

KH-CP-009 - Patient Safety Incident Response and Learning Policy

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KH-CP-009 - Patient Safety Incident Response and Learning Policy

Contents

Section	Page
1. Purpose	
2. Scope	
3. Policy Statement	
4. Definitions	
5. Roles and Responsibilities	
6. Immediate Response to a Patient Safety Incident	
7. Reporting and Escalation	
8. Incident Review and Learning Response	
9. Communication, Duty of Candour and Support	
10. Confidentiality, Records and Evidence	
11. Fair and Open Culture	
12. Learning, Improvement and Assurance	
13. Training and Dissemination	
14. Monitoring and Review	
15. References and Linked Guidance	
Appendices	

KH-CP-009 - Patient Safety Incident Response and Learning Policy

1. Purpose

This policy sets out Kleyn Healthcare's arrangements for recognising, responding to, reporting, reviewing and learning from patient safety incidents, serious incidents and other significant adverse events. It replaces historic Serious Untoward Incident terminology with a current patient safety incident response and learning approach.

The purpose of the policy is to ensure that immediate action is taken to protect patients, staff and members of the public; that incidents are escalated appropriately; that affected people are treated with openness, compassion and respect; and that learning is translated into practical improvements.

2. Scope

This policy applies to all Kleyn Healthcare services, including NHS-funded community ultrasound activity, private healthcare activity, administrative services, remote support and any work undertaken by employed staff, self-employed clinicians, contractors, agency workers, students or volunteers acting on behalf of Kleyn Healthcare.

- Patient safety incidents affecting patients, relatives, carers, staff, visitors or members of the public.
- Unexpected, avoidable or unexplained harm, including moderate harm, severe harm, prolonged psychological harm or death.
- Incidents affecting the safe delivery of services, including equipment failure, IT failure, information governance incidents, safeguarding concerns, infection prevention concerns, medicines or clinical process failures, significant complaints and adverse media or reputational concerns.
- Events that require notification to commissioners, CQC, LFPSE, safeguarding partners, the police, insurers, professional bodies or other external agencies.

3. Policy Statement

Kleyn Healthcare is committed to a fair, open and learning-focused approach to patient safety incidents. The organisation will prioritise the safety and wellbeing of patients, staff and others; respond promptly and proportionately; comply with statutory Duty of Candour requirements where applicable; and ensure that learning is shared and embedded.

This policy should be read alongside the Duty of Candour Policy, Incident Reporting Policy, Risk Management Policy, Complaints Policy, Safeguarding Policy, Infection Prevention and Control Policy, Information Governance and Data Protection Policy and Whistleblowing Policy.

KH-CP-009 - Patient Safety Incident Response and Learning Policy

4. Definitions

Term	Meaning
Patient safety incident	Any unintended or unexpected incident that could have, or did, lead to harm for one or more patients receiving healthcare.
Significant incident	An incident requiring senior review because of actual or potential harm, risk, service disruption, safeguarding concern, regulatory concern, reputational impact or need for external notification.
Serious incident / historic SUI	Historic terminology used for serious incidents. Kleyn Healthcare will use current patient safety incident response terminology while recognising that commissioners or external bodies may still use older terms in some communications.
Notifiable safety incident	An incident that meets the statutory Duty of Candour threshold under CQC Regulation 20.
Learning response	A proportionate review, investigation, thematic review, after-action review, multidisciplinary case review or other method used to understand what happened and what can be improved.
Action plan	A clear record of the improvements required, owner, timescale, evidence of completion and assurance that the change has been embedded.

5. Roles and Responsibilities

Role	Responsibilities
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KH-CP-009 - Patient Safety Incident Response and Learning Policy

All staff and clinicians	Act immediately to protect safety; report incidents promptly; preserve evidence; provide factual information; maintain confidentiality; participate in reviews and learning.
Line managers / site leads	Ensure immediate actions are completed; support staff; escalate to senior management; ensure forms and records are completed.
Operational Manager / Deputy Manager	Coordinate operational response, incident logging, communication with relevant teams, evidence gathering and action tracking.
Clinical Director / Medical Director	Provide clinical oversight, determine severity and escalation requirements, approve clinical communications and ensure learning is clinically appropriate.
Managing Director / Director of Operations	Provide executive oversight, determine external reporting requirements, liaise with commissioners and external bodies where required and ensure Board assurance.
Investigating / reviewing manager	Lead the agreed learning response, gather evidence, speak to relevant people, prepare the report and action plan, and ensure a fair and proportionate approach.

6. Immediate Response to a Patient Safety Incident

1. Make the area safe and arrange urgent clinical assistance where required, including 999 for immediate life-threatening emergencies.
2. Provide immediate care, treatment or support to any person affected.
3. Remove from use and clearly label any equipment, consumables, medication, system access or documentation suspected to be involved, where safe to do so.
4. Notify the most senior manager available and the Clinical Director or Medical Director as soon as possible.

KH-CP-009 - Patient Safety Incident Response and Learning Policy

5. Record factual information only. Do not speculate, blame or alter records retrospectively.
6. Preserve relevant evidence, including equipment details, batch numbers, appointment records, clinical images, referral information, reports, emails, call notes, rota records and audit trail information.
7. Consider safeguarding, infection prevention, information governance, equipment safety, police, commissioner, CQC, insurer and Duty of Candour requirements.

7. Reporting and Escalation

All significant incidents must be reported promptly using the incident reporting process and escalated to the Operational Manager, Clinical Director, Medical Director or Managing Director according to severity and risk. Incidents must not be delayed because all facts are not yet known.

