NHS
Cambridgeshire and Peterborough
NHS Foundation Trust

BEING OPEN AND DUTY OF CANDOUR POLICY

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AUTHOR’S CHECKLIST

Document Title:	Being Open and Duty of Candour Policy
Secretariat Index Number:	PS01

To be completed when reviewing existing published documents

	Consideration for all documents	Y/N	Action to be taken	
			‘Yes’	‘No’
1.	Is the document still required?	Y	Go to question 2.	Arrange document removal with the Executive Lead/Approval Group and inform the Corporate Governance Team (corporateoffice@cpft.nhs.uk)
2.	Has there been any change in guidance or national policy since the previous version?	Y	Go to question 4.	Go to question 3.
3.	Can Executive authorisation (only) be granted if ***minor*** changes have been made to the document?	Y	Executive lead to approve new review date by email. Update dates on the document and send the updated document and Exec email to the Corporate Governance Team (corporateoffice@cpft.nhs.uk)	Go to question 3.
4.	Can formal ratification be granted if ***major*** changes have been made to the document?	Y	Agree content at Level 1 Specialty Oversight Group. Seek Approval at Level 2 Exec Led Approval Group.	Go to question 3.

VERSION CONTROL SUMMARY

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V1.2	Apr 2013	Interim Risk Manager			
V4.0	Nov 2023	Patient Safety & Complaints Team	Addendum added at the end of the Policy		

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1.0 INTRODUCTION

1.1 Duty of Candour has proven to make an important contribution to creating a culture of openness, transparency and honesty which always places the safety and the needs of the patient and family above the reputation of the organisation.

1.2 Until 2014, there was no legal duty on care providers to share information with the people who had been harmed, or their families. What is needed is a culture of openness and honesty, stimulated by a Duty of Candour, which is wholeheartedly adopted by organisations and individuals. This will enable our patients to be reassured that when things go wrong, we will learn, and we will improve. (Dalton Review 2014).

1.3 There are two types of Duty of Candour: statutory and professional. Statutory Duty is regulated by CQC, and professional Duty is overseen by professional bodies.

1.4 Statutory Duty of Candour was brought into law in 2014 for NHS Trusts and 2015 for all other providers and is now seen as a crucial, underpinning aspect of a safe, open and transparent culture. This was introduced legally as a direct response to Recommendation 181 of the Francis Inquiry report (2013) into the Mid Staffordshire NHS Foundation Trust.

1.5 This organisational duty requires health providers to act in an open and transparent way. It includes all aspects of statutory Duty of Candour (DoC) and, in addition, the actions which providers must undertake when the threshold of a 'notifiable safety incident' (definition in section 4.1) is reached. These are as follows:

- Carry out a thorough review into the causes of the incident and share relevant details and findings with the patient and/or relevant other.
- Provide an apology in writing, following the verbal apology in person.
- Provide reasonable support to the patient in relation to the incident.
- Establish a formal and defined process.

1.6 Thereby, following the occurrence of a notifiable patient safety incident of moderate (physical/ psychological) harm, severe (physical/ psychological) harm or fatal harm/death, we, at Cambridgeshire and Peterborough NHS Foundation Trust (hereafter referred to as 'the Trust or CPFT') are required to fulfil responsibilities under CQC Regulation 20.

1.7 The professional Duty of Candour is explicitly stated by the professional bodies governing Trust's clinical staff including the General Medical Council (GMC), the Nursing and Midwifery Council (NMC) and the Healthcare Professions Council (HCPC).

2.0 PURPOSE

2.1 CPFT's Being Open and Duty of Candour Policy is aimed to ensure that patients, their families and/or their carers', and staff, all feel supported when a patient safety event occurs

or when things go wrong. This Policy aims to improve the quality and consistency of communication with patients, their families and/or their carers when a patient safety event occurs.

2.2 This Policy provides guidance on how a meaningful apology should be offered. NHS Resolution (2017) describe that 'saying sorry' meaningfully when things go wrong is vital for everyone involved in an incident, including the patient, their family, carers, and the staff that care for them. 'Saying sorry' is always the right thing to do and is not an admission of liability and acknowledges that something could have gone better.

2.3 This Policy is designed to provide clear information to staff on what they do when they are involved and the support available to them to cope with the consequences of what happened and to communicate with patients, their families and/or their carers effectively.

3.0 SCOPE of this POLICY

3.1 This policy is applicable to incidents in which patients and staff at the Trust are directly involved.

3.2 CPFT promotes staff to report all patient safety events, including those where there was no harm or it was a prevented patient safety event ('near miss').

3.3 This policy only relates to those incidents where patients have been harmed as a result of the incident, the level of harm is moderate (physical or psychological), severe (physical or psychological) or has resulted in fatal harm or patient's death, and where things have gone wrong.

3.4 CPFT recognises that such unexpected or unintended patient safety event(s) may be the subject of a complaint or a claim as well as requiring incident investigation and that the principles of 'Being Open and Duty of Candour' apply across all these processes.

