



Incident Management Policy

This procedural document supersedes CORP/RISK 33 v.1 Incident Management Policy



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Executive Sponsor(s):	Dr Nicholas Mallaband – Interim Executive Medical Director	
Author/reviewer: (this version)	Nicola Severein-Kirk – Lead Nurse Patient safety	
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Amendment Form

Please record brief details of the changes made alongside the next version number. If the procedural document has been reviewed **without change**, this information will still need to be recorded although the version number will remain the same.

Version	Date Issued	Brief Summary of Changes	Author
Version 2	23 June 2025	 Please read in full. A full review in line with Patient Safety Incident Response Framework 	Nicola Severein-Kirk
Version 1 (amended 22 May 2018)	22 May 2018	 A link relating to Public Health England Screening Programmes has been added within section 8. 	Lisette Caygill
Version 1	12 October 2017	 This new procedural document incorporates: CORP/RISK 4 v.3 – Policy for Supporting Staff Involved in Incidents, Complaints and Claims; CORP/RISK 13 v.2 – Policy for the Reporting and Management of Incidents and Near Misses; CORP/RISK 20 v.1 – Learning from Incidents, Complaints and Claims; CORP/RISK 24 v.1 – Investigating Incidents, Complaints and Claims. Please read in full. 	Louise Povey Lisette Caygill

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1 INTRODUCTION

Incident reporting is a fundamental tool of risk management. The ultimate aim is to reduce the risk of harm to patients, staff and other users of Trust premises through improving the safety culture, quality of services and the environment. This will be addressed by undertaking qualitative and quantitative data analysis of incidents to highlight any trends.

Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust (DBTH) recognises that in a service as large and complex as the NHS things go wrong. When they do, the Trust supports the view that the response should not be one of blame and retribution but of organisational learning with the aim of encouraging participation in the overall process and supporting staff, rather than exposing them to recrimination. Therefore, the Trust is committed to developing a "Just Culture" and to encourage a willingness to admit mistakes without fear of punitive measures. In support of this, the Trust accepts that reporting an incident via the incident reporting system (Datix) does not constitute an admission of liability and will not result in automatic disciplinary action.

2 PURPOSE

This policy will cover the following areas:

- When and how to report an incident/ safety event
- Investigation of incidents/ safety events
- Learning from incidents/ safety event
- Support to staff when affected by an incident/ safety event

3 DUTIES AND RESPONSIBILITIES

These are the individual and departmental roles and levels of responsibility for incident management within the Trust.

3.1 All Staff

All staff have a responsibility for ensuring that incidents and near misses are reported. All staff should be aware of what constitutes an incident, safety event or near miss and the process for reporting and management of such incidents.

3.2 The Incident Reporter

The reporter must:

Ensure the immediate safety of the patient/staff/visitor involved in the incident.

- Report the incident on Datix (DIF1) as soon after the incident occurred or knowledge of the incident.
- For patients ensure the Learning From Patient Safety Events (LFPSE) section is completed.
- Ensure that the team leader or department manager is informed of the incident as soon as possible after the incident.
- When it is a patient that has been affected by the incident, the relevant medical team should be informed and the event should be recorded in the patient record.
- If there has been any harm impact on a patient then the patient should be informed in line with duty of candour principles. Where the patient cannot be informed, then their named contact should be informed.

3.3 Incident Approver

Each department will have an incident approver(s), which will typically be the ward or department manager. Divisional Quality and Compliance (DQAC) Leads, clinical governance leads and the Patient Safety team may also undertake incident approval where required in order to progress initial investigation and allocation of responsibility. They will:

- Assess the content of the incident form to determine:
 - o The outcome of the incident, updating the result field on the DIF2 form on Datix.
 - The actual harm caused by the incident and update the severity field of the DIF2 form as required. (See Appendix 1)
- Check and confirm the LFPSE section is completed and if the reporters assessment of whether it is a patient safety event is correct.
- Where the information is insufficient to determine the outcome and harm caused, undertake initial investigation into the outcome and harm.
- Undertake a risk grading based on the potential consequence and likelihood.
- If there is evidence of harm, then proportional investigation of the cause of the incident should be undertaken.
- Where there is no harm caused and there is a high risk grade, then proportional investigation should be undertaken.
- The current status field should be updated to reflect the stage of approval and completion.
- If an incident has not caused harm, and is classified as low or moderate risk, then local investigation is discretionary, but the incident can be finally approved and closed at this point.
- Complete DIF2 with the findings of the initial and any subsequent proportional investigation.
- Record details of the actions necessary to reduce or eliminate the risk of recurrence and communicate with the relevant manager with responsibility to undertake the actions required. All agreed actions must be undertaken within 3 months, or an exception report be provided through the local specialty or department governance meetings.
- Update actions planned by the deadline set.
- Complete RIDDOR form when applicable and following advice from Health & Safety Manager.

