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<th>Title</th>
<th>Incident Reporting, Investigation and Management Policy</th>
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<tr>
<td><strong>Description of document</strong></td>
<td>This policy provides a framework for the reporting, investigation and monitoring of all incidents and near misses and risk assessments. Section 1: describes the Reporting Process Section 2: describes the Investigation Process Section 3: describes the Risk Management Process including risk assessment and the management of Risk registers</td>
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<td><strong>Scope</strong></td>
<td>All NCH&amp;C staff</td>
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<tr>
<td><strong>Author and Designation</strong></td>
<td>Jo Hardcastle, Risk Manager (NCH&amp;C)</td>
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<td>Care Quality Commission (CQC) Regulation Requirements NHSLA Standard 1.5; 5.2; 5.5</td>
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<td><strong>Review Arrangements</strong></td>
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## Incident Reporting, Investigation and Management Policy

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- Appendix C: Never Events
- Appendix D: Incidents involving Equipment
- Appendix E: Management of Information Security Incidents
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- Appendix M: Guidance on risk assessment across different types of incident
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1. Introduction

1.1 This policy provides a framework for the reporting, investigation and management of clinical and non-clinical incidents and near misses. It describes the process by which risk is assessed through reporting, and how organisational learning is supported to underpin patient and staff safety.

1.2 Incident reporting is a key requirement to improve patient safety and of assuring staff, patients and the public that systems for managing risk are robust and effective.

1.3 It is part of the wider approach to managing risk in the Trust and can provide an early indicator that a system or process that is believed to be working well may not be.

1.4 If incidents are not managed properly, they may result in avoidable harm to patients and a loss of public confidence in the services provided.

1.5 **NB: Low levels of incident reporting do not indicate a safe system.**

1.6 Evidence of an effective reporting system is one where the number of incidents increases but the severity of the events goes down.

1.7 This indicates that staff are risk aware, can identify events early and at the stage where interventions can be made to reduce the adverse effect.

1.8 To do this, staff must feel able to report and capture events before they can cause harm to patients.

1.9 This requires a well developed safety culture and strong leadership for safety from all staff from the Chief Executive to the front line teams and is a key role for managers and those involved in reporting, investigating and managing incidents when they occur.

1.10 The Trust expects staff to report incidents promptly both as part of their professional accountability and to ensure that appropriate steps are taken to maintain the safety of the patient.

1.11 The overriding emphasis is to identify why mistakes have occurred and to learn from the process, not to attribute blame and punish.

1.12 This does not absolve staff from professional accountability but it is important that all the facts of an incident are reviewed. It is rarely one person’s ‘fault’ when a mistake occurs, but usually a combination of events, requiring consideration of all contributory factors and a thorough investigation prior to deciding any action required.
1.13 Balanced in this approach is the need to counsel and support staff, relatives and carers through any incident, potential or actual, and ensure appropriate action is taken to reduce the risk of the event occurring again.

2. **Purpose**

2.1 The purpose of this policy is to ensure staff understand what is required of them to report, investigate and manage incidents at all levels of the Trust and to describe:

2.1.1 the process for reporting all incidents and near misses involving staff, patients and others using the Datix risk management system

2.1.2 the roles and responsibilities of staff to report incidents as they occur

2.1.3 the process for investigating incidents and near misses appropriate to the severity of the event

2.1.4 the process for reporting to external agencies where appropriate

2.1.5 the process to share lessons learnt and to follow up on required actions as a result of investigations

2.1.6 the means by which staff are able to raise concerns

2.1.7 the systematic approach used for assessing all types of risk using a common assessment matrix to ensure consistency

2.1.8 the systematic approach used to record and escalate risks using the risk register at local, corporate and Trust Board level

2.1.9 the management responsibility and authority of staff at different levels within the organisation to manage and escalate risk in line with the Risk Strategy

2.1.10 the training available to staff to support them to carry out these roles and responsibilities

3. **Scope**

3.1 This policy applies to all NCH&C staff to ensure that all incidents, including near misses, are reported in a timely manner.

3.2 The safety of the patient is paramount and without reporting no learning can take place to identify the means to reduce the risk of an incident occurring again.

3.3 This policy is not part of the Trust disciplinary process and all staff both clinical and non clinical are expected to report events when they occur as part of their roles as accountable professionals.
3.4 The key priority is to make sure the patient or party affected is safe, assistance is sought and the patient/person is removed from the vicinity of harm if appropriate and safe to do so.

3.5 The Trust uses the Datix risk management system which is available to all staff online. The system can be accessed via Citrix at http://dublin/datix/live/index.php

4. Definitions

Within the context of this policy, the following definitions are used:

4.1 Adverse Event / Incident

Any event or circumstance arising during NHS care that could have or did lead to unintended or unexpected harm, loss or damage. This could be to a patient, staff member, visitor, contractor or that adversely affects the reputation of NCH&C or its services. Examples of incidents that require reporting are given in Appendix A.

4.2 Harm

Harm is defined as injury (physical or psychological), disease, suffering, disability, or death. In most instances, harm can be considered to be unexpected if it is not related to the natural cause of the patient’s illness or underlying condition.

4.3 Prevented incidents or Near Miss incidents

These are incidents that did not lead to harm, but could have and were prevented from occurring e.g. when a staff member identifies that an infusion pump is set at the wrong rate and stops it before it can harm the patient.

These incidents must still be reported, as by identifying the risk it may stop another member of staff from making the same mistake. It can also identify through aggregation of these reported incidents that certain activities or pieces of equipment appear riskier than others and action can be taken to mitigate this by sharing learning and reviewing training to avoid that incident causing harm in the future.

4.4 Loss or damage

Loss or damage occurring within the context of clinical risk to the patient, can equally apply to their family, carer, staff or the organisation and may be both financial and/or to reputation. Clinical risk can occur due to latent decisions e.g. changes to service delivery which create different risks but which may not be apparent at the time the change is made.

4.5 Serious Incident Requiring Investigation (SIRI)

4.5.1 A SIRI is an incident where an event or circumstance has caused serious harm, has the potential to cause serious harm, is likely to attract
public and media interest and that occurs on NHS premises or in the provision of an NHS service. (See Appendix B for examples of SIRI’s and Section 2 for the investigation process)

4.5.2 SIRI’s include events which may have the potential to affect the Trust reputation or ability to continue providing a registered service.¹

4.6 **Never Event**

Never events are serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented. These are defined and agreed nationally (See Appendix C).

4.7 **Hazard**

A hazard is anything with the potential to cause harm.

4.8 **Risk**

Risk is the effect of the hazard, either its impact or consequence, if it is not controlled to reduce the risk. A standard risk matrix and format is used to assess the level of risk (See Section 3: Risk Management Process)

4.9 **RIDDOR**

Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995. (See Health & Safety Policy for the definition and additional actions required to report a RIDDOR incident)

4.10 **Security Incident**

Certain security incidents are required to be reported as SIRI’s to ensure action is taken to ensure NHS staff and property are better protected (Appendix B)

4.11 **Unexpected Death**

Death can be considered to be unexpected if it does not appear to be related to the natural cause or course of the patient’s illness or underlying condition.

4.12 **Abuse**

Violation of an individuals human rights by any other person(s). This may be physical, psychological, verbal, neglect, acts of omission, sexual, exploitation of a vulnerable person

¹ All providers of health care have to be registered with the Care Quality Commission and comply with Health and Social Care Act 2008 (Regulated Activities) Regulations 2010
SECTION 1: Process for Reporting an incident or near miss involving, staff, patients and others

5. Types of Incidents that must be reported
5.1 Examples of the type of incident to be reported are given in Appendix A. These are for guidance only and if you think something should be reported then complete a Datix form.²

5.2 Appendix B gives examples of Serious Incidents Requiring Investigation (SIRI’s) to be reported.

5.3 Appendix C provides information on reporting patient safety incidents which are defined as Never Events.

5.4 Appendix D provides information on reporting patient safety incidents and near misses involving equipment;

5.5 Appendix E provides information on reporting Information Governance incidents;

5.6 Appendix F provides a flow chart of reporting an incident

5.7 Appendix G provides a flow chart of the SIRI (non pressure ulcer) reporting process

5.8 Appendix H provides a flowchart of the Pressure Ulcer SIRI reporting process

5.9 For incidents involving defective medicines (rather than wrong dose, wrong route, wrong time, wrong patient) please contact the Head of Medicines Management and refer to the Medicines Management Policy.

6. Process to report an incident
6.1 Duties of member of staff reporting an incident

   6.1.1 Incidents must be reported as near to the time of the event as possible but within 24 hours maximum using the Datix reporting system.

   6.1.2 Complete the form following the instructions on the screen, giving the following details as a minimum:

   6.1.2.1 Person or party affected i.e. patient or member of staff

   6.1.2.2 Incident type and category – this can be accessed via drop down list

² The Quality & Risk Manager or a member of the Quality & Risk team can be contacted by phone and email to prevent delays in the event of uncertainty as to whether an incident is reportable
6.1.2.3 Nature of the incident – facts only not opinions, what has happened and the effect on the patient
6.1.2.4 Do not include patient identifiable data in the free text boxes
6.1.2.5 Immediate action taken – include times where known
6.1.2.6 Degree of harm – this is the outcome for the person affected by the incident
6.1.2.7 For incidents graded as severe\(^3\) and unexpected death the line manager must be contacted as soon as possible after the event as well as completing the form. Out of hours this will to the on call Tier 1 manager.
6.1.2.8 Select line manager – this will automatically notify the line manager that an incident has been reported which needs their attention.

6.2 Duties of Line Manager on notification of an incident being reported via Datix
6.1.3 Check content and adequacy of information provided
6.1.4 Check patient identifiable data has been removed from the free text boxes
6.1.5 Refer back to the reporter if any additional information is required
6.1.6 Refer back to the reporter if actions identified do not reflect the seriousness of the event reported for clarification
6.1.7 Consider other reporting requirements that may be needed e.g. RIDDOR, SIRI, Adult Safeguarding (see Health & Safety Policy, Safeguarding Policy).
6.1.8 Grade the incident in terms of the harm that has occurred as a result of this incident and the likelihood of it recurring for this patient or staff member using the risk matrix on Datix (See Section 3: Risk Management Process for additional guidance)
6.1.9 For near miss incidents, grade the level of harm that could have occurred as a result of this incident if it had not been prevented and the likelihood of it occurring again.
6.1.10 Consider whether any action is required by reporter or themselves to support either the patient and their family, carers or staff members involved.
6.1.11 Assess whether an investigation or additional action is required. (See Section 2: Investigation Process)

\(^3\) Other than for Grade 3 & 4 pressure ulcers
6.1.12 If so, agree what needs to be done, by whom and with a time scale for follow up by the line manager

6.1.13 Approve contacts and ensure injury / harm details are accurate and complete

6.1.14 Once the line manager is confident that the form clearly reflects the detail of the incident, action taken at the time and any follow up action required, change status to ‘awaiting final approval’

7. Duties of Additional Senior Managers included in reporting trigger

7.1 For the following incident categories, trigger alerts are received by staff with additional specialist skills. This includes but is not exclusive to the following:

7.1.1 Medication incidents
7.1.2 Information Governance
7.1.3 Infection Control
7.1.4 Health & Safety
7.1.5 Moving & Handling
7.1.6 Information Technology
7.1.7 Adult Safeguarding
7.1.8 Children’s Safeguarding
7.1.9 Death/ Severe Incident
7.1.10 Estates / security incidents
7.1.11 Blood Transfusion incidents

7.2 The designated senior manager will review the incident and be available for specialist advice and support if needed.

7.3 They identify if any additional actions or external reporting is required and will liaise with the line manager to ensure this occurs and that any additional actions identified are completed.

