University Hospitals of Leicester NHS
NHS Trust

Duty of Candour (Being Open) Policy

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Author / Originator(s):	**Head of Patient Safety**
Name of Responsible Committee/Individual:	**Andrew Furlong, Medical Director**
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CONTENTS

REVIEW DATES AND DETAILS OF CHANGES MADE DURING THE REVIEW

September 2015 - V1 of this Policy was completely re-written to incorporate the new requirements of the statutory duty of candour (Regulation 20 Health and Social Care Act 2008) which came into force on 27th November 2014 for NHS bodies and 1st April 2015 for all other health care providers regulated by the Care Quality Commission (CQC). It includes explicit and associated guidance on how to meet the requirements with examples of good practice for use within the appendices.

November 2016 - New point added in relation to recognised complications leading to moderate or severe harm. All references throughout relating to filing of written letters to patients / relatives stored in medical records amended to state uploading on to the Datix system. Duty of Candour Flow Diagram updated to incorporate processes for recognised complications and uploading letters on to Datix.

November 2017 – Moved 'Being Open' section to become an appendix. Removal of Trust 'Being Open' leaflet to sit as independent leaflet within Trust document management system.

August 2021 – minor amendment to amend wording in section 5.5 and flow diagram on page 7 regarding Duty of Candour requirements for incidents of recognised complications. Change of title from Director of Safety and Risk to Director of Quality Governance. Addition of new reference for CQC website.

KEY WORDS

Being open and honest, Duty of Candour, apology, transparency, saying sorry, candour

SUMMARY

i. A statutory Duty of Candour came into force on 27th November 2014 for NHS bodies and 1st April 2015 for all other health care providers regulated by the Care Quality Commission (CQC).
ii. Health care professionals must assess whether a patient safety incident is one which requires notification in line with this duty and, if notification is required, inform patients both in person and in writing that they have been involved in an incident, give an immediate apology to them and advise them what further actions will be carried out to meet the entirety of the Duty of Candour requirements.
iii. The outcomes of any enquiries should also be shared with the patient along with an account of what further actions are to be taken.
iv. The Duty of Candour will be overseen and enforced by the Care Quality Commission (CQC) which has a range of strengthened enforcement actions.

1 INTRODUCTION AND OVERVIEW

1.1 University Hospitals of Leicester NHS Trust (UHL) is committed to promoting an open and honest environment where patients' concerns can be addressed and thorough investigations and explanations given following patient safety incidents, however they may be identified by or to the organisation. The Trust aims to support and empower staff to ensure communication is effective and a no-blame culture is evident. This Policy represents the Trusts approach to meeting the Duty of Candour requirements.

1.2 This policy is aimed at all healthcare staff responsible for patient care and aims to ensure that an infrastructure is in place to promote openness and honesty between healthcare professionals and patients and/or their carers, specifically for use following a notifiable patient safety incident.

1.3 Adherence to this policy will help patients and/or carers feel confident in the Trust's communication and provision of information, and help healthcare professionals feel supported in delivering it.

1.4 The Trust's Incident and Accident Reporting Policy encourages staff to report all patient safety incidents, including those where there was no harm or where it was a prevented patient safety incident (near miss). This policy relates to those incidents that are graded moderate harm, severe harm or death as defined in the Trust's incident and accident reporting policy.

2 POLICY SCOPE

2.1 This document sets out the Trust process for meeting the requirements of the statutory Duty of Candour.

2.2 The aim of this policy is to ensure that UHL staff are aware of their responsibilities for duty of candour and being open by:

a) Providing a clear process for meeting the requirements of Duty of Candour.
b) Ensuring that the Trust is meeting the statutory requirement of duty of candour.

2.3 There are 6 supporting documents to this policy (Appendices 1-6 as detailed on the Contents Page).

2.4 This Policy applies to all members of staff employed by University Hospitals of Leicester NHS Trust and includes those employed on bank, agency or honorary contracts.

