Doncaster and Bassetlaw Teaching Hospitals
NHS Foundation Trust

Being Open, Saying Sorry and Duty of Candour Policy

This procedural document supersedes: CORP/RISK 14 v.6 – Being Open, Saying Sorry and Duty of Candour Policy

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Amendment Form

Version	Date Issued	Brief Summary of Changes	Author
Version 7	**07 October 2024**	**Amendment** Extensive review to align with the Patient Safety Incident Response Framework (PSIRF). Please read in full	**N Severein-Kirk**
Version 6	3 June 2020	**Amendment** Minor updates over local monitoring of Duty of Candour.	L Wilson
Version 5	23 April 2019	Extensive review and structure change, please read in full.	L Wilson
Version 4	April 1 2015	Incorporating Statutory Duty of Candour.	M Dalton
Version 3	14 April 2014	• Extensive review in response to the Francis report. • Roles and responsibilities changed • Edited to simplify text • Addition of NHSLA being open principles	N King M Dalton
Version 2	May 2010	Considerable changes in line with NPSA alert. Please read in full.	M Dalton

Contents

DUTY OF CANDOUR PROCESS FLOWCHART

(Correspondingly inserted as Appendix 1)

Applies in the following circumstances:

- Moderate harm or above; non-permanent serious injury or Prolonged psychological harm lasting over a month.
- The death of a patient when due to treatment received or not received

Stage 1: Patient Safety Event/Incident Identified, reported and graded
On identification of a patient safety incident, an incident report must be completed by the healthcare professional on the incident reporting system (DATIX) and a degree of harm assigned.

Stage 2a: Identify Lead for Duty of Candour
Identify Duty of Candour lead (Ward/Department Lead, Matron, Departmental Leads or Consultant).

Stage 2b: Duty of Candour Conversation
Offer a **verbal apology and Initial Communication**, preferably face-to-face, to the patient/Relevant person and enter into clinical records and onto DATIX the date which it took place. This should ideally be done within **24 hours** of the incident coming to light. Patient must be offered the Duty of Candour leaflet (although the patient/relative can decline this). An objective factual conversation must take place, highlighting any concerns or specific questions. The investigation process should also be explained, explaining the expectation of investigation (in line with DBTH Patient Safety Incident Response Plan)

Stage 3: Duty of Candour Letter (1):
A written **letter of apology** summarising the above conversation must be sent to the patient/ Relevant Person within **10 working days**. A copy of the letter must be uploaded to the incident report on DATIX. Refusals of discussions or failure to contact patient/ Relevant Person must also must be recorded in the patient notes and on DATIX. The Lead Investigator should establish how the patient and/or relevant person would like to receive any further information, including the final report/ resulting action plan/ updates.

Stage 4: Duty of Candour Letter (2):
Once all further enquiries have been completed the Lead Investigator is responsible for providing the patient/relevant person with the outcome of the further enquiries and the learning identified. Give a final apology. Record details of the conversation in the patient clinical records and on the incident report on DATIX. A written letter summarising the conversation must be sent to the patient/relevant person. A copy of all Duty of Candour correspondence, including attempts to contact patient/relevant person, letters, etc. must be uploaded to the incident report on DATIX

Duty of Candour leaflets are available in each ward and department (WPR 42262) and in the document section of Datix
Duty of Candour Template letters are available in the document section of Datix

1 INTRODUCTION

The NHS Constitution for England states that patients have a right to an open and transparent relationship with the organisation providing their care.

Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust, hereafter referred to as 'the Trust', is committed to the provision of high quality health care in all aspects of its services to patients, relatives, visitors, local community and staff. As part of this objective, the Trust has a duty to limit the potential impact of a wide variety of clinical and non-clinical risks and put in place robust and transparent systems to make sure that all incidents which might cause actual or potential harm to patients, visitors and staff are identified, investigated and rectified. Promoting a culture of openness and truthfulness is a prerequisite to improving the safety of patients, staff and visitors as well as the quality of healthcare systems. It involves apologising and explaining what happened to patients who have been harmed as a result of their healthcare treatment as in-patients or outpatients of the Trust.

The Trust endorses the principles of the Duty of Candour by committing to:

- acknowledging, apologising and explaining when things go wrong,
- providing support for those involved, both patients and their family/carers/relevant person, and staff as required,
- and, where necessary, conducting a thorough review of the event, involving and engaging the patient and/or relevant person and keeping them informed throughout the process.

1.1 Being Open, Saying Sorry and the Duty of Candour

The Duty of Candour (DoC) is a legal duty for all healthcare providers who are required by law to be compliant. This policy outlines when Duty of Candour is triggered and how to fulfil the legal Duty. This policy however also extends to other incidents or events not covered by the **statutory Duty of Candour**, where the Trust wants to reflect the culture of being open and transparent.

The legal Duty of Candour is triggered by a notifiable safety incident, and applies where more significant harm has been, or thought to have been, sustained by the patient. A 'notifiable safety incident' is any unintended or unexpected incident involving a patient receiving care that could result in or has resulted in harm which is moderate harm or more serious harm.

