Being Open Policy

(including Duty of Candour)

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Author (name):	[redacted]
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Version	Type of Change	Date	Revisions from previous issues
1	New Policy	Jan 2023	Being Open policy written to replace Duty of Candour Policy. The policy includes Trust commitment to being open and honest and also includes statement regarding statutory Duty of Candour duties. The policy is supported by the Trust Duty of Candour Procedure document (formally Duty of Candour policy).This policy includes the additional role of Family Liaison Officer.

Equality Impact

Bolton NHS Foundation Trust strives to ensure equality of opportunity for all service users, local people and the workforce. As an employer and a provider of healthcare Bolton NHS FT aims to ensure that none are placed at a disadvantage as a result of its policies and procedures. This document has therefore been equality impact assessed to ensure fairness and consistency for all those covered by it regardless of their individuality. The results are shown in the Equality Impact Assessment (EIA).

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1 Introduction

1.1 The Bolton NHS Foundation Trust (the Trust) is committed to the principles of duty of candour and encouraging a culture of openness and transparency at all levels of the organisation. This is an integral part of the Trust's safety culture and supports organisational and personal learning.

1.2 The Trust expects its staff to be open and transparent with patients and or Families /Next of Kin in relation to their care and treatment, including an obligation for candour when patients experience any level of harm. These expectations are in line with the contractual requirements for candour as described in the NHS Standard Contract and professional requirements for candour of individual clinicians.

2 Purpose

2.1 This document outlines the Trust's policy on the principles of openness, honesty and transparency at all levels following a patient safety incident, particularly when communicating with patients or other relevant persons in relation to care and treatment. This policy also outline's the Trust's policy on carrying out its obligations under the statutory Duty of Candour.

2.2 The statutory duty of candour relates to patient safety incidents that result in moderate harm, significant harm or death of a patient or service user. As detailed in, Regulation 20 of The Health and Social Care Act 2008 (Regulated Activity) Regulations 2014.

2.3 This policy should be followed in conjunction with the Trust Incident Reporting Policy and Serious Incident Policy. However, the Duty of Candour requirement can be triggered following a wide variety of events including (but not limited to) incidents, claims, complaints, serious incidents, never events, PALS contacts, Structured Judgement Reviews. Therefore, Duty of Candour will always be considered as part of the Trust's quality assurance processes.

3 Scope

3.1 This policy is applicable to all staff. The principles of openness, transparency and honesty apply to all incidents and any failures in care or treatment. The statutory duty of candour applies to all regulated activities delivered by any of the Trust clinical services to patients and their families. Regulated activities are certain health and adult social care services and activities that are specified in the Health and Social Care Act 2008 and must be registered with the CQC.

4 Definitions

4.1 **Openness**: enabling concerns and complaints to be raised freely without fear and questions asked to be answered.

4.2 **Transparency:** allowing information about the truth about performance and outcomes to be shared with staff, patients, the public and regulators.

4.3 **Apology** – An expression of sorrow or regret in respect of a notifiable safety incident.

4.4 **Notifiable safety incident** – A specific type of incident defined in the Duty of Candour regulation and should not be confused with other types of safety incidents and notifications. A notifiable safety incident must meet all of the following criteria:

i. It must be an unintended or unexpected incident that occurred in respect of a person using the service during the provision of care and treatment that appears to have resulted:
ii. In the reasonable opinion of a healthcare professional, already has, or might, result in death to the person receiving care, rather than due to natural course of any underlying condition/illness, or led to the person experiencing severe or moderate harm or prolonged psychological harm
iii. It must have occurred during the provision of a CQC registered regulated activity.

4.5 **Relevant person(s)** – A person lawfully acting on behalf of a patient under the following circumstances:

i. The patient has died
ii. The patient is under 16 and not competent to make a decision in relation to their care and treatment
iii. The patient is 16 and over and lacks capacity in relation to the matter.

4.6 **Moderate harm** – significant but not permanent harm that requires a moderate increase in treatment.

4.7 **Severe harm** – A permanent lessening of bodily, sensory, motor, physiological or intellectual function that is directly related to the incident and not related to the natural course of any underlying illness/condition.

4.8 **Prolonged psychological harm** – Psychological harm which the person using the service has experienced or is likely to experience, for a continued period of at least 28 days.