4.0 DEFINITIONS

4.1 Notifiable Patient Safety Incident

4.1.1 The definition of a 'notifiable safety incident' which will trigger the Duty of Candour, is any unintended or unexpected incident in the provision of a regulated activity which, in the reasonable opinion of a healthcare professional, could result in, or appears to have resulted in or requires treatment to prevent:

- Fatal Harm/death or
- Moderate physical harm and/or
- Moderate Psychological harm or
- Severe physical harm and/or
- Severe psychological harm

4.1.2 When there are multiple patients or service users involved, the Duty of Candour applies to all individuals involved.

4.1.3 There will be exceptions to implementing the Duty of Candour, such as it may cause unacceptable additional distress/mental health issues to the individual or when the Trust may be required to await advice or guidance of the Trust's legal team, especially when criminal proceedings may be underway. These must be very sound reasons, which must be clearly recorded, for not having the Duty of Candour principles applied.

4.2 **Degree of Harm Definitions**

4.2.1 Patient safety incident harm definitions should always be applied based on the best information about the actual impact of the incident at the time of recording.

4.2.2 The National Reporting and Learning System (NRLS) guidance is being superseded by the Learn from Patient Safety Events (LFPSE) service. This service will allow capture of information on psychological harm. Previously in the NHS, harm grading included psychological harm as well as physical harm within one measure. Following feedback from staff, patients and families, physical and psychological harm have been separated out and each can now be recorded in the LFPSE service.

4.2.3 Where practical, it is good practice to discuss the degree of harm with the patient affected and to consider the patient's perspective on the harm definitions. The table below is adapted from LfPSE policy guidance document published in April 2023:

Table 1. Degree of Harm grading, LfPSE guidance 2023

Physical harm grades	Definition	Psychological harm grades	Definition	Being Open/ DoC
No physical harm	No physical harm occurred.	No psychological harm	Staff should only use 'no harm' if they are not aware of any specific psychological harm	Being Open
Low physical harm	Is when **all of the** following apply: Minimal harm occurred -patient(s) required extra observation or minor treatment. -Did not or is unlikely to need further healthcare beyond a single GP, community care, emergency department (ED) or clinic visit. -Did not or is unlikely to need further treatment beyond	Low psychological harm	Is when **at least one** of the following apply: -Distress that did not or is unlikely to need extra treatment beyond a single GP, community care, ED or clinic visit. -Distress that did not or is unlikely to affect the patient's normal activities for more than a few days.	Being Open

Physical harm grades	Definition	Psychological harm grades	Definition	Being Open/ DoC
	dressing changes or short courses of oral medication. -Did not or is unlikely to affect that patient's independence. -Did not or is unlikely to affect the success of treatment for existing health conditions.		-Distress that did not or is unlikely to result in a new mental health diagnosis or a significant deterioration in an existing mental health condition.	
Moderate physical harm	Is when **at least one** of the following apply -Has needed or is likely to need healthcare beyond a single GP, community care, ED or clinic visit, and beyond dressing changes or short courses of medication, but less than 2 weeks additional inpatient care and/or less than 6 months of further treatment and did not need immediate life-saving intervention. -Has limited or is likely to limit the patient's independence, but for less than 6 months. -Has affected or is likely to affect the success of treatment, but without meeting the criteria for reduced life expectancy or accelerated disability described under severe harm.	Moderate psychological harm	Is when **at least one** of the following apply: -Distress that did or is likely to need a course of treatment that extends for less than six months. -Distress that did or is likely to affect the patient's normal activities for more than a few days but is unlikely to affect the patient's ability to live independently for more than six months. -Distress that did or is likely to result in a new mental health diagnosis, or a significant deterioration in an existing mental health condition, but where recovery is expected within six months.	**Duty of Candour required**
Severe physical harm	Is when **at least one** of the following apply: -Permanent harm / permanent alteration of the physiology. -Needed immediate life-saving clinical intervention. -Is likely to have reduced the patient's life expectancy. -Needed or is likely to need additional inpatient care of more than 2 weeks and/or more than 6 months of further treatment.	Severe psychological harm	Is when **at least one** of the following apply: -Distress that did or is likely to need a course of treatment that continues for more than six months. -Distress that did or is likely to affect the patient's normal activities or ability to live independently for more than six months.	**Duty of Candour required**

Physical harm grades	Definition	Psychological harm grades	Definition	Being Open/ DoC
	-Has, or is likely to have, exacerbated or hastened permanent or long term (greater than 6 months) disability, of their existing health conditions. -Has limited, or is likely to limit, the patient's independence for 6 months or more.		-Distress that did or is likely to result in a new mental health diagnosis, or a significant deterioration in an existing mental health condition, and recovery is not expected within six months.	
Fatal	-Staff should select this option if, at the time of reporting, the patient has died and the incident may have contributed to the death, including stillbirth or pregnancy loss. Staff will have to document if they consider that a patient safety incident has contributed to the death.	NA	NA	**Duty of Candour required**

4.3 **Saying Sorry**

As mentioned before in the Purpose section, NHS Resolution (2017) describes that 'saying sorry' meaningfully when things go wrong is vital for everyone involved in an incident, including the patient, their family, carers, and the staff that care for them.

