KH-CP-012 Incident Reporting and Investigation Policy

Document Information	Corporate Policy		
Title	Incident Reporting and Investigation Policy		
Document Ref	KH-CP-012		
Version	V1.1		
Version History	Version Number	Date of Update	Description
	1.0	Feb 2019	
	1.0	Feb 2020	
	1.1	May 2021	L Brearley
	1.2	Feb 2023	J Markendale
	1.2	May 2024	
Document Owner/Contact	Amanda Collins		
Email	Amanda.Collins@nhs.net		
Author(s)	Suzanne Briggs - Lead Sonographer Ultrasound		
Contributors			
Review	This document will be reviewed annually, or earlier if there are changes in legislation		
Date Approved	February 2019		
Approved By	Dr Raj Kumar Managing Director		
Modifications			
Review Date	May 2025		

KH-CP-012 Incident Reporting and Investigation Policy

Contents

Appendices

KH-CP-012 Incident Reporting and Investigation Policy

1. Introduction and purpose

This policy describes the processes within Kleyn Healthcare for the reporting, management and investigation of incidents including near misses and serious untoward incident (SUI's).It follows the latest guidance from the various authoritative bodies, reference Appendix 10. Including the recently dis-established National Patient Safety Agency The investigations of SUIs will follow the National Patient Safety Agency's Incident Decision Tree (IDT) and Root Cause Analysis (RCA) technique. We also aim to use the Institute for Healthcare Improvement's (IHI Boston) SBAR technique and overall we will focus on establishing the root cause of the incident to understand what happened and how and why it happened.

1.1 This policy is based on the principle that Kleyn Healthcare is a learning organisation. As a learning organisation we would always try to understand the factors that have led to an incident and in turn share the learning within and with partner organisations.

1.2 The purpose of reporting and investigating incidents is to:

- Identify Risks
- Learn from incidents that have occurred
- Improve the quality of care for our patients
- Maintain the safety of our patients, staff, visitors and contractors
- Share the outcomes of the learning with commissioners and other providers

1.3 This policy also includes the principles of Being Open, as first defined in 2009 by the National Patient Safety Agency. This is now reflected within contractual arrangements for Kleyn Healthcare as Duty of Candour. This policy will also describe the involvement of and co-operation with other healthcare organisations, healthcare teams, patients, their families, staff, carers and external agencies with regard to the reporting, investigation and management of incidents.

2. Policy statement

2.1 It is the policy of Kleyn Healthcare that all types of incidents must be reported, and it is expected that all staff will co-operate with implementing this policy. It is also the policy of Kleyn Healthcare that all Serious Untoward Incidents (SUI) will be investigated in a uniform manner applying the principles of Root Cause Analysis (RCA). Kleyn Healthcare recognises that it has a responsibility to investigate circumstances were patients have been harmed or had the potential to be harmed as a result of omissions or actions related to their care and treatment and when an incident occurs, it must be reported to all relevant bodies.

2.2 Kleyn Healthcare aims to ensure that:

Incidents are reported, managed and investigated in line with best practice including the National Framework for Serious Untoward Incidents (SUI);

Risks related to the safety and wellbeing of patients, staff, contractors and visitors as a result of investigation are recorded and appropriately managed and monitored;

Through investigation and subsequent learning, we improve standards of care and treatment for our patients and visitors and provide a safe place of work for our staff and others.

We share the learning from investigations across the organisation.

Kleyn Healthcare also recognises that incidents and investigations can have a significant impact on the patient, carers, family members and the staff who are involved.

Duty of Candour is defined in Robert Francis' report as: *'The volunteering of all relevant information to persons who have or may have been harmed by the provision of services, whether or not the information has been requested and whether or not a complaint or a report about that provision has been made.'*

Kleyn Healthcare's principle is that communication with healthcare teams, staff, patients, their relatives and carers must be as open as possible. This is in order to offer an explanation, a sincere apology, condolences and support; and provide them with the opportunity to raise their concerns and views so that these can be reflected as part of the investigation.

2.3 It is important that the views and concerns of patients and/ or their family/ carers are gained early in the process to ensure these are properly addressed, excepting restrictions on disclosure such as the following:

- Best interests – clinical opinion indicates that disclosure would adversely affect the patient's current health;
- Any written instructions from the patient regarding the disclosure of any information to others;
- Circumstances whereby there are serious concerns relating to a safeguarding adult/ child issue;
- Circumstances whereby there are serious concerns that the patient's representative (e.g. relatives / family / carers / advocate) is not acting in their best interests.

3. Scope

3.1 This policy applies to all investigations undertaken by Kleyn Healthcare in relation to incidents and will be implemented across all areas of the organisation.

3.2 As well as reporting incidents, staff can raise concerns through the processes outlined within the 'Raising Concerns at Work - Whistleblowing policy': 2010 the National Patient Safety Agency published in the National Framework for Reporting and Learning fromSerious Incidents Requiring Investigation (updated March 2013). This policy is aligned to that framework.

The National Framework defines a SUI requiring investigation as follows: *"A serious incident requiring investigation is defined as an incident that occurred in relation to NHS funded services and care resulting in one of the following":*

Unexpected or avoidable death of one or more patients, staff, visitors or members of the public; Serious harm to one or more patients, staff, visitors or members of the public or

where the outcome requires life-saving intervention, major surgical/medical intervention, permanent harm or will shorten life expectancy or result in prolonged pain or psychological harm (this includes incidents graded under the NPSA definition of severe harm);

A scenario that prevents or threatens to prevent a provider organisation's ability to continue to deliver healthcare services, for example,
Actual or potential loss of personal / organisational information, damage to property, reputation or the environment, or IT failure.

Allegations of abuse of a patient by a member of staff;

Adverse media coverage or public concern about the organisation or the wider NHS

3.3 National Never Events

Included in the description of SUIs are the nationally defined Never Events. A Never Event is:

"*A serious, largely preventable patient safety incident that should not occur if the available preventative measures have been implemented by healthcare providers".* Where a national Never Event occurs, Kleyn Healthcare will follow the recommended steps set out in the Never Events Framework.

3.4 Root Cause Analysis

Kleyn Healthcare uses Root Cause Analysis (RCA) methodology to support incident investigation. The aim of RCA is to solve problems by attempting to identify and correct the root causes of events, as opposed to simply addressing their symptoms. The primary aim of root cause analysis is to identify the factors that resulted in the nature, the magnitude, the location, and the timing of the harmful outcomes (consequences) of one or more past events in order to identify what behaviours, actions, inactions, or conditions need to be changed to prevent recurrence of similar harmful outcomes and to identify the lessons to be learned to promote the achievement of better outcomes.