8. Process for Final Approval of Incidents reported on Datix

8.1 Management of the incident, including taking action to reduce the risk and securing the persons safety is not dependent on final approval

8.2 The final approval process is not agreeing whether an incident has occurred. It is a quality and assurance check for consistency of content and to ensure relevant actions have been identified and assigned where appropriate.
8.3 This includes ensuring any patient identifiable data is removed from the free text boxes if this has not been completed at the earlier checking process.

8.4 Review of whether an investigation is required if not already being actioned and the level required.

8.5 The decision is made when the Quality & Risk Manager or designated senior manager finally approves the incident as to whether it is reportable to the National Reporting & Learning System (NRLS).

8.6 The record is marked accordingly once the quality check has been completed and all patient identifiable data has been removed.

9. Responsibility of staff who may wish to raise a concern

9.1 While the aim would be for any concern regarding patient safety or other practice observed or known of in the Trust to be raised in the first instance with their line manager or by using the incident reporting system, it is acknowledged that for some staff they may not feel able or comfortable to do so.

9.2 Where a staff member has such concerns they have a responsibility to report them.

9.3 The member of staff should follow the process described in the Raising & Escalating Concerns Policy (Whistle Blowing).

9.4 This may include but is not limited to, concerns regarding the welfare of patients, unlawful issues, misuse of Trust property, inappropriate conduct, financial malpractice or dangers to the public or the environment.

9.5 Each query will be investigated thoroughly and openly in line with the Raising & Escalating Concerns Policy.

9.6 Every manager has a duty to ensure that their staff know how to raise a concern, are easily able to express their concern, understand that any issue raised will be taken seriously, dealt with promptly, fairly and professionally without detriment to themselves when raised in the context of preventing crime, improving safety and reducing the risk of harm or poor practice.

10. Duties, roles and responsibilities of other staff in reporting or managing an incident

10.1 All staff
10.1.1 All staff employed by NCH&C are required to report incidents in a timely manner and are actively supported to do so whether permanent, interim contractors or temporary staff.

10.1.2 Without reporting there is no learning and additional support is provided for those staff who require it following any serious or traumatic event.

10.2 Modern Matron / Locality Manager / Head of Service

10.2.1 For incidents reported by your teams in general:
10.2.2 Ensure a process is in place to review incidents reported by your staff and monitor for trends
10.2.3 Align this with team / department/ locality meetings to ensure reported incidents are discussed and any actions required to prevent the incident happening in a different part of the service is taken.

10.2.4 For incidents graded as Moderate, Severe\(^4\) or above:
10.2.5 Check the incident has been documented appropriately in patient’s record if the incident has affected a patient.
10.2.6 Check that relevant people have been contacted/been involved.
10.2.7 Check that the relevant medical professional responsible for the patients care has been informed if the incident is graded as moderate or above
10.2.8 Check staff support provision is adequate
10.2.9 Review actions and any recommendations from investigations to ensure that they are robust and that they are appropriate to mitigate the risk of re-occurrence.
10.2.10 Ensure that communication routes have been established. i.e. with the family / carers of the affected patient and with the staff involved
10.2.11 Work with staff identified to undertake any investigation into specific incidents to ensure required information is provided within agreed timescales
10.2.12 Review investigation reports prior to being submitted to the Quality & Risk Manager in line with local governance and quality check procedures
10.2.13 Facilitate learning from the monthly and aggregated reports from reported incidents and following completion of the 45 day SIRI Root Cause Analysis and specified 7 day reports across their teams and departments.

\(^4\) Incidents requiring additional procedures eg all fractures, long term damage, Major harm or unexpected death
10.2.14 Monitor action plans within their own teams and any recommendations relevant to their areas from incidents and Root Cause Analysis occurring in other teams or departments

10.2.15 Identify any additional risks which need to be included in the local risk register or that need referring to the locality business unit for inclusion in the risk register (See Section 3: Risk Management process)

10.3 Notification out of Hours – roll of the on call Manager

10.3.1 Staff designated on call may have specific action to take in the event of a serious incident occurring. This is included in the on call Manager Folder.

10.4 Quality & Risk Manager

10.4.1 Ensures a process is in place to finally approve reported incidents, to investigate and share learning from them, providing advice, guidance and support as necessary

10.4.2 Depending on each individual case, consider whether an incident needs to be reported externally. See Appendix K for specific requirements and responsibilities re external reporting.

10.4.3 Seeks additional information from the clinical team or reporter as required.

10.4.4 Where the incident is moderate or above, or a significant near miss the need for further local action will be considered including the use of specific investigative tools such as root cause analysis (RCA) or additional actions

10.4.5 Where the incident is severe or above, or meets the SIRI reporting criteria, identify with the local team appropriate staff to undertake a full RCA and ensure the SIRI reporting process is completed.

10.4.6 Check whether the SIRI has been escalated to the relevant Assistant Director and / or members of the Executive Team as appropriate

10.4.7 Ensure a process is in place to monitor timescales to comply with internal and external reporting requirements

10.4.8 Ensure other expertise is sought within the Trust as appropriate to ensure the incident is fully investigated.

10.4.9 Ensure monthly reports on incidents are provided to the locality teams and a summary of lessons learned and actions taken are included in the relevant reports to Trust Committees e.g. Quality & Risk Assurance Committee.

10.4.10 Reviews reported incidents and works with the Complaints & Claims Manager and Pals Lead to ensure information is aggregated and used to inform areas for improvement and shared as part of the learning events.
10.5 **Assistant / Deputy Directors - Locality, Specialist and Corporate Services**

10.5.1 Ensure appropriate senior support is available for staff to report, and investigate incidents

10.5.2 Act on escalated incidents/risks to reduce their impact as far as is reasonably practical, escalating further as appropriate and in line with the internal team and locality management structure

10.5.3 Ensure that staff involved in any investigation or undertaking an investigation are supported

10.5.4 Ensure that relevant action plans are implemented

10.5.5 Ensure that risks are added to the team and locality business unit risk register and escalated to the corporate risk register as appropriate (See Section 3: Risk Management process

10.5.6 Review reported incidents at team and locality meetings as part of the locality governance process as a standing agenda item, including finalised investigation and aggregated reports as available.

10.6 **Assistant Director, Risk Management & Information Governance**

10.6.1 Provides advice and support to the Quality & Risk Team, clinical and corporate services and executives on the management and reporting of incidents to support learning and reduce risk to the lowest possible levels.

10.7 **Executive Directors**

10.7.1 Are responsible for ensuring the teams and services within their remit are supported to report and investigate incidents in line with this policy

10.7.2 They ensure their teams and services have a process to review reported incidents and relevant aggregated reports to assess applicability to their own areas and to share the learning identified.

10.7.3 Nominated Executives take a lead role in this process including the Medical Director, Director of Quality Risk and Executive Nurse, and the Director of Operations

10.8 **Chief Executive**

10.8.1 The Chief Executive is accountable for ensuring the correct governance and reporting frameworks are in place to support effective incident reporting, investigation and management.

10.8.2 They support the processes in place to maintain patient and staff safety, to encourage staff to report and support those that do so and to ensure that investigations are thorough, fair, open and transparent to establish the root cause of events.
11. Committee Responsibilities

11.1 Quality & Risk Assurance Committee (QRAC)

11.1.1 The QRAC is the committee with the overarching responsibility for risk management and receives reports on clinical and non-clinical incidents and their management as per its workplan and terms of reference.

11.1.2 It receives reports from those committees with additional responsibilities for specific areas of risk management including but not exclusive to for example Infection Control, Medicines Management, to enable assurance to be provided to Trust Board that risks are identified, action plans monitored, risk reduction measures introduced and their effectiveness assessed.

11.2 Trust Management Team (TMT)

11.2.1 TMT reviews the learning from completed RCA reports and identifies the appropriate means to share learning across the organisation through weekly messages, team briefs and management fora.

11.3 Clinical Management Team (CMT)

11.3.1 Reviews learning from aggregated incident reports and RCA’s to identify relevance to their areas and services and any actions required to implement the learning

11.3.2 Members include this feedback in their local service and team meetings.

11.4 Locality Business Unit meetings

11.4.1 Include as part of their standing agenda items review of incidents, complaints or other reported information to identify and review risk areas and share learning from relevant investigation reports

11.4.2 They are responsible for ensuring required changes identified relevant to their services or teams are risk assessed, introduced where appropriate into their service areas and departments and appropriately monitored for effectiveness

12. Reporting to External agencies

12.1 In certain circumstances, there is a requirement to report incidents to external agencies. The responsibility to do so sits with a designated manager. The process to do so is given in Appendix K.

13. Management of an incident

13.1 For management of no harm, low harm or moderate incidents see flow chart at Appendix F
13.2 For severe or catastrophic incidents (e.g. Fractures, Severe harm incidents, those causing permanent damage, unexpected death). These are classed as Serious Incidents Requiring Investigation (SIRI's). See flow chart at Appendix G.

13.3 For management of Pressure Ulcers grade 3 or 4 acquired while in the care of NCH&C these are reported as SIRI's. See Appendix H

14. Immediate care of the affected person(s)

14.1 The immediate priority is making sure the patient or party affected is safe.

14.2 For patient errors, inform the person in charge of the ward / team / department. Seek appropriate medical advice as necessary to assess the patient’s clinical condition and likelihood of any detrimental affect on their care, or immediate action required.

14.3 Document the effect of the error (if known), any treatment necessary and any communication with the patient and their relatives in the patient’s health record, whether electronic, paper or patient held.

14.4 Moderate harm incidents or above⁵ must be notified to the patient and their family / carers as a minimum. This may need support from another appropriate senior staff member, clinician or their GP to do so.

14.5 Consider whether it may be necessary to retain any equipment involved in, or which may have contributed to, the incident (Appendix D).

14.6 Once immediate action has been taken to ensure the safety of the person involved and appropriate help sought, complete the incident form on Datix as above.

15. Additional actions that may be required by the line manager

15.1 For an incident graded as severe or above, you may be contacted directly by the person involved.

15.2 Identify with them the exact nature of the incident, the effect on the patient and their current status, any immediate actions required or taken and who has been informed so far.

15.3 Once the situation is under control or for incidents of a less serious nature, support the staff member to identify exactly ‘what’ happened and ‘why’ if known at that stage or arrange to follow up with them once they have had time to reflect.