It is important to remember that saying sorry is not an admission of liability and is the right thing to do. Patients/service users have a right to expect openness in their healthcare.

5.0 REGULATORY REQUIREMENTS

5.1 **CQC Regulation 20** is very specific about exactly how the duty must be carried out in relation to:

- the definition of notifiable safety incidents
- the various process steps, meetings and records that must take place
- what those meetings and records should cover
- that the process should be carried out in a timely manner
- that appropriate support should be provided to the person harmed or their representative

5.2 **The Duty of Candour requirements** involve:

- Recognising when an event occurs that impacts on a patient in terms of harm;
- Acknowledging when things go wrong;
- **Verbal notification**: Notifying the patient in person or representative, explaining that something unintentional or unexpected has occurred and providing a true account of what happened **within 10 working days**.
- **Written notification**: Apologising to the patient and/or representative in writing **within 10 working days**;
- Conducting a thorough investigation or learning response as per escalation process form Rapid Review (RR) Panel into the event and reassuring patients, their families, and carers that lessons learned will help prevent the incident.
- ***Written notification of Incident investigation***: When the RR panel identifies a formal learning response or review, a further verbal and written notification ensuring the patient, family and carers are appropriately and adequately supported and kept informed following the event and during the investigative process.
- Keeping proper records of all steps in the process
- Supporting those involved to cope with the physical and psychological consequences of what happened.

5.3 **CQC Compliance monitoring**

As part of CQC compliance monitoring, the Trust may be asked to provide following all or some information:

- Follow up incidents reported through STEIS or LfPSE or CQC notifications to inform CQC about recent incidents.
- Follow up on reports of incidents from the public or people using services
- Ask people who have experienced a notifiable safety incident how the provider responded.
- Explore understanding of frontline staff of the Duty of Candour and notifiable safety incidents.
- Question policies and processes for recording and carrying out the duty, and for training staff.
- Investigate senior staff and board members' level of understanding of the duty and how they ensure staff feel supported to speak up and be open and honest about incidents.

5.4 **Enforcement**: Where the CQC believes that the organisation is not compliant with Regulation 20, it can use powers of enforcement, and can prosecute the organisation for breaches of the regulation.

6.0 DUTIES and RESPONSIBILITIES

6.1 **Chief Executive and Board**

The Chief Executive and Board have a responsibility to actively promote an open and fair culture that fosters support and discourages the attribution of blame.

The Registered person/ Executive responsible to ensure compliance with the Regulation 20 is the Chief Nurse for the Trust

6.2 Associate Directors of Nursing, General Managers, Service Managers and Team Managers

All managers are responsible for implementing the Being Open and Duty of Candour Policy with their staff and acting promptly when patient safety incidents are brought to their attention.

6.3 Patient and Family Liaison Officer

The Patient and Family Liaison Officer (PFLO) is responsible for assisting staff in providing direct liaison with service users, families and carers to ensure CPFT delivers our duty of candour in line with the legislation. To work closely with staff in the directorates and investigation teams in the provision of advice and support to deliver the Duty of Candour.

The PFLO will analyse data on the delivery and compliance of Duty of Candour via MI reporting or Datix data collection and facilitate learning for staff service users and families on 'Being Open' and Duty of Candour using a variety of learning methods.

6.4 Employees

All employees have the responsibility to report all accidents/incidents using CPFT's online Incident Reporting system, DATIX and to inform their manager immediately if an accident/incident occurs that has resulted in moderate or serious harm or the death of a patient. In line with the Incident Management Policy including Serious Incidents and Near Misses and Patient Safety Incident Response Policy, any employee involved in an incident may be involved with the investigation, if required, but will certainly be expected to provide a statement of events when requested.

6.5 Staff acting as Investigators

Staff undertaking investigations have a responsibility to ensure that the policy is implemented during their investigation. This includes ensuring that the Datix Incident Form Duty of Candour section is completed; all documentation is uploaded into the Incident Form on Datix. PFLO will be a point of contact for support and guidance as relevant.

7.0 INFORMATION, INSTRUCTION and TRAINING

7.1 The Duty of Candour, incident investigation and Datix reporting information is available on the Trust's intranet and Patient Safety SharePoint.

7.2 The PFLO will provide training to staff through awareness sessions, and through providing advice and guidance with verbal and written notifications.

8.0 THE BEING OPEN and DUTY of CANDOUR PROCESS

To ensure that CPFT is compliant with the Regulatory requirements as well as to improve the quality and consistency of communication with patients, their families and/or their carers when a patient safety event occurs, the following steps are identified for the candour process. The summarised version is in Appendix 1.