- Seek advice from relevant specialist staff to investigate and manage the incident, such as
 Pharmacists, Medical Technical Services, Resuscitation & Manual Handling Lead, Local
 Security Management Specialist, Information Governance team, Radiation Protection advisor
 and Counter Fraud Specialist.
- For Patient Safety Events that are to be discussed at Divisional Patient Safety Events Review Panel (DSERP), ensure DQAC is aware of incident and the date of discussion at DSERP is completed on the incident report (Datix).

3.4 Divisional Director, Divisional Nurse (or Deputy), Head of Therapies & Heads of Departments

Divisional senior management teams and department heads must ensure they have delegated the responsibility of incident management to appropriate individuals within their areas of responsibility, such as DQAC's, Matrons, Ward and Department Managers, Assistant Divisional Directors and Clinical Governance Leads. They are responsible for promoting effective risk management and ensuring there are operational systems in place within their teams to fulfil the requirements of this policy.

The Divisional management team are also responsible for agreement on the content of action plans from Patient Safety Incident Investigations (PSII), or other learning response (such as After Action Reviews) and Divisional approval of PSII reports.

3.5 Divisional Clinical Governance Leads

These posts will provide oversight of the incident reporting process and ensure the provision of analysis of incident reporting, to be triangulated with other activities to determine quality and clinical governance and reporting to the Divisional Clinical Governance meetings. The monitoring of action plan completion is a key function which will be reported through clinical governance meetings for each specialty and Division. Oversight of overdue actions is monitored through the Patient Safety Committee.

3.6 Divisional Quality and Compliance Leads

The Divisional Quality and Compliance Leads will ensure they have systems and processes in place to review all incidents categorised as moderate, severe or death and confirm accuracy of severity. They will provide advice, assistance and support to Line Managers and other employees as appropriate. The Divisions will hold bi-weekly Divisional Patient Safety Events Review Panels (DSERP), which will identify the learning response required or escalation to the Trust Learning from Patient Safety Events Panel. .

3.7 Patient Safety Investigation Leads and Lead Nurse – Patient Safety

The Patient Safety Investigation Leads will be involved in leading Patient Safety Incident investigations, working with the divisions.

The Lead Nurse for Patient Safety will track and monitor the status of the divisional Patient Safety Incident Investigations. This will be reported to the Learning from Patient Safety Panel and Trust Executive Patient Safety Oversight Group.

3.8 Executive Medical Director and Chief Nurse

The Executive Medical Director and Chief Nurse are the Executive leads via the Trust Executive Patient Safety Oversight Group, which meets fortnightly.

The Learning From Patient safety Events Panel meet bi-weekly to have oversight of the patient safety events and decision making on the learning response in line with the Trusts Patient Safety Incident Response Plan.

3.9 Chief Executive

The Chief Executive has ultimate responsibility for patient safety and risk management across the Trust and will ensure that all incidents are dealt with appropriately and that the just culture of fair blame is upheld.

3.10 Senior Incident Risk Owner (SIRO)

Is responsible for ownership of information risk across the Trust and for ensuring the Board is adequately briefed on information security risks and incidents.

4 COMMITTEES WITH RESPONSIBILITY FOR INCIDENT MANAGEMENT PROCESSES

4.1 Learning from Patient Safety Events Panel

The Learning from Patient safety Events (LFPSE) panel members include the following roles:

- Associate Medical Director Clinical safety (Chair)
- Associate Chief Nurse Patient safety and Quality (Vice chair)
- Deputy Chief Nurse
- Lead Nurse Patient safety
- Safeguarding Lead (when needed)
- Patient Safety Administrator (admin for the panel)

The LFPSE panel meet bi-weekly basis, with exceptions when bank holidays or other commitments prevent the panel meeting. LFPSE panel meetings dates and times are rearranged when there are bank holidays or other commitments to ensure consistency and continuity.

4.2 Patient Safety Review Group (PSRG)

PSRG will receive a monthly report on Patient Safety Incident Investigations and other learning responses, in line with the national Patient Safety Incident Response Framework. The PSRG will recommend actions required to ensure the reduction of risk in patient safety and prevent future reoccurrence.

PSRG's role is to ensure actions are taken as a result of trend analysis, and the cascading of information throughout the organisation.

PSRG will monitor the Trusts compliance to action plans completion targets generated from all Patient Safety Incident Investigations and duty of candour regulation compliance.

4.3 Patient Safety Committee (PSC)

PSC will receive a report of all Patient Safety Incident Investigations and other learning responses every 2 months . They will receive assurance that systems and processes are in place to address and learn from all incidents and near misses and to ensure effective Risk Management across the Trust.

