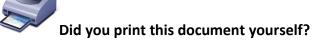




Serious Incident (SI) Policy Reporting, Investigating & Learning from Serious Incidents

This procedural document supersedes: CORP/RISK 15 v.5 – Serious Incidents (SI) Policy

Please Note: This policy is currently under review and is still fit for purpose.



The Trust discourages the retention of hard copies of policies and can only guarantee that the policy on the Trust website is the most up-to-date version. **If, for exceptional reasons, you need to print a policy off, it is only valid for 24 hours.**

Executive Sponsor(s):	Tim Noble, Medical Director	
Author/reviewer: (this version)	Liam Wilson, Head of Patient Safety & Experience	
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Target audience:	All staff, Trust-wide	

Amendment Form

Brief Details of Changes Made:

Version	Date Issued	Brief Summary of Changes	Author	
Version 6	17 June 2020	 Amendment Sub-section 4.7b – Trust-wide Learning – additional phrasing regarding the completion of a 'Shared Learning Report', a short, ideally one page, learning document to be created for each 'care issue' SI. Section 6 - Monitoring – inclusion of annual monitoring of the 'Shared Learning Report'. 	Liam Wilson	
Version 5	26 June 2019	 Flowcharts updates Staff group updated Process refined. Incident Decision Tree replaced with Just Culture guide. Addition of Yorkshire Contributory Factors Framework and guidance around creation of SMART and Strong actions Please read in full. 	Liam Wilson	
Version 4	24 July 2017	 Significant changes throughout to reflect the NHS Serious Incident Framework 2015 and Care Group implementation and structure 	Louise Povey Lisette Caygill	
Version 3	December 2013	 Flowcharts updated Staff group updated Definition of Serious incident changed in accordance with SI Framework 2015 	Mandy Dalton	
Version 2	November 2008	This document has been reviewed, without change.		
Version 1	November 2007	This is a new procedural document, please read in full.		

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SERIOUS INCIDENT POLICY – 10 KEY POINTS

- Following any incident, ensuring the safety of patients, staff and the environment is
 of paramount importance. Immediate actions to manage the incident must be the
 priority before the incident is reported on Datix. Escalation should be considered
 as soon as it is safe to do so.
- 2. In the case of a Serious Incident (SI) it is important to identify who will provide the initial support to the patient and/or family.
- 3. It is important that any incident suspected as a SI is notified to the Patient Safety Team as soon as possible. The notification ensures communication of incidents and the mobilisation of help and support. Even when it is decided an incident is not a SI the notification can be very valuable.
- 4. Root Cause Analysis (RCA) methodology will be used by the Patient Safety Lead who will conduct the investigation. In conjunction with the Divisional Director, Divisional Governance Lead(s) and Associate Director(s) of Nursing/Heads of Nursing/Midwifery/Therapy an independent (to the investigation) staff member will be identified to support the process and provide clinical/specific expertise (aligned to professional knowledge in the context of the serious incident).
- 5. SI investigations are intended to establish learning in order that services can be improved and that recurrence of such incidents can be significantly reduced in the future.
- 6. The principles of Duty of Candour must be applied. Patients (and where relevant relatives and carers) should be supported to raise questions within the investigation and have the outcomes shared with them. The nature of the contact with the family across the period of investigation should be agreed with the patient, or when appropriate, their relative or carer, taking into account their individual needs and preferences. The lead investigator will offer a meeting to the patient to explain the report.
- 7. All staff involved in a SI investigation should be offered appropriate support and have the opportunity to receive feedback on conclusion of the SI investigation.
- 8. Concluded SI investigation reports are anonymised to maintain confidentiality. They are provided to the persons agreed through the Duty of Candour process, the staff involved and to the relevant Divisions. Summaries of these reports are provided to the Trust's Division Clinical Governance Committees and Patient Safety Review Group (PSRG), for wider learning consideration. They will be shared with external agencies where relevant e.g. Coroner.
- 9. Additional support and guidance when a SI occurs outside of normal working hours is available via the on call manager(s).
- The timeframe allocated for completion of SI reviews reflects national requirements set out in the NHS England Serious Incident Framework <u>click here to view</u>.

Figure 1 - Serious Incident Timeline Overview

•SI Occurs •Incident is reported on Datix •Confirmed by Patient Safety Team **Immediately** •A Lead Investigator is appointed •Establish facts, to aid 72 hour report 1 - 2 Days • Duty of Candour requirements Scoping and information gathering Request interviews Days 1 - 10 Investigation •Interviewing of key staff members Attendance at Serious Incident Panel Days 1 - 15 Analysis of information gathered • Draft report written with recommendations • Draft report reviewed by investigation team and Division(s) Day 16 - 40 • Recommendations and action plan agreed with Division. •Report approved by Trust Executive • Report submitted to Clinical Commissioning Group for approval Days 41 - 60 •Trust approved report distributed to staff involved, patient/family and those identified in distribution list. Learning disseminated across the Trust through various methods Day 60

onwards

Completion of Recommendations and Action plans

•Head of Patient Safety and Experience appoints a Patient Safety Lead to be Lead Investigator for all Divisional investigations.

•The Division will appoint a Lead Investigation for all appropriate Pressure Ulcers and Falls.

Day 1 - 3

Duty of Candour

•Notify patient/family of incident and arrange a discussion with the patient (and/or relevant family).

•Monitor the Duty of Candour process

Day 4 -

Scoping & Information Gathering •Complete scoping document including staff key (name, position, involvement) - save in electronic Investigation file

•Collect relevant information (rotas, staff lists, patient results etc)

• Request interviews from relevant individuals.

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•Interview key staff members

•Should a delog be considered liaise directly with CCG

•Attend first Serious Incident review panel meeting arranged by the Patient Safety Team

Investigation

Report

•Using relevant Trust investigation report (attached to the Datix) that includes:

- •Terms of Reference
- Incident details
- Any family concerns
- Analysis

Duty of Candour compliance

• Relevant contents of scope

•Send draft report to Head of Patient Safety & Experience, Investigation Team, Division Lead/s for agreement and formulation of the recommendations & action plan

•Send agreed report to Patient Safety Team for onward circulation to SI Panel members

09 - 0t

•Meet with Divsion to agree recommendations and action plan.

