Leicestershire Partnership NHS Trust

Serious Incidents (SI) Policy Reporting, Investigating and Learning from Serious Incidents

Using principles of 'Serious Incident Framework
Supporting learning to prevent recurrence' (2015)

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Which Relevant CQC Fundamental Standards?	*Regulation12 – Safe Care and Treatment* *Regulation 17 – Good Governance* *Regulation 20 – Duty of Candour*	

Contents

Version number	Date	Comments (description change and amendments)
1	October 2022	Initiation
2	December 2022	Final Draft
3	January 2023	Final changes post consultation

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Equality Statement

Leicestershire Partnership NHS Trust (LPT) aims to design and implement policy documents that meet the diverse needs of our service, population and workforce, ensuring that none are placed at a disadvantage over others. It considers the provisions of the Equality Act 2010 and promotes equal opportunities for all. This document has been assessed to ensure that no one receives less favourable treatment on the protected characteristics of their age, disability, sex (gender), gender reassignment, sexual orientation, marriage and civil partnership, race, religion or belief, pregnancy, and maternity.

Due Regard

LPT will ensure that Due regard for equality is taken and as such will undertake an analysis of equality (assessment of impact) on existing and new policies in line with the Equality Act 2010. This process will help to ensure that:

- Strategies, policies, and services are free from discrimination.
- LPT complies with current equality legislation.
- Due regard is given to equality in decision making and subsequent processes.
- Opportunities for promoting equality are identified.

Please refer to due regard assessment (Appendix 4) of this policy.

Definitions that apply to this Policy

Serious Incident	Serious incidents in health care are events where the potential for learning is so great, or the consequences to patients, families and carers, staff or organisations are so significant that they warrant our particular attention to ensure these incidents are identified correctly, investigated thoroughly and, most importantly, trigger actions that will prevent them from happening again. NHS England, 2015 describe the following: 'A serious Incident investigation is not an inquiry, and it does not seek to assign blame or to hold individuals to account; there are other processes that address these concerns. Its primary purposes are to establish exactly what has happened, what lessons can be learned and how these can be used to prevent a recurrence. This will be achieved by investigations that follow a systems-based approach, ensuring that any issues with our care delivery and any 'root causes' are identified. Any recommendations that are identified are then used to positively influence future practice (NHS England,2015). Serious incidents can extend beyond incidents which affect patients directly and include incidents which may indirectly impact patient safety or an organisation's ability to deliver ongoing healthcare'. The proposed PSIRF is moving away from root cause analysis to system-based investigations which is the aspiration of Leicestershire partnership Trust.
Duty (culture) of Candour	DUTY OF CANDOUR is a statutory (legal) duty to be open and honest with patients (or 'service users'), or their families, when something goes wrong that appears to have caused or could lead to significant harm in the future. It applies to all health and social care organisations registered with the regulator, the Care Quality Commission (CQC) in England. It si also linked to CQC regulation 20. LPT's policy a 'culture of candour' describes our commitment of a general duty to be open and transparent with people receiving care We work with patients to involve them in the planning of their care and keep them informed where care has not gone as expected
Being Open	Discussing and communicating openly, promptly, fully, effectively and compassionate with those involved in incidents, complaints or claims. It is about being open and transparent with service users about their care and treatment, including when it goes wrong.
Apology	An 'apology' is an expression of sorrow or regret in respect of a notifiable safety incident. It is not an admission of guilt. Saying 'Sorry' is always best practice
Patient Safety Incident Response Framework (PSIRF)	The Patient Safety Incident Response Framework (PSIRF) sets out the NHS's approach to developing and maintaining effective systems and processes for responding to patient safety incidents for the purpose of learning and improving patient safety. The framework represents a significant shift in the way the NHS responds to patient safety incidents and is a major step towards establishing a safety management system across the NHS. It is a key part of the NHS patient safety strategy. https://www.england.nhs.uk/patient-safety/incident-response-framework/
Incident Review Meeting (IRM)	Trust weekly meeting to review escalated incidents that have occurred usually in the last week that have the potential for investigation beyond local review. It is chaired by the Head of Patient Safety, with core membership of other relevant and specialist professionals, The purpose is to consider the factors surrounding an incident that is initially identified. Based upon this discussion, a review of the

	circumstances around the incident is undertaken and decision made as to what level of investigation is required, if any, or what further information is outstanding, to ensure that an appropriate and timely decision can be made. It is also a venue to offer assurance to the Trusts stakeholders and is used for any immediate learning/sharing/action
CPST	Corporate Patient Safety Team
ICB	Integrated Care board formerly clinical commissioning group (CCG)
CQC	Care Quality Commission - Regulator of NHS Care Providers
DoC	Duty of Candour
Never Event	'Never Events' are serious incidents that are entirely preventable because guidance or safety recommendations providing strong systemic protective barriers are available at a national level and should have been implemented by all healthcare providers. https://www.england.nhs.uk/patient-safety/revised-never-events-policy-and-framework/
Incident Oversight Group	Also known as 'IOG' Trust group that monitors and receives information in relation to incident reporting, investigation management and the process and compliance with action plans.
Trust Quality Forum	Trust wide meeting that monitors quality and safety within the organisation led by executive Nurse or deputy

Serious Incident Policy – 10 Key Points (can be used as a flyer for staff)

1.Following any incident, ensuring the safety of patients, staff (and any others present) and the environment is of paramount importance. Immediate actions to manage the incident must be the priority before the incident is reported on Ulysses. Escalation should be considered as soon as it is safe to do so.

2. In the case of a Serious Incident (SI) it is important to identify who will provide the initial support to the patient and/or family and staff.

3. It is important that any incident suspected as a SI is notified to Corporate Patient Safety Team as soon as possible (verbal/email), please include the incident (EIRF) number. The notification ensures communication of incidents and the mobilisation of help/support. Even when it is decided an incident is not a SI the notification can be very valuable.

4. Systems based methodology will be used by the investigator who will also be supported by a staff member with service knowledge identified to support the process and provide clinical/specific expertise (aligned to professional knowledge in the context of the serious incident and not linked to the team/ward involved or know to the patient/family).

5. SI investigations are intended to establish learning in order that services can be improved, and that recurrence of such incidents can be significantly reduced in the future. They are '**NOT for blaming or SEEKING to blame'** individuals or teams. This is measure of a mature safety culture/Learning Organisation.

6. The principles of Duty of Candour/Being Open must be applied. Patients (and where relevant relatives and carers) should be supported to raise questions within the investigation and have the outcomes shared with them. The nature of contact with the family during the investigation should be agreed with the patient, or when appropriate, their relative or carer, considering their individual needs and preferences. The lead investigator will offer a meeting to the patient to explain the report upon completion.

7. All staff involved in a SI investigation should be offered appropriate support and the opportunity to have right to reply and receive feedback on conclusion of the SI investigation.

8. Concluded SI investigation reports are anonymised to maintain confidentiality. They are provided to the persons agreed through the 'Duty of Candour/Being Open' process, the staff involved and to relevant Directorates.
Summaries of these reports are provided to the Trust's Directorate Clinical Governance Committees and Patient Safety Improvement Group (PSIG), for wider learning consideration predominantly in the format of a Learning Board /Patient Story. The CPST bimonthly report for Board includes learning and patient stories
Completed reports will be shared with external agencies e.g., Commissioners/ Collaborative/Integrated Care Boards, Care Quality Commission, Local Authority and Coroner (where relevant).

9. Additional support and guidance when a SI occurs outside of normal working hours is available via the on-call manager(s).

10. The timeframe allocated for completion of SI reviews reflects national requirements set out in the NHS England Serious Incident Framework (2015)
https://www.england.nhs.uk/patient-safety/serious-incident-framework/

1.0. Purpose of the Policy

The aim of this policy is to respond in an appropriate way to continually learn and improve the way in which care is delivered and to keep our patients safe.
The purpose of this policy is to outline the overarching governance arrangements for the management of Serious Incidents and/or Never Events and ensure that patient safety and other reportable incidents are appropriately managed within commissioned and contracted NHS services to address the concerns of the patients and promote public confidence. The policy describes the requirements for Serious Incident and Never Event reporting and management. This policy provides a framework to ensure that:

- Serious incidents are identified promptly (see incident reporting and management policy)
- Investigations are timely system based and thorough
- Patients / families / carers are informed about the incident and the investigation through Duty of Candour and are supported appropriately
- Patients / families / carers are involved in the process and receive feedback in accordance with their wishes
- Learning is identified, actions implemented, and learning is shared widely
- Staff are supported to participate in the process and receive support during the process
- The Trust meets its statutory and contractual obligations.

The reporting of incidents is the first and most crucial link, in the chain of the Patient Safety process and is critical to our ability to improve drive forward an open and 'just' culture where individuals are not punished for mistakes, omissions or decisions taken by them based on their professional experience and training, balanced by an intolerance of gross negligence, wilful violations and destructive acts. The remaining links concern learning from experience, implementing change, embedding this change into practice and in turn, improving the safety of our services for all.

The trust is expected to follow the principles applied in the NHS England Serious Incident Framework: Supporting learning to prevent recurrence (2015). (NB 2022/23 the trust will be preparing and transitioning to the principles of the new Patient Safety Incident Response Framework, also known as PSIRF).

The policy provides a framework for internal concise and comprehensive investigations. When independent investigations are thought to be required i.e., those with independent or specialist investigators as all or part of the team, the underlying principles of this policy will apply, and specific terms of reference and methodology will be agreed

This policy is designed to be read in conjunction with Trust's Culture of Candour Policy (2021)
and the requirements of the Incident Reporting and Management Policy (2022) which can be found on the Trust Website.

2.0. Summary and Key Points

Serious incidents within healthcare occur and have the potential to carry significant, permanent, and long lasting psychological and/or physical consequences for those who rely upon our care; it is recognised that the impact upon carers, families and staff can also be just as significant. 'The occurrence of such an event is strongly suggestive of a weakness in the process or system' (NHS England, 2015).

The trust is committed to continually improving the care that it provides. When an incident

occurs and it is identified that the potential for learning is so great, or that the consequence to others is so significant, then it is appropriate that this incident or occurrence is investigated comprehensively and by those with the skills and support to undertake this.

The Trust recognises and promotes three key components of high-quality patient care:

- Patient safety
- Patient experience
- Patient outcomes and effectiveness

It is through the promotion of an open and honest reporting culture and thorough investigation process when safety incidents do occur that provides learning and the opportunity to prevent recurrence. The process described in this policy aims to optimise patient outcomes and supports engagement of the patient and / or family.

Policy Aims

This policy is to be used to:

- Support staff in ensuring that incidents are reported and investigated appropriately with system learning as the focus, highlighting both good practice and where improvements can be made.

- Facilitate the process of lessons learned and appropriate actions taken; both in the interests of preventing future harm, enhancing patient safety, improving the patient experience, and promoting staff learning.

The key principles in the management of all Serious Incidents (SI's) (NHS England 2015), adhered to by the Trust are:

- **'Open and transparent**: The NHS Being Open guidance (CQC Regulation 20 relating to Duty of Candour) will be followed by all relevant staff and monitored via the CPST.

- **Preventative:** That there is a focus on learning from systems/processes, whilst justifying accountability and, there is a zero tolerance for inappropriate/individual blame.

- **Objective:** Investigators must not be involved in the direct care of those patients, carers and staff who are affected/involved.

- **Timely and responsive:** The CPST will report SIs onto StEIS within two working days of the incident being identified by the Incident Review Meeting (IRM) and will co-ordinate the investigation, providing support and guidance where required keeping NHS stakeholders involved and monitoring timescales.

- **Systems based:** Utilising a methodology and style of investigation undertaken by staff with the appropriate skills, training, and capacity.

- **Proportionate:** investigators allocated to a SI will be determined based on the complexity of the incident and the associated level of harm. It is expected that the inclusion of specialist advice being always sought based on the type of incident and the guiding terms of reference i.e., pharmacy, health and safety, security, positive and safe. Any unexpected death meeting SI criteria should include the input of a doctor or Advanced Nurse Practitioner as part of the named investigating panel.

- **Collaborative:** Where a joint investigation is required a discussion with the other provider(s) and where required the ICB's / Collaborative should identify who will lead and co-ordinate the investigation. When the lead provider is recognised as Leicestershire Partnership NHS Trust (LPT) CPST will report the SI onto StEIS and in conjunction with the Directorate Leads, produce a 72hour report, detailing all other care providers; this will indicate how LPT will engage with those providers and how they will co-ordinate any multi-agency investigation report. This process should be clearly highlighted within the SI terms of reference. Where LPT is not the lead investigating organisation, CPST will co-ordinate and review the response, forwarding this to the correct provider, within the specified timeframe'.

3.0. Introduction

LPT (the Trust) is committed to continually improving the quality and safety of all services and be open and transparent with patients, families, and staff when care has not gone to plan or potentially gone wrong during the delivery of healthcare.

Serious Incidents in health care are defined as adverse events, where the consequences to patients, families and carers, staff or organisations are so significant or the potential for learning is so great, that a heightened level of response is justified. Serious incidents in healthcare are rare, but when they do occur everyone must make sure that systematic measures to investigate and respond to them are followed in an efficient and timely manner.