4.9 **Candour** - 'The volunteering of all relevant information to persons who have or may have been harmed by the provision of services, whether or not the information has been requested and whether or not a complaint or a report about that provision has been made' (Francis, 2013).

4.10 **Systems based approach –** A systems based approach focuses on the multiple, complex and adaptive systems of people, events, processes and cultures that are working together at any one time. Problems can arise with either deficiency in

individual system elements, or in their relationship with each other. A systems based approach reframes our understanding as to how care is delivered and can be improved. (Clarkson et al, 2018).

4.11 Thresholds of Harm

Level of Harm	NRLS Definition	Level of response
No Harm / Near Miss	**No harm (Impact prevented)** – Any patient safety incident that had the potential to cause harm but was prevented, resulting in no harm to people receiving NHS-funded care. This may be locally termed a **'near miss'.** **No harm (impact not prevented)** - Any patient safety incident that ran to completion but no harm occurred to people receiving NHS funded care	Duty of Candour does not apply.
Low Harm	**Low (Minimal harm - patient(s) required extra observation or minor treatment)** Any unexpected or unintended incident that required extra observation or minor treatment and caused minimal harm to one or more persons receiving NHS-funded care	Open discussion between the staff providing the patient's care and the patient and/or their carers. The core principles of openness, transparency and candour will apply. (see section 5.1)
Moderate Harm	**Moderate (Short term harm - patient(s) required further treatment, or procedure)** Any unexpected or unintended incident that resulted in a moderate increase in treatment, possible surgical intervention, cancelling of treatment, or transfer to another area, and which caused significant but not permanent harm, to one or more persons receiving NHS-funded care.	These are Notifiable patient safety incidents* that have caused significant harm to a patient/ service user and statutory Duty of Candour (see section 5.3) applies.
Severe Harm	**Severe (Permanent or long term harm)** Any unexpected or unintended incident that appears to have resulted in permanent harm to one or more persons.	

5. Roles and Responsibilities

5.1 Chief Executive

The Chief Executive on behalf of the Trust Board is responsible for ensuring that there is a robust system in place for reporting and managing such events, which includes supporting staff in being open and transparent with persons directly involved in an incident or other relevant persons.

5.2 **Chief Nurse**

The Chief Nurse is nominated by the Trust Board to lead on quality and ensure patients are safe. They should be actively involved in supporting/mentoring senior lead officers in implementing this policy.

5.3 **Medical Director**

In exceptional circumstances where there has been a delay in an incident coming to light through a mortality review, the Medical Director will consider the action to be taken, the impact of the information for the patient's family and whether this policy is to be applied.

5.4 **Director of Quality Governance**

The Director of Quality Governance is responsible for ensuring there is a policy which supports staff and the Trust to meet their statutory obligations in the respect of the Duty of Candour. They are also responsible for ensuring that the duty of candour is integrated in governance processes. Along with the Assistant Director of Clinical Governance, they must ensure a robust training package is available to all relevant staff.

5.5 **Assistant Director of Clinical Governance**

The Assistant Director of Clinical Governance is the responsible author for the Duty of Candour Policy, and for ensuring that the Trust is kept up to date with any significant developments, national changes or implications to the Duty of Candour process.

The Assistant Director of Clinical Governance is responsible for ensuring the Patient Safety Incident Report is updated with the percentage of Duty of Candour metrics (stage 1 and stage 2 Duty of candour letters) completed within the month.

The Assistant Director of Clinical Governance is responsible for providing guidance and quality assuring Duty of Candour letters on request, to maintain the standard set by the Trust.

5.6 **Divisional Medical Directors, Divisional Nurse Directors, Divisional Directors of Operations, Governance Leads, Matrons and Operational Business Managers**

The Divisional Medical Directors are accountable for compliance with Duty of Candour in their respective divisions.

The Divisional Medical Directors are responsible for ensuring that all events are reported as and when they are identified. They must ensure this process is monitored through their divisional governance structures. In addition, they must work with key members of the corporate quality governance team to ensure that this policy is fully complied with.

Divisional Nurse Directors must act as the Duty of Candour Lead in the event of a serious incident.