•Submit report to Executive Lead for 'Sign Off'

•Send authorised signed report to the Patient Safety Team to send to the Clinical Commissioning Group

•Ensure that the Division receive the final report to facilitate distribution to the patient/ family to meet DoC requirements and for Trust wide/local shared learning.

Monitoring

• All SI report(s) to be presented at PSRG with discussion on learning and actions. A quarterly review of completion of SI actions.

Report - Day 1 - 40

Day 40 - 60

Figure 3 - Role of the Patient Safety Administrative Team in SIs

• Review and confirm grading of Serious Incident - whether externally reportable SI • Rate incident severity with the SI Panel Review Group members **Datix Form** Received Never Event •All Never Events are SIs Serious Incident • Notify relevant Clinical Governance Lead, Division / Directorate Manager and appropriate Executive Team Notification Liaise directly with Doncaster & Bassetlaw Clinical Commissioning Group and record via STEIS Upload incident to NRLS Receive staff key PSL writes report in collaboration with investigation team Co-ordinate and attend first and final panel meetings Organise an incident de-brief (if relevant) Investigation •Ensure all investigative interviews with key staff are completed and checked for accuracy •On receipt of request to delog Serious Incident liaise directly with the CCG Update STEIS as needed Receive signed off report from Lead Investigator •Submit Trust approved (Executive signed) report to CCG by Day 60 and confirm submission with Lead Investigator •Monthly: • Patient Safety Review Group: Notify of New Serious Incidents and open/incomplete Report action plans via the Integrated Risk Management Report •Clinical Governance Committee: Provide monitoring of SIs in the Integrated Risk Management Report •Submit data to the Acute Clinical Quality Review Group • Follow progress of all Trust Serious Incident reports and action plans

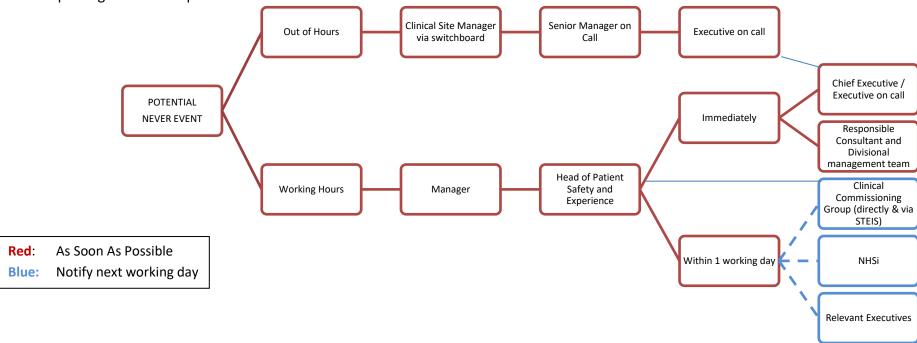
Monitoring

- Escalate non-compliance with Serious Incident Action Plans and DoC to Clinical Governance Committee via the RIsk Management Report.

Figure 4 - Reporting Never Events

Never Events follow the SI procedure with the following additions

1. Reporting cascade for potential Never Events.



- 2. All documentation will state 'NEVER EVENT' and the investigation report should describe the Never Event
- 3. Serious Incident panel must include the Head of Patient Safety and Experience or the Medical Director/Director of Nursing.
- 4. If decision is taken outside of SI panel this must be discussed with either the Medical Director/Director of Nursing.
- 5. Investigation permitted over **60** working days

Figure 5: Role of all staff involved in a Serious Incident (Including Datix reporter)

- Secure the area
- Ensure the patient is safe
- Inform immediate manager for escalation and confirmation of severity
- Report the incident on Datix
 - In the additional details section, click on the tick box asking "Is this a Serious Incident" (This will ensure that the incident is automatically sent to the Patient Safety Team for review)
- It may be helpful to keep a memory capture document to enable better recollection of accounts of the incident.

You may be invited to discuss the events via an interview to aid the investigation with gathering information with the Lead Investigator; you will be notified if you are required

1 INTRODUCTION

Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust (the Trust) is committed to continually improving the quality and safety of all services. The Serious Incident (SI) policy outlines the quality standards and procedure for the review of all SIs. SI reviews are conducted to identify learning which will be used to improve services. This document is the policy and procedure for the reporting of Serious Incidents for all Trust services in all settings.

2 PURPOSE

The Trust will report, manage and learn from Serious Incidents (SIs), wherever they occur, as part of its commitment to maintaining high quality services, supporting staff and maintaining public confidence in the Trust, the NHS and Social Care as a whole.

The purpose of a SI investigation is to understand what happened, why it happened and how we can learn from the Incident to significantly reduce the risk of recurrence. The focus after completing the investigations is to share the learning Trust wide.

3 DUTIES AND RESPONSIBILITIES

3.1 Chief Executive

The Chief Executive has ultimate responsibility for patient safety and risk management across the Trust and will ensure that there is a system so that all incidents are dealt with appropriately, promoting a just culture for accountability, openness and candour.

3.2 Medical Director and Director of Nursing, Midwifery and Allied Health Professionals

The Medical Director is the executive lead for Governance and the Director of Nursing Midwifery and Allied Health Professionals supports and deputises as required. Their teams provide the day to day oversight of decision making with regard to SI reporting and investigation. The Directors and Deputies are responsible for signing off the investigation reports.

3.3 Serious Incident Panel

The core SI panel members include the following roles:

- Deputy Medical Director x 2.
- Deputy Director of Nursing, Midwifery and Allied Health Professionals.
- Deputy Director of Quality and Governance.

- Head of Patient Safety and Experience.
- Education Quality and Governance Manager.

When required, individual specialist members attend to aid decision making when an incident is being initially assessed as to whether it meets the threshold for a SI and when the SI report is in its final draft.