A key role of any investigation is to ensure the Trust can continually improve the safety of the services and care we provide to our patients. We know that healthcare systems and processes can have weaknesses that can lead to errors occurring and, sadly, these errors sometimes have serious consequences for our patients, their families, and our staff, in addition to the consequences for the reputation of the Trust. It is therefore necessary for all staff to continually strive to reduce the occurrence of avoidable harm.

Over the last decade the NHS has made significant progress in developing a standardised way of recognising, reporting, and investigating when things go wrong and a key part of this is the way the system responds to serious incidents. Following the implementation of the Health and Social Care Act 2012, NHS England Serious Incident Framework: Supporting learning to prevent recurrence (2015) have been used to reflect the changed structures in the NHS and the requirement for openness, transparency, and learning.

When an incident occurs, it is essential that it is reported through the Trusts own reporting structure (Ulysses) and subsequently if identified as an SI it must be reported externally to our Clinical Commissioners (Collaboratives, and Integrated Care Boards (formally generically referred to as 'commissioners/CCG's)) by reporting onto the Strategic Executive Information System (StEIS), It is also a requirement of all registered organisations to report serious incidents to the Care Quality Commission (CQC). This task is undertaken by the Corporate Patient Safety Team (CPST) overseen by the Trust's Executive Director of Nursing & Allied Health Professionals.

The Healthcare Safety Investigation Branch (HSIB) began operating in April 2017 and are a team of experienced safety investigators who aim to conduct thorough and impartial investigations into clinical incidents to raise standards, improve patient safety and support learning across all health care in England. Their investigations look at factors that have harmed or may harm NHS patients. They work closely with patients, families and healthcare staff affected by patient safety incidents, and we never attribute blame or liability. Their investigations are delivered through two programmes: national and

maternity. The Trust will work with the HSIB as required in supporting investigations as required predominantly in collaboration with our neighbouring acute providers of maternity and new-born care and reviewing publications related to national patient safety investigations and utilising their education programmes where appropriate.

Going forward the Trust, in response to the new NHS patient safety strategy, will be aligning its response to patient safety incident investigations utilising the PSIRF; a new approach to responding to patient safety incidents. The PSIRF supports the development and maintenance of an effective patient safety incident response system that integrates four key aims:

1. Compassionate engagement and involvement of those affected by patient safety incidents.
2. Application of a range of system-based approached to learning from patient safety incidents.
3. Considered and proportionate responses to patient safety incidents.
4. Supportive oversight focused on strengthening response system functioning and improvement.

https://www.england.nhs.uk/patient-safety/incident-response-framework/

4.0. Background and Process

Identification of a Serious Incident

'The occurrence of an SI demonstrates weaknesses in a system or process that needs to be addressed to prevent future incidents leading to; avoidable death/serious harm to patients or staff, future incidents of abuse to patients or staff, or future significant reputational damage to the organisations involved. SIs can be isolated, single events or multiple linked or unlinked events, signalling systemic failures within the Trust'. (NHSE 2015).

There is no national definitive list of incidents that constitute a SI. However, there is a definitive list of 'Never Events' determined by NHSE, and these must always be reported as a SI. A current list is accessible at:
http://www.england.nhs.uk/ourwork/patientsafety/never-events/

Within the context of NHSE (2015) framework, serious harm can be defined as an incident resulting in (the list is not exhaustive):

- Severe harm (patient safety incident that appears to have resulted in permanent harm to one or more persons receiving NHS funded care)

- Chronic pain (continuous, long-term pain of more than 12 weeks or after the time that healing would have been thought to have occurred in pain after trauma or surgery)

- Psychological harm, impairment to sensory, motor, or intellectual function or impairment to normal working or personal life which is not likely to be temporary (i.e., has lasted, or is likely to last for a continuous period of at least 28 days).

Although all incidents are reviewed on an individual basis whilst considering The Framework, incidents that are more likely to be determined as SIs include:

- Unexpected or avoidable death of one or more people. This includes suicide/self-inflicted death. Unexpected or avoidable injury to one or more people that has resulted in serious harm

- Patients detained under the Mental Health Act (1983), Community Treatment Order or subject to recall
  An incident that falls within the criteria of a 'Never Event' (2018). It is important to note that a 'Never Event' can be declared where serious harm has not occurred.
- Sub-optimal care of the deteriorating patient
- Unexpected or avoidable injury to one or more people that requires further treatment by a healthcare professional to prevent the death of the patient or serious harm
- Actual or alleged abuse; sexual abuse, physical or psychological ill-treatment, or acts of omission which constitute neglect, exploitation, financial or material abuse, discriminative and organisational abuse, self-neglect, domestic abuse, human trafficking, and modern-day slavery.
- The Trust did not take appropriate action/intervention to safeguard against such abuse occurring; or abuse occurred during the provision of the Trust's care. This includes abuse that resulted in (or was identified through) a Serious Case Review (SCR), Safeguarding Adult Review (SAR), Safeguarding Adult Enquiry or other externally led investigation, where delivery of NHS funded care caused/contributed towards the incident
- An incident (or series of incidents) that prevents, or threatens to prevent, the organisation's ability to continue to deliver an acceptable quality of healthcare services, including (but not limited to) the following
- Failures in the security, integrity, accuracy, or availability of information often described as data loss and/or information governance related issues
- Property damage, Security breach/concern
- Incidents in population wide healthcare activities like screening and immunisation programmes where the potential for harm may extend to a large population
- Inappropriate enforcement/care under the Mental Health Act (1983) and the Mental Capacity Act (2005) including Mental Capacity Act, Deprivation of Liberty Safeguards (MCA DoLS)
- Systematic failure to provide an acceptable standard of safe care (this may include incidents, or series of incidents, which necessitate ward/ unit closure or suspension of services) or
- Activation of Major Incident Plan
- Major loss of confidence in the service, including prolonged adverse media coverage or public concern about the quality of healthcare
- A serious near miss incident where the potential for harm or impact on the organisation would have been significant if the incident had not been prevented
- A cluster of incidents that individually would not constitute an SI, but may suggest a system failure of quality of care and where there is the potential for Trust-wide learning
- In addition, the Trust will investigate all unexpected deaths unless there is a clear definitive and recordable reason for not doing so

Other escalation/notification of identification of SIs:

- Complaints/Concerns/PALS information
- Claims
- Safeguarding notification through Local Authority
- Safeguarding notification from 3rd party i.e., Police, Ambulance Service, Fire and Rescue Services, other healthcare providers
- CQC Notification from patients/families/carers and 3rd party notification i.e., Police, Ambulance Service, Fire and Rescue Services, other healthcare providers

All staff must consider whether incidents or communications could meet SI criteria and is patient safety concern (including serious allegations) and the CPST must be contacted

without delay for further advice, incident reported and reviewed for decision next steps via IRM.

Examples of Levels of Harm applied in Patient Safety Incident:

Near Miss: These incidents are those that have the potential to cause severe harm or worse if current systems/processes remain unchanged. Each case will be considered individually for categorisation and reporting as a serious near miss SI. (In particular the method of identifying the near miss will be considered i.e., by identified process or 'by chance')

No Harm:
Impact was prevented – any patient safety incident that had the potential to cause harm and was prevented, resulting in no harm to people receiving NHS-funded care.

Impact not prevented – any patient safety incident that ran to completion and no harm occurred to people receiving NHS-funded care.

Low/Minor: A patient safety incident that required extra observation or minor treatment, not requiring intervention from an acute provider i.e., transfer to Emergency Department and caused minimal harm, to one or more persons receiving NHS-funded care.

Moderate: A patient safety incident that resulted in the patient requiring the intervention of an acute provider i.e., transfer to Emergency Department and which caused significant but not permanent harm, to one or more persons receiving NHS-funded care. Staff injury i.e., because of assault may also fall under this category.

Severe: A patient safety incident that appears to have resulted in permanent harm (or 12 months in duration/physical or psychological) to one or more persons receiving NHS-funded care.

Catastrophic/Death: A patient safety incident that directly resulted in the death of one or more persons receiving NHS-funded care.

A patient safety incident where the learning is so great: it is recognised and is a positive approach to investigating some incidents that result in no or low harm, however, would benefit from a system wide investigation reported under the serious incident framework.

The above is not an exhaustive list of serious incidents and professional judgement will always need to be made. This includes incidents that are considered serious because of their potential risk rather than actual harm caused

Immediate Actions following a potential Serious Incident
Staff involved, or person discovering the incident must:

- Ensure that all actions are taken to make the area and any patients involved safe (including staff)
- Where equipment is involved in the incident, it must be secured by the person in charge/manager of the area and retained for investigation purposes. Secured equipment must be detailed within the Ulysses Incident report.
- Ward Matrons and clinical/service managers must ensure that where an actual or potential SI has occurred, that immediate checks are made to ensure the risk of potential further harm to other patients (and staff) is addressed. Details of all actions taken must be included within Ulysses incident report.

- In some instances (crime scene or inpatient death from self-harm incident), it may be necessary to secure a clinical area. The manager of the service must keep the On-Call Manager, Executive team and others updated.
- It is important to note that when Police are involved in the management of an incident, they take over jurisdiction of that area and will work in conjunction with clinical teams. (In addition, SI's or other full escalation to LPT investigation can only be undertaken if the police agree once their investigation is complete.
- Where staff can, the manager of the area must secure factual accounts from staff before the end of their shift and submit these to the CPST so that these can be shared with the investigator(s).
- Dependent on the incident type the CQC may need formal notification prior to submission of 72hr report; this is done in conjunction with CPST.
- Dependent on the incident type the appropriate 'commissioner' (ICB/Collaborative) may need formal notification prior to submission of 72hr report; this is undertaken by the CPST.
- Dependent on the incident type NHSE may need formal notification prior to submission of 72hr report (i.e. homicide) to 'commissioner'; this is undertaken by the CPST.

Summary of Role of all staff involved in a SI

- Ensure the patient is safe and supported.
- Secure the area, including equipment if involved.
- Ensure staff/colleagues are safe and supported.
- Inform immediate manager for escalation and confirmation of severity.
- When appropriate and safe to do so, Report the incident on Ulysses. In the risk/Outcome additional details section, click on the tick box asking 'SI' (Is this a Serious Incident) (this will ensure that the incident is automatically sent to the CPST and will trigger sharing with others)
- It may be helpful to keep a factual account (memory capture) to enable better recollection of accounts of the incident.
- Provide a list of all potential witnesses to include anyone present or on duty that could potentially provide information to the investigation; utilise this facility on Ulysses when reporting the incident.
- You should be contacted and invited to discuss the events via an interview to aid the investigation with gathering information with the Lead Investigator and share your account of the incident'.

Senior Person (including Managers-On-Call) on Duty

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

- Preserving equipment in the case of failure of a medical device
- Restricting use of any medicines that may be involved in an adverse reaction
- Protecting potential crime scenes if Police involvement appears likely
- When suspicion of crime exists then contacting the Police
- Ensure the incident has been reported on the Ulysses system
- In case of clinical concern, the service or Directorate lead clinician must be informed
- In consultation with clinical staff inform the patient and where appropriate their relatives or next of kin
- Support staff
- Get support for yourself

********On-Call directorate Managers should strongly consider coming in out of hours for staff support and for information confirmation to escalate to the executive representative on-call***.
There will be a need to risk assess based on initial information related to attendance based on the incident. All directorates should consider formalising this as part of out of hours operational support.

Reporting

- Staff must report all incidents on Ulysses. For those that have the potential to meet the SI criteria CPST must also be contacted verbally/email, to report the incident. Out of hours, an email should be sent ideally with verbal contact taking place the following working day
- Any email correspondence **must include the Ulysses incident/EIRF number** related to the incident.
- Further information will be requested by CPST using corporately held initial service managers review (version will be determined by the category of incident) which will be requested to be returned within 72 hours.
- Where it is felt that an incident demonstrates a potential service delivery problem, or meets the SI criteria outlined within this policy, the incident must be presented to the IRM Group to consider the level and method of investigation required.
- CPST will report SIs onto StEIS within 2 working days of IRM investigation decision.

- A record of IRM discussions is retained, outlining the rationale for investigation decisions, immediate learning (and action by directorate representatives to take away) for internal and external assurance.

- Pending the allocation of an investigator(s), the local manager (or delegated) will engage with the patient/family/others involved in the incident and provide an apology / condolence and 'say sorry', explain next steps and how to contact named LPT staff member for any query. A record of contacts or attempts to contact individuals must be shared with CPST for uploading to Ulysses and inclusion on the Duty of Candour/Being Open Assurance Template.

- It is recognised that in some cases engagement with the patient/family/others may not/is not, refused, or maybe delayed; this must be documented on Ulysses/escalated by email to the CPST along with reasons why.

- 72hr Reports should be shared with the appropriate commissioners of services, collaboratives, integrated care boards as per service delegation; CPST are responsible for this with 3 working days of notification to StEIS.