Table 1: Harm grading aligned with Being open/candour process (devised from LfPSE guidance document)

Harm assessment	Communication process
No harm	Being Open
Minor harm	Being Open
Moderate harm	Duty of Candour
Severe harm	Duty of Candour
Fatal harm or death	Duty of Candour

Step 1: Notifiable Patient Safety Incident is identified

The first step of the process is the recognition of an incident and when the level of harm dictates that it is appropriate to apply Duty of Candour. This can be identified by any of the following mechanisms:

- Via staff at the time of the incident
- Via staff retrospectively
- By the patient/family/carer raising a concern, either at the time, or via a complaint or claim in retrospect
- Via the incident reporting system
- Via other sources, such as the incident being highlighted by another patient, visitor or non-clinical staff
- Via concerns raised as part of cause of death or post-mortem information

An incident may be identified by a patient/service user, their family and/or their carer, a member of staff, or an independent contractor. Support must be given to the patient/service user and staff affected. A verbal apology should be offered to the patient/service user and their family that the incident occurred.

Following an incident, the patient/service user should continue to receive all usual treatment and should continue to be treated with respect and compassion by CPFT staff. Should the patient/service user wish to receive treatment from another healthcare team, arrangements should be made to facilitate this wish if possible.

Patients/service users, their family and/or their carers should be reassured that the incident and its investigation will not impact upon the continuing treatment provided.

Step 2: Reporting on incident reporting system, Datix

Learning from patient safety events' service (LfPSE) provides the definitions of the patient safety event types that have been included in the new LfPSE service. This publication supersedes any previous guidance for the NRLS.
Recording the appropriate level of harm associated with a patient safety incident is important so that:

- we have an accurate description of the event and its impact on the patient, based on the best information at the time
- there is consistency and comparability within the organisation's own data.
- the national patient safety team can use the recorded information to analyse, triage and learn from consistent and high-quality data
- other policies such of Duty of Candour can be enacted appropriately.

Thereby it is important to complete the sections relevant to degree of harm grading, the related Duty of Candour box and other relevant sections on the incident reporting form. Please refer to the Figure 1 below:

Figure 1-Duty of candour section in Datix system

Severity and Result

Result
mandatory (PD16,PD12,PD10)

Degree of Harm — MOD
mandatory (PD09)

Duty of Candour and Being Open
As a result of the CQC's recent consultation, A New Start, the CQC has issued guidance on how providers can meet Government regulations around the quality and safety of care. The new Duty of Candour process came in to force on 1.10.2014.

Duty of Candour applies to cases of MODERATE and SEVERE harm or DEATH incidents.

Duty of Candour - Is this report a patient safety incident graded MODERATE HARM or ABOVE?

Was the Harm attributed to services provided by CPFT?

Duty of Candour - Being Open Process
This should include an apology for the injury / harm and assurance that the patient/next of kin /carer has been provided with information regarding the purpose of the investigation and commitment to prevent re-occurrence and learn from the incident.

Duty of Candour - date written apology given

Step 3: Discussion at Rapid Review Panel and or senior support

All incidents submitted within DATIX and correctly graded as moderate harm or above (3 and above) and assessed as attributable to CPFT will be discussed at Rapid Review Panel. This panel is executive led panel occurring weekly to review patient safety incidents and decide on proportionate investigation response and planning. The panel will support, and offer guidance for ensuing compliance with Duty of candour process. A Duty of Candour (Being Open) lead will also be identified for these incidents at this point. This role is currently supported by the Patient & Family Liaison Officer.

Please seek support from your line manager or senior staff as appropriate during the process. Please refer to 'Supporting Staff Following Traumatic or Distressing Events Policy' as appropriate.

Step 4: Initial Disclosure and Verbal Apology

A member of the service clinical team involved directly with the patient/service user's care should confirm to the patient/service user, their family and/or their carers that an incident has occurred and that this will be investigated. The initial Being Open discussion with the patient/service user, their family and/or their carers should occur as soon as possible after recognition of the patient safety incident and must be within 10 working days of the incident occurrence. A verbal apology for any distress or harm should be offered at this point as well as a written letter of apology which confirms the harm identified (please use the template in Appendix 1 as a guide).

Saying sorry to a patient/service user, their family and/or their carers is not an admission of liability.

Factors to consider before holding this discussion include:

- The clinical condition of the patient/service user. Some patients/service users may require more than one meeting to ensure that all the information has been communicated to and understood by them.
- The availability of key staff involved in the incident and in the Being Open process.
- The requirement for truthfulness, timeliness and clarity of communication
- The availability of the patient/service user's family and/or their carers
- Assess inclusivity: The availability of additional support, for example an interpreter or an independent advocate, if required
- Patient/service user preference (in terms of when and where the meeting takes place and who leads the discussion)
- Privacy and comfort of the patient/service user
- Arranging the meeting in a sensitive location.

Identify support needed by a patient/service user, their family and/or their carers or staff

Patients/service users, their family, and/or their carers may need support from the Patient Advice and Liaison Service (PALS), an independent patient advocate or an interpreter at any stage throughout the process and the offer of information on access to these should be reiterated at regular intervals throughout the procedure. Staff should facilitate this process. If a patient/service user is incapacitated as a result of the incident and does not have family/carers to assist them, an independent representative may be assigned.