4.4 Divisional Clinical Governance Groups and Specialty Clinical Governance Groups

Must have systems and processes in place to ensure that:

- All incidents are reviewed and investigated at a level appropriate to the incident.
- Any recommendations made following investigations are carried through to a SMART action plan which is monitored for completion
- The Statutory Duty of candour is complied with in all cases of "moderate" "severe" and "death" incidents
- Local and organisational learning takes place.
- Report to PSRG and PSC as defined in the terms of reference.

5 PROCEDURE FOR INCIDENT REPORTING

5.1 Reporting the Incident: Completing an incident Report Form DIF1

When an incident occurs, the first response must be to make the situation safe and ensure the patient and/or staff member receive appropriate treatment and ongoing management. All evidence should be protected and secured, e.g., damaged equipment retained, IT activity logs copied, etc, in case of the need for further investigation.

The Incident must then be reported onto Datix (DIF1) recording all the facts as are known at the time and categorising the known harm to the person affected or harmed. An incident should be reported to the most senior member of the department at the time, for their consideration of escalation to senior managers in respect of any management action or potential serious incident management.

5.2 Duty of Candour (DoC)

Duty of Candour is a statutory requirement to ensure health care providers operate in an open and transparent way. The regulation for Duty of Candour applied to health service bodies from 27 November 2014. This regulation requires an NHS body to:

- Make sure it acts in an open and transparent way with relevant persons in relation to care and treatment provided to people who use services in carrying on a regulated activity.
- Tell the relevant person in person as soon as reasonably practicable after becoming aware that a 'notifiable safety incident' has occurred, and provide support to them in relation to the incident. This should be carried out within 2 working days and a letter should be sent/given to the patient/family or carer within 10 working days.
- Provide an account of the incident which, to the best of the health service body's knowledge, is true of all the facts the body knows about the incident as at the date of the notification.
- Advise the relevant person what further enquiries the health service body believes are appropriate.
- Offer an apology. Follow this up by giving the same information in writing, and providing an update on the enquiries. Keep a written record of all communication with the relevant person on the incident reporting system (Datix).
- On conclusion of the investigation the findings and/or report will be shared with the patient/family/carer unless they decline to be informed of the outcome, including the Duty of Candour letter 2.
- See Appendix 1 for flowchart.

5.3 Reviewing the incident (DIF2)

Each section within Datix needs to be completed fully in order to provide clear evidence of acknowledgement, investigation, actions and learning. Each of the sub menus (list on the left hand side of the screen), need to be completed. See Appendix 2 detailing the process.

5.4 Investigation Process

This Patient Safety Incident Response plan (PSIRP CORP/RISK 36.v1) sets out how Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust intends to respond to patient safety events reported by staff and patients, their families and carers as part of work to continually improve the quality and safety of the care we provide.

The Patient Safety Event Decision Response Flow (Appendix 3) sets out the response, which includes daily review of the Datix incident reported in the last 24 hours, to identify the appropriate level of investigation, the severity and the level of risk must be considered and based on what is known at the time of reporting and subsequent review. Fact finding initial investigation steps may be required to determine the appropriate level of investigation decision. The Divisional Quality, Assurance and Compliance Lead will work with clinical colleagues to establish the relevant details to aid decision making

and for discussions at divisional Patient Safety Event Response Panels (DSERP), where thresholds for investigation are unclear or a potential Patient Safety Incident Investigation, the Learning from Patient Safety Events panel will make the decision.

The lead investigator appointed by the Patient Safety Team will establish the key facts, determine the staff members who were involved in the safety event and investigate. The staff key template will be completed and kept in the investigators file.

A copy of the clinical records should be taken as soon as possible (original clinical records are often required by pathology or other clinicians).

The lead investigator will gather all the relevant information required to perform a comprehensive investigation and conduct interviews with staff as appropriate. The lead investigator along with allocated independent Subject Matter Advisor will attend LFPSE panel meetings in line with the PSIRP, dates of the attendance will be provided by the Patient Safety Team.

5.5 Action Plans

Action plans should be produced post investigation ensuring they are:

Specific

Measurable

Achievable

Realistic

Timed

These must be agreed by all parties involved in the investigation.

Action plans must be monitored by the local clinical governance groups. Any actions that have wider organisation implications will be agreed at the Trust Executive Patient safety Oversight Group (TEPSOG) and monitored via Patient Safety Committee.

Completion of action plans may be the responsibility of a line manager, nominated individual or a group/committee. Action plan compliance is monitored through governance and via the incident reporting system (Datix).

