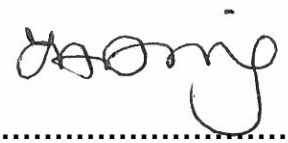
Cambridgeshire and Peterborough NHS Foundation Trust

Being Open and Duty of Candour Policy

Author:	Patient Safety and Complaints Team
Sponsor/Executive:	Director of Nursing and Quality
Responsible committee:	Patient Safety and Clinical Governance Committee
Ratified by:	Quality, Safety and Clinical Governance Committee
Consultation & Approval: (Committee/Groups which signed off the policy, including date)	Patient Safety Executive Group
This document replaces:	3.0
Date ratified:	20th December 2017 (Electronically)
Date issued:	January 2018
Review date:	31 May 2022 (extended to May 2023)
Version:	4.0
Policy Number:	PS01
Purpose of the Policy:	This policy is aimed at all Trust staff into support openness between healthcare professionals, organisations, teams and patients/service users, their family and/or their carers following an incident.
If developed in partnership with another agency, ratification details of the relevant agency	Not applicable
Policy in-line with national guidelines:	CQC Regulation 20 – Duty of Candour



Signed on behalf of the Trust: ……..

Tracy Dowling, Chief Executive

Elizabeth House, Fulbourn Hospital, Fulbourn, Cambs, CB21 5EF Phone: 01223 726789

Version Control Page

Version	Date	Author	Comments
1.0	December 2008	Tim Bryson	Policy ratified by the Healthcare Governance Committee
1.1	April 2010	Patient Safety and Risk Assurance Manager	Amendments made to policy which were ratified by the Patient Safety Committee - April 2010
1.2	April 2013	Interim Risk Manager	Amendments made to policy to take account of revisions to Being Open Framework and updating references
2.0	October 2014	Head of Patient Experience	Amendments made to Being Open Policy to incorporate the mandatory requirements for Duty of Candour
3.0	September 2015	Patient Safety & Complaints Team	Harmonisation of the Cambridgeshire Community Services NHS Trust policy and CPFT policy
4.0	October 2017	Patient Safety & Complaints Team	Standard operating procedure and letter templates updated. Changes to point 5.4 Inclusion of Family Liaison post.
4.0	November 2022	Patient Safety & Complaints Team	Addendum added at the end of Policy.

Policy Circulation Information

Notification of policy release: All recipients; Staff Notice Board; Intranet;	All staff
Key words to be used in DtGP search.	Being Open, Duty of Candour, openness, sorry, apology

CQC Standards	CQC New Fundamental Standards CQC Regulation 20

Contents

1 Introduction

1.1 The effects of harming a patient can be widespread. Patient safety incidents can have devastating emotional and physical consequences for patients/service users, their family and/or their carers, and can be distressing for the professionals involved.

1.2 Being open about what happened and discussing patient safety incidents promptly, fully and compassionately can help patients and professionals to cope better with the after effects. Openness and honesty can also help to prevent such events becoming formal complaints and litigation claims.

1.3 This policy is based on guidance from the National Patient Safety Agency (NPSA), Seven Steps to Patient Safety and the Duty of Candour (2014), and the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 20. The original guidance documents encouraged healthcare staff to apologise to patients who are harmed as a result of healthcare treatment, to provide an explanation and information, and to explain that an apology is not an admission of liability.

1.4 The guidance was revised in 2010 in response to changes in the healthcare environment and by the Department of Health in order to strengthen Being Open throughout the NHS. A new statutory requirement has been added to be used when any risk incident has been graded as attributable to CPFT services and which results in 'moderate' or 'severe' harm (including death incidents) occurring. From 1 October 2014 there was a statutory requirement for Trusts to implement the Duty of Candour and the Care Bill. Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 sets out what is required of all providers. The intention of the Regulation is to ensure that providers are open and transparent with people who use services and other "relevant persons" (people acting lawfully on behalf of patients) in general in relation to care and treatment.

1.5 This policy is aimed at all Trust staff supporting openness between healthcare professionals, organisations, teams and patients/service users, their family and/or their carers following an incident.

1.6 Openness and honesty towards patients is strongly supported by the Trust and 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).

1.7 Elements of the Being Open and Duty of Candour policy are related to other government initiatives and recommendations from major inquiry reports, including:

- Recommendations in the Francis Report into the failures of care at Mid-Staffs NHS Foundation Trust.

