Reporting and Learning from Near Misses, Incidents and Patient Safety Events Policy and Procedure Including Duty of Candour [Mandatory Read]

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Policy

Standard Operating Procedure (SOP)

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Policy

1 Purpose and Objectives

The Purpose of this document is to ensure that the Children's Trust continually learns from events incidents and near misses in an open and transparent culture. As an NHS commissioned service, the Trust will manage patient safety incidents and near misses in line with the NHS Patient Safety Incident Response Framework and will be compliant with requirements for the legal Duty of Candour. This policy covers management of all patient safety events, incidents and near misses within the Trust including health and safety, however it is recognised that differing methodology may be required for incidents not directly related to patient safety. Nevertheless, the ethos of the policy is consistent organisation wide in that all learning will be focussed on an open and transparent culture.

The objectives of the policy and this procedure are to:

- Establish and assign clear accountability for identifying, reporting patient safety events, incidents and near misses and learning responses at all levels of the Organisation.
- Ensure that all colleagues are aware of their individual responsibilities for incident and near miss reporting and investigations.
- Comply with the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014; Health and Safety at Work Act (1974); Duty of Candour Regulation 20, Care Quality Commission.
- To support the Trust to identify key risks or learning and take mitigating action to reduce the risk of harm to CYP, their families and staff.
- To ensure that staff employed by the Children's Trust are appropriately supported if they are involved in a near miss or incident and contribute to any learning response.
- To ensure that children and young people and their families are involved and supported during learning processes as appropriate.

Relevant laws and regulations include but are not limited to:

- Health and Social Care Act 2008
- Health & Safety at Work Act (1974)
- Provision and Use of Work Equipment Regulations (1998)
- Management of Health and Safety at Work Regulations (1999)
- CQC The duty of candour: guidance for providers (30 June 2022)
- Children Act 1989.

2 Scope

This policy applies to:

- All colleagues across The Children's Trust;

3 Definitions

Unless otherwise stated, the words or expressions contained in this document shall have the following meaning:

CYP	A child or young person. Whilst this is a patient safety policy and procedure, it is recognised that not all our children or young people are patients. Therefore, throughout this document they are referred to as CYP.
Duty of Candour	The Statutory Duty of Candour is applicable for organisations providing care commissioned by the NHS. It requires the Children's Trust to ensure that CYP/families are informed of errors causing moderate, severe harm or death resulting in services regulated by the CQC. This regulation does not include The Children's Trust School or Surrey Teaching Centre, however The Children's Trust expects the principles will be followed in all settings. The CYP and family must also be provided with support. This includes receiving an apology, as appropriate, and the investigations findings and actions to prevent recurrence are shared.
Incident Management System	The organisations electronic system used to report and manage and incidents. analyse data and produce reports (currently IRAR)
Integrated Care Board (ICB)	Integrated Care Boards (ICBs) have a responsibility to establish and maintain structures to support a coordinated approach to oversight of patient safety incident responses in all the services within their health and care system. This includes oversight of all learning from Patient Safety Incident Investigations. The TCT is unable to close a PSII without review and approval by the ICB.
Investigations	In non-patient safety incidents, it remains appropriate to use the term investigation.
Just Culture	A just culture considers wider systemic issues when things go wrong, enabling staff to learn without fear of retribution. Generally, in a just culture, inadvertent human error is not subject to sanction to encourage reporting of safety issues. In a just culture investigators principally focus on why failings occurred and how the system led to the failure. However, a just culture also holds people to account where there is evidence of gross negligence or deliberate acts. Just culture is applicable regardless of the type of event or incident.
Learn from Patient Safety Events Service (LFPSE)	This is a national NHS system for the recording and analysis of patient safety events that occur in healthcare. This supports national learning. The Children's Trust, as an NHS Provider, is required to upload key information to this national electronic system.
Learning responses	The NHS Patient Safety learning toolkit promotes a range of system-based approaches for learning from

	patient safety incidents. This replaces the previous term “investigation”.
Learning Response Lead / Investigator	These terms are used to define the person who will undertake or lead the learning response. For patient safety incidents they will be known as the Learning Response Lead. For non-patient safety incidents, they will be known as the investigator. Nevertheless, key responsibilities remain the same.
Learning Response Review and Improvement Tool	This tool supports the development of a written report and supports peer reviewers to provide constructive feedback on the quality of reports and to earn from the approach of others.
Near miss	The term near miss applies to an event which could have led to harm but was averted before any injury occurred. This may include damage to property. These serve as critical opportunities to learn, identify vulnerabilities and implement preventive measures. This term applies for incidents which are not related to patient safety
Never Event	Never Events are incidents that are wholly preventable because guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and should have been implemented by healthcare providers. These follow the same process as a patent safety event but require a higher level of scrutiny and approval within the organisation and will require notification as a PSII.
Patient Safety Incident Investigation (PSII)	A patient safety incident investigation (PSII) is undertaken when an incident or near-miss indicates significant patient safety risks and potential for new learning.
Patient Safety Incident Response Framework (PSIRF)	The National Patient Safety Incident Response Framework sets out the NHS approach to developing and maintaining effective systems and processes for responding to patient safety incidents for the purpose of learning and improvising safety. This approach may also be applicable to some non-patient safety incidents.
Patient safety event	This is any circumstance or action that could have resulted or did result to a patient while under the care of healthcare professionals. However, to make it easier for staff, all patient safety events which do not cause harm will be reportable internally and referred to within the procedure as near misses to avoid confusion.
SOP	Standard Operating Procedure
The Charity/ organisation/ TCT	means The Children’s Trust

