



INCIDENT REPORTING POLICY

			POLICY
Reference	G/IR-01		
Approving Body	Patient Safety Committee		
Date Approved	8 th November 2021		
For publication to external SFH website	the content does not	t risk the safety of	he approving body that f patients or the public:
	YES	NO	N/A
	X		
Issue Date	December 2021		
Version	v7.0		
Summary of Changes from Previous Version	 Scheduled review and update undertaken. Procedural information unchanged, but minor wording amends made to some sections to aid clarity. Job titles/ roles and Trust committee/ group names updated as applicable. Roles and responsibilities updated to reflect current requirements Section 6.4, information added regarding a new field on the Datix to record 'actual harm' Section 6.4, information added to describe the SFHFT investigation levels next to the 3 recognised levels used in the NHS England Serious Incident Framework Section 6.8, information for some of the specialist processes confirmed to be in or moved to subject related policy/ procedural documents. Appendix A (SFHFT Serious Incident Flowchart Process) split into three simpler flowcharts (now Appendices A,B & C) and subsequent appendices 		
Supersedes	re-lettered.	2020 to Review D	Date Sept 2021 (ext ¹)
Document Category	Governance		
Consultation Undertaken	Clinical Director for Patient Safety Head of Regulation and Deputy Head of Clinical Governance Quality Governance Leads		
Date of Completion of Equality Impact Assessment	October 2021		
Date of Environmental Impact Assessment (if applicable)	Not Applicable		
Legal and/or Accreditation Implications	Regulatory requiren	nent with CQC	-
Target Audience	third parties wor all areas in sup both clinical and • The policy appli by the Trust, or	king on behalf of port of the Trust corporate. es to all premise at other locations	staff, contract staff and the Trust. It applies to t's business objectives s owned and operated s where work is carried The policy also applies

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NHS Foundat			
	where employees are required to work in the community or travel between locations as part of their job.		
Review Date	November 2024		
Sponsor (Position)	Medical Director		
Author (Position & Name)		overnance, Meg Haselden	
Lead Division/ Directorate	Corporate	, 9	
Lead Specialty/ Service/ Department	Nursing/ Governal	nce Support Unit	
Position of Person able to provide	<u> </u>	ical Governance	
Further Guidance/Information	 Quality Gove 	ernance Leads	
Associated Documents/ Information	, ,	Date Associated Documents/ Information was reviewed	
 Surgery Division Serious Incident SO Urgent and Emergency Care Divisio SOP 	Medicine Division Serious Incident SOP Surgery Division Serious Incident SOP Urgent and Emergency Care Division Serious Incident SOP Vomen and Children's Division Incident, Trigger and		
<u>TOOLKIT</u>		The toolkit provides the standard/ specialist subject scoping and investigation report templates and other additional guidance for staff – all have been reviewed and updated where necessary during 2020 and 2021. All are in-date.	
Datix Incident Reporting Form (DIF-1) (Hard copy form to use for business continuity purposes)		Last updated Feb 2020	

June 2020

Template control

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1.0 INTRODUCTION

- **1.1** This policy is issued and maintained by the Medical Director (the sponsor) on behalf of the Trust, at the issue defined on the front sheet, which supersedes and replaces all previous versions.
- **1.2** In accordance with national guidance and legislation, the Trust is required to record all incidents/serious incidents (adverse events / patient safety incidents) and 'near misses', which may be observed and reported by staff/patients or the general public, whether they are:
 - major/ minor;
 - clinical or non-clinical;
 - affect one person or more persons and related to patients, staff, students, contractors or visitors to the Trust premises;
- **1.3** Sherwood Forests Hospitals NHS Foundation Trust is committed to identifying incidents/serious incidents and near misses to enable the Trust to identify opportunities for learning and risk management.

This policy together with its associated standard operating procedures (which describe the divisional processes) and toolkit (which includes additional guidance and scoping/investigation templates), is intended to ensure that:

- ➤ All incidents/serious incidents or 'near misses' which occur on Trust premises or in the course of the employees duties are recorded.
- > Incidents/serious incidents or 'near misses' are investigated at an appropriate level.
- Action is taken to prevent or reduce the risk of reoccurrence.
- ➤ A prompt and accurate report of incidents/serious incidents and 'near misses' are made available to appropriate external agencies.
- > Staff who may have been directly or indirectly affected by the incident/ serious incident are supported.
- ➤ The Trust enacts it responsibilities to the Duty of Candour in relation to being open with patients and or their family/representative, commissioners, inspectors and regulators.
- 1.4 The following external documents must be used in conjunction with this policy:
 - 1. Never Event list 2018 (NHS Improvement, 2018) last updated Feb 2021
 - 2. Never Events Policy and Framework (NHS Improvement, revised January 2018)
 - 3. <u>Serious Incident Framework: Supporting learning to prevent recurrence</u> (NHS England, March 2015)
- 1.5...The following divisional standard operating procedures must also be used in conjunction with this policy:
 - 1. Diagnostics and Outpatients Divisional Serious Incident SOP
 - 2. Medicine Division Serious Incident SOP
 - 3. Surgery Division Serious Incident SOP
 - 4. Urgent and Emergency Care Division Serious Incident SOP
 - 5. Women and Children's Division Incident, Trigger and Serious Incident Process SOP

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2.0 POLICY STATEMENT

- **2.1** The Trust aims to take an integrated approach to learning from all incidents/serious incidents in order to improve its services, whether clinical or non-clinical.
- **2.2** The philosophy of '*incident reporting and investigation*' is not to apportion blame, but to use the information gained to help the Trust to improve working practices and the environment, so as to improve the management of risk throughout the Trust.

The prompt and accurate reporting of incidents is also essential so that the Trust may support its staff to deal with the incident itself and with any subsequent developments such as legal action or coronial investigations.

- **2.3** The aim of this policy is to set out the Trust's commitment to ensuring an effective approach to the reporting, investigating, learning lessons, implementing and sustaining change as a result of investigation findings and analysis of incidents in order to provide safe, high quality care to our patients and a safe environment for our staff and members of the public. The Trust recognises that identifying risks and ensuring these are managed effectively, provides opportunities to improve patient care and safety.
- **2.4** The initial recording and investigation of these incidents will follow the process outlined in this policy. The level of investigation will be determined by the incident severity, complexity and/or the opportunity for learning.
- 2.5 Some more serious incidents with wider implications are to be reported to various outside agencies. Executive leads, with the support of the Governance Support Unit (GSU), will report according to the process detailed within this policy.
- **2.6** All staff work to fulfil the Trust's commitment to the Trust vision for healthier communities and outstanding care for all to the best of their ability and within available resources. Occasionally despite our best efforts things go wrong and it is important to emphasise that the 'Incident Reporting Policy' is about promoting a just, fair and responsible culture which fosters learning and improvements as a result of mistakes.
- **2.7** Being open and honest with the patient and or their representative that an incident has occurred is an integral part of incident management. This notification should be done in person and recorded in the records then followed up in writing. Duty of Candour will apply to every incident that warrants scoping and formal Duty of Candour is required for every incident graded moderate or above. For further information see the Trust's Duty of Candour Policy.
- **2.8** The Trust has a positive, non-punitive approach to incident reporting. However, the Trust's Disciplinary Policy may be applied where misconduct or gross misconduct has occurred, for example where an investigation has identified evidence of malpractice, a disregard for training, maliciousness, intent to harm, theft or fraud.