- Recommendations in the 5th Shipman Inquiry Report about appropriate documentation of patient deaths.
- The NHS Litigation Authority's Striking the Balance on providing support for healthcare professionals involved in a complaint, incident or claim.
- Transforming Care: A national response to Winterbourne View Hospital, DoH (2012)
- A Promise to Learn – a commitment to act: Improving the safety of patients in England, (2013).
- Hard Truths: The Journey to Putting Patients First (2014)

2 Purpose

2.1 The Trust's Being Open and Duty of Candour Policy is developed to ensure that patients, their families and/or their carers, and staff, all feel supported when patient safety events occur or things go wrong. This Policy aims to improve the quality and consistency of communication with patients, their families and/or their carers when patient safety events occur so that they receive promptly the information they need to enable them to understand what happened.

2.2 This Policy provides guidance on how a meaningful apology should be offered and the actions that need to be taken to ensure that a similar type of patient safety event does not recur.

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 Scope

3.1 This policy is applicable to incidents in which patients and staff at Cambridgeshire and Peterborough NHS Foundation Trust (hereafter referred to as 'the Trust') are directly involved. The Trust also encourages all staff including independent contractors working with the Trust to adopt the policy, or to develop similar procedures also based on the NPSA's guidance.

3.2 The Trust's Incident Management Policy including Serious Incidents and Near Misses encourages staff to report all patient safety incidents, including those where there was no harm or it was a prevented patient safety incident ('near miss'). This policy only relates to those incidents where patients have been harmed as a result of the incident, the level of harm is moderate, severe or has resulted in the patient's death, and where things have gone wrong.

3.3 The Trust recognises that such serious incidents 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 of these processes.

4 Definitions

4.1 A patient safety incident is defined by the National Patient Safety Agency (NPSA) as “any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving NHS care”. Throughout this policy, the terms ‘patient’ and ‘service user’ may be used to refer to individuals receiving treatment and care from Trust services.

4.2 **Being Open** means:

- Acknowledging, apologising and explaining as soon as possible when things go wrong
- Conducting a thorough investigation into the incident and reassuring patients/service users, their family and/or their carers that lessons will help prevent the incident recurring.
- Providing support for those involved to cope with the physical and psychological consequences of what happened.

4.3 **Duty of Candour**

Duty of Candour means ‘any patient harmed by the provision of healthcare service is informed of the fact and an appropriate remedy offered, regardless of whether a complaint has been made or a question asked’ (Francis 2013).

There is a legal and contractual duty for NHS organisations to ensure patients/service users, and where appropriate their families and/or carers, are informed of any incidents that result in either moderate, severe harm or death as soon as possible. This includes receiving an apology as appropriate, the investigation findings and actions to prevent recurrence.

4.4 **Saying Sorry**

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.

4.5 **Benefits of Being Open**

A Trust culture of being open benefits patients/service users, their family and/or their carers, staff and the Trust:

The Trust and Teams	Trust Staff	Patients/service users, their families, and/or their carers
Reputation of respect and trust	Confident in communicating effectively when things go wrong	Receive a meaningful apology and explanation
Reinforces a culture of openness	Supported in apologizing and explaining to patients/service users, their family and/or their carers	Feel their concerns and distress have been heard

The Trust and Teams	Trust Staff	Patients/service users, their families, and/or their carers
Potentially reduces the costs of litigation	Satisfied that communication has been handled in the best way	Reassured that the Trust will learn lessons to prevent harm happening to someone else
Improves patient experience and satisfaction	Improved understanding of incidents from the perspective of the patient and carers	Reduce the trauma felt when things go wrong
A reputation for supporting staff when things go wrong	Know that lessons learned will help prevent them recurring	Have greater respect and trust for the Trust
Embodies the NHS Constitution for England	Gain a good reputation for handling a difficult situation well	Reassured that they will continue to be treated according to their needs.
Opportunity to learn when things go wrong.	Able to improve practice	Prevent the same issue reoccurring for another patient

5 Duties

5.1 Chief Executive and Board

Responsibility is vested in the Trust Board, and compliance with this policy will be achieved by ensuring that there are systems in place to facilitate the policy implementation.

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 Trust should work towards a culture where human error is understood to be a consequence of flaws in the healthcare system, not necessarily the individual as laid out in the Seven Steps to Patient Safety (2008).

