INCIDENT INVESTIGATION

Standard Operating Procedure (SOP)

Ref No: 2146
Version: 3

Prepared by: Health and Safety Manager
Patient Safety Lead

Presented to: QIG Health and Safety Committee	**Date:** 30 March 2017 30 March 2017
Ratified by: QIG Health and Safety Committee	**Date:** 30 March 2017 30 March 2017
	Review date: 27 April 2021
Relating to policies:	Incident Reporting and Management Policy (Ref 0848) Being Open a Duty of Candour Policy (Ref 0898) SOP for reporting an incident through Incident reporting System SOP to review an incident Health and Safety Policy Information Governance Policy

1. Incident Grading and Appropriate Levels of Investigations

Incidents, including near misses, are subject to an appropriate level of investigation and root cause analysis and where relevant an action plan for improvements prepared. Not all events need to be investigated to the same extent or depth and the investigation and analysis should be relative to the seriousness, complexity of the event and/ or whether it resulted in actual harm and the potential for learning, such as those which are high frequency but may be of low severity.

2. Responsibility for Investigation

The level of the investigation required will be determined by the incident severity, and in line with our Incident reporting policy 0848. The Service Delivery Unit (SDU) is responsible for appointing an appropriate Investigator in liaison with the central governance team. Timescales for completion of the investigation report will be within 45 days or extended through agreement with the necessary parties.

Where other internal/external organisations need to be brought into the management of any incident the central Safety Teams will advise the investigator accordingly.
Each organisation involved will appoint a lead, with one investigator overseeing the entire investigation.

3. Investigator

An investigator may be appointed who is not a manager or supervisor. Anyone appointed as an investigator must have completed appropriate training. An investigator is responsible for completing an investigation into an incident while adhering to this policy and the Investigation Policy. For most clinical issue this may the SDU Governance Coordinator. They will ensure that a comprehensive report and recommendations are provided to the appropriate individuals and committees. A copy of the Incident RCA templates can be found at Appendix 1

4. Training

Root Cause Analysis (RCA) investigator training is provided at the Trust Horizon training centre as a course or can also be provided to an investigator on a 1:1 basis if necessary.

5. Involvement of Relevant Stakeholders

External agencies such as the Health and Safety Executive (HSE), Medicines and Healthcare products Regulatory Agency (MHRA), the Police or the Environmental Health Agency etc, may investigate certain incidents. These officers will contact the Trust Leads directly.

6. Further Actions by the Investigator

Depending on the severity of the incident the following actions should be performed by the Investigator or Manager (unless otherwise stated). The Safety teams will monitor, review and follow up these actions with appropriate management and Director level support. This is in line with the NHS England framework for reporting and learning from serious patient incidents requiring investigation.

- If there is a suggestion that a criminal offence has been committed, the police should be contacted

- If a Serious Incident Requiring Investigation (SIRI) requires reporting to the Police or the HSE an Incident Coordination meeting will need to be held as per the Memorandum of Understanding between the NHS, Police and HSE.

- Where an incident occurs which could result in a significant impact on the Trust including legal, media or other interest, it is important to ensure that the situation is managed appropriately to safeguard service users, staff and the organisation. This means that any person affected by the incident should, where possible, be notified prior to the media being informed.

- The Chief Executive, Chief Operating Officer, Medical Director, Chief Nurse and the Trust Communications team must be informed of all incidents that may involve or attract the attention of the media; this would usually be done via the Director on Call

7. Strategic Executive Information System (STEIS)

Patient SIRI's must be reported to the STEIS system within 48 hours of identifying that the incident is a SIRI. The Patient Safety Lead or appointed deputy approves which patient incidents are classed as a SIRI prior to being reported onto STEIS.

The Patient Safety and Clinical Risk Team will request a chronology/72 hour report (to be completed in 2 working days if possible and found as Appendix 1) where a SIRI is suspected. The chronology must be reviewed by the Patient Safety Lead, Service Delivery Unit Clinical Governance Coordinator, the Deputy Director of Nursing, their deputies or other appropriate persons delegated this task. If the chronology identifies the incident as a SIRI, it is inputted into the STEIS system and submitted under the appropriate incident grade. Once an incident is input on to STEIS, the Clinical Commissioning Group (CCG), Care Quality Commission (CQC) and NHS England are automatically notified through the STEIS system. The SIRI incident details will be uploaded from Incident reporting System to the NRLS once reported onto STEIS. The Patient Safety Lead or deputy, and/or the Director/Deputy Director of Nursing and Professional Practice will ensure that all the required external bodies have been notified.

'Never events' are classed as SIRI's and must be reported on STEIS. The Trust ensures compliance with reporting and liaison requirements with agencies such as NHSi, the Care Quality Commission (CQC), Public Health England, the Health and Safety Executive, and Coroners. Never Events are clearly defined as serious incidents and therefore, must be reported to the CQC. A NHS England 'Never events' list can be seen at Appendix 2

The local actions to take when a Never Event is suspected can be seen at Appendix 3.

Where further clarity regarding grading is required, guidance can be sought from the central the Patient Safety and Clinical Risk Team

8. Timescales

The expected timescales for completion and closure of incidents reported on Incident reporting System is dependent on the severity rating:

- Low harm/no harm/near miss incidents – 1 month from reported date
- Moderate/severe/catastrophic incidents – 45 to 50 days from reported date which allows for appropriate investigations to take place and then 10 days to review and send to the Commissioners by day 60

This means the time from first reporting the incident to when it is 'Finally Approved'. There will be exceptions to these timescales which will be determined by the Safety Leads

The timescale for completion of investigations for clinical SIRI's will be dependent on the grade of the serious incident as reported on STEIS. The timescales that apply which are in line with the current 2015 serious incident investigation framework can be seen in Appendix 4.