6 SUPPORT FOR STAFF

The Trust is committed to and transitioned to a restorative just culture within the organisation. The main goals of restoration when an event has happened have been outlined as follows:

- Moral engagement
- Emotional healing
- Reintegration of the practitioner
- Organisational learning
- Prevention

The health and well-being of staff can be affected if they are involved in traumatic incidents. Staff may be distressed, anxious and concerned about their own involvement in what happened, the consequences of this for the patient, family, themselves and their colleagues. Some staff may recover their equilibrium more quickly than others, but for some the distress and loss of confidence involved can seriously affect the individual's ability to continue to work and maintain a normal home life.

Examples of traumatic incidents, may include the following (though not exhaustively):

- Patient Safety Event
- Unexpected patient death
- Allegations of gross negligence/manslaughter
- Dealing with a major incident (eg a serious road traffic accident)
- Assaults
- Suicide
- Any other situation that the member of staff considers to be of a traumatic nature.

The first line of support is the line manager who should be involved as soon as possible. Much of the reassurance required by the staff member can be given by the manager, informing the staff member of the process and referring them to appropriate resources.

Dependent on the nature of the incident it may be necessary for the manager to provide support to staff during the incident, for example where patients or relatives may be getting increasingly disruptive or are unwilling to listen or cooperate with staff.

The line manager should be aware of those members of staff who may be especially vulnerable perhaps due to similar past experiences or who have particularly close involvement with the incident or with those involved in it. Staff should be seen individually and extra support provided if required.

The fitness of staff to undertake or continue their full range of duties following a stressful event should be risk assessed and consideration given to appropriate adjustments to duties or responsibilities should this be necessary.

It is the responsibility of the line manager to provide staff with immediate support and information on how to access the Trust Health and Well-being support services. By supporting colleagues' wellbeing, it is recognised that this has a direct impact on positive patient care. The offer includes access to counselling services through the Vivup Employee Assistance Provision, clinical supervisor/college tutor, Chaplaincy department or professional bodies.

Staff may decide that they do not wish to access support services at the time of the incident. However there is a possibility that it may become apparent at a later date that they require additional support and it is the responsibility of the line manager to ensure that they can access support services retrospectively.

Following the conclusion of the incident investigation a debrief can be offered where appropriate. Staff will be kept informed by their line manager and/or lead investigator of the incident.

6.1 Staff who are involved in a complaint

At the beginning of the investigation any member of staff involved in a complaint will be informed immediately of any serious allegations made against them i.e. safeguarding issues, theft or cases which may have medico legal implications. They should in the first instance seek advice from their line manager. In cases where there may be a conflict of interest between the member of staff and the Trust, staff should be advised of their rights to seek help from their professional association or trade union. In most cases staff will be asked for a written report of events.

6.2 Staff who are involved in a claim

The Trust recognises the importance of ensuring that staff are appropriately supported during what can be a lengthy and stressful litigation process. Staff will receive the necessary support from their line manager and will be kept regularly informed via the Legal Team of any developments during the process.

6.3 Learners involved in an incident

As a teaching hospital and early adopter of the NHSE 2024), our ambition is to provide the best learning experience for our colleagues and learners. We recognise that sometimes our learners may require support following an incident and by accurate reporting on Datix, our Education Teams can provide timely bespoke support for the learner, and if required their supervisor, whilst informing the education provider where necessary to ensure a wrap-around approach.

The Education Teams will, on notification of 'learners' that are involved in an incident, ensure that appropriate support is provided in conjunction with the individual's Clinical Supervisor/College Tutor/Mentor/Personal Tutor/Clinical Tutor or Link Lecturer. Relevant reports will be completed for the Further and Higher Education Institute (HIE) or as outlined in our responsibilities as a Local Education Provider (LEP). A learner may be an individual who are on NHS England (NHSE) training scheme along with all recognised learners within the organisation including Post Graduate Doctors in Training (PGDiTs) as well as work experience learners, Trainee Advanced Clinical Practitioners (ACP) and those on direct commissioned programmes between Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust (DBTH) and the Higher Education Institutes (HEI).

7 LEARNING FROM INCIDENTS

The outcome of any investigation is designed to identify learning points and take steps to change practice, leading to improvements in safety and quality of the care and services we provide, in line with the Trust Values. In order to achieve this, the outcome of investigation will need to detail that there are no learning points or that there are learning points requiring action. These may be local or wider impact actions depending on the nature of the incident or cause identified. This aspect should be evidence in the investigation reports produced or on the DIF2 incident reports and will be tracked.

In addition to the learning from individual cases, analysis of trends and themes may provide wider learning points and identify areas to focus on initiatives to improve the safe provision of care, or promote reporting of specific incidents.

The patient safety team will ensure the actions from the investigation are recorded on the incident reporting system (Datix) for the division to monitor completion through governance.

All incidents and actions taken are entered onto the Trust management information system (DATIX). This allows the Trust to analyse incidents and identify trends in a number of different ways.

