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.4 – Being Open and Duty of Candour Policy

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Amendment Form

Version	Date Issued	Brief Summary of Changes	Author
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

(Correspondingly inserted as Appendix 1)

Applies in the following circumstances:

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

Staff members registered with a regulatory body must also ensure they are compliant with Duty of Candour requirements as stipulated in the relevant body's Code of Conduct (NMC, GMC, HCPC etc.).

Identify Duty of Candour lead (Ward/Department Lead, Matron, Departmental Leads or Consultant). Offer a **verbal apology *(Initial Communication)***, preferably face-to-face, to the patient, family or relative and enter 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. 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 (Local, Moderate, Serious Incidents (60 days to complete)

This must be followed within 10 working days with a **letter of apology** including a summary of the discussions that have taken place. Details of discussions must be recorded in patient notes and a summary provided within the incident record on Datix ***(Letter 1)***. Refusals of discussions or failure to contact next of kin must also be recorded in the patient notes and Datix. The Lead Investigator should establish how the patient and/or their family/carer would like to receive the final report and any resulting action plan.

The Lead Investigator is responsible for providing the patient and/or their family/carer with a copy of the final report and action plan within 10 working days of notification of commissioner approval ***(Letter 2)***.

Duty of Candour leaflets are available in each ward and department. (WPR 42262)
Template letters 1, 2 & 3 are available in the document section of Datix web.

* If there is a delay in identification of the incident, it is recommended that the patient / relevant other are contacted by letter, using Letter 3.

1 INTRODUCTION

Doncaster and Bassetlaw Teaching Hospitals NHS Foundation 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. It also involves apologising and explaining what happened to staff or visitors who have suffered harm. It encompasses communication between healthcare organisations, healthcare teams and patients and/or their relatives/carers, staff and visitors and makes sure that openness, honesty and timeliness underpins responses to such incidents.

Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust takes Duty of Candour seriously, and have included it in the 'Ensuring we are Caring' section in the Organisational Clinical Governance Strategy 2017-2022.

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 the Duty is triggered and how to fulfil the legal Duty of Candour. This policy however also extends to other incidents 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 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 & 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, 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 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:

- **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 all incidents involving patients occur, being open and transparent applies. However the particular requirement for legal Duty of Candour (DoC) only apply to incidents where a harm has been, or thought to have been, at least at a moderate level or above (See definitions section).

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

As soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred an appropriate member of staff must notify the patient (or relevant other person) that the incident has occurred and provide reasonable support to the patient in relation to the incident.

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.

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 Canodur 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 Medical Director, Director of Nursing, Midwifery and Allied Health Professionals (or Deputies)

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

4.3 Divisional Director/ Associate Director of Nursing/ 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 Head of Patient Safety and Experience

- 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 Trust's process for encouraging open communication is reflected in the 'Ten Principles of Being Open' as identified in the National Patient Safety Agency's document 'Being Open: communicating patient safety incidents with patients and their relatives/carers' (NPSA, 2009).

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 communication sheet within 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, 2014 has a slightly different definition and is triggered by a 'notifiable safety incident' which is detailed below:

"A 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.

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.

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

- BMA Consent toolkit: https://www.bma.org.uk/advice/employment/ethics/consent/consent-tool-kit
- GMC Consent http://www.gmc-uk.org/guidance/ethical_guidance/consent_guidance_involving_children_and_young_people.asp
- MPS Consent: http://www.medicalprotection.org/uk/england-factsheets/consent-children-and-young-people

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.

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 NPSA Incident Decision Tree.

9 LINKING WITH EXTERNAL STAKEHOLDERS

9.1 Clinical Commissioning Groups

In line with the Trust's Incident Management Policy CORP/RISK 33, all serious incidents (see definition) must be reported to the Clinical Commissioning Group.

9.2 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).

9.3 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.

9.4 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.

9.5 Public Statements and Press Releases

Any public statements made by the Trust 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 Head of Patient Safety & Experience.

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 Head of Patient Safety & Experience 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 Risk Management Report, providing compliance of completion.
- The annual Serious Incident Report provides evidence of compliance with the Being Open and Duty of Candour Policy. This is distributed to the Clinical Commissioning Groups, Patient Safety Review Group and the Clinical Governance Committee.
- Review complaint responses and feedback from serious 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.	Head of Patient Safety & Experience, Divisional Governance Leads, Associate Directors of Nursing, Head of Nursing (Paediatrics), Head of Midwifery	Monthly	Reviewed in Divisional Governance meetings. Data is taken from Datix. The data is presented via the Risk Management 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)
- Fair Treatment for All (CORP/EMP 4)
- 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

17 REFERENCES

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APPENDIX 1 - DUTY OF CANDOUR PROCESS

Applies in the following circumstances:

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

Staff members registered with a regulatory body must also ensure they are compliant with Duty of Candour requirements as stipulated in the relevant body's Code of Conduct (NMC, GMC, HCPC etc.).

Identify Duty of Candour lead (Ward/Department Lead, Matron, Departmental Leads or Consultant). Offer a **verbal apology *(Initial Communication)***, preferably face-to-face, to the patient, family or relative and enter 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. 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 (Local, Moderate, Serious Incidents (60 days to complete)

This must be followed within 10 working days with a **letter of apology** including a summary of the discussions that have taken place. Details of discussions must be recorded in patient notes and a summary provided within the incident record on Datix ***(Letter 1)***. Refusals of discussions or failure to contact next of kin must also be recorded in the patient notes and Datix. The Lead Investigator should establish how the patient and/or their family/carer would like to receive the final report and any resulting action plan.