A nominated Executive has been appointed to assume lead responsibility in the implementation of this policy. The lead Executive responsible is the Director of Nursing and Quality.

5.2 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 harm incidents are brought to their attention.

5.3 Family Liaison and Investigation Facilitator

The Family Liaison and Investigation Facilitator is responsible for assisting staff in providing direct liaison with service users, families and carers to

ensure the Trust 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 facilitator will analyse data on the delivery of Duty of Candour and produce reports, and facilitate learning for staff service users and families on 'Being Open' and duty of candour using a variety of learning methods.

5.4 Employees

All employees have the responsibility to report all accidents/incidents using the Trust's online Incident Reporting system 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, 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.

5.5 Staff acting as investigators of incidents of harm

Staff undertaking investigations have a responsibility to ensure that the policy is implemented in the course of their investigation. This includes ensuring that the Datix Incident Form Duty of Candour section is completed; all documentation is uploaded into the Incident Form, and the patient's clinical records. The Being Open & Duty of Candour Checklist (Appendix 3) can be used as a guide for staff completing the Duty of Candour process.

6 Information, Instruction and Training

The Trust has developed two leaflets: one aimed at staff and one aimed at patients, relatives and carers to provide them with an understanding of the Duty of Candour process.

The Family Liaison and Investigation Facilitator will provide training to staff through awareness sessions, and through providing advice and guidance.

7 The Principles of Being Open

The National Patient Safety Agency ("NPSA") identifies ten principles to being open:

1) Principle of Acknowledgement

All patient safety incidents should be acknowledged and reported as soon as they are identified. In cases where the patient, their family and carers inform healthcare staff when something untoward has happened, it must be taken seriously from the outset. Any concerns should be treated with compassion and understanding by all healthcare professionals.

2) Principle of Truthfulness, Timeliness and Clarity of

Communication

Information about a patient safety incident must be given to patients/service users, their family and/or their carers in a truthful and open manner by an appropriately nominated person. Patients should be provided with a step-by- step explanation of what happened and that considers their individual needs. Communication should also be timely; patients/service users, their family and/or their carers should be provided with information about what happened as soon as practicable. It is also essential that any information given is based solely on the facts known at the time. Healthcare professionals should explain that new information may emerge as an incident investigation is undertaken, and patients/service users, their family and/or their carers will be kept up to date with the progress of an investigation.

3) Principle of Apology

Patients/service users, their family and/or their carers should receive a sincere expression of sorrow or regret for the harm that has resulted from a patient safety incident.

'Saying sorry to patients, their family and/or their carers is not an admission of liability'.

Verbal apologies are essential because they allow face-to-face contact between the patient/service user, their family and/or their carers and the team. This should be given as soon as staff are aware an incident has occurred. A written apology, which clearly states the Trust is sorry for the suffering and distress resulting from the incident, must also be given. It is important not to delay giving a meaningful apology as this is likely to increase the patient/service user, their family and/or their carers' anxiety, anger or frustration.

4) Principle of Recognising Patient and Carer Expectations

Patients/service users, their family and/or their carers can reasonably expect to be fully informed of the issues surrounding a patient safety incident, and its consequences, in a face-to-face meeting with representatives from the Trust. They should also be provided with support appropriate to their needs including additional support, such as an independent patient advocate or an interpreter if needed. Information about the Patient Advice and Liaison Service ("PALS") should be given as soon as possible.

5) Principle of Professional Support

The Trust must create an environment in which all staff, whether directly employed or independent contractors, are encouraged to report patient safety incidents. Staff should feel supported throughout the

incident investigation process because they too may have been traumatised by being involved.

Staff should not be unfairly exposed to punitive disciplinary action, increased medico-legal risk or any threat to their registration. Where there is reason for the Trust to believe a member of staff has committed a punitive or criminal act, the Trust should take steps to preserve its position and advise the member(s) of staff at an early stage to enable them to obtain separate legal advice and/or representation from relevant professional bodies such as the GMC, royal colleges, the MDU and the Nursing and Midwifery Council.

6) Principle of Risk Management and Systems Improvement

Root Cause Analysis or similar techniques should be used to uncover the underlying causes of a patient safety incident. These investigations should focus on improving systems of care, which will then be reviewed for their effectiveness. The Duty of Candour and Being Open policy should be integrated into local incident reporting and risk management policies and processes.