3.0 DEFINITIONS/ ABBREVIATIONS

3.1 Definitions		
The Trust / SFHFT	Means Sherwood Forest Hospitals NHS Foundation Trust	
Staff	Means all employees of the Trust including those managed by a	
Starr	third party organisation on behalf of the Trust	
Duty of Candour	Principles that healthcare staff should use when communicating	
1	with patients, their families and carers following an incident/	
	serious incident.	
Adverse Event	Any untoward medical occurrence in a patient.	
Hazard	means a source of potential harm or a situation with a potential to	
	cause loss.	
Patient Safety	Any unintended or unexpected incident(s) that could have or did	
Incident	lead to harm for one or more person(s) receiving NHS funded	
	healthcare. (NPSA)	
Near Miss	Means any event, which does not, but has the potential to result in	
	harm, injury, damage or loss.	
Incident	Means any event that has given, or may give rise to actual or	
	possible personal injury, to patient dissatisfaction, or to property	
	loss or damage	
Serious Incident	A serious incident is one that meets the Serious Incident	
(SI)	Framework criteria and is reportable to the co-ordinating Clinical	
	Commissioning Group. It is an incident in which a patient, member	
	of staff or members of the public suffers serious injury, major	
	permanent harm, or unexpected death, (or the risk of death or	
	injury), on hospital premises. It could be an incident where the	
	actions of healthcare staff are likely to cause significant public	
	concern. It can also be an incident that might seriously impact	
	upon the delivery of service plans and/or may attract media	
	attention and/or result in litigation and/or may reflect a seriou	
NDCA Incident	breach of standards or quality of service.	
NPSA Incident	(3.3.3.7.7.13.1.1.1	
Grading	(Grade 2) Low – Minimal Harm Patient required extra	
	observations or minor treatment.	
	(Grade 3) Moderate – Short term harm – Patient required	
	further treatment procedure: an example of a moderate	
	incident is an overdose of paracetamol administered by	
	hospital staff and the patient was identified as having short	
	term effects following the overdose that required treatment.	
	(Grade 4) Severe – Permanent or long term harm: an example of a severe incident is a patient falls and sustains a fractured.	
	of a severe incident is a patient falls and sustains a fractured neck of femur.	
	 (Grade 5) Catastrophic – Death: death as a direct result of an incident 	
Never Event	Never Event is an incident that meets the criteria of the Never	
TOTOL EVOID	Events list and is a serious largely preventable patient safety	
	incident that should not occur if the available preventative	
	measures have been implemented.	
	madalida hava baah impiamantaa.	
DIF 1	Datix Incident Form 1 (for reporting an incident)	
DIF 2	Datix Incident Form 2 (management form to log the investigation)	
DII Z	Dative indicent i offit 2 (management form to log the investigation)	

3.2 Abbreviations		
ASMS	Accredited Security Management Specialist	
CCG	Clinical Commissioning Group	
CQC	Care Quality Commission	
DOC	Duty of Candour	
GSU	Governance Support Unit	
HSIB	Healthcare Safety Investigation Branch	
IRMER	Ionising Radiation (Medical Exposures) Regulations	
MASH	Multi-Agency Safeguarding Hub	
MHRA	Medicines and Healthcare products Regulatory Agency	
NHSI	NHS Improvement	
NPSA	National Patient Safety Agency.	
NRLS	National Reporting and Learning Systems	
PSC	Patient Safety Committee	
QC	Quality Committee	
SABRE	Serious Adverse Blood Reactions and Events	
SHOT	Serious Hazards of Transfusion Scheme	
StEIS	Strategic Executive Information System	

4.0 ROLES AND RESPONSIBILITIES

4.1 Chief Executive

 The Chief Executive has overall responsibility for the management of health and safety and being open within the Trust. The Chief Executive has delegated responsibility for the incident reporting systems within the Trust to the Medical Director.

4.2 Medical Director/Chief Nurse

- Under the Trust's scheme for delegation, the Medical Director has overall responsibility for ensuring that the Trust has a system in place for reporting, recording and analysing incidents.
- The Medical Director/Chief Nurse will designate officers of the Trust to report serious incidents (SIs) to the CCG.
- The Medical Director/Chief Nurse or designated deputy will directly report incidents that meet the reporting requirements of NHSI and the Care Quality Commission (CQC)

4.3 Head of Clinical Governance/ Wider Governance Team

- The Head of Clinical Governance with the support of the Quality Governance Leads will screen reported incidents within 2 working days and verify the severity coding of incidents to help detect moderate or potential serious incidents, or significant trends and themes that required escalation to the Divisional Governance Forums.
- The Head of Clinical Governance will ensure that the GSU supports the process of discharging the Trust's Duty of Candour in relation to incidents that require a higher level of investigation and that formal DOC is discharged for incidents that have been verified as moderate/severe or catastrophic.

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- The Head of Clinical Governance with support from the Quality Governance Leads will also identify complaints that are potential serious incidents. Where necessary an incident will be raised on Datix and managed accordingly.
- The Head of Clinical Governance with the support of the Quality Governance Leads will analyse trends and triangulate incident, claims and complaints data in order to identify key risk themes and escalate to the appropriate Trust Governance Forums.
- The Head of Clinical Governance with the support of the Quality Governance Leads will through a process of selective monitoring provide a level of validation of the management of incidents by handlers.
- The Head of Clinical Governance will ensure the GSU has clear processes for sharing incidents that require further investigation by other NHS providers.
- The Head of Clinical Governance with the support the wider GSU team monitors and manages a process through the clinical governance forums to ensure actions have been progressed through to closure and fully implemented as necessary. Timely completion of actions will be monitored and escalated through the Trust's Quality Assurance groups via the Patient Safety Committee Quality Metrics Dashboard.
- The Head of Clinical Governance with the support the Quality Governance Leads and the Quality Governance Advisor will support investigation management training and will ensure delivery of relevant investigation and report writing training.
- The Head of Clinical Governance will provide incident management reports to quality working groups and the Patient Safety Committee.
- The Head of Clinical Governance with support from the wider GSU team will analyse trends and triangulate incidents, claims and complaints data in order to identify key risk themes and subsequently ensure these are assessed and managed and added to the Datix Risk Register as appropriate.
- Establish processes to ensure incident analysis reports provide themes and trends that enable the Board, Executive Teams and Divisions to ensure the effective management of risks associated with incident trends.
- Following an incident/ serious incident the Governance Support Unit may be required to assist other key stakeholders in their investigation as appropriate.
- The GSU team will identify when a complaint may have the potential to be a serious incident and will manage this accordingly.
- The Head of Clinical Governance with the support of the wider GSU Team will provide trends and themes to support the triangulation of quality information for reporting into the governance forums.
- Providing relevant reports to the various Trust Committees/ Groups as outlined by their rolling work plans.



4.4 Divisional Triumvirates

- Divisional triumvirates are required to foster a culture of shared learning from incidents and encourage all disciplines to report incidents and near misses via the Datix incident reporting system.
- Divisional triumvirates are to ensure that each ward and department has a nominated handler and deputies for the management of the incidents through the Datix incident reporting system, for receiving and taking action on incident reports.
- Divisional triumvirates are responsible for establishing Clinical Governance Forums at divisional and specialty level which will receive incident reports and action appropriately.
- Divisional triumvirates are required to have an over sight of serious incidents or 'Never Events' that directly and indirectly affect their areas of responsibility.
- Divisional triumvirates are required to have systems and processes in place at divisional level for approval of investigation reports including those requiring subsequent submission for executive sign off
- Divisional triumvirates are required to have systems and processes in place to monitor the completion of action plans and sign off the evidence as applicable.
- Where appropriate Divisional triumvirates are required to introduce a programme of audit or monitoring to ensure that changes as agreed in the action plans are embedded within practice.
- Divisional triumvirates are required to ensure incidents are escalated to the appropriate department in order to be reported externally as required eg SHOT, IRMER, HSIB and that the relevant specialist is involved in the investigation – see section 4.7

4.5 Heads of Service

- Heads of Service must ensure that they, and the staff for whom they are responsible, are fully aware of the Trust's Incident Reporting Policy and that staff are able to report incidents using the Datix incident reporting system accessed via the homepage of the Trust intranet site.
- Heads of Service are nominated as DIF2 Handler's.
- Heads of Service with the Support of the Specialty Clinical Governance Lead/ Handlers will investigate incidents as appropriate and have systems and processes in place at specialty level to monitor the completion of actions plans for local investigations.
- Heads of Service are responsible for ensuring Clinical Governance Forums are taking place at specialty level which will receive incident reports and action appropriately and escalate concerns to the Divisional Clinical Governance Forums as necessary.

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4.6 Line Managers

- Line managers must ensure that they and the staff for whom they are responsible are fully aware of the Trust's Incident Reporting Policy and that staff are able to report incidents using the Datix incident reporting system access via the Trust intranet site. Paper copies of the datix incident form (DIF1) are stored in the cupboard in the "Control Room / Classroom 2 / room number 061118" (along the corridor from HQ) and should only be used if the Datix incident reporting system is not functioning. Contact security for access.
- If a paper DIF1 incident form has been completed it will need to be retained by the reporter and the details added to the Datix incident reporting system when the system becomes available.
- Line managers or their designated deputy will provide support for staff that have been affected by an incident. Support can be found via the Trust's Occupational Health or counseling services, as well as the Trust's Policy for Managing Work Related Stress.
- An incident must be raised on the Datix incident reporting system for all cases of physical assault on/violence towards a member of staff and must be completed in all instances as soon as possible which will enable the Trust Accredited Security Management Specialist (ASMS) to be alerted automatically. The legal definition for physical assault is as follows: 'The intentional application of force to the person of another without lawful justification resulting in physical injury or personal discomfort.' The ASMS has been specially trained and authorised to support staff through the investigation process and it is advisable that incident handlers contact the ASMS for advice and guidance where necessary. The initial criminal investigation of violent incidents must be reported to and investigated by the police. Any staff member can report a crime or assault to the police via 101 or for non-emergency crimes by going online through Nottinghamshire Police website (https://www.nottinghamshire.police.uk/). (Either google Nottinghamshire Police (or use link above) and scroll down the homepage to the button for 'report a crime'). This then generates a crime number and this can be added to the incident raised on Datix. In an emergency situation use 999.