The culture of being open should be intrinsic throughout the Trust in all relationships with and between patients, the public, staff and other healthcare organisations.

This policy is based on the Care Quality Commission (CQC) guidance on the Duty of Candour and relevant Regulations, guidance from the NHS Resolution (formerly NHSLA) document "Saying Sorry" from 2017 and the Nursing and Midwifery Council (NMC) and

General Medical Council (GMC) joint document 'Openness and honesty when things go wrong' guidance from 2015.

The guidance states that 'Saying sorry';

- is always the right thing to do;
- is not an admission of liability;
- acknowledges that something could have gone better; and
- is the first step to learning from what happened and preventing it recurring.

Elements of this policy reflect other historic government initiatives and recommendations from major inquiry reports such as the 5th Shipman Inquiry Report (2004) and the NHS Litigation Authority's Striking the Balance (NHSLA initiative 2003 – now NHS Resolution). These identify the need for clear and accurate documentation and the importance of providing support for healthcare professionals involved in a complaint, incident or claim.

An apology should demonstrate sincere regret that something has gone wrong and this includes recognised complications referred to in the consent process. Saying sorry should be done in person ideally, and involve the right people involved in the team. It is the starting point of a longer conversation, acronyms should be avoided, and explanations need to be coherent and easy to understand.

Since 2013 there has been a contractual requirement by NHS Trusts to ensure compliance with the Duty of Candour within the NHS Standard Contract for those incidents that result in moderate or severe harm, or death (utilising the National Patient Safety Agency (NPSA) definitions).

Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, amended in 2015, is a direct response to recommendation 181 of the Francis Inquiry report into Mid Staffordshire NHS Foundation Trust. This recommendation states that a statutory duty of candour should be imposed on healthcare providers. In interpreting the regulation on the duty of candour, the Care Quality Commission (CQC) has guidance on how this will be regulated and inspected.

The CQC have used the definitions of openness, transparency and candour used by Robert Francis in his report, The Public Inquiry into failings at Mid Staffordshire NHS Foundation Trust (2013):

- **Openness** – enabling concerns and complaints to be raised freely without fear and questions asked to be answered.
- **Transparency** – allowing information about the truth about performance and outcomes to be shared with staff, patients, the public and regulators.
- **Candour** – any patient harmed by the provision of a healthcare service is informed of the fact and an appropriate remedy offered, regardless of whether a complaint has been made or a question asked about it.

The regulation and its implementation reflect the approach proposed by the Dalton/Williams review in 2014, including defining a notifiable safety incident to include moderate harm, severe harm, death, and prolonged psychological harm. These

definitions are contained within Regulation 20 itself. NHS bodies have been encouraged for some time to voluntarily report moderate incidents.

The legal Duty of Candour became a requirement from November 2014 for the NHS and compliance is monitored by the CQC. A failure to comply with the legal Duty of Candour can result in enforcement action, including criminal prosecution with significant financial penalties.

2 PURPOSE

When patient safety events involving patients occur, being open and transparent applies. The core objectives of this policy are to ensure that:

- Service users/patients and their family/carers have the Duty of Candour applied if something goes wrong with the care and treatment the Trust have provided; and are given appropriate support.

- Saying 'sorry' is a genuine and meaningful communication made in person, unless the patient/relevant person requires otherwise, or is unable to be contacted.

- Trust staff are aware of their responsibility to implement Duty of Candour as part of their professional responsibility, and, where necessary, the statutory requirements as described by Regulation 20: Duty of Candour of the Health and Social Care Act 2008 (Regulated Activities) Regulations (Amendment) 2015.

- A culture that encourages openness, honesty and transparency is demonstrated at every opportunity and embedded at all levels throughout the Trust.

2.1 The Legal Duty of Candour (DoC) requirements are:

Duty of Candour is a moral and, where appropriate, a legal responsibility to be open and honest when things go wrong, which MUST be carried out as part of your role working for the Trust. Being open about what happened and discussing patient safety events 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.

There are three categories of Duty of Candour:

- **Professional**
- **Statutory**
- **Contractual**

Professional Duty of Candour

Every healthcare professional has an individual responsibility to be open and honest with patients when something goes wrong with the delivery of treatment or care which causes, or has the potential to cause, harm or distress.

Healthcare professionals must also be open and honest with their colleagues, employers and other relevant organisations, and take part in reviews and investigations when requested. You must support and encourage each other to be open and honest, and not stop someone from raising concerns.

The Professional Duty of Candour extends to all incidents, regardless of the level of harm caused, and is regulated by professional bodies, e.g., General Medical Council, Nursing and Midwifery Council, and the Health Care Professionals Council.

Statutory Duty of Candour

Statutory Duty of Candour is regulated by the Care Quality Commission (CQC) under Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) - Regulations 2014 and applies to actual, or suspected, patient safety incidents that occur within the Trust and that result in, or are suspected to result in moderate harm, prolonged psychological harm, severe harm or death.