The purpose of the SI Panel is to oversee, monitor and direct the SI process. This includes:

- To undertake an initial assessment of all new incidents and confirm where appropriate
 that the incident meets the threshold to be investigated and reported as a Serious
 Incident.
- To provide guidance on the focus of the SI investigation (initial scoping, 72 hour report, first draft and final draft).
- To agree the Terms of Reference for the SI investigation.
- To seek assurance that duty of candour responsibilities are undertaken.
- To identify the lead investigator and appropriate clinical support for the investigation.
- To monitor progress of investigations through to completion of reports and seek to address any delay in the process.
- To Quality Assure SI investigations and reports.
- To monitor the completion of SI action plans.
- To ensure that learning from SI investigations is disseminated.
- To identify any learners (Student Nurses/Midwives/AHP's/Doctors in training and apprentices) to support them during the investigation process, appropriately exception report to Health Education England (HEE) and Higher Education Institutes (HEI's) and meet our responsibility as a Local Education Provider (LEP).
- To agree the executive with responsibility for SI report sign off.
- Where incidents do not meet the SI criteria, but an Incident Investigation Report is required, completion of these is monitored by the SI panel.

The Director of Nursing, Midwifery and Allied Health Professionals and Medical Director may attend and contribute when required. The panel meet predominantly on a weekly basis, with exceptions for bank holidays or when other commitments prevent the panel meeting. Additional panel meetings are arranged as and when required. Discussions on SIs may take place electronically, dependent on severity and complexity.

3.4 Head of Patient Safety and Experience

- Allocate a SI lead investigator from the Patient Safety Team.
- Brief regulatory bodies and commissioners as appropriate.
- Quality assures all final SI reports before final sign off by the Trust lead.
- Liaise with the Clinical Commissioning Group (CCG) Incident Management Group (IMG).

- Inform the Legal Services Manager of any incidents that have the potential to become a claim or Inquest.
- Ensure Key Divisional people are aware of any new SIs for their division.
- Create the Terms of Reference for each SI investigation.
- Provide operational management of the SI process and Patient Safety Team, guiding investigation and analysis.
- Where a specific need is identified, undertake SI Lead investigator duties.
- Ensure appropriate provision of reports to trust committees as per Trust requirement.

3.5 Patient Safety Leads

The Patient Safety Leads will:

- Fulfil the duties of the Patient Safety Lead of the Day.
- Undertake fact finding activities to establish if an incident meets the threshold for reporting a SI.
- Complete the scoping document if considering a SI.
- Attend SI Panel when required, to present findings and update on progress.
- Work to achieve deadlines.
- Complete 72 hour report for allocated SIs (requires approval from Head of Patient Safety and Experience).
- Identify and interview relevant staff as part of the investigation.
- Develop the investigation plan in line with the GANTT chart, agreeing any variance to the schedule with the Head of Patient Safety and Experience.
- Contact the patient, family or relative to update them on progress of investigation.
- Monitor allocated Division compliance with Duty of Candour and SI Actions.
- Lead and facilitate investigations, supporting Division clinicians and managers.
- Develop and agree the recommendations, actions and reports with the Division.
- Upon completion of SI report, attend CCG IMG and PSRG for presentation.
- Work with other members of the Patient Safety Team, Legal Services and Patient Advice and Liaison Service (PALS) to provide effective communication to benefit investigations that may span these functions.

These posts are aligned to working with the Clinical Governance Lead(s) and Divisional management teams to provide analysis of incident and risk data, producing monthly and quarterly reports for the Division and specialties, as required.

3.6 Patient Safety Team

Patient Safety Coordinator (Serious Incidents) will:

• Support the Patient Safety Leads with fact finding activities to establish if an incident meets the threshold for reporting as a SI.

- Produce a GANTT chart at the start of Serious Incident Investigations they are assigned to – this maps out the timeline for achievement of defined investigation milestones.
- To monitor the SI investigation timeline for those investigations they are assigned to weekly this will help ensure investigation team on track for milestones.
- Obtain and digitise the relevant patient records when a SI is declared.
- Support the Patient Safety Leads in recording the investigatory meetings and interviews.
- Ensure SI report actions and incidentals are added to the Datix system and assigned appropriately following trust sign off of reports.

Risk Management Coordinator will:

- Administer all aspects of the SI process and provide tracking documents for timeline compliance with national reporting standards (including reporting to STEIS).
- Coordinate the SI Panel, scheduling SIs at appropriate times during their 60 day time period.
- Take action notes from SI Panel.
- Support investigators responsible for Division SIs i.e. Pressure Ulcers, Falls.
- Supporting where Serious Incident report actions and incidentals are to be added to the Datix system and assigned appropriately following trust sign off of reports.
- Quality and accuracy checks on Datix.
- Plan and diarise investigation deadlines.
- Submit 72 hour report to the Clinical Commissioning Group (CCG)
- Format and provide review of all finalised SI reports before sending to the CCG.
- Close liaison with CCG regarding scheduling SI reports for the CCG Incident Management Group (IMG).
- Manage CCG IMG SI tracker, escalating to the Head of Patient Safety and Experience with any concerns.

3.7 Divisional Director, Associate Directors of Nursing, Heads of Nursing/Midwifery/Therapy and Divisional Governance Leads

The Divisional Director, Associate Directors of Nursing, Heads of Nursing/Midwifery/Therapy and Divisional Governance Leads will:

Divisional Director will:

• Be accountable for the accuracy of SI reports and ensuring delivery of actions detailed within the report.

Associate Directors of Nursing, Heads of Nursing/Midwifery/Therapy and Divisional Governance Leads will:

• Confirm that relevant staff are aware of the SI policy and procedure.