However, if the police consider there is insufficient evidence to take further action or if the member of staff or the Trust remain unhappy with the outcome of police enquires, the ASMS will make further investigations into the circumstance. Any action considered by the Trust will be made in conjunction with the victim and with the authorisation of the Executive Security Management Director (SMD).

4.7 Specialists

- The specialists will be able to view the incident and it is their role to support the investigation as required or on the request of the handler.
- Specialist leads when assigned to lead the investigation have the responsibility to complete investigations within the agreed time frame.
- Specialists will receive email notification of incidents that fall within their areas of responsibility or specialist knowledge. The name of the specialist lead is made available to the handler through the notifications list within the DIF2 investigation form.

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- All communications should be completed through the communication section within the Datix incident reporting system; this will ensure an auditable evidence trail.
- Specialists are required to ensure incidents are reported externally as required eg SHOT, IRMER, HSIB

Specialist leads include the following:

- Accredited Security Management Specialist
- Assistant Chief Pharmacist/ Medicines Safety Officer
- Communications Team
- Dementia Specialist Nurse
- Duty Nurse Managers
- Falls Prevention Practitioner
- Health and Safety Manager
- Information Governance Manager
- Learning Disability Specialist Nurse
- Maternity Risk Manager
- Matrons
- Medical Equipment Training Facilitator
- Medical Physics Manager (Medical Equipment Management Department)
- Mental Health Specialist Nurse
- Moving and Handling Coordinator
- Night Team Leaders
- Pharmacy/Medicines Management
- Radiology Manager
- Restrictive Practices Specialist
- Safeguarding Leads
- Senior Information Risk Owner (SIRO)
- Sepsis Lead Nurse
- Specialist Fire Advisor
- Speciality Governance Leads
- Tissue Viability Nurse
- Transfusion Practitioner

4.8 Reporter (all staff groups)

- The reporter will report an incident or near miss as close to the incident as possible and identify the level of harm and the severity of the incident. Guidance is available on SFHFT intranet via the Datix incident reporting system home page.
- The reporter also has the responsibility to ensure that a verbal apology is provided to the patient or their representative, at the time the reporter identifies that an incident has resulted in harm (this may or may not be the reporter). The incident details and confirmation of the verbal apology must be recorded within the medical records.
- The reporter has the responsibility of ensuring that any consequence of the incident is assessed to reduce any risks that may endanger patients, employees or members of the public. The assessment of the situation should be delegated to the most senior member of the Ward/Department.
- All staff groups must ensure that appropriate escalation of incidents should be completed in a time sensitive manner, through the Trust's management structures.
 This will enable the most senior member of staff to judge if the incident requires escalation outside the immediate ward or department.

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 Once the investigation into the incident/near miss has taken place the reporter should expect to receive feedback from the Handler with regard to action taken and lessons learnt. The reporter should only use their NHS.net account when completing the DIF1 as feedback can only be given to a secure email address to prevent an information governance breach.

4.9 Nominated DIF2 Handler and Deputy

- The handler is the person responsible for managing the incident on the Datix incident reporting system. In most cases this will be the Ward/Department Lead for where the incident/near miss has taken place.
- The handler will review the incident on the Datix incident reporting system, establish the impact of the incident, check the severity code as recorded by the reporter and amend as required. This severity code will help determine the level of investigation and the escalation as required. This should be completed within *2 working days of the incident occurring. This will allow the uploading of severe or death related incidents to the National Reporting and Learning System (NRLS) within the required time frame.

*The 2 working day period will be considered to:

- Exclude weekends and bank holidays
- Run from 23:59 on the day the incident occurred to 23:59 on the day the incident is received in the National Reporting and Learning System (NRLS).

If there is no harm and the incident details are completed including any lessons learnt the handler should progress the incident to awaiting final approval.

For incidents where low harm (Grade 2) has been selected the handler should review the incident or identify who is the most appropriate person to review the incident and communicate with that person through the communication section on the DIF2. The handler should review and move to awaiting final approval Grade 2 incidents within 45 workings days.

Support is available for handlers from the Quality Governance Leads in the GSU.

Divisional Management teams will nominate the investigation leads for Grade 3, 4 or 5 incidents and these require investigation within a time frame of 60 working days.

The handler may need to liaise with 'specialists'. The specialists will be able to view the incident and it is their role to support the investigation if required. The handler can see which specialist lead has been emailed the incident by viewing the notifications list within the DIF2 investigation form.

See section 4.7 for a list of Specialist Leads.

Once the investigation is completed the handler will complete the lessons learnt section and this will be emailed as feedback to the reporter of the incident/ near miss.

Compliance with timescales is monitored and escalated via the monthly specialty and divisional clinical governance reports and the monthly KPI reports.

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Before the incident is progressed to awaiting final approval the handler should check the following is undertaken:

- Category and Sub Category reflects the incident details.
- Severity, Result and Risk Grading is complete.
- Should remove any person identifiable information from the following fields: Description, Action Taken, Investigation, Handler/ Specialist Action Taken and Lessons Learned.
- If an incident has been particularly well reported be sure to feed this back to the reporter thus encouraging continued reporting/ congratulate them if they have managed the incident well.
- If an incident relates to a re-occurring issue, include information regarding on-going projects, risks included on the risk register or controls that have been put in place.
- Lessons learnt section must be completed in full "see report"; "see attached"; or "in line with Trust policy" etc will not be accepted as lessons learnt.
- Feedback must be provided for the reporter if the reporter has raised the incident and recorded their personal email, this is not to be used and handlers should give direction to staff on the use of the Trust email. Agency/ Temporary Staff must use their line managers email address.

If a decision is made to move the incident to *Awaiting Final Approval* and the investigation is not fully complete the relevant Quality Governance Lead must be informed by email in order for the GSU to advise with regard to the progression of the investigation.

• The DIF2 Handler will complete reports to the Health & Safety Executive (HSE) in accordance with the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) 2013. (Click here for guidance on reporting to the Health and Safety Executive). Any RIDDOR reports submitted via the web to the incident contact centre should be saved to the hard drive and forwarded via e-mail to the Datix System Manager. This report will then be entered onto the Datix risk management system. It should be noted that all RIDDOR reports to the HSE should be made within 10 working days or sooner if there is a death or major injury. It is recommended that handlers discuss the incident with the Health and Safety Manager prior to submitting a patient related report to the HSE. If the Health and Safety Manager is not available advice is also available from the GSU.

4.10 Datix System Manager

• The role of the Datix System Manager is to act as the in-house expert for the Datix incident reporting system and provide on-going support and training on the use of the system. This includes ensuring optimum and innovative use of the system, data analysis, supporting the production of reports (with the emphasis on training individuals to access reports) and improving data quality. The Datix System Manager is to ensure all reporting complies with requirements of external agencies e.g. NRLS whilst maintaining the integrity and security of the Datix incident reporting system.



4.11 Trust Scoping Group

- This is a multi-disciplinary forum to review incidents warranting escalation beyond divisions due to the severity level (moderate and above), complexity, potential for learning or potential reputational implications. The level of investigation, key lines of enquiry and investigation report can be signed-off when agreed (ie divisional or Trust). Any incident deemed to meet the serious incident framework and/or never event criteria will be discussed with the relevant executive for agreement for escalation to StEIS.
- If media interest is thought to be likely, the Trust's Communications Team will provide support with the management of public and media interest with regards to incidents. They will also provide communication statements on request from NHS England following notification of a serious incident or 'never event'. See Appendix G

4.12 Trust Sign-Off Group

- Incident investigation reports which are deemed at Trust Scoping Group meeting
 to require Trust Sign-off with Executive presence are presented at this meeting
 before they are closed on the divisional trackers and/or submitted to the CCG for
 closure on StEIS. A critique tool is available (see <u>Toolkit</u>) to use to quality check
 the report details.
- If media interest is thought to be likely, the Trust's Communications team will provide support with the management of public and media interest with regards to incidents.
 They will also provide communication statements on request from NHS England following notification of a serious incident or 'never event'.