4 Policy Statement

The Children's Trust is committed to being an open, learning organisation. The organisation will strive to enable a positive culture where staff and families feel safe to raise concerns. Processes will be in place to ensure that appropriate learning processes are completed in a timely way to enable contemporaneous learning and to monitor emerging trends. The organisation will celebrate best practice when identified.

4.1 The Children's Trust will have in place a policy and clear standard operating procedure for the management of patient safety events or incidents

4.2 All staff from floor to Board will be appropriately trained, supported and given appropriate time to fulfil their role.

4.3 Robust governance processes will be in place to ensure that risks are appropriately escalated, and that learning is shared across the organisation.

4.4 The Children's Trust will have processes in place and staff will be supported to carry out Duty of Candour and compliance with national legislation will be monitored.

4.6 When a patient safety event, occurs CYP and their families will be supported. A just culture approach will be used to look at what happened and support our staff.

4.6 Processes will be in place to ensure that when a patient safety event / incident occurs which is required to be notified externally to the organisation, it occurs within expected timescales and, when necessary, the organisation will work alongside other key agencies to support learning or an external investigation.

5 Stakeholder Consultation

Key stakeholders who contributed to design of the revised procedure include:

- Director of Nursing and Quality
- Medical Director
- Director or Therapies
- Head of Clinical Support and Education / Interim Patient Safety Lead
- Bank Patient Safety Lead
- Head of Nursing
- Head of Audit and Risk
- Risk and Assurance Manager
- Infection Prevention and Control lead
- Head of Health and Safety
- Clinical Quality and Compliance Manager
- Head of Rehab Therapies
- Lead Analyst and Impact Manager
- Doctors
- Safeguarding team
- House Managers
- Headteacher
- Human Resources
- Lead Pharmacist

Additional stakeholder engagement is listed in appendix 9

6 Related Policies and Procedures

The following policies and procedures stated below support the effective application of this policy and SOP:

- Confidentiality Policy
- Health and Safety Policy and Procedures
- Human Resources disciplinary procedure.
- Organisations Emergency Procedures
- Patient Safety Incident Response Framework Policy
- Record Keeping Policy
- Risk Management Policy
- Safeguarding and Child Protection Policy and SOP
- Sudden Unexpected Death of a Child Policy

7 External References and Guidance

The following external resources and guidance were consulted in drafting this policy and SOP:

- Patient Safety Incident Response Framework (NHS England online resources).
- Regulation 20: Duty of Candour (Care Quality Commission)
- Health and Social care Act 2008 (Legislation.gov.uk)
- Never Events Policy and Framework (NHSE, Revised January 2018)
- Keeping Children Safe in Education Statutory Guidance for Schools and Colleges (Dept for Education September 2024

Standard Operating Procedures (SOP)

1 Roles and responsibilities

The **Board of Trustees** is responsible for:

- Providing senior leadership to embed and monitor application of this policy
- Supporting a positive patient safety culture organisation wide.
- Ensuring all Board members are trained at an appropriate level relating to patient safety

The **Chief Executive** is responsible for:

- Ensuring that notification if made to the Charity Commission if required.
- Ensuring that this policy and procedure is appropriately applied organisation wide.
- Ensuring that all members of the organisation are trained, supported and have time for patient safety elements of their role.
- Supporting a positive patient safety culture organisation wide.

The **Director of Nursing and Quality** is responsible for:

- Providing overarching leadership for the clinical governance portfolio
- Advising the Clinical Governance and Safeguarding Committee and Board of Trustees, in relation to all seven pillars of clinical governance and regulatory compliance.
- Leading on the seven pillars of clinical governance for the organisation including the management of complaints, incidents, inquiries, and investigations (through PSIRF framework) ensuring that the outcomes from these inform continuous improvement in the quality of services provided.
- Lead on the organisational attendance and content at all external reviews following incidents within TCT including child death processes, ICB closure panels and inquests.
- Through PSIRF, promote a transparent culture in the management of complaints, incidents, inquiries, and investigations ensuring that the outcomes from these inform continuous improvement in the quality of services provided.

All **Directors** are responsible for:

- Ensuring that this policy and procedure is applied correctly across their directorate.
- Ensuring that all staff within their Directorate have the appropriate level of training, support and time to commit to their role, including learning from events / incidents
- Supporting a positive safety culture organisation wide and that staff are supported to report actual patient safety events / incidents and near misses.
- Ensuring that all staff experience a just culture when involved in an incident.
- Ensuring that a multiprofessional approach to learning is supported organisation wide
- Ensuring that learning pertinent to their directorate is embedded and monitored appropriately
- To ensure that staff within their directorate understand and can undertake Duty of Candour as appropriate to their role.
- Ensuring that CYP and their families are supported and appropriately involved in learning events.