4. Process for the reporting and management of incidents

4.1 Reporting of incidents

4.1.1 All incidents and near misses must be reported within 24 hours of staff being made aware of the incident, not only as best practice but to also ensure that Kleyn Healthcare complies with its regulatory and contractual obligations.

Kleyn Healthcare's reporting processes for all Significant Untoward incidents includes:

- Care Quality Commission (CQC)
- National reporting and learning system
- CCG Within 3 days of the incident being identified relevant to SUI and service contract

In addition the CCG will review all significant incidents of which the SUI cannot be closed without review or approval of the appropriate CCG:

All incidents must be reported using Kleyn Healthcare's significant event incident reporting proforma **Appendix 1.**

4.1.2 Kleyn also has a number of processes for reviewing the quality of care and treatment including complaints and the mortality review process. If any concerns are identified in relation to care or treatment as part of these or other audit processes these will also be recorded in the SUI template and escalated and graded in line with this policy.

4.2 Immediate action to be taken and reporting procedure

4.2.1 It is important that after the incident has occurred, an immediate review is undertaken by the responsible manager and team to eradicate or minimise the risk of recurrence and to ensure that learning is shared where applicable, across other areas of the organisation and at the earliest opportunity.

The first action after any incident is to ensure the safety and well being of patients and staff. Any equipment suspected of being the cause of, or implicated in the incident must, as far as possible, be withdrawn from use Incidents that occur during 'office hours' will initially be managed by the relevant clinical and management team. It is the responsibility therefore of all members of staff, involved in, discovering or observing a SUI to immediately report the incident to the Clinical Director and/or the most senior manager available. In doing so the staff should use the proforma in **Appendix 1.**

Incidents that occur out of hours should be reported to the Director of Operations – Julie McCann on 07841863183.

Staff must comply with the Caldicott principles of confidentiality when reporting an SUI and must not refer to patients by name or by any other identifiable information. Statements should be obtained from witnesses as soon as possible as a written record of their recollections of events. Use proforma in **Appendix 2.**

4.2.2 Preservation of evidence

Kleyn Healthcare recognises that following the most serious incidents (including sudden and unexpected death) the site may be deemed a crime scene. When responding to such an incident**,** Kleyn Healthcare's staff must not allow this to prohibit emergency action or treatment, but they must consider preservation of evidence and take appropriate actions to ensure this is maximised. Actions may include isolating areas, quarantining medical devices/equipment, prohibiting access for all individuals and not allowing restorative work or cleaning until clearance has been given by appropriate forensic experts. The Executive Medical Director or appropriate executive must be informed if access to any of Kleyn Healthcare's area is restricted due to the need to preserve evidence.

4.2.3 Process for reporting to external agencies

Some incidents require reporting to external agencies. The types of incidents that require reporting and the designations of the individuals who are responsible for reporting these incidents are outlined below in **Appendix 3**.

4.3 Grading of Incidents and timeframes for investigation

Incidents within Kleyn Healthcare are graded as category A - E. The following matrix provides guidance on categorisation based on the severity of the incident. To comply with contractual obligations, Kleyn Healthcare must adhere to the timeframes outlined in **Appendix 9**

4.3.1 On occasions, there will be external factors that influence the timeframe for completion of an investigation. Examples of this are complex safeguarding investigations, police investigations, availability of witnesses, complex multi-agency involvement, joint investigations, the extent of patient / family concerns, coroners' requests and liability claims, etc. These factors may impact on Kleyn Healthcare's ability to complete the investigation within the designated timeframe but may also require Kleyn Healthcare to provide an investigation in a shorter timescale. In these instances a decision will be taken with the l Medical Director (MD) to agree a plan to progress the required actions. If an extension is required for an SUI investigation, the investigating manager must flag this up within 30 working days of commencing the investigation, and liaise with the relevant commissioner to request an extension to the timeframe.

4.3.2 Kleyn Healthcare has adopted national guidance from the former National Patient Safety Agency and more recently the NHS Commissioning Board on SUIs. There are three levels of RCA investigation and these are described in **Appendix 9**

4.4 Procedure for conducting different levels of investigations including Serious Untoward Incidents – Appendix 3.

4.4.1 Kleyn Healthcare will have an identified group of senior staff who will be investigating managers and to provide family / patient / staff support for RCA investigations within Kleyn Healthcare. At least one member of the investigation team must be trained in RCA methodologies.

4.4.2 The investigating team at the outset of the investigation a team must be established involving staff members who are able to contribute to the investigation. It is not acceptable for an RCA investigation to be conducted by one person. The number of staff required as part of the investigating team will be determined on a case by case basis. However, as a minimum the following roles will apply:

- Investigation manager;
- Clinical Lead;
- Patient / family support; and

For Categories A and B incidents the Executive Medical Director will provide advice and support

The investigation manager will be appointed by the Executive Medical Director but they must be independent of the incident and not involved in the team where clinical care was being provided. **Appendix 6**

It is policy that at least one member on the investigation team who is outside of the clinical team where the incident occurred. It is also preferable for the investigation team to have members who have expertise in the area under review. If this is not possible, then it must be agreed at the outset who will be consulted by the investigating team to provide expert advice. There must be clinical leads appointed to support the investigation manager, one of which must be medical and/or nursing dependent on the incident. If a staff side representation is considered appropriate, a request must be made by the investigating manager to the appropriate staff side group. A final report form will be completed by Clinical Lead **Appendix 4**

4.4.3 Incidents confirmed as category D and E severity

Confirmed category D and E incidents are managed and reviewed through Kleyn Healthcare's clinical governance arrangements;
There must be consideration as to whether any lessons can be learned from these incidents;
Completion of the lessons learned section within the managers' sign off form in Kleyn Healthcare's SUI form is a mandatory field where all lessons learned must be recorded; and
Significant Lessons learned will also be included within the Learning from Experience Report (LFE)

4.4.4 Incidents confirmed as category C severity

Will be reviewed by the Kleyn Healthcare's Medical Director with the Clinical Director within 72 working hours, to confirm the grade of incident;
The manager for the department must complete the investigation tool within the SUI reporting form and If the categorisation is subsequently escalated to category A or category B, for example if the patient deteriorates or new issues emerge, then these incidents are investigated as such. If the categorisation remains unchanged, then these incidents are investigated as detailed in **Appendix 9**

4.4.5 Incidents reported as category A and B – Serious Untoward Incidents

Following confirmation of an SUI, immediate action must be taken to ensure that patients, staff and the public are safe. Kleyn Healthcare's Medical Director and Clinical Lead where the incident occurred must undertake an immediate review to help to identify any immediate actions that need to be taken to reduce the risk of recurrence of another SUI, and:

- ensure that the incident details are clear;
- determine the need for further information;
- agree the grading / categorisation;
- screen out natural causes / expected deaths; and
- advise of the outcome of their review

4.4.6 Kleyn Healthcare's Medical Director and Clinical Lead must be advised that the incident has occurred within 24 working hours, of the SUI being confirmed to ensure that it is able to meet external reporting timeframes. Subsequently category A and B SUIs must undergo either a comprehensive or concise RCA investigation respectively.