⁵ An incident graded as moderate or above is one where harm has occurred and requires intervention, additional treatment or is likely to cause short term harm
15.4 For incidents where an investigation is required see Section 2: Investigation Process

15.5 Consideration also needs to be taken into how likely the incident is to recur. This will form the basis of what action (if any) is needed (See Section 3: Risk Management Process)

15.6 Communicate with any other relevant departments or teams involved in the incident and document this accordingly

15.7 Escalate the incident as appropriate.

15.8 Update the Incident form following completion of any actions taken

15.9 Update the Quality & Risk Manager of any additional investigation being undertaken

15.10 For incidents where harm has occurred discuss and agree with the Quality & Risk Manager whether additional support for staff or discussion with the local team or other agencies is necessary

16. **Management of a SIRI - Non Pressure ulcer**

16.1 The process of investigation followed by NCH&C is completion of a Root Cause Analysis. See Appendix I and Section 2: Investigation Process.

16.2 Compliance with timescales is monitored centrally by the Quality & Risk team and reports are included as part of the existing performance monitoring process within the Trust

16.3 Final RCA reports are provided to the Quality & Risk Assurance Committee and NHS Norfolk. Anonymised reports or themes are shared internally to promote learning and reduce the risk of similar incidents occurring wherever possible.

17. **Management of a SIRI – Pressure Ulcer**

17.1 For Management of a pressure ulcer SIRI see flowchart (Appendix H)

17.2 Pressure Ulcers Grade 3 & 4 acquired in the care of NCH&C are reported as SIRI’s

17.3 On completion of the Incident form, the locality manager is informed and identifies the appropriate member of staff to co-ordinate the investigation.
17.4 The investigation report includes as a minimum the clinical condition of the patient, any contributory factors, equipment in place or required, information regarding the nature and treatment of the pressure ulcer, actions taken and recommendations in line with the requirements of NHS Norfolk reporting process.

17.5 Compliance with timescales is monitored centrally by the Quality & Risk team and reports are included as part of the existing performance monitoring process within the Trust.

17.6 Reports are provided for the locality and team meetings, the monthly Quality & Risk report and aggregated into reports for designated committees.
18. **SECTION 2 : Investigation Process Root Cause Analysis (RCA)**

18.1 Appendix I provides a flowchart to describe the process used to carry out a level 2 RCA.

18.2 Appendix J gives the contributory factors to be considered when undertaking an investigation.

18.3 Appendix N provides a copy of the NPSA Incident Decision Tree to assist managers to identify required actions following completion of an investigation.

18.4 The Root Cause Analysis (RCA) is a structured investigation which aims to identify the true cause of a problem and the actions that are necessary to either eliminate or significantly reduce the risk.

18.5 An RCA investigation will be completed for all SIRI’s. The decision to undertake a root cause analysis for incidents not reportable as SIRI’s will be taken by the Quality & Risk Manager in discussion with local teams and managers if it is felt that this would support learning from commonly reported events, near misses or incidents identified through aggregated analysis.

18.6 A concise RCA may be carried out for certain SIRI’s eg Pressure Ulcers or in the event of near misses. The purpose of the concise RCA is to assist in departmental and organisational learning. Concise RCA’s will be managed locally with support from the Quality & Risk Manager as appropriate. Action plans developed following a concise RCA will be monitored locally by the locality business unit meetings but monitored centrally by the Quality & Risk team to share learning.

18.7 Progress against action plans are monitored locally and reported back to QRAC.

18.8 For non serious incidents, line managers are responsible for determining any action plans, documenting these on the incident form, and discussing at the local team meetings and adding to the risk register if appropriate.

18.9 The level of the investigation is triggered by the degree of harm experienced by the patient. This is in line with the first stage of assessing the consequence of the event.

18.10 NCH&C follows the guidance of the NPSA in the approach to investigation to ensure this is carried out at a level appropriate and proportionate to the incident, claim, complaint or concern under review using a Root Cause Analysis technique.
19. Levels of Investigation

<table>
<thead>
<tr>
<th>Level 1 – Concise investigation</th>
<th>Level 2 – Comprehensive investigation</th>
<th>Level 3 – Independent investigation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Most commonly used for incidents, claims, complaints or concerns that resulted in no, low or moderate harm to the patient.</td>
<td>• Commonly conducted for actual or potential ‘severe harm or death’ outcomes from incidents, claims, complaints or concerns.</td>
<td>As per Level 2, but in addition: • Must be commissioned and conducted by those independent to the provider service and organisation involved.</td>
</tr>
<tr>
<td>Also useful as an executive summary to communicate findings from full, comprehensive or independent investigation reports, following actual or potential ‘severe harm or death’ outcomes.</td>
<td>• Conducted to a high level of detail, including all elements of a thorough and credible investigation. • Includes use of appropriate analytical tools (e.g. tabular timeline, contributory factors framework, change analysis, barrier analysis).</td>
<td>• Commonly considered for incidents, claims, complaints or concerns of high public interest or attracting media attention.</td>
</tr>
<tr>
<td>• Commonly involves completion of a summary or one page structured template.</td>
<td>• Normally conducted by a multidisciplinary team, or involves experts/expert opinion/independent advice or specialist investigator(s). • Conducted by staff not involved in the incident, locality or directorate in which it occurred.</td>
<td>• Conducted for mental health homicides which meet Department of Health guidance.</td>
</tr>
<tr>
<td>• Includes the essentials of a thorough and credible investigation, conducted in the briefest terms.</td>
<td>• Overseen by a senior manager, director or facilitator.</td>
<td>• Should be conducted where Article 2 of the European Convention on Human Rights is, or is likely to be, engaged.</td>
</tr>
<tr>
<td>• Involves a select number of RCA tools (e.g. timeline, 5 why’s, contributory factors framework).</td>
<td>• Led by person(s) experienced and/or trained in RCA, human error and effective solutions development.</td>
<td></td>
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<tr>
<td>• Conducted by one or more people (with a multidisciplinary approach if more than one investigator).</td>
<td>• Includes patient/relative/carer or may link to independent representation or advocacy services.</td>
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<tr>
<td>• Often conducted by staff local to the incident ward/department.</td>
<td>• May require management of the media via the organisation’s communications department.</td>
<td></td>
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<tr>
<td>• Should include person(s) with knowledge of RCA, human error and effective solutions development.</td>
<td>• Includes robust recommendations for shared learning, locally and/or nationally as appropriate.</td>
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</tr>
<tr>
<td>• If a patient is directly effected, they/relative/carer should be involved.</td>
<td>• Includes a full report with an executive summary and appendices.</td>
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<tr>
<td>• Includes plans for shared learning – locally and/or nationally as appropriate</td>
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</tr>
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</table>

Examples of Concise report

<table>
<thead>
<tr>
<th>Examples of Comprehensive Investigation</th>
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</thead>
<tbody>
<tr>
<td>Pressure ulcer RCA</td>
</tr>
<tr>
<td>Unexpected death</td>
</tr>
<tr>
<td>Fracture, serious harm event</td>
</tr>
</tbody>
</table>

Example of Independent Investigation

<table>
<thead>
<tr>
<th>Example of Independent Investigation</th>
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<tbody>
<tr>
<td>Death in Custody</td>
</tr>
<tr>
<td>Safeguarding death</td>
</tr>
<tr>
<td>Professional practice issues</td>
</tr>
<tr>
<td>High profile incidents as required</td>
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<tr>
<td>by the SHA</td>
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</tbody>
</table>
19.1 In the event of a Level 2 investigation being required, named staff who have completed RCA training will co-ordinate the investigation.

20. **Duties of staff in respect of RCA investigations**

20.1 All staff involved in an incident requiring investigation are required to participate in the investigation. This may be through providing information to the investigator regarding the timing or sequence of events, provision of a written account of the events as they observed them, or attending investigation meetings.

20.2 Managers of staff involved have a responsibility to ensure those staff are supported by themselves and their colleagues. The aim of the investigation is to identify the facts of an event not to blame or punish.

20.3 The Quality & Risk Manager is responsible for ensuring staff have been identified to undertake investigations, have received appropriate training, using a buddy system for support where appropriate and delivering training.

20.4 The Patient Safety & Compliance Manager is responsible for supporting staff locally and undertaking Root Cause analysis with teams.

20.5 The Assistant Director for Risk Management & Information Governance is responsible for ensuring the Training Needs Analysis is updated annually, that training sessions are advertised to staff through the training team process and that staff attend prior to undertaking an RCA.

20.6 Monitoring attendance and follow up is by the training department.

20.7 Executive directors are responsible for ensuring that completed RCA’s are shared through their governance process across their localities and departments.

20.8 The Director of Quality & Risk and Executive Nurse, Medical Director and Director of Operations are responsible for ensuring the learning from RCA’s are incorporated into the quarterly learning events as appropriate and shared with relevant external agencies.

20.9 This includes, NHS Norfolk through the SIRI process and review of completed reports; with the SHA as part of performance review meetings; internally at the management forum and with key learning points to staff through weekly messages.

20.10 Summarised learning is included in external reports such as the Quality Account and received internally by the Quality & Risk Assurance Committee once finalised.
20.11 Following each RCA, an action plan will be agreed by the local team with their relevant Assistant Director. The action plan will state the agreed course of action to manage the risk, who is responsible for leading on this work and the process to provide updates and the frequency at which this will occur on progress against the action plan. Wherever possible this will be to an established committee or designated group depending on the nature of the incident being investigated.

20.12 The RCA process is about finding facts and the root cause of an event. Senior Managers and investigators must ensure that the process is fair, thorough and transparent.

20.13 The Incident Decision Tree is given at Appendix N to assist in decision making once the full facts, contributory factors (Appendix J) of the event are known and the investigation is complete.

20.14 Depending on the nature of the incident it may be in the staff members best interests to consider with them whether a change of work location is appropriate while the investigation is carried out. Advice must be sought from the relevant Director and Personnel before this decision is made to ensure that any such act is not seen as blaming the individual(s) concerned or pre empting the investigation.
21. **Section 3: Risk Management Process**

21.1 Appendix L provides an example of the Risk Register template

21.2 Appendix M provides guidance on assessment of the consequence of a range of incident types and scenarios

22. **Risk Management System and Tools**

22.1 The risk management process ensures that all types of risk are assessed systematically and that common tools are used to record, assess, document and report incidents and risks regardless of the source or type of risk.

22.2 These include the use of the web based Datix system to report, grade and manage incidents;

22.3 A 5x5 matrix to assess likelihood and consequence when assessing the outcome of an incident or identified risk;

22.4 The use of the same matrix and scoring when undertaking risk assessments and to record the scores and level of risk;

22.5 The use of the common risk register template to record risk assessments and actions required. This is aligned with the Corporate Risk Register and Board Assurance Framework format to facilitate the escalation process.

22.6 The use of the grading and prioritisation system of the 5x5 matrix to assess the original risk rating and residual risk levels

22.7 The assessment of the degree of harm as a result of the outcome of an incident using clinical judgement where appropriate and a common language to describe this

22.8 The same assessment process is used by staff to update their risk registers and monitor actions identified as part of the risk assessment, investigation or service review process.

22.9 It ensures local risk registers are linked to the corporate risk register and Board Assurance framework through a process of escalation and risk assessment to identify controls, assurance and any deficits in resilience.