- Provide support to staff involved in SIs.
- Ensure potential SIs are identified on a timely basis by the Division and escalated to the Corporate Patient Safety Team for review.
- When a SI is declared, within the first 10 working days, have reviewed the scope to ensure the Terms of Reference are appropriate for the SI investigation.
- Attend the relevant SI panel meetings, when a SI is declared in their area.
- Identify appropriate staff (independent of direct involvement) to contribute their clinical expertise, assisting, as part of the investigation team for the SI (aligned to professional knowledge in the context of the serious incident).
- Nominate an appropriate subject matter advisor (ideally the clinical lead or governance lead for the speciality) to assist the investigation, when necessary.
- Review the draft reports, to ensure the analysis and assumptions of the findings are correct by day 40 of the investigation.
- Agree a meeting with the SI report author early in the investigation process between day 40-50 of the SI investigation process to create recommendations and actions in response to the findings of the investigation.
- Ensure that there are systems in place to monitor the completion of each action until the action plan has been delivered.
- Ensure that the clinical governance arrangements within the Division enable shared learning and demonstrate embedding practice changes.

3.8 Divisional Clinical Governance Lead

Clinical Governance Leads will report and monitor SI activity within their Division at Clinical Governance meetings. Additionally, the Clinical Governance Leads may form part of the investigation team, have the opportunity to comment on the draft reports and contribute to agreeing the appropriate recommendations and action plan prior to the SI report being issued formally.

The Governance lead will ensure that the findings of the SI investigation and the action plan are shared at the Divisional Clinical Governance meeting. The monitoring of action plan completion is a key function which will be reported through Clinical Governance committees for each speciality and Division.

3.9 Education Quality and Governance Manager

The Education Quality and Governance Manager will identify staff that are involved in a SI who are on Health Education England (HEE) training schemes and all recognised learners within the organisation (e.g. 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)). In doing so, appropriate support will be provided via the individual's Clinical Supervisor/College Tutor/Mentor/Personal Tutor/Clinical Tutor or Link Lecturer. Relevant reports will be completed for the Further/Higher Education institute or HEE as outlined in our responsibilities as a Local Education Provider (LEP).

3.10 Ward/Departmental Managers

- Must be familiar with, and implement the procedure for reporting SIs (see <u>Serious</u> Incident Timeline Overview).
- Ensure that all staff they line manage understand the incident reporting/review processes and are given appropriate training to support this. Identify any potential issues that may impede staff members reporting/investigating incidents and take appropriate action to support the member of staff.
- Ensure that all staff know how to contact managers within working hours, and oncall managers outside of normal working hours.
- Take the lead in supporting staff as a priority following a SI and, where appropriate, refer to the Occupational Health Department and/or signpost to the Employee Assistance Programme.
- Notify their Divisional Director and Heads of Nursing/Midwifery/Therapy/ Line Managers at the earliest opportunity following report of a SI.
- Ensure that a debrief meeting is called, appropriate to the nature of the incident in a timely way and that staff are supported to attend.
- Ensure that staff attend to immediate needs, re-establish a safe care environment and preserve evidence (suspected crime or equipment failure).
- Ensure staff are allocated sufficient time to attend Root Cause Analysis meetings and write witness statements as appropriate.

3.11 All Staff

- To be familiar with, and implement the procedure for reporting SIs (see <u>Serious Incident Timeline Overview</u> and <u>Role of Staff Involved in a Serious Incident</u>
- The senior person on duty must report the incident immediately to their Line Manager (during working hours) or the Clinical Site Management Team (outside working hours) via switchboard.
- Staff must attend to immediate needs, to re-establish a safe care environment and preserve evidence (suspected crime or equipment failure).

4 PROCEDURE

4.1 When to report an incident as a Serious Incident

SIs in healthcare are adverse events, where the consequences to patients/families and carers, staff or organisations are so significant or the potential for learning is so great that a heightened level of response is justified.

SIs include acts and/or omissions occurring as part of NHS-funded healthcare (including in the community) that result in:

- Unexpected or avoidable death of one or more people. This includes suicide, selfinflicted death and homicide by a person in receipt of mental health care within the recent past.
- Unexpected or avoidable injury to one or more people that has resulted in serious harm.
- Unexpected or avoidable injury to one or more people that requires further treatment by a healthcare professional in order to prevent the death of the service user or serious harm.
- Actual or alleged abuse, sexual abuse, physical or psychological ill-treatment, or acts
 of omission which constitute neglect, exploitation, financial or material abuse,
 discriminative and organisational abuse, self-neglect, domestic abuse, human
 trafficking and modern day slavery where healthcare did not take appropriate
 action/intervention to safeguard against such abuse occurring or where abuse
 occurred during the provision of NHS-funded care.
- A Never Event all Never Events are defined as SIs although not all Never Events necessarily result in serious harm or death.
- An incident (or series of incidents) that prevents or threatens to prevent an
 organisations ability to continue to deliver an acceptable quality of healthcare
 services.
- A serious breach of Confidence or Data Protection as measured through NHS
 Digital's Information Governance Toolkit: under Serious Incidents Requiring
 Investigation (SIRI) as a level 2 SIRI.

NHS England Serious Incident Framework <u>click here to view</u>. NHS England Never Events List <u>click here to view</u>.

SIs may also be identified through the Claims, Inquest and Complaints process.

4.2 How to report a Serious Incident

4.2a Working hours

A Datix incident form must be completed as soon as possible once staff are aware of the potential SI. The category of harm must be selected and the SI category indicated. This will then begin the Trust decision making process. An email will be sent automatically to the Patient Safety Team who will identify a Patient Safety Lead to scope the incident. An automated message from Datix will be sent to the management team within the Division.

4.2b Out of hours

The Clinical Site Management Team must be informed of any potential SI occurring in the out of hour's period.

If a Never Event occurs out of hours, weekends, or bank holidays, the Clinical Site Manager will inform the senior manager on call who will then notify the executive on call. See flowchart 4.

4.3 Immediate Action following a Serious Incident

Person identifying the SI

Take action to attend to the immediate needs of the individual(s) involved (including staff, patients, visitors, contractors, members of the public, etc.).

Take immediate steps to re-establish a safe care environment/situation, and rectify or limit any damage and preserve evidence (suspected crime or equipment failure).

The incident must be reported to the most senior person on duty in the area, or the person who is designated 'in charge' for the relevant team at the time.

When appropriate and safe to do so, report the incident on Datix.