5.0 APPROVAL

This policy (v7.0) has been approved by the Trust's Patient Safety Committee.



6.0 DOCUMENT REQUIREMENTS (POLICY NARRATIVE)

Please also use the relevant divisional standard operating procedures in conjunction with this policy:

- 1. Diagnostics and Outpatients Divisional Serious Incident SOP
- 2. Medicine Division Serious Incident SOP
- 3. Surgery Division Serious Incident SOP
- 4. Urgent and Emergency Care Division Serious Incident SOP
- 5. Women and Children's Division Incident, Trigger and Serious Incident Process SOP

6.1 How to Raise and Manage an Incident on the Datix Incident Reporting System

Identifying an incident or near miss is the first stage of risk management. Immediate action to be taken following an incident is described below.

Any member of staff present when an incident is discovered must take immediate action to reduce further risk and in maintaining safety, ensure that their own safety is not compromised.

Once the immediate situation has been addressed, it is the responsibility of all members of staff to bring an incident or near miss to the attention of the most senior member of staff on duty in the designated area.

The following factors should be taken into account in order to determine the necessary escalation:

- The extent of harm caused and the immediate first aid and support needed to the injured or traumatised
- The adequacy of the immediate nursing, medical and management response, and the need for specialist advice/support
- The safety of the situation and the potential for further harm
- The need to inform the patient/s and or their family/representative.
- The need to support service users, staff and others affected by the incident.

The most senior member of staff has the responsibility of verbally reporting potential serious incidents (SIs) via the management structures. This will ensure that potential SIs are investigated in a timely manner therefore identifying and rectifying any immediate risks. See section 6.5 for *Management of a Serious Incident*, to help identify what a potential serious incident may be.

The Trust has implemented the Datix incident reporting system which is accessed through the intranet homepage using the following icon:

All incidents and near misses should be reported on the Datix incident reporting system as close to the time of the incident as practicably possible. To support the interrogation of trends and themes the reporter is required to allocate the incident a category and subcategory. As the reporter is usually the person who witnessed the incident they are in a unique position in understanding the events.

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Having the correct category and sub-category supports the process of mapping the Trust's patient related incidents to the national data base – NRLS.

Assistance for completing the initial DIF1 can be accessed here: How to report an incident.

If the system is down for planned technical reasons staff will be informed via internal communications and advice will be given on the reporting requirements during this period. In an emergency situation hard copy forms are held in the "Control Room / Classroom 2 / room number 061118" (along the corridor from HQ). Contact security for access.

If staff have difficulties with any aspect of completing an incident form, support can be accessed by via the Quality Governance Leads in the GSU.

6.2 Incident Severity Grading

Every NHS organisation should ensure that the degree of harm recorded for each incident describes the *actual harm* to the patient *as a direct result of the incident*.

The 'degree of harm' on incident reports should relate to the actual harm resulting directly from the incident itself. It is therefore incorrect to record potential harm rather than actual harm as a result of the incident. Similarly it is inaccurate to record the degree of harm in relation to the outcome of the medical condition rather than the direct result of the incident itself, e.g. "severe" should only be recorded when the patient has been permanently harmed as a result of the incident and "death" should only be recorded when the incident has resulted in the death of the patient.

Source: National Reporting and Learning System (NRLS) Data Quality Standards (Sept 2009).

Handlers can access advice on severity coding from the GSU. Support is available for handlers from the Quality Governance Leads in the GSU.

Incidents should be severity coded at the time of reporting the incident and graded in the following way:

- (Grade 1) No Harm incidents identified as Grade 1
- (Grade 2) Low Harm incidents minimal harm to patient but required extra observations or minor treatment.

Please note: neurological observations following an un-witnessed fall are not classed as extra observations as this level of observations is dictated by the Trust's Head Injury Policy on Hospital Premises and may not be in response to harm. Therefore only the harm not the level of observation should be recorded)

- (Grade 3) Moderate Short term harm Patient required further treatment procedure.
- (Grade 4) Severe Permanent or long term harm:
- (Grade 5) Catastrophic Death: death as a direct result of a patient safety incident.

(Please note: If the patient's death is not directly associated with the incident the degree of harm should be proportionate to the incident details and not the death)



Incidents identified should be reviewed, investigated and transferred to awaiting final approval within 45 days of the incident occurring. In instances where an SI is identified and the investigation is allocated to another lead not the Ward/ Department Manager, the Handler will be re-allocated to the GSU and the timeframe for completion will be adjusted accordingly (this is dictated by the CCG and StEIS requirements).

For all grades of incident there needs to be a narrative account in lay-man's terms setting out the key facts (timeline, acts/ omissions), analysis and conclusion to include lessons learnt and actions taken.

It will depend on the grade/ severity of the incident, potential for learning and anticipated audience (for example coroner) as to whether this information is simply recorded within Datix, a scoping paper or an investigation report.

6.3 Quality checking

All staff that access the incident record on the Datix incident reporting system, have the responsibility to quality check the recorded details to ensure all relevant fields are completed and in line with the incident description, all relevant documents should be attached, lessons learnt have been recorded and redact patient or staff identifiers within the description to avoid Information Governance breaches.

Assistance for completing the initial DIF1 can be accessed here: How to report an incident.

If, during the final approval process, issues are identified the incident will be moved back into awaiting review by the GSU. Communication will be sent via Datix incident reporting system communication section to explain the reasons why the incident cannot be approved by the GSU.

6.4 Reporting to the National Reporting Learning System (NRLS)

All incidents/serious incidents must be uploaded by the Datix System Manager to the National Reporting Learning System (NRSL) within agreed timescales.

The Datix System Manager or deputy will up-load incidents to the NRLS monthly or within 2 days of a serious incident occurring, however it is strongly encouraged to report on a weekly basis.

All incidents raised on the Datix incident reporting system which are classified as 'Serious Incidents' must be uploaded within 2 working days of the incident occurring, once the investigation has been completed the severity coding should be readdressed, if changes are made then the incident should be re-uploaded. It is the responsibility of the investigator to review the severity code against the findings of the investigation, once completed they are also responsible for notifying the handler and the Datix System Manager.

At SFHFT an additional field has been added so we are able to record both actual harm to the patient and Trust apportioned harm. Trust Apportioned Harm will be agreed and finalised once the investigation is complete.

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6.5 The Management of a Serious Incident

All staff have a duty to report potential serious incidents, initially through their line manager who on recognising the significance of the event will notify the GSU.

The NHS England Serious Incident Framework (March 2015) sets out the criteria for what constitutes a serious incident. A serious incident demonstrates weaknesses in a system or process that needs to be addressed to prevent future incidents leading to avoidable death or serious harm to patients or staff, future incidents of abuse to patients or staff, or future significant reputational damage to the organisations involved. SIs therefore require investigation in order to identify the factors that contributed towards the incident occurring and the fundamental issues that underpinned these. Serious incidents can be isolated, single events or multiple linked or unlinked events signaling systemic failures within a commissioning or health system.

There are 3 levels of investigation described in the NHS England Serious Incident Framework (March 2015):

- Level 1 (concise) within the Trust, this is a local investigation managed within the division
- Level 2 (comprehensive) within the Trust, this is discussed at Trust Scoping and brought back to Trust Sign Off
- Level 3 (independent/ external) within the Trust, this is discussed at Trust Scoping and brought back to Trust Sign Off
- Any variation from the above will be discussed and agreed via Trust Scoping/ Sign Off meetings.

Once a potential SI is recognised, a scoping of the incident will be undertaken by the relevant clinical team, the Quality Governance Leads will coordinate this to ensure a summary report is available to go through the Divisional process. Following this, if the criteria for a potential SI is met or the complexity, potential for learning or potential reputational implications warrant discussion at Trust level, the incident will be escalated through Trust scoping meeting. Trust Scoping meetings are prearranged three times a week.

The evidence collated for the scoping should be sufficient to aid the decision making process in determining the level of investigation and reporting required.

The following will also be discussed at the scoping meeting:

- 1. The Duty of Candour response to date.
- 2. The person responsible for communicating with the patient or relative/representative (Duty of Candour/formal or informal).
- 3. Specific key lines of enquiry for the investigation to be identified.
- 4. If the SI framework has been met for declaration on StEIS, final decision for escalation sits with Medical Director/ Chief Nurse/designated deputy.