22.10 Provision of a common format supports consistency of scoring and understanding of what the different levels or scores mean and required actions regardless of what is being assessed
22.11 This ensures that a systematic and continuous approach is taken to assessing risk across NCH&C at all levels of the organisation.

23. **Risk Scoring**

23.1 The 5x5 matrix is used when assessing the severity of the risk of an actual event or any potential or near miss eg an incident reported on Datix and the outcome for the patient or person affected.

23.2 The same method is used when assessing the risk of a potential event, a risk identified for inclusion on the risk register or for any other type of risk eg reputational, financial.

23.3 Using the 5x5 matrix the likelihood of the risk or incident occurring is assessed against the impact or consequence if it does. This produces a risk score and grading.

23.4 For a potential risk or one that nearly happened, the risk is scored for its potential impact and likelihood of occurring again.

23.5 The grading provides guidance on the action required.

23.6 The score assists in prioritising risks and actions in the event of several risks graded the same.

23.7 Incidents which are graded as High or above, trigger the investigation process (See Section 2).

23.8 This enables a baseline level of risk to be identified and enables regrading to occur where appropriate, based on review of the effectiveness of the control identified to mitigate and manage the risk.

24. **Risk Matrix**

The Risk matrix used in NCH&C is given below.
25. **Assessment of the Level of Harm**

25.1 The assessment of level of harm is based on the outcome for the patient.

25.2 This is assessed as no harm, low harm, moderate harm or severe harm.

25.3 Additional guidance to assist in the assessment of harm is available from the Quality & Risk Manager and included in staff training sessions to support clinical judgement.

25.4 Examples of the potential impact of an incident in different situations including non-clinical incidents are given in Appendix M.
26. **Risk Assessment**

26.1 Minimising risk requires the hazard to be identified, the risk assessed and a decision to be taken as to what control is required to mitigate that risk.

26.2 Risk assessments are a fundamental part of the process to identify the level of risk by assessing the likelihood of an event occurring and the impact if it does.

26.3 They are used to inform decisions about the required actions to be implemented to control, reduce and mitigate the effect of the risk to its lowest level possible.

26.4 The use of a standardised tool across NCH&C ensures that a systematic approach to all risk assessments is followed regardless of the type of risk being assessed and whether the risk is operational or strategic.

26.5 It provides a consistent means for clinical and corporate staff to identify the key areas of risk which need to be incorporated into their risk registers, financial plans or into the business planning cycle.

26.6 This may include change to any of the following: Trust procedures, environmental, financial, health and safety or the introduction of a new service or process.

26.7 They may be required following a specific event to assess the degree of risk posed to patients, staff or the Trust and may be internally or externally driven.

26.8 They must be documented to assist in assessing the action required. This may be by using a designated risk register, the Datix risk management module or in report format if this is more appropriate to the forum in which the assessment is to be considered.

26.9 As a minimum, the risk assessment must include a description of the risk, the source of the risk, the likelihood of the risk occurring and the impact if it did.

26.10 It must include the date the risk assessment took place and any subsequent review date and the current controls or assurance process in place and where there are gaps.

26.11 Where appropriate, consideration of resource and reputational risk should be included and actions being undertaken or required to reduce the gaps and make controls more robust.

26.12 Risk assessment is most effective when undertaken using a multidisciplinary approach wherever possible or as part of a team meeting.
26.13 This ensures the risk can be considered for its broadest effect on the service, department, stakeholders etc, and documented on the risk register.

26.14 It assists in identifying whether escalation is required to ensure the risk is considered at the appropriate level in the Trust.

27. **Roles & responsibilities of risk assessment**

27.1 It is the Head of Service, ward, team or department manager’s responsibility to ensure that risk assessments relevant to their services are undertaken and risks to patients, staff and others are reduced to acceptable levels. This includes clinical and non clinical e.g. COSHH, and statutory risk assessments.

27.2 It is the responsibility of locality managers to ensure that these risk assessments and any subsequent action plans are reviewed systematically as part of the documented internal governance structure in place within the locality and escalated as appropriate.

27.3 It is the responsibility of the Assistant Directors to consider potential risks for escalation to the Corporate Risk Register.

27.4 It is the responsibility of the Operational Managers Group to review the Corporate Risk Register and escalated risks to ensure the grading, content and controls to reduce the risks are appropriate and working and to escalate to the BAF in line with the escalation process.

27.5 It is the responsibility of the Trust Secretary to ensure risks escalated from the Corporate Risk register are put forward for inclusion in the Board Assurance Framework.

27.6 It is the responsibility of the Executive Director Team to review the risks put forward for inclusion in the Board Assurance Framework to be presented to Trust Board to ensure that grading, controls and any actions identified are appropriate, and monitored.

28. **Actions required following risk assessment**

28.1 Risks identified with a residual risk score up to 8 are documented on the local risk register. These need to be kept under review by the local team.

28.2 Risks identified with a residual risk score up to 12 are documented on the local risk register and put forward for inclusion in the Locality Business Unit Risk Register. They are discussed at the Locality Business unit meeting.
28.3 Risks identified with a residual risk score of above 12 are reviewed for inclusion in the Corporate Risk register by the locality Assistant Director and the Operational Managers Group.

28.4 Risks identified as having a residual risk score of 15 or above are reviewed for inclusion in the Board Assurance Framework.

28.5 Even after all safety measures have been implemented, some risk usually remains.

28.6 The aim is to implement additional measures to reduce the risk to ‘Low’ as far as possible or practicable.

28.7 This may require specific action which must be documented on the risk register and updated and reviewed monthly to assess whether they are working.

28.8 Where deficits continue these risks must be escalated as described below.

29. Management of Risk Registers

29.1 Purpose of Risk Registers

29.1.1 The Risk Register provides a means to identify and prioritise the principal risks that may affect either service delivery or the environment in which services are delivered. In this way they are applicable to every clinical, non-clinical and corporate unit or department.

29.2 Local Risk Registers

29.2.1 Local Risk registers are made up of the key reported events for each unit or department and any specific issues of concern affecting local service delivery or business continuity. They are maintained and updated by the clinical unit or local department, and monitored by the locality managers.

29.2.2 A risk identified for inclusion in the register may be from any source eg internal or external factors, adverse events, complaints, claims, audits, resource issues both staffing and/or financial or by potential changes to other services within the organisation.

29.2.3 It could be as a result of a trend following analysis of reported incidents, or something which may affect service delivery or the ability of the unit or department to meet the Trust objectives. Prior to inclusion in the register, it must be agreed with the head of service to ensure the risk has been assessed appropriately and controls identified to mitigate it.
29.2.4 Risks escalated to the locality business unit register are approved by the Assistant Director before including to ensure appropriate controls are in place and the risk has been assessed and is monitored appropriate.

29.2.5 Risks scored as having a residual risk of 8 or above are escalated for consideration in the locality risk register.

29.3 Corporate Risk Register

29.3.1 The Corporate Risk Register is an assimilation of the locality and department risk registers, and is held and updated by the Quality & Risk Team.

29.3.2 Risks with a residual risk score of 12 or above are discussed at the Operational Managers Group to check scoring, assess the risk, ensure the risk is described accurately and identify those for inclusion in the corporate risk register or further escalation to the Board Assurance Framework.

29.3.3 Where risks are identified as not for escalation these are still held on the locality risk register and reviewed monthly to identify those which may require escalation at a later date.

29.3.4 The high risks with a residual risk score of 15 and above from the Corporate risk register and any additional strategic risks are themed and escalated into the Board Assurance Framework.

29.3.5 The Corporate Risk Register is reviewed by the Trust Management Team monthly.

29.4 Board Assurance Framework (BAF)

29.4.1 The Board Assurance Framework (BAF) identifies the principal risks to the Trust achieving its objectives and is managed by the Trust Secretary.

29.4.2 Risks identified on the BAF are subject to review monthly by designated committees and to the assurance committees and Trust Board in line with their workplans.

29.4.3 Where any difficulty in mitigating risk occurs at local or operational level, these are escalated to the relevant Executive Director or their deputy.

29.4.4 If no alternative means to control the risk is identified, unmitigated high risks are escalated to the Executive Team and raised with Trust Board through the BAF in line with the Escalation and Assurance Policy to assess whether a risk is to be accepted but kept under constant review.
29.4.5 Risk management and quality issues are a standing item on meeting and committee agendas to support systematic review of risks including those on the risk registers.

29.4.6 Information to inform this process for clinical, non-clinical risk, complaints, and audit is supplied by the Quality & Risk Manager.

29.4.7 Compliance with the required frequency of risk review is a performance indicator and is monitored by the Assistant Director for Risk Management & Information Governance.

30. **Managing Communications with the Media and other External Agencies**

30.1 Incidents will, on occasion, attract media attention. Any media representatives arriving on NCH&C property must be referred to the Communications team and the Director of Operations or their deputy informed. Out of hours the on call manager is informed.

30.2 No member of NCH&C staff must communicate with the media before receiving explicit instructions from the Communications Team. This is to ensure that in the early stage of an incident, regardless of source, when facts may not be known, it is important that a clear and consistent message is given.

30.3 Any press statements will be written and communicated by NCH&C’s Communications Team. No media statements will be made before informing affected or closely involved individuals.

30.4 As NCH&C has a number of joint services/partnership arrangements the Communications and Executive team liaises closely with any other stakeholders at Director and Head of Communications level. The aim will be to ensure that any press releases or press statements are co-ordinated and that any joint messages are agreed.

30.5 The Quality & Risk Manager, Locality Assistant Director, Service lead and relevant Director together with NCH&Cs Communications Team will ensure that appropriate communications occur with other organisations, trusts or agencies involved in patient care, including the Strategic Health Authority and any statutory bodies such as the NPSA or Care Quality Commission.

31. **Establishing a Hotline**

31.1 Depending on the nature of the incident, a telephone hotline may need to be established for a large scale or high profile incident or issue of patient safety which will impact on patients / patient services and raise questions of public concern.
31.2 There may be some warning that a hotline will need to be established eg as a result of a government report due to be published relevant to NCH&C services; as a result of a known serious adverse clinical event e.g. where harm has occurred to a patient; as a result of personnel queries or practitioner practice; or in the event of a known threat e.g. infectious outbreaks or pandemics.

31.3 This will be agreed by the Chief Executive or Lead Executive director, with support by the Communications team.

31.4 The aim of the hotline is to provide clear and consistent information as a result of an adverse event or issue of patient safety which will impact on patients / patient services and will raise questions of public concern.

31.5 This information may be provided for:

31.6 Patients and /or families, carers, staff directly affected

31.7 Other patients and members of the public who may be concerned

31.8 Others working in the NHS or with the NHS

31.9 Provide direct advice or make appropriate referral to expert advice for patients and/or families and NHS staff directly affected or concerned

31.10 Sign post or reassure people who are concerned or distressed about a health issue not related to the event

32. **Examples of when a hotline may be required**

32.1 A hotline may be needed for any high profile incident including where:

32.1.1 the death of one or more persons has occurred

32.1.2 the event is likely to cause national adverse publicity

32.1.3 there is a high risk of litigation occurring

32.1.4 the event has a risk of huge financial loss/ reputation to the organisation or its staff

32.2 The responsibility for deciding to establish a hotline rather than use existing services rests with the Executive Team, and informed by the Comms team. The decision will be based on:

32.2.1 the nature of the incident

32.2.2 the potential number of multiple enquiries which are anticipated

32.2.3 the length of time a hotline may need to be available
32.2.4 the resource implications required.
32.2.5 whether the event requires multi agency or multi organisational involvement

32.3 A core group of staff will be established to take calls to ensure that the correct expertise is available and to keep disruption of normal service delivery to a minimum.