Divisional Nurse Directors, Governance Leads and Matrons must ensure:

- Events that occur within their areas of responsibility are reported in line with the Trust's Incident Reporting Policy.
- In the case of a notifiable safety incident, the patient's consultant must be informed of the event.
- In the event of a serious incident involving a patient, the Divisional Medical Director must be informed.
- In all cases, ensure the immediate safety of the patient and any relevant mitigating actions are put in place.
- Staff involved in implementing this policy have attended Duty of Candour awareness sessions.

Managers must also be aware that any staff member who is involved in an event which results in another person being harmed will also need support.

5.7 Duty of Candour Lead

The Duty of Candour Lead should be the Assistant Divisional Nurse Director or a Senior Nurse. However, in the event of a serious incident, one of the divisional Senior Leadership Team members - Divisional Director of Operations, Divisional Medical Director or Divisional Nurse Director must act as the Duty of Candour lead.

5.8 Family Liaison Officer (FLO)

A Family Liaison Officer must be appointed within the Division to keep in contact with the family regarding updates about the investigation at a minimum of every three weeks.

6 Reporting Requirements

6.1 The Trust Incident Reporting Policy will be followed when reporting and investigating all patient safety incidents. The level of harm associated with a patient safety incident will be validated as per the Incident Reporting Policy and the level of response, in relation to duty of candour, will be linked to the level of

harm as determined using the National Reporting and Learning System definitions (NRLS).

6.2 An open and honest conversation must take place with the patient, relatives and/or relevant person as soon as we become aware that harm has been caused.

6.3 Being open about what happened and discussing patient safety incidents promptly, fully and compassionately with patients and/or relevant persons can:

- Help patients and/or relatives cope better with the after-effects;
- Ensure that a thorough investigation into the patient safety event takes place and provide assurance that lessons learned will help prevent to ensure a similar type of incident from recurring;
- Provide an environment where patients and/or their carers, healthcare professionals and managers feel supported when things go wrong.

7 Recording Incidents

7.1 Details of how to record an incident on the Safeguard system can be found in the Incident Reporting Policy and Serious Incident Policy.

7.2 It is essential that all incidents are fully recorded at the time and any discussion with the patient or relevant person is also detailed to ensure clarity and a robust audit trail.

8 Patient Information/support

8.1 Patients/service users and their family may need considerable practical and emotional help and support after experiencing a patient safety incident. It is therefore important to discuss their individual needs directly with them and consider the types of support available.

8.2 Where the patient needs more detailed long term emotional support, advice should be provided on how to gain access to appropriate counselling services.

9 Statutory Duty of Candour Requirements

9.1 All registered providers must demonstrate that they are meeting regulatory requirements of the statutory Duty of Candour in order to register with CQC and then continue to deliver regulated services. CQC Regulation 20: Duty of Candour, requires that “as soon as reasonably practical after becoming aware of a notifiable safety incident (moderate, severe, prolonged psychological harm for at least a continuous period of 28 days and death) the health service body MUST:

- Notify the service user/someone lawfully acting on their behalf (the “relevant person”) that the incident has occurred

- Provide “reasonable support” to the service user/relevant person

9.2 The procedure for discharging Duty of Candour at the Trust is described fully in Appendix 1: Trust Duty of Candour Procedure. All staff must follow this procedure when discharging their responsibilities in relation to the Duty of Candour to ensure all statutory requirements are met.

9.3 Once an incident has been validated as having caused ‘Moderate’ or above, the requirement to undertake the Duty of Candour process is initiated.

9.4 For the incidents where moderate harm has been caused the Duty of candour process must be led by a member of the Senior Divisional Leadership team and can be delegated to the Assistant Divisional Nurse Director.

9.41 For the incidents where severe harm or above has been caused the Duty of candour process must be led by a Senior Divisional Leadership team.

9.5 Professionals with a responsibility for communicating Duty of Candour are accountable for ensuring that they have completed Level 1 and 2 of the national Patient Safety Syllabus and have received appropriate training in key communication skills. They should also ensure they are familiar with this document, the Duty of Candour Procedure document and the Trust Incident Reporting Policy.

9.6 The formal Duty of Candour process must be undertaken regardless of whether a member of staff has already spoken to the patient regarding the incident at the point of occurrence/ identification. Any previous discussions prior to the formal Duty of Candour discussions are not to be recorded as Duty of Candour within Safeguard.