8 INVOLVEMENT OF RELEVANT STAKEHOLDERS

The Learn from Patient Safety Events (LFPSE) service is a national NHS system for the recording and analysis of patient safety events that occur in healthcare. The service introduces a range of innovations to support the NHS to improve learning from the over 2.5 million patient safety events recorded each year, to help make care safer

LFPSE is now in use across the NHS, and organisations have switched to recording patient safety events onto the new LFPSE service using LFPSE-compliant local systems, rather than the National Reporting and Learning System (NRLS), which was decommissioned on 30 June 2024. The Strategic Executive Information System (StEIS) is still in use while the next version of LFPSE is rolled out to replace it

Health and Safety Executive - HSE: Those specific incidents that are reportable to the Health and Safety Executive (HSE) under the Reporting of Injuries, Diseases and Dangerous Occurrence Regulations 2013 (RIDDOR) are reported by the Head of Department.

Medicines & Healthcare Regulatory Agency - MHRA: Notifiable incidents are reported by the Trust's Medical Devices Manager. Health and Safety incidents are reported to the Health and Safety Executive by the Trust's Health & Safety Manager.

The Senior Information Risk Officer (SIRO) is responsible for notifying the Department of Health of any category 1-5 information security incident.

Consideration should be made regarding reporting relevant incidents to the Human Tissue Authority. (See link for guidance) - Post Mortem HTA Reportable Incidents (HTARIS) | Human Tissue Authority-

Where other external bodies such as the Department of Health, the Police or Environmental Health Agency need to be informed, the Chief Executive will determine who should contact the relevant body.

Consideration should be made regarding reporting relevant incidents relating to Public Health England Screening Programmes. (See link for guidance) - <u>Managing safety incidents in NHS screening programmes</u> - <u>GOV.UK</u>

9 RAISING CONCERNS

Staff must be aware of how to raise concerns regarding all incidents and near misses without a fear of recrimination. Please refer to CORP/EMP 14 – Freedom to Speak Up Policy 'Speak up to make a difference'

10 TRAINING/SUPPORT

All staff will receive awareness training on incident reporting through local induction. Managers should ensure that all members of their staff receive sufficient training to enable them to fulfil their individual responsibilities under this policy.

The training requirements of staff will be identified through a training needs analysis. Role specific education will be delivered by the service lead.

The Patient Safety Investigation Leads will attend the Health Services Safety Investigations Body (HSSIB) A systems approach to investigating and learning from patient safety incidents course.

Level 1 and 2 patient safety syllabus training are entry-level training courses within the NHS Patient Safety Syllabus, designed to provide a foundation in patient safety principles. Level 1, "Essentials for Patient Safety," focuses on foundational knowledge, while Level 2, "Access to Practice," builds upon this foundation with practical applications.

11 MONITORING COMPLIANCE WITH THE PROCEDURAL DOCUMENT

What is being Monitored	Who will carry out the Monitoring	How often	How Reviewed/ Where Reported to
The Patient Safety Incident Investigations and other learning responses via the PSII's OVERVIEW & LFPSE OUTCOMES report to PSRG and PSC. The level of compliance with Duty of Candour Regulations.	Lead Nurse – Patient Safety and Patient Safety team Divisional Governance – compliance with DoC and Action plans	Monthly PSII's OVERVIEW & LFPSE OUTCOMES report	Reported to PSRG & PSC

The upload of LFPSE gives	Patient Safety team	TBC – additional	Reported to PSRG & PSC
providers and		functionality to be	
commissioners access data		added	
that has been submitted to			
better understand local			
recording practices and			
culture, and to support			
local safety improvement			
work.			

12 **DEFINITIONS**

Throughout this policy, the word 'incident' should be taken to include 'near-misses' unless otherwise specified.

Death – when the incident was avoidable and has impacted on the death of the patient.

DIF2 – The incident reporting form accessible following reporting from the web-based risk management system, Datix. (Datix Incident Form 2).

DIF2 standard investigation is essentially the local management investigation process, which should be sufficient to feed back to the reporter and satisfy the management team that sufficient proportional learning takes place in each ward and department.

DoC process is the Duty of Candour, specified in the Duty of Candour regulations issued by the Care Quality Commission. This requires open disclosure of the incidents that may have caused death, severe, or moderate harm.

Incident – any accident, event or circumstance that led to harm, loss or damage to people, property, reputation, or other occurrence that could impact on the organisation's ability to achieve its objectives.

Incident Report form (DIF1) - The incident reporting form, openly accessible on the intranet (Datix Incident Form 1).

Low harm – harm with less than a week recovery time.

Moderate harm – harm with an impact for more than one week, but not permanent or typically longer than 1-3 months.

Near-miss – an incident that did not lead to harm, loss or damage.