The **On Call Director** is responsible for:

- Providing an on-site presence if required
- Ensuring this Procedure is followed.
- Ensuring that safety has been restored or the event or risk mitigated as far as reasonably practicable.
- Managing external agencies on site
- Managing any media interest
- Reporting to the Chief Executive and other relevant Directors at the earliest opportunity.

All **Managers** are responsible for:

- Supporting a positive safety culture by ensuring that their staff are appropriately trained, supported and have time to commit to their role, including learning from events / incidents and near misses.
- Ensuring that staff experience a just culture when involved in an incident.
- Ensuring that staff understand Duty of Candour and to support or staff or undertake Duty of Candour as appropriate to role.
- Ensuring that learning applicable to their service is embedded and to escalate any concerns or risks.
- Ensuring that CYP and their families are supported and appropriately involved in learning events.

The **On-call Manager** is responsible for:

- Providing an on-site presence in the event of a patient safety event / incident which is likely to meet the Patient Safety Incident Investigation (PSII) threshold or which, in their professional opinion, requires a presence.
- Ensuring that safety has been restored or the event or risk mitigated as far as reasonably practicable.
- Ensuring that the notes have been photocopied if a CYP has gone to hospital as a result of the incident.
- Collecting contemporaneous information and information from staff
- To ensure that this policy and procedure are followed
- Ensuring that the incident is reported on the incident management system (IRAR)
- Notifying the family / carer and supporting as able. This includes an assessment of whether the manager deems that formal Duty of Candour is required.
- Supporting staff.
- Notifying the Director on call if appropriate.

The **CQC Registered Manager** is responsible for:

Making statutory notifications of Patient Safety Incident Investigations to the Care Quality Commission within statutory timescales.

The **Clinical Governance Team** will be responsible for:

- Daily oversight (weekdays) of the application of the policy and procedure
- On weekdays will review all newly reported near misses or incidents and provide additional expertise or escalation as required.
- Providing expertise to learning responses as required.

- To prepare information on the near misses or incidents to be discussed at weekly patient safety event and incident review meeting.
- To provide expertise and support to investigators who are leading responses.
- To monitor the progress of learning responses and subsequent actions via the incident management system and escalate to Manager / Director Level, as required, regarding any delays.
- To initially quality assure all reports relating to After Action Reviews, Root Cause analysis, Patient Safety incident Investigations and ensure that all final drafts are approved by the appropriate governance route.
- To regularly review how the policy and procedure is being applied and provide appropriate reporting via the agreed clinical governance route.
- To work collaborative with the Integrated Care Board to provide assurance as to how the policy and procedure are working in practice and provide anonymised reports as appropriate.
- To ensure that patient safety events are appropriately reported via the national LFPSE service
- To work collaboratively with the ICB Patient Safety team, engaging in system wide and regional learning processes
- To Ensure that PSIIs are submitted to the ICB patient safety team and attend system wide closure meetings.

The Safeguarding / Infection Prevention and Control / Health and Safety Leads / Lead Pharmacist and Designated Safeguarding Lead (school) are responsible for:

- Providing relevant expertise to determine whether external notifications such as the UK Medicines and Healthcare products Regulatory Agency (MHRA), Local Authority Designated Officer, Integrated care Board or the Health and Safety Executive are required and undertake the notifications.
- Provide relevant expertise or leading learning events / investigations as appropriate
- To quality assure relevant learning / investigation reports prior to submission for closure via governance routes.
- Monitoring trends and identifying risks and mitigation for their area of expertise.
- Any other statutory functions as appropriate to their individual role.

The Learning Response Lead or Investigator is responsible for:

- Timely completion of the learning response or investigation
- Updating the incident management system (IRAR) as appropriate throughout the learning / investigation.
- Informing line manager if work capacity will impact on completion of investigation and agree a way forwards.
- Alerting clinical governance team and relevant lead (above) of potential delays.
- Using PSIRF methodology for all patient safety events.
- Involving staff appropriately in the learning and supporting them
- Engaging CYP / family as appropriate.

All Staff are responsible for:

- Following this policy and procedure
- Attending training when advised by their line manager
- Informing their line manager at the time of risks which may lead to an incident, any near misses and patient safety events / incidents.

- Completing the risk management system notification (IRAR).

2 Procedure

2.1 Identification of a near miss or patient safety event / incident

- If appropriate, take immediate actions to treat the CYP or person affected, following the organisations emergency procedures as applicable.
- If appropriate ensure the area is made safe.
- Inform the parent / family / guardian as necessary and document in CYP records.
- Inform line manager / person in charge.
- Complete your records as appropriate.

2.2 Immediately after initial management

- Record on incident management system (IRAR) as soon as possible - all clinical incidents by end of shift. Other incidents by 24 hours at the latest. Information must include all safety actions and whether a conversation had been had with parents / family / guardian / child's social worker and documented in records. The IRAR information must include the date and time of conversation (being open – see Appendix 1).

- If the incident management system is not available, a printable incident form is available on the loop.