4.4.7 The Clinical Lead will escalate all A & B category incidents to the Medical Director who will confirm the grading and level of investigation.

4.5 Root Cause Analysis Reports

4.5.1 Category A and B RCA investigation reports must be approved by the Medical Director. As part of this approval process, the Medical Director must be assured that the investigation has been conducted to a high standard, that all reasonable outcomes have been drawn fromthe analysis contained in the investigation, and that the recommendations of the investigation are robust enough
These decision making processes must be indicated by completion of the RCA approval checklist in **Appendix C.**

4.5.2 Completion and sign off RCA reports category A and B **-** The RCA reports for Category A and B incidents must be approved by the Clinical Lead. They must be anonymised and forwarded to the Medical Director and Kleyn Healthcare's Board for final approval. Once approved, reports will be forwarded by the Executive Medical Director to the appropriate CCG commissioning unit and commissioner

4.5.3 Action Plans – Within 10 working days of the SUI report being completed an action plan containing all recommendations from the investigation has to be developed and approved bythe Medical Director

4.5.4 RCA reports must be developed and managed via Kleyn Healthcare's appropriate template for the level of RCA report. **Appendix 6.**

4.6 Incident Decision Tree

4.6.1 The Incident Decision Tree aims to help move away from attributing blame and insteadfind the cause when things go wrong. The goal is to promote fair and consistent staff treatment within and between healthcare organisations. Details of the IDT can be found within **Appendix 7.** The IDT must be used as part of all Category A and B SUI investigations.

4.7 Duty of Candour

5.7.1 Involving and supporting people following an incident is an important part of the investigation process in Kleyn Healthcare .Kleyn Healthcare's principle is that communication with healthcare teams, staff, patients, their relatives and carers must be as open as possible. Following a death or serious untoward incident, it is the responsibility of the Medical Director toensure that a senior clinician / manager is nominated for the patient /family or carer to:

offer an explanation, a sincere apology, condolences and support; and provide them with the opportunity to raise any concerns and views so that these can be reflected as part of the investigation.

4.7.2 It is important that the views and concerns of patients and/ or their family/ carers are gained early in the investigation process to ensure these are properly addressed, excepting restrictions on disclosure such as the following:

Best interests – clinical opinion indicates that disclosure would adversely affect the patient's current health; Any written instructions from the patient regarding the disclosure of any information to others;
Circumstances whereby there are serious concerns relating to a safeguarding adult/ childissue;

Circumstances whereby there are serious concerns that the patient's representative (e.g. relatives / family / carers / advocate) is not acting in their best interests.

4.7.3 Involvement in any investigation can be distressing for staff so it is important that they areprovided with support and advice. This should be agreed by their line manager /supervisor at the outset of any investigation. This should also apply if the member of staff is required to attend and give evidence at an inquest.

4.7.4 Investigations involving more than one patient, such as an infection outbreak, or loss of confidential data still need to be shared with the patient/relatives or carers. In situations such as this a report should be produced that describes the generic details and background to the incident. Appended to this should be a summary of the impact /outcome for each individual patient that can be shared with them or their family /carer along with the generic report. This must not contain details of the other patients involved.

4.7.5 It is essential that the patient / family / carer are advised as soon as possible of the incident and investigation. This must be within and no longer, than 10 days of the incident occurring. If there are any extenuating circumstanced why this cannot be achieved this must beflagged to Kleyn Healthcare and the reason recorded within Safeguard. Timescales and the process for communication are described in **Appendix 3**.

4.8 Statements

4.8.1 Statements will be requested at the commencement of an RCA to inform the RCA investigation report: they will be held on file to provide evidence for any associated inquest, complaint or claim. This will reduce the risk for any potential discrepancy in the factual accountsprovided and increase the reliability of the witness statement, since it is taken as early as possible following the incident

4.8.2 Staff will be afforded 15 working days from the start of the investigation to have their witness statement approved.

4.9 Disciplinary action

4.9.1 Kleyn Healthcare wants to encourage open and honest reporting. Where an employee makes a self-report of an adverse event which relates to their own misconduct, as defined within the Kleyn Healthcare's staff handbook.

4.9.2 In instances where there may be a disciplinary case to answer, the incident investigation can continue but the member/s of staff must be informed that the matter will be dealt with in accordance with Kleyn Healthcare's policy and processes, and any statement taken during the review may be required as part of the disciplinary process. It is important to note that staff may be supported by their union or an appointed representative throughout the incident investigation process should they wish.

4.9.3 Managers involved in the incident investigation review team must not participate in the disciplinary process other than to refer their findings to the investigating manager appointed in accordance with the trust's policy and procedure**.** The disciplinary investigation andreport will be a separate process and conducted independently of the incident investigation,but can be conducted at the same time. If the incident investigation indicates further referralto human resources processes, this must be reported and investigated in line with Kleyn Healthcare's policy and procedure.

4.10 Incident investigations and the complaints and claims process

4.10.1. Where any investigation has commenced and a complaint is subsequently received, the patient /family will be advised that their concerns raised in the formal complaint will be answered as part of the RCA

4.10.2 Claims are not formally graded, but when a claim, or intention to claim, is received Kleyn Healthcare will search the Safeguard system and liaise with colleagues to ascertain what previous information Kleyn Healthcare has e.g. from a SUI, or complaint investigation. All formal letters of claim are notified to the Medial Director who will escalate for formal investigation if appropriate and if no previous investigation has been undertaken.

4.11 Special considerations in respect of safeguarding incidents

4.11.1 For incidents where there are concerns around safeguarding, staff will identify these incidents within the SUI Incident Reporting System. The decision to report a safeguarding incident as an SUI must be taken by the executive lead for safeguarding . This must also be reported to the Care Quality Commission without delay.

4.11.2 The Medical Director will also inform the relevant commissioners and the relevant local safeguarding children/adult board. Where there is a multi-agency serious case review (SCR) Kleyn Healthcare may be asked to do an Individual Management Review (IMR) as part of this multi-agency investigation.

4.11.3 The learning from SCRs is shared throughout Kleyn Healthcare

Independent reviews

NHS England is responsible for commissioning independent investigations. This includes determining when an independent investigation is necessary, appointing an independent investigation team, agreeing terms of reference, publishing and distributing the resultant report and ensuring a process for subsequent action to address the issues raised. Kleyn Healthcare and its employees are responsible for co-operating with an independent review. Kleyn Healthcare will co-operate and work within memoranda of understanding which have been agreed by the NHS and other national bodies including the Health and Safety Executive, the Counter Fraud and Security Management Service, the Police and the Crown Prosecution Service.