9.7 The assigned Duty of Candour Lead must attempt to make initial verbal contact with the patient or relevant person **within 24 hours** of a Serious Incident/further investigation being declared.

9.8 The incident record on Safeguard must be updated with all Duty of Candour progress, including failure to contact and reasons for any delays.

9.9 A **Family Liaison Officer (FLO)** must be appointed within the Division to keep in contact with the family regarding updates about the investigation at a minimum of every three weeks.

10 Communication

10.1 Every reasonable attempt must be made to contact the patient or relevant person through all available means of communication. If verbal contact is impossible but

an address is on file for the patient, then a letter must be sent to the address which includes a request for the individual to make contact with the Trust. All attempts to contact the patient or relevant person must be documented in the incident record on Safeguard.

10.2 All reasonable attempts should be made to communicate with the patient or relevant person in a format/using a means that will assist them in fully understanding the process and subsequent findings (e.g. translator, independent advocate). Do not use 'unofficial translators' and/or the patient's family or friends.

10.3 Consideration should also be given to alternative forms of communication such as the use of visual aids or easy read documentation to support patients or relevant persons in understanding the apology and the reason for it.

10.4 If the patient or relevant person does not wish to communicate with the Trust, their wishes should be respected and this should be recorded in the patient's medical notes and incident record on Safeguard.

10.5 If the patient has died and there is no relevant person to act lawfully on their behalf this should be recorded in the incident record on Safeguard.

10.6 Duty of Candour Leads must discuss any of these issues with the Director of Quality Governance to ensure all reasonable attempts have been made before formal approval of exemption.

10.7 Any exemptions to the Duty of Candour process (as outlined in section 11 of this policy) must be escalated to the Director of Quality Governance, who will consider the modification and confirm any exemption with the Chief Nurse (or in their absence, the Medical Director). The reason for any delay or agreed exception to Duty of Candour must be documented on the incident record on the Safeguard system.

10.8 Any exemptions must then be reported to the Clinical Governance and Quality Committee via the monthly Patient Safety report.

11 Specific Considerations

11.1 The approach to the Duty of Candour may need to be modified according to the person's personal circumstances. Where any modifications conflict with the Duty of Candour process and pose a risk of a breach by the Trust this must be escalated to the Director of Quality Governance, who will consider the modification and confirm any exemption with the Chief Nurse (or in their absence, the Medical Director). The reason for any delay or agreed exemption to Duty of Candour must be documented on the incident record on the Safeguard system.

11.2 Where compliance with Duty of Candour is considered to be psychologically harmful to the patient, again this must be discussed with the Director of Quality

Governance who, where agreed, will seek authority to delay or exempt Duty of Candour from the Chief Nurse (or in their absence, the Medical Director). Once confirmation has been received, an explanatory note must be placed on the incident record on Safeguard.

11.3 Children and Young People

11.3.1 The legal age of maturity for giving consent to treatment is 16. It is the age at which a young person acquires the full 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 in decision making.

11.3.2 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. 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 Duty of Candour process after a patient safety incident.

11.3.3 The opportunity for parents/carers/guardians, to be involved should still be provided unless the child expresses a wish for them not to be present.

11.3.4 Where children are deemed not to have sufficient maturity or ability to understand, consideration needs to be given to whether information is provided to the parents, carers/guardians alone or in the presence of the child. In these instances, the parents' views on the issue should be sought.

11.3.5 Where the patient is 16 or over and lacks capacity in relation to the matter (i.e. lacks capacity specifically in relation to the incident and subsequent process), the duty of candour process should be followed with the person lawfully acting on their behalf (such as a person appointed by way of Lasting Power of Attorney for health and welfare, or the person to be consulted in the service user's best interests under the Mental Capacity Act 2005 and the Mental Capacity (Amendment) Act 2019). The Trust is not required to liaise with all potential persons identified who could meet the 'best interests' role, but should identify key persons.

11.4 Patients with mental health issues

11.4.1 Duty of Candour for patients with mental health issues should follow normal procedures, unless there are issues with mental capacity (see below). The only circumstances in which it is appropriate to withhold patient safety incident information from a mentally ill patient is when advised to do so by a consultant psychiatrist who feels it would cause adverse psychological harm to the patient.