Senior Person on Duty

Having made the environment safe and assessed immediate risk, decisions must be made appropriate to the nature of the incident. This can include:

- Preserving equipment in the case of failure of a medical device
- Restricting use of any medicines that may be involved in an adverse reaction
- Protecting potential crime scenes if police involvement appears likely
- When suspicion of crime exists then contacting the police
- Ensure the incident has been reported on the Datix system
- In case of clinical concern, the service or Division lead clinician must be informed
- In consultation with clinical staff inform the patient and where appropriate their relatives or next of kin (see Being Open, Saying Sorry and Duty of Candour policy (CORP/RISK 14).

4.4 Communicating with the Patient/family or carer

Working with patients/families following a SI Duty of Candour (DoC)

The culture of being open should be intrinsic throughout the Trust in relationships with and between patients, the public, staff and other healthcare organisations.

This policy is based on guidance from the NHS Resolution (formerly NHSLA) document "Saying Sorry" from 2017 and the Nursing & Midwifery Council (NMC) and General Medical Council (GMC) joint document 'Openness and honesty when things go wrong' guidance from 2015.

The guidance states that 'Saying sorry';

- Is always the right thing to do;
- Is not an admission of liability;

- Acknowledges that something could have gone better; and
- Is the first step to learning from what happened, preventing it recurring.

When undertaking the DoC, the following steps must be taken – ensuring that:

- DoC is initially undertaken verbally (face to face where possible) unless the patient (or relative) declines.
- This verbal notification (or decline) must be documented in the patient's medical record, including any responses by the patient (or relative if the patient is unable to be involved in the process themselves), ensuring that the associated incident number is documented.
 - An apology must be provided
 - A step by step explanation of what happened, in plain English, must be offered as soon as is practicable.

Lack of clarity whether a patient safety incident, or the degree of harm, has occurred, is not a reason to avoid disclosure.

- Follow up of the verbal notification must be in writing, outlining the process of the investigation, potential timescales and relevant contact details must be provided.
- Sharing the investigation report must be offered to the patient or relative/carer within 10 working days of the investigation being signed off as complete by the Trust.

A meeting will be offered to explain the report and give an opportunity for the family to ask questions or clarify elements in the report. This will be done, usually, after the CCG IMG has approved the investigation report.

There may be occasions where the severity of harm is low but the nature of the incident requires a SI investigation. In this instance it is essential that DoC is instigated as for all other SIs.

Please see DoC policy for more information.

Click here for more information on Duty of Candour.

4.5 Investigating the Incident (including 72 hour report)

The lead investigator will establish the key facts, determine the staff members who were involved in the SI and request an interview. The staff key template will be completed and kept in the investigator's file.

Within the 72 hour (3 working day deadline) of a SI being declared on STEIS, the investigation lead is required to create a 72 hour report with a progress update, which is sent to the CCG. All 72 hour reports are to be approved by the Head of Patient Safety and Experience (or Deputy Director for Quality & Governance if Head of Patient Safety and Experience is absent).

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

To assist with the investigation, the Lead Investigator may find benefit in using the Yorkshire Contributory Factors Framework (Appendix 1).

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 Division representative will attend 2 Serious Incident panel review meetings, the dates of which will be provided by the Patient Safety Team.

If through the investigation, it is determined that the incident does not meet the threshold of an SI, then the SI can be delogged if there is agreement to do so with the CCG. This requires a discussion with key contacts at the CCG, taking into account any incidental findings and their relevance.

4.6 Report and Action Plan

The final draft report and action plan will be written and approved on behalf of the Trust and 'signed off', as complete, by the Director of Nursing, Midwifery and Allied Health Professional, Medical Director or their deputies. Prior to sign off, the final draft report should be consulted on with all those involved, and agreed by the investigation team and by the Divisional Director or Heads of Nursing, Midwifery or Therapies. This includes completing, where relevant, the Just Culture Guide (see appendix 2).

The final report must be provided to the Clinical Commissioning Group within 60 working days, therefore planning and adhering to an appropriate schedule to achieve sufficient depth of investigation, report completion, consultation and sign off.

All SI action plans must be discussed at local Clinical Governance groups. The nominated leads identified in the action plan must be aware of the actions prior to sign off and deliver within the agreed timescales.

Overall accountability for this process lies with the Division. The responsibility for completing the investigation and developing a SMART action plan lies with the Division with support from the lead investigator. This will be monitored by the SI Panel and will be reported through the Clinical Governance Committee (CGC). Guidance on creation of SMART and Strong action plan is found at Appendix 3.

In exceptional circumstances, where SI actions are no longer relevant this must be escalated to CGC for consideration and review.

When an investigation is completed, the report is sent to the CCG. The CCG will schedule the SI investigation report for discussion at the most suitable slot (alternate Wednesday mornings) at their IMG meetings. The investigation team /Author will attend to present the report to the CCG IMG for overall approval and closure.

In most instances, the report will then be shared with the family when the SI investigation has been approved by the CCG. However, this is to be considered by the SI panel on an individual basis as some reports may need to be shared with a family at the point of Trust approval.

4.7 Learning from incidents

4.7a Staff involved in the incident

The lead investigator will share the final report with all staff directly involved in the SI. These arrangements will be recorded on the final report in the distribution list.

4.7b Trust-wide learning

A short, ideally one page, learning document will be created for each 'care issue' Serious Incident (by the SI investigator) to highlight the salient points of the incident and subsequent learning and actions. This collectively will be known as the 'Shared Learning Report' and prepared by the Head of Patient Safety and Experience. It will cover the following points:

- What happened?
- Why did it happen?
- What actions have been instigated to mitigate recurrence?
- What learning has been highlighted?

Learning must take place following an incident and the lessons learned identified. These can be shared with the Patient Safety Team for immediate dissemination across the Trust, as appropriate. In addition, the team will directly liaise where required with the Trust Training and Education department to determine appropriate education needs and how these will be met.

Some incidents may require additional training and education at either individual, departmental, Divisional or Trust level. The Education Quality and Governance Manager will support the delivery of the training requirements which may also include clinical simulation scenarios and facilitated training.