4.12 HM Coroners' enquiries and inquests

4.12.1 The management of inquests within Kleyn Healthcare is the responsibility of the Medical Director. RCA investigations will on occasions be aligned to coroners' inquests and the processes for investigation described within this policy will apply. When an investigation commences that is linked to an inquest the same statements for the investigation will also be provided to the Coroner to support the inquest. This process will be led by the Clinical Director with overall responsibility being passed to the Executive Medical Director.

4.12.2 On certain occasions, the coroner may request information related to the investigation that will need to be provided outside of the timeframes described in **Appendix 3.** This will be identified at the start of Kleyn Healthcare's investigation so that timeframes can be adjusted accordingly. The process for the management of inquests is outlined in **Appendix 8.**

4.12.3 Guidelines are available at Kleyn Healthcare for staff who have to attend inquestand provide written reports or statements for the coroner.

4.13 Communication

The investigating manager will be responsible for keeping informed patients, relatives, staff, and members of the public affected by an incident. The Clinical Director will in discussion with the Medical Director agree how to involve the patient/relatives in the investigation as part of Being Open.

Once the investigation begins, staff other than the investigating manger should refrain from direct discussion with the patient or family concerned on any matters relating to the incident. Any such queries should be redirected accordingly.

Staff involved in providing information should limit any accounts of adverse incidents to their own involvement, rather than speculation or criticism of the roles of others. Their statements should be factual and should be written as quickly as possible following the incident.

Any media enquiries must be referred to the Medical Director.

The Medical Director will be responsible for informing Commissioners or any other external bodies.

Confidentiality
Incidents related to SUIs are of a confidential nature. Staff involved in the handling of information or investigations concerning untoward incidents must not divulge information which could breach confidentiality.

Any breach of confidentiality will be treated as a serious matter and may lead to disciplinary action

4.13.1 Media or Press Enquiries related to investigations
It is essential that all contact with the media (press/radio/TV) is co-ordinated through Kleyn Healthcare

4.14 Process for Learning from Investigations

4.14.1 Sharing of lessons learnt

The sharing of lessons learnt post investigation is a critical part of incident management.

Following a review of the incident, the Medical Director will ensure that procedures are adopted or altered to reflect the lessons learnt from such incidents.

The Operational Manager will ensure that such procedures are disseminated to all staff.

Our commitment to an open and fair culture

A clinical or non-clinical error, accident or incident, however serious, is rarely caused wilfully. It is not, in itself evidence of carelessness, neglect or a failure to carry out a duty of care. Errors are often caused by a number of factors including, process problems, human error, individual behaviours and lack of knowledge or skills. Learning from such incidents can only take place when they are reported and investigated in a positive, open and structured way.

To promote a fair and open culture and encourage the reporting of incidents Kleyn Healthcare will take a non-punitive approach to incidents.

Staff remain accountable to patients, Kleyn's Healthcare and their professional bodies for their actions, but a non-punitive approach means that disciplinary action will not be taken against a member of staff for reporting an incident, except in the rare circumstances where there is evidence of:

- Gross professional or gross personal misconduct
- Repeated breaches of acceptable behaviour or protocol
- An incident that results in a police investigation

Support for Staff

Kleyn Healthcare recognises that an SUI is potentially stressful for all staff, both for those who are directly involved and those who are not.

Kleyn Healthcare will ensure that appropriate support is available to all staff.

The expectation is that line managers will offer staff involved appropriate support including the opportunity to talk through what happened with managers and colleagues.

Additional support such as individual counselling will be provided to those staff who request it.

4.12.2 Process for how recommendations and actions plans will be developed and monitored

4.13.3 Action plans for Category A & B investigations will be developed by the Clinical Lead with the support of the relevant senior managers.

Any actions that have organisation wide relevance will also be developed and agreed with the Clinical Lead and Medical Director. When the recommendations and actions have been agreed and approved these will be logged into Kleyn Healthcare's incident reporting system.

4.14.4 The Clinical Lead(s) is / are responsible for ensuring that governance processes are in place to implement and monitor actions for all recommendations and also have accountability for ensuring changes in practice are made in order to embed learning and mitigate the potential for recurrence of similar incidents. Monitoring will be as follows:

Monitor progress against the status of all relevant action plans and recurring themes at each governance meeting through the monthly clinical dashboard report

Kleyn Board will receive and review the Learning from Experience (LFE) report.

4.14.5 Process for how incidents, complaints and other learning isanalysed

A summary of incidents, complaints is written and reported monthly through Kleyn Healthcare's monthly governance report

4.14.6 Process for how the information is combined to provide a risk profile for the organisation (including timescales)

The LFE Report, will contribute to the risk profile for the organisation and as such if any risks / assurances are highlighted in the report this will be escalated and managed in accordance with Kleyn Healthcare's risk management processes. However, it should be noted that any potential risk identified from an incident, complaint or claim investigation must also be with outlined risk reduction measures at any time following such an occurrence.

4.14.7 Process for how this information will be shared with relevant individual staff or groups (including timescales)

4.14.8 The Learning from Experience Report will be submitted to the Kleyn Board of Directors, Monthly staff governance meetings will be responsible for following up and monitoring actions and risks identified as part of the Learning from Experience Report and for escalating any concerns related to this as required.

4.14.9 It will be the responsibility of the Clinical Lead to ensure that learning from investigations is communicated across all areas
.
4.14.10 Process for monitoring SUI investigations

4.14.11 Monitoring the progress of SUI investigations will be as follows:

A weekly report will be produced for all open investigations including deadlines for completion of investigations, submission to the CCG, requests for extension and requirements for complying with Duty of Candour; CMCCG.seriousincidents@nhs.net

A monthly report will be produced identifying the progress against SUI action plans and including where the action planning meeting has not occurred, closed actions, actions within date and those that have breached their deadline;

A monthly report will be produced related to investigations that are aligned to Coroners' inquests

5. Roles & Responsibilities

5.1 All employees have a responsibility to:

Observe and comply with this policy and associated procedures.
Participate in induction and all relevant mandatory training for incident reporting and investigation.
Ensure that they report all adverse incidents and that details are recorded accurately within 24 hours of the date of the incident or date of identification, whichever is later;
Report any adverse incident they are involved in, or are aware of to their manager once all immediate actions have been completed following the incident.Complete witness statements as required;
Co-operate fully with incident review procedures, providing written statements as appropriate to their involvement in the accident/ incident event;
In the event of an incident, ensure that patients, their family and or carers are informed and provided with an apology if appropriate.