9. Recommendations and Action Planning

The Investigator should provide recommendations in their report to the relevant manager(s) and Safety teams, and an Action Plan should be drawn up by the relevant manager. Action plans must include who is responsible and the date for completion. These should then be shared with the Safety teams, and the relevant Committees (depending on the type of incident). A copy of a Smart Action plan can be found at Appendix 5

10. Monitoring of Action Plans

Action Plans are monitored by the Ward/department, SDU, Specialist groups e.g. Falls group and Local Governance Boards. For serious incidents, the actions are monitored as above and also by the Serious Adverse Events Group (SAE) and the Commissioners via STEIS. The owner of the action plan will be required to report on progress at agreed intervals in line with the due completion dates for the actions.

11. Learning and Sharing Lessons Learnt

Following an investigation and the production of an Action Plan it is important to ensure that the organisation takes risk reduction measures. The sharing of the lessons learnt post investigation is a critical part of incident management. Learning from safety incidents is a collaborative and reflective process. Learning is a process of change evidenced by demonstrable, measurable and sustainable change in knowledge, skills, behaviour and attitude. Learning can be demonstrated at Trust level by reductions in incidents and/or changes and improvements in process, policy, systems and procedures relating to safety. Individual learning can be demonstrated by changes and improvements in behaviour, beliefs, attitudes and knowledge of staff.

12. What Constitutes Learning

Examples of learning are given below:

- Solutions to address root cause of incidents which may be relevant to other teams, services and provider organisations
- Identification of good practice which reduced the potential impact of the incident, and how they were developed and supported
- Systems and processes that allowed early detection or intervention which reduced the potential impact of the incident
- Lessons from conducting the investigation which may improve the management of investigations in future

Learning points should be grouped to help identify those points applicable to teams, services, specialities, divisions or wider Trust.

13. Identifying Issues which may be of National Significance

Investigations may identify issues of national significance or where the dissemination of national learning is appropriate. Organisations such as the NRLS, MHRA, HPA, HSE, etc. have review, response and alert mechanisms. As already stated, relevant incidents should be notified to these bodies and provider organisations should subsequently share findings from investigations with these bodies, where issues of potential national learning for wider sharing are identified.

14. Learning from Safeguarding Adults Serious Case Reviews (SCR)

Executive representatives from the NHS are part of the local Safeguarding Adults Board (SAB) arrangements in each area and they are responsible for ensuring that communication between the SAB and the NHS Board is maintained. Learning lessons is the prime rationale of SCRs, and SABs are responsible for commissioning each SCR; sharing the learning across all organisations; and monitoring at agreed review periods whether the lessons have been taken on board. The SAB is responsible for ensuring that they receive regular progress reports on a commissioned SCR and to take action if the delay appears unreasonable.

15. Reporting to External Agencies

With the exception of STEIS, the reporting to other external agencies should be done by the relevant lead (where required/appropriate) - see Appendix 6.

16. Duty of Candour

In compliance with the NHS Constitution and statutory requirements for Duty of Candour and the Trusts Being Open – a duty to be Candid Policy, all patient safety incidents that occur during care provided by the Trusts services that result in moderate or severe harm or death (using NRLS definitions) the following actions to inform patents, families or carers must take place. (Contractually this does not apply to low/no harm incidents however best practice is that these should be reported to the patient). They must also be informed if there is a suspected incident where it is unclear what occurred, or what degree of harm was caused. Full details of the Trust's "Being Open" policy is available on the web site.

The initial verbal notification and apology (face to face where possible) with an offer of a written notification (unless the patient cannot be contacted in person or declines notification) must be recorded by the reporter on the Incident reporting System and in the patient notes.

All clinical SIRI investigations which are submitted to the Commissioners contain clarification as to whether the Duty of Candour has been applied. Copies of the documentation and information given to the patient and their family / carer will be available on request, observing compliance with contractual requirements, data protection and Caldicott principles.

There may be circumstances where a patient safety incident is not reported on the incident reporting system, but the Trust becomes aware from a third party e.g. commissioners, CQC, MP letter. These incidents (if resulting in moderate or severe harm or death) are also subject to the contractual duty of candour and, in addition, may represent further failures in reporting. Incidents that have not been reported are, by their nature, harder to detect and verify. Where a relevant patient safety incident is found to have occurred and not been reported on Incident reporting System and to the patient, this should be treated extremely seriously.

For incidents assessed as a clinical SIRI, a senior clinician will be identified as the key point of contact with the service user / relatives/ family or to undertake this discussion and ensure that the service user is kept informed. The incident report must be updated with all the people involved.

17. Practical guidance on the flow and management of an incident

Full guidance procedures for managing and investigating incidents can be found at Appendix 7

18. A Just Culture Guide

The Just culture guide is a new document which builds on and replaces the Incident Decision Tree. This guide supports a conversation between managers about whether a staff member involved in a patient safety incident requires specific individual support or intervention to work safely. Action singling out an individual is rarely appropriate - most patient safety issues have deeper causes and require wider action.