- Person in charge or line manager will ensure that all immediate actions have been taken and whether additional immediate internal escalation is required e.g. specialist, for example safeguarding / health and safety / Lead Pharmacist or senior manager / director level (including on call).

- The Person in charge will consider whether formal Duty of Candour needs to be considered. The clinical governance team can assist in this decision making. (See Appendix 1 and 2)

- Early learning is essential and should begin at this point with a record kept of all learning and actions using the incident management system. Key learning will be evident at this time, and it is essential to capture this on the incident management system even if it is apparent that a more in-depth learning methodology will be required as per PSIRF.

- Support to the CYP, family, person affected, and staff is essential early after the event / incident.

- In a very small number of cases consultation with the Human Resources Business Partner regarding application of the disciplinary policy may be required and should occur as soon as the concern is identified.

2.3 If escalation is required

- An escalation call can be held either out of hours or on the next working day as appropriate. (See appendix 5 for checklist)

- This meeting will look at:

- whether the initial learning and actions were appropriate or whether further actions need to be taken.
- Whether additional escalation or external notification is required.
- Whether internal escalation is now evident based on any new information.
- Whether formal Duty of Candour is required.
- Does a statutory notification need to be made? (See section 4)
- Key salient points will be recorded on the incident management system

- Decisions and actions will be recorded on the incident management system as soon as posible

2.4 Weekly Review

- All new incidents and near misses will be reviewed at the weekly patient safety event and incident review meeting

- This meeting will review:
  - Progress so far
  - Actions taken
  - Whether Duty of Candour is required and check if undertaken; (See appendix 1 and 2)
  - agree learning methodology and lead investigator for more complex events if not already agreed
  - Consider additional immediate actions or further escalation
  - Is formal notification required? (see section 4)

- Appendix 6 can be used if the incident management system is not available

2.5 Learning Response / Investigations.

- An initial learning response / investigation should take place as soon as practicable after the event. However, a more detailed response may be required. The type of response will be determined by the nature of the event and, patient safety events will be in line with the National Patient Safety Incident Response Framework. Internal timescales for completion of learning and closure routes have been defined as follows in figure 1:

Figure 1

Learning Response	**Timescale for completion**	**Governance route for final closure**
Incidents with local actions only – no further learning response	Should be closed within 14 days of the date of incident report.	Service manager
After Action Reviews	The meeting should take place no later than 14 days after the incident report and the report should be completed within a further 14 days.	Monthly incident / patient safety event review meeting
Thematic or Multidisciplinary team reviews	Report be completed within 3 months of the date incident reported	Via appropriate governance route e.g. medicines management then clinical governance meeting.

Patient Safety Incident investigations	Report should be completed within 3 months of the date incident reported	Clinical governance meeting via Monthly incident / patient safety event review meeting
Root cause analysis	Report should be completed within 3 months of the date incident reported	If patient safety related: via Monthly incident / patient safety event review meeting, then clinical governance meeting Non patient safety: via Monthly incident / patient safety event review meeting then clinical Governance Meeting. The final report may also be reported at an additional appropriate senior governance meeting which will be agreed specifically dependent on nature of incident.

- On rare occasions an investigation or learning response may require additional time to reach a conclusion and produce a report. This cannot be assumed by investigators and extensions can only be granted via the Monthly incident patient safety event review meeting and with the approval of the Director of Nursing. A short summary of the delay and plans to complete the report must be provided in writing with the request. Extensions to timescales for PSIIs should also be discussed with the ICB Patient Safety Team.

- A checklist to support Learning Response Leads /Investigators to consider key aspects of the process, responsibilities and Duty of Candour requirements is in Appendix 7. This must be completed at the start of any learning response and updated as appropriate throughout the process

- The Learning Response Lead should also refer to the NHSE Learning Response Review and Improvement tool when writing their report.

- Completed draft reports for patient safety events will be submitted by the Learning Response Lead to the Clinical Governance Team for initial review prior to governance for closure.

- Other investigations or learning events may require review by relevant specialist prior to closure e.g. Health and Safety, Infection prevention and control, safeguarding.

Closure

- All reports will be completely anonymised. On rare occasions families request to have their child's or their own first names used. This must be specifically stated at the start of the report

- When considered for closure, all patient safety event reports will be considered using the NHS Learning Response Review and Closure Tool.

- Reports will be submitted via the appropriate governance route for internal closure (see figure 1).

- PSII reports are closed by the Integrated Care Board but must proceed through internal governance prior to this.

- As appropriate reports for notified events / incidents will be shared with relevant agency.

2.6 Post closure learning

This will be shared as appropriate via a variety of ways. This may be specific to the area where the incident occurred or may have implications for wider organisational learning. This should be considered by the Learning Response Lead / investigator and the governance closure process.

3.0 Governance

3.1 Internal governance arrangements up to and including the Board (as appropriate) will:

- Formally approve learning response reports as appropriate to the meeting / Committee.
- Monitor numbers and trends of incidents and compliance with timescales within this procedure and seek additional assurance when required.
- Monitor compliance with Duty of Candour requirements.
- Monitor quality of reports as appropriate to meeting.