Staff members involved in the incident may also be affected and, if so, should be fully supported by their line manager. The HR team, Occupational Health and Staff Counselling are additional sources of support if required. See Appendix 2 for a list of support groups.

Face-to-face meeting with a patient/service user, their family and/or their carers and appropriate members of CPFT staff

A meeting should be set up at the earliest convenience to discuss the incident and the issues involved. The patient/service user, their family and/or their carers may express a preference regarding which staff should attend the meeting and all the relevant CPFT staff should introduce themselves and explain their role. An official, independent interpreter should be in attendance if required. If the patient/service user, their family and/or their carers require any support to deal with the consequences of the incident, information on where this support can be obtained should be provided. Information about the complaint's procedure may also be provided.

Patients/service users, their family and/or their carers should be advised of whom their information will be shared with and it is possible that they may raise objections. It should be explained to them that when information has to be shared to meet legal requirements, or disclosure is justified in the public interest, information may be shared without the patient's consent. It should be taken into account that even when the face to face meeting is being conducted correctly, it may still be possible that the patient/service user, their family and/or their carers may express anger or anxiety.

Incident Investigation

When an investigation is undertaken as part of the learning of the incident in accordance with CPFT's policies and procedures for Incidents, Patient Safety Incident Investigations, Serious Incidents, Structured Judgement Reviews, Safeguarding or Complaints. This reflects the understanding that incidents usually result from system failures, rather than individual actions and ensures that all possible contributory factors are identified and considered.

The manager or clinician must contact the patient/service user (or next of kin) within 10 working days of completion of the investigation to offer to go through the outcome of the investigation including any learning. A copy of the investigation summary will be offered to the patient or next of kin.

Documentation

The communication of patient safety incidents must be recorded. Duty of Candour disclosures and meetings must be recorded in the patient/service user care records with the time, place, date as well as the name and relationships of all attendees and the outcome. Required documentation includes:

- Patient/service user care record entries must be annotated as 'Duty of Candour' as a header for ease of reference and future audit purposes.
- a copy of relevant clinical information, which should be filed in the patient/service user's care/case records
- incident reports
- records of the investigation and analysis process
- Copies of all correspondence to the patient or next of kin.

There should also be documentation of discussion meetings regarding the incident, including:

- the time, place, date, as well as the name and relationships of all attendees
- the plan for providing further information to the patient/service user, their family and/or their carers
- offers of assistance and the patient/service user, their family and/or their carers' response

- questions raised by the patient/service user, their family and/or their carers and the answers given
- plans for follow-up as discussed
- progress notes relating to the clinical situation and an accurate summary of all the points explained to the patient and/or their carers
- copies of letters sent to patients/service users, their family and/or their carers and the GP for patient safety incidents not occurring within primary care
- copies of any statements taken in relation to the patient safety incident
- a copy of the incident report

Updating patients/service users, their family and/or their carers on progress with the Investigation

Patients/service users, their family and/or their carers should be given regular updates on the progress of the investigation either verbally, in writing or by further meetings, adhering to the principles in previous stages of this procedure. Before information is provided to the patient/service users, their family and/or their carers, this should be confirmed by an appropriate senior member of staff involved in the investigation.

The following guidelines should assist in making the communication effective:

- The discussion should occur at the earliest practical opportunity, once there is additional information to report
- Consideration should be given to the timing of the meeting, based on both the patient's health and personal circumstances
- Consideration should be given to the location of the meeting e.g. the patient/service user's home. Feedback should be given on progress to date and information provided on the investigation process
- There should be no speculation or attribution of blame. Similarly, the healthcare professional communicating the incident must not criticise or comment on matters outside their own experience or expertise
- The patient/service user, their family and/or their carers should be offered an opportunity to discuss the situation with another relevant professional where appropriate or if requested
- A written record of the discussion should be kept and shared with the patient/service user, their family and/or their carers
- all queries should be responded to appropriately
- If completing the process at this point, the patient/service user, their family and/or their carers should be asked if they are satisfied with the investigation and a note of this made in the patient's records.
- The patient/service user should be provided with contact details so that if further issues arise at a later date there is a conduit back to the relevant healthcare professionals or an agreed substitute

Step 5: Completion of 'Being Open' Procedure and Written Apology

After completion of the incident investigation, feedback should take the form most acceptable to the patient/service user. The manager or clinician must contact the patient/service user, their family and/or their carers within 10 working days on completion of the investigation to offer to go through the outcome of the investigation including any learning. A copy of the investigation summary will be offered to the patient/service user, their family and/or their carers including:

- the chronology of clinical and other relevant facts
- details of the patient/service user's, their family and/or their carer's concerns and complaints
- a repeated apology for the harm suffered and any shortcomings in the delivery of care that led to the patient safety incident
- a summary of the factors that contributed to the incident
- Information on what has been and will be done to avoid recurrence of the incident and how these improvements will be monitored. It is expected that in most cases there will be a complete discussion of the findings of the investigation and analysis. In some cases information may be withheld or
- Restricted, for example: where communicating information will adversely affect the health of the patient/service user; where investigations are pending the Coroner's Office processes; where specific legal requirements preclude disclosure for specific purposes. In these cases the patient/service user will be informed of the reasons for the restrictions.
- The patient/service user, their family and/or their carers should be given the opportunity to respond to the outcome of the investigation. Any responses should be documented.