7) Principle of Multi-disciplinary Responsibility

To ensure multidisciplinary involvement in the Being Open process, the Trust has clinical, nursing and managerial leaders who support it and undertake root cause analysis when harm has occurred. Senior managers and senior clinicians should participate in incident investigation and clinical risk management.

8) Principle of Clinical Governance

Being Open requires the support of the Trust's quality (risk management) processes for investigation and analysis of patient safety incidents, to find out what can be done to prevent their recurrence. Findings should be disseminated to Trust staff so that they can learn from patient safety incidents.

9) Principle of Confidentiality

The Trust policy and procedure for Being Open gives full consideration of, and respect for patients/service users, their family and/or their carers and staff privacy and confidentiality in line with the CQC's guidance. Details of a patient safety incident should at all times be considered confidential.

The consent of the individual concerned should be sought prior to disclosing information beyond the clinicians involved in treating the patient, in line with the CQC's guidance. Where this is not practical or an individual refuses to consent to the disclosure, it may still be lawful if justified in the public interest, or where those investigating the incident have statutory powers for obtaining information.

Communications with parties outside the department/clinical team should also be on a “strictly need to know” basis and, where practicable, records should be anonymous. In addition, it is good practice to inform the patient/service user, their family and/or their carers about who will be involved in the investigation before it takes place, and give them the opportunity to raise any objections.

10) Principle of Continuing Care

Patients/service users are entitled to expect that they will continue to receive all usual treatment and continue to be treated with respect and compassion. If a patient/service user expresses a preference for their healthcare needs to be taken over by another team, the appropriate arrangements should be made for them to receive treatment elsewhere.

8 The Being Open and Duty of Candour Process

This process is summarised in the Standard Operating Procedure (Appendix 1).

Step 1: Incident is identified

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 Trust 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: Datix Incident Reporting

A form should be completed on the Trust’s online Incident Reporting system and the member of staff’s line manager must be notified in accordance with the Trust's Incident Reporting Policy including Serious Incidents and Near Misses. The Duty of Candour box on the incident reporting form must be completed for all Duty of Candour reporting and monitoring purposes.

Step 3: Discussion with Senior Staff

A member of staff from the team directly involved in the incident should discuss the incident with their line manager and, if identified as a serious incident, it should be reported to the on-Call Manager via telephone in the out of hours period. The team must agree on who will hold the initial disclosure discussion with the patient/service user, their family and/or their carers and when this will take place.

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).

For staff identifying a Grade 3 (moderate harm) or Grade 4 (severe harm) pressure ulcer which is believed to have developed under the care of the Trust, the apology template in Appendix 5 should be used.

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
- 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 6 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 the Trust 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 Trust 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 complaints 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

An investigation into the cause of the incident must be conducted in accordance with the Trust's policies and procedure for Incidents, SIs, 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 taken into account. The investigation should include the use of the Root Cause Analysis approach if the incident is identified as an SI.

The manager or clinician must contact the patient/service user (or next of kin) 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 or next of kin (please use DoC outcome letter template 2 as a guide – Appendix 4).

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 (please use the DoC letter template 2 as a guide – Appendix 4) 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 Trust'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 the Trust website are all available to help communicate with staff.

9 Communication of lessons learned throughout the Trust and the wider NHS

Learning the Lessons

The Trust will communicate with the wider body of Trust staff regarding learning from serious incidents, complaints and claims. This will be through Lessons in Practice bulletins, and through the Patient Safety and Clinical Risk Group.

The Wider NHS

NHS Improvement publishes patient safety alerts, safer practice notices and patient safety information notices through the Safety Alert Broadcast System (SABS) to highlight common factors that cause patient safety incidents, and to publicise its advice and solutions to the service. The primary aim will be to help reduce the risk of such incidents recurring. It will also use its website https://improvement.nhs.uk/ plus a number of specialist web resources to share this and supporting background information with healthcare staff throughout the NHS. The Trust will notify NHS Improvement via the National Reporting Learning System of any relevant incidents that require their attention if and when these occur.

10 Monitoring and Feedback

Any recommendations for systems improvements and changes implemented will be detailed in an action plan arising from the incident.

11 Monitoring Implementation of this Policy

The Trust will monitor implementation of this policy through:

- Monitoring of complaint investigation responses which should clearly identify the application of the Being Open process.
- Learning from complaints, serious incidents, and claims will be included within Lessons in Practice Bulletins, the Patient Safety and Clinical Risk Group, and Clinical Governance and Patient Safety Group.