32.4 This group will retain management responsibility for the hotline with direct reporting to the Chief Executive and Executive team.

32.5 Additional staff may be added to the group if appropriate and depending on the nature of the incident.

32.6 A system to record contacts will be used in case the event requires further follow up with the caller.

32.7 The Executive team will agree the information to be given, will be consistent and in line with any press statements and reviewed on a daily basis or more frequently if necessary, depending on the nature of the event eg flu or similar pandemic.

32.8 The hotline will be located through from switchboard to a central contact point. This may be within existing offices of the staff allocated to respond to external queries or within the most appropriate alternative area of the Trust eg Elliot House or Woodlands House

32.9 Depending on the number of calls received, arrangements may be needed to increase the number of lines available at short notice or to establish an ‘0800’ number via BT. This responsibility will lie with the Executive team in liaison with NHS Norfolk and / or the SHA relevant press offices.

32.10 Depending on the nature of the incident and the number of queries, press, public or national interest, briefings will occur between the Executive team and those staff designated to receive enquiries, and the Communications team and external stakeholders.

32.11 If the hotline needs to be activated as a result of an internal event eg as a result of a known serious patient safety incident, or as a result of queries regarding a certain practitioner or practice by a member of NCH&C staff, the Communications team will advise on the best way to advertise the contact process and how information can be obtained.

32.12 This process will be supported by NHS Norfolk and the SHA to ensure where escalation is needed to other Health agencies eg Department of Health, that this occurs in a managed way.
32.13 A lead will be identified at local level, by the Director of Operations to co-ordinate any local response. Information internally will be provided by means of targeted Trust wide email to be cascaded to staff, patients and carers as necessary, once the Executive team has assessed the situation.

32.14 This will identify contact sources for internal and external enquiries, which may need to include postal as well as electronic means. The level of action taken will be agreed by the Executive team based on an assessment of the type of incident and its possible affect on public confidence in NCH&C.

33. Process for monitoring compliance with this policy

33.1 The following aspects of this policy are monitored as follows and reported to locality, team meetings and the identified committees as indicated below.

<table>
<thead>
<tr>
<th>What</th>
<th>When</th>
<th>How</th>
<th>By</th>
<th>Reported to</th>
<th>Assurance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compliance with duties relating to completing incident forms eg time</td>
<td>Annual</td>
<td>Audit</td>
<td>Risk Manager</td>
<td>Locality meetings</td>
<td>QRAC</td>
</tr>
<tr>
<td>between event and report</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Compliance with reporting incidents internally and content eg trends</td>
<td>Monthly</td>
<td>Datix report</td>
<td>Risk Manager</td>
<td>Locality team / service</td>
<td>QRAC</td>
</tr>
<tr>
<td>in levels of incident reporting, by service, location, staff group,</td>
<td></td>
<td></td>
<td></td>
<td>meetings</td>
<td></td>
</tr>
<tr>
<td>key themes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Compliance with SIRI reporting timescales internally and externally</td>
<td>Monthly</td>
<td>Monitoring</td>
<td>Risk Manager</td>
<td>Quality &amp; Risk Report</td>
<td>QRAC</td>
</tr>
<tr>
<td></td>
<td></td>
<td>report</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Compliance with SIRI report content and learning identified</td>
<td>On completion of each 45 day report</td>
<td>Report audit</td>
<td>Risk Manager</td>
<td>Trust Management Team</td>
<td>QRAC</td>
</tr>
<tr>
<td>Compliance with SIRI report content ( short /7day reports)</td>
<td>Quarterly</td>
<td>Audit</td>
<td>Risk Manager</td>
<td>Trust Management Team</td>
<td>QRAC</td>
</tr>
<tr>
<td>Use of Whistleblowing policy</td>
<td>Annual</td>
<td>Report from</td>
<td>HR</td>
<td>EDT</td>
<td>QRAC</td>
</tr>
<tr>
<td></td>
<td></td>
<td>HR team</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Learning identified from SIRI’s and aggregated analysis documented | Quarterly | Monitoring report | Risk Manager | Non Executive Director Meeting | QRAC
---|---|---|---|---|---
Use of themes and aggregated analysis in learning events | Quarterly | Evidence of attendance | Risk Manager | Trust Management Team | QRAC
Receipt of reports by designated committees at local and corporate level | Annually | Audit | AD Risk | Trust Management Team | QRAC
Documented local structure for decision making, governance and risk management in pace with evidence of risk discussion and assessment | Annually | Audit | AD Risk | Trust Management Team | QRAC
Link between local risk registers, corporate risk register, BAF | Annually | Audit | AD Risk External auditors | QRAC Audit Committee | Trust Board

### 34. Training

#### 34.1 The Quality & Risk Team provides training on risk management and incident reporting to all staff including the process to report and investigate SIRI’s. (See Risk Management Training Policy).

#### 34.2 All new staff receive training as part of their local and corporate induction.

#### 34.3 Additional training is provided for Board members, senior managers with specific roles or those who may be required to lead or undertake investigations as identified in the Training Needs Analysis.

#### 34.4 All training undertaken and attended is recorded locally and on the central training database and non attendance reported by the Learning Education & Development Team through the performance reporting system.

#### 34.5 Non attendance or failure to complete training is monitored centrally and followed up as per the Mandatory Training Policy.
## Appendix A: Examples of Incidents to be reported

<table>
<thead>
<tr>
<th>Access, Admission, Transfer, Discharge</th>
<th>Accident</th>
<th>Abuse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discharge, Self discharge, Lack of / delayed availability of beds, Transfer, Transport, Admission.</td>
<td>Contact with electricity, Exposure to harmful substance, Exposure to Radiation, Exposure to Asbestos, Moving &amp; Handling, Display Screen Equipment issues, Struck by Falling object, Contact with hot / cold, Road Traffic Accident, Slip, Trip, Fall, Contact with Furniture Fittings.</td>
<td>Verbal, Physical assault, Racial Harassment, Sexual Harassment, Bullying.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Children’s Safeguarding</th>
<th>Community</th>
<th>Communications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Failure to follow Children’s Safeguarding Protocol</td>
<td>Dog / household pets, Unhygienic environment, Unsafe environment Inadequate support, Delay / failure to provide social care, Delay / failure of care agency to provide care. Delay / failure of voluntary agency to provide care.</td>
<td>Failure to follow up missed appointment, Appointment recording error, Referral within NCHC With external agencies.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Clinical Assessment and Treatment</th>
<th>Consent &amp; Documentation</th>
<th>Equipment issues</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allergic reaction, Delay / difficulty in obtaining clinical assistance, Delay obtaining bleep holder or on-call staff, Diagnosis, Treatment, Patient incorrectly identified, Blood Transfusion error, Scans, X rays, Specimens, Test request form, Undertaking of Tests, Test results / report, Pressure Ulcer, Resuscitation.</td>
<td>Not obtained for that procedure, Incomplete, Not requested, Not received, Not fully understood, Withheld.</td>
<td>Bleep system failure, Failure of device / equipment, Delay / failure to provide equipment to user, Lack Unavailability of device / equipment, User error of device / equipment, Wrong device or equipment used, Inadequate check on equipment / supplies, Failure to maintain equipment, Failure / delay in collection / delivery systems, Funding Issues.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>IT issues</th>
<th>Infection Control</th>
<th>Information Governance Issues</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Medication</th>
<th>Organisational issues</th>
<th>Security issues</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescribing, Dispensing and</td>
<td></td>
<td>Lone Worker issue, Staff location</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Literature Review</th>
<th>Literature Review</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>supply</td>
<td>Environmental issue, Flooding Oil Pollution, Effluent Pollution, Food issue, Service failure (Lighting / Power / Heating), On-call systems failure.</td>
</tr>
<tr>
<td>------------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Administration, Monitoring and Follow up, Medicine Storage and Security, Admission/Transfer Issue.</td>
<td>Service User issues</td>
</tr>
<tr>
<td>Service User issues</td>
<td>Failure to recognise deterioration of patients condition, Death - Unexpected or Suspicious, Death – Suicide, Suicide attempted Issue concerning Patient Privacy / Dignity, Alcohol / illegal drugs used, Chaperone issues, Patient Self Harm, Sudden onset of illness, deterioration</td>
</tr>
<tr>
<td>Staff</td>
<td>Inadequate levels, Inadequate skills mix, Concern over competence, Inadequate supervision. Acting beyond scope of practice, Alcohol/illegal drug issue.</td>
</tr>
<tr>
<td>Surgical / Theatre issues</td>
<td>Theatre list details incorrect, Late amendments to list, Incomplete pre-operative preparation of patient, Tourniquet problem, Operation site wrongly marked, Wrong operation performed, Incorrect swab or instrument count, Deep vein thrombosis no prophylaxis, Unplanned return to theatre, Unexpected acute admission.</td>
</tr>
</tbody>
</table>
Appendix B: Examples of Serious Incidents to be reported (SIRI’s)

A serious incident requiring investigation is defined as an incident that occurred in relation to NHS-funded services and care resulting in one of the following:

1. Unexpected or avoidable death of one or more patients, staff, visitors or members of the public

2. Serious harm to one or more patients, staff, visitors or members of the public or where the outcome requires life-saving intervention, major surgical/medical intervention, permanent harm or will shorten life expectancy.

3. Where the outcome is prolonged pain or psychological harm including incidents graded under the NPSA definition of severe harm e.g. Fracture, wrong blood transfusion.

4. Grade 3 & 4 Pressure ulcers acquired in the care of NCH&C services

5. Medication errors resulting in death or severe harm

6. A scenario that prevents or threatens to prevent NCH&C’s ability to continue to deliver healthcare services, for example, actual or potential loss or damage to property, reputation or the environment, information loss, or systems/utility failure. This may also need reporting to CQC.

7. Allegations of abuse – consideration should also be given Adult Safeguarding and Child Protection incidents.

8. Security incidents including fraud

9. Adverse media coverage or public concern about the organisation or the wider NHS

10. One of the core set of ‘Never Events’ as defined by the National Patient Safety Agency

11. Healthcare Associated Infections (HCAIs), specifically:

   11.1. Outbreaks of healthcare associated infection (this includes the presumed transmission within a hospital and causes significant morbidity, mortality and/or impacts significantly on hospital activity)

   11.2. Infected healthcare workers (incidents which necessitate consideration of a look back exercise)

   11.3. Breakdown of infection control procedures and/or serious decontamination failures with actual or potential for cross infection and other high profile incidents.
12. Grade 3&4 pressure ulcers acquired outside the care of NCH&C are reported through the Safeguarding route (See Safeguarding Policy)

13. Information Governance incidents with a Level of severity 1 - 5

2. Security Event SIRI’s

2.1 Security events are reported through the Security Incident Reporting System (SIRS) using the Datix online form. The intention is to ensure that NHS staff and property are adequately supported and that security events are identified and managed appropriately.