11.4.2 However, such circumstances are rare and a second opinion (by another consultant psychiatrist) would be needed to justify withholding information from

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

11.5 Mental Capacity and Best Interests

11.5.1 Where the patient has been assessed as not having capacity (in accordance with the Mental Capacity Act 2005 and the Mental Capacity (Amendment) Act 2019), a verbal apology should still be made to the patient (unless it is believed that this would cause unnecessary psychological harm or distress), and noted in the incident record. It is recognised that the patient may not retain knowledge of the apology.

11.6 Other than the situations outlined above, information should only be disclosed to family members or carers where the person using the service has given their express or implied consent.

12 Confidentiality

12.1 When dealing with a patient safety incident consideration must always be given to the confidentiality of all service users, carers and staff and information disclosure and sharing is subject to confidentiality and information governance restrictions. Further details are provided in section 13 of the Trust Duty of Candour Procedure.

13 Training and Resources

13.1 The implementation of this policy will be supported by a robust Duty of Candour training package based on key competencies for those delivering Duty of Candour.

14 Monitoring Compliance

Areas to be monitored	Methodology	Lead	Reporting to	Frequency
Duty of candour process is being followed	Audit	Assistant Director of Clinical Governance	CG&Q Committee	Annual
Outstanding DOC letters	Report Status of outstanding DOC letters	Assistant Director of Clinical Governance	CG&Q Committee	Monthly

Outstanding DOC letters	Report to Divisions weekly	Divisional Governance Leads	Divisional Governance meetings	Monthly

14.1 Feedback from patients following an incident subject to the duty of candour process may also be used where available to ensure that they felt informed, supported and understood the outcomes.

15 Associated Documents

The following procedural documents should be read in conjunction with this document:

- Duty of Candour Procedure
- Incident Reporting Policy
- Raising Concerns Policy
- Serious Incident Policy
- Mortality Review Policy

16 References

Care Quality Commission (2022) Regulation 20: Duty of candour - Care Quality Commission (cqc.org.uk)
Dalton, D and Williams, N (2014) Building a Culture of Candour — Royal College of Surgeons (rcseng.ac.uk)
Department of Health (2013) Patients First and Foremost: The Initial Government Response to the Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry
Francis, R (2013) Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry - GOV.UK (www.gov.uk)
NHS Resolution (2018) Saying Sorry Read saying sorry (duty of candour) - NHS Resolution
Royal College of Surgeons (2023) Duty of Candour — Royal College of Surgeons (rcseng.ac.uk)
National Quality Board (2018) ngb-national-guidance-learning-from-deaths.pdf (england.nhs.uk)
Healthcare Safety Investigation Branch (2018) Maternity investigations — HSIB
NHS England (2018) NHS England » NHS Standard Contract 2017/18 and 2018/19 General Conditions (full length)
Clarkson et al (2018) A systems approach to healthcare: from thinking to practice - PMC (nih.gov)

Appendix 1 – Trust Duty of Candour Procedure

A summary of the Duty of Candour process is in figure 1 below:

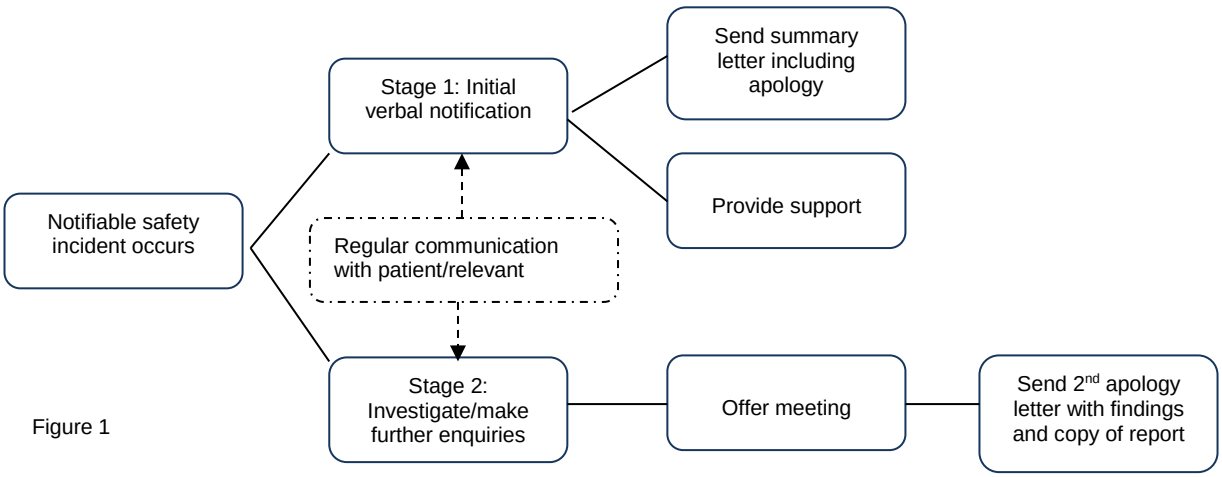

Figure 1

Stage 1a - initial verbal contact within 2 working days of declaration

The assigned Duty of Candour Lead must attempt to make initial verbal contact with the patient or relevant person **on the same day** of a Serious Incident/further investigation being declared.

Wherever possible/appropriate the initial contact with the patient or relevant person should be face to face.
Where this is not possible/appropriate, then an initial telephone call must be made to alert the patient or relevant person that an incident has potentially taken place and to offer to meet with them to discuss this in detail.
If at this stage the patient or relevant person requests that further information is given over the telephone, then this is acceptable. Whether the initial discussion is through a face to face meeting or via the telephone it must include the detail as outlined below:

- An apology on behalf of the Trust to express genuine sympathy/regret that the incident/harm has occurred (Acknowledgment should be considered that at this stage, it will not be known if any preventable error has occurred).
- A brief description of the event/incident (Explanation of the facts known at this stage). This account must be given in a manner the patient or relevant person can understand.
- Detail of the investigation process, what will happen next, further enquiries that will be carried out into the incident
- An opportunity should be provided for the patient or "Relevant Person" to raise any concerns/questions that they wish to be addressed as part of the investigation [and] they must be asked if they wish to provide a statement of their own recollection of

events to assist the investigation (this may also include seeking any input from other friends/ family which may be relevant)
- A target date* for completion of the investigation and sharing the findings
- An offer of practical/emotional support if required e.g. transport, bereavement counselling, support in dealing with the media, and potentially signposting to other organisations which provide bereavement or post-traumatic stress counselling etc.
- Our commitment to sharing the outcome of our investigation and ensuring that we learn from our findings
- The Duty of Candour lead's contact details, should the patient or relevant person wish to enquire about the investigations progress or make an offer to contribute at a later stage

*If an investigation exceeds its target date the Family Liaison Officer must keep in regular contact with the family until the report is ready

It is essential that the following does not occur during the conversation:

- Speculation
- Attribution of blame
- Denial of responsibility
- Provision of conflicting information from different individuals

In instances where initial verbal contact cannot be established within 10 working days despite reasonable attempts (including phone calls at varying times of day; mornings, afternoons and evenings) a request for contact letter/or email can be sent (where the address is known) and attempts documented on the incident record within Safeguard. In this situation the organisation will be compliant with Stage 1a of the Duty of Candour process.

Where the DoC Lead is unable to contact the patient or Relevant Person or where there is no Relevant Person see section 10 of this policy.

Stage 1b – Initial written contact
- Following verbal notification (stage 1a), a letter summarising the above discussion must be sent to the patient or relevant person within five working days of the investigation commencement date.
- The letter should follow the general outline of the Trust Letter Template which is contained within Appendix 2. Although this may need to be individualised to meet the specific circumstances of the situation, the letter should contain all of the relevant information detailed within the template. The letter must be proof read to ensure that it is accurate and free of spelling and grammatical errors before being sent to the patient or "Relevant Person".
- A copy of this summary letter must be logged /attached onto the incident record on the Safeguard system.

Stage 2 – Sharing the findings

Within 3 working days of a Concise or Serious Incident Investigation report being fully signed off, the Duty of Candour Lead will contact the patient or relevant person by telephone (where possible) to confirm how they would prefer to receive the investigation findings.

Where and how the investigation findings are discussed/shared should be dependant of the preference of the patient/family. Options include; a meeting at the patient/family home, a meeting on Trust premises (or other meeting place), or for the report to be sent via post or email.