3.2 Key learning such as PSII investigations will be shared with Commissioners

3.3 The independent Visitor who attends to meet the requirements of Regulation 44 of the Children's Home regulation 2015 reviews the incident reports within the Children's Trust Houses and includes the findings in the monthly report. A copy is retained and made available to Ofsted Inspectors and will be circulated to the Board of Governors.

4.0 Statutory Notifications

4. 1 Care Quality Commission

4.2 The following notifications are required by law to be reported to the Care Quality Commission / Ofsted by the Registered Manager.

- Death of a child / young person that occurred whilst services were being provided. In the Children's Trust school, all deaths must be reported to the Minister of Education (see End of Life Policy).
- Any abuse or allegations of abuse – abuse in relation to the child / young person means sexual, physical, psychological ill treatment, theft, misuse or misappropriation

of money or property, or neglect and acts of omission which cause harm or place at risk of harm (see safeguarding policy).

- Events that stop or may stop the service from running safely and properly - a level of staff absence or vacancy, or damage to the service's premises that mean that people's assessed needs cannot be met; the failure of a utility for more than 24 hours; the failure of fire alarms, call systems or other safety-related equipment for more than 24 hours; and other circumstances or events that mean the service cannot, or may not be able to meet service user assessed needs safely.
- Serious injuries to people who use the service which include injuries: that lead to or are likely to lead to permanent damage or damage that lasts or is likely to last more than 28 days; injuries or events leading to psychological harm.
- Where there is any incident relating to a child which the Registered Manager considers to be serious.
- **The person involved must only be identified by the use of initials**

4.3 Medicines and Healthcare Products Regulatory Agency (MHRA)

4.4 The incident will be reported as a medication incident and the Lead Pharmacist is responsible for ensuring that, if appropriate, a MHRA yellow card is completed

4.5 Infection outbreak

4.6 Refer to M1 Medical Emergency Incident – Major Outbreak

4.7 Reporting of Injuries, Diseases and Dangerous Occurrences (RIDDOR 2013)

4.8 Refer to Health and Safety Policy.

4.9 Local Authority Designated Officer

4.10 Refer to Safeguarding policy

4.10 Death of a child

4.11 Refer to sudden death of a child policy

4.12 Child placement

4.13 The Local Authority placing the Child and the Designated Nurse for Looked After Children in the placing ICB should be notified.

4.14 Charity Commission

4.15 Thresholds for referral to the Chrity Commission are:

- Harm to your charity's beneficiaries, staff, volunteers or others who come into contact with your charity through its work (who are collectively referred to throughout this guidance as people who come into contact with your charity through its work)
- Loss of your charity's money or assets
- Damage to your charity's property
- Harm to your charity's work or reputation

For the purposes of this guidance, “significant” means significant in the context of your charity, taking account of its staff, operations, finances and/or reputation.

4.16 Apparent criminal incidents will be reported to the Police. These may include assaults, actual or threatened, theft vandalism, suspicious activity or unexpected deaths.

An electronic incident form must be completed for all incidents involving the Police.

5.0 Monitoring and Audit

5.1The policy will be monitored by the following indicators:

- All investigations will be within procedure timelines unless an extension is granted
- Compliance with Duty of Candour
- Routine governance sign off for learning events at appropriate levels, including meeting ICB timescales for PSIIs
- Trend analysis
- Appropriate governance meetings will ensure that actions are completed within timescales and that assurance is reviewed and provided.

6.0 Review

6.1 This policy and procedure will be reviewed at intervals not exceeding 3 years, or more frequently is there are significant Organisational procedure changes or Statutory policy change.

Document Change Control

Version	Status	Description (of changes)	Reviewed by	Reviewed/ Issued Date
0.1	Draft	Policy and procedure completely rewritten and named to reflect: • national changes relating to the Patient Safety Incident Response Framework in terms of methodology, terminology for patient safety events and cultural work. • Internal business needs in terms of governance and assurance. • Internal business needs in terms of addressing challenges and gaps in existing process. • Tools have been added to the appendices to aid the process and quality of learning.		
0.2	Draft	Minor revisions following review by critical readers		
0.3	Draft	Minor changes to MHRA reporting following clinical governance meeting		
1.0	Final	Approved	CGSC	March 2025

Appendix 1 Being Open / Duty of Candour

'Being open' begins with the detection of an event. The first step of the process if the recognition of an incident and when the level of harm dictates that is appropriate to apply the 'Duty of Candour' approach. *The response should be graded by the level of severity of the event.*

Staff are encouraged to apologise when things go wrong, offering sympathy and demonstrating a caring attitude. An apology is not an admission on liability. The Duty of Candour Policy does not require prevented patient safety incidents to be reported to CYP / parents. The decision of whether to communicate these depends on local circumstances and advice can be sought form a line manager

The Statutory 'Duty of Candour will apply to moderate, severe harm or death incidents. These should be graded using the matrix below