5.2 Kleyn Board

Kleyn Board of Directors is responsible for receiving and scrutinising the Learning from Experience (LFE) report.

5.3 Executive Medical Director

Has delegated overall responsibility for the management and investigation of incidents for ensuring that a framework is in place which meets legal, regulatory and contractual requirements; and reporting to Kleyn Board on all Category A and B incidents that have beenreported to the relevant CCG within 3 days

5.4 All other Executive Directors

Will ensure incident reporting and investigation processes, including external reporting, are implemented within their service areas in accordance with this policy.

5.6 Clinical Lead(s)

Responsible for Governance and Risk processes within Kleyn Healthcare, including ensuring that there is a robust governance process with relation to reporting, investigation and learning from incidents within Kleyn Healthcare. Also ensuring that systems are in place to ensure that any risks identified from incident reporting are risk assessed, appropriately recorded, escalated with any mitigations monitored appropriately.

Responsible for ensuring the incident reporting and management policy and framework meets statutory, regulatory and contractual requirements and is monitored appropriately; Responsible for informing and updating CCG's and Commissioners about any SUIs (Category A and B) and monitoring contractual targets for completion of SUI investigations and negotiating extensions with the appropriate commissioner or advising of delays due to external involvement;

Determining the appropriate level of investigation

Responsible for operationally overseeing investigations into SUIs (Category A or B incidents) and ensuring that Kleyn Healthcare complies with the contractual timescales.

Nominating with the Medical Director managers within the division to investigate incidents;

Nominating and supporting clinicians / managers to provide support and liaison topatients / families /carers and staff involved in incidents;

Undertaking specific SUI investigations as agreed with the Medical Director

Supporting and advising staff including their role in the management and investigation of incidents;

Monitoring performance against KPIs for the investigation of incidents, including the quality and completion of reports, Duty of Candour requirements, development and closure of divisional / local action plans;

Supporting the Medical Director to develop systems for the dissemination and sharing of lessons learned and for ensuring that these are embedded across the organisation ;

Requirements under Duty of Candour are met and applied to all relevant investigations so patients / families /cares receive timely and sensitive feedback;

Ensure the Incident Decision Tree is applied to all investigations involving staff

5.7 Line Managers

Ensure that staff report all adverse incidents and that details are recorded accurately within 24 hours of the date of the incident or date of identification, whichever is later;

Where the nature of the accident / incident involves serious injury, loss or damage line managers will be responsible for immediately advising their manager and taking any remedial action as appropriate;

Responsible for ensuring that key information is shared with all others who may be affected

by the adverse incident

Responsible for investigating and identifying lessons that can be learned, developing and delivering appropriate remedial action recommendations, monitoring event trends and ensuring appropriate staff support;

Ensure that there is an identified deputy to undertake the reporting on their behalf during any period of the manager's absence, e.g. annual leave.

Other key roles and responsibilities are described throughout the policy and in **Appendix 3**.

6. Dissemination and implementation of this policy

Senior Managers will be responsible for ensuring their staff are fully aware of the procedure for reporting all Incidents.

Formal training for all staff will be via the mandatory induction training for new staff and refresher training for existing staff.

This policy will be disseminated via email and hardcopies will be available at each site for reference.

APPENDICES

Appendix 1

KLEYN HEALTHCARE SERIOUS UNTOWARD INCIDENT REPORTING FORM **To be completed within 24 hours of the incident occurring**	
TIME & DATE OF MAKING THE REPORT	**TIME:** **DATE:**
INCIDENT REFERENCE NUMBER (to beassigned by Operational Manager)	
LEAD DIRECTOR	
INVESTGATING MANAGER	
WHEN DID THE INCIDENTOCCUR?	**TIME:** **DATE:**
WHERE DID THE INCIDENT OCCUR?	

INFORMATIONABOUT PATIENT/s INVOLVED (patient description, initials only NOTname(s); includegender and age)	
INFORMATIONABOUT STAFF INVOLVED (Designations NOT names)	
WHAT HAPPENED (givea factual account of the incident including a description of any medical equipment involved)	
DESCRIBE ANY IMMEDIATE ACTION TAKEN TO PROTECT AND/OR IMPROVE PATIENT/STAFF SAFETY	
ANY OTHER RELEVANT INFORMATION	

Form completed by:

Name:.....Designation.....

Appendix 2

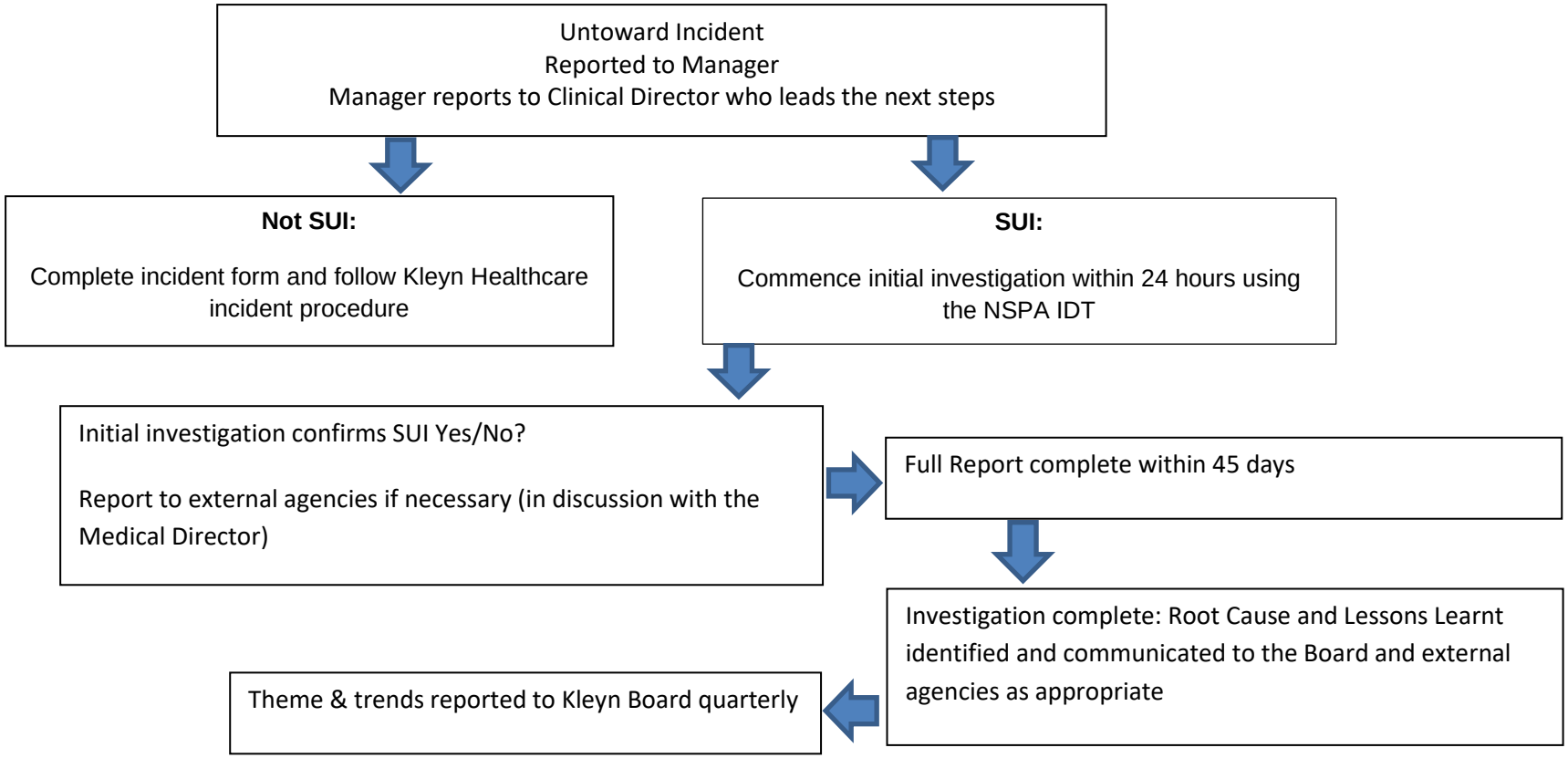
WITNESS STATEMENT
A copy of one of these forms is to be completed by all witnesses to the incident. They must complete the form in their own words and they should sign the statement immediately after the last line. Diagrams can be added is necessary.
Name:
Date:

Signature:

Page No.....

Appendix 3

Serious Untoward Incident Process Flowchart within Kleyn



Appendix 4

KLEYN HEALTHCARE **SUI Final Report**
Incident No:
Date of incident: **Site where incident took place:** **Reported by:**
Situation:
Background:
Assessment :
Recommendation/s:
Clinical Director (signed): **Date:**

- ***Based on SBAR***

Appendix 5.

Process for reporting to external agencies

Incident type (As defined by the relevant agency)	External agency	Duties & responsibility
Adverse drug reaction (serious or related to new drug) https://yellowcard.mhra.gov.uk	Medicines Healthcare product Regulatory Agency (MHRA)	Any health professional Medical Director
Any significant reputational issues for example, any adverse national press attention	Monitor & Clinical Commissioning Group	Medical Director Kleyn board
Estates/ Environment issue	Kleyn Healthcare	Medical Director
Fire – *Inform through ERIC returns*	DH Estates and Facilities Management	Medical Director Kleyn board
HCAI Outbreak	Health Protection Agency /NHS England / Clinical Commissio ning Groups or other commissioners (as appropriate	Medical Director Kleyn board
Human Tissue incidents related to : Post mortems, the HTA guidance is at: http://www.hta.gov.uk/_db/_documents/Guidance_for_reporting_HTARI s.pdf. (Section 3 lists the types of incident that are reportable) Research; and Transplant licences	Human Tissue Authority	Designated Individuals (DI) are responsible for ensuring that the HTA is notified of HTARIs (HTA Reportable Incidents Medical Director
Incidents likely to result in litigation	NHS Litigation Authority	Medical Director Kleyn board

Information governance: Major breaches of confidentiality such as the loss or theft of personal identifiable records or information (including missing notes). An incident involving the actual or potential loss of personal information that could lead to identity fraud or have other significant impact on individuals should be considered as serious.	Information Governance Lead	Operations Manager Clinical Director Medical Director Kleyn Board
Ionising Radiation (Medical Exposure) Regulations 2000 (IRMER)	Care Quality Commission	Clinical Director Medical Director KLEYN board
Inquest linked to Kleyn Healthcare investigation	HM Coroner	Clinical Director Medical Director Kleyn board
Medical devices / equipment incidents http://www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/De vices/index.htm	Medicines Healthcare product Regulatory Agency (MHRA)	Operations Manager Clinical Director Medical Director Kleyn board
Never Events - National framework	Clinical Commissioning Groups/NHS England for specialist commissioning	Medical Director Kleyn board

NHS Blood and Transplant (NHSBT) Organ Donation and Transplantation reporting Urgent incidents must be reported to the NHS Blood and Transplant (NHSBT) Organ Donation and Transplantation (ODT) Directorate Duty Office on 01179 757580 immediately upon discovery	NHSBT	Medical Director Kleyn board
Physical assault against staff- For physical assaults report to Kleyn Healthcare & NHS reporting of Violence Against Staff statistics.	Police & Security Management Service	Medical Director Kleyn board
RIDDOR (Reporting of Injuries, Diseases and Dangerous Occurrence Regulations	Health and Safety Executive	Operations Manager Clinical Director Medical Director Kleyn board
Safeguarding incident – children and adults	Referred to local authority (as appropriate as per safeguardin g reporting thresholds)	Medical Director for Safeguar ding Children & for Vulnerab le Adults Kleyn board
Serious Untoward Incidents (Category A or B)	Clinical Commissio ning Groups / NHS England for specialist commission ing	Clinical Director Medical Director Kleyn board
Significant disruption to service continuity / major incident	Health ProtectionAgency /NHS North Clinical Commissio ning Groups or other commissioners (as appropriate)	Operation Manager Clinical Director MedicalDirector

Appendix 6.

RCA approval checklist for Medical Directors

Safeguard No: **Category:** **Date of incident:**

Investigating Manager:

Was the patient and / or family involved in the investigation? *If not, are you satisfied that this was an appropriate decision – e.g.were there any issues raised regarding disclosure of information?*	YES	NO
Have any issues identified by the patient and / or family beenincluded and addressed in line with their expectations in the report		
Was appropriate clinical and medical advice obtained to support the investigation?		
Were all appropriate people interviewed during the investigation? *To include any temporary staff*		
Are there any discrepancies between witness statements and theinformation in the investigation report? *If Yes please state action taken:*		
Were Root Cause Analysis (RCA) methodologies / tools used – *e.g. Change analysis, fishbone, 5 whys*?		
Is there evidence of outcomes of the investigation being formulated specifically as a consequence of using root cause analysis methodologies / tools?		
Is there a clear, accurate and specific chronology of events relevant tothe incident?		
Is all relevant information detailed in the investigation? Was the Incident Decision Tree applied to determine whether thecausal factor/s were as a result of systems failure/s or individual practitioner acts or omissions?		
Do the recommendations provide assurance that the issues that contributed and/ or caused the incident will be mitigated to reduce thepotential for recurrence?		
Are the actions SMART (Specific, Measurable, Achievable, Realistic Timely) and directly relate to the findings / recommendations?		
Are there learning/ actions which should also be shared outside the locality and/ or specialty? Please indicate what and which areas would be appropriate to share:		
Please describe how you now plan to share and disseminate the learning across Kleyn Healthcare List the/meetings that you propose to take this to including the dates.		
RCA Y / N approved? If No, please state action:		