Communicating with the Patient/family or carer (Culture of Candour (Being Open)) post incident

Where incidents meet the threshold of 'Statutory Duty of Candour' NHS healthcare providers have a responsibility to be open and transparent with those affected by incidents and comply with the CQC Regulation 20 Duty of Candour and be compliant with Duty of Candour as a national requirement within the NHS standard contract since 2014/15 (Section 35) – updated 2021/22. https://www.england.nhs.uk/nhs-standard-contract/previous-nhs-standard-contracts/21-22/ .

A summary of the duties associated with 'Being Open' (with timescales) is detailed in the LPT Culture of Candour Policy (2022). The Trust is however, required to include confirmation within SI reports that it has complied with the Initial Duty of Candour responsibilities and as best practice 'being open' for those incidents which do not meet the threshold of duty of candour. In particular:

- Acknowledged and sincerely apologised/given condolences and said ‘sorry’, with explanations, when things have gone wrong as soon as is practicably possible verbally and then followed up in writing within 10 working days of notification onto StEIS
- That the patient / family / carer has been involved and supported from the onset of an incident with conversation/explanation and a meeting to explain what action is being taken and how they can be informed of what support processes have been put in place.
    - Given the opportunity to raise concerns or questions and for these to be included in the investigation Terms of Reference and to ensure their voice is heard throughout the report.
    - To acknowledge and agree on how the findings of the investigation and any learning actions will be shared

All the above information must be recorded on Ulysses, shared with CPST and investigator and the appropriate ‘duty of candour ‘or ‘being open’ assurance template completed.

Final sharing of investigation findings and report are also required in writing within best practice 10 working days of closure of the report.

LPT Culture of Candour Policy is based on guidance from the NHS Resolution document “Saying Sorry” from 2017 and the Nursing & Midwifery Council (NMC) and General Medical Council (GMC) joint document ‘Openness and honesty when things go wrong’ guidance from 2015. The guidance states that ‘Saying sorry’:

- Is always the right thing to do
- Is not an admission of liability
- Acknowledges that something could have gone better; and
- Is the first step to learning from what happened, preventing it recurring.

Further explicit information/variables regarding ‘culture of candour’ can be found in the Trusts Culture of Candour Policy on the Trusts website.

Initial review of the Incident (including requesting Initial Service Managers Review (ISMR ⟹ 72hr report)

CPST Function:

- CPST will request an ISMR via Directorate Governance Teams to establish what is initially known and gain information on patients wellbeing, requesting a return within 72hrs (48hrs if meets ‘Never Event’ & Data Privacy Information Commissioners Threshold).

- Presented by Directorate representative at weekly Incident Review Meeting and decision made to escalate and report onto StEIS as a SI.

- Request sent by CPST to Lead Nurse/Head of Service for incident area for ISMR to be reviewed any ‘new information’ added and terms of reference for investigation agreed. This must be returned as **72hr report** by 48 -72hrs of CPST logging incident onto StEIS for sharing in Pdf format with ICB, Collaboratives, CQC and depending on incident category – NHSE, Coroner.

- All 72hr reports returned are to be checked by Head of Patient Safety, Lead Nurse CPST or Patient Safety Manager (Directorate Mental Health (DMH) SI Lead) ensuring no patient/staff identifiable information (except completer), ’jargon’,

abbreviations without meaning & grammar/spelling/date format check prior to sharing.

- 72hr report shared with Lead Investigator and can be offered for sharing with patient/family/carer with explanation as evidence of openness and transparency/early learning.

- All document version to be uploaded to Ulysses.

Serious Incident Reported – next steps for investigation – Summary

- CPST will share request for initial duty of candour/being open timescales for this to be undertaken and provide documentation to responsible Directorate Governance Teams generic email,
- All investigation documents (pack, 72hr report, incident report, complaint /section 42/ CQC concern should also be included) and timescales shared in email to responsible Directorate Governance Teams generic email to allocate to Lead Investigator allocated (see Serious Incident Timeline flowchart).
- If Corporate Investigator or DMH the allocation to Lead Investigator comes from CPST otherwise Directorates Heads of Nursing/Service allocate this.
- All investigators should be allocated a local to specialty (not the area of the incident)/directorate 2nd investigator; this will assist in the timely supply of information i.e. care pathways, policies, point of record storage on SystmOne to help inform the investigation
- Where Police have been involved in the incident the CPST will confirm if full investigation can go ahead. Police investigation does not mean that initial gathering of information relevant to care pathways, timelines, policy reviews etc.cannot go head. 'Stop the clock' will only be made by CPST in conjunction with formal written notification from the Police.
- **Expert Opinion** - Medical Oversight, Safeguarding, health and safety/security and Pharmacy oversight should be considered at IRM, based on incident information and be clear in the request for investigation from CPST.
- CPST will monitor SI progress through weekly meetings with Directorates led investigations and update Ulysses using contact tab and investigation tab initialing entries.
- CPST Excel Trackers should contain minimum amount of information to monitor key points decided in team and predominantly default to Ulysses.
- Head of Patient Safety, Lead Nurse/SI Lead can request to ICB/ collaboratives for extension of up to 20 working days

Standards for Lead Investigator(s) and investigating panel:

- Not be involved in the delivery of care/ward/team associated with the incident being investigated.
- Have received training in investigation methodology and where this is not in place be 'buddied' with a trained/experienced investigator.
- Have the capacity to undertake the investigation via liaison with their line manager.

- Contact patient/family/carer as applicable to share information about their role. Investigation aims and process, hear their voice and invite them to contribute to the investigation and how they would like feedback. Agree contact frequency/method during investigation and how they or their loved one is to be referred to in the report. Photos can also be used to share the person behind the incident.
- Review all patient records and get assistance with allocated 2nd investigator from service, understand 'how things are done round here' by meeting staff, undertake a site visit where possible, establish the key facts, determine the staff members who were involved in the SI and request meeting, meet with completer of 72hr report and Ward/Team Manager.
- Utilise the support of the local management structure (i.e. Ward Manager/Team Leader) in arranging investigation interviews
- Receive and request factual accounts if not undertaken
- Meet with key staff with an appreciative enquiry approach and clear explanation of reason to meet, provide copy of incident form and 72hr report in email correspondence
- Keep records/correspondence (emails/accounts) or record the meetings via MS teams with staff notification and are shared with CPST for uploading to Ulysses
- Escalate any non-engagement to meet with Lead investigator local manager and CPST
- If professional practice concerns are identified around staff practice; this must escalated at the point of identification formally and in writing to the responsible Head of Nursing/Service/CPST without delay; this must not wait until the end of the investigation.
- If any patient safety/safeguarding concerns are identified as part of the investigation these must be escalated at the point of identification formally and in writing to the responsible Head of Nursing/Service/Safeguarding/CPST without delay; this must not wait until the end of the investigation.
- Utilise skills of others and support of CPST.
- Keep to timescales, escalate where possible of delays due to fact finding, staff meetings, and other investigation delays i.e., cross specialty / cross providers. If there is a genuine reason for the request of an extension, this must be discussed with CPST at least 5 working days prior to the deadline.
- Engage with and support staff through the investigation process, including agreeing accounts and interpretation of meetings/discussions to inform the investigation report
- Consider all aspects of the terms of reference and revisit these regularly as you investigate– if any queries escalate as soon as possible to CPST
- Produce an investigation report using the template supplied unaltered, meeting the standards required that includes ensuring no patient identifiable information, 'jargon', abbreviations without meaning & grammar/spelling check, use a glossary where possible for explaining systems, medical term, drugs etc. – avoid that in the body of the report (See Appendix E for Standards and Checkpoint Guide).
- Demonstrate compliance with Being Open (under our Duty of Candour) by completion of a template within the report.

- Identify the investigation panel/investigator, role, and their objectivity.
- All the terms of reference must be addressed within the report.
- Outline of the methodology used– for example use of the contributory factor framework, Systems Engineering Initiative for Patient Safety (SEIPS) (Appendix B), Yorkshire Contributory Factors Framework (Appendix A) and use of systems approach to investigations
- A chronology of significant events, also known as a timeline, should be completed as part of the investigation process and inform the narrative. It should not simply be a cut and paste of all the clinical notes. The chronology is not required to feature in the body of the report and should be included as an appendix.
- Consider human factors, system issues.
- Ensure conclusions and recommendations are evidenced and reasoned and that the recommendations are SMART (Specific, Measurable, Attainable, Realistic and Timely) – see Appendix C.
- Develop a learning/improvement plan from the recommendations and ensure leads for service, have been involved in a discussion surrounding the draft report, plan and have agreed to lead them.
- Once recommendations have been identified within the report, a discussion with the service lead for the area responsible for implementing an action; (ideally in person) must take place. This is to ensure that local knowledge of the service and clinical practices can inform the recommendations, and that actions are not developed which are not achievable. This discussion and acceptance of responsibility must be evidenced by email and submitted to the CPST.
- Be available to attend the report sign off at directorate level to give brief resume and provide insight for queries/next steps if needs further review.
- Share the investigation report with the patient / family / others within 10 working days of internal sign off.
- Once notification of sign off is provided by CPST they will liaise with the manager of the incident area to ensure that the report and associated learning is fed back to all staff within that area.
- Evidence of all these actions is to be recorded and sent to the CPST for Ulysses update.

Additional Information/Tips

- To assist with the investigation, the Lead Investigator should consider using the Yorkshire Contributory Factors Framework (Appendix A) and use of systems approach to investigations (SEIPs) (Appendix B) to assist with analysis, concluding and compiling a factual well written report.
- Consider using photos for site visits in the report
- Always reference guidelines, policies, local and national standards (e.g. NICE)
- Ensure the staff/patient voice is heard
- Avoid regurgitating patient records in the report, analyse and summarise without losing the story
- Be factual, compassionate, and kind, using recovery focused language.
- Avoid words like ‘failure’, ‘non-compliance’, ‘good communication’, ‘busy’

Role of 2nd Investigator: example of how to influence their role

- Usually is allocated from service where the incident took place but not the team/ward
- Can be allocated to support at review meetings with staff
- Identify key polices/procedures etc.
- Support with analysis of findings
- Set up meetings
- Gather specialty feedback
- Staffing/education & training compliance information gathering
- Review the draft report once completed by Lead Investigator be the friendly critique
- Provide support / listening

Downgrading of SI

If through the investigation, it is determined that the incident does not meet the threshold of an SI, then the SI can be requested to be removed from StEIS via ICB/collaboratives considering any incidental findings and their relevance. This is a rare occurrence and will only be approved following review by the Head of patient Safety and appropriate 'commissioner' and a formal written record made and stored on Ulysses.

In relation to the investigation process CPST will:

- Monitor progress with investigations and produce monthly performance reports, escalating delays to the Head of Patient Safety, Heads of Nursing and Deputy Directors (as required).
- Assist with the production of investigation reports, in terms of report structure and action planning.
- Update Ulysses.
- Ensure that investigation reports are quality assured before submission for Executive sign off and onward sharing with patients, families/carers, ICB/Collaboratives, coroners and CQC.
- Submit completed SI investigation reports to those detailed above.
- Facilitate responses to any queries raised from ICB/Collaboratives review.
- Facilitate responses to any questions raised by the patients, families/carers, Coroner, CQC.

Completed Report and action/improvement plan.

The final draft report and action/improvement plan will be written and approved on behalf of the Trust and 'signed off', as complete, by the Executive Director of Nursing, Medical Director, or their deputies.

Prior to sign off, the final draft report should be consulted on with all those involved and agreed by the investigation team and by the Head of Nursing and/or Director (varies according to Directorate). This includes completing, where relevant, the Just Culture Guide (see appendix C) Further information at https://www.england.nhs.uk/patient-safety/a-just-culture-guide/

The final report must be provided to ICB/Collaborative within the current NHSE 60 working days guidance, therefore planning, and adhering to an appropriate schedule to achieve sufficient depth of investigation, report completion, consultation and sign off.

CPST will upload actions on Ulysses to allow automated sharing of actions to those designated to undertake them and then will receive the completed and fully populated action plans with evidence for final closure once approved locally.

CPST and will upload the plan to Ulysses and close on the CPST action plan tracker during this process monthly meetings will be held with Directorate Clinical Quality Governance representative and report/monitoring of progress will be reported and information shared for inclusion into the monthly incident management report shared at Incident Oversight Group (IOG) and Trust Quality Forum (TQF).

Overall accountability for this process lies with the Directorate. The responsibility for completing the investigation and developing a SMART action plan lies with the Directorate with support from the lead investigator. SMART equals; Specific, Measurable, Achievable, Realistic, Timely.

NHSE SI Framework 2015 describes the following minimum requirements for an action plan to include the following:

- ‘Action plans must be formulated by those who have responsibility for implementation, delivery, and financial aspects of any actions (not an investigator who has nothing to do with the service although clearly their recommendations must inform the action plan).
- Every recommendation must have a clearly articulated action that follows logically from the findings of the investigation.
- Actions should be designed and targeted to significantly reduce the risk of recurrence of the incident. It must target the weaknesses in the system which resulted in the lapses/acts/omissions in care and treatment identified as causing or contributing towards the incident.
- A responsible person (job title only) must be identified for implementation of each action point.
- There are clear deadlines for completion of actions.
- There must be a description of the form of evidence that will be available to confirm completion and also to demonstrate the impact implementation has had on reducing the risk of recurrence’.