Grade of incident	National Patient Safety Definition	Actions
No harm (including prevented patient safety incident/near miss)	Incident prevented that had potential to cause harm but was prevented and no harm caused. Incident not prevented and occurred, but no harm was caused.	Children/parents are not usually contacted or involved in investigations and these types of incidents are outside the scope of Duty of Candour. It is decided locally whether 'no harm' events (including prevented patient safety incidents) are discussed with parents, their families and carers, depending on local circumstances and what is in the best interest of the child.
Low harm	Any safety incident that required extra observation or minor treatment and caused minimal harm. Minor treatment is first aid, additional therapy or additional medication.	Unless there are specific indications or the parent requests it, the communication, investigation and analysis of the event, and the implementation of changes will occur at local level with the participation of those directly involved in the event. Reporting to the Clinical Governance team will occur through standard incident reporting mechanisms and be analysed centrally to detect high frequency events. Review will occur through aggregated trend data and local investigation. Where the trend data indicates a pattern of related events, further investigation and analysis may be needed. Communication should take the form of an open discussion between the staff. Low incidents are outside the scope of Duty of Candour but staff should apply the principles of being open.
Moderate harm	Any safety incident that results in a moderate increase in treatment and / or caused significant but not permanent harm Moderate harm may also be caused by negligent acts or omissions.	A higher level of response is required in these circumstances. Once the level of harm is validated to be moderate or higher, the 'Being Open' process should be applied. **Apply the Duty of Candour process**

	Moderate increase in treatment is transfer to hospital as in an inpatient or outpatient or prolonged episode of additional care	
Severe, significant harm or death	Any safety incident that directly results in death. Serious harm to one or more children, 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 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, adverse media coverage or public concern about the organisation One of the core sets of 'Never Events' outlined by the NPSA	A higher risk of response is required in these circumstances. The Director of Nursing and Quality, Medical Director and Director of Therapies should be notified immediately and be available to provide support and advice during the *Being open* process if required. **Apply the Duty of Candour process**

Duty of Candour Process

See flow chart Appendix 2

The regulation states that you must:

1. Tell the relevant person, face-to-face, that a notifiable safety incident has taken place.
2. Apologise.
3. Provide a true account of what happened, explaining whatever you know at that point.
4. Explain to the relevant person what further enquiries or investigations you believe to be appropriate.
5. Follow up by providing this information, and the apology, in writing, and providing an update on any enquiries.
6. Keep a secure written record of all meetings and communications with the relevant person.

Identifying who should be responsible
In determining who will be responsible for communicating with the child/ family carers the individual should:

- Have a good relationship with the child and / or their parents
- Have a good understanding of the relevant facts
- Be senior enough or have sufficient experience and expertise in relation to the type of incident to be credible to the child, parents and colleagues
- Have excellent interpersonal skills, including being able to communicate with children and / or their parents in a way they can understand
- Be willing and able to offer an apology, reassurance and feedback to the child and /or their parents.
- Be able to maintain a relationship with the child and / or their parents and to provide continued support and information
- Be culturally aware and informed about specific needs of the child or their parents

When should the initial discussion be held?
The initial Duty of Candour discussion with the child and / or their carers should occur as soon as possible after recognition of the incident. Delay in disclosure should be avoided whenever possible. If the incident occurs out of hours, it may be necessary to wait until a senior member of the team is available to contact the parents. The communication can occur by any appropriate means – face to face is best, but it can be a telephone call or e-mail to those parents who prefer this method of communication.

Initially, it is worth noting that something has gone wrong but that the cause is not yet known. It must be communicated to the child and their family/ carers that we will be taking the event extremely seriously, that the event will be investigated and that the findings of the investigations will be shared with them.

This initial communication must be recorded in the child's records with a heading 'Duty of Candour Meeting'. Date, time and people present or taking part in the phone call. Outline the apology, what was discussed, concerns raised by the family and arrangements for future communications and support.

An offer to meet should be made to the family, this is usually at the end of the investigation so the findings can be shared and discussed but may also occur before the investigation starts or during the