Name of Medical Director:
Date:
Date of feedback to patient / family / carer:
This must be within 10 days of approval of the investigation, where appropriate)

Appendix 7

Incident decision tree flowchart

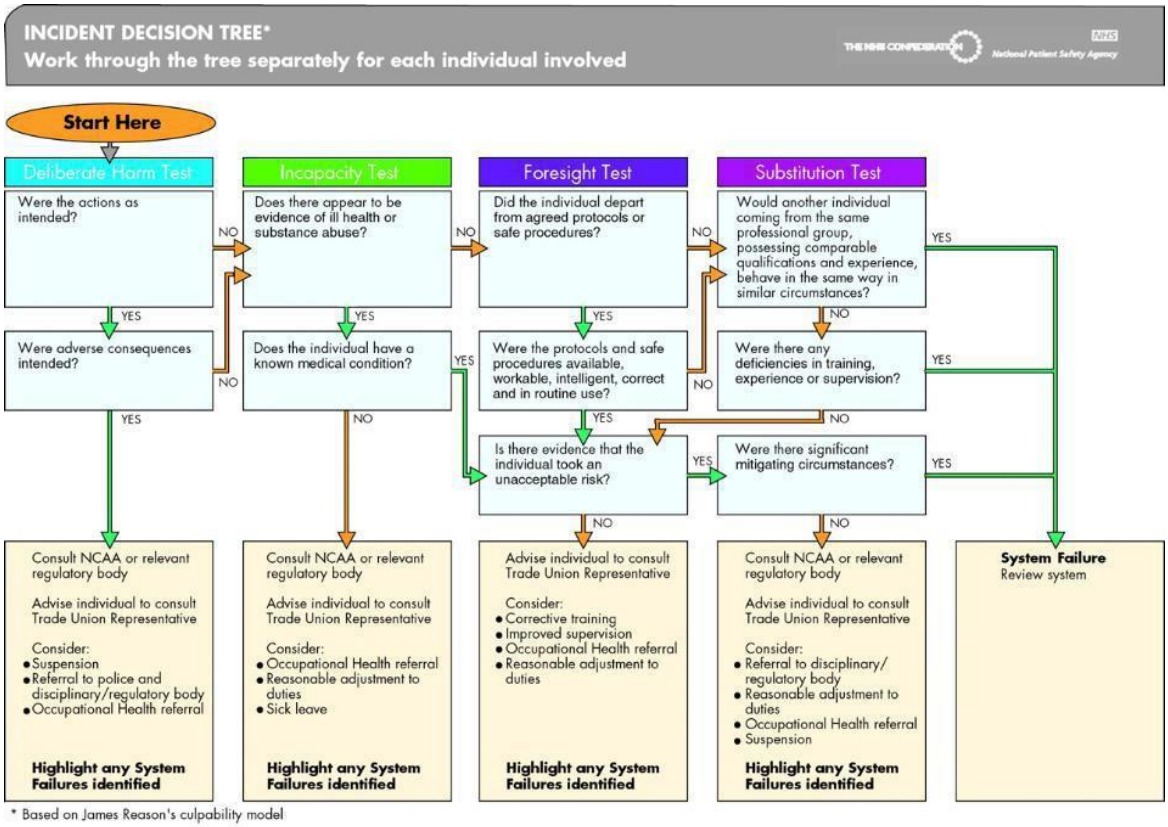
Responses to serious safety incidents require careful consideration of the contributory systems failures,which research has shown are often the root causes. Analysis of systems failures must be undertaken before disciplinary actions or staff suspension are considered. Disciplinary actions must always be considered in accordance with guidance and policy provided byKleyn Human Resources.

The incident decision tree (IDT) must be used for all category A and B RCA investigations to:

- decide whether, in certain circumstances, it is necessary to suspend staff from duty / clinical duties
- following a patient safety incident understand if systems are safe and if policies and procedure are adequate
- explore alternatives to suspension, such as temporary relocation or modification of duties;
- consider other possible measures to be taken as the investigation progresses

The IDT can also be used for other investigations including Category C and HR investigations

Incident Decision Tree Flow Chart



Appendix 8

Process for the Management of Inquests

Kleyn Healthcare receives Coroner's request for documents with stated time scales Kleyn Healthcare records case in Safeguard and notifies Kleyn Board of timescales toprovide a statement / report
Statements, etc. within 15 working days
Failure to provide a statement will incur a Coroner's fine of £1,000 to the *individual* * Kleyn Healthcare must return all documents to the Coroner's Office by the date specifiedby the Coroner
The Coroner will then review the case file and decide which witnesses are required toattend the Inquest and will list a date for the Inquest and notify Kleyn Healthcare Kleyn Healthcare and Staff member(s) will be informed of the requirement and date toattend.
Kleyn Healthcare will coordinate availability and support for staffThe Inquest is held by the Coroner
The conclusion is recorded on Safeguard.
The relevant Kleyn Healthcare parties are notified
If the Coroner flags a potential risk or concern, he/she may issue a Notice to PreventFuture Deaths (PFD)*
Kleyn Healthcare will coordinate the response to the team.
Lessons Learned to be cascaded throughout Kleyn Healthcare as part of the Learningfrom Experience Report
Inquest is opened by the Coroner and asks Kleyn Healthcare to provide the name of the leading clinician within 7 days.

TIMEFRAME

The Inquest must be completed within 6 months

Clinical statements must be returned to Kleyn Healthcare investigation team by thestipulated date.