Guidance on creation of SMART and Strong action plan is found in Appendix D.

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

Quality Improvement/Learning from SI’s

The development of strong actions is guided by the hierarchy of effectiveness and the aim is to develop actions that affect the system rather than attempt to modify the behaviour of individuals. For example, personal reflection and the retraining of individuals is discouraged and more system-based actions are encouraged.

The improvement plan is divided into two section to support this- those actions that are directorate/locally owned and those that are trust wide.

Directorates will oversee the implementation of those locally owned and sign these off through their local governance processes and inform the CPST when signed off.

Those that are trust wide will be overseen by the appropriate governance group and confirmed to the IOG.

Where there is already a Quality Improvement programme in place the action plan will reference the relevant QI project and the report will be used to inform:

1. If the current actions within the project are appropriate in relation to investigation findings

2. The impact (positive/negative) of any actions taken so far

Learning from SI's

The investigation process is designed to identify 'lessons to be learned' from these actions/improvements are developed and implemented. For 'lessons to have been learned' the action will need to be implemented/embedded and assurance received of improvement, this may also include the need for ongoing monitoring of action(s) to ensure there is a thorough evaluation.

Local and cross directorate learning can also be shared by the development of 'Learning Boards' as part of the improvement plan.

Sign off of Final draft Report

When the above process has been completed and there is a final draft of the report each directorate currently has a sign off group with agreed terms of reference (TOR) and attendees. Each Directorate has a different membership of their sign of meeting and their TOR should describe their Governance process and who ultimately, they are delegating the authority to sign off their reports.

This will be weekly or as a minimum fortnightly depending on the volume of reports to be reviewed.

The reports will be shared with group members in a shared area for their review and comment prior to the meeting.

Group members will review the report for robustness/accuracy and to consider the appropriateness of the actions to reduce the risk of recurrence.

Any suggested amendments will be added in tracked change comment for agreement with the report author who will be present at the sign off meeting to discuss and expand on their findings.

The process of 'sign off' of SI's is for assurance that:

- Terms of reference for investigation have been addressed and if not, described as to why.

- The patient and/or family voice have been heard and any concerns raised identified and answered.
- The staff voice have been heard and any concerns raised identified and answered.
- There has been a robust open and transparent investigation that has identified the learning.
- The recommendations are appropriate and aim to reduce the risk of recurrence
- The actions to deliver the recommendations are robust proportionate 'SMART' and timely – see appendix D.

Executive Director Sign off

Following the above process, the report is share with the CPST for final checks that include SIRAN (SIRAN = SIRAN is a quality improvement and accreditation network for mental health organisations' SI processes) **standards** (it is expected that directorates who share reports will ensure that reports also follow this basic set of standards – see appendix E) and for onward review from CPST by email and signed off by the Director of Nursing/Medical Director or their nominated deputy. Suggested changes are also made in tracked changes and agreed with the author/CPST

This report then becomes the 'Final Draft'.

Final Draft

The final draft of the SI report remains in final draft whilst reviewed by the patient/relatives and the ICB/collaboratives – Amendments will be made in discussion with the author either internal/external and through the above sign off/review process if fundamental to the learning.

All the above process is recorded on Ulysses in designated 'investigation, contact/information' along with all emails, report versions/information stored in documents on the same system.

Where there is disagreement with patients/families and staff involved in the incident related to findings and learning (all SI reports either externally or internally investigated)

LPT is committed to working closely with our patients/relatives and staff to ensure that our Serious Incident reports are accurate/robust and fair. This will take place through the Duty of Candour.

The above-described governance process is designed to ensure that there is opportunity to discuss and provide evidence for any changes requested to be agreed with the report author.

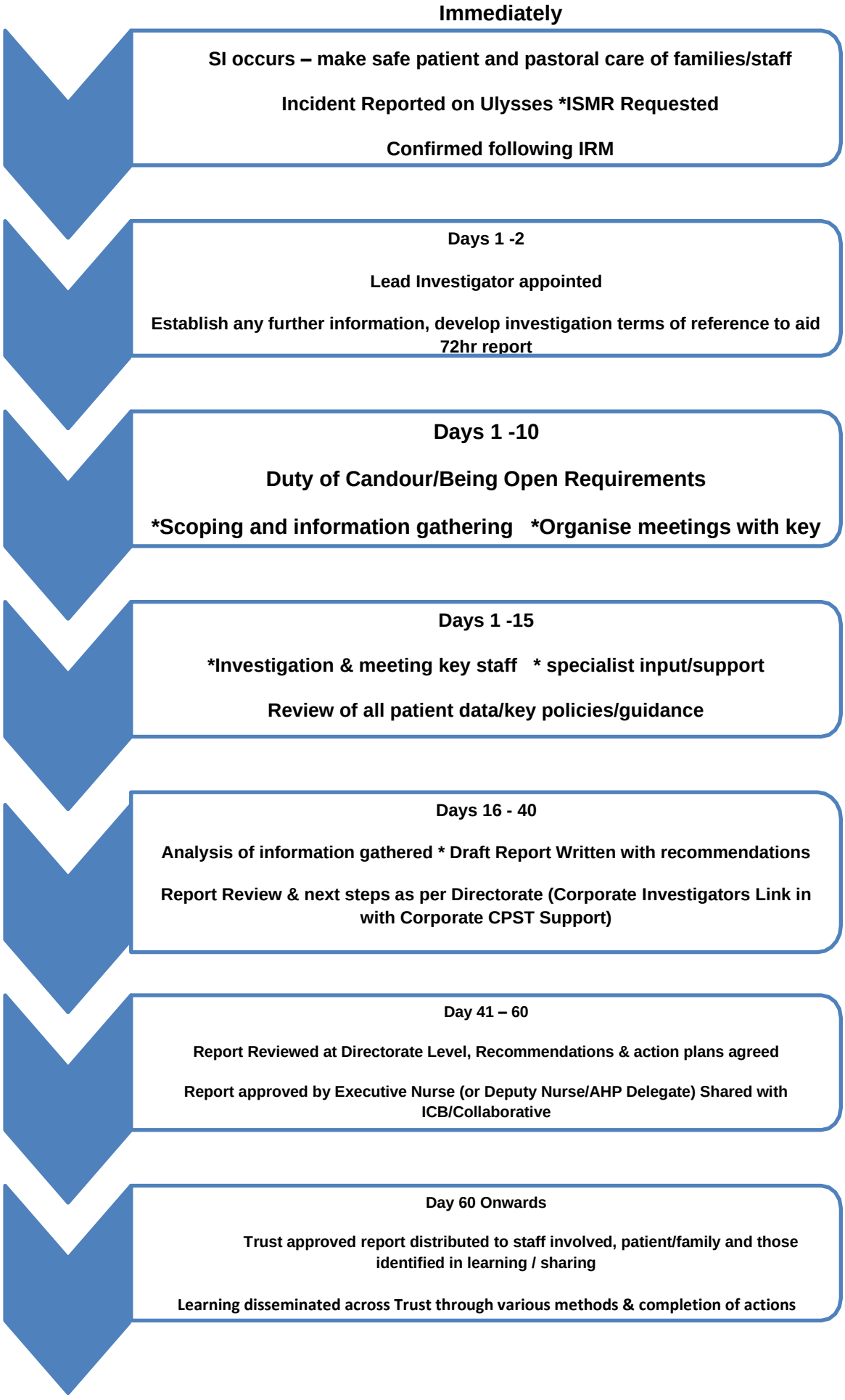
The aim is for this process to ensure all parties are comfortable, where there are differences of opinion that cannot be reconciled the report can describe these (the purpose of the report is for learning and not avoid ability apportioning of blame).

Where this cannot be achieved, and any party remains unhappy the appropriate Director/Director of Nursing and Medical Director should consider the concerns and address if possible.

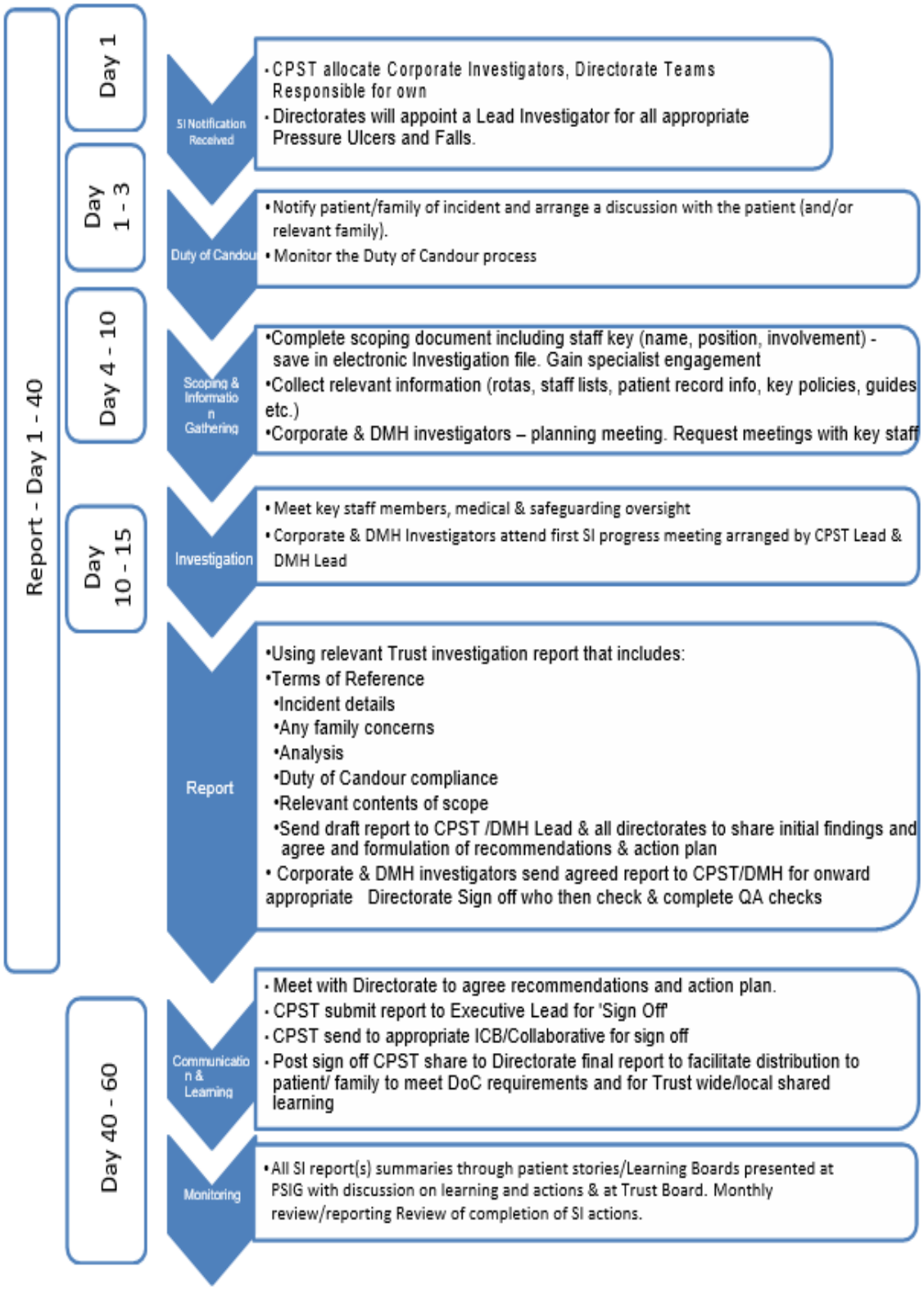
In the rare circumstance where there remains dispute the patient/relatives should have a final duty of Candour letter with an apology and be referred to the Parliamentary Health Services Ombudsman (PHSO) for residual area of dispute.

Staff disputes will be managed on an individual basis and in conjunction with the legal team as they may need to be directed to their own union and or individual legal representative.