No harm – where no actual harm occurred and there was the potential for harm.

Severe harm – when an incident results in avoidable permanent harm, chronic pain (continuous or for more than 12 weeks) or psychological harm for more than 28 days.

13 EQUALITY IMPACT ASSESSMENT

The Trust aims to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that none are disadvantaged over others. Our objectives and responsibilities relating to equality and diversity are outlined within our equality schemes. When considering the needs and assessing the impact of a procedural document any discriminatory factors must be identified.

An Equality Impact Assessment (EIA) has been conducted on this procedural document in line with the principles of the Equality Analysis Policy (CORP/EMP 27) and the Equality Diversity and Inclusion Policy (CORP/EMP 59).

The purpose of the EIA is to minimise and if possible remove any disproportionate impact on employees on the grounds of race, sex, disability, age, sexual orientation or religious belief. No detriment was identified. (See Appendix 4).

14 ASSOCIATED TRUST PROCEDURAL DOCUMENTS

Complaints Handling Policy (Including Concerns)- CORP/COMM 4

Claims Handling Policy - CORP/RISK 5

Risk Identification, Assessment and Management Policy – CORP/RISK 30

Being Open and Duty of Candour Policy - CORP/RISK 14

Patient Safety Incident Response Policy (PSIRF)- CORP/RISK 36

Maternity Services Risk Management Strategy - CORP/RISK 16

Health and Wellbeing Policy - CORP/EMP 31

Freedom to Speak Up Policy 'Speak up to make a difference' - CORP/EMP 14

Mental Capacity Act 2005 – Policy and Guidance, including Deprivation of Liberty Safeguards (DoLS) - PAT/PA 19

Eliminating Mixed Sex Accommodation, whilst Maintaining Privacy and Dignity Policy- PAT/PA 28 Information Risk Management Policy - CORP/ICT 21

Equality Diversity and Inclusion Policy-CORP/EMP 59

Equality Analysis Policy - CORP/EMP 27.

15 DATA PROTECTION

Any personal data processing associated with this policy will be carried out under 'Current data protection legislation' as in the Data Protection Act 2018 and the UK General Data Protection Regulation (GDPR) 2021.

For further information on data processing carried out by the trust, please refer to our Privacy Notices and other information which you can find on the trust website: https://www.dbth.nhs.uk/about-us/our-publications/information-governance/

15 **REFERENCES**

Health and Safety Executive Riddor http://www.hse.gov.uk/riddor/

Never Event Frame Work https://www.england.nhs.uk/wp-content/uploads/2020/11/2018-Never- Events-List-updated-February-2021.pdf

Regulation 20 Duty of Candour

https://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-20-duty-candour

Patient Safety Incident Response Framework

APPENDIX 1 – DUTY OF CANDOUR PROCESS FLOWCHART

Applies in the following circumstances:

- Moderate harm or above; non-permanent serious injury or Prolonged psychological harm lasting over a month.
- The death of a patient when due to treatment received or not received

Stage 1: Patient Safety Event/Incident Identified, reported and graded

On identification of a patient safety incident, an incident report must be completed by the

Stage 2a: Identify Lead for Duty of Candour

Identify Duty of Candour lead (Ward/Department Lead, Matron, Departmental Leads or Consultant).

Stage 2b: Duty of Candour Conversation

Offer a **verbal apology and Initial Communication**, preferably face-to-face, to the patient/Relevant person and enter into clinical records and onto DATIX the date which it took place. This should ideally be done within **24 hours** of the incident coming to light. Patient must be offered the Duty of Candour leaflet (although the patient/relative can decline this). An objective factual conversation

Stage 3: Duty of Candour Letter (1):

A written **letter of apology** summarising the above conversation must be sent to the patient/
Relevant Person within **10 working days**. A copy of the letter must be uploaded to the incident report on DATIX. Refusals of discussions or failure to contact patient/ Relevant Person must also must be recorded in the patient notes and on DATIX. The Lead Investigator should establish how the patient and/or relevant person would like to receive any further information, including the final report/ resulting action plan/ updates.