The following factors should be considered when undertaking a stage 2 face to face meeting:

- The meeting should be arranged at the earliest practical opportunity
- Consideration should be given to the timing of the meeting, based on the patient or relevant person's health and personal circumstances etc.
- The location of the meeting should be at the patient or relevant person's convenience, wherever possible
- A written record of the discussion should be kept and shared with the patient or relevant person
- The patient or relevant person should be asked if they are satisfied with the investigation findings and a note of this made in the investigation file
- The patient or relevant person should also be informed that there will be opportunity for further communication at a later date if they have any more questions

If the patient or relevant person declines a face to face meeting, the option to send the investigation report by post should be offered. When the investigation report is sent via post, the covering letter must:

- reiterate the apology
- apologise for the formal nature of the report and any clinical language used
- offer the opportunity to have a meeting at a later date.

The final investigation report will be redacted of all staff and patient names.

The incident record on Safeguard must be updated with all Duty of Candour progress, including failure to contact and reasons for any delays.

Follow up meetings

- Any follow up meetings will be arranged if requested by the patient or relevant person, at a time convenient to them.

- Before the meeting, the patient or relevant person will be advised of the identity and the role of all the people who will be attending. This allows them the opportunity to ensure that they are comfortable with all the individuals they will meet. The patient or relevant person may bring another individual with them as support if they so wish. Where there is a separate family liaison person, the Duty of Candour Lead must suggest inviting them as support for the patient or relevant person.

- All questions (relating to the patient safety incident) raised by the patient or relevant person as part of the initial notification, should be addressed.

- Notes (minutes) should be taken at the meeting and typed up to provide a summary record of the discussion and any actions agreed. A final copy of these minutes must be attached and saved on the incident record on the Safeguard system*.

*All documents relevant to Duty of Candour, including letters of apology and any minutes of meetings, must be uploaded to the incident record on Safeguard as evidence of compliance with contractual and statutory requirements.

Appendix 2 – Stage 1b Duty of Candour Letter Template

Dear …

Thank you for speaking with me on [insert date]. On behalf Bolton NHS Foundation Trust may I once again offer my sincerest apologies for the incident which occurred on [date] when [describe briefly the incident providing an account of facts known].

We will be undertaking an internal investigation/review into the care and treatment that [you/your father/your mother etc.] received whilst in the care of our organisation. The investigation/review will help us to establish the circumstances surrounding [the incident] and identify if there were any opportunities for us to have done things differently.

The investigation/review will also identify any actions that can be taken to improve the care that we provide to our patients in the future and to prevent such an incident happening again.

When we spoke on [date] you mentioned a number of concerns/issues that you would like to be addressed within the investigation and I have outlined these below:
1.
2.
3.
Or When we spoke on [date] you advised that there were no particular concerns that you wished for me to consider as part of the investigation, but should this change at any stage you should feel free to raise these with me directly.

The Trust is committed to being open and honest when something has gone wrong and to providing a full explanation and apology to you. It is important to us that we communicate our findings with you and we will contact you once the investigation is complete in order to do so. If you require any support or assistance during the investigation, then please contact me on the number below. I will endeavour to update you at regular intervals with the progress of the investigation, but please feel free to contact me directly if you need to.

The investigation team may need to meet or speak with you to ask about your experience and if this is the case I will be in touch.

I anticipate that the investigation/review report will be available by [insert date], after which I will contact you to arrange a date for us to meet to discuss the outcome and findings. On behalf of Bolton NHS Foundation Trust can I once again offer our sincerest [apologies/condolences] and give you our commitment to sharing with you in full, the outcome of our investigation/review and to ensuring that we learn from our findings.

Yours Sincerely
[Name]
[Designation]
[Contact number]

Appendix 3 Equality Impact Assessment Tool

To be completed and attached to any procedural document when submitted to the appropriate committee for consideration and approval.

		Yes/No	Comments
1.	**Does the document/guidance affect one group less or more favourably than another on the basis of:**		
	• Race	No	
	• Ethnic origins (including gypsies and travellers)	Yes	The policy emphasises the need to communicate with patients/ relevant persons in their preferred method to assist them in fully understanding the process and subsequent findings. Patients/relevant persons from travelling communities may be difficult to contact as a permanent address is required. In such instances a preferred means of communication is to be agreed.
	• Nationality	Yes	Patients/relevant persons for whom English is not the first language - Where a patient or relevant person's first language is not English, all reasonable attempts should be made to communicate in a format/using a means that will assist them in fully understanding the process and subsequent findings.
	• Gender (including gender reassignment)	No	
	• Culture	No	
	• Religion or belief	No	
	• Sexual orientation	No	
	• Age	Yes	Where the patient is under 16 and is not competent to make a decision in relation to their care and treatment, the duty of candour process should be followed with the person lawfully acting on their behalf (such as an individual with parental responsibility). However, it should not be assumed that because a person is under 16 that they