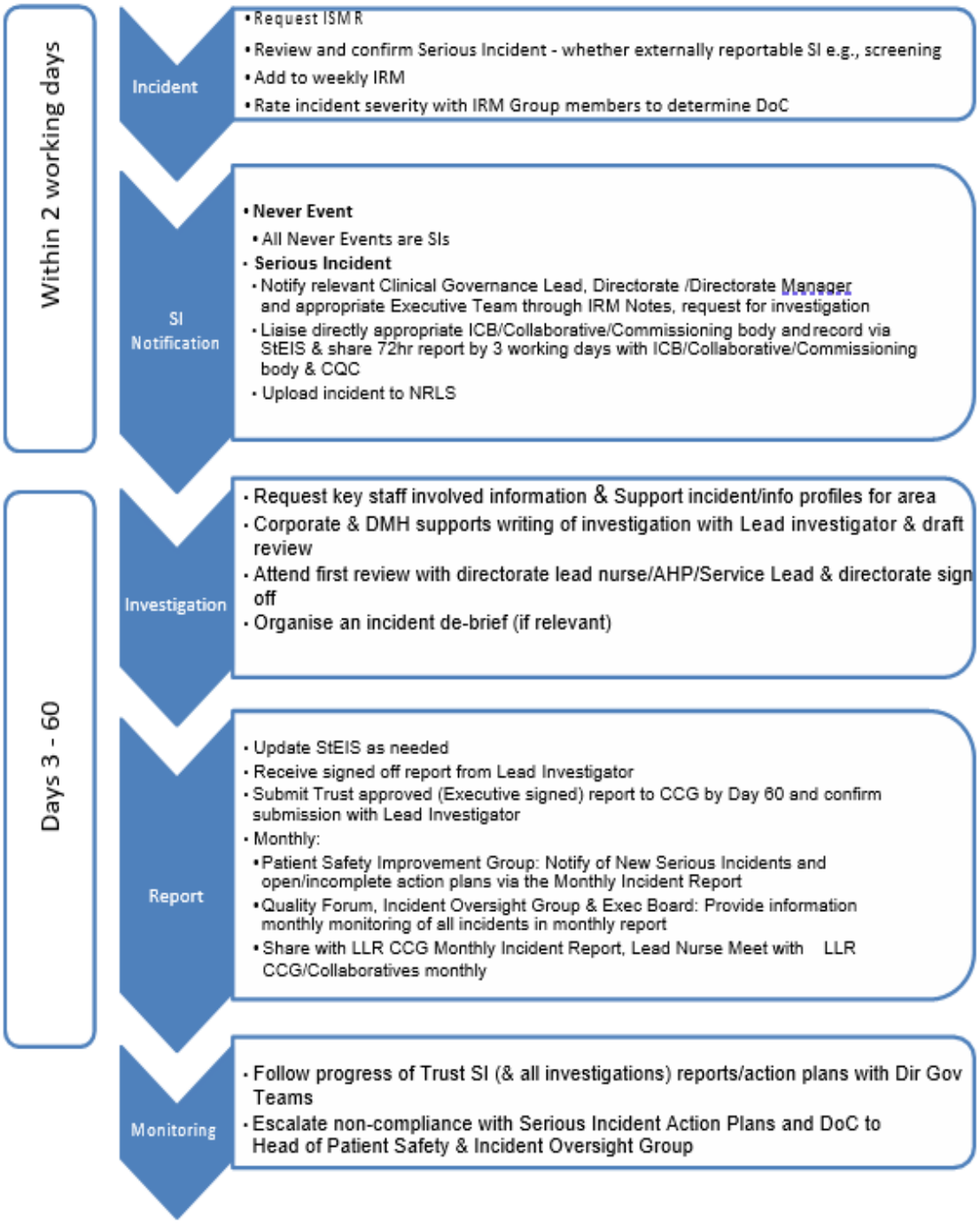
Serious Incident Timeline Overview



Role of Lead Investigator



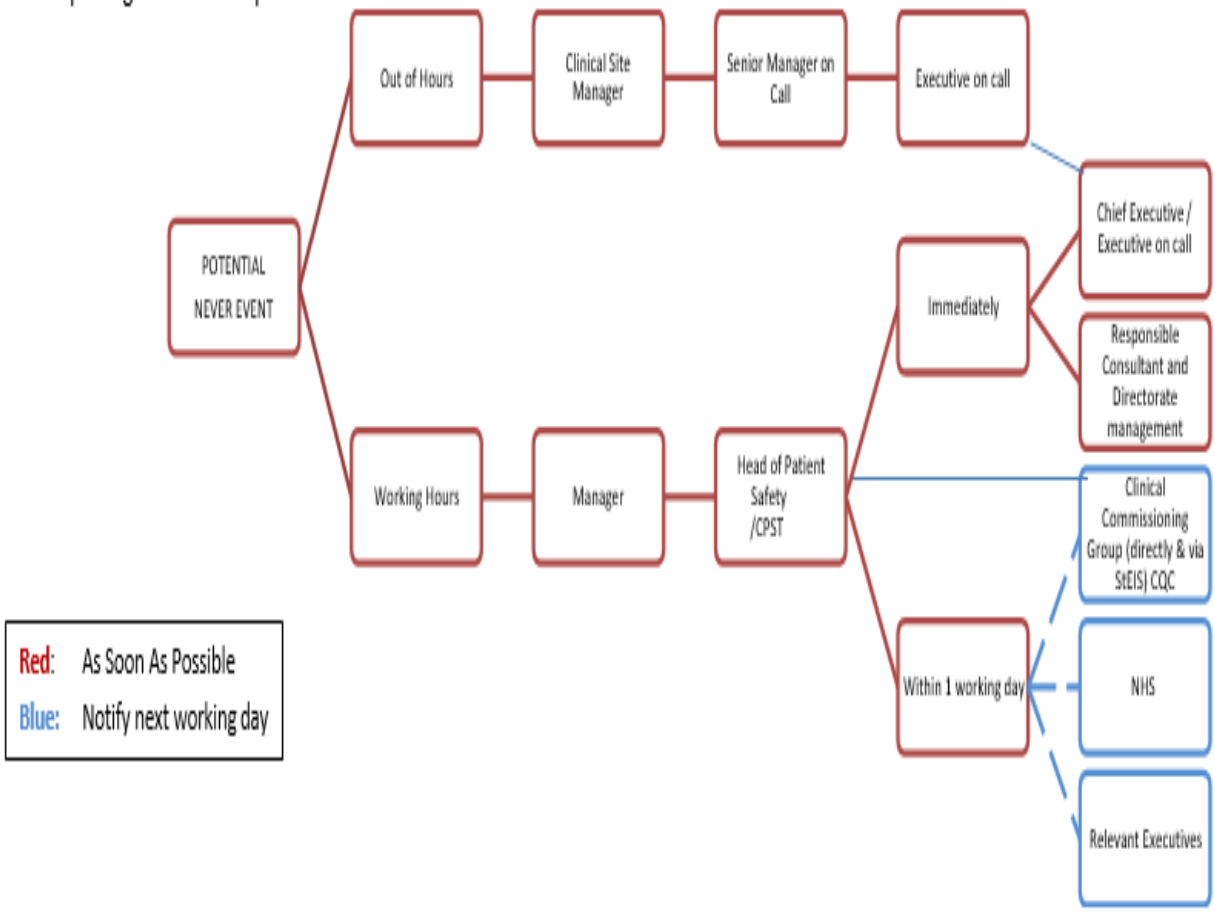
Role of the CPST in SIs



Reporting Never Events

Never Events follow the SI procedure with the following additions

1. Reporting cascade for potential Never Events.



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

Investigation types and time scale according to NHS England (2015): Serious Incident Framework: Supporting learning to prevent recurrence.

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 capacity/ capability of the available individuals and/or number of organisations involved (see Appendix 1 and 3 for further details)	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 processes are being investigated.	6 months from the date the investigation is commissioned

5.0. Duties within the Organisation

5.1 The Trust Board has a legal responsibility for Trust policies and for ensuring that they are carried out effectively.

5.2 Trust Board Sub-committees level 2 have the responsibility for receiving appropriate assurance that processes are in place. Level 3 groups for ratifying policies and protocols.

5.3 Executive Director of Nursing, AHP's and Quality/Medical Director and nominated others will:

- Give approval for the quality assurance on all SI investigation reports prior to submission to external stakeholders and appropriately delegate to others the responsibility of feedback of the SI.
- Ensure that this policy is implemented through robust systems and processes

and that there are effective reporting and monitoring processes in place.
- Ensure that internal and external reporting requirements are met.
- Ensure that all incidents are investigated according to the identified level of harm
- Work closely with the Head of Patient Safety in the quality assurance process of checking SI investigation reports and action plans.
- Review and sign all completed SI investigation reports.
- Ensure that effective analysis and learning systems are in place within their care pathway and that assurance and monitoring takes place.
- Ensure that their care pathway follows 'Being Open' with all those affected by an incident, together with effective support mechanisms for staff.
- Consider incident and aggregated data in the identification of risks and address risks through risk reduction measures and to improve quality of services.
- Ensure that staff attend training to comply with the requirements of this policy according to the training needs analysis shown in the Trust's Statutory and Mandatory Training Policy.
- Adhere to policies of commissioning organisations, taking responsibility for producing reports that meet the required timescale and to report to the Trust Board of Directors on investigation findings and learning.
- Ensure that medical staff are fully aware of this policy and engage in supporting the SI investigation process.
- As Caldicott Guardian, ensure that effective systems are in place to maintain the security of identifiable data.

5.4 Directorate Directors and Heads of Service are responsible and nominated others for:

- Have systems and processes in place to deliver on the required duties of directors as listed above.
- Ensure that all staff within their area are aware of and understand this policy.
- Ensure that all incidents are reported and investigated according to the to this policy, working closely with Directors and the Head of Patient Safety and CPST.
- Ensure that an appropriate number of staff have completed the Patient Safety Incident Investigation training and are adequately supported during the investigation process.
- Allocate staff to complete investigations as requested by the Patient Safety Team.
- The directorate has appropriate governance processes to monitor this

The Head of Patient Safety /Delegated Corporate Patient Safety Team will:

- Monitor the performance management of SIs on a weekly basis working closely with the Directorate governance teams.
- Work with and support care pathway operational groups that consider incidents, providing incident information as required.
- Keep an electronic record using Ulysses that contain all documents relating to the reporting, investigation, learning and communication with external stakeholders and others.

- Quality assures the reporting and approach to grading of incidents and provide feedback reports to managers where there are issues of concern, offering support and re-training.
- Provide support to staff on all aspects of the incident management.
- Produce bi-monthly (and at other requested intervals) Trust Board Patient Safety Incidents (this includes SIs) reports to Directors for analysis.
- Issue notification of SIs to relevant directors and lead staff providing guidance on internal and external deadlines.
- Support and co-ordinate Individual Review Meeting (IRM) all documentation and provide reports as required and keep a centralised store of all information and uploading the IRM note/outcomes for each incident reviewed on Ulysess A record of IRM discussions are retained, outlining the rationale for decisions, immediate learning, (including actions for directorate representatives to take away) for internal and external assurance
- Review Coroner requests (in conjunction with the Legal Team) and provide appropriate information as requested
- Review Care Quality Commission (CQC) requests (in conjunction with the Compliance Team) and provide appropriate information as requested
- Review the completed SI reports and action plans
- Upload completed and agreed action plans to Ulysses
- Support the dissemination of learning lessons across the organisation in partnership with others
- Coordinate and communicate with external stakeholders, i.e., ICB, Collaboratives, NHSE and other NHS providers.

5.5 Managers, Team leaders, Heads of Nursing and Quality, Service Leads, Directorate Clinical Quality Governance Teams are responsible for:

- Ensure that they and the staff they are responsible for are aware, familiar, and compliant with the content of this policy.
- Ensure that the staff they are responsible for have access to training in the form of local induction covering incident reporting on Ulysses and further training as identified.
- Ensure Trust-wide learning systems are in place to ensure learning takes place from SI outcomes.
- Review themes that emerge from Ulysses and SI/Clinical Review action plans and support the CPST in ensuring that learning and awareness is spread within the Trust
- Ensure that staff report all incidents effectively and local investigations are undertaken, where appropriate, and learning identified, implemented, and documented on Ulysses.
- Ensure that Ulysses incidents that are reported within their area are reviewed for accuracy of detail and level of harm within 72 hours, by either the manager or delegates.
- Consider incident data in risk assessments undertaken as part of the Risk Register process.
- Correctly clarify level of harm for incidents and approve them before submission to the risk management database, Ulysses.
- Participate and ensure in any incident investigation.
- Collate factual accounts from staff within 24 hours of reporting any incident

that is serious in nature, where possible, and submitting originals to CPST.
- Support staff involved in and/or affected by an incident.
- Ensure that lessons identified are fed into/triangulated with other data in local forums, team meetings and supervision. Review incident trends on a regular basis utilising Ulysses dashboard and where necessary, develop action plans to reduce likelihood.
- Ensure a regular reporting mechanism exists with line manager, Matron, Team Leaders, or Head of Service.