An externally reportable serious incident will be reported to the CCG and on the Strategic Executive Information System (STEIS) by a member of the GSU after authorisation from the Medical Director and/ or Chief Nurse/deputy. An Initial *Review and Notification of a Serious Incident* report will be prepared and emailed to the CCG and members of the Trust Board ensuring patient confidentiality and in line with Information Governance Policies.



For additional information see:

- Appendix A When An Incident Is Identified
- Appendix B Scoping Process
- Appendix C Investigation Process
- Appendix D SFHFT Framework for the Management of a Serious Incident
- Appendix E NHSI Just Culture Guide

The Trust may require an independent person to support a serious incident investigation – Guidance for the Coordination of Independent Investigations / Seeking an Expert Opinion is attached at Appendix F.

Documents to support the investigation (including Guidance on Statement Writing) can be found in the **TOOLKIT**.

6.6 Never Events

All Never Events are defined as serious incidents although not all Never Events necessarily result in serious harm or death. A Never Event is an incident that meets the criteria of the Never Events list and is a serious largely preventable patient safety incident that should not occur if the available preventative measures have been implemented.

See <u>Revised NHS England Never Events Policy and Framework</u> (NHS England, January 2021) for the national definition and further information

6.7 Learning From Incidents

The investigation and analysis of individual incidents, near misses and from themes and trends will usually identify issues and barriers to service delivery and care from which valuable learning can be extracted. The learning may be applicable to the individual ward/department involved, an entire Division or indeed across Divisions and for the Trust as a whole. Similarly investigations will also often identify areas of good practice from which we can learn.

How such learning is to be shared and who with should be captured in the action plan and monitored accordingly. See Appendix G - Cascade of information / learning following an incident or serious incident.

By identifying and sharing learning and experiences it may be possible to prevent similar incidents from occurring again. The GSU team can offer support with developing action plans and sharing learning.

6.8 Specialist Processes

6.8.1 Wrong Blood In Tube (WBIT)

When a wrong blood in tube incident occurs, or there has been a near miss the pathology staff have a duty to firstly ensure that the clinical team responsible for the patient(s) affected have been informed. The clinical team have the responsibility to assess the impact on the patient/s and change the care pathway accordingly.

The patient(s)/or family(ies)/representative(s) should be informed of the error.

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Transfusion Practitioner or deputy to report the WBIT incidents, where appropriate to the Serious Adverse Blood Reactions and Events (SABRE) system to the Serious Hazards of Transfusion Scheme (SHOTS).

The incident should be raised on Datix and local investigation should be initiated.

Non-transfusion related WBIT incidents will be managed in-line with the usual incident management and escalation processes.

SHOT reportable WBIT incidents relating only to potential transfusion error will be formally investigated as a serious incident and escalated through the Trust Serious Incident Review process as per any other incident.

6.8.2 Reporting Incidents to the Medical Education Centre

The Trust is required to ensure incidents relating to *Doctors in Training* are fed through to the Medical Education Centre. To enact this, the Medical Lead will receive alerts from Datix and will take action as required.

The GSU will also inform the Medical Lead if a Doctor in training is identified as part of a serious incident.

As part of the GSU's daily work, if it is noted that the same *Doctor in Training* appears to be linked with several incidents this will also be raised as soon as this has become recognised.

6.8.3 NHS Screening Programmes & Screening Quality Assurance

Quality Assurance (QA) is the process of checking that national standards are met (ensuring that screening programmes are safe and effective) and encouraging continuous improvement.

Public Health England (PHE) is responsible for the NHS Screening Programmes and the Screening Quality Assurance Service (SQAS). PHE is an executive agency of the Department of Health and works to protect and improve the nation's health and wellbeing, and reduce health inequalities.

If any incidents occur relating to screening programmes then the following guidance should be considered alongside the trust procedures: Managing Safety Incidents in NHS Screening Programmes (updated 16th July 2021). The guidance applies to all organisations that provide NHS Screening Programmes in England whether an NHS trust, NHS foundation trust, general practitioner or private provider. A Screening Incident Assessment Form (updated June 2021) should be completed within 5 days of the suspected incident being identified.

The guidance details the accountabilities for reporting, investigating and managing NHS screening programme safety incidents and should also be read alongside the NHS England's Serious Incident Framework

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6.8.4 Cold chain and vaccine incidents

Cold chain and vaccine Incident reporting: As part of NHS England, the <u>Screening and Immunisation Team</u> (SIT) are responsible for commissioning and performance managing the routine immunisation programmes. This includes ensuring safe and effective delivery of these programmes. Because of this any cold chain and vaccine incident should be reported directly to SIT. NHSE would like to improve its response to incidents and this relies on accurate and timely reporting by providers because occasionally incidents may require a wider public health response. Contact ENGLAND.SCRIMMS@nhs.net

6.8.5 Other

For the following other specialist processes/ information, see relevant procedural documents as listed/linked below:

Subject	Policy
Safeguarding	 Safeguarding Adults Policy Safeguarding Children and Young People Policy Dealing with safeguarding allegations or concerns about individuals undertaking work with children, young people and vulnerable adults in the Trust policy
Child Death Review Process	 Child Death Referral Process Chart Reporting of Perinatal Deaths Procedure
Inpatient falls that result in a serious injury	Falls Policy
Pressure ulcers	Pressure Ulcer Prevention and Management Policy
Infection control and healthcare acquired infections	Operating Policy for Infection Prevention and Control (ICP 1)
Resuscitation	Governance process for the management of in-hospital cardiac arrest and sudden death
Learning from deaths	Mortality Management Policy (learning from deaths)
Human Tissue Authority (HTA) reportable incidents	Guidelines for reportable incidents to the HTA



7.0 MONITORING COMPLIANCE AND EFFECTIVENESS

Minimum Requirement to be Monitored	Responsible Individual	Process for Monitoring e.g. Audit	Frequency of Monitoring	Responsible Individual or Committee/ Group for Review of Results
(WHAT – element of compliance or effectiveness within the document will be monitored)	(WHO – is going to monitor this element)	(HOW – will this element be monitored (method used))	(WHEN – will this element be monitored (frequency/ how often))	(WHERE – Which individual/ committee or group will this be reported to, in what format (eg verbal, formal report etc) and by who)
How all incidents and near misses involving staff patients and others are reported.	GSU and Divisional Management Teams	Review of the Datix incident reporting system for the number, type and trends of incidents reported.	Quarterly	Quarterly CLIPS report to PSC
How the Trust reports incidents to external agencies.	GSU	KPI which the GSU is measured against for NRLS upload	Six Monthly	PSC exception reporting
How staff can raise concerns, for example whistleblowing, open disclosure etc	Handler	Review of individual incidents by the Handler via the Datix incident reporting system.	Ad-hoc, in response to concerns raised.	Escalate through organisational management structure
Quality of the information held regarding each reported incident.	GSU	Quality Assurance process within GSU.	Ongoing with six monthly review prior to NRLS upload	GSU
Serious incident process	Head of Clinical Governance and Serious Incident Review and Sign Off Group	 Incidents recorded on the 'SI tracker' and 'SI Action plan tracker' until closure. 	Trackers sent weekly to divisions for action. Monthly SI report	PSC

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8.0 TRAINING AND IMPLEMENTATION

A user guide for <u>How to report an incident or near miss</u> is published to the intranet for all staff to access. It can be found by either using the intranet search engine or from the homepage of the Datix (Incident Reporting) intranet site.

Information on how to report incidents is made available to all new clinical staff members (except doctors/ medical staff) during the Trust Induction day.

Doctors/ medical staff are informed of how to reports incidents on their induction course and also signposted to the user guide on 'How to report an incident or near miss' accessed from the homepage of the Datix (Incident Reporting) intranet site.

An in-house training course called *Incident Reporting Using Datix* can be booked using the on-line booking system via the Training, Education and Development intranet site. This is for new starters to the Trust and staff already using Datix as a refresher.

Handler training is provided to all new handlers and on request or identified through the quality checking process.

On-going handler guidance is provided through the communication section within Datix web.

Investigation training is facilitated by the Head of Clinical Governance and supported by the GSU.

All staff involved in any aspect of reporting and management of incidents must be aware of and be able to access this policy. They should be familiar with the content of this policy, particularly their responsibilities and the tools provided.