			automatically lack capacity (as per Consent process and Gillick competence standards)
	• Disability - learning disabilities, physical disability, sensory impairment and mental health problems	Yes	Consideration as to the requirements of the MCA 2005 and MCA (Amendment) 2019 must be given as outlined in the policy to ensure that the relevant person is still informed when capacity may be an issue. Consideration should also be given to the use of alternative forms of communication such as visual aids and easy read documents to aid patient understanding. The policy reinforces the need to communicate with patients/ relevant persons in their preferred format as part of the investigation and to feedback. Every effort will be made to make reasonable adjustments to ensure patients remain central to the process. Patients and relevant persons can request meetings at their convenience and as needed.
2.	**Is there any evidence that some groups are affected differently?**	Yes	As outlined under the Special Considerations section. Communication considerations will need to given when supporting people for whom English is not their first language i.e. ethnic groups and people with disabilities
3.	**If you have identified potential discrimination, are there any valid exceptions, legal and/or justifiable?**	Yes	As outlined under the special consideration section: Delayed identification of an incident particularly following a patient's death – to contact the family may be distressing and should be reviewed on a case by case basis with the medical Director.
4.	**Is the impact of the document/guidance likely to be negative?**	No	
5.	**If so, can the impact be avoided?**	N/A	

6.	**What alternative is there to achieving the document/guidance without the impact?**	N/A	
7.	**Can we reduce the impact by taking different action?**	N/A	

If you have identified a potential discriminatory impact of this procedural document, please refer it to the Equality and Diversity Co-ordinator, together with any suggestions as to the action required to avoid/reduce this impact.

Appendix 4 - Document Development Checklist – Document Control Policy

Section 1	To be completed by Lead Author
Type of document :	Policy
Lead author:	[redacted]
Is this new or does it replace an existing document?	New- replaces the existing Duty of Candour policy
What is the rationale/ Primary purpose for the document	Ensuring patients receive appropriate communication where harm has occurred Duty of Candour legislation introduced 27 November 2014, CQC monitoring framework for Regulation 20 on Duty of Candour
What evidence/standard is the document based on?	Given in the reference section: CQC Guidance on Regulation 20 Royal College of Surgeons guidance on Duty of Candour NHS Contract Mental capacity Act 2005 Mental Capacity (Amendment) Act 2019
Is this document being used anywhere else, locally or nationally?	No
Who will use the document?	All Trust staff
Staff/stakeholders consulted:	Director of Quality Governance, Chief Nurse, Divisional Governance Teams,
What is the implementation and dissemination plan? (How will this be shared?)	A briefing note will be sent to the divisional management teams, matrons and ward managers
Are there any service/resource implications? (How will any change to services be met? Resource implications?)	No This should already be in practice
Are there any additional training requirements? If so have these been discussed as part of the implentation plan?	Duty of candour training to be reviewed
How will the document be reviewed? (When, how and who will be responsible?)	Reviewed in 3 years (unless amendment is required sooner)

Keywords (Include keywords for the document controller to include to assist searching for the policy on the Intranet)	Being Open, Duty of Candour, Candour, incident, investigation
Any document that gives an instruction to prescribe or administer a medicine should have that instruction reviewed by the senior divisional pharmacist before it goes for ratification.	
Signed and dated by Chair of validating committee/group *Local/Divisional level scrutiny*	Signed: [redacted] Designation: Assistant Director of Clinical Governance Date: 20th April 2023
Signed and dated By Chair of Approving Committee/Group *PDOC Chair (approval for submission to Execs). Leave blank for guidelines or where there have been minimal changes to policies.*	Signed: [redacted] Designation: Assistant Director of Clinical Governance Date: 20th April 2023
Final Sign off Signed and dated *Executive Director meeting Chair (or PDOC chair for guidelines or where there have been minimal changes to policies)*	Signed: [redacted] Designation: Chief Executive Date: 15/05/2023