Proactive Leadership Role of Ward/Departmental Managers outside of an SI and for knowledge and skills following a SI

- Must be familiar with and implement the procedure for reporting SIs.
- Ensure that all staff they line manage understand the incident reporting/review processes and are given appropriate training to support this.
- Identify any potential issues that may impede staff members reporting /investigating incidents taking appropriate action to support staff members.
- Ensure that all staff know how to contact managers within working hours, and on-call managers outside of normal working hours.
- Take the lead in supporting staff as a priority following a SI and, where appropriate, refer to the Occupational Health Department and/or signpost to the Employee Assistance Programme; this includes temporary staff in conjunction with central staffing bank.
- Notify their Heads of Nursing/Therapy/Line Managers at the earliest opportunity following report of a SI.
- Ensure that a debrief meeting is called, appropriate to the nature of the incident in a timely way and that staff are supported to attend in line with the Debriefing Staff Guidance.
- Ensure that staff attend to immediate needs, re-establish a safe care environment and preserve evidence (suspected crime or equipment failure).
- Ensure staff are allocated sufficient time to attend investigation meetings and undertake factual accounts to inform the investigation; this includes temporary staff.
- Pro-actively manage any non-compliance by staff with the investigation process in a supportive and compassionate way

5.6 Responsibility of Staff

- Attend the required mandatory training relevant to this policy as required.
- Read, ensure they understand and act within the spirit of this policy.
- Staff must attend to immediate patient needs, to re-establish a safe care environment and preserve evidence (suspected crime or equipment failure) after a potential SI.
- Report all incidents that they are involved in or witness/discover on Ulysses and with their local manager / nurse / AHP in charge.
- To never communicate directly with the media relating to incidents. All staff should direct enquiries from the media to the Trust Communication Lead
- Ensure that they are familiar with the out of hours procedure for reporting a SI.
- Comply with the requirements of the Culture Of Candour Policy (in relation to

incidents in communicating incident information to those affected as soon as possible.

- Participate and contribute to the implementation of learning from incidents in line with professional, local, and national learning.
- Act on and report in accordance with this policy and the Management of and Reporting of Incidents Policy any incident that is brought to their attention by a patient, visitor, or contractor.

6.0. Training needs

Training on incident reporting is mandatory for all staff and is undertaken locally as part of induction and promotion and overseen by the Directorate Clinical and Quality Governance Teams supported by CPST where required.

In addition, Patient Safety training is provided during the corporate induction and is also delivered to incoming junior doctors as part of their training available on Ulearn as part of the national patient safety programme and delivery of the NHS Patient Safety Strategy.

There is a need for training identified within this policy. In accordance with the classification of training outlined in the Trust Learning and Development Strategy this training has been identified as 'Patient Safety Incident Investigation' which is currently delivered by CPST. There are also external providers such HSIB who provide investigation methodology training.

A record of the event will be recorded on CPST Training Record and will be shared monthly with the directorates.

The governance group responsible for monitoring the training is Incident Oversight Group and local quality and assurance in directorate.

7.0. Monitoring Compliance and Effectiveness

Compliance being monitored	Method of Monitoring	Person Responsible	Frequency	Group/committee receive findings	Group/ committee person responsible for actions
Timeliness for identification and reporting SI's	Audit of files/IRM notes	Head of Patient Safety (HOPS) in conjunction with CPST	Bi-annual	Trust Board, ICB, collaboratives and Incident Oversight Group	HOPS
Compliance with Being Open /Duty of Candour	Audit of files/ investigations Documentary evidence from clinicians	Head of Patient Safety (HOPS) in conjunction with CPST	Bi-annual	Trust Board, ICB, collaboratives and Incident Oversight Group	HOPS
Standard of investigations	Review of queries raised	Head of Patient	quarterly	Head of Patient Safety in	HOPS

	by commissioners	Safety (HOPS) in conjunction with CPST		conjunction with CPST IOG	
Learning assurances and timely completion of actions		Head of Patient Safety (HOPS) in conjunction with CPST	ongoing	Trust Board, ICB, collaboratives and Incident Oversight Group Quality Forum	HOPS& Directorate Heads & Deputy Heads of Nursing/ services leads
Learning Across the Trust		Head of Patient Safety (HOPS) in conjunction with CPST		Trust Board	HOPS & Directorate Heads & Deputy Heads of Nursing / service leads

8.0. Standards/Performance Indicators

TARGET/STANDARDS	KEY PERFORMANCE INDICATOR
Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 Regulation 12 (Safe care and treatment) and 17 (Good governance)	Safe care, good governance. Monitoring of numbers of serious and internal investigations, feedback from patients, families/carers and staff
Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 Regulation 20 (Duty of candour)	Being Open/Statutory Duty of Candour – monthly and bi-monthly reports to executive trust team and quality forum on initial and final duty of candour compliance and against best practice 10 working days for initial duty of candour.
Monitoring against current SI 60 working days NHSE compliance of completion	Monthly and bi-monthly reports to executive trust team and quality forum

9.0. References and Bibliography

The policy was drafted with reference to the following:

NHS England (2015): Serious Incident Framework: Supporting learning to prevent recurrence.
https://www.england.nhs.uk/patient-safety/serious-incident-framework/

Incident Reporting and Management Policy (2022)

A Culture of Candour Policy (Incorporating 'Being Open' and 'Duty of Candour) (2022)

NHS standard contract since 2014/15 (Section 35) – updated 2022/23.
https://www.england.nhs.uk/nhs-standard-contract/

The Never Events (2018)
https://www.england.nhs.uk/patient-safety/never-events-data/

NHS Resolution 'Saying Sorry' (2018)
https://resolution.nhs.uk/resources/saying-sorry/

Care Quality Commission: Regulation 20: Duty of candour
https://www.cqc.org.uk/guidance-providers/all-services/regulation-20-duty-candour

The policy was drafted with review of the following:
Bibliography

NHS England (2018): An independent review of the Independent Investigations for Mental Health Homicides in England (published and unpublished) from 2013 to the present-day Section two (Main report).
https://www.england.nhs.uk/london/wp-content/uploads/sites/8/2019/10/External-Review-Independent-Investigation-report-FINAL.pdf

Article 2 of the European Convention on Human Rights and the investigation of serious incidents in mental health services (2015)
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/474020/Article_2_advice_acc.pdf

https://www.gov.uk/government/publications/echr-article-2-investigations-into-mental-health-incidents

Information Commissioners Office. https://ico.org.uk/

Being fair: Supporting a just and learning culture for staff and patients following incidents in the NHS. NHS Resolution (2019)

Kok J et al (2018) Patient and family engagement in incident investigations:

exploring hospital manager and incident investigators' experiences and challenges.

(2021) National learning report: A thematic analysis of HSIB's first 22 national investigations Independent report by the Healthcare Safety Investigation Branch I2020/01

Insights from a Just Culture in practice focus group: NHSI (undated)

NCISH: 10 standards for investigating serious incidents (undated)

CQC: Learning from serious incidents in NHS acute hospitals A review of the quality of investigation reports. (2016)

Fetherston T, (2015) The importance of critical incident reporting – and how to do it https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4675258/

Review of the Following NHS organisations Trust Policies to inform the development of this policy:

Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust: Serious Incident (SI) Policy: Reporting, Investigating & Learning from Serious Incidents (June 2020)
https://www.dbth.nhs.uk/

Poole Hospital NHS Foundation Trusts Serious Incident Policy (2018)
https://www.poole.nhs.uk/pdf/Serious%20IncidentPolicy.pdf

Nottinghamshire Healthcare NHS Trust: Managing Serious Incidents (SI) and Reporting and Learning from Deaths (2019)
https://www.nottinghamshirehealthcare.nhs.uk/download.cfm?doc=docm93jijm4n9205.pdf&ver=19162

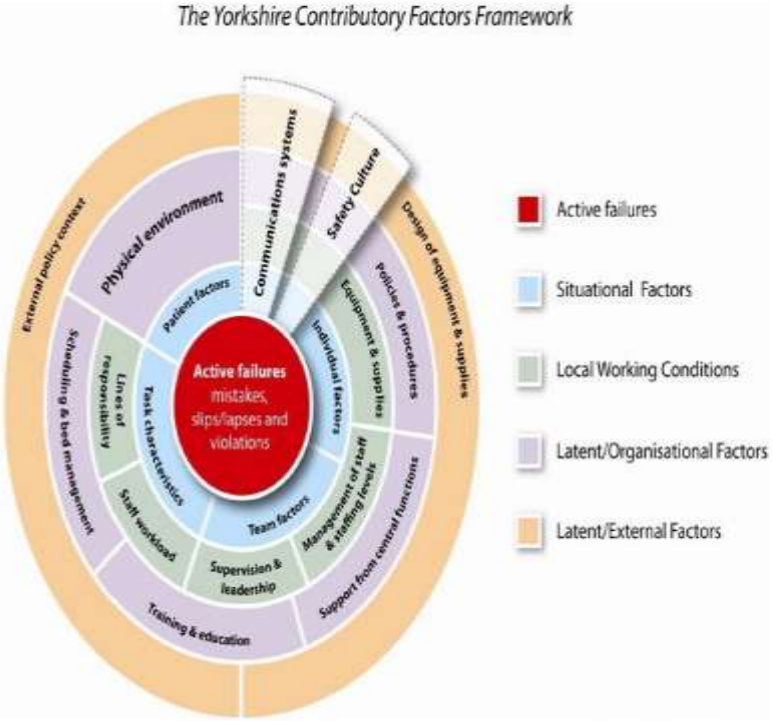
Torbay and South Devon NHS Foundation Trust: Incident Investigation – Standard Operating Procedures (2020).

Sussex Foundation NHS Foundation Trust: Incidents and Serious Incidents Policy and Procedure (2022)

Northamptonshire Healthcare NHS Foundation Trust: The Reporting and Management of Serious Incidents Policy (2020)

Appendix A - YORKSHIRE CONTRIBUTORY FACTORS FRAMEWORK

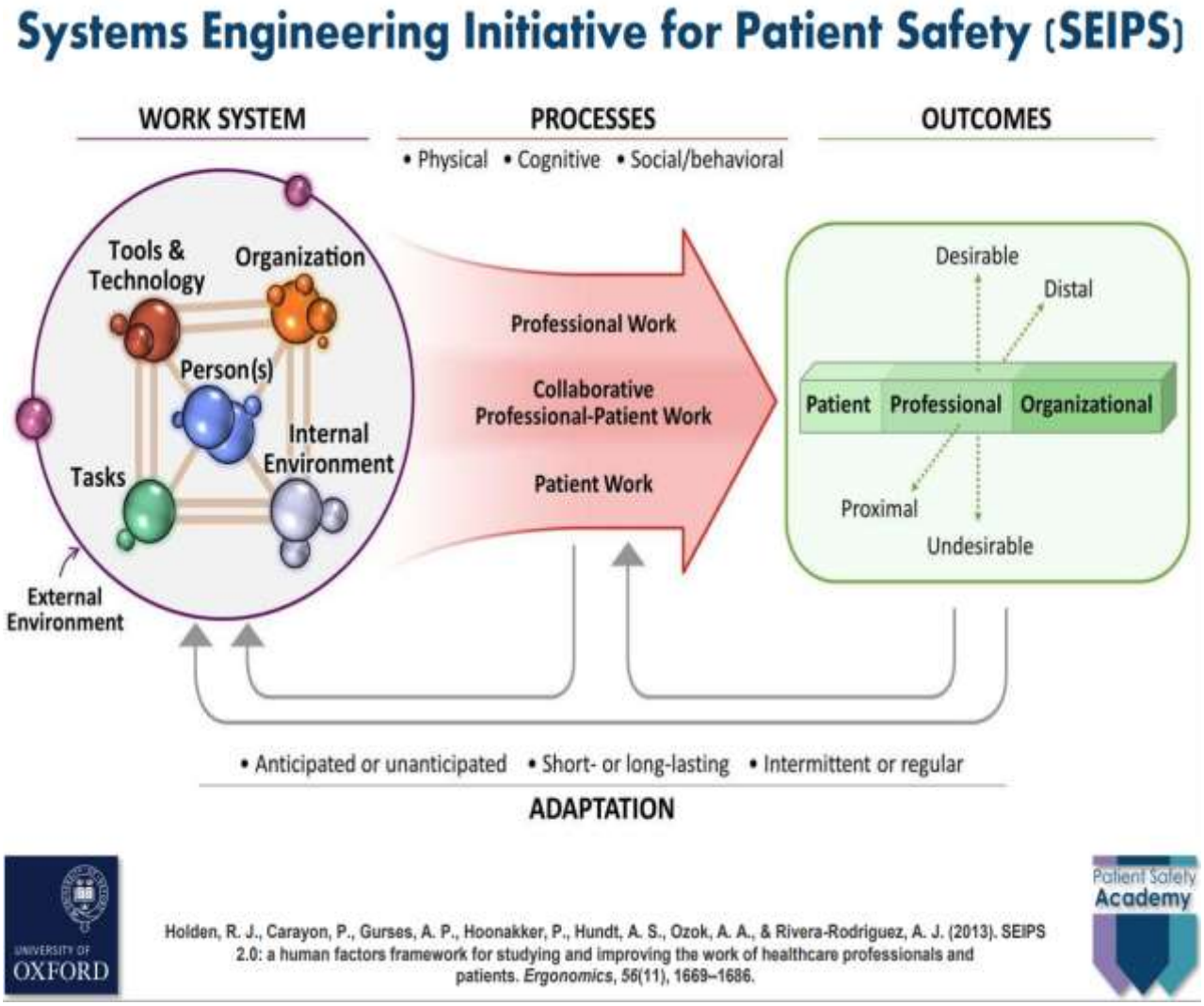
Were there any problems from other departments?	□ Yes □ Maybe □ No	**Support from other departments** This includes support from IT, HR, porters, estates or clinical services such as radiology, phlebotomy, pharmacy, biochemistry, blood bank, microbiology, physiotherapy, medical or surgical sub-specialities,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



YQSR
Yorkshire Quality and Safety Research Group

Copyright Bradford Teaching Hospitals NHS Foundation Trust

Appendix B - Systems Engineering Initiative for Patient Safety (SEIPS)



Appendix C – Just Culture Guide

NHS Improvement

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:

Appendix D = SMART Actions – reference Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust

NHS
Doncaster and Bassetlaw Teaching Hospitals
NHS Foundation Trust

Guidance for developing SMART and Strong Actions

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

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

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

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

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

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

Words to avoid in action planning:	Words that strengthen actions:
Consider, Discuss, Raise, Remind, Reflect, Reiterate and Tell.	Complete, Develop, Evaluate, Introduce, Monitor and Trial.