Both the statutory and the professional duties of candour have similar aims - to ensure that those providing care are open and honest with the people using their services, particularly when something has gone wrong. However, the statutory Duty of Candour applies to organisations rather than individuals, and only in certain situations, known as 'notifiable safety incidents'.

This notification must be given in person by a member of staff, provide an account, which to the best of the staff's knowledge is true, of all the facts they know about the incident as at the date of the notification, advise the patient what further enquiries into the incident the staff member believes are appropriate, include an apology, and be recorded in a written record which is kept securely by the Trust.

The verbal notification must be followed by a written notification given or sent to the patient containing the information, details of any enquiries to be undertaken, the results of any further enquiries into the incident, and an apology.

For evidencing the Duty of Candour requirements, the Trust uses it Risk Management System, Datix, to provide the detail.

Please see Appendix 2 for the Care Quality Commission's Regulation 20 or click here.

3 SCOPE

This policy runs in parallel to processes with incidents, complaints and claims and details the appropriate arrangements for communication with patients, relatives and/or their relatives/carers who have suffered harm within the Trust. Although the legal Duty of Candour does not apply to staff and visitor incidents, the same principles and process of being open and saying sorry, should be applied if a member of staff or visitor suffers harm as a result of an incident within the Trust's property.

This policy is aimed at any healthcare staff member, clinical or non-clinical, responsible for making sure that the infrastructure is in place to support openness between healthcare professionals and patients and/or their relatives/carers following an incident, complaint or claim. It describes the processes of 'being open' with patients, the legal Duty of Candour and gives advice on the 'dos and don'ts' of communicating with patients and/or their relatives/carers following harm.

Figure 1: **Grading of patient safety incidents to determine level of response**

Incident	Level of response	Does Being Open apply?
No harm (including near misses)	Patients are not usually contacted or involved in investigations and these types of incidents are outside the scope of the Being open policy. This will depend on the severity of the incident. Individual healthcare organisations decide whether 'no harm' events (including near misses) are discussed with patients, their families and carers, depending on local circumstances and what is in the best interest of the patient.	✗
Low harm (Minimal harm caused – Non-permanent up to 1 month)	Unless there are specific indications or the patient requests it, the communication, investigation and analysis, and the implementation of changes will occur at local service delivery level with the participation of those directly involved in the incident. Reporting to the risk management team will occur through standard incident reporting mechanisms and be analysed centrally to detect high frequency events. Review will occur through aggregated trend data and local investigation. Where the trend data indicates a pattern of related events, further investigation and analysis may be needed. Communication should take the form of an open discussion between the staff providing the patient's care and the patient, their family and carers.	✓ Apply the **principles of saying sorry**
Legal Duty of Candour applies to the below		
Moderate harm severe harm or death (See definition section)	A higher level of response is required in these circumstances. The risk manager or equivalent should be notified immediately and be available to provide support and advice during the Being open process if required.	✓ Apply the ***Duty of Candour process (Appendix 1)***

Adapted from NPSA (2009a)

4 ROLES AND RESPONSIBILITIES

4.1 Chief Executive and Trust Board

- To ensure and demonstrate Trust commitment to the Being Open principles
- To ensure Statutory Duty of Candour is implemented.

4.2 Executive Medical Director, Chief Nurse (or Deputies)

- To facilitate the Being Open and Duty of Candour processes
- To promote a culture of openness and transparency.

4.3 Divisional Director/ Divisional Nurse / Divisional Governance Leads

- To promote a culture of openness within their areas and ensure processes are in place to deliver the Statutory Duty of Candour.

4.4 Lead Nurse Patient Safety and Quality

- To monitor compliance with the statutory duty of candour
- To provide training corporately, on request.
- Duty of Candour Champion

4.5 Matrons, Ward Sisters, Charge Nurses and Department Managers

- To promote a culture of honest and open communication within their areas
- Ensure that staff receive appropriate training to enable them to report incidents.
- Address concerns with patients, relatives and carers openly and honestly.
- Duty of Candour Leads on the frontline.

4.6 Incident Investigator

- Will determine the most appropriate personnel to undertake any *being open* discussions. They are responsible for notifying all key personnel of the incident.

4.7 Patient's Responsible Consultant

- In the event of a serious incident, the patient's responsible consultant should be informed by the incident investigator.

4.8 Matrons

- Must ensure that the Being Open policy is implemented throughout their area of responsibility. They should encourage first line resolution of patient concerns at all times.

4.9 All staff

- All staff should be aware of and apply the principles of Being Open and Duty of Candour
- Report all incidents using the Trust's Datix electronic incident reporting system.

5 'BEING OPEN' PROCESS

The Patient Safety Incident Response Framework promotes systematic, compassionate, and proportionate responses to patient safety incidents, anchored in the principles of openness, fair accountability, learning and continuous improvement – and with the aim of learning how to reduce risk and associated harm.

The *Being Open* process is divided into the 2 areas:

1) First line resolution situations and
2) Detecting and recognising an incident.

5.1 First line resolution

Whenever a patient, member of their family or carer raises a concern about any aspect of their healthcare adopt an open and honest approach and offer an apology.