Patients/service users, their family and/or their carers not satisfied with the outcome
Should this occur, a mutually acceptable mediator should be engaged to help identify areas of disagreement. Each point of disagreement should be addressed and a response provided in writing. The patient/service user, their family and/or their carers should also be informed of how to make a formal complaint in accordance with the CPFT's Complaints Policy Procedure.

Step 6: Communication of changes to staff

Effective communication with staff is a vital step in ensuring that recommended changes are fully implemented and monitored. It will also facilitate the move towards increased awareness of patient safety issues and the value of Being Open. Team meetings, newsletters and CPFT website are all available to help communicate with staff.

9.0 LINKS to OTHER DOCUMENTS

9.1 This policy should be read in conjunction with:

- Incident Management Policy including Serious Incidents and Near Misses
- Complaints, Concerns and Compliments Policy

- Risk Management Strategy and Policy
- Patient Safety Incident Response Framework Policy and plan
- Claims policy
- Confidentiality policy
- Supporting Staff Following Traumatic or Distressing Events Policy
- Capability (performance) Policy and Procedure
- Principles of Data Protection and Caldicott Principles

10.0 REFERENCES

Introducing the Statutory Duty of Candour': a consultation on proposals to introduce a new CQC registration regulation, Department of Health, March 2014

Policy Guidance on Recording Patient Safety Events and Levels of Harm; Developed by the NHS England National Patient Safety Team. Version 1.1; April 2023

Regulation 20: Duty of candour - Care Quality Commission; cqc.org.uk

NHS Resolution Saying Sorry Publication, 2018;

NHS-Resolution-Saying-Sorry-2023.pdf

Patient Safety Incident Response Framework; NHS England; Version 1, August 2022

Patient Safety Incident Response Framework supporting guidance; Engaging and involving patients, families and staff following a patient safety incident; Version 1, August 2022

Essential Standards of Quality and Safety. Care Quality Commission, 2010.

Listening, Responding, Improving – A guide to better customer care, Department of Health, 2009

Mid-Staffs NHS Foundation Trust Public Enquiry report of Robert Francis QC, February 2012.

Supporting health service staff involved in a complaint, incident or claim - an NHSLA initiative. Kaplan C and Hepworth S. NHSLA Journal. 3: 11–13, 2004

Transforming Care: A National Response to Winterbourne View Hospital, 2012

A Promise to Learn – a Commitment to act: Improving the safety of patients in England, August, 2013.

Hard Truths: The Journey to Putting Patients First, January 2014.

MONITORING COMPLIANCE

Document Section		Control	Check to be carried out	How often will the check be carried out	Responsible for carrying out the check	Results of check reported to	Frequency of reporting
Page	Section	WHAT?	HOW?	WHEN?	WHO?	WHERE?	WHEN?
12-17		Completion of the Statutory Duty of Candour	Triage of all reported incidents. Monitoring of patient safety dashboards Monthly compliance reports Quarterly compliance reports	Daily Monthly Quarterly	Patient Safety Team Patient & Family Liaison Officer	Directorate-level Quality and Safety Group; Patient Safety and Clinical Governance Committee	Monthly Quarterly
Page 17		Monitor the litigation claims against CPFT arising from patient safety adverse events and other adverse events provide a report on findings and any lessons to be learned	Managed by the Claims and Inquest team in line with the regulatory requirements and relevant policies	As required, Monthly, Quarterly	Inquest and Claims team	Report to the Executive team	Monthly, Quarterly

APPENDIX 1: DUTY of CANDOUR

DUTY OF CANDOUR

Standard Operating Procedure for all notifiable patient safety incidents (Moderate, Severe harm and fatal harm or death) attributable to CPFT services

*** An apology is not an admission of guilt ***

Remember Being Open principles for No harm and Low harm incident!

Notifiable patient safety incident occurs
Provide immediate support to patient and staff affected

→ If the incident involves safeguarding concerns refer to the appropriate safeguarding lead and Team Manager within 24 hours of incident occurrence

↓

As soon as possible record incident on Datix and inform your manager as relevant.

→ Patient Safety Team follow incident management process/ triage to escalate as per process

↓

The notifiable patient safety event is discussed at Rapid Review panel for decision making on appropriateness of degree of harm, fact finding and determining a proportionate learning response.

↓

**** If incident is attributable to CPFT services ****
Agree who will hold disclosure discussion with patient or identified next of kin and when

↓

Initial Disclosure and Apology

- To be done **as soon as possible** and must be within **10 working** days of incident
- To be done by designated Duty of Candour lead of the ward / team
- Must be done face-to-face, providing all known facts.
- Manager or clinician to confirm with patient/next of kin/representative/carer their preference for final feedback e.g. via phone or letter
- Provide patient/next of kin/representative/carer with outline of investigation process or next steps
- Agree how/when the patient/next of kin/representative/carer will be kept in touch
- Written notification to be offered to patient/next of kin/representative/carer. Consider contacting **PFLO for support** with the written notification.
- Copy of all correspondence to be filed in the patient's clinical records.
- Discussions to be recorded in the progress notes of the patient's clinical records using entry heading 'Duty of Candour' for audit purposes.
- Upload correspondence into the Datix Incident records
- If the patient/next of kin/representative/carer declines this should be documented in the patient's clinical records and the Datix Incident record.