Each SI occurring as a result of sub-optimal care will be presented to the Patient Safety Review Group (PSRG). The 'Shared Learning Report' (which will include the individual one page learning summaries from the SI investigations) will be distributed through the Patient Safety Review Group as the primary source following which this can then be disseminated through the Clinical Governance Coordinator to the appropriate divisional and speciality governance teams. The full SI investigation report can be shared if and when required.

The PSRG also receive a monthly risk management report containing identified themes and trends from SIs. This report should be distributed by PSRG members to all Divisions and Heads of Departments for organisational learning.

The Patient Safety and Legal Team contribute to a monthly bulletin called 'Sharing How We Care' which will give examples of lessons learned during serious incidents.

4.8 Staff Support

DBTH take Health & Wellbeing seriously and there are a variety of services available. Staff involved in the investigation process will have the opportunity to access professional advice

from their line manager, relevant professional body or union, staff counselling and occupational health services. Staff will be supported through the investigation and be provided information regarding the stages.

To ensure a robust and consistent approach to investigation the Trust will refer to the NHS Improvements Just Culture Guide (see appendix 2).

5 TRAINING/SUPPORT

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

6 MONITORING

What is being Monitored	Who will carry out the Monitoring	How often	How Reviewed/ Where Reported to
Completion of SI Investigation in 60 days	Head of Patient Safety and Experience	Quarterly	Report received by Patient Safety Review Group and Clinical Governance Committee
Monitoring feedback from IMG for approval	Head of Patient Safety and Experience	Quarterly	How many SIs are not approved first time at CCG IMG. Report received by PSRG & CGC.
Quality audit of SI actions plans	Division / Head of Patient Safety and Experience	Quarterly	Audit 10 actions to ensure SMART criteria met.
Shared Learning Report to be an agenda item at speciality and divisional governance meetings.	Head of Patient Safety and Experience	Annually	Auditing 10 sets of governance minutes to confirm shared learning report discussion.

7 DEFINITIONS

Never Events - Never Events arise from failure of strong systemic protective barriers which can be defined as successful, reliable and comprehensive safeguards or remedies e.g. a uniquely designed connector to prevent administration of a medicine via the incorrect route - for which the importance, rationale and good practice use should be known to, understood by, and robustly sustained throughout the system from suppliers, procurers, requisitions, training units, and front line staff alike. The link to the NHS Never Events can be accessed here:

https://improvement.nhs.uk/documents/2266/Never Events list 2018 FINAL v5.pdf

Clinical Governance - A Framework through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish.

Commissioner - An organisation with responsibility for assessing the needs of service users, arranging or buying services to meet those needs from service providers in both the public, private or voluntary sectors, and assuring itself as to the quality of those services.

Clinical Commissioning Group - Clinically-led organisation that commissions most NHS-funded healthcare on behalf of its relevant population. CCGs are not responsible for commissioning primary care, specialised services, prison healthcare, or public health services.

Abbreviations

PSRG - Patient Safety Review Group

NHSI – National Health Service Improvement

NHSE – National Health Service England

NRLS – National Reporting and Learning System

STEIS - Strategic Executive Information System

CCG - Clinical Commissioning Group

IMG - Incident Management Group

SI – Serious Incident

DoC - Duty of Candour

YCFF - Yorkshire Contributory Factors Framework

CGC – Clinical Governance Committee

SHWC - Sharing How We Care

SMART - Specific, Measurable, Achievable, Realistic, Timely actions

DBTH - Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust

8 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 Fair Treatment For All Policy (CORP/EMP 4).

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)

9 ASSOCIATED TRUST PROCEDURAL DOCUMENTS

Fair Treatment for All - CORP/EMP 4
Equality Analysis Policy - CORP/EMP 27
Information Risk Management Policy - CORP/ICT 21
Incident Management Policy - CORP/RISK 33
Being Open, Saying Sorry and Duty of Candour Policy - CORP/RISK 14

Complaints, Concerns, Comments and Compliments: Resolution and Learning - CORP/COMM 4 Mental Capacity Act 2005 Policy and Guidance, including Depravation of Liberty Safeguards (DoLS) - PAT/PA 19

10 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 General Data Protection Regulation (GDPR) 2016.

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/uk-data-protection-legislation-eu-general-data-protection-regulation-gdpr/

11 REFERENCES

Department of Health, 'A promise to learn – a commitment to act: improving the safety of patients in England', August 2013.

https://www.gov.uk/government/publications/berwick-review-into-patient-safety.

The Health and Social Care Act 2008 (Registration of Regulated Activities) Regulations 2014, http://www.legislation.gov.uk

Home Office Multi-agency Statutory Guidance for the Conduct of Domestic Homicide Reviews (2016)

https://www.gov.uk/government/publications/revised-statutory-guidance-for-the-conduct-of-domestic-homicide-reviews

Human Rights Review (2012) Article 2: The Right to Life

https://www.equalityhumanrights.com/sites/default/files/human-rights-review-2012.pdf

NHS Digital Checklist Guidance for Reporting, Managing and Investigating Information Governance Serious Incidents Requiring Investigation (2015)

https://www.igt.hscic.gov.uk/KnowledgeBaseNew/HSCIC%20SIRI%20Reporting%20and%20Checklist%20Guidance.pdf

Never Event Frame Work

https://improvement.nhs.uk/documents/2266/Never Events list 2018 FINAL v5.pdf

Serious Incident Framework

https://improvement.nhs.uk/resources/serious-incident-framework/

Regulation 20 Duty of Candour

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

Health and Safety Executive Riddor

http://www.hse.gov.uk/riddor/

APPENDIX 1 – YORKSHIRE CONTRIBUTORY FACTORS FRAMEWORK (YCFF)



A Framework for Patient Safety Incident Investigation: Yorkshire Contributory Factors Framework (YCFF)