9.0 IMPACT ASSESSMENTS

- This document has been subject to an Equality Impact Assessment, see completed form at Appendix I
- This document is not subject to an Environmental Impact Assessment

10.0 EVIDENCE BASE (Relevant Legislation/ National Guidance) AND RELATED SFHFT DOCUMENTS

Evidence Base:

- An organisation with a memory Report of an expert group on learning from adverse events in the NHS chaired by the Chief Medical Officer first published 2000 reviewed April 2013.
- <u>A promise to learn a commitment to act: improving the safety of patients in England</u>.
 Professor Don Berwick publication. August 2013.
- Managing Safety Incidents in NHS Screening Programmes (updated July 2021).
- National Patient Safety Agency Defining a patient safety incident
- National Recording Learning System Data Quality Standards September 2009
- Never Event list 2018 (NHS Improvement, 2018) last updated Feb 2021
- Never Events Policy and Framework (NHS Improvement, revised January 2018)
- <u>Serious Incident Framework: Supporting learning to prevent recurrence</u> (NHS England, March 2015)

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Related SFHFT Documents

This policy should be read in conjunction with the following Trust policies:

- Duty of Candour Policy
- Risk Management and Assurance Policy
- Maternity Services Risk Management Procedure
- Speaking Up Policy (previously Raising Concerns Whistleblowing Policy and Procedure)
- Information Governance Policy
- Management of Work Related Stress Policy
- Major Incident Plan and Action Cards

There are also a number of other policies, procedures and guidelines that may be relevant to an incident depending on the nature of that incident. For example:

- Head Injury Policy management of patients following a head injury on hospital premises
- Health and Safety Policy
- HIV post-exposure prophylaxis (PEP) policy following occupational exposure to HIV in the healthcare setting
- Management of Work Related Stress Policy
- Medicines Policy
- Medication incidents management guideline
- Mortality Management Policy (Learning from Deaths)
- Moving and Handling Policy
- Guidance for the management of work related violence and aggression
- Sharps and Needlestick Policy (including any bodily fluid exposures or inoculation injury)
- Slips, Trips and Falls Prevention Policy
- Transfusion Policy, Procedures and Guidelines

11.0 KEYWORDS

IRP, serious, never event, framework, and procedure, toolkit, route cause analysis, RCA, adverse event

12.0 APPENDICES

As per contents table

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Appendix A - When An Incident Is Identified

Potential serious incident occurs/or is identified



Risk assess the impact/mitigate any immediate risk/make area safe



Inform patient or family – complete Duty of Candour – DOCUMENT everything



Escalate to immediate line manager or Matron or OOHs the DNM



Consider support to staff (<u>refer to just culture guide</u>) and other immediate actions such as statements/quarantine of equipment/hot de-brief



Escalate to the Divisional Management Team (DMT)



Raise incident on DATIX – if an incident has the potential to meet the <u>Serious Incident Framework Criteria</u>, it must be escalated to the appropriate Divisional Management Team



If scoping is required – follow the process for scoping in <u>Appendix B</u>

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Appendix B – Scoping Process

If scoping is required complete the scoping summary ensuring engagement with all specialties and relevant parties involved and seek advice from GSU if required.



On completion seek approval from the relevant manager and submit to the appropriate Quality Governance Lead for submission to the Divisional Senior Leader



Reviewed by division and level of progression of incident is determined. Progression may include:

- Managing via Datix
- Local investigation
- Escalation to Trust scoping



If progression to Trust scoping is required – the key lines of enquiry are to be identified.



A member of the Divisional Management Team/Ward Leader/Lead will present the incident to the scoping group – if StEIS criteria is met, discuss with Medical Director/Chief Nurse and report on StEIS



The Scoping meeting will consider the following:-

- 1. Level of investigation
- 2. The key lines of enquiry
- 3. Professional accountability
- 4. Duty of candour
- 5. Reporting requirements
- 6. Level of harm

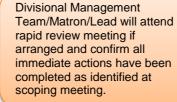


Appendix C – Investigation Process

Act on any immediate issues identified during scoping and nominate an investigation lead considering specialism and independence required.



The Quality Governance Leads/GSU team will support investigation lead and confirm date for sign off meeting.





Investigation lead to commence investigation in-line with the Trust's investigation process, taking formal statements using agreed templates and guidance.

Investigation report progressed through specialty clinical governance and divisional sign off processes and action plan developed and agreed.



Amendments made as required following pre-meet



GSU will take report to a pre meet for first level quality assurance and ensure all key lines of enquiry have been addressed.



The investigating lead will conduct the investigation, liaising with duty of candour lead to complete the investigation report and make recommendations.

Investigating lead to ensure final report is fit for purpose, reflects agreed key lines of enquiry and action plan has been agreed by divisional teams. – Ensure that staff involved have had opportunity

to review report before final

draft is approved.



Submit report three working days before the sign off meeting and attend the meeting to present summary findings and actions to the group.



If report approved:-

- members will sign off the report and action plan and agree final severity of harm grading.
- 2. Submit the report for closure and distribute the final report to the relevant teams Divisional Management Team, Lead investigator, DOC lead
- 3. Make the final report available to external agencies as required
- 4. Upload final version to Datix

If report not approved the GSU will:-

- 1. Liaise with CCG for an extension for StEIS level investigations
- 2. Identify amendments to be made and by whom
- 3. Confirm date for completion
- 4. Liaise with DOC lead to inform patient of delay
- 5. At Sign Off meeting, method for final approval post requested amendments will be agreed



Final Sign Off agreed

Divisional Management Team to finally agree evidence and closure of actions.



GSU will verify the final severity of harm on DATIX as agreed at Trust Sign Off and start the process of obtaining evidence of closed actions.



Share final report with all those named in action plan



Duty of candour lead to contact patient or family in line with DOC policy – offer to share final report and agree how this will be shared.



Exec or nominated deputy/Head of Clinical Governance/Deputy to report back to NHSI and/or CQC as required.

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Appendix D

SFHFT FRAMEWORK FOR THE MANAGEMENT OF A SERIOUS INCIDENT

SECTION A – IN HOURS REPORTING

SECTION B – OUT-OF-HOURS ESCALATION REPORTING

Definitions

- Deputy = person in charge of ward/ department at the time of incident
- Divisional Management Team = Divisional Clinical Chairs, Divisional General Manager, Divisional Matrons.
- Independent = an Investigating Lead who can provide objectivity who is preferably not from the specialty where the Incident occurred
- Key Lines of Enquiry (KLOE)/ Terms of Reference (TOR) = the pertinent questions that will need to be answered in order to determine the root cause
- Corporate Team = a person / team whom has identified an Incident outside of a routine ward based incident

Abbreviations

- GSU = Governance Support Unit
- NRLS = The National Reporting and Learning System a central database for the reporting of patient safety incident.
- CCG = Clinical Commissioning Group
- CQC = Care Quality Commission



SECTION A - IN HOURS REPORTING

INHOURS		
Responsible Lead officer	Action	Time frame
Ward/ Department Leader or Deputy	uty	
Corporate Team	 Potential serious incident raised by an alternative source e.g. Datix review, complaint, mortality reviews or whistleblowing etc. The corporate team will inform the appropriate Speciality and Divisional Management Team. 	(First 24 hours)
Ward/ Department Leader or Deputy	Risk assess impact and mitigate any immediate risk.	
Consultant with the Ward/ Department Leader or Deputy	Inform patient or patient's representative – refer to Policy for Duty of Candour (Being Open)	
Ward/ Department Leader or Deputy	 Verbally escalate to the Matron or Immediate Line manager (out of hours see flowchart Appendix A and Appendix D, Section B: Out of Hours Escalation Process) 	
Matron or Immediate Line manager	Escalate to the Divisional Management Team	
Ward/ Department Leader or Deputy	Report on the Trust's incident reporting system (Datix)	
GSU	 If the GSU identifies a potential serious incident from Datix, GSU will report to the appropriate Divisional Management Team 	
Divisional Management Team	 Initially investigate the sequence of events to help determine the level of severity of the incident (scoping) and identifying how the Incident meets the SI Framework criteria The GSU to be informed if the level of the severity of the incident requires consideration as a serious incident. (to include internal or externally reportable serious incidents considering the Guidance published by the CCG)) 	
GSU	 Prearrange 3x weekly scoping meeting which includes the Clinical Director for Patient Safety/Deputy and or Head of Clinical Governance/ Deputy. In exception circumstances where executive level attendance is required for the discussion, the Medical Director and/ or Chief Nurse will be notified to chair the meeting. If the SI has involved a death, the Trust Solicitor will be invited to attend – liaison as appropriate with coronial office. The divisional scoping meeting should be arranged within 48hrs of recognising the severity of the incident prior to being presented at the trust level scoping meeting (if the incident clearly meets the STEIS reporting criteria then this must be discussed with Medical Director, Chief Nurse and Head of Clinical Governance for consideration of STEIS escalation prior to the meeting). 	Day 1 (24 – 48 working hours)