↓

On completion of investigation

- Manager or clinician to contact patient/next of kin/representative/carer within **10 working days of completion of the investigation**
- Offer to go through the outcome of investigation including any learning
- Offer to send a copy of the report summary (Consider contacting **PFLO for support** with the written notification)
- Upload correspondence into the Datix Incident records
- If the patient/next of kin/representative/carer declines this should be documented in the patient's clinical records and the Datix Incident record.

APPENDIX 2: SUPPORT GROUP INFORMATION

NATIONAL ORGANISATIONS

The Child Bereavement Trust
A national UK charity providing specialised training and support for professionals to help them respond to the needs of bereaved families. Resources and information for bereaved children and families as well as the doctors, nurses, midwives, teachers, police, emergency services and voluntary sector support services.
Aston House, West Wycombe, High Wycombe, Bucks HP14 3AG Information and support service line: 0845 357 1000
enquiries@childbereavement.org.uk
www.childbereavement.org.uk

Cruse Bereavement Care
A charity providing information to anyone who has been affected by a death.
Also offers education, support, information and publications to anyone supporting bereaved people. A national charity with over 6,000 trained counsellors.
Home - Cruse Bereavement Support

Supportline
A helpline providing confidential emotional support to children, young people and adults on any issue - referring callers to sources of help in their immediate area. PO Box 1596, Ilford, Essex, IG1 3FW Helpline: 020 8554 9004 (opening hours vary)
www.supportline.org.uk

British Association for Counselling and Psychotherapy
The 'Seeking a Therapist' section of the website gives lists of qualified counsellors and psychotherapists available in your area. This service is also available over the phone.
1 Regent Place, Rugby, Warwickshire CV21 2PJ Tel: 0870 443 5252
www.bacp.co.uk

Depression Alliance
A UK charity offering information to people with depression, and run by sufferers of depression.
35 Westminster Bridge Road, London SE1 7JB Textphone/Minicom: 020 7928 9992
www.depressionalliance.org

Samaritans
24 hour confidential emotional support for anyone in a crisis. Helpline: 08457 90 90 90 (24 hours)
www.samaritans.org

SUPPORT FOR CARERS

Carers Trust
Information, support and practical help for all carers through a network of Princess Royal Trust for Carers centres. 142 Minories, London, EC3N 1LB Tel: 020 7480 7788
www.carers.org

Age UK
Free national information service for senior citizens, their carers and relatives. England, Scotland, Wales: 0808 800 6565 (free phone)
Northern Ireland: 0808 808 7575 (free phone)
The lines are open Monday to Friday between 9am - 4pm.
www.ageuk.org.uk

Alzheimer's Society
Devon House
58 St. Katharine's Way London, E1W 1LB 0207 423 3500
Helpline: 0300 222 1122
www.alzheimers.org.uk

HELP FOR YOUNG PEOPLE

Hope Again
The youth branch of Cruse set up to help young people after the death of someone close.
Helpline: 0808 808 1677 answered by trained volunteers aged between 16- 25, 4pm - 7pm, Monday to Wednesday
www.hopeagain.org.uk

Winston's Wish
A charity that offers support to young people who have experienced bereavement.
The Clara Burgess Centre, Gloucestershire Royal Hospital, Great Western Road, Gloucester GL1 3NN
Helpline: 0845 2030405 (9.30am-5pm, Mon-Fri; 9.30am-1pm, Sat)
www.winstonswish.org.uk

ChildLine
Helpline: 0800 1111
Free, 24-hour helpline for children and young people who need to talk about any problem they may have.
www.ChildLine.org.uk

Childhood Bereavement Network
A new national resource for bereaved children and young people, their parents and care givers.
Huntingdon House, 278-290 Huntingdon Street, Nottingham NG1 3LY Tel: 0115 911 8070
www.childhoodbereavementnetwork.org.uk

Find out more about local services at Patient UK
www.patient.co.uk

APPENDIX 3: EQUALITY AND DIVERSITY IMPACT ASSESSMENT

An Equality and Diversity Impact Assessment has been completed to assess the potential impact this policy might have upon protected groups or how it is likely to influence the Trust's ability to comply with the Public Sector Equality Duty.

The author of this document has considered any potential impacts. There are *no* specific adverse impacts for people with protected characteristics identified.

If you require this policy in a different format (e.g. larger print, Braille, different language or audio) please contact the Corporate Governance Team (corporateoffice@cpft.nhs.uk).