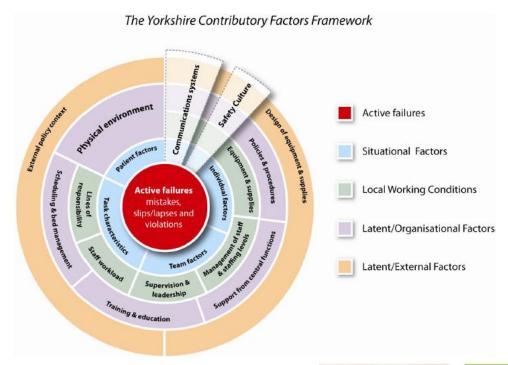
	Relevant to	CONTRIBUTORY FACTOR DOMAIN
Prompting question	Incident?	Situational Factors
Did the staff involved function as a team?	□ Yes	Team Factors - For example:
		Conflicting team goals
	□ Maybe	Lack of respect for colleagues
		Poor delegation
	□ No	Absence of feedback
On the day of the incident, how did you feel?	□ Yes	Individual Staff Factors - For example:
		Fatigue
	□ Maybe	Stress
		Rushed
	□ No	Distraction
		Inexperience
Did the task features make the incident more likely?	□ Yes	Task Characteristics - For example:
	□ Maybe	 Unfamiliar task
		Difficult task
	□ No	Monotonous task
Were there any reasons this incident was more likely	□ Yes	Patient Factors - For example:
to occur to this particular patient?		 Language barrier
	□ Maybe	 Uncooperative
		 Complex medical history
	□ No	 Unusual physiology
		• Intoxicated
Prompting question	Relevant to	CONTRIBUTORY FACTOR DOMAIN
Trompang question	Incident?	Local Working Conditions
Did staff provision match the expected workload	□ Yes	Workload & Staffing issues - For example:
around the time of the incident?		High unit workload
	□ Maybe	 Insufficient staff
	□ No	Unable to contact staff
		Staff sickness
Did everyone understand their role?	□ Yes	Leadership, Supervision & Roles - example:
	□ Maybe	Inappropriate delegation
	□ No	Unclear responsibilities
		Remote supervision
Were the correct drugs, equipment & supplies	□ Yes	Drugs, Equipment & Supplies - For example:
available and working properly?	Marries	Unavailable drugs
	□ Maybe	Equipment not working
	□ No	Inadequate maintenance
	Relevant to	No supplies delivery CONTRIBUTORY FACTOR DOMAIN
Prompting question		
Diddh and an income the last	Incident?	Latent/Organisational Factors
Did the ward environment hinder your work in any way?	□ Yes	Physical Environment - For example:
way:	□ Maybe	Poor layout
	Li Maybe	Lack of space Excessive noise / heat / cold
	□ No	
		 Poor visibility (e.g. position of nurses' station)
		Poor lighting Poor accept to national
		Poor access to patient

Were there any problems from other departments?	□ Yes	Support from other departments
		This includes support from IT, HR,
	□ Maybe	porters, estates or clinical services such
		as radiology, phlebotomy, pharmacy,
	□ No	biochemistry, blood bank, microbiology,
		physiotherapy, medical or surgical sub-
		specialities, theatres, GP, ambulance
Did any time or bed pressures play a role in the	□ Yes	Scheduling & Bed Management - example:
incident?		 Delay in the provision of care
	□ Maybe	 Transfer to inappropriate ward
		 Difficulties finding a bed
	□ No	 Lack of out-of-hours support
Were there any issues with staff skill or knowledge?	□ Yes	Staff Training & Education - For example
		 Inadequate training
	□ Maybe	 No protected time for teaching
		 Training not standardised
	□ No	No regular/yearly updates
Did local policies & protocols help or hinder?	□ Yes	Local Policies, Protocols & Procedures - e.g.
		No protocol exists
	□ Maybe	Protocol too complicated
	,	Lack of standardisation
	□ No	Contradictory policies exist
	Relevant to	CONTRIBUTORY FACTOR DOMAIN
Prompting question	Incident?	Latent/External Factors
le those any characteristic about the equipment	n Yes	Design of Equipment, Supplies & Drugs - e.g.
Is there any characteristic about the equipment, disposables or drugs used that was unhelpful?	II Tes	
uisposables of urugs used that was difficiplui.	□ Maybe	
	LI Iviaybe	Equipment not fit for purpose
	□ No	Similar drug names
		Ambiguous labelling & packaging
Have any national policies influenced this incident?	□ Yes	National Policies - For example:
	Maricha	Commissioned resources
	□ Maybe	National screening policy
		Interference by government
	□ No	organisations
		 National medical / nursing standards
		4 hour Emergency Department target
Prompting question	Relevant to	CONTRIBUTORY FACTOR DOMAIN
Trompang decation	Incident?	General Factors
How would you describe the culture of your clinical	□ Yes	Safety Culture - For example:
area in relation to patient safety?	□ Maybe	 Patient safety awareness
		 Fear of documenting errors
	□ No	 Attitude to risk management
Were the notes available, accurate & readable?	□ Yes	Communication
		Written and Verbal Communication
	□ Maybe	For example:
		 Poor communication between staff
Did poor or absent verbal communication worsen	□ No	Handover problems
the situation?		Lack of communication/notes
		Unable to read notes
		Inappropriate abbreviations used
		Unable to contact correct staff
I .		Notes availability

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CORP/RISK 15 v.6







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APPENDIX 2 – JUST CULTURE GUIDE



A just culture guide

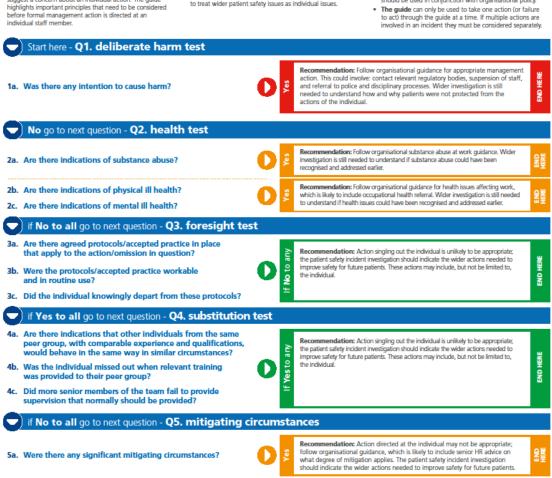
Supporting consistent, constructive and fair evaluation of the actions of staff involved in patient safety incidents

This guide supports a conversation between managers about Inis guine supports a conversation between managers about whether a staff member involved in a patient safety incident requires specific individual support or intervention to work safety. Action singling out an individual is rarely appropriate most patient safety issues have deeper causes and require wider action.