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Divisional Management Team	The member of the DMT, Matron, Dept/Ward Leader will present the incident to the scoping group including the following: 1. Verbal summary of the event 2. Level of harm 3. Was this as a result of any act or omission 4. Update on current status of the patient 5. Confirmation of verbal apology if appropriate 6. Name of designated Duty of Candour Lead 7. Internal/external agencies already informed e.g HR, police, CQC, NHS ENGLAND, CCG 8. Immediate learning and management of risk.	
Head of Clinical Governance/	The chair leading the scoping meeting will consider the following:	
Deputy/ Director for Patient Safety	1. The level of investigation 2. The Key Lines of Enquiry/ Term of Reference for the investigation 3. Any immediate concerns re professional accountability / Fitness to Practice concerns (NMC / GMC / NCAS) 4. Duty of Candour requirements 5. The reporting requirements (STEIS/MONITOR/CQC etc) 6. Declare STEIS level investigation	
GSU	 For STEIS reportable incidents prepare Initial Review and Notification report for distribution to the Trust Board members, Clinical Commissioning Group. Report on STEIS <u>and</u> report to the Clinical Commissioning Group. CQC and NHSI are notified via StEIS, however depending on the severity/nature of the incident direct escalation may be required. This will be decided on collaboration with Medical Director/Chief Nurse. Report on STEIS the level of investigation to be completed. Level 2 comprehensive Level 3 independent Establish dates for presentation at Divisional Governance Meeting(s) and SI sign off group 	
Divisional Management Team	 Act on any immediate problems that have been identified during the scoping exercise Nominate an Investigation Lead or approach another Division where specialism or Independence is required. 	
GSU	 The QGLs/ GSU team will support the investigation lead for example: coordinate a panel meeting as required; support the investigation interview process; provide the relevant reporting template and associated documents required for the investigation; provide support and guidance for report writing, proof reading and formatting. Confirm date for SI sign off meeting. 	



	NHS Foundation Trust	
Nominated Investigating Team	 Commence Investigation within the Trust Serious Incident Review and Sign of process. To take formal statements using agreed statement template and guidance. Identify any staff/witnesses to be interviewed. 	
GSU	 Initially grade the incident based on the information available and change the handler on Datix to the serious incident handler profile. Initial incident to be uploaded to NRLS prior to full investigation. 	
Investigating Lead	 Conduct the investigation . Liaise with Duty of Candour lead to include patient concerns in the investigation. Complete the investigation report and make recommendations. Arrange panel meeting with the investigating team to review the investigation findings. Apply the Care and Service Delivery classification code (see toolkit) 	48hrs - Day 21 (working days)
Divisional Management Team Matron/Clinical Chair or deputy	 To attend the panel meeting if arranged. Confirm that all immediate actions have been completed if identified at the scoping meeting. 	
GSU	Exception report on barriers to progress of completing the investigation within the agreed timeframe at the two weekly SI sign off meetings.	
Divisional Management Team	 Agree and/or prepare action plan. Present final report and action plan to: Specialty Clinical Governance Meeting. Divisional Clinical Governance Meeting. Serious Incident Sign Off Group. 	Day 21 working days onwards up to 45
Investigating Lead	 Ensure final investigation report is fit for purpose, reflects the agreed KLOE/TOR's and that divisional teams have agreed the action plan in readiness for SI Sign Off Ensure that staff involved have had the opportunity to review relevant sections of the report before the final draft is approved. Submit report three working days before SI sign off meeting and attend the pre-agreed date to present the summary findings and actions 	
Serious Incident Review and Sign off Group	 Attend SI Sign off to present the report to the group including: 1. Verbal summary of the investigation report. 2. Recommendations made in the report. 3. Actions identified in the report. 4. Update on completed actions. 5. Any further concerns/limitations highlighted throughout the investigation. 	45 to 60 working days are required to manage the Trust SI sign off process.

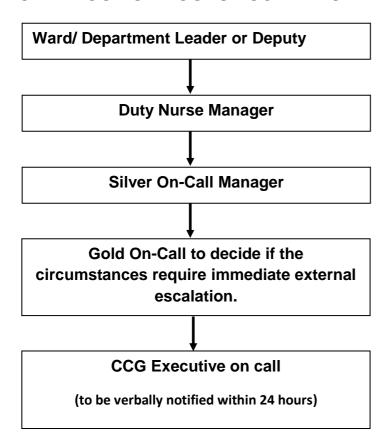


	 Members will approve the report and action plan or will commission further work. Complete the critique tool if required Agree the final report or identify clear actions to be completed prior to sign off and process for sign off
GSU	 If report not approved, the GSU will liaise with the CCG Lead for extension. Clearly identify amendments to be made and by whom Date for completion Process for sign off Liaise with DOC lead to inform patient of delay Liaise with CCG if necessary for extension GSU will submit the report for closure and distribute the final report to the relevant teams/staff/action leads. If SI involved a death, inform Trust Solicitor of status of report and if not approved advise immediately of the agreed extension to ensure the coronial office is aware When the report is signed off GSU will Proof read and prepare the final report. Distribute the final report to the DMT, Lead Investigator and DOC Lead. Make the final report available to external agencies as required i.e CCG, CQC, NHSE. Upload the final version onto Datix.
Divisional Management Team	 Arrange to see patient or patient's representative in line with duty of candour / policy (being open). Forward the final report to all persons named in the action plan.
GSU	 Check that final incident grading on Datix matches initial upload to NRLS. If there have been any changes re-upload Datix Incident form to NRLS. Start the process for obtaining evidence of closed actions.
Executive or nominated representative	Report back to NHSI and/ or CQC as required.

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SECTION B - OUT-OF-HOURS ESCALATION REPORTING





Appendix E

Supporting consistent, constructive and fair evaluation of the actions of staff involved in patient safety incidents (NHS Improvement – A just culture guide)

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.

Use this link to access the full guide: https://www.england.nhs.uk/wp-content/uploads/2021/02/NHS_0932_JC_Poster_A3.pdf

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Appendix F

Guidance for the Coordination of Independent Investigations / Seeking an Expert Opinion

1. Introduction

This guidance is intended to describe, and to clarify, the process for the coordination of independent investigations or occasions whereby an expert opinion is required to support an internal investigation; from the point of such an investigation being commissioned right through to the sign off of the resulting action plan as fully implemented.

The main objectives of the guidance are to ensure that:

- An Independent Investigator / Expert is properly supported in their role
- Trust staff receive appropriate support and advice
- Good communication takes place between all parties
- Recommendations are implemented in a timely and effective manner
- Risk to the Trust's reputation is minimised

The guidance is based on the current Trust Incident Reporting Policy and current implementation, monitoring and oversight practices, which in turn are informed by guidance from the National Patient Safety Agency (NPSA) and our commissioners.

2. Responsibilities

The Medical Director and the Chief Nurse are the Board leads for SIs, including those high level investigations which may result in an independent investigations or whereby it is deemed an expert opinion will support the internal investigation process. In relation to concerns regarding fitness to practice the decision makers are the Medical Director, the Chief Nurse, the HR director and the Chief Executive. They have overall responsibility for coordination of investigations which are deemed to require an expert opinion, and will be supported by the Head of Clinical Governance / Clinical Director for Patient Safety and GSU Team.

The SI Review and Sign Off Group receives all completed investigation reports and will include independent investigation reports on behalf of the Patient Safety Committee. The Patient Safety Committee is the Trust group with overall responsibility for monitoring the management of SIs and for ensuring that learning takes place from all incidents.

3. Criteria for Independent Investigations

- Independent investigations are required where the integrity of the internal investigation
 and its findings are likely to be challenged or where it will be difficult for an organisation
 to conduct a proportionate and objective investigation internally due the individuals or
 number of organisations involved. Independent investigations avoid conflicts of interest
 and should be considered if such conflicts exist or are perceived to exist.
- An independent investigation can be used as a means of assessing whether an
 account of an incident has been fairly presented to give credit to the findings and
 assurance that lessons will be learnt to prevent recurrence, or it can be used to obtain
 an objective assessment of the nature and causes of an incident irrespective of
 whether or not any investigative work has been or is to be undertaken.