An apology and expression of regret is not an admission of liability.

Detail these discussions in the patient's clinical records and discuss it with your line manager/matron.

Refer to the Complaints, Concerns, Comments and Compliments: Resolution and Learning policy CORP/COMM 4.

5.2 Detecting and recognising an incident

The Being Open process begins with the acknowledgement that a patient has suffered harm as a result of a patient safety incident. Please refer to the Trust's Incident Reporting Procedure for detail on the process of completing an incident form via the Datix system.

The legal Duty of Candour applies where more significant harm (moderate or above) has been, or thought to have been, sustained by the patient. The legal Duty of Candour, 2020, has a slightly different definition and is triggered by a 'notifiable safety incident'

'Notifiable safety incident' is a specific term defined in the duty of candour regulation. It should not be confused with other types of safety incidents or notifications.

A notifiable safety incident must meet all 3 of the following criteria:

- It must have been unintended or unexpected.
- It must have occurred during the provision of an activity we regulate.
- In the reasonable opinion of a healthcare professional, already has, or might, result in death, or severe or moderate harm to the person receiving care.

If any of these three criteria are not met, it is not a notifiable safety incident (but the overarching duty of candour, to be open and transparent, always applies).

6 THE 'DUTY OF CANDOUR' PROCESS

The Duty of Candour process is triggered by a notifiable safety incident. This contractual and statutory duty means that patients or where appropriate, their family/carer must be informed of a suspected or actual patient safety incident that has resulted in moderate or severe harm, death or prolonged psychological harm lasting at least a month, within **10 working days of the incident being reported** on the incident reporting system. The Trust must keep documentary evidence of compliance with this duty.

A failure to comply with the CQC regulation, which is a registration requirement for the organisation, may result in criminal prosecution and financial penalty.

6.1 How to undertake Duty of Candour

When an incident triggers the Duty of Candour, the following steps must be taken – ensuring that:

- Duty of Candour is initially undertaken verbally (face to face where possible) unless the patient (or relative) declines.
- This verbal notification (or decline) must be documented in the patient's medical record, including any responses by the patient (or relative if the patient is unable to be involved in the process themselves), ensuring that the associated incident number is documented.

    - An apology must be provided
    - A step by step explanation of what happened, in plain English, must be offered as soon as is practicable.

Lack of clarity whether a patient safety incident, or the degree of harm, has occurred, is not a reason to avoid disclosure.

- Follow up of the verbal notification must be in writing, outlining the process of the investigation, potential timescales and relevant contact details must be provided.
- Sharing the investigation report must be offered to the patient or relative/carer within 10 working days of the investigation being signed off as complete by the Trust.

A table simplifying the process of Duty of Candour can be found at Appendix 1.

Illustrative Examples of those notifiable incidents that would require the Duty of Candour (as provided by the Care Quality Commission) can be found at Appendix 3.

The patient and/or relative (where appropriate) can decline to receive any correspondence regarding the incident. However, in this instance a copy of all correspondence/communication with the relevant person must be documented. This should be done in the Patient's clinical records and recorded on Datix reporting system.

7 SPECIAL CIRCUMSTANCES

7.1 When a patient has died

When a patient safety incident causes a patient's death, it is crucial that communication is sensitive, empathic and open and takes account of other processes (such as a Post-mortem, Coroner's inquest or a possible police investigation). It is important to consider the emotional state of the bereaved relatives or carer and to involve them in deciding when it is appropriate to discuss what has happened. The Bereavement Officer will inform the patient's next of kin of the processes involved following the death.

Issue an apology as soon as possible after the patient's death, together with condolences and if relevant, an explanation that the Coroner's process has been initiated. Provide a realistic time frame of when the family and/or carers will receive more information.

7.2 Being Open with Children

The legal age of maturity for giving consent to treatment is 16. This is when a young person acquires certain rights to make decisions about their own treatment and their right to confidentiality becomes vested in them rather than their parents or guardians. However, it is still considered good practice to encourage competent children to involve their families, or a person of their choice, in decision making.

The courts have stated that younger children who understand fully what is involved in the proposed procedure can also give consent. This is sometimes known as Gillick competence or the Fraser guidelines (NSPCC, 2012). Where a child is judged to have the cognitive ability and the emotional maturity to understand the information provided, he/she should be involved directly in the Being Open process after a patient safety incident.

Parents should still have the opportunity to be involved unless the child expresses a wish for them not to be present. Where children are deemed not to have sufficient maturity or ability to understand, consider whether information is provided to the parents alone or in the presence of the child. In these instances, the parent's views on the issue should be sought. However, it may be appropriate to offer children support from an appropriate staff member for example in the case of young children a member of the hospital play team.
Further information can be found here

- GMC Consent http://www.gmc-uk.org/guidance/ethical_guidance/consent_guidance_involving_children_and_young_people.asp

7.3 Patients with Mental Health Issues

Being open for patients with mental health issues should follow normal procedures, unless the patient also has cognitive impairment (see below). It is only appropriate to withhold information about the patient safety incident when advised to do so by a Consultant Psychiatrist who feels it would cause adverse psychological harm. These circumstances are rare and a second opinion (by another consultant psychiatrist) is needed to justify withholding information from the patient. This should be documented in the medical records to explain such circumstances.