12 Links to Other Documents

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

13 References

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

Apologies and Explanations, NHS Litigation Authority (NHSLA) circular 02/02 (February 2002)

Being Open: communicating patient safety incidents with patients and their carers. National Patient Safety Agency. 2005.

Being Open Framework, National Patient Safety Agency/National Reporting and Learning Service, 2009

Essential Standards of Quality and Safety. Care Quality Commission (2010).
Harold Shipman's clinical practice 1974-1998: a clinical audit Commissioned by the Chief Medical Officer, Department of Health (2001)

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)

NHS Constitution for England. Department of Health (January 2009)

Seven Steps to patient safety in mental health (2008)

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)

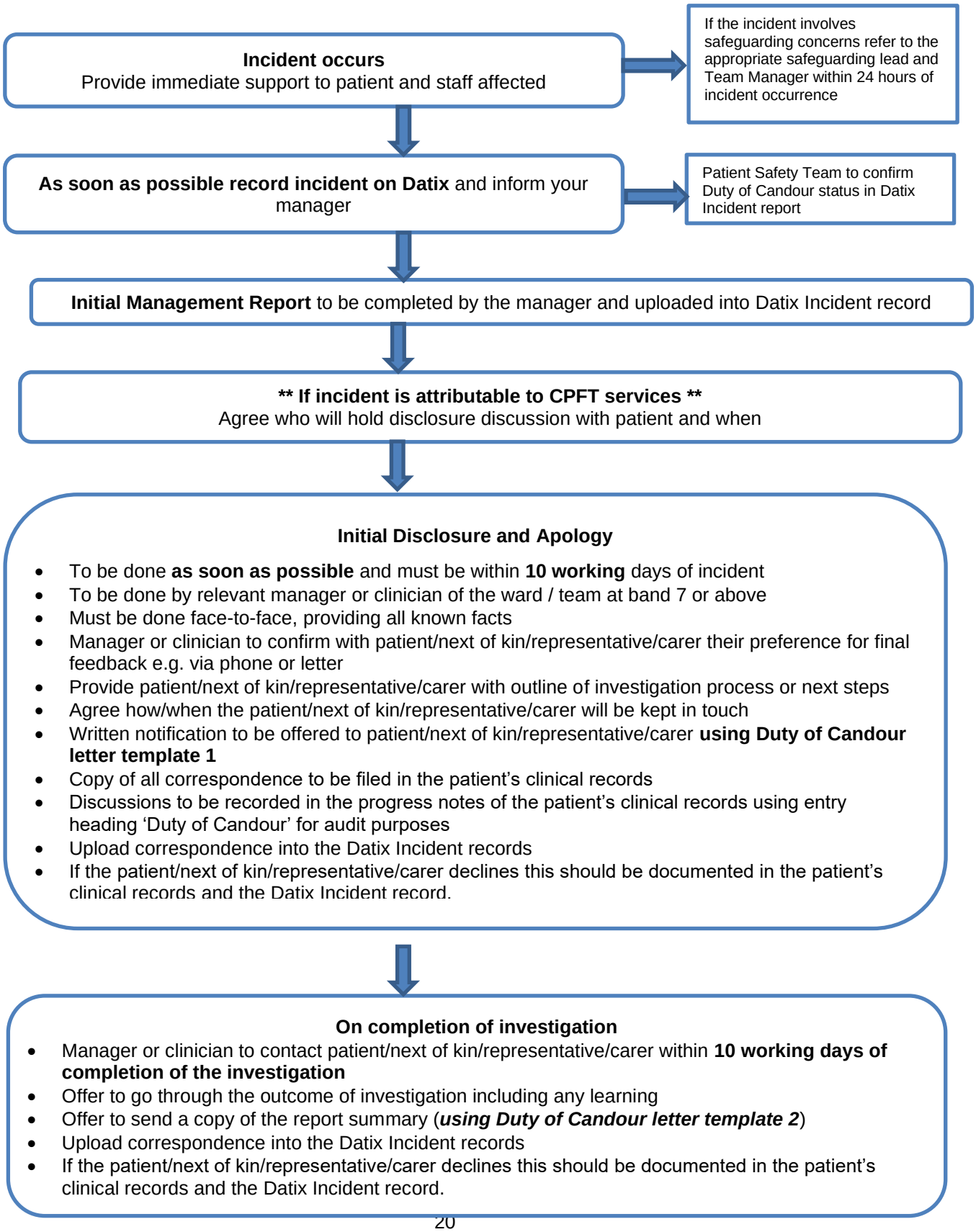
Transforming Care: A National Response to Winterbourne View Hospital (2012)