Incident type	Minimum internal escalation	Additional consideration
No harm / near miss	Line manager and operational lead	Local review, trend monitoring and learning.
Low harm	Line manager, operational lead and clinical lead where clinical issue	Local review and action plan if required.
Moderate harm, severe harm, death or prolonged psychological harm	Senior manager, Clinical Director / Medical Director and Managing Director	Duty of Candour assessment, external reporting consideration and formal learning response.
Safeguarding, abuse, information governance, fraud, media, service continuity or serious equipment issue	Relevant senior manager and executive lead immediately	External reporting, specialist advice and preservation of evidence.

8. Incident Review and Learning Response

The level of review must be proportionate to the actual or potential harm, likelihood of recurrence, complexity of the event and opportunity for learning. Not every

KH-CP-009 - Patient Safety Incident Response and Learning Policy

incident requires a full formal investigation, but all incidents require appropriate recording, triage and learning consideration.

- Initial triage should normally begin within 24 hours of a significant incident being reported.
- The severity, immediate actions, external notification needs and Duty of Candour threshold must be considered at triage.
- A senior reviewing manager should be appointed for significant incidents and should be sufficiently independent from the incident where possible.
- The review should focus on systems, processes, communication, equipment, environment, workload, training, human factors and governance, rather than blame.
- A final report and action plan should be completed within a reasonable timescale agreed by the senior lead. Where commissioner or contractual timescales apply, these must be followed.

Review methods may include factual chronology, after-action review, multidisciplinary case review, thematic review, audit review, contributory factors analysis, root cause analysis, SBAR summary or another recognised patient safety learning method.

9. Communication, Duty of Candour and Support

Communication with patients, relatives, carers and staff must be open, compassionate and coordinated. Where the statutory Duty of Candour threshold is met, Kleyn Healthcare must follow the Duty of Candour Policy, including verbal notification, apology, written follow-up, support and written records.

- The affected person should be told what is known, what is not yet known, what immediate action has been taken and what will happen next.
- Communication must be jargon-free, factual and adapted to the person's communication needs.
- Only authorised managers or clinicians should communicate investigation findings to patients, relatives, commissioners, media or external bodies.
- Staff affected by incidents should be offered support, debrief and signposting to further help where needed.

10. Confidentiality, Records and Evidence

Incident records are confidential and must be handled in line with UK GDPR, the Data Protection Act 2018, Caldicott principles and Kleyn Healthcare's information governance policies. Information must be shared only with those who need it for

KH-CP-009 - Patient Safety Incident Response and Learning Policy

patient safety, investigation, regulatory, contractual, safeguarding, legal or governance purposes.

- Patient identifiers should be limited to what is necessary.
- Records must be factual, dated, signed or attributable and retained securely.
- Clinical records must not be altered to hide or minimise an incident. Any correction must be made transparently in line with record keeping standards.
- Witness accounts should be obtained as soon as practicable and should be the witness's own factual account.

11. Fair and Open Culture

Kleyn Healthcare recognises that most incidents arise from a combination of system, process, environmental, communication, workload, equipment and human factors. Staff are encouraged to report concerns and incidents without fear of blame or detriment.

A fair and open culture does not remove individual accountability. Disciplinary, professional, safeguarding or police processes may be considered where there is evidence of deliberate harm, wilful neglect, gross misconduct, reckless behaviour, repeated serious breaches, dishonesty, concealment or criminal conduct.

12. Learning, Improvement and Assurance

- Learning and action plans will be shared with relevant staff through governance meetings, team briefings, training, policy updates, audit feedback or targeted supervision.
- Actions must have a named owner, due date, evidence of completion and assurance that the change has been embedded.
- Themes and trends will be reviewed through clinical governance, operational governance and Board reporting.
- Where required, learning will be shared with commissioners, host practices, external providers or other stakeholders.

13. Training and Dissemination

All staff will be made aware of this policy at induction and through periodic refresher training or briefing. Staff involved in incident review, Duty of Candour communication, governance or management responsibilities will receive additional guidance appropriate to their role.

KH-CP-009 - Patient Safety Incident Response and Learning Policy

14. Monitoring and Review

Monitoring area	Method	Frequency / oversight
Incident reporting	Incident log review, severity grading and action tracking	Monthly operational review / clinical governance
Significant incidents	Senior review, report approval and action plan assurance	As incidents occur; Board summary quarterly where appropriate
Duty of Candour	Check notification, apology, support and written records	As incidents occur
Learning actions	Evidence of completion and effectiveness check	Governance action tracker
Policy effectiveness	Audit, themes, complaints, staff feedback and external guidance changes	Annual review or sooner if required

15. References and Linked Guidance

- NHS England: Patient Safety Incident Response Framework (PSIRF).
- NHS England: Learn from Patient Safety Events (LFPSE) service and patient safety event recording guidance.
- CQC Regulation 12: Safe care and treatment.
- CQC Regulation 17: Good governance.
- CQC Regulation 20: Duty of Candour.
- Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.
- Data Protection Act 2018 and UK GDPR.
- Kleyn Healthcare Duty of Candour Policy and related governance policies.

Appendices

- Appendix 1 - Immediate Patient Safety Incident Response Quick Guide
- Appendix 2 - Patient Safety Incident Reporting Form
- Appendix 3 - Witness Statement Template
- Appendix 4 - Patient Safety Incident Review Report Template
- Appendix 5 - Risk Grading Matrix and Action Plan

KH-CP-009 - Patient Safety Incident Response and Learning Policy

- Appendix 6 - Learning and Improvement Action Log