2.2 The following security incidents that must be reported include:

2.2.1 Any security event involving physical assault of NHS staff

2.2.2 Non-physical assault of NHS staff (including verbal abuse, attempted assault and harassment)

2.2.3 Theft or criminal damage (including burglary, arson, and vandalism) to NHS property or equipment (including equipment issued to staff)

2.2.4 Theft or criminal damage to staff or patient personal property, damage to Trust property
Appendix C: Never Events

1.1 Never Events are serious, largely preventable incidents that should not occur if the available preventive measures have been implemented. These are updated annually and are based on the National Patient Safety Agency (NPSA) guidance.

1.2 Those Never Events identified as relevant to NCH&C services currently include:
   - 1.2.1 wrong-site surgery;
   - 1.2.2 wrong implant or prosthesis
   - 1.2.3 retained foreign object post-operation;
   - 1.2.4 wrongly prepared high-risk injectable medication
   - 1.2.5 maladministration of Potassium containing solutions
   - 1.2.6 wrong route administration of chemotherapy
   - 1.2.7 wrong route administration of oral/enteral treatment
   - 1.2.8 intravenous administration of epidural medication
   - 1.2.9 maladministration of insulin
   - 1.2.10 overdose of midazolam during conscious sedation
   - 1.2.11 opioid overdose of an opioid naïve patient
   - 1.2.12 inappropriate administration of daily oral methotrexate
   - 1.2.13 inpatient suicide using non-collapsible curtain or shower rail
   - 1.2.14 falls from unrestricted windows
   - 1.2.15 entrapment in bed rails
   - 1.2.16 transfusion of ABO incompatible blood components
   - 1.2.17 misplaced nasogastric or orogastric tube
   - 1.2.18 wrong gas administered, or failure to administer gas through designated gas pipeline or connected directly to a portable gas cylinder
   - 1.2.19 failure to monitor and respond to O2 saturations
   - 1.2.20 air embolism introduced during intravascular infusion / bolus administration
   - 1.2.21 Misidentification of patients
   - 1.2.22 Severe scalding of patients

If a never event occurs, these are investigated using a full RCA Level 2 investigation and are reported as SIRI’s.
Appendix D: Reporting harm or near miss Incidents where equipment is involved

1.1 Basic Principles

The following basic principles are taken from the guidance given by the Medical Devices Directorate at the Department of Health (Doing No Harm, 1994). It is the responsibility of ward / department managers to ensure that these principles are observed:

In the event of equipment being involved in a harm or near miss incident:

1. Ensure the patient is safe and assistance sought as necessary
2. Complete an incident form and include full details of the equipment (e.g. serial number, batch number, settings if applicable);

Preservation of equipment

1. Keep the device involved in the incident, including packaging and instructions, where appropriate - if it is a machine eg an infusion pump, ensure that all settings at the time of the incident are documented but try to leave all switches and controls as they were at the time of the incident, unless they have to be changed to make them safe;
2. Do not return the device to the manufacturer, before it is examined by an appropriate person e.g relevant contracted EBME department.
3. If the item is part of a batch, check the remaining stock and ask if the defect has arisen due to faulty storage. The batch may need to be withdrawn.
4. Consider whether the equipment needs to be retained as part of any investigation as to why the incident may have occurred.
5. Situations may occur where staff feel that the equipment cannot be removed from the ward or decontaminated before investigation. Advice must be sought from the Risk Manager in the first instance or on call manager out of hours.
6. Disposable devices involved in an incident which may be needed as part of an investigation will be sent for decontamination but appropriately marked for return
7. Follow up may include contacting the manufacturer and reporting the defect to the MHRA through the NRLS system.
Appendix E: Management of Information Security Incidents

An information security event is an identified breach of information security policy, failure of safeguards or an unexpected event which could lead to business disruption, loss emergency or crisis. (See Information Governance Policy).

1. Definition of an IG SIRI

1.1 Any incident involving the actual or potential loss of personal information that could lead to identity fraud or have other significant impact on individuals e.g. incidents relating to breaches of confidentiality involving person identifiable data and data loss. This includes information thought to have been lost both internally or externally to the Trust.

1.2 This applies irrespective of the format in which the information was held and includes the loss of data held in both electronic and paper media.

1.3 Incidents with a Severity of loss level of 1-5 (see 4.1) should be reported as a SIRI.

2. Action required on identifying the loss or potential loss

2.1 The following is assessed as a minimum:

2.2 Nature of the loss- Theft, accidental loss, inappropriate disclosure, procedural failure etc.

2.3 The number of patients / staff (individual data subjects) involved

2.4 The number of records involved

2.5 The media (paper, electronic) of the records

2.6 If electronic media, whether encrypted or not

2.7 The type of record or data involved and sensitivity

2.8 Where and when it was lost

2.9 Whether the information could damage the reputation of an individual, a work-team, an organisation or the NHS as a whole

2.10 Whether there are legal implications for the trust

3. Rating the severity of the Loss

Incident Reporting, Investigation & Management Policy
NCH&C

ver 3.0 March 2012
3.1 All incidents must be rated according to the scale below as this assists in identifying the required action.

<table>
<thead>
<tr>
<th>Incident Rating</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No significant reflection on any individual or body. Media interest very unlikely.</td>
</tr>
<tr>
<td>1</td>
<td>Damage to individuals reputation. Possible media interest e.g. celebrity involved.</td>
</tr>
<tr>
<td>2</td>
<td>Damage to a team’s reputation. Some local media interest that may not go public.</td>
</tr>
<tr>
<td>3</td>
<td>Damage to an organisation’s reputation/local media coverage.</td>
</tr>
<tr>
<td>4</td>
<td>Damage to NHS reputation/national media coverage.</td>
</tr>
<tr>
<td>5</td>
<td>Serious breach of confidentiality e.g. up to 100 people affected.</td>
</tr>
</tbody>
</table>

3.2 Incidents where the loss of data affects over 100 people must be reported to the Information Commissioner. This is done by the Information Governance Lead. In addition the Executive Director team, Caldicott Guardian, SIRO and communications team are informed and NHS Norfolk as part of the SIRI reporting process.

3.3 For the management of Information Technology incidents, see the IT Security Policy.

4. Actions required

4.1 For incidents where person identifiable data is lost the following process must be followed by all staff.

<table>
<thead>
<tr>
<th>Who</th>
<th>Action required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Person identifying loss</td>
<td>Inform Line manager immediately. Provide details of type of information source e.g. paper, electronic, email, fax, safestick, laptop and content if known. Include any additional information e.g. encryption, password protected information. Out of hours inform Tier 1 manager. Complete incident form giving initial details of loss, type and content of data and action taken to date once manager has been informed.</td>
</tr>
<tr>
<td>Line Manager</td>
<td>Assess scope of loss using the severity table given in 3 above to assist you N.B. The content or nature of the information may make the incident severe, not just the number of individuals affected. If in doubt obtain advice from the Information Governance Lead (IGL). Ensure they have been informed of the loss within 24 hours or by the next working day. Once confirmed that personal or sensitive data is involved, supports local investigation and staff involved, work with Communications Team to contact individuals whose data has been lost. Ensure learning from any subsequent investigation is shared within local team.</td>
</tr>
<tr>
<td>IG Lead</td>
<td>Assess with the line manager content and volume of loss identified if known and severity rating. If volume or content of data in doubt or...</td>
</tr>
</tbody>
</table>
unknown, treat as a serious breach until confirmed. Inform relevant Executive Director, SIRO and Caldicott Guardian. Inform external agencies on identification of the breach including ICO office as appropriate. Act as contact point for external agencies if required. Inform Risk Manager of Serious Incident occurrence. Oversee and monitor progress of any investigation.

| Risk Manager | Co-ordinate and support investigation using Root Cause Analysis techniques to obtain the facts of the event on which further action or recommendations may need to be taken. Include in SIRI reporting and follow up processes to share learning and reduce risk of further breach as appropriate |
| Comms Team | Advise on methods to contact individuals involved. Assist in preparing Press statement and any media handling as required |
| Lead Executive Director for team involved | Agree severity with IG Lead taking advice from SIRO and Caldicott Guardian as necessary. Liaise with Comms team to prepare Press statement as necessary. Inform CEO or other Executives. Ensure appropriate support for ward/department team and whether additional resource may be required to manage contact with patients or staff/department team has been put in place. Consider appropriate support for staff involved in the breach as well as those affected. Review outcome of investigation and refer to other departments for advice eg HR as necessary. |

4.2 Prompt action is necessary to ensure the loss is managed properly and potential damage to the organisation or the person whose data has been lost, is limited as far as possible.

4.3 Where a serious breach has been identified following a full and thorough investigation to establish the facts, for example as a result of failure to follow procedure, it may be necessary to invoke the Disciplinary Policy under guidance from the Human Resources team.
Appendix F: Incident Reporting Flow Chart

Incident Reporting (non SIRI)

- Incident occurs
- Make patient/party affected safe
- Staff member report on Datix as per Incident Reporting, Investigation & Management Policy

Additional Senior Manager with Specialist Skills
- Reviews Incident
- Request clarification on issues as appropriate
- Consider if investigation required

  Yes
  Investigator updates Datix when investigation complete
- No

Assigns investigator to incident within Datix
- Consider if any actions required

  Yes
  Staff member updates Datix when investigation complete
  Assigns action to appropriate staff within Datix
- No

Line Manager
- Reviews Incident
- Risk grades incident
- Request clarification on issues as appropriate
- Consider if investigation required

  Yes
  Investigator updates Datix when investigation complete
  Assigns investigator to incident within Datix
- No

Assigns investigator to incident within Datix
- Consider if any actions required

  Yes
  Staff member updates Datix when investigation complete
  Assigns action to appropriate staff within Datix
- No

Continue on next page
Move to awaiting final approval

**Final Approver**
Reviews incident

Reviews Risk Grade

Reviews investigators assigned

Reviews actions assigned

Request clarification on any points/issues as appropriate

Consider if any further investigations/actions required

Staff member updates Datix when investigation/action complete

Assigns investigator/actions to Datix

Finally approves incident

Indicates if reportable to NPSA

Quality and Risk upload incident To NPSA
Serious Incident Management Process (Non Pressure Ulcers)

Local Management

1. Locality Manager identifies staff to undertake initial SIRI investigation report
2. Staff begin initial investigation report
3. Level 2 SIRIs Brief update report to be drafted
4. Review by Locality Manager
5. Forward to SeriousIncidents@nchc.nhs.uk

Corporate Management

1. Review of SIRI
2. Clarification of any issues with Locality Manager
3. Submit to NHS Norfolk
4. Quality & Risk attach form to DATIX and update SIRI Log
5. Quality & Risk receive acknowledgement from NHS Norfolk and SIRI level, reporting deadlines and SHA Reference No.
6. Quality and Risk forward information to Locality Manager
7. Quality and Risk update SIRI Log and Datix
8. Quality and Risk Report
9. Clarification of any issues with Locality Manager
10. Quality and Risk submit report to NHS Norfolk
11. Quality and Risk update Datix and SIRI Log

Within 48 hours of incident occurring
Within 72 hours of incident occurring
Within 3 working days of the SIRI being reported

Appendix G: SIRI Reporting Flow Chart
**Level 1 & 2 SIRIs**
Initial Investigation Report to be drafted

Review by Locality Manager

Forward to SeriousIncidents@nchc.nhs.uk

**Level 1**
Local staff identified

Draft Report to be sent to Locality Manager and Assistant Director for review

Report to be sent to Quality and Risk for review

**Level 2**
Local staff and one other / Quality & Risk support

Draft Report to be sent to Locality Manager for review and actions identified from recommendations

Report to be sent to Quality and Risk for review

**Level 3**
External investigator identified –

Draft Report to be sent to Director for review and actions identified from recommendations

Report to be sent to Quality and Risk for review

**Locality Manager and Quality and Risk Manager agree type of further investigation**

**Within 7 working days of the SIRI being reported**

**Corporate Management**

Quality and Risk Review Report

Clarityfication of any issues with Locality Manager

Submit report to NHS Norfolk

Update Datix and SIRI Log

Within 30 working days of the SIRI being reported

Quality and Risk feedback to Locality Manager/Directorate
Incident Reporting, Investigation & Management Policy
NCH&C
version 3.0 March 2012

Final report reviewed by Locality Manager. Actions/recommendations identified.