The Lead Investigator is responsible for providing the patient and/or their family/carer with a copy of the final report and action plan within 10 working days of notification of commissioner approval ***(Letter 2)***.

Duty of Candour leaflets are available in each ward and department. (WPR 42262)
Template letters 1, 2 & 3 are available in the document section of Datix web.

* If there is a delay in identification of the incident, it is recommended that the patient / relevant other are contacted by letter, using Letter 3.

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

Examples	Interpretation
A patient arrived for planned surgery but had not been given the correct advice to discontinue their Warfarin treatment. The surgery had to be postponed.	This would be an example where an incident appeared to have resulted in moderate harm (regulation 20 (8) (b))
During a difficult appendectomy the patient's bowel was accidentally perforated. This was recognised the day after surgery when the patient became increasingly unwell. The patient returned to theatre where the problem was fixed and the patient made a full recovery.	This would be an example where an incident appeared to have resulted in moderate harm (regulation 20 (8) (b))
Wrong site surgery: The identities of two patients on the list are mixed up and one patient undergoes the wrong operation on the incorrect site. The patient is permanently harmed as a result	This would be an example where an incident appeared to have resulted in severe harm (regulation 20 (8) (b))
An elderly patient undergoes a coronary artery bypass operation. The patient is appropriately consented for the risks of the operation, including stroke and death. Unfortunately, the patient sustained a large stroke during the operation, and subsequently died as a result.	This would be an example where an incident resulted in death (regulation 20 (8) (a))
A patient experienced pain during an elective Caesarean section due to incomplete anaesthesia from an epidural line. The patient found this experience traumatic and subsequently had an acute episode of severe anxiety and depression which lasted more than 28 days	This would be an example where an incident appeared to have resulted in prolonged psychological harm (regulation 20 (8) (b))

MEDICINE

Examples	Interpretation
A doctor causes a pneumothorax whilst placing a Central Venous Catheter (a recognised complication). The patient requires a chest drain to be inserted and a short stay on the Intensive Care Unit. The patient makes a full recovery	This would be an example where an incident appeared to have resulted in moderate harm (regulation 20 (8) (b))
A patient developed a small grade 2 pressure ulcer during an admission to treat an acute cardiac problem. Although they were now fully mobile, they need district nursing visits after discharge home to check and dress the ulcer until healing was complete two weeks later	This would be an example where an incident appeared to have resulted in moderate harm (regulation 20 (8) (b))
A patient incurs an extravasation injury (soft tissue burn) from an intravenous line causing irreversible scarring and bone damage.	This would be an example where an incident appeared to have resulted in severe harm (regulation 20 (8) (b))
A confused elderly patient was supposed to have 1:1 supervision on a medical ward. The patient was left unsupervised for a period of time whilst the shift change was occurring, and the patient fell out of bed, sustaining a severe head injury from which they later died.	This would be an example where an incident resulted in death (regulation 20 (8) (a))
A patient who is normally very shy sustains an extravasation injury (soft tissue burn) from an intravenous line. This causes irreversible and extensive scarring on her arm and as a result she becomes severely socially anxious for which she needs a prolonged period of therapy.	This would be an example where an incident appeared to have resulted in prolonged psychological harm (regulation 20 (8) (b))

MATERNITY

Examples	Interpretation
A mother had significant post-partum haemorrhage after a difficult delivery, and there was some delay in obtaining blood for transfusion. As a result, she needed treatment in the high dependency unit for 24 hours before making a full recovery.	This would be an example where an incident appeared to have resulted in moderate harm (regulation 20 (8) (b))
A pregnant woman was seen in A&E at 12 weeks gestation with abdominal pain and PV bleeding. A high vaginal swab was taken by the Gynae SHO which grew Group B Streptococcus (GBS). When the woman went in to labour 28 weeks later, the midwife attending the birth did not check the laboratory results which showed the GBS growth and so the woman was not given intra-partum antibiotic prophylaxis as per national guidelines. The child then went on to develop GBS septicaemia in the days following delivery and required treatment in the Neonatal Intensive Care unit for 5 days before making a full recovery.	This would be an example where an incident appeared to have resulted in moderate harm (regulation 20 (8) (b))
An expectant mother who rang the maternity unit to report possible blood loss and reduced foetal movements was given inappropriate reassurance rather than asked to come for assessment. The baby later was born with severe disabilities.	This would be an example where an incident appeared to have resulted in severe harm (regulation 20 (8) (b))
A woman requiring a blood transfusion for a post-partum haemorrhage received the wrong unit of blood after an error in labelling sample tubes. As a result the woman suffered a severe reaction leading to multi-organ failure and a fatal cardiac arrest.	This would be an example where an incident resulted in death (regulation 20 (8) (a))
An expectant mother with a past history of severe mental health problems was not appropriately assessed at her antenatal appointment. As a result she was not offered NICE recommended psychological therapies, prophylactic medications or specialist follow-up. After delivery she became symptomatic, and these errors led to delays to her diagnosis and treatment. This resulted in a prolonged deterioration in her mental health for more than 28 days.	This would be an example where an incident appeared to have resulted in prolonged psychological harm (regulation 20 (8) (b))

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	Director of Nursing, Midwifery and Quality	Liam Wilson	Existing Policy	22 January 2019

1) Who is responsible for this policy? Name of Division/Directorate: Directorate of Nursing , Midwifery and Allied Health Professionals

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: March 2022

Checked by: Cindy Storer **Date: 22 January 2019**