Stage 4: Duty of Candour Letter (2):

Once all further enquiries have been completed the Lead Investigator is responsible for providing the patient/relevant person with the outcome of the further enquiries and the learning identified. Give a final apology. Record details of the conversation in the patient clinical records and on the incident report on DATIX. A written letter summarising the conversation must be sent to the patient/relevant person. A copy of all Duty of Candour correspondence, including attempts to contact patient/relevant person, letters, etc. must be uploaded to the incident report on DATIX

Duty of Candour leaflets are available in each ward and department (WPR 42262) and in the document section of Datix

Duty of Candour Template letters are available in the document section of Datix

APPENDIX 2 – REVIEWING THE INCIDENT (DIF2)

Reviewing the Incident (DIF2)

Each section within Datix needs to be completed fully in order to provide clear evidence of acknowledgement, investigation, actions and learning. Each of the sub menus (list on the left hand side of the screen), need to be completed as follows:

Name and Reference

- ID and Reference Number identify the individual incident
- Name ensure that this is the name of the person affected by the incident, or if it is an organisation incident, succinctly describes the event e.g. Staffing issues
- Handler This is the person with overall responsibility for ensuring that the incident is investigated and finally approved
- Department Manager The person who is aware of the incident but will not investigate or close
- Investigator Person responsible for investigating the incident
- RIDDOR State "Yes" if this is a staff injury and they have been off work MORE THAN 7 days
- Report to LFPSE If the incident affects a patient, the question is the reporters assessment of
 whether this is a patient safety event correct? is "Yes" and the LFPSE section must be completed
- Approval Status Click on the drop down box and change the status ensure that ALL incidents are moved from "Holding Area" within 3 days
- Closed If Investigation / Incident Summary / Duty of Candour / Action Plans are completed, the Incident can be Finally Approved and closed

Incident Details

This contains all of the details of the incident. Make sure you check:

- Accuracy of Location
- Diabetes and Cancer says Yes or No
- Correct Category of Incident compared with the description
- Result and Severity is accurate does it need to be downgraded or escalated? Remember this is ACTUAL HARM if the incident occurred or POTENTIAL HARM if the incident is a NEAR MISS
- Additional Questions Identifying if the incident is a Never Event hyperlinks to policies
- Reporter the name of the person reporting the incident, ensure you let them know the outcome of your investigation
- Other Specialties Affected other areas you may need to involve in your investigation, and notify of your outcome

If any of the details are incorrect - you have the authority to **CHANGE** them

Duty of Candour

If the incident severity grading is Moderate, Severe or Death, the Duty of Candour section will appear.

- If this is an incident involving a patient, either the patient or when a patient lacks capacity, a relative/carer must be informed of the circumstances of the incident offering a verbal apology
- Ensure that the verbal apology is recorded on Datix and documented in the case notes
- Duty of Candour Letter 1 should confirm this apology and be sent out within 10 days of the incident.
- Duty of Candour Letter 2 should be sent with a copy of the final investigation report

People directly and indirectly involved in the incident

- Ensure all contacts are approved
- Add in any contacts that have not been identified

Investigation Process (Actions)

- Ensure ALL actions and recommendations arising from the investigation are recorded on this section (including report action plans)
- This section can be used to send reminders to yourself or actions to others in the course of your investigation

Incident Summary

This is where you demonstrate the findings of your investigation, every section is MANDATORY

- Root Causes/ Contributory Factors leading to the incident. This is free text, record all your findings
- Summary Root Causes A drop down list of root causes, click in the smaller of the 2 boxes, you can single click as many as are applicable and then double click one you have highlighted to add them to the main box above.
- Action Taken (Investigation) a free text box to describe the actions you took during your
 investigation and what subsequent actions are required in order to minimise the risk of this incident
 occurring again
- Action Taken Codes A drop down list, use as per the summary root case
- **Key Findings** This is for Patient Safety Incident Investigations (PSII) only and is filled in by the Patient Safety Team Administrator
- Risk Grading All incidents need to be risk graded on likelihood of occurrence and the consequence should it occur
- Outcome of Investigation identify whether the incident was avoidable or unavoidable and whether there are further actions which need to be actioned (ensure they are on the action plan)
- Lessons Learned enter the results of your investigation in this field to facilitate learning from this event/incident and to provide feedback to the incident reporter
- Have we reduced the Risk? Answer Yes or No

Serious Incident Details

This section summarises the processes involved and timeline for completion of the Patient Safety Incident Investigation report. This section is for the Patient Safety Team only, If you need an explanation on this section please call the Patient Safety Team on extension 642276

Inquest Details

This section summarises the processes and details of an Inquest. This section is for the Legal team only. If you are involved in an Inquest and need an explanation on this section please call extension 642167

Communication and feedback

This is the email facility within Datix. If you need to contact a member of staff or respond to a message on an incident, please ensure that this is completed in this section.