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)
Further information can be found at www.npsa.nhs.uk

Appendix 1

DUTY OF CANDOUR
Standard Operating Procedure for all incidents of Moderate and Severe harm (including death) attributable to CPFT services
*** An apology is not an admission of guilt ***



Appendix 2

WARD ADDRESS
Tel: XXXX
Website: www.cpft.nhs.uk

Date:

Ref: Datix Number /SI

PRIVATE AND CONFIDENTIAL
ADDRESS

Dear Patient/Relative (as appropriate inserting title & name)

You/Your …….. (Insert relative) have/has been involved in an incident, which related to (brief description) .....on (date).

On behalf of the Trust and members of the team involved in the care of your *son/ /daughter/father/mother, (insert name)* we would like to extend to you our condolences at this sad time and we are sorry that …… has sadly died.

OR

Please accept my sincere apology that this has occurred.

We aim to provide a quality service to patients/service users and families, and to investigate incidents promptly and share findings with those involved.

To support anyone involved in an incident, Cambridgeshire and Peterborough NHS Foundation Trust has a Being Open and Duty of Candour policy. In line with this policy, you will be contacted by the investigations manager to discuss this with you. If you wish to talk about this beforehand, please do not hesitate to contact me on……..

When our investigation is complete you will be contacted about the findings. However if you do not wish to be contacted regarding the investigation please do not hesitate to contact me on …….

Please be assured that it is not our intention to intrude upon you or your family at what must be a very difficult time. However, it is important to keep you informed.

At this stage I/ Staff member XXXXX am acting as your lead contact for the duration of this process.

Yours sincerely

Ward Manager/Team Leader
Contact details

Appendix 3

Being Open/Duty of Candour Checklist

This checklist can be used as a prompt for patient safety incidents covered by the *Being Open and Duty of Candour Policy,* where things have gone wrong and patients are harmed as a result. When all steps in the process have been completed, the steps should be documented in the Datix Incident form, and in the patient/service user's care records.

Please provide a brief summary of the incident below:
Incident:

Datix number:

Being Open Process – assurance checks	**Comments**
1. An appropriate member of staff has been identified to be the main point of contact/communication between the team/service and the patient/service user/their family and/or their carers.	
2. The patient/service user/their family and/or their carers have been given information about and offered assistance from the PALS team, an advocate and/or translator to support them throughout this process.	
3. A face-to-face meeting has been arranged with the patient/service user/their family and/or their carers and appropriate members of the Trust staff to discuss the incident as soon as possible and within 10 days of the incident. **Note:** If the patient/service user/their family and/or their carers decline the offer of a face-to-face meeting, alternative means of communicating the incident and other required information must be agreed.	
4. The patient/service user has been informed of the incident where he/she was not aware that the incident had occurred.	
5. The patient/service user's family and/or their carers have been informed about the incident, including the issues surrounding the incident, its consequences and the action taken in response to the incident (i.e. investigation and action plans).	
6. If sharing of information relating to the incident is necessary in the provision of safe and effective care, the patient/service user/their family and/or their carers: • have been informed who this information will be shared with. • have given consent to the sharing of information.	
7. If sharing of information relating to the incident is necessary to meet legal requirements, or disclosure is justified in the public interest, **consent is not required** but the patient/service user/their family and/or their carers must be informed who this information will be shared with.	
8. Staff involved in the incident have been offered appropriate support where necessary.	
9. Duty of Candour incidents are recorded in the patient/service user care records.	

Appendix 4

WARD ADDRESS
Tel: XXXX
Website: www.cpft.nhs.uk

Date:

Ref: Datix Number /SI

PRIVATE AND CONFIDENTIAL

Dear Patient/Relative (as appropriate inserting title & name)

As agreed following our initial letter dated, please find below a summary of the investigation findings into the incident/event/unexpected death of (name/relative) which happened on (date).