19. Appendices

Appendix 1 - Incident RCA Investigation Templates

Appendix 2 - NHS England Never Event List 2015/16

Appendix 3 - Never Event - Local Actions to take

Appendix 4 - Timescales for completion of investigations for clinical SIRI's

Appendix 5 - SMART action plan

Appendix 6 - Reporting to External Agencies

Appendix 7 - Guidance Procedure for Managing and Investigating Incidents

Appendix 8 – A Just Culture Guide

Amendment History

Issue	Status	Date	Reason for Change	Authorised
1	Ratified	7 April 2017	New SOP	QIG Health and Safety Committee
2	Ratified	7 July 2017	Appendix 1 – Non Patient RCA and Clinical Code Investigation Concise: Links removed. Minor amendments to text	Patient Safety Lead
2		2 February 2018	Review date extended from 2 years to 3 years	
3	Revised	27 April 2018	Point 18 and Appendix 3 added – "A Just Culture Guide)	Patient Safety Lead

Appendix 1

Patient Safety Incident RCA Investigation Template

- **Clinical Investigation 72 hour report template**
  https://icon.torbayandsouthdevon.nhs.uk/areas/safebook/Documents/Root%20Cause%20Analysis%20tools%20and%20info/RCA%20Templates%20front%20sheet.docx

- **Clinical Investigation Root Cause Analysis (RCA) Investigation Template**
- https://icon.torbayandsouthdevon.nhs.uk/areas/safebook/Documents/Root%20Cause%20Analysis%20tools%20and%20info/RCA%20Templates%20front%20sheet.docx

Appendix 2

NHS England Never Event List 2015/16

	Description
1.	Wrong site surgery
2.	Wrong implant / prosthesis
3.	Retained foreign object post-procedure
4.	Mis-selection of a strong potassium containing solution
5.	Wrong route administration of medication
6.	Overdose of Insulin due to abbreviations or incorrect device
7.	Overdose of methotrexate for non-cancer treatment
8.	Mis – selection of high strength midazolam during conscious sedation
9.	Failure to install functional collapsible shower or curtain rails
10.	Falls from poorly restricted windows
11.	Chest or neck entrapment in bedrails
12.	Transfusion or transplantation of ABO-incompatible blood components or organs
13.	Misplaced naso- or oro-gastric tubes
14.	Scalding of patients
15	Unintentional connection of a patient requiring oxygen to an airflow meter
16	Undetected oesophageal intubation (Currently Suspended Pending Review)

For the full NHS England document detailing Never Events please follow the following links:
2015-2016 Never Events Policy Framework
2015-2016 Never Events List
2015-2016 Never Events Frequently Asked Questions

Appendix 3

Never Event - Local Actions to take.

Diagram reproduced from 2015-2016 Never Events Policy Framework

Appendix 4

Timescales for Investigations

STEIS SIRI Level	Application	Product/ outcome	Owner	Timescale for completion
Level 1 **Concise internal investigation**	Suited to less complex incidents which can be managed by individuals or a small group at a local level	Concise/ compact investigation report which includes the essentials of a credible investigation	Provider organisation (Trust Chief Executive/relevant deputy) in which the incident occurred, providing principles for objectivity are upheld	Internal investigations, whether concise or comprehensive must be completed within 60 working days of the incident being reported to the relevant commissioner All internal investigation should be supported by a clear investigation management plan
Level 2 **Comprehensive internal investigation** (this includes those with an independent element or full independent investigations commissioned by the provider)	Suited to complex issues which should be managed by a multidisciplinary team involving experts and/or specialist investigators where applicable	Comprehensive investigation report including all elements of a credible investigation	Provider organisation (Trust Chief Executive/relevant deputy) in which the incident occurred, providing principles for objectivity are upheld. Providers may wish to commission an independent investigation or involve independent members as part of the investigation team to add a level of external scrutiny/objectivity	
Level 3 **Independent investigation**	Required where the integrity of the investigation is likely to be challenged or where it will be difficult for an organisation to conduct an objective investigation internally due to the size of organisation or the	Comprehensive investigation report including all elements of a credible investigation	The investigator and **all** members of the investigation team must be independent of the provider. To fulfil independency the investigation must be commissioned and undertaken entirely independently of the organisation whose actions and	6 months from the date the investigation is commissioned

	capacity/ capability of the available individuals and/or number of organisations involved.		processes are being investigated.	

On rare occasions, extensions to the above timescales can be agreed. Extensions must be agreed with the Lead Commissioner. The reason for the extension must be included in the 'further information' section of the Strategic Executive Information System (STEIS) incident form. Requests for deadline extensions will be managed by the Patient Safety and Clinical Risk Team via the CCG

Appendix 5

SMART Action Plan

STEIS Reference Number:-	Incident reference number:	Patient's Initials:-	Locality/Divisional Manager/Lead/Matron:-

Ref no from section 9.	**Recommendation identified from the Investigation and root causes.**	**Action required, how will it be achieved and to whom?**	**How will the outcome be measured as evidence the action is complete?**	**Accountable Action Lead(s).** **(Job title not names)**	**Deadline.** **(Date completed if applicable)**
9.1					
9.2					
9.3					
9.4					

Appendix 6

Reporting to External Agencies

With the exception of STEIS the reporting to other external agencies should be done by the relevant lead (where required/appropriate):

