Open) Policy and Procedure (January 2016).

Learning from Events

HCS expects that all teams / services / divisions will regularly review departmental events and present them at their local governance forums as part of the learning process.

Timescales

Report an event on Datix as soon as possible.

- An investigation must be undertaken within two weeks of the event being reported.
- An event must be Finally Approved within two weeks of the investigation being completed.

In total, you have 4 weeks to complete the Datix report.

Appendix 4 Trigger Lists

Maternity triggers

Misdiagnosis of an antenatal screening test	Maternal death	Unplanned transfer of patient to HDU or ITU
Unexpected return to theatre	Eclampsia	Maternal collapse
Antepartum haemorrhage	Postpartum haemorrhage >1500mls	3rd / 4th degree tear
Delay>30 minutes CAT 1 LSCS	LSCS at full dilatation	Shoulder dystocia
Cord pH<7.1 at delivery	Apgars <6 at 5 minutes	Intra-uterine death
Cord prolapse	Undiagnosed breech presentation	Inter-uterine transfers
Intrapartum transfers for home births	Prolonged active 2nd stage 3 hrs in nulliparous / 2hrs in parous women	Damage to the bladder or other soft tissue damage
Retained swab	Born before arrival	Uterine rupture
Inverted uterus	Re-admission of mother	Stillbirth and neonatal death

Neonate triggers

Stillbirth	Neonatal death	Birth injury
Unsuspected fetal abnormality	Low cord pH value at birth (<7.1)	Hypothermia on admission
Re-admission to SCBU	A clinical event of concern, such as a ‘near miss’	Advanced resuscitation of neonate
>37 weeks to NNU	Neonatal seizure	Brachial plexus injury
Neonatal readmission	Extravasation of IV fluids	Meconium aspiration

Orthopaedic triggers

Died within 7 days of orthopaedic surgery
Hip replacement dislocation within 30 days and 1 year of surgery
Readmission to theatre within 7 and 30 days of surgery
Revision of joint replacement within 30 days and 1 year of surgery
Surgical site infection within 30 days and 1 year of surgery

Haematology triggers

Hospital acquired thrombosis