Include (do not use these as headings)

- *a description of what occurred*
- *The immediate actions taken*
- *The investigation findings*
- *Any lessons learned*
- *How these lessons learned will be shared across all departments:*

I hope that this will help assure you that appropriate steps have been taken to identify the care and treatment issues relevant to the incident, and that recommendations for action have been prioritised.

Yours sincerely

Ward Manager/Team Leader
Contact details

Appendix 5
Duty of Candour: Notification of a Pressure Ulcer - Patients/Service users/their family and/or their Carers

Patient Name:			
NHS Number:			
Incident Date:		Incident Time:	
Incident Report No (Datix):			

Whilst undertaking a routine skin inspection we noted a pressure ulcer Category

A management care plan is in place with the aim of improving the condition of your skin and the underlying tissue. If you have any questions or concerns please do not hesitate to speak to a member of the nursing or medical staff. An incident report has been completed to allow us to investigate the cause and to prevent future occurrences.

We wish to express our sincere apologies that this event has occurred and to ensure you that the Trust aims to investigate promptly and share the findings with those involved. If you would like to know the outcome of our investigation please advise your visiting nursing team.

If you would like to know more about how we deal with adverse events or errors, please speak to one of the healthcare professionals involved in your care or alternatively, contact the Patient Advice and Liaison Service (PALS) at the Trust. To support anyone involved in an adverse incident, the Trust has a Being Open and Duty of Candour Policy which is available on request.

Actions taken to prevent recurrence:	
Skin assessment /skin inspection and care plan reviewed:	☐
Surface equipment reviewed for example mattress/ cushion upgrade**:**	☐
Keep Moving: the importance of regular repositioning discussed with the patient/ family/ carer:	☐
Repositioning frequency reviewed and documented:	☐
Incontinence discussed/ equipment reviewed/ plan updated:	☐
Nutrition diet and fluids discussed/ reviewed:	☐
Referral to dietician:	☐

Copy of SSKIN Leaflet (Prevention of Pressure Ulcers) provided:	Yes ☐	No ☐
If No please state reason for non-issue:		

Signature of Healthcare Professional:			
Print name:			
Designation:			
Date:		Time:	
Telephone:		Email:	
Address for correspondence:			

NB: Healthcare professional must ensure that this notification is recorded in the patient's notes and/or on SystmOne.

Appendix 6

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.
Cruse Bereavement Care, Cruse House, 1
26 Sheen Road, Richmond TW9 1UR Tel: 0870 167 1677
www.crusebereavementcare.org.uk

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.

Cruse Bereavement Care, Cruse House, 126 Sheen Road, Richmond, Surrey TW9 1UR
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.ukChildLine
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.uk

Addendum

This policy is currently being reviewed and updated

The Patient Safety Incident Response Framework (PSIRF) has been introduced across NHS Trusts and ICSs in England from June 2022, representing a significant shift in the way providers respond to patient safety incidents by promoting a more proportionate and effective response for learning and improvement. Organisations are expected to transition to PSIRF within 12 months and expected completion is currently set as Autumn 2023.

Due to this, it is expected that changes will affect this policy and those linked. It should be read alongside documents such as Trust Incident Management Including Serious Incidents and Near Misses and the Trust's Mortality Policy.

It is therefore expected that changes and reviews will be ongoing, and it is recommended that the Patient Safety Team is consulted as an interim measure to ensure safe practice.

Guidance from CQC on Regulation 20 has also been updated in June 2022 which are as below

Notifiable patient safety incident in respect to CQC Regulation 20: Any unintended or unexpected incident that occurred during the provision of a regulated activity that, in the reasonable opinion of a health care professional, did or could result in:

- *The death of the service user, where death relates directly to the incident rather Being Open and Duty of Candour than to the natural course of the service user's illness or underlying condition, or*

- *Severe harm, moderate harm or prolonged psychological harm to the service user.*

- *Moderate harm – This means harm that requires a moderate increase in treatment, and significant, but not permanent harm, for example a 'moderate increase in treatment' means an unplanned return to surgery, an unplanned re-admission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, or transfer to another treatment area (such as intensive care, or*

- *Severe harm - A permanent lessening of bodily, sensory, motor, physiologic or intellectual functions, including removal of the wrong limb or organ or brain damage that is related directly to the incident and not related to the natural course of the service user's illness or underlying condition, or*

- *Prolonged psychological harm - Means psychological harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days*