Type of Incident	External Agency	Trust Lead / Manager
STEIS reportable incidents (excluding Infection control incidents)	Department of Health	Patient Safety Lead
RIDDOR or Dangerous Occurrence incidents	HSE	Health and Safety Manager
Radiation incidents	Care Quality Committee – IRMER	IRMER lead
Incident involving a medical device	MHRA	Medical Devices Safety Officer
Any breach of confidential personal identifiable information	Information Commissioner Office (ICO), Strategic Health Authority (SHA)	Head of Information Governance
Incidents likely to result in litigation against the Trust	NHS Litigation Authority	NHSLA Litigation Officer
Drug incident	Medicines Control Agency	Medicines Safety Officer
Security Incidents	SIRS	Resilience (Security, Emergency Planning and Fire) Manager
Infection Control Incidents and Communicable or notifiable diseases	Health Protection Authority (HPA)	Lead Infection Control Nurse / Director of Infection Prevention and Control (DIPC)
Fire	Fire Service	Fire Safety and Emergency Planning Manager
Food Hygiene	Environmental Health	Head of Facilities
Fuel leak	Environment Agency	Head of Estates

Appendix 7

Guidance Procedure for Managing and Investigating No Harm, Near Miss and Low Harm incidents

Action required within:-	Patient Safety Incidents	Action Lead	Staff and Visitor Incidents	Action lead
Immediately	Patient/Service User attended and assessed by staff	Staff	Staff/Visitor attended to and assessed by staff/first aider and further treatment rendered	Staff/first aider
As soon as possible after the incident	Incident is reported onto the Incident reporting system.	Staff member involved or witnesses incident	Incident is reported onto the Incident reporting system.	Staff member involved or witnesses incident
As soon as possible after incident	Community Services. Staff to inform senior Staff/team leads if there is a level of concern	Community Ward Staff or Staff visiting patient	Visitor or Staff advised to A&E/MIU if concerned or advised to see GP. Staff to also be advised to contact Occupational health if necessary.	Senior Staff
	Duty doctor informed by Senior Staff if there is a level of concern	Senior Staff		
24 Hours	Patient for whom there is concern is examined by medical staff. Outcome of examination recorded in medical notes.	Doctor	Harm caused to Staff or Visitor to be notified to senior staff and more details added to the incident report if necessary.	
24 Hours	Next of Kin/relatives informed and any information given to the patient or relatives recorded in medical notes. Refer to Trust's "Being Open" policy for more information.	Senior Staff	Any information given to staff or visitors to be documented on the incident reporting system Duty of Candour section.	Senior Staff
72 Hours	**Initial Incident report review**		**Initial Incident report review**	

72 Hours	Incident reports to be reviewed by the Incident reviewer/Owner. Additional information requested where necessary. Clinical Governance Team to review the incident and action any required additional escalations. Medicines Governance, Infection control, Tissue Viability. Medical Electronics teams to review relevant incident reports.	Senior Staff	Incident reports to be reviewed by the Incident reviewer/Owner. Health and Safety Team to review incident form and action any further investigation required. Additional information requested where necessary. Clinical Governance Team to review the incident and action any required additional escalations. If a member of staff has 8+ days lost time because of the incident, this must be report to Health & Safety Manager as will be RIDDOR reportable.	Senior Staff/ Health & Safety Manager
72 hours	The Clinical Governance Co-ordinator will check the form is correctly completed, including incident grading, and re-grade where necessary	Clinical governance Co-ordinator/Lead	Check the form is correctly completed, including incident grading, re-grading where necessary. Check that all staff who witnessed the incident have been identified.	Clinical Governance co-ordinator / Health and Safety Team
5-10 Working Days	Where appropriate or requested, the Clinical Governance Co-ordinator will liaise with the manager/matron/service lead/team lead to ensure that an appropriate investigation is actioned / undertaken and that any further reports are completed by the Team lead/manager/Ward Matron or other nominated person.	Clinical Governance Co-ordinator	Where appropriate or requested, the Clinical Governance Co-ordinator will ensure that an investigation is undertaken and that any further reports are completed by the Team lead/manager/Ward Matron or other nominated person.	Clinical Governance Co-ordinator/ Health & Safety Manager
5-25 days	Ensure that all necessary actions if required have been taken. Incident form to be checked for accuracy and then saved “awaiting final approval”.	Manager, Matron Service /team lead (Incident reviewer)	Ensure that all necessary actions if required have been taken. Incident form to be checked for accuracy and then saved “awaiting final approval”.	Manager, Matron Service /team lead (Incident reviewer)
25-28 days	The Clinical Governance Co-ordinator will ensure any problems have been identified and remedial action taken by the incident reviewer/owner.	Clinical Governance Co-ordinator	Ensure any remedial action required has been taken and further reports completed.	Clinical Governance Co-ordinator/ Health & Safety Manager

28 days	**Final Review** Review the incident form and confirm any actions required after the incident have been completed.	Clinical Governance Co-ordinator	**Final Review** Review the incident form, the incident grading and investigation or additional completed documentation.	Health & Safety Manager
28 days	Incident is saved as “Final Approved”. If the incident was caused whilst the patient was “in receipt of our care/caused by us”, details will be uploaded to the NRLS.	Clinical Governance Co-ordinator	Incident saved as “Final Approved”	Health and Safety Manager