Apart from exceptional circumstances, it is never appropriate to discuss patient safety incident information with a carer or relative without the express permission of the patient. This is an infringement of the patient's human rights.

7.4 Patients with Cognitive Impairment

Some individuals have conditions that limit their ability to understand what is happening to them. They may have an authorised person to act on their behalf by an enduring power of attorney. In these cases, steps must be taken to ensure this extends to decision-making and to the medical care and treatment of the patient. The Being Open discussion would be held with the holder of the power of attorney. Where there is no such person, the clinicians may act in the patient's best interest in deciding who the appropriate person is to discuss incident information with regarding the welfare of the patient as a whole and not simply their medical interests. However, the patient with a cognitive impairment should, where possible, be involved directly in communications about what has happened. An advocate with appropriate skills should be available to the patient to assist in the communication process.

Appropriate advocates may include carers, family or friends of the patient. Further information can be provided through Patient Advisory and Liaison Service (PALS) and from the Safeguarding Team. Where a patient has difficulties in expressing their opinion verbally, assess whether they are also cognitively impaired (see above). If the patient is not cognitively impaired, use alternative communication methods (e.g. give the opportunity to write questions down). Under the Mental Capacity Act 2005 – Policy and Guidance, including Deprivation of Liberty Safeguards (DoLS) - (PAT/PA 19), an independent mental capacity advocate should be offered when no family or friends of the patient are available. The advocate should assist the patient during the Being Open process by ensuring that the patient's views are considered and discussed.

7.5 Patients with Learning Disabilities

Where an adult patient has difficulties in expressing their opinion verbally, an assessment should be made about whether they are also cognitively impaired (see 'Patients with cognitive impairment'). If the patient is not cognitively impaired they should be supported in the Being open or Duty of Candour process by alternative communication methods (e.g. given the opportunity to write questions down). An advocate, agreed on in consultation with the patient, should be appointed. Appropriate advocates may include carers, family or friends of

the patient. The advocate should assist the patient during the Being open or Duty of Candour process, focusing on ensuring that the patient's views are considered and discussed.

7.6 Patients who disagree with the Information Provided

Sometimes, despite the best efforts of healthcare staff or others, the relationship between the patient and/or their carers and the healthcare professional breaks down. They may not accept the information provided or may not wish to participate in the Being Open process. The following strategies may assist:

- Deal with the issue as soon as it emerges;
- Where the patient agrees, ensure their carers are involved in discussions from the beginning;
- Ensure the patient has access to support services;
- Where the senior health professional is not aware of the relationship difficulties, provide mechanisms for communicating information, such as the patient expressing their concerns to other members of the clinical team;
- Offer the patient and/or their carers another contact person with whom they may feel more comfortable. This could be another member of the team or the individual with overall responsibility for clinical risk management;
- Use a mutually acceptable mediator to help identify the issues between the healthcare organisation and the patient, and look for a mutually agreeable solution;
- Ensure the patient and/or their carers are fully aware of the formal complaints procedures;
- Write a comprehensive list of the points the patient and/or their carer disagree with and reassure them you will follow up these issues.

7.7 Patients with Different Language or Cultural Considerations

The Trust uses an interpretation service; information is available on all wards and departments. Further information or assistance can be provided through the Patient Advisory and Liaison Service (PALS).

7.8 Patients with Different Communication Needs

A number of patients will have particular communications difficulties, such as a hearing impairment, learning disabilities etc. Plans for the meeting should fully consider these needs. Knowing how to enable or enhance communications with a patient is essential to facilitating

an effective *Being Open Process*, focusing on the individuals and their families and being personally thoughtful and respectful.

7.9 Duty of Candour arising from another healthcare professional or healthcare body

Where the Trust becomes aware of a patient safety incident involving a DBTH patient from an episode of care delivered by an external body/professional, outside the organisation the Legal Duty of Candour sits with the Trust. However, best practice suggests that the healthcare professional or body involved should be alerted to the safety incident and any harm that has been found, in order for all parties to consider their responsibilities in order to fulfil the legal Duty of Candour.

8 SUPPORT

8.1 Patients

Patients and or their carers may need considerable practical and emotional help and support following a patient safety incident. It is therefore important to discuss their individual needs.

Support may also be provided by the following:

- Patient's family
- Social worker
- Religious representatives
- PALS
- Independent Complaints Advocacy Service (ICAS)

Where the patient needs more detailed long-term emotional support, give advice on how to access appropriate counselling services.

8.2 Staff

DBTH take Health & Wellbeing seriously and there are a variety of services available. Staff Involved in the investigation process will have the opportunity to access professional advice from their relevant professional body or union, staff counselling and occupational health services. Staff will be supported through the investigation and be provided information regarding the stages.