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

Appendix E — Pre-Submission Quality Assurance Checklist

LPT Serious Incident Report – Pre-Submission Quality Assurance Checklist

This document serves as a Checklist for Investigation Teams (IvT), Panels, Directorate Teams and the Corporate Patient Safety Team (CPST) to use during a Serious Incident (SI) Investigation. This Checklist is intended to be used to ensure SI investigations/reviews are of the highest quality. Please use this Checklist from the outset and complete the boxes on the right-hand side as you progress through your investigation/review. This will help you to check your report prior to submission.

The checklist is based on the original NPSA Quality Assurance Tool and what was identified as 'important' to patients/families during consultation for the NHS Patient Safety Strategy 2019 and best practice for mental health serious incident reviews as described by the Royal College of Psychiatrists 'Standards for Serious Incident Reviews' 2019.

Please ensure you use the correct SI report template (sent out by Corporate Patient Safety Team) as this will help ensure aspects of this checklist are achieved.

This Checklist is set out in three Sections.

- Section 1 includes key information required.
- Section 2 can be used to inform/review the quality of the report during the investigation/review.
- Section 3 is designed to ensure that you have met what Patients and Families think is important and that they have been given an opportunity to both give and receive feedback on the report.

NB: There is a guide which accompanies this checklist this includes useful information regarding formatting, examples of Recovery Language and information on Just Culture.

SECTION 1

Key Information	
StEIS Number:	Click here to enter text.
Ulysses Incident /EIRF Number:	Click here to enter text.
Concise or Comprehensive	Click here to enter text.
Date of final Submission	Click here to enter a date.
Are you using the **Template sent out by CPST?**	
General Guidance/Checks	
Formatting for SI Reports	

Hospital Logo on front page?	Click here to enter text.
Front Page includes: • 'Confidential' watermark • StEIS Number • Ulysses Incident /EIRF Number • Title of Report • Names & Titles/professional role of IvT/Panel members (RCP) • Date of Final Report • Date of the Incident • Version Number	Click here to enter text.
Footer throughout includes: • 'Confidential' mark • StEIS Number • Ulysses Incident /EIRF Number • Version Number • Page Numbers (X of X) (bottom right)	Click here to enter text.
Arial 12 font for main text (14 for titles), spacing 1.15, normal margins.	Click here to enter text.
All dates are written in correct format i.e. 01/05/2020 or 1st May 2020 and this is consistent throughout the report.	Click here to enter text.
Readability	
Glossary of terms included at beginning or end of the report. (RCP)	Click here to enter text.
References clearly cited, ideally with Vancouver or Harvard system?	Click here to enter text.
Language used; does it make sense to patients/family? **(RCP)**	Click here to enter text.
Fully proof read with spelling and grammar checked in English (not American spelling i.e. 'organization' when it should be 'organisation'	Click here to enter text.
Abbreviated terms written in full the first time they are used?	Click here to enter text.
All drugs mentioned start with a 'capital letter' i.e. Paracetamol	Click here to enter text.
All professionals in the report are addressed with capital letter i.e. 'Police' not 'police'	Click here to enter text.
Sensitivity, kindness, and Compassion	
Has the patient/family been involved in the report and a description for Duty of Candour described? (RCP)	Click here to enter text.
Is the language sensitive (ask yourself; would I want to receive this report)?	Click here to enter text.

Is the document fully anonymised with key used where staff are anonymised?	Click here to enter text.
Is the patient addressed by their agreed name/initial(s) and is this consistent throughout the report?	Click here to enter text.
Recovery based language is used for patients under care of mental health service.	Click here to enter text.
Accuracy	
Is the report consistent throughout?	Click here to enter text.
Is the document factually accurate based on identifiable evidence?	Click here to enter text.
The patient/and or family were invited to check for factual accuracy prior to publication of the report? (RCP)	
Has the document had factual accuracy checks with all the staff involved? (RCP)	Click here to enter text.
If a staff member has been criticised, has the staff member had opportunity to review and reply? (RCP)	Click here to enter text.
If a Speciality/Directorate has been criticised, has the Head of Service/ Directorate Team had an opportunity to review and reply? (RCP)	Click here to enter text.
Have significant disagreements in factual accuracy been identified in the report?	Click here to enter text.
Structure, content, checking accuracy	
Executive Summary	
An Executive Summary is present and includes summary of the events, key findings, conclusion and recommendations?	Click here to enter text.
Is the Executive Summary as succinct and focussed as possible?	Click here to enter text.
Does the Executive Summary introduce any new information?	Click here to enter text.
Background and Context	
Does the report provide enough background around the patient and staff involved?	Click here to enter text.
Is the context described to allow reader understanding of the events and factors that contributed.	Click here to enter text.
Are relevant policies and guidance described and referenced indicating the expectations of staff in similar situations?	Click here to enter text.

Are relevant risk assessments included with consideration of actions already in place and their effectiveness?	Click here to enter text.
The report states whether there are, or have been other reviews related to this Incident?	Click here to enter text.
Investigation Methodology and Chronology	
Are staff who attended roundtables/interviews anonymously identified with their role in the incident / investigation?	Click here to enter text.
If unable to access certain staff/records for the investigation, is this acknowledged? (RCP	Click here to enter text.
Have the IvT/panel considered all relevant information in the investigation?	Click here to enter text.
Is a clear timeline of events presented?	Click here to enter text.
Is the outcome and impact on the patient / family described?	Click here to enter text.
Are the early actions taken after the incident, particularly to prevent future events, described?	Click here to enter text.
Being Open / Duty of Candour/Support for staff	
Does the report describe openness and transparency with the patient / family?	Click here to enter text.
Any delays in the review process – were these explained to the patient/family? If no why not? **(RCP)**	Click here to enter text.
Does the report describe how staff have been supported and if there are any professional practice concerns raised during investigation how these are being managed; have these been included, if not why? Please consider this **(RCP)**	Click here to enter text.
If staff went the extra mile – over and beyond expected has this been acknowledged in t final report? (good record keeping is not going the extra mile)	Click here to enter text.
Analysis	
Are there clear statements of <u>WHAT</u> went wrong that impacted on the outcome (e.g. what did happen that shouldn't have and what did not happen that should have)? These are key events.	Click here to enter text.

Is there a clear and structured exploration of the factors that contributed to the key events? These are contributory factors.	Click here to enter text.
If concerns / complaints have been raised by the family; are these included in the investigation or being managed by Complaints Team? Is the process by which these being addressed / managed clear in the report? **(RCP/CQC/AVMA)**	Click here to enter text.
Any significant incidental findings outside the Terms of reference are noted and acted upon? (RCP)	Click here to enter text.
Conclusions	
Is a clear, succinct and sensitive conclusion written based on the analysis?	Click here to enter text.
Does the conclusion include some consideration of preventability? This may not be possible to ascertain, but should be commented on (e.g., it is not possible to draw conclusions on preventability).	Click here to enter text.
Does the conclusion add any new information? If yes, this should be included In the main body of text.	Click here to enter text.
Are the lessons for the organisation clear and there is evidence of how they will be shared (may be in recommendations)**? (RCP)**	Click here to enter text.
Recommendations and Action Plan	
Are factors that contributed to the incident happening linked to recommendations? If a factor is identified as a risk, but did not contribute to the incident, it should be acknowledged and used to inform other actions within a Directorate. **(RCP)**	Click here to enter text.
Are recommendations proportionate and as strong as possible? They should also identify recommendations to factors beyond the humans involved?	Click here to enter text.
Are core recommendations around **1. Sharing the report with the patient (unless patient is deceased) / family,** **2. An apology,**	Click here to enter text.

3. Sharing with staff included?	
Recommendations refer to existing organisation's action plans and quality priorities as appropriate? (RCP)	Click here to enter text.
Improvement/Action plan included? With name of person accountable. Delegated names, timescales and means to demonstrate action/completion and monitorin method **(RCP)**	Click here to enter text.
Improvement/Action Plan is achievable / implementable? (RCP/NHSI)	Click here to enter text.
Finally……..	
Does the report address the initial Terms of Reference? If 'no' needs addressing before you submit.	Click here to enter text.
Are there any unanswered questions? If 'yes', then answer them; this needs addressing before you submit your review.	Click here to enter text.
Patient and/or family have been invited to check the final draft report for **factual accuracy?** If 'no' needs completing before you submit**.**	Click here to enter text.
Staff and professional stakeholders have been invited to check the final draft report for factual accuracy. If 'no' needs completing before you submit**.**	Click here to enter text.
Are you proud to have been involved in writing this report?	Click here to enter text.
Will this report help the patient /family in understanding what happened and **provide evidence that LPT is learning?**	Click here to enter text.
Would you be happy to stand up in a Coroner's Inquest (if required) to **present this report?** Report authors are occasionally asked to present their findings at Inquest and discuss any concerns / factual challenges.	Click here to enter text.
Who is the named executive/senior member of LPT with responsibility for sending the apology letter?	Click here to enter text.

SECTION 2 –

This serves as a Checklist for the Investigation Team, Directorate Teams and the Corporate Patient Safety Team to review and ensure SI investigations/reviews are of the highest quality.
If you answer No rather than N/A to any question please discuss with CPST to understand if we need to do anything differently.

Key Information	
Will this report be required by coroner?	Click here to enter text.
Are IvT members aware of the final submission date?	

Initial Care for the Patient/Family and Duty of Candour Compliance	
Contact has been made with the patient/family within 3 working days of the incident b identified as SI to provide support at outset of initial review– describe date and contact whom **(RCP /CQC)**	Click here to enter a date.
'LPT Family Liaison person' allocated by Corporate Patient Safety Team for all Panel Reviews/Coroners?	Click here to enter text.
Formal Duty of Candour has been undertaken and local contact person identified?	Click here to enter text.
Patient/Family has been given the opportunity and invited to contribute to report? (RCP)	Click here to enter text.
Patient/family is aware of the agreed timescales for completion of investigation? (RCP)	Click here to enter text.
Patient/family has agreed how they would like to be referred to in the report?	Click here to enter text.
Patient/family has been informed who will be undertaking the review?	Click here to enter text.

Terms of Reference	
Terms of Reference (TOR) are clear, free from jargon, succinct and in plain English?	Click here to enter text.
Terms of Reference have been agreed by senior Directorate Leadership Team? (RCP)	Click here to enter text.
Terms of Reference are specific to the incident review with clear timescale? (RCP)	Click here to enter text.
Terms of References are available for all IvT members and 'stakeholders'? (RCP)	Click here to enter text.
Patient/Family views have been considered when formulating scope of review/ Terms of Reference? (RCP)	Click here to enter text.

Investigation Team Members	
Investigation Team members:	Click here to enter text.

Were there should be a minimum of 2 people per review? **Was at least one person independent from the treating team? (RCP)** **Was the review led by someone who has relevant experience, expertise or training in serious incident reviews?** **Best practice is that at least one reviewer has service specific expertise relevant to the review or, if not was there an agreed named specialist advisor? (RCP)** **Where medication has been identified to contribute to the incident, a member of the pharmacy team must be consulted for guidance and accuracy related to medicines via th Head of Pharmacy?**	
Staff and professional 'stakeholders'	
Staff and professional stakeholders have been identified by IvT members?	Click here to enter text.
Staff and professional stakeholders involved in the care have been informed who is undertaking the review at the outset? (RCP)	Click here to enter text.
Staff and professional stakeholders involved in the review have been informed of the timescales; if not why? (RCP)	Click here to enter text.
Staff and professional stakeholders involved in the review have been informed of the TOR? (RCP)	
Staff and professional stakeholders have been 'formally' contacted involved in the care at the outset of the review process? (RCP)	Click here to enter text.
Staff and professional stakeholders invited to contribute to the review either as individuals or as part of roundtable discussion? (RCP)	Click here to enter text.
Factual accounts actively sort from Staff and professional stakeholders' pre meeting? (RCP)	Click here to enter text.
Staff and professional stakeholders were made aware of how to access support during review? (RCP)	Click here to enter text.
Planning and Investigation Team members support	
Have IvT members put aside dedicated time to undertake the investigation?	Click here to enter text.
Have the IvT sought any possible administration support?	Click here to enter text.