Guidance Procedure for Managing and Investigating Moderate Harm incidents

Action required within:-	Patient Safety Incidents	Action Lead	Staff and Visitor Incidents	Action lead
Immediately	Patient/Service User attended and assessed by staff	Staff	Staff/Visitor attended to and assessed by staff/first aider and further treatment rendered	Staff/first aider
As soon as possible after the incident.	Incident is reported onto the Incident reporting system. Relevant notifications to Patient Safety Lead will be automatically sent out by the incident reporting system	Staff member involved or witnesses incident	Incident is reported onto the Incident reporting system.	Staff member involved or witnesses incident
As soon as possible after the incident.	Community Services. Staff to inform senior Staff/team leads if there is a level of concern	Community Ward Staff or Staff visiting patient	Visitor or Staff advised to A&E / MIU if concerned or advised to see GP. Staff to also be advised to contact Occupational health if necessary.	Senior Staff
	Duty doctor informed by Senior Staff if there is a level of concern	Senior Staff		
24 Hours	Patient for whom there is concern are examined by medical staff. Outcome of examination recorded in medical notes.	Doctor	Harm caused to Staff or Visitor to be notified to senior staff and more details added to the incident report if necessary.	
24 Hours	Next of Kin/relatives informed and any information given to the patient or relatives recorded in medical notes. Refer to Trust's "Being Open" policy for more information.	Senior Staff	Any information given to staff or visitors to be documented on the incident reporting system Duty of Candour section.	Senior Staff
72 Hours	**Initial Incident report review**		**Initial Incident report review**	

72 Hours	Incident reports to be reviewed by the Incident reviewer/Owner. Additional information requested where necessary. Clinical Governance Team to review the incident and action any required additional escalations. Medicines Governance, Infection control, Tissue Viability. Medical Electronics teams to review relevant incident reports.	Senior Staff	Incident reports to be reviewed by the Incident reviewer/Owner. Health and Safety Team to review incident form and action any further investigation required. Additional information requested where necessary. Clinical Governance Team to review the incident and action any required additional escalations. If a member of staff has 8+ days lost time because of the incident, this must be report to Health & Safety Manager as will be RIDDOR reportable.	Senior Staff/ Health & Safety Manager
72 hours	The Clinical Governance Co-ordinator will check the form is correctly completed, including incident grading, and re-grade where necessary. Chronology requested.	Clinical governance Co-ordinator/Lead	Check the form is correctly completed, including incident grading, re-grading where necessary. Check that all staff who witnessed the incident have been identified.	Clinical Governance co-ordinator / Health and Safety Team
2 working days	Initial Chronology completed, (SSKIN Chronology if Pressure Ulcer (PU)), to enable clarification if avoidable harm caused and the timeline of events	Clinical Governance Co-ordinator/ Team Lead/Matron, Ward manager, Service Lead.		
5 working Days	Chronology received and reviewed. Decision made if incident meets the SIRI criteria and if STEIS reportable. Once incident **identified** as a SIRI/STEIS reportable, details reported to STEIS within 48 hours. Once identified as STEIS the form is sent to the Serious Adverse Events (SAE) group to be acknowledge and managed through this group	Clinical Governance Co-ordinator/ Patient Safety lead		

48 hours of STEIS reportable	Incident details to be uploaded to NRLS	Clinical Governance Co-ordinator/ Patient Safety lead		
5-25 days	Ensure that all necessary actions if required have been taken. Incident form to be checked for accuracy and then saved "awaiting final approval".	Manager, Matron Service /team lead (Incident reviewer)	Ensure that all necessary actions if required have been taken. Incident form to be checked for accuracy and then saved "awaiting final approval".	Manager, Matron Service /team lead (Incident reviewer)
50 working days from STEIS report.	RCA Investigation carried out into the incident and submitted to the SAE Group, Clinical Governance Co-ordinator and Patient Safety Lead	Clinical Governance Co-ordinator/ Team Lead/Matron, Ward manager, Service Lead.		
60 working days from STEIS report.	RCA Investigation, Action plan and Chronology submitted to the CCG/SIRI Panel and root cause uploaded to STEIS once approved by Patient Safety Lead and/or Clinical Governance Co-ordinator.	Clinical Governance Co-ordinator/ Patient Safety lead		
Until actions completion date	Actions identified during the RCA to be monitored for completion by the target date. "Confirmation of actions complete" to be received by the action lead.	Clinical Governance Co-ordinator/ Team Lead/Matron, Ward manager, Service Lead.		
28 days if not STEIS.	The Clinical Governance Co-ordinator will ensure any problems have been identified and remedial action taken by the incident reviewer/owner.	Clinical Governance Co-ordinator		
28 days if not STEIS.	**Final Review** Review the incident form and confirm any actions required after the incident have been completed.	Clinical Governance Co-ordinator	**Final Review** Review the incident form, the incident grading and investigation or additional completed documentation.	Health & Safety Manager
28 days if not STEIS	Incident is saved as "Final Approved". If the incident was caused whilst the patient was "in receipt of our care/caused by us", details will be uploaded to the NRLS.	Clinical Governance Co-ordinator	Incident saved as "Final Approved"	Health and Safety Manager

Guidance Procedure for Managing and Investigating Severe (Major) or Death (Catastrophic) incidents.