To ensure a robust and consistent approach to investigation the Trust will refer to the NHS Just Culture Toolkit.

9 LINKING WITH EXTERNAL STAKEHOLDERS

9.1 CQC, Monitor and Other Regulators

Any statement made to a regulator or a commissioner in the course of its statutory duties must be completely truthful and not misleading by omission (Francis, 2013).

9.2 Coroner

All cases of untimely, unexpected or unexplained death and suspected unnatural deaths need to be reported to the Coroner. A Coroner may request the case not to be discussed with other parties until the facts have been considered. If necessary, the Coroner will advise on whether an apology should proceed. However, this should not preclude a verbal and written apology or expression of regret where appropriate.

In this situation, it should be made clear to the family that a full discussion of the circumstances and any residual concerns will be arranged at a date to suit both parties after the Coroner's assessment has finished. It should also be recognised that Coroners inquests are stressful for patients, families/carers and healthcare professionals. Counselling and advice should be offered at the outset of a Coroner's inquest from individual line managers.

In exceptional circumstances the Coroner may request cases not to be discussed with other parties. In cases of police involvement, further advice should be sought.

9.3 General Practitioners

Consider contacting the referring GP for incidents that have implications for continuity of care. By informing them early they can offer support to the patient/family/carer.

9.4 Public Statements and Press Releases

Any public statements made by the Trust, via the Communications team, about its performance must be truthful and not misleading by omission (Francis, 2013).

10 TRAINING & EDUCATION

Duty of candour training is provided at Trust induction and updates form part of the annual training plan. Bespoke training can be requested via the Lead Nurse – Patient Safety and Quality.

11 DOCUMENTATION (IN RELATION TO THE DUTY OF CANDOUR)

It is important to record discussions with the patient, their family and carers as well as the incident investigation. This must be filed within the patient's medical records and kept as part of the Trust's clinical governance reports on Datix as evidence that the DoC has been complied with. Template DoC letters can be found on Datix.

Written records of the being open discussion should include:

- Time, date, place and attendees
- Plan for providing further information & meetings
- Questions raised by the patient, family and carers and answers given
- Accurate summary of all points explained
- Any other documentation produced as part of the investigation should be kept but not as part of the patients notes.

12 MONITORING AND EFFECTIVENESS

- The Lead Nurse – Patient Safety and Quality reviews all moderate and severe harm incidents on a monthly basis and monitors Duty of Candour compliance within the Datix system, providing feedback to the Divisions via the Patient Safety Report , providing compliance of completion.
- The Patient Safety Report provides evidence of compliance with the Being Open and Duty of Candour Policy. This is distributed to the Integrated Care Board, Patient Safety Review Group and the Clinical Governance Committee.
- Review complaint responses and feedback from incidents where the principles of Being Open and Duty of Candour are pertinent.

What is being Monitored	Who will carry out the Monitoring	How often	How Reviewed/ Where Reported to
Duty of Candour compliance. Percentage of compliance within deadlines.	Lead Nurse – Patient Safety and Quality, Divisional Governance Leads, Divisional Directors, Divisional Nurses and Head of Midwifery	Monthly	Reviewed in Divisional Governance meetings. Data is taken from Datix. The data is presented via the Patient Safety Report at Patient Safety Review Group & Clinical Governance Committee

13 EQUALITY IMPACT ASSESSMENT

An Equality Impact Assessment (EIA) has been conducted on this procedural document in line with the principles of the Equality Analysis Policy (CORP/EMP 27) and the Fair Treatment For All Policy (CORP/EMP 4).

The purpose of the EIA is to minimise and if possible remove any disproportionate impact on employees on the grounds of race, sex, disability, age, sexual orientation or religious belief. No detriment was identified. (See Appendix 4)

14 ASSOCIATED TRUST PROCEDURAL DOCUMENTS

This policy document should be followed in conjunction with:

- Claims Handling Policy (CORP/RISK 5)
- Complaints, Concerns, Comments and Compliments: Resolution and Learning (CORP/COMM 4)
- Equality Analysis Policy (CORP/EMP 27)
- Equality Diversity and Inclusion Policy (CORP/EMP 59 v 1)
- Incident Management Policy (CORP/RISK 33)
- Raising Concerns: 'We Care, We Listen, We Act' (CORP/EMP 14)
- Mental Capacity Act 2005 Policy and guidance, including deprivation of liberty safeguards (DoLS) (PAT/PA 19)

15 DATA PROTECTION

Any personal data processing associated with this policy will be carried out under 'Current data protection legislation' as in the Data Protection Act 2018 and the General Data Protection Regulation (GDPR) 2016.

For further information on data processing carried out by the trust, please refer to our Privacy Notices and other information which you can find on the trust website: https://www.dbth.nhs.uk/about-us/our-publications/uk-data-protection-legislation-eu-general-data-protection-regulation-gdpr/ .