2.5 This policy relates to those incidents that are graded moderate harm, severe harm or death as defined in the Trust's incident and accident reporting policy.

3 DEFINITIONS

Patient Safety Incident (PSI)	Any incident affecting service users*

	irrespective of the consequences (impact). This is a clinical incident affecting the care or outcome for the patient
Apology	An expression of sorrow or regret in respect of a notifiable patient safety incident
Harm	Physical or mental damage or injury
Moderate harm	Harm that requires a moderate increase in treatment **AND** significant but not permanent harm
Moderate increase in treatment	Unplanned return to surgery, an unplanned readmission, a prolonged episode of care, extra time in hospital or as an out-patient, cancelling of treatment, or transfer to another treatment area (such as intensive care)
Notifiable safety incident	Any unintended or unexpected incident that occurred in respect of a service user (regardless of harm) during the provision of a regulated activity that, in the reasonable opinion of a healthcare 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
Prolonged psychological harm	Psychological harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days
Relevant person	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; c) Where the service user is 16 or over and lacks capacity (as determined in accordance with the Mental Capacity Act 2005) in relation to the matter
Major harm	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

*Service user is the term used in the regulations and means 'patient' for NHS services

4. ROLES AND RESPONSIBILITIES

4.1 **The Trust Board** has a duty to ensure that the requirements of Duty of Candour are fulfilled giving a public commitment to implement the principles within this document. To actively promote an open and fair culture that fosters peer support and discourages the attribution of blame.

4.2 **The Chief Executive** is the Board level lead for Duty of Candour and will ensure that there is Board level commitment to implementing the principles of 'Being Open' and meeting the statutory duty of candour. They are responsible for ensuring that the policy complies with all legal, statutory and good practice guidance reports.

4.3 **The Medical Director** has the delegated responsibility for ensuring compliance and for ensuring that adequate corporate structures, roles and responsibilities are in place to fulfil the said requirements.

4.4 **The Director of Quality Governance** has the delegated responsibility for ensuring compliance and for engaging with Clinical Management Group (CMG) and Corporate Directors to ensure compliance and a transparent and open safety culture. They will provide compliance performance reports to Executive Quality Board, Quality and Outcomes Committee and Clinical Quality Review Group.

4.5 **Executive Quality Board** will receive quarterly reports on compliance with the Duty of Candour regulations as part of the NHS Standard Contract for monitoring.

4.6 **Quality Committee** will receive quarterly reports on compliance with the Duty of Candour regulations as part of the NHS Standard Contract for monitoring.