All relevant documents must be returned to the Coroner (by the stipulated date)The Inquest must be completed within 6 months

Appendix 9

Table 1. Guidance for grading of Incidents and timeframes for investigation

Category	RCA Report / Review and timescales	Responsibility for management of the investigation	Level of harm / outcome	General definition and Examples of types of incident
A	Comprehensive report 45 working days ***OR*** Specific category A incidents involving e.g. police or an external / internal inquiry Comprehensive report up to 6 months	Medical Director ***OR*** Agreed by the Executive Medical Director & Kleyn board	Death / Catastrophic	Incidents that result in death or cause such serious harm that they place a patient or staff members' life in jeopardy: Fall resulting in death Significant safeguarding referral Maternal death e.g. massive obstetric haemorrhage Deteriorating patient where death could have been avoided Apparent suicide Allegations of abuse; Adverse media coverage or public concern about the organisation or the wider NHS Infection Prevention – examples: A patient develops a bacteraemia and the organism causing the bacteraemia is the same as the outbreak organism. i.e. MRSA outbreak identified and a patient on the same ward develops an MRSA bacteraemia. A patient develops post operative infection complications with long term implications and the infection is the same organism as the outbreak i.e. MRSA outbreak and a patient on the same ward develops a deep wound infection caused by MRSA to their new hip joint and it has to be removed Specific organism relating to the outbreak i.e. there is a high incidence of wound infections on a ward but they would only be reported if they were all caused by the same organism. Never Events (Never Events Framework)

B	**Concise report 45 working days**	**Divisional Medical Director**	**Severe / Major**	Incidents that are not life threatening, but which acutely jeopardise the wellbeing of a patient or member of staff: Fall resulting in a serious injury, e.g. fractured neck of femur or significant head injury Allegations of patient abuse, neglect, or sexual assaults Grade 3 / 4 pressures ulcers developed whilst in KLEYNS care or if on first assessment not previously known to any provider Serious breach of information governance reported to the Information Commissioner's Office. General definition and Examples of types of incident
C	**Concise RCA report 10 working days**	**Clinical Director**	**Moderate**	Incidents which moderately affect, or have the potential to affect, the health or the psychological wellbeing of the individual involved: Fall resulting in a moderate injury, e.g. deep cut which may require stitches, marked bruising, etc. Grade 2 pressures ulcers developed whilst in KLEYNS care or if on first assessment not previously known to any provider Accidental injuries Assaults resulting in moderate harm Deliberate self-harm resulting in moderate injury Near miss Never Event
D	**Complete the review within 10 working days**	**Clinical Director**	**Low / minor**	Incidents which result in minor injury: Fall resulting in a minor injury. Grade 1 pressures ulcers developed whilst in KLEYNS care or if on first assessment not previously known to any provider. Accidental injuries Assaults resulting in minor harm
E	**Complete the review within 10 working days**	**Clinical Director**	**No / none**	Incidents which result in no injury and are classed as a near miss: Fall resulting in no injury Medication incidents that are picked up prior to potentially causing harm

Appendix 10

Table 1 Consequence scores
Choose the most appropriate domain for the identified risk from the left hand side of the table Then work along the columns in same row to assess the severity of the risk on the scale of 1 to 5 to determine the consequence score, which is the number given at the top of the column.

	Consequence score (severity levels) and examples of descriptors				
	1	**2**	**3**	**4**	**5**
Domains	**Negligible**	**Minor**	**Moderate**	**Major**	**Catastrophic**
Impact on the safety of patients, staff or public (physical/psychological harm)	Minimal injury requiring no/minimal intervention or treatment. No time off work	Minor injury or illness, requiring minor intervention Requiring timeoff work for >3days	Moderate injury requiring professional intervention Requiring time off work for 4-14 days	Major injury leading to long- term incapacity/disability Requiring time off work for >14 days	Incident leading to death Multiple permanent injuries or irreversible health effects

		Increase in length of hospital stay by 1-3 days	Increase in length of hospital stay by 4-15 days RIDDOR/agency reportable incident An event which impacts on a small number of patients	Increase in length of hospital stay by >15 days Mismanagement of patient care with long-term effects	An event which impacts on a large number of patients
Quality/complaints/audit	Peripheral element of treatment or service suboptimal Informal complaint/inquiry	Overall treatment or service suboptimal Formal complaint (stage 1) Local resolution Single failure to meet internal standards	Treatment or service has significantly reduced effectiveness Formal complaint (stage 2) complaint Local resolution (with potential to go to independent review)	Non-compliance with national standards with significant risk to patients if unresolved Multiple complaints/ independent review Low performance rating Critical report	Totally unacceptable level or quality of treatment/service Gross failure of patient safety if findings not acted on Inquest/ombudsman inquiry Gross failure to meet national standards

		Minor implications for patient safety if unresolved	Repeated failure to meet internal standards Major patient		
		Reduced performance rating if unresolved	safety implications if findings are not acted on		

Human resources/ organisational development/staffing/ competence	Short-term low staffing level that temporarily reduces service quality (< 1 day)	Low staffing level that reduces the service quality	Late delivery of key objective/ service due to lack of staff Unsafe staffing level or competence (>1 day) Low staff morale Poor staff attendance for mandatory/key training	Uncertain delivery of key objective/service due to lack of staff Unsafe staffing level or competence (>5 days) Loss of key staff Very low staff morale No staff attending mandatory/ key training	Non-delivery of key objective/service due to lack of staff Ongoing unsafe staffing levels or competence Loss of several key staff No staff attending mandatory training /key training on an ongoing basis

Statutory duty/ inspections	No or minimal impact or breech of guidance/ statutory duty	Breech of statutory legislation Reduced performance rating if unresolved	Single breech in statutory duty Challenging external recommendations/ improvement notice	Enforcement action Multiple breeches in statutory duty Improvement notices Low performance rating Critical report	Multiple breeches in statutory duty Prosecution Complete systems change required Zero performance rating Severely critical report
Adverse publicity/ reputation	Rumours Potential for public concern	Local media coverage – short-term reduction in public	Local media coverage – long-term reduction in public confidence	National media coverage with <3 days service well below reasonable public expectation	National media coverage with >3 days service well below reasonable public expectation. MP concerned

		confidence Elements of public expectation not being met			(questions in the House) Total loss of public confidence
Business objectives/ projects	Insignificant cost increase/ schedule slippage	<5 per cent over project budget Schedule slippage	5–10 per cent over project budget Schedule slippage	Non-compliance with national 10–25 per cent over project budget Schedule slippage Key objectives not met	Incident leading >25 per cent over project budget Schedule slippage Key objectives not met

Finance including claims	Small loss Risk of claim remote	Loss of 0.1–0.25 per cent of budget Claim less than £10,000	Loss of 0.25–0.5 per cent of budget Claim(s) between £10,000 and £100,000	Uncertain delivery of key objective/Loss of 0.5–1.0 per cent of budget Claim(s) between £100,000 and £1 million Purchasers failing to pay on time	Non-delivery of key objective/ Loss of >1 per cent of budget Failure to meet specification/ slippage Loss of contract / payment by results Claim(s) >£1 million
Service/business interruption Environmental impact	Loss/interruption of >1 hour Minimal or no impact on the environment	Loss/interruption of >8 hours Minor impact on environment	Loss/interruption of >1 day Moderate impact on environment	Loss/interruption of >1 week Major impact on environment	Permanent loss of service or facility Catastrophic impact on environment