16 DEFINITIONS

Being Open	This is defined as being open and honest if things go wrong
Saying Sorry:	Apologising if things go wrong or the patient does not have the expected outcome is not an admission of liability, but an opportunity to learn and improve.
Duty of Candour:	Is a contractual and statutory duty that requires the Trust to apologise to patients or their family/carer. The patient, family or carer must be informed of a suspected or actual patient safety incident that has resulted in moderate or severe harm, or death, within 10 working days. This process is detailed in Appendix 1.
Serious Incident (taken from the Serious Incident framework 2015)	Serious Incidents are events in health care where the potential for learning is so great, or the consequences to patients, families and carers, staff or organisations are so significant, that they warrant using additional resources to mount a comprehensive response.
No Harm:	No harm caused incident (included near misses)
Low Harm:	Minimal harm caused by the incident - Non-permanent up to 1 month

Below are the definition taken from the CQC Regulation 20 where the legal Duty of Candour is required	
Moderate Harm:	Moderate harm is a. harm that requires a moderate increase in treatment, **and** b. significant, but not permanent, harm; "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)
Severe Harm:	Severe harm" means 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.
Death:	Death caused by the incident

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APPENDIX 1 - DUTY OF CANDOUR PROCESS FLOWCHART

(Correspondingly inserted as Appendix 1)

Applies in the following circumstances:

- Moderate harm or above; non-permanent serious injury or Prolonged psychological harm lasting over a month.
- The death of a patient when due to treatment received or not received

Stage 1: Patient Safety Event/Incident Identified, reported and graded
On identification of a patient safety incident, an incident report must be completed by the healthcare professional on the incident reporting system (DATIX) and a degree of harm assigned.

Stage 2a: Identify Lead for Duty of Candour
Identify Duty of Candour lead (Ward/Department Lead, Matron, Departmental Leads or Consultant).

Stage 2b: Duty of Candour Conversation
Offer a **verbal apology and Initial Communication**, preferably face-to-face, to the patient/Relevant person and enter into clinical records and onto DATIX the date which it took place. This should ideally be done within **24 hours** of the incident coming to light. Patient must be offered the Duty of Candour leaflet (although the patient/relative can decline this). An objective factual conversation must take place, highlighting any concerns or specific questions. The investigation process should also be explained, explaining the expectation of investigation (in line with DBTH Patient Safety Incident Response Plan)

Stage 3: Duty of Candour Letter (1):
A written **letter of apology** summarising the above conversation must be sent to the patient/ Relevant Person within **10 working days**. A copy of the letter must be uploaded to the incident report on DATIX. Refusals of discussions or failure to contact patient/ Relevant Person must also must be recorded in the patient notes and on DATIX. The Lead Investigator should establish how the patient and/or relevant person would like to receive any further information, including the final report/ resulting action plan/ updates.

Stage 4: Duty of Candour Letter (2):
Once all further enquiries have been completed the Lead Investigator is responsible for providing the patient/relevant person with the outcome of the further enquiries and the learning identified. Give a final apology. Record details of the conversation in the patient clinical records and on the incident report on DATIX. A written letter summarising the conversation must be sent to the patient/relevant person. A copy of all Duty of Candour correspondence, including attempts to contact patient/relevant person, letters, etc. must be uploaded to the incident report on DATIX

Duty of Candour leaflets are available in each ward and department (WPR 42262) and in the document section of Datix
Duty of Candour Template letters are available in the document section of Datix

APPENDIX 2 – REGULATION 20 (CQC) – DUTY OF CANDOUR

REGULATION 20: DUTY OF CANDOUR 1/2

20.— (1) registered persons must act in an open and transparent way with relevant persons in relation to care and treatment provided to service users in carrying on a regulated activity.

(2) as soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred a registered person must— (a) notify the relevant person that the incident has occurred in accordance with paragraph (3), and (b) provide reasonable support to the relevant person in relation to the incident, including when giving such notification.

(3) the notification to be given under paragraph (2)(a) must— (a) be given in person by one or more representatives of the registered person, (b) provide an account, which to the best of the registered person's knowledge is true, of all the facts the registered person knows about the incident as at the date of the notification, (c) advise the relevant person what further enquiries into the incident the registered person believes are appropriate, (d) include an apology, and (e) be recorded in a written record which is kept securely by the registered person.

(4) the notification given under paragraph (2)(a) must be followed by a written notification given or sent to the relevant person containing— (a) the information provided under paragraph (3)(b), (b) details of any enquiries to be undertaken in accordance with paragraph (3)(c), (c) the results of any further enquiries into the incident, and (d) an apology.

(5) but if the relevant person cannot be contacted in person or declines to speak to the representative of the registered person — (a) paragraphs (2) to (4) are not to apply, and (b) a written record is to be kept of attempts to contact or to speak to the relevant person.

(6) the registered provider must keep a copy of all correspondence with the relevant person under paragraph (4).