Action required within:-	Patient Safety Incidents	Action Lead	Staff and Visitor Incidents	Action lead
Immediately	Patient/Service User attended and assessed by staff	Staff	Staff/Visitor attended to and assessed by staff/first aider and further treatment rendered	Staff/first aider
Immediately	Community Services. Staff to inform senior Staff/Team leads.	Community Ward Staff or Staff visiting patient	Visitor or Staff advised to A&E / MIU if concerned or advised to see GP. Staff to also be advised to contact Occupational health if necessary.	Senior Staff
	Duty doctor informed by Senior Staff.	Senior Staff		
Immediately	Patient examined and treatment ordered - incident confirmed as major/catastrophic. Outcome of examination recorded in medical notes.	Duty Doctor		
Immediately	Duty Doctor will inform the Consultant.	Doctor		
Immediately	Senior Staff on duty will grade incident as major or catastrophic & contact SDU A.D.N or Matron/ Senior Nurse or On-Call Manager (outside office hours)	Senior Staff	Senior Staff on duty will grade incident red & contact SDU /Department Manager/Senior Nurse or On-call Manager (outside office hours)	Senior Staff
1 Hour	The SDU/Department Manager/ Matron/Senior Nurse/On-Call Manager will contact the SDU Clinical Governance Co-ordinator or Associate director of Nursing the Risk lead or Governance & Patient Safety lead through the Chief Nursing office.	SDU/D/Dept./On-Call Manager	The SDU /Department Manager/Senior Nurse/On-Call Manager will contact the SDU/ Clinical Governance Coordinator and the Health & Safety Advisor/Director Responsible for Health & Safety	**Dir. / Dept./On-Call Manager**

Guidance Procedure for Managing and Investigating Severe (Major) or Death (Catastrophic) incidents.

Action required within:-	Patient Safety Incidents	Action Lead	Staff and Visitor Incidents	Action lead
2 Hours	The Chief Nursing Office will inform the Chief Executive and the Communications Officer (as necessary).	Clinical Governance Coordinator / Patient Safety lead	The Health & Safety Advisor/Director Responsible for Health & Safety will inform the Chief Executive and the Communications Office (if necessary)	**Health & Safety Advisor/ Director Responsible for Health & Safety/**
2 Hours			If a RIDDOR Incident, the Health & Safety Advisor/ Director Responsible for Health & Safety/ On-Call Manager will inform the Health & Safety Executive & Incident Contact Centre/HSE website	**Health & Safety Advisor/ Director Responsible for Health & Safety/ On-Call Manager**
3 Hours	The Senior Clinician in charge of the case must ensure that the patients and/or their relatives are informed of the incident and offered the appropriate level of counselling and support. This needs to be done sensitively and does not constitute an admission of liability and any information given to the patient, staff or the public should be documented	Consultant/GP	Division /Department Manager/Senior Nurse must ensure that the next of kin is informed of the incident and offered the appropriate level of counselling and support. This needs to be done sensitively and does not constitute an admission of liability. Any information given to staff or the public to be documented	**SDU/Dept Manager/ or on-call Manager**
As soon as possible after the incident but no later than end of shift.	Incident is reported onto the Incident reporting system. Relevant notifications to Patient Safety Lead will be automatically sent out by the incident reporting system	Staff member involved or witnesses incident	Incident is reported onto the Incident reporting system.	**Staff member involved or witnesses incident**
24 Hours	Patient for whom there is concern are examined by medical staff. Outcome of examination recorded in medical notes.	Doctor	Harm caused to Staff or Visitor to be notified to senior staff and more details added to the incident report if necessary.	
1 Working Day	If Never event or SIRI report on STEIS System if initial chronology not required to clarify if meets criteria.	Clinical Governance Coordinator / Patient Safety lead	If a RIDDOR incident, the Health & Safety Advisor /Director Responsible for Health & Safety will send complete a report to the Health & Safety Executive via the Incident Contact Centre/HSE website.	**Health & safety Manager**

Guidance Procedure for Managing and Investigating Severe (Major) or Death (Catastrophic) incidents.				
72 Hours	**72 hour report Initial Incident report review**		**Initial Incident report review**	
72 Hours	Incident reports to be reviewed by the Incident reviewer/Owner. Additional information requested where necessary. Clinical Governance Team to review the incident and action any required additional escalations. Medicines Governance, Infection control, Tissue Viability. Medical Electronics teams to review relevant incident reports. 72 hour report generated distributed accordingly to CN, MD, CEO. 72 hour report logged in SAE pack for next meeting	Senior Staff Patient safety Lead	Incident reports to be reviewed by the Incident reviewer/Owner. Health and Safety Team to review incident form and action any further investigation required. Additional information requested where necessary. Clinical Governance Team to review the incident and action any required additional escalations. If a member of staff has 8+ days lost time because of the incident, this must be report to Health & Safety Manager as will be RIDDOR reportable.	Senior Staff/ Health & Safety Manager
72 hours	The Clinical Governance Co-ordinator will check the form is correctly completed, including incident grading, and re-grade where necessary. Chronology requested.	Clinical governance Co-ordinator/Lead	Check the form is correctly completed, including incident grading, re-grading where necessary. Check that all staff who witnessed the incident have been identified.	Clinical Governance co-ordinator / Health and Safety Team
2 working days	Initial Chronology completed, (SSKIN Chronology if Pressure Ulcer (PU)), to enable clarification if avoidable harm caused and the timeline of events	Clinical Governance Co-ordinator/ Team Lead/Matron, Ward manager, Service Lead.		
5 working Days	Chronology received and reviewed. Decision made if incident meets the SIRI criteria and if STEIS reportable. Once incident **identified** as a SIRI/STEIS reportable, details reported to STEIS within 48 hours. Once identified as STEIS the form is sent to the Serious Adverse Events (SAE) group to be acknowledge and managed through this group	Clinical Governance Co-ordinator/ Patient Safety lead		