The actions of staff involved in an incident should **not** automatically be examined using this *just culture guide*, but it can be useful if the investigation of an incident begins to suggest a concern about an individual action. The guide

An important part of a just culture is being able to explain the Please note: An important part of a just culture is being able to explain the approach that will be taken if an incident occurs. A just culture guide can be used by all parties to explain how they will respond to incidents, as a reference point for organisational HR and incident reporting policies, and as a communication tool to help staff, patients and families understand how the appropriate response to a member of staff involved in an incident can and should differ according to the circumstances in which an error was made. As well as protecting staff from unfair targeting, using the guide helps protect patients by removing the tendency to the at wider nations can be considered in the staff of the control of the c to treat wider patient safety issues as individual issues.

- A just culture guide is not a replacement for an investigation of a patient safety incident. Only a full investigation can identify the underlying causes that need to be acted on to reduce the risk of future incidents.
- A just culture guide can be used at any point of an investigation, but the guide may need to be revisited as more information becomes available.
 A just culture guide does not replace HR advice and should be used in conjunction with organisational policy.



if No

Recommendation: Follow organisational guidance for appropriate management action. This could involve individual training, performance management, competency assessments, changes to role or increased supervision, and may require relevant regulatory bodies to be contacted, staff suspension and disciplinary processes. The patient safety incident investigation should indicate the wider actions needed to improve safety for future patients.

improvement.nhs.uk

Based on the work of Professor James Reason and the National Patient Safety Agency's Incident Decision Tree



























collaboration trust respect innovation courage compassion

APPENDIX 3 – SMART AND STRONG ACTIONS



Guidance for developing **SMART** and Strong Actions

The purpose of an action plan on a Risk Assessment, or any Incidents Investigation (including Serious Incident investigations) is to identify an action that when completed will reduce the consequence or likelihood of the risk or the chance of the incident re-occurring.

Actions need to be Strong as well as SMART. The most effective action plans have stronger actions than education or reminders alone.

Weaker actions include anything where there is a possibility of human error, for example staff following procedures or reading signs or posters.

Stronger actions do not depend on staff to remember to do the right thing, they include:

- · Testing new devices, processes and documentation
- Leadership checks of process and documentation
- · Simplifying processes, hardware and software enhancements and modifications
- · Standardising equipment or processes to reduce variation

Always ensure that Action Plan Leads have agreed to own the action and that the time frame is realistic prior to submitting. Do not use abbreviations or jargon in action plans.

Words to avoid in action planning:

Consider, Discuss, Raise, Remind, Reflect, Reiterate and Tell.

Words that strengthen actions:

Complete, Develop, Evaluate, Introduce, Monitor and Trial.

S Specific	The action should spell out precisely what you hope to achieve. It should detail an observable action, behaviour or achievement and, where possible, be linked to a rate, number percentage or frequency.
M Measurable	A system is needed to track or record the action, behaviour or achievement to establish if it is on target, overdue or has been reached. The updated NHS England guidance for Serious Incident Framework requires that evidence is made available, to show whether or not the action plan has resulted in the practice or system improvement anticipated.
A Achievable	The objective needs to be realistic and capable of being reached. Plainly ridiculous actions can demotivate people and prevent them from to completing them. Ensuring the action has been agreed between involved participants, rather than enforced, will help to ensure the likelihood of successfully completing the action.
R Realistic	An appropriate action is something that the Action Plan Lead can actually impact upon or change and is important to the organisation. Once achieved it will ensure that the risk has been reduced or has prevented reoccurrence of the incident.
T Timely	There needs to be a realistic timescale and completion date. In order to make communicating the development of the action easier, it is better to have a completion date which occurs on the last day of the month.

APPENDIX 4 - EQUALITY IMPACT ASSESSMENT PART 1 INITIAL SCREENING

Service/Function/Policy/Project/	Division/Executive Directora	te Assessor (s)	New or Existing Service or	Date of Assessment		
Strategy	and Department	, , ,	Policy?			
Serious Incident (SI) Policy -	Patient Safety and	Liam Wilson	Existing	02 April 2019		
CORP/RISK 15 v.5	Experience/Medical Director					
1) Who is responsible for this policy	? Name of Division/Directorate: N	Medical Director				
2) Describe the purpose of the servi	ce / function / policy / project/ st	rategy? To outline key principles a	and staff responsibilities in manag	ing the Serious Incident		
process.						
3) Are there any associated objective	es? Legislation, targets national ex	pectation, standards: NHS SI Fran	nework 2015			
4) What factors contribute or detract	t from achieving intended outcor	nes? – Non-compliance with polic	У			
5) Does the policy have an impact in			I orientation, marriage/civil part	nership,		
maternity/pregnancy and religior	- , ,	-				
	rent or planned activities to addr		onsultation] –			
6) Is there any scope for new measu	•	ty? [any actions to be taken] N/A				
7) Are any of the following groups a						
	Protected Characteristics Affected? Impact					
a) Age	No					
b) Disability	No					
c) Gender	No					
d) Gender Reassignment	No					
e) Marriage/Civil Partnership	No					
f) Maternity/Pregnancy	No					
g) Race	No					
h) Religion/Belief	No					
i) Sexual Orientation	No					
8) Provide the Equality Rating of the service / function /policy / project / strategy − tick (✓) outcome box						
Outcome 1 Outcome 2	Outcome 3	Outcome 4				
*If you have rated the policy as having an outc		at a detailed assessment and complete a L	Detailed Equality Analysis form – see COI	RP/EMP 27.		
•	•					
Checked by: Fior	na Dunn	Date: 06 April 2019				