REGULATION 20: DUTY OF CANDOUR 2/2

(7) in this regulation— "apology" means an expression of sorrow or regret in respect of a notifiable safety incident; "moderate harm" means— (a) harm that requires a moderate increase in treatment, and (b) significant, but not permanent, harm; "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); "notifiable safety incident" has the meaning given in paragraphs (8) and (9); "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; "prolonged pain" means pain which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days; "relevant person" means the service user or, in the following circumstances, a person lawfully acting on their behalf— (a) on the death of the service user, (b) where the service user is under 16 and not competent to make a decision in relation to their care or treatment, or (c) where the service user is 16 or over and lacks capacity in relation to the matter; "severe harm" means 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.

(8) in relation to a health service body, "notifiable safety incident" means any unintended or unexpected incident that occurred in respect of a service user during the provision of a regulated activity that, in the reasonable opinion of a health care professional, could result in, or appears to have resulted in— (a) the death of the service user, where the death relates directly to the incident rather than to the natural course of the service user's illness or underlying condition, or (b) severe harm, moderate harm or prolonged psychological harm to the service user.

APPENDIX 3 - ILLUSTRATIVE EXAMPLES OF INCIDENTS THAT TRIGGER THE THRESHOLDS FOR DUTY OF CANDOUR

These examples have been developed by the Care Quality Commission to illustrate examples of notifiable safety incidents that trigger the threshold for the duty of candour regulation. The following examples presented are illustrative only and not an exhaustive list.

SURGERY

What happened

An elderly woman undergoes a coronary artery bypass operation. The operation is carried out according to plan, with no unexpected or unintended incidences. But the woman suffers a large stroke during the operation and dies soon after.

Does this qualify as a notifiable safety incident?

1. Did something unintended or unexpected happen during the care or treatment?

   No. In this case, nothing unexpected or unintended occurred during the course of treatment.

2. Did it occur during provision of a regulated activity?

   Yes. The incident occurred during provision of the regulated activity 'Surgical procedures'.

3. Has it resulted in death or severe or moderate harm?

   Yes. The incident resulted in death. The woman was receiving care in an NHS hospital so the definitions in Regulation 20(8) apply.

Conclusion

In this case, one of the answers to the three questions is “no”. So, this does not qualify as a notifiable safety incident. Of course the overarching aspect of the duty of candour, to be open and transparent about what happened, always applies, whether or not something is a notifiable safety incident.

MATERNITY

What Happened

A woman in an NHS hospital experienced pain during an elective caesarean section. She found this experience traumatic and subsequently had an acute episode of severe anxiety and depression that lasted more than 28 days. It was discovered that she had been not receiving enough anaesthesia from an epidural line.

Does this qualify as a notifiable safety incident?

1. Did something unintended or unexpected happen during the care or treatment?
   Yes. The woman had not received enough anaesthesia.

2. Did it occur during provision of a regulated activity?
   Yes. The incident occurred while the woman was receiving care under the regulated activity 'maternity and midwifery services'.

3. Has it resulted in death or severe or moderate harm?
   Yes. The incident has resulted in “prolonged psychological harm” (psychological harm lasting more than 28 days).
   The woman was receiving care in an NHS hospital so the harm definitions in Regulation 20(8) apply. If the maternity care had been delivered in an independent hospital, Regulation 20(9) would apply instead.

Conclusion

The answers to all three questions are 'yes'. So this qualifies as a notifiable safety incident. And all steps outlined in the duty of candour (Regulation 20) should be carried out.

APPENDIX 4 - EQUALITY IMPACT ASSESSMENT PARTIAL SCREENING

Service/Function/Policy/Project/Strategy	Division/Executive Directorate and Department	Assessor (s)	New or Existing Service or Policy?	Date of Assessment
CORP/RISK 14 v.5 - Being Open, Saying Sorry and Duty of Candour Policy	Corporate Nursing	Nicola Severein-Kirk	Existing Policy	January 2024

1) Who is responsible for this policy? Name of Division/Directorate: Chief Nurse

2) Describe the purpose of the service / function / policy / project/ strategy? Who is it intended to benefit? What are the intended outcomes? To comply with the legal framework: Statutory Duty of Candour

3) Are there any associated objectives? Legislation, targets national expectation, standards as above

4) What factors contribute or detract from achieving intended outcomes? – None

5) Does the policy have an impact in terms of age, race, disability, gender, gender reassignment, sexual orientation, marriage/civil partnership, maternity/pregnancy and religion/belief? Details: [see Equality Impact Assessment Guidance] - No

- **If yes, please describe current or planned activities to address the impact** [e.g. Monitoring, consultation] –

6) Is there any scope for new measures which would promote equality? [any actions to be taken] No

7) Are any of the following groups adversely affected by the policy?

Protected Characteristics	Affected?	Impact
a) Age	No	
b) Disability	No	
c) Gender	No	
d) Gender Reassignment	No	
e) Marriage/Civil Partnership	No	
f) Maternity/Pregnancy	No	
g) Race	No	
h) Religion/Belief	No	
i) Sexual Orientation	No	

8) Provide the Equality Rating of the service / function /policy / project / strategy – tick (✓) outcome box

Outcome 1 ✓	Outcome 2	Outcome 3	Outcome 4

Date for next review: February 2027

Checked by: Marie Hardacre **Date: February 2024**