Reviewed by Assistant Director – Actions/Recommendations identified

Forwarded to SeriousIncidents@nchc.nhs.uk

Within 40 working days of the SIRI being reported

Local Management

Discuss within Locality Meeting and Team Meeting

Corporate Management

Quality and Risk review Report

Clarification of any issues with Assistant Director / Director

Submit to NHS Norfolk requesting closure

Quality and Risk update SIRI Log and Datix

Report to Quality and Risk Assurance Committee

Report to Board

Within 45 working days of the SIRI being reported
Response received from NHS Norfolk

NHS Norfolk confirm closure

NHS Norfolk confirm closure subject to actions

Actions monitored By Locality Manager

Locality Manager updates Quality & Risk on progress

Quality & Risk inform NHS Norfolk and request Final Closure

NHS Norfolk confirm final closure to Quality & Risk

Quality & Risk advise Locality Manager
Appendix H: Pressure Ulcer SIRI reporting flow chart

SIRI Process – Grade 3 or 4 Pressure Ulcer identified as being acquired within the care of NCH&C

1. Complete DATIX Incident form
2. Escalate to Locality Manager
3. Locality Manager to complete SIRI form and send to SeriousIncidents@nchc.nhs.uk
4. Q&R team review SIRI form and clarify as appropriate. Q&R send to NHS Norfolk.

Within 24 hours of incident:

1. NHS Norfolk advise SIRI Level, Reference number and reporting deadlines
2. Q&R forward this information to Locality Manager
3. Locality Manager identifies person to complete Pressure Ulcer Root Cause Analysis (PU RCA)
4. PU RCA validated by Locality Manager
5. PU RCA sent to SeriousIncidents@nchc.nhs.uk

Within 5 working days of incident:
Within 7 working days of incident occurring:

Q&R review PU RCA and clarify as appropriate

Q&R send to NHS Norfolk and request closure of SIRI

NHS Norfolk confirm closure

Quality & Risk advise Locality Manager

NHS Norfolk confirm closure subject to actions

Actions monitored by Locality Manager

Locality Manager updates Quality & Risk on progress of actions

Quality & Risk inform NHS Norfolk and request Final Closure

NHS Norfolk confirm final closure to Quality & Risk

Quality & Risk advise Locality Manager

See separate folder
Appendix I: RCA Process Level 2 Investigation

1. Director request to undertake internal RCA

2. TOR agreed and Lead Investigator identified included any additional resource. Consider family/patient involvement.

3. Buddy identified external to the team or with expertise in the area

4. Lead contacts AD for area or other senior manager involved e.g. On Call, and requests summary of event

5. Supports lead to collect Additional information e.g. Datix, Copy records, Staff accounts, Relevant policies, documentation

6. Contacts Local team Line Manager. May require multiple team/agency involvement

7. Checks staff support in place and available with local manager

8. Explains and agrees process to go forward with Line Managers

9. Explains process to staff involved, roles of lead, buddy and expert. Identify

10. Lead/Buddy/expert review documentation. Establish a timeline and gaps, sense check, documents to be used during RCA

11. All involved in a room Records for staff, timeline visible; Lead facilitates session supported by buddy and expert; Summarises purpose, ground rules; outcome and how to get there

12. What happens next, process to share and learn going forward

13. Review timeline, care problems, contributory factors using RCA techniques eg 5 Why’s Identify clearer timeline; Identify Root Causes; Agree actions – including what needs to be done by whom and when, how monitored; Identify learning – agree process to share

14. Draft Report prepared by lead and out to agree factual accuracy of content

15. Updated draft report to Assistant Director for agreement re actions and monitoring process; Process identified to share learning

16. Final report to Director for sign off

17. Agree share process e.g. learning event, anonymised to other teams, recommendations made available and how including to patient/family/carers

18. Report to relevant operational committees and through to QRAC
Appendix J: Contributory Factors relevant to Incidents occurring and the investigation process

7.1 Individual Factors

<table>
<thead>
<tr>
<th>Individual Factors</th>
<th>Components</th>
</tr>
</thead>
</table>
| **Physical issues** | General Health (e.g. nutrition, diet, exercise, fitness)  
                       Physical disability (e.g. eyesight problems, dyslexia)  
                       Fatigue |
| **Psychological Issues** | Stress (e.g. distraction / preoccupation)  
                           Specific mental health illness (e.g. Depression)  
                           Mental impairment (e.g. illness, drugs, alcohol, pain)  
                           Motivation (e.g. boredom, complacency, low job satisfaction)  
                           Cognitive factors (e.g. attention deficit, distraction, preoccupation, overload and boredom) |
| **Social Domestic** | Domestic / lifestyle problems |
| **Personality Issues** | Low self confidence / over confidence  
                          Gregarious / interactive, reclusive  
                          Risk averse / risk taker |

7.2 Team and Social Factors

<table>
<thead>
<tr>
<th>Team Factors</th>
<th>Components</th>
</tr>
</thead>
</table>
| **Role Congruence** | Is there parity of understanding  
                           Are role definitions correctly understood  
                           Are roles clearly defined |
| **Leadership** | Is there effective leadership – clinically  
                           Is there effective leadership – managerially  
                           Can the leader lead  
                           Are leadership responsibilities clear and understood  
                           Is the leader respected |
| **Support and cultural factors** | Are there support networks for staff  
                                         Team reaction to patient safety incidents  
                                         Team reaction to conflict  
                                         Team reaction to newcomers  
                                         Team openness |

7.3 Communication Factors

<table>
<thead>
<tr>
<th>Communication</th>
<th>Components</th>
</tr>
</thead>
</table>
### 7.4 Task Factors

<table>
<thead>
<tr>
<th>Task Factors</th>
<th>Components</th>
</tr>
</thead>
</table>
| Guidelines, Procedures and Policies | Up-to-date  
Available at appropriate location (e.g. accessible when needed)  
Understandable / useable  
Relevant; Clear; Unambiguous; Correct Content; Simple  
Outdated; Unavailable/missing; Unrealistic  
Adhered to / followed  
 Appropriately targeted (e.g. aimed at right audience) |
| Decision making aids        | Availability of such aids e.g. CTG machine, risk assessment tool, fax machine to enable remote assessment of results  
Access to senior / specialist advice  
Easy access flow charts and diagrams  
Complete information - test results, informant history |
| Procedural or Task Design   | Do the guidelines enable one to carry out the task in a timely manner  
Do staff agree with the ‘task/procedure design’  
 Are the stages of the task such that each step can realistically be carried out |

### 7.5 Education and Training Factors

<table>
<thead>
<tr>
<th>Education and Training</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Competence</td>
<td>Adequacy of knowledge</td>
</tr>
<tr>
<td>Adequacy of skills</td>
<td>Adequacy of supervision</td>
</tr>
<tr>
<td>-------------------------</td>
<td>----------------------------------</td>
</tr>
<tr>
<td>Length of experience</td>
<td>Availability of mentorship</td>
</tr>
<tr>
<td>Quality of experience</td>
<td>Adequacy of mentorship</td>
</tr>
<tr>
<td>Task familiarity</td>
<td></td>
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<table>
<thead>
<tr>
<th>Testing and Assessment</th>
<th>Supervision</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Adequacy of supervision</td>
</tr>
<tr>
<td></td>
<td>Availability of mentorship</td>
</tr>
<tr>
<td></td>
<td>Adequacy of mentorship</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Supervision Adequacy of supervision</th>
<th>Availability of mentorship</th>
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</thead>
<tbody>
<tr>
<td>Adequacy of supervision</td>
<td>Availability of mentorship</td>
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<tr>
<td></td>
<td>Adequacy of mentorship</td>
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</tbody>
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<table>
<thead>
<tr>
<th>Availability / accessibility</th>
<th>On the job training</th>
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</thead>
<tbody>
<tr>
<td>On the job training</td>
<td>Emergency Training</td>
</tr>
<tr>
<td>Team training</td>
<td>Core skills Training</td>
</tr>
<tr>
<td>Core skills Training</td>
<td>Refresher courses</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Availability / accessibility</th>
<th>On the job training</th>
</tr>
</thead>
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<td>Emergency Training</td>
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<td>Core skills Training</td>
</tr>
<tr>
<td>Core skills Training</td>
<td>Refresher courses</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Appropriateness</th>
<th>Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>Content</td>
<td>Target audience</td>
</tr>
<tr>
<td></td>
<td>Style of delivery</td>
</tr>
<tr>
<td></td>
<td>Time of day provided</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Appropriateness</th>
<th>Content</th>
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</thead>
<tbody>
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<td>Content</td>
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<tr>
<td></td>
<td>Style of delivery</td>
</tr>
<tr>
<td></td>
<td>Time of day provided</td>
</tr>
</tbody>
</table>