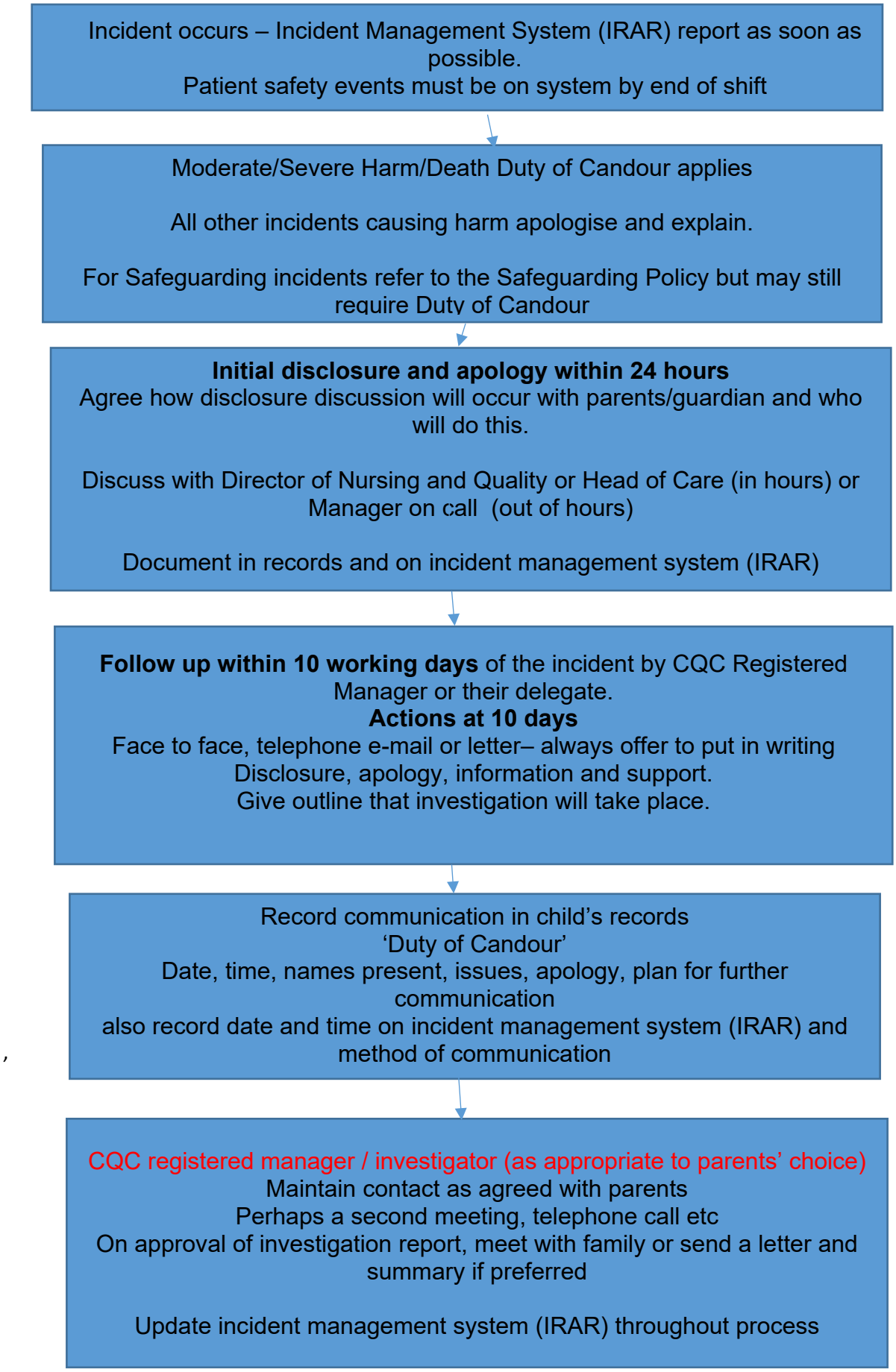
process. The approach is agreed with the family, and this may change at any stage during the investigation.

Factors to consider when timing this discussion include:

- Some families may require more than one meeting to ensure that all the information has been communicated to and understood by them.
- Availability of key staff involved in the incident and in the Duty of Candour process.
- Availability of the child's family and / or carers
- Availability of support staff, for example a translator or independent advocate, if required
- Arranging the meeting in a sensitive location.

Written information regarding the content of this meeting must be given to the family.
See Appendix 3 and 4 for Letter templates

Appendix 2 Duty of Candour Flow Diagram



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Appendix 3 Duty of Candour Letter template *(letters should be adapted for the circumstances).* This template contains the bare minimum of information required to comply with Duty and Candour but should be stylised to fit with conversation with parents according to individual circumstances. This should be written on The Children's Trust headed paper

Dear [name]

I am writing following the conversation you had with *insert name* on *insert date.*

I would like to express my sincere apologies that your son/daughter *insert name* has been involved in an event – *insert details.*

I would like to assure you that we are taking the event very seriously and we are undertaking a patient safety incident investigation in order to understand exactly what happened and, once this is completed, we would like the opportunity to discuss our investigation and findings with you.

The initial patient safety event learning may take up to 45 working days to complete and there may be several learning actions that come out of the investigation. There may also be additional information that comes to light as the investigation proceeds and we have agreed that we will contact you via telephone/e-mail / letter *(delete as appropriate)* to ensure you are kept informed.

When our investigation is complete, we will contact you to arrange a mutually convenient time to discuss our findings. *Insert name of investigator* is leading the investigation and you can contact them on xxxxxxx or by e-mail xxxxxxxx.

If there is anything else, you would like to mention to assist us with our investigation please do contact *name of investigator.*

Yours sincerely

Name

CQC Registered Manager

Add contact details

Appendix 4 Summary letter Duty of Candour

This template contains the bare minimum of information required to comply with Duty and Candour but should be stylised to fit with conversation with parents according to individual circumstances. This should be written on the Children's Trust headed paper

Dear

Further to the letter sent to you on *insert date*, I am writing following the completion of the investigation into *(give details of the patient safety event)*. I would also like to thank you for meeting with *insert name* to discuss the findings and recommendations of the investigation.