Guidance Procedure for Managing and Investigating Severe (Major) or Death (Catastrophic) incidents.				
48 hours of STEIS reportable	Incident details to be uploaded to NRLS	Clinical Governance Co-ordinator/ Patient Safety lead		
5-25 days	Ensure that all necessary actions if required have been taken. Incident form to be checked for accuracy and then saved "awaiting final approval".	Manager, Matron Service /team lead (Incident reviewer)	Ensure that all necessary actions if required have been taken. Incident form to be checked for accuracy and then saved "awaiting final approval".	Manager, Matron Service /team lead (Incident reviewer)
50 working days from STEIS report.	RCA Investigation carried out into the incident and submitted to the SAE Group, Clinical Governance Co-ordinator and Patient Safety Lead	Clinical Governance Co-ordinator/ Team Lead/Matron, Ward manager, Service Lead.		
60 working days from STEIS report.	RCA Investigation, Action plan and Chronology submitted to the CCG/SIRI Panel and root cause uploaded to STEIS once approved by Patient Safety Lead and/or Clinical Governance Co-ordinator.	Clinical Governance Co-ordinator/ Patient Safety lead		
Until actions completion date	Actions identified during the RCA to be monitored for completion by the target date. "Confirmation of actions complete" to be received by the action lead.	Clinical Governance Co-ordinator/ Team Lead/Matron, Ward manager, Service Lead.		
28 days if not STEIS.	The Clinical Governance Co-ordinator will ensure any problems have been identified and remedial action taken by the incident reviewer/owner.	Clinical Governance Co-ordinator		
28 days if not STEIS.	**Final Review** Review the incident form and confirm any actions required after the incident have been completed.	Clinical Governance Co-ordinator	**Final Review** Review the incident form, the incident grading and investigation or additional completed documentation.	Health & Safety Manager
28 days if not STEIS	**Incident is saved as "Final Approved". If the incident was caused whilst the patient was "in receipt of our care/caused by us", details will be uploaded to the NRLS.**	Clinical Governance Co-ordinator	**Incident saved as "Final Approved"**	Health and Safety Manager

Appendix 8

NHS Improvement – A 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 whether a staff member involved in a patient safety incident requires specific individual support or intervention to work safely. 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 highlights important principles that need to be considered before formal management action is directed at an individual staff member.

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 treat wider patient safety issues as individual issues.

Please note:

- **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.
- **The guide** can only be used to take one action (or failure to act) through the guide at a time. If multiple actions are involved in an incident they must be considered separately.

Start here - **Q1. deliberate harm test**

1a. Was there any intention to cause harm?

Yes → **Recommendation:** Follow organisational guidance for appropriate management action. This could involve: contact relevant regulatory bodies, suspension of staff, and referral to police and disciplinary processes. Wider investigation is still needed to understand how and why patients were not protected from the actions of the individual. → END HERE

No go to next question - **Q2. health test**

2a. Are there indications of substance abuse?

Yes → **Recommendation:** Follow organisational substance abuse at work guidance. Wider investigation is still needed to understand if substance abuse could have been recognised and addressed earlier. → END HERE

2b. Are there indications of physical ill health?

2c. Are there indications of mental ill health?

Yes → **Recommendation:** Follow organisational guidance for health issues affecting work, which is likely to include occupational health referral. Wider investigation is still needed to understand if health issues could have been recognised and addressed earlier. → END HERE

if **No to all** go to next question - **Q3. foresight test**

3a. Are there agreed protocols/accepted practice in place that apply to the action/omission in question?

3b. Were the protocols/accepted practice workable and in routine use?

3c. Did the individual knowingly depart from these protocols?

If **No** to any → **Recommendation:** Action singling out the individual is unlikely to be appropriate; the patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. These actions may include, but not be limited to, the individual. → END HERE

if **Yes to all** go to next question - **Q4. substitution test**

4a. Are there indications that other individuals from the same peer group, with comparable experience and qualifications, would behave in the same way in similar circumstances?

4b. Was the individual missed out when relevant training was provided to their peer group?

4c. Did more senior members of the team fail to provide supervision that normally should be provided?

If **Yes** to any → **Recommendation:** Action singling out the individual is unlikely to be appropriate; the patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. These actions may include, but not be limited to, the individual. → END HERE

if **No to all** go to next question - **Q5. mitigating circumstances**

5a. Were there any significant mitigating circumstances?

Yes → **Recommendation:** Action directed at the individual may not be appropriate; follow organisational guidance, which is likely to include senior HR advice on what degree of mitigation applies. The patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. → END HERE

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. → END HERE

improvement.nhs.uk

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

Supported by:

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The Mental Capacity Act 2005

The Mental Capacity Act provides a statutory framework for people who lack capacity to make decisions for themselves, or who have capacity and want to make preparations for a time when they lack capacity in the future. It sets out who can take decisions, in which situations, and how they should go about this. It covers a wide range of decision making from health and welfare decisions to finance and property decisions

Enshrined in the Mental Capacity Act is the principle that people must be assumed to have capacity unless it is established that they do not. This is an important aspect of law that all health and social care practitioners must implement when proposing to undertake any act in connection with care and treatment that requires consent. In circumstances where there is an element of doubt about a person's ability to make a decision due to 'an impairment of or disturbance in the functioning of the mind or brain' the practitioner must implement the Mental Capacity Act.