- Recipients—This is your equivalent to the "To" box in Outlook. The top section will state the names of the Handler and Reporter; the middle box holds the names of all staff that have a Datix login and the third box is a free-text box so you can add any other member of staff. Please note you may only add NHS email addresses and you may email any number of staff at the same time
- Message—the first box has a default subject heading, the larger box has some text already in—please leave this text—and enter your message after the prompt "The feedback is:"
- Remember to feedback your findings to the reporter
- Press the "Send message "box
- Notifications these show the people who were notified of this incident when it was reported

Documents and Templates

- **Documents** this is where you add documents as evidence of your investigation, these could be reports, letters (Duty of Candour), photographs (NEVER attach any photographs of patients) or general supporting evidence. Click on "Attach a new document" to start the process, identify the type of document, give it a short title and press "Browse" to look for the file on your computer.
- Templates the drop down box contains templates of Duty of Candour letters, witness statements, scoping and report templates. Click on the document required and press "Merge in MS Word"

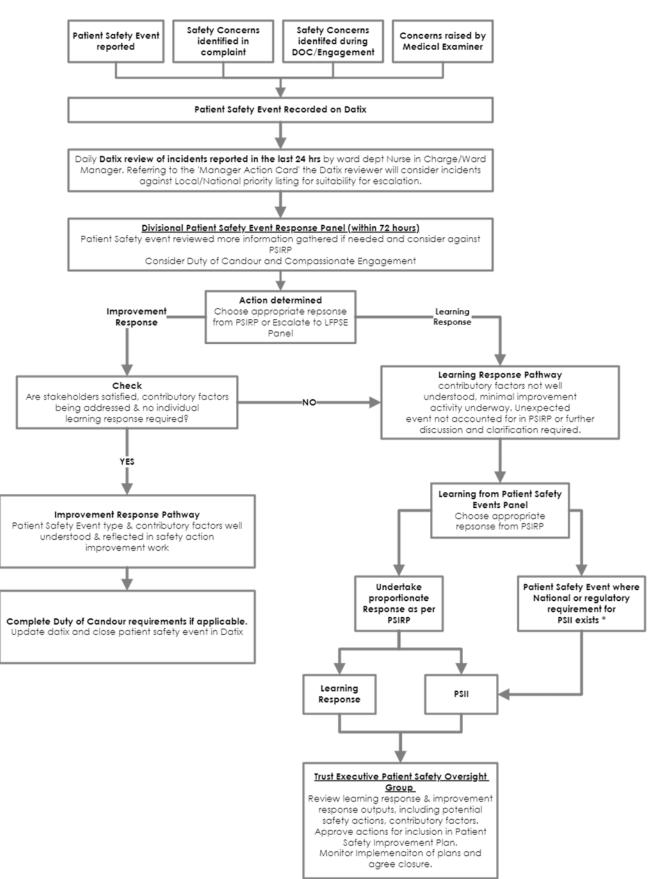
Progress Notes

This is where you can document findings, progress and general notes on the incident you are investigating. All you need to do it type in the large text box and then press "Save". Datix will Date and Time stamp the note with the name of the person logged in to Datix.

Linked Records

In order to help the Datix User, Incidents can be linked to Complaints and to Claims. This is carried out by the Patient Experience Team and the Patient Safety & Legal Teams.

For further information on any of the above sections, please contact the Datix Administrator on extension 642275



Appendix 3: Decision-making process illustration

	Care Gro	up/Executive	Assessor (s)	New or Existing Service or	Date of
Strategy	Care Group/Executive Directorate and Department			Policy?	Assessment
ORP/RISK 33 v.2 – Incident	Nick Mallaband		Nicola Severein-Kirk	Existing policy - review	May 2025
lanagement Policy					
Who is responsible for this policy	? Name of Care	Group/Directorate:			
Describe the purpose of the servi	ice / function / pe	olicy / project/ strat	egy? Who is it intended to b	enefit? What are the intended outco	omes?
Are there any associated objective	ves? Legislation, t	argets national expe	ctation, standards:		
What factors contribute or detra	ct from achieving	intended outcomes	5? –		
Does the policy have an impact in	n terms of age, ra	ce, disability, gende	r, gender reassignment, sex	ual orientation, marriage/civil part	nership,
maternity/pregnancy and religion	n/belief? Details:	[see Equality Impact	t Assessment Guidance] -		
If yes, please describe cu	rrent or planned	activities to address	the impact [e.g. Monitoring	g, consultation] –	
Is there any scope for new measu	ures which would	promote equality?	[any actions to be taken]		
Are any of the following groups a	adversely affected	d by the policy?			
Protected Characteristics Affected? Impact					
a) Age	No				
b) Disability No					
c) Gender	No				
d) Gender Reassignment	No				
e) Marriage/Civil Partnership	No				
Maternity/Pregnancy	No				
g) Race	No				
n) Religion/Belief	No				
) Sexual Orientation					
Provide the Equality Rating of the	e service / function	on /policy / project /	strategy — tick (√) outcome box	1	
Outcome 1 ✓ Outcome 2	Outco	me 3	Outcome 4		
f you have rated the policy as having an outo	come of 2, 3 or 4, it is	necessary to carry out a	detailed assessment and complete	α Detailed Equality Analysis form – see CO	RP/EMP 27.