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4. Commissioning the investigation

For those occasions when the Trust identifies that an external expert is necessary for providing assurance of oversight and remedial actions for example if there is concern that an event may represent significant systemic service failure or to supplement our own internal SI investigation; this would be commissioned by the executive team after due consideration at the Serious Incident Scoping Review and/or Sign Off Group.

The decision to commission an independent investigation by the CCG (or other external body) will normally be taken after receipt of the Trust's internal SI investigation report (and in the case of homicides, after the conclusion of criminal proceedings). The CCG will consider the quality of the Trust's internal investigation when determining the scope and process for the independent investigation.

5. Support and communication systems

When the Trust identifies there may need to be an independent investigation / expert opinion commissioned, staff should be informed and given information to describe the process.

When the Trust is notified by the CCG (or other external body) that an independent investigation is being commissioned, the GSU will inform all relevant staff/managers.

The executive team will discuss the support to be put in place for staff, including the need for specialist external advice. The exact nature of support to be put in place will vary according to the nature and scope of the independent investigation, and the circumstances of the particular incident. It may include some of the following:

- A briefing meeting at the outset of the investigation
- Provision of written information outlining the process
- Support in statement writing and at interviews
- Access to local managers/professional leads/executive directors
- Access to unions and professional bodies
- Access to the Employee Assistance Programme and occupational health services
- Individual meetings as appropriate
- A meeting prior to publication of the report

The Trust's Duty of Candour Policy will apply.

6. Initiating, conducting and supporting the investigation

At the outset of the scoping of the SI investigation or at the Serious Incident Review and Sign Off Group a meeting will be arranged with all stakeholders to agree timescales, ground rules, sharing of information and terms of reference. This will include specifically what information is shared with the expert to support their investigation for example, medical records, statements already obtained as part of initial investigation and access to any relevant clinical and non-clinical databases.

The GSU will be the Trust's lead contact for the investigation manager, and will ensure that all requests for documentation, meetings and other evidence is supplied in a timely manner.

The investigation manager will be requested to send any correspondence via GSU to individual staff (i.e. requests for interviews) and ensure appropriate support can be put in place for staff.

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7. Receipt of the draft report

The Trust will be provided with a copy of the draft report and asked to respond to matters of factual accuracy. Any concerns regarding individual members of staff that are criticised in the report, will be shared with the executive team regarding fitness to practice. The staff member(s) will be given the opportunity to respond to the findings. A meeting will normally be held with the member of staff to support them during this stage of the process.

The Trust will receive a final draft, and will prepare an action plan in response to recommendations made (which are relevant to the Trust). This will be led by the Chief Executive, Chief Nurse, Medical Director, HR Director and any other relevant staff.

The Trust's response will be approved by the Medical Director and the Chief Nurse.

The final draft report and action plan will be submitted for formal Trust sign off to the Serious Incident Sign Off Group and will be communicated to all members of staff interviewed during the investigation.

8. Implementing the action plan and monitoring implementation

The responsibility for implementation of action plans sits with the respective Divisions/ Departments. GSU monitors and manages a process through the clinical governance forums to ensure actions have been progressed through to closure and fully implemented as necessary. Timely completion of actions will be monitored and escalated through the Trust's Quality Assurance groups via the Patient Safety Committee Quality Metrics Dashboard.

9. Archiving

All documentation relating to any investigation including independent investigations must be stored electronically on the Datix incident reporting system.

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Appendix G

Cascade of Information/ Learning following an Incident or Serious Incident

Information/ Learning requires sharing

For Immediate Communication (e.g. learning from a serious incident)

PDM Team/Corporate Team/Divisional Teams walk the wards with script for comms cell – signature log gathered.

Ward Department Lead/Deputy sign to say they have received the message and will cascade to their team.

Request an urgent email from Chief Nurse and/or Medical Director and cascade via comms cells/handovers/meetings.

Consider using signature logs to evidence staff have received the message

Contact Communications Team for advice as to whether a Learning Matters or iCare2 would be appropriate.

Once above message routes have been activated **consider** following up with the non-urgent pathway.

For Non-Urgent Communication

Consider contacting the communications team for advice on how best to share information.

Consider email from Chief Nurse and/or Medical Director and cascade via comms cells/handovers/meetings.

Consider using signature logs to evidence staff have received the message.

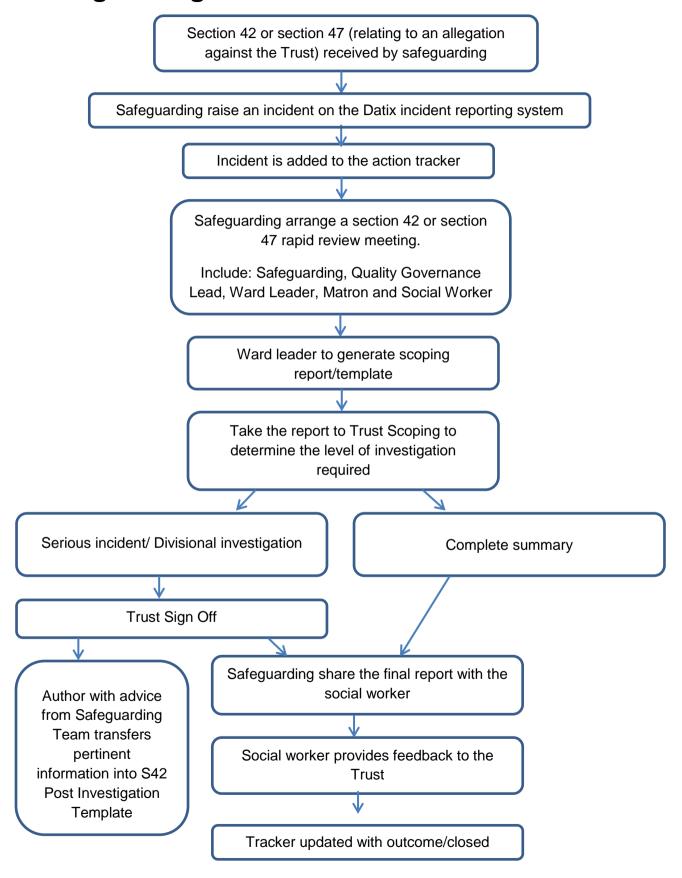
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Appendix H

Safeguarding Section 42 and Section 47 Process



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APPENDIX I - EQUALITY IMPACT ASSESSMENT FORM (EQIA)

New or existing serv	/ice/policy/procedure: Existing		
Date of Assessment			
	icy/procedure and its implementation and policy or implementation down into area		st each characteristic (if relevant
Protected Characteristic	a) Using data and supporting information, what issues, needs or barriers could the protected characteristic groups' experience? For example, are there any known health inequality or access issues to consider?	b) What is already in place in the policy or its implementation to address any inequalities or barriers to access including under representation at clinics, screening?	c) Please state any barriers that still need to be addressed and any proposed actions to eliminate inequality
The area of policy o	r its implementation being assessed:		
Race and Ethnicity	None known	Applies to all patients irrespective of protected characteristic group.	None known
Gender	None known	As above	None known
Age	None known	As above	None known
Religion	None known	As above	None known
Disability	None known	As above	None known
Sexuality	None known	As above	None known
Pregnancy and Maternity	None known	As above	None known
Gender Reassignment	None known	As above	None known
Marriage and Civil Partnership	None known	As above	None known
Socio-Economic Factors (i.e. living	None known	As above	None known

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		NHS Foundation trust	
in a poorer neighbourhood / social deprivation)			
What consultation with pro	otected characteristic groups includ	ing patient groups have you carried o	out?
		pective of protected characteristic gro	
 What data or information did you use in support of this EqIA? None required as the policy applies to all patients irrespective of protected characteristic group. 			
As far as you are aware are comments, concerns, com None		taken into account such as arising fr	om surveys, questionnaires,
Level of impact			
From the information provided above and following EQIA guidance document Guidance on how to complete an EIA (<u>click here</u>), please indicate the perceived level of impact:			
Low Level of Impact			
For high or medium levels of impact, please forward a copy of this form to the HR Secretaries for inclusion at the next Diversity and Inclusivity meeting.			
Name of Responsible Person undertaking this assessment: Meg Haselden, Head of Clinical Governance			
Signature:			
Date: October 2021	_		

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