The legal framework provided by the Mental Capacity Act 2005 is supported by a Code of Practice, which provides guidance and information about how the Act works in practice. The Code of Practice has statutory force which means that health and social care practitioners have a legal duty to have regard to it when working with or caring for adults who may lack capacity to make decisions for themselves.

"The Act is intended to assist and support people who may lack capacity and to discourage anyone who is involved in caring for someone who lacks capacity from being overly restrictive or controlling. It aims to balance an individual's right to make decisions for themselves with their right to be protected from harm if they lack the capacity to make decisions to protect themselves". (3)

All Trust workers can access the Code of Practice, Mental Capacity Act 2005 Policy, Mental Capacity Act 2005 Practice Guidance, information booklets and all assessment, checklists and Independent Mental Capacity Advocate referral forms on iCare

http://icare/Operations/mental_capacity_act/Pages/default.aspx

Infection Control

All staff will have access to Infection Control Policies and comply with the standards within them in the work place. All staff will attend Infection Control Training annually as part of their mandatory training programme.

Rapid (E)quality Impact Assessment (EqIA) *(for use when writing policies)*

Policy Title (and number)				**Version and Date**	
Policy Author					
An (e)quality impact assessment is a process designed to ensure that policies do not discriminate or disadvantage people whilst advancing equality. Consider the nature and extent of the impact, not the number of people affected.					
Who may be affected by this document?					
Patients/ Service Users ☐	Staff ☐	Other, please state… ☐			
Could the policy treat people from protected groups less favorably than the general population? ***PLEASE NOTE: Any 'Yes' answers may trigger a full EIA and must be referred to the equality leads below***					
Age	Yes ☐ No☐	Gender Reassignment	Yes ☐ No☐	Sexual Orientation	Yes ☐ No☐
Race	Yes ☐ No☐	Disability	Yes ☐ No☐	Religion/Belief (non)	Yes ☐ No☐
Gender	Yes ☐ No☐	Pregnancy/Maternity	Yes ☐ No☐	Marriage/ Civil Partnership	Yes ☐ No☐
Is it likely that the policy could affect particular 'Inclusion Health' groups less favorably than the general population? (substance misuse; teenage mums; carers[1]; travellers[2]; homeless[3]; convictions; social isolation[4]; refugees)					Yes ☐ No☐
Please provide details for each protected group where you have indicated 'Yes'.					
VISION AND VALUES: Policies must aim to remove unintentional barriers and promote inclusion					
Is inclusive language[5] used throughout?					Yes ☐ No☐ NA ☐
Are the services outlined in the policy fully accessible[6]?					Yes ☐ No☐ NA ☐
Does the policy encourage individualised and person-centred care?					Yes ☐ No☐ NA ☐
Could there be an adverse impact on an individual's independence or autonomy[7]?					Yes ☐ No☐ NA ☐
EXTERNAL FACTORS					
Is the policy a result of national legislation which cannot be modified in any way?					Yes ☐ No☐
What is the reason for writing this policy? (Is it a result in a change of legislation/ national research?)					
Who was consulted when drafting this policy?					
Patients/ Service Users ☐	Trade Unions ☐	Protected Groups (including Trust Equality Groups) ☐			
Staff ☐	General Public ☐	Other, please state… ☐			
What were the recommendations/suggestions?					
Does this document require a service redesign or substantial amendments to an existing process? ***PLEASE NOTE: 'Yes' may trigger a full EIA, please refer to the equality leads below***					Yes ☐ No☐
ACTION PLAN: Please list all actions identified to address any impacts					
Action				**Person responsible**	**Completion date**
AUTHORISATION: By signing below, I confirm that the named person responsible above is aware of the actions assigned to them					
Name of person completing the form				**Signature**	
Validated by (line manager)				**Signature**	

Please contact the Equalities team for guidance:
For South Devon & Torbay CCG, please call 01803 652476 or email marisa.cockfield@nhs.net
For Torbay and South Devon NHS Trusts, please call 01803 656676 or email pfd.sdhct@nhs.net
This form should be published with the policy and a signed copy sent to your relevant organisation.

Clinical and Non-Clinical Policies – New Data Protection Regulation (NDPR)

Torbay and South Devon NHS Foundation Trust (TSDFT) has a commitment to ensure that all policies and procedures developed act in accordance with all relevant data protection regulations and guidance. This policy has been designed with the EU New Data Protection Regulation (NDPR) in mind and therefore provides the reader with assurance of effective information governance practice.

NDPR intends to strengthen and unify data protection for all persons; consequently, the rights of individuals have changed. It is assured that these rights have been considered throughout the development of this policy.

Furthermore, NDPR requires that the Trust is open and transparent with its personal identifiable processing activities and this has a considerable effect on the way TSDFT holds, uses, and shares personal identifiable data. The most effective way of being open is through data mapping. Data mapping for NDPR was initially undertaken in November 2017 and must be completed on a triannual (every 3 years) basis to maintain compliance. This policy supports the data mapping requirement of the NDPR.

For more information:

- Contact the Data Access and Disclosure Office on dataprotection.tsdft@nhs.net,
- See TSDFT's Data Protection & Access Policy,
- Visit our GDPR page on ICON.