### 7.6 Equipment and Resources Factors

<table>
<thead>
<tr>
<th>Equipment</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Displays</td>
<td>Correct information</td>
</tr>
<tr>
<td></td>
<td>Consistent and clear information</td>
</tr>
<tr>
<td></td>
<td>Legible information</td>
</tr>
<tr>
<td></td>
<td>Appropriate feedback</td>
</tr>
<tr>
<td></td>
<td>No interference</td>
</tr>
<tr>
<td>Integrity</td>
<td>Good working order</td>
</tr>
<tr>
<td></td>
<td>Appropriate size</td>
</tr>
<tr>
<td></td>
<td>Trustworthy</td>
</tr>
<tr>
<td></td>
<td>Effective safety features</td>
</tr>
<tr>
<td></td>
<td>Good maintenance programme</td>
</tr>
<tr>
<td>Positioning</td>
<td>Correctly placed for use</td>
</tr>
<tr>
<td></td>
<td>Correctly stored</td>
</tr>
<tr>
<td>Usability</td>
<td>Clear controls</td>
</tr>
<tr>
<td></td>
<td>User manual</td>
</tr>
<tr>
<td></td>
<td>Familiar equipment</td>
</tr>
<tr>
<td></td>
<td>New equipment Standardisation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Equipment</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Displays</td>
<td>Correct information</td>
</tr>
<tr>
<td></td>
<td>Consistent and clear information</td>
</tr>
<tr>
<td></td>
<td>Legible information</td>
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<tr>
<td></td>
<td>Appropriate feedback</td>
</tr>
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<td></td>
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<td>Clear controls</td>
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<tr>
<td></td>
<td>User manual</td>
</tr>
<tr>
<td></td>
<td>Familiar equipment</td>
</tr>
<tr>
<td></td>
<td>New equipment Standardisation</td>
</tr>
</tbody>
</table>
### 7.7 Working Conditions

<table>
<thead>
<tr>
<th>Work Environment Factor</th>
<th>Component</th>
</tr>
</thead>
</table>
| Administrative factors  | The general efficiency of administrative systems e.g. reliability  
                          | Systems for requesting medical records  
                          | Systems for ordering drugs  
                          | Reliability of administrative support |
| Design of physical environment | Office design: computer chairs, height of tables, anti-glare screens, security screens, panic buttons, placing of filing cabinets, storage facilities, etc.  
                                    | Area design: length, shape, visibility, cramped, spacious |
| Environment | Housekeeping issues – cleanliness  
                        | Temperature  
                        | Lighting  
                        | Noise levels |
| Staffing | Skill mix  
               | Staff to patient ratio  
               | Workload / dependency assessment  
               | Leadership  
               | Use Temporary staff  
               | Retention of staff / staff turnover |
| Work load and hours of work | Shift related fatigue  
                              | Breaks during work hours  
                              | Staff to patient ratio  
                              | Extraneous tasks  
                              | Social relaxation, rest and recuperation |
| Time | Delays caused by system failure or design  
          | Time pressure |

### 7.8 Organisational and Strategic Factors

<table>
<thead>
<tr>
<th>Organisational Factor</th>
<th>Components</th>
</tr>
</thead>
</table>
| Organisational structure | Hierarchical structure, not conducive to discussion, problem sharing, etc.  
                          | Tight boundaries for accountability and responsibility  
                          | Clinical versus the managerial model |
| Priorities | Safety driven  
                     | External assessment driven e.g. Star Ratings |
### Financial balance focused

<table>
<thead>
<tr>
<th>Externally imported risks</th>
<th>Locum / Agency policy and usage</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Contractors</td>
</tr>
<tr>
<td></td>
<td>Equipment loan /PFI</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Safety culture</th>
<th>Safety / efficiency balance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Rule compliance</td>
</tr>
<tr>
<td></td>
<td>Terms and Conditions of Contracts</td>
</tr>
<tr>
<td></td>
<td>Leadership example (e.g. visible evidence of commitment to safety)</td>
</tr>
<tr>
<td></td>
<td>Open culture</td>
</tr>
</tbody>
</table>

## 7.9 Patient Factors

<table>
<thead>
<tr>
<th>Patient Factors</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical condition</td>
<td>Pre-existing co-morbidity</td>
</tr>
<tr>
<td></td>
<td>Complexity of condition</td>
</tr>
<tr>
<td></td>
<td>Seriousness of condition</td>
</tr>
<tr>
<td></td>
<td>Treatability</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Social factors</th>
<th>Culture / religious beliefs</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Life style (smoking/ drinking/ drugs/diet)</td>
</tr>
<tr>
<td></td>
<td>Language</td>
</tr>
<tr>
<td></td>
<td>Living accommodation (e.g. dilapidated)</td>
</tr>
<tr>
<td></td>
<td>Support networks</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Physical factors</th>
<th>Physical state – malnourished, poor sleep pattern, etc.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Mental/ psychological factors</th>
<th>Motivation (agenda, incentive)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Stress (family pressures, financial pressures)</td>
</tr>
<tr>
<td></td>
<td>Existing mental health disorder</td>
</tr>
<tr>
<td></td>
<td>Trauma</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Interpersonal relationships</th>
<th>Staff to patient and patient to staff</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Patient to patient</td>
</tr>
<tr>
<td></td>
<td>Inter family – siblings, parents, children</td>
</tr>
</tbody>
</table>
Appendix K: External Reporting Roles and Responsibilities

1. The National Patient Safety Agency (NPSA)

The Trust will comply with the requirements of the National Patient Safety Agency. All clinical incidents are reported anonymously to the NPSA using the National Reporting and Learning System. Staff can report on line to the NPSA instead of via the Trust incident reporting system if they wish. Staff who do this must understand that the incident report will be logged only, and no feedback will be given to them by the NPSA.

The Quality & Risk Manager or other designated senior manager is responsible for reporting all relevant incidents to the NPSA. Reports on compliance are received from the NPSA on a 6 monthly basis and reported to QRAC.

2. NHS Norfolk and Strategic Health Authority (SHA)

The Trust reports all relevant serious incidents to NHS Norfolk. In turn these may be reported to the SHA by NHS Norfolk especially if the incident is considered likely to cause political or media concerns. If this is the case, links to the Department of Health are established through the Chief Executive’s Office, Communications team, Director of Operations and Quality & Risk team as appropriate. The Quality & Risk Manager is responsible for ensuring all relevant incidents are reported to NHS Norfolk.

3. GP Out of Area reports

The Trust reports on a monthly basis all incidents and SIRIs in respect of contacts with patients who are registered with a non-Norfolk GP to the appropriate PCT. This is managed by the Quality & Risk Manager.

4. Information Commissioner

In the event of loss of personal, identifiable data the Information Commissioner may need to be informed. This is done by the IG Lead. The loss may be of data in any format eg paper, electronic, loss of USB stick etc. If in doubt, advice must be sought from the IG Lead.

5. Infection Control incidents

In the event of an outbreak, the Director of Infection Prevention and Control is responsible for reporting to NHS Norfolk, the Strategic Health Authority and the Health Protection Agency.
6. **Health & Safety Executive (HSE)**

The Health & Safety Manager has responsibility to ensure that all relevant incidents are reported to the HSE (refer to Health & Safety policy) and in the appropriate timescales e.g RIDDOR.

7. **Violence Against Staff incidents**

The Local Security Management Specialist (LSMS) has responsibility to report all incidents of Violence against Staff (VAS) and Security Incident Reports as part of the annual return to NHS Protect.

8. **Security Incident Reporting (SIRS) - Fire**

In the event of actual fire events occurring (not false alarms), these are reported by the Fire Officer to the Department of Health Estates using electronic facilities management software.

9. **Police & Coroners**

The Trust has a responsibility to report relevant incidents (e.g., unexpected deaths in the inpatient areas) to the Police as they occur. These may be referred to the Coroner subsequently by the Police or direct by the relevant medical practitioner who has been caring for the patient.

10. **Adult Safeguarding / Children’s Safeguarding**

Adult safeguarding events and Children’s safeguarding events are reported by the designated leads to relevant statutory, health and social care agencies.

11. **Care Quality Commission**

Any incidents requiring to be reported to the CQC will normally be through the Datix reports to the NPSA via the National Reporting and Learning System. In the event of an incident occurring which prevents delivery of a service or where there is any query as to whether the registration of a service may be in doubt, the matter must be raised with the Director of Operations as the Nominated Individual, who will seek advice as necessary direct from the CQC.
### Appendix L: Risk Register Template – Minimum content

<table>
<thead>
<tr>
<th>No.</th>
<th>Source of Risk</th>
<th>Principal Risk Describe the risk here</th>
<th>Initial Risk rating (LxC)</th>
<th>Key Controls (list top 1-5max)</th>
<th>Gaps in controls</th>
<th>Internal Assurance</th>
<th>External Assurance on controls</th>
<th>Gaps in assurance</th>
<th>Residual Risk rating (after mitigation)</th>
<th>Action required (including dates)</th>
<th>Date of next review</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><em>Risk identifier generated by Datix</em></td>
<td>What's the risk? If…. then…. This can help you identify what the risk is</td>
<td>Eg 4x4=12</td>
<td>What is in place to reduce the risk eg a policy, staff training, competency assessment, project plan?</td>
<td>What's missing? What wasn’t there to stop the risk occurring?</td>
<td>Assurance answers the question – ‘How do you know your controls are working?’ Are they monitored, audited, reported to specific committees?</td>
<td>Do reports go externally to other agencies as part of an external monitoring or audit process?</td>
<td>Where are the gaps?</td>
<td>Eg 4x3=12 This is level of remaining risk in spite of the controls you have in place</td>
<td>What action is still required to reduce this risk further? Does it need to be escalated? Does it require additional support or resource to manage it?</td>
<td>Date the risk register is due for review. Align to your regular team and department meetings as a rolling item to ensure this review occurs monthly and is documented</td>
</tr>
</tbody>
</table>

- **Date of review and Date of next review** – this enables an audit trail to be followed as to when the risk register was last reviewed and when it is next due for review. High risks 12 and above are reviewed monthly as a minimum. Lower graded risks must be reviewed at the same time to ensure they have not changed in the previous period since last reviewed.
- **Source of Risk** – risks may be identified from any source eg incidents internal or external to NCH&C; complaints; claims; patient and staff feedback; publication of external reports or guidance relevant to services delivered by NCH&C; following internal risk assessments or external visits, inspections, accreditations; as a result of horizon scanning and plans for reconfiguration of services, acquisition or disposal of services.
- **Principal Risk** – the description must answer the question – What’s the risk? Using ‘If’ and ‘then’ can help this process.
- **Risk Score – Initial score** using the 5x5 matrix. How likely is something to happen and what is the outcome if it does. In an actual event, what was the outcome for the patient for example?; **Residual risk score** – once the controls in place to reduce the risk have been identified has the level of risk changed?
- **Action required** – including dates. This section is the action plan summary. Local and corporate registers include who is responsible for completing the actions. The Board Assurance Framework identified the director who is responsible for the risk and ensuring actions identified are completed.
## Appendix M: Guidance on assessment of the degree of harm as a result of the consequence of different types of incident

<table>
<thead>
<tr>
<th>Consequence score (severity levels) and examples of descriptors</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Domains</strong></td>
</tr>
<tr>
<td>Impact on the safety of patients, staff or public (physical/psychological harm)</td>
</tr>
<tr>
<td>Quality/complaints/audit</td>
</tr>
<tr>
<td>Human resources/organisational development/staffing/competence</td>
</tr>
<tr>
<td>Adverse publicity/reputation</td>
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<tr>
<td>----------------------------</td>
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<tr>
<td>Potential for public concern</td>
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<tr>
<td><strong>Business objectives/projects</strong></td>
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<tr>
<td><strong>Finance including claims</strong></td>
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<tr>
<td></td>
</tr>
<tr>
<td><strong>Service/business interruption Environment impact</strong></td>
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<td></td>
</tr>
</tbody>
</table>
Appendix N – Incident Decision Tree (NPSA Model)