Who will be affected by the content of this document? (e.g. staff, patients, service users etc.)	**Staff, patients/ service users and their families**
What are the desired outcomes of this document?	**All staff have a good understanding of Being Open Principles and Duty of candour** **100% compliance with Duty of Candour requirements**
What does this policy, function, process link to in terms of wider business plans and objectives?	**Regulatory Requirement from CQC** **To continue to promote Being Open Culture**

Evidence Considered:
Please see References Section

When assessing potential impacts of this document on equality groups, the following has been demonstrated, in accordance with General Duty of the Equality Act 2010:

(Please tick the appropriate boxes)

Age *Consider age ranges on old and younger people. This can include safeguarding, consent and child welfare.*	● Positive	○ None	○ Negative	○ Unknown
Armed Forces Community	● Positive	○ None	○ Negative	○ Unknown
Disability *Consider any attitudinal, physical and social barriers.*	● Positive	○ None	○ Negative	○ Unknown
Carers *Consider part-time working, shift-patterns, general caring responsibilities.*	● Positive	○ None	○ Negative	○ Unknown

Gender Identify or Reassignment *Consider transgender and transsexual people. This can include issues such as privacy of data and harassment.*	● Positive	○ None	○ Negative	○ Unknown
Marriage and Civil Partnership	● Positive	○ None	○ Negative	○ Unknown
Pregnancy and Maternity *Consider working arrangements, part-time working, infant caring responsibilities.*	● Positive	○ None	○ Negative	○ Unknown
Race *Consider difference ethnic groups, nationalities, Roma gypsies, Irish travellers, language barriers.*	● Positive	○ None	○ Negative	○ Unknown
Religion or Belief *Consider people with different religions, beliefs or no belief*	● Positive	○ None	○ Negative	○ Unknown
Sex (Gender) *Consider men and women (potential to link to carers below).*	● Positive	○ None	○ Negative	○ Unknown
Sexual Orientation *Consider heterosexual people as well as lesbian, gay and bi-sexual people.*	● Positive	○ None	○ Negative	○ Unknown
Other *Consider and include the source of any evidence on different socio-economic groups, area inequality, income, resident status (migrants) and other groups experiencing disadvantage and barriers to access.*	● Positive	○ None	○ Negative	○ Unknown

Engagement and involvement

Have you consulted or engaged stakeholders in testing and/or gathering evidence to support the content of this policy? If so, with whom? Joanne Griffin, Patient Safety Partner, paid Volunteer role has reviewed V5 of the policy from Service user/carer perspective. Comments were taken on board and updated accordingly. If not, why not?

If any box is marked as ‘Negative’, or ‘Unknown’, please escalate to the Equality and Diversity Team (EDI@cpft.nhs.uk) for further support and development of an action plan. Please then sign the box below:

Action Planning for Improvement:

	Action/s required to address gap:	Target Date	Executive Lead
Gaps and Challenges	Nil noted		
Monitoring, evaluating & reviewing	In line with next review date of the policy.		

Agreement by:	Signature:	Date:
Equality, Diversity and Inclusion Lead (if required)	Alexandra Anyanwu	27/06/2023
Chair of Approving Executive Led Group (Level 2)	Penny Snowden	06/07/2023
Document Author	Lekha Kuriakose	27/06/2023

APPENDIX 4: QUALITY ASSURANCE CHECKLIST

TO BE COMPLETED BY THE CORPORATE GOVERNANCE TEAM

		Y/N	Comments
1.	Title of document		
	Is the title clear and unambiguous	Y	
2.	Type of document (e.g. policy, guideline etc)		
	Is it clear whether the document is a policy, guideline or procedure?	Y	
3.	Introduction		
	Is the introduction clear?	Y	
	Are reasons for the development of the document clearly stated?	Y	
4.	Content		
	Is the correct corporate template used?	Y	
	Is the document in the correct format?	Y	
	- Paragraphs numbered consecutively?	Y	
	- Headers: logo on front page only?	Y	
	- Footers: on every page except front page?	Y	
	Are the version control numbers correct on the front page and in footer?	Y	
	Are objectives/aims clearly stated?	Y	
	Are duties, roles and responsibilities clearly explained? (Policies only)	Y	
	Are definitions of terms clearly explained?	Y	
	Does this document concern the handling, moving or storage of personal identifiable or commercially sensitive information? If yes, has there been engagement with the Information Governance Team?	N	
5.	Evidence Base		
	Is the type of evidence to support the document explicitly identified?	Y	
	Are associated documents referenced?	Y	
6.	Approval		
	Does the document identify which Oversight Working Group is responsible for reviewing the content?	Y	
	Does the document identify which Exec Led Approval Group is responsible for approval?	Y	
	Does the document identify which NED led Ratification Group is responsible for ratifying?	Y	
7.	Review Date		
	Is the review date identified and 3 years (max) following initial development (sign off by Oversight Working Group)?	Y	
8.	Equality and Diversity		
	Is a completed Equality Impact Assessment attached?	Y	
9.	Monitoring Compliance		
	Has section 'Monitoring Compliance' been completed?	Y	

If answers to any of the above questions is 'no', then this document is not ready for approval and needs further review.