I and the staff at The Children's Trust are very sorry for any suffering and distress caused as a result of this patient safety event. I wish to assure you that we have conducted a full and thorough investigation and have learnt from the events surrounding *insert child's name.* As a result of the investigation, we have agreed to implement the following actions:

Insert learning actions

I would like to thank you for bringing this matter to our attention / your assistance with our learning (*delete as appropriate)* with our investigation and once again, apologise for any distress this has caused *name of child* and you.

If you have any further questions, please do not hesitate to contact me.

Yours sincerely

Name

CQC Registered Manager

Add contact details

Appendix 5 Rapid Review Report for urgent escalation call

Date/Time/Location of Incident	
Incident type	Accident/Incident Medication Behavioural Health and Safety Safeguarding Other
Verbal summary of what has happened	
Immediate actions taken including actions to mitigate any further risk, including safety actions	
Update on CYP or individual's status	
Any additional escalation required? E.g. safeguarding subject matter specialist, on call director	
Does this meet Duty of Candour requirements – see annex 1	
Details of contact with or planned contact patient/family or carers. Including Duty of Candour	
Details of any police or potential media involvement/interest	
Details of any immediate learning **Add to incident management system**	
Plans to support the staff involved	
Details of other organisations/individuals to be notified or already notified	Date Ofsted informed: Date CQC informed: Date statutory SW informed:
Report completed by **Designation** **Date / time report completed**	

Appendix 6 Template for individual incident review at Weekly patient safety event and incident review meeting - this form is to be used if the incident management system is not available.

Date/Time/Location of Incident	
Incident type	Accident/Incident Medication Behavioural Health and Safety Safeguarding Other
Verbal summary of what has happened	
Immediate actions taken including actions to mitigate any further risk, including safety actions	
Update on CYP or individual's status	
Any additional escalation required? E.g. safeguarding subject matter specialist, on call director	
Does this meet Duty of Candour requirements – see annex 1	
Details of contact with or planned contact patient/family or carers. Including Duty of Candour	
Details of any police or potential media involvement/interest	
Details of any immediate learning **Add to incident management system**	
Plans to support the staff involved	
Details of other organisations/individuals to be notified or already notified	Date Ofsted informed: Date CQC informed: Date statutory SW informed:
Type of learning response required	
Additional terms of reference if required	

Appendix 7 Checklist for Learning Response Lead / investigator

	Notes
Are you clear on the Type of learning response or investigation and specific terms of reference?	
Are you clear on timescales?	
What information do you need to use to inform your learning e.g. records, body map, conversations with staff? Current policies and procedures? Current organisational risks? Incident / event trend analysis?	
Are you clear about whether there have been any external notifications?	
Who is the contact with the CYP / family?	
Is Duty of Candour appropriate and has it been undertaken?	
How will you involve the young person or family and keep them updated?	
How will you involve the staff and keep them updated?	
Do you have the correct template to write your report?	
Have you discussed any actions with the manager / Director who will be required to implement them and are they SMART *(specific, measurable, achievable, relevant and timebound).*	
Have you checked to ensure that your report is completely anonymised. This includes not using initials to identify staff, professionals, family or the CYP. The house should also not be identified. If the family request that that child or family first names are used this should be explicit at the start of your report.	

Appendix 8 – Stakeholder Engagement

Review and complete the following checklist to indicate which stakeholders were consulted in the development of this policy.

#	Question	Yes/ No	Stakeholder(s) to be consulted
1	Is there a statutory requirement to have in place this particular policy/ does the policy need to comply with detailed legislation?	Yes	Audit, Risk and Governance team
2	Is implementation of the policy (or any element of it) dependent on the use of new or existing information technology?	Yes	To work effectively and meet commissioning expectations this requires an effective incident management system which is currently being considered by the TCT. The clinical governance team are working with IT to consider appropriate systems.
3	Does implementation of the policy (or any element of it) place any demands on/ or affect the activities of the Estates and Facilities teams (e.g. does it impact the provision or maintenance of premises, equipment, vehicles or other TCT assets)?	Yes	Incident learning may involve learning about estates. Head of Health and Safety has contributed to development of this policy.
4	Does implementation of the policy or any element of it involve/ impact the processing of personal data?	Yes	Data Protection Officer
5	Does implementation of the policy require significant unbudgeted operational or capital expenditure?	Yes	To work operationally effectively and meet commissioning expectations this requires an effective incident management system which is currently being considered by the TCT. A business case is being developed for SLT.
6	Does implementation of the policy (or any element of it) directly or indirectly impact on the delivery of services / activities in other areas of the organisation? E.g. a policy written by a clinical lead in CF&S might impact on the delivery of care for CYP attending the School.	Yes	Relevant, OLT members and key specialists for related policies have been part of design and review. E,g, clinical leads
7	Is there a need to consider Health and Safety or potential environmental impacts in developing and implementing the policy?	Yes	Health and Safety Manager contributed to development of policy
8	Have you consulted with a representative of those who will be directly impacted by the policy?	Yes	
9	Is there a need to consider Equity, Diversity and Inclusion in developing and implementing the policy?	No	This is based on national statute and NHSE requirements which have EDI assessment.
10	Is there a need to consider sustainability and potential environmental impacts in developing and implementing the policy?	No	
11	Please detail any other stakeholder groups consulted, if applicable.	Within document.	