IvT members should put aside dedicated time to check in on progress and review progress?	Click here to enter text.
IvT are confident that they can access the specialist advice in a timely manner if needed?	Click here to enter text.
Agreed timescales are clear and IvT understand the need for adherence to them and need for early escalation if delays encountered? (RCP)	Click here to enter text.
Contents list on page 2 with correct page numbers?	Click here to enter text.
Glossary of terms included at beginning or end of the report. (RCP)	Click here to enter text.

This final 'process' checklist for the IvT, Panels, Directorate Teams and the Corporate Patient Safety Team allows you to review that you met what patients/families identified as 'important' during the consultation of the NHS Patient Safety Strategy 2019 and best practice for mental health serious incident reviews as described by the Royal College of Psychiatrists 'Standards for Serious Incident Reviews' 2019.

NB: This should be seen as part of LPT continuous improvement and 'Stepping Up to Great' not as a criticism.

Key Information	
Were there any delays during investigation/review?	Click here to enter text.
Did the panel have difficulties accessing records/information?	Click here to enter text.
Did the panel have difficulties accessing specialist support if required?	Click here to enter text.
Was learning was recognised in the review process; did staff/patient/family offer solutions/suggestions?	**Click here to enter text.**
Patients/Families/Professional Stakeholders	
Have you sought feedback regarding to how staff felt and the panels approach to their involvement?	
Staff/professional stakeholders were able to review their contribution to the review by either being informed of where a final copy of the report is stored or offered a copy? (RCP)	
Contact has been made with the patient/family about the outcome of the review and they have been invited to comment on the findings of the review. (RCP/CQC)	**Click here to enter text.**

Contact has been made with the staff/professional stakeholders about the outcome of review and invited to comment on the findings of the review? (RCP)	Click here to enter text.
Have there been any concerns raised about how the review was conducted by the IvT/panel?	Click here to enter text.
IvT / Panel Members	
Do IvT/panel members consider they have been supported/ known where they could get support during the investigation process by the Corporate patient Safety Team?	Click here to enter text.
Do IvT/panel members consider they have been supported/ known where they could get support during the investigation process by the Reviews Directorate Governance Team?	Click here to enter text.

If at any time the IvT or Panel need advice, the investigation is off track or ideas need to be discussed; contact the relevant Directorate Governance Team or Corporate Patient Safety Team at lpt.patientsafety@nhs.net

Appendix F

Training Requirements

Training Needs Analysis

Training topic:	Patient Safety Incident Investigation Training
Type of training: (see study leave policy)	☐ Mandatory (must be on mandatory training register) x☐ Role specific x☐ Personal development
Directorate(s) to which the training is applicable:	☐ x Mental Health ☐ x Community Health Services ☐ x Enabling Services ☐ x Families Young People Children & Learning Disability and Autism Services ☐ Hosted Services
Staff groups who require the training:	*Please specify…all who intend to undertake or be nominated to undertake patient safety incident investigations*
Regularity of Update requirement:	Ad hoc
Who is responsible for delivery of this training?	CPST
Have resources been identified?	Ongoing
Has a training plan been agreed?	Yes
Where will completion of this training be recorded?	x☐ ULearn x☐ Other (please specify) CPST Training Record
How is this training going to be monitored?	Through monthly feedback to directorates

Appendix G

The NHS Constitution

Complete the Check List in order to provide evidence that you have considered the principles of the NHS Constitution. For further details please refer to the Development of Procedural Documents Policy

The NHS will provide a universal service for all based on clinical need, not ability to pay. The NHS will provide a comprehensive range of services

Shape its services around the needs and preferences of individual patients, their families and their carers	☐x
Respond to different needs of different sectors of the population	☐x
Work continuously to improve quality services and to minimise errors	☐x
Support and value its staff	☐x
Work together with others to ensure a seamless service for patients	☐x
Help keep people healthy and work to reduce health inequalities	☐x
Respect the confidentiality of individual patients and provide open access to information about services, treatment and performance	☐x

Appendix H

Stakeholders and Consultation

Key individuals involved in developing the document

Name	Designation
Sue Arnold	Lead Nurse – Interim Corporate Investigator Oversight
Tracy Ward	Head of Patient Safety
Michelle Churchard – Smith	Deputy Director of Nursing

Circulated to the following individuals for comment

Name	Designation
Incident Oversight Group	Trust core group members
Penny Murphy	Corporate Patient Safety Incident Investigators (feedback received)
Gavin Simpson	As above (feedback received)
Rachael Tolley	As above
Genine Thompson	As above
Zoe La-Rosa	As above
Kate Dixon	As above
Helen Van-Ristell	As above
Sharon Hames	As above
Emma Gartland	As above
Jane Martin	Interim Head of Nursing & Quality Directorate of mental Health (feedback received)
James Mullins	Group Director of Safety (feedback received)
Sarah Latham	Head of Nursing & Quality CHS (feedback received)
Heather Darlow	Trust Lead for Clinical & Quality Governance (feedback received)
Trust Policy Expert Group	

Appendix I

Due Regard Screening Template

Section 1	
Name of activity/proposal	Serious Incidents (SI) Policy Reporting, Investigating and Learning from Serious Incidents - Using principles of 'Serious Incident Framework:Supporting learning to prevent recurrence' (2015)
Date Screening commenced	November 2022
Directorate / Service carrying out the assessment	CPST _ Enabling Directorate
Name and role of person undertaking this Due Regard (Equality Analysis)	Sue Arnold
Give an overview of the aims, objectives and purpose of the proposal:	
AIMS: to provide direction, explanation and expectation of staff involved in the process of serious investigations	
OBJECTIVES:	

Section 2	
Protected Characteristic	**If the proposal/s have a positive or negative impact please give brief details – NOT Applicable**
Age	
Disability	
Gender reassignment	
Marriage & Civil Partnership	
Pregnancy & Maternity	
Race	
Religion and Belief	
Sex	
Sexual Orientation	
Other equality groups?	

Section 3			
Does this activity propose major changes in terms of scale or significance for LPT? For example, is there a clear indication that, although the proposal is minor it is likely to have a major affect for people from an equality group/s? Please <u>tick</u> appropriate box below.			
Yes		No	
High risk: Complete a full EIA starting click here to proceed to Part B		Low risk: Go to Section 4.	

Section 4			
If this proposal is low risk please give evidence or justification for how you reached this decision:			
Signed by reviewer/assessor		**Date**	
Sign off that this proposal is low risk and does not require a full Equality Analysis			

Appendix J

Head of Service Signed		**Date**	

DATA PRIVACY IMPACT ASSESSMENT SCREENING

Data Privacy impact assessment (DPIAs) are a tool which can help organisations identify the most effective way to comply with their data protection obligations and meet Individual's expectations of privacy. **The following screening questions will help the Trust determine if there are any privacy issues associated with the implementation of the Policy. Answering 'yes' to any of these questions is an indication that a DPIA may be a useful exercise. An explanation for the answers will assist with the determination as to whether a full DPIA is required which will require senior management support, at this stage the Head of Data Privacy must be involved.**		
Name of Document:	Serious Incidents (SI) Policy Reporting, Investigating and Learning from Serious Incidents Using principles of 'Serious Incident Framework Supporting learning to prevent recurrence' (2015)	
Completed by:	**Sue Arnold**	
Job title	Lead Nurse/ CPST	Date: 30/11/2022

Screening Questions	**Yes / No**	**Explanatory Note**
1. Will the process described in the document involve the collection of new information about individuals? This is information in excess of what is required to carry out the process described within the document.	No	
2. Will the process described in the document compel individuals to provide information about them? This is information in excess of what is required to carry out the process described within the document.	Yes	When completing a ISMR and SI report name will and role will be required to be recorded and contact details
3. Will information about individuals be disclosed to organisations or people who have not previously had routine access to the information as part of the process described in this document?	Yes	Families, other staff, other organisations (we have information sharing agreements with organisations)
4. Are you using information about individuals for a purpose it is not currently used for, or in a way it is not currently used?	No	
5. Does the process outlined in this document involve the use of new technology which might be perceived as being privacy intrusive? For example, the use of biometrics.	Yes	Use of email for communicating with service users and staff as a primary means of contact
6. Will the process outlined in this document result in decisions being made or action taken against individuals in ways which can have a significant impact on them?	No	
7. As part of the process outlined in this document, is the information about individuals of a kind particularly likely to raise privacy concerns or expectations? For examples, health records, criminal records or other information that people would consider to be particularly private.	Possible	Details of patients medical and social records will be detailed as part of report writing/information collecting. They will be made aware of this and have the option to give permission to use their name; only by agreement
8. Will the process require you to contact individuals in ways which they may find intrusive?	No	

If the answer to any of these questions is 'Yes' please contact the Data Privacy Team via Lpt-dataprivacy@leicspart.secure.nhs.uk In this case, ratification of a procedural document will not take place until review by the Head of Data Privacy.	
Data Privacy approval name:	**Sue Arnold**
Date of approval	**September 2023**

Acknowledgement: This is based on the work of Princess Alexandra Hospital NHS Trust

Data Privacy Impact Screening Guidance Notes

The following guidance notes should provide an explanation of the context for the screening questions and therefore assist you in determining your responses.

Question 1: Some policies will support underpinning processes and procedures. This question asks the policy author to consider whether through the implementation of the policy/procedure, will introduce the need to collect information that would not have previously been collected.

Question 2: This question asks the policy author if as part of the implementation of the policy/procedure**,** the process involves service users/staff providing information about them, over and above what we would normally collect

Question 3: This question asks the policy author if the process or procedure underpinning the policy includes the need to share information with other organisations or groups of staff, who would not previously have received or had access to this information.

Question 4: This question asks the author to consider whether the underpinning processes and procedures involve using information that is collected and used, in ways that changes the purpose for the collection e.g. not for direct care purposes, but for research or planning

Question 5: This question asks the author to consider whether the underpinning processes or procedures involve the use of technology to either collect or use the information. This does not need to be a new technology, but whether a particular technology is being used to process the information e.g. use of email for communicating with service users as a primary means of contact

Question 6: This question asks the author to consider whether any underpinning processes or procedures outlined in the document support a decision-making process that may lead to certain actions being taken in relation to the service user/staff member, which may have a significant privacy impact on them

Question 7: This question asks the author to consider whether any of the underpinning processes set out how information about service users/staff members may intrude on their privacy rights e.g. does the process involve the using specific types of special category data (previously known as sensitive personal data)

Question 8: This question asks the author to consider whether any part of the underpinning process(es) involves the need to contact service users/staff in ways that they may find intrusive e.g. using an application based communication such as WhatsApp

If you have any further questions about how to answer any specific questions on the screening tool, please contact the Data Privacy Team via
LPT-DataPrivacy@leicspart.secure.nhs.uk

Appendix K

CQC Fundamental Standards – (with effect) 1st April 2015

The Fundamental Standards of quality and safety came into effect from 1st April 2015 and replace the 16 Essential Standards (2010).

There are 13 **Fundamental Standards** associated with the quality and safety of care which every staff member must comply with. The Care Quality Commission register, inspect and rate all NHS providers of care to ensure they are demonstrating compliance with the expected **legal minimum standards when delivering patient care.**

Here is a summary of the **standards** that everybody has a right to expect when they receive care, standards which our care must never fail to achieve.

Regulation 9 **Person-centred care**
The care and treatment of service users must be appropriate, meet their needs and reflect their preferences.

Regulation 10 **Dignity and respect**
Service users must be treated with dignity and respect.

Regulation 11 **Need for consent**
Care and treatment of service users must only be provided with the consent of the relevant person.

Regulation 12 **Safe care and treatment**
Care and treatment must be provided in a safe way for service users.

Regulation 13 **Safeguarding service users from abuse and improper treatment**
Service users must be protected from abuse and improper treatment.

Regulation 14 **Meeting nutritional and hydration needs**
The nutritional and hydration needs of service users must be met.

Regulation 15 **Premises and equipment**
All premises and equipment used by the service provider must be: clean, secure, suitable for the purpose, for which they are being use, properly used, maintained and appropriately located for the purpose for which they are being used.

Regulation 16 **Receiving and acting on complaints**
Any complaint received must be investigated and necessary and proportionate action must be taken in response to any failure identified by the complaint or investigation.

Regulation 17 **Good governance**
Systems or processes must be established and operated effectively to ensure compliance with these regulations.

Regulation 18 **Staffing**
Sufficient numbers of suitably qualified, skilled and experienced persons must be employed.

Regulation 19 **Fit and proper persons employed**
Persons employed must be of good character, have the qualifications, competence, skills and experience.

Regulation 20 **Duty of Candour**
Providers are open and transparent with people who use services and other 'relevant persons' in relation to care and treatment.

Regulation 20A **Requirement to display performance assessments**
When providers have received a CQC inspection for their service, ratings must be displayed legibly at each location delivering a clinical service and on the Trust website.

Every member of staff has a duty to ensure they are demonstrating compliance with the Fundamental Standards, in their day to day practice. If you have any concerns about your ability to demonstrate compliance with these standards, please discuss this with your line manager in the first instance, your Governance Lead, or the Regulation and Assurance team –contact via email @ Compliance@leicspart.nhs.uk

Appendix L

Si Process Flowchart

Serious Incident
Process Map V2 13.03