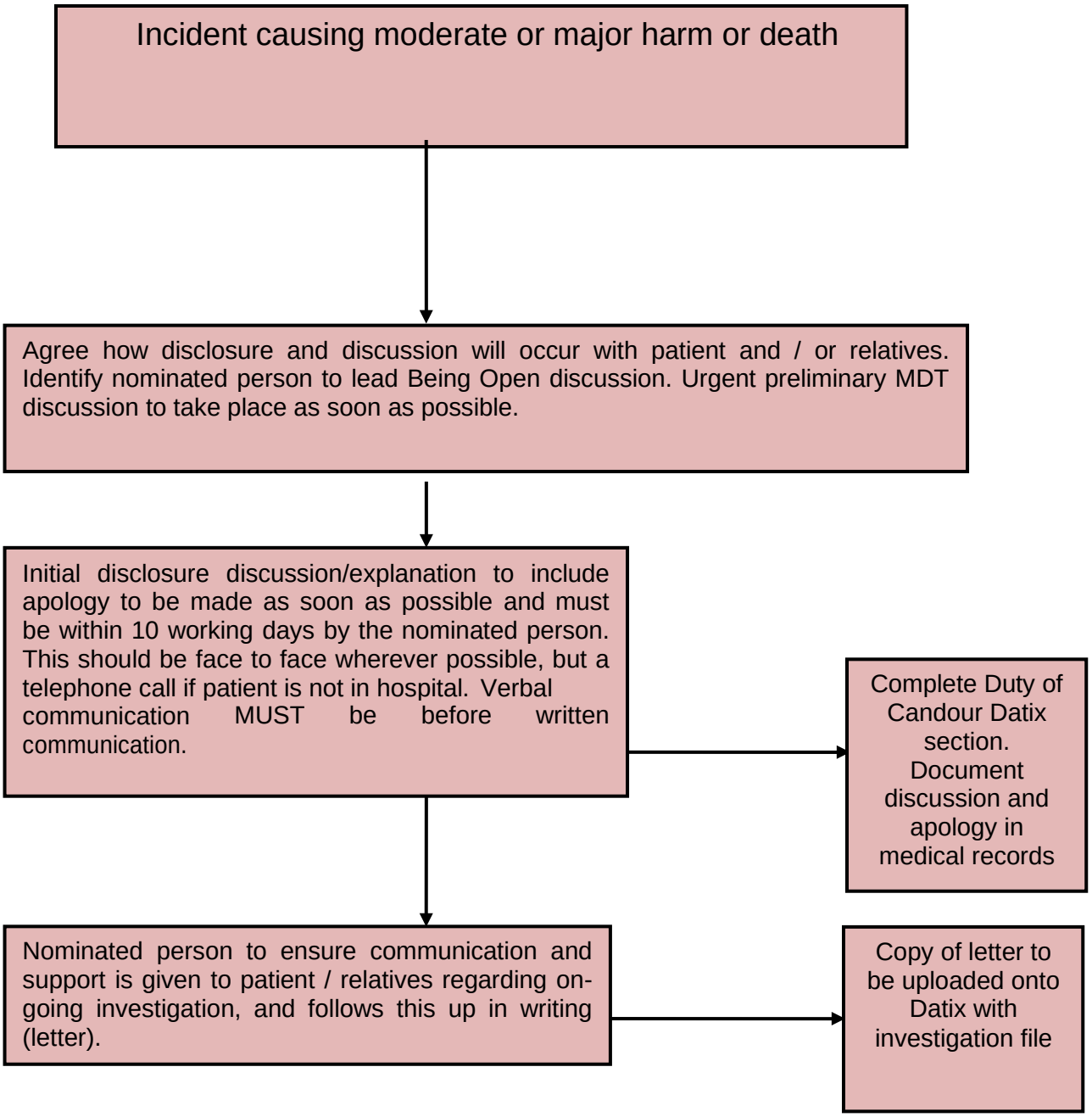
4.7 **The Clinical Management Groups (CMG Director, Head of Operations and Head of Nursing)** are responsible for ensuring effective structures, processes and resources are in place within their areas to ensure compliance with the requirements of Duty of Candour and principles of 'Being Open'. They must ensure that healthcare professionals involved in patient safety incidents graded moderate or above are supported in the candour process.

4.8 The **Corporate Patient Safety Team** are responsible for delivering training to clinicians and other relevant staff.

4.9 All Members of Staff, including temporary, bank and agency are required to comply with the requirements of Duty of Candour and the principles of 'Being Open'. Staff are required to understand that Duty of Candour sits alongside existing professional responsibilities and must understand their own obligations and the roles of those around them in relation to the duty. (Ref; NMC and GMC published joint guidance 'Openness and honesty when things go wrong: the professional Duty of Candour').

Duty of Candour Flow Diagram

University Hospitals of Leicester NHS
NHS Trust



5. POLICY STATEMENTS

Key Elements of Being Open

5.1 Effective communication with patients begins at the start of their care and must continue throughout their time with the Trust. This should be no different when a patient safety incident occurs. Openness about what happened and discussing patient safety incidents promptly, fully and compassionately can help patients cope better with the after-effects. Patient safety incidents also incur extra costs through litigation and further treatment; openness and honesty can help prevent such events becoming formal complaints and litigation claims. Openness when things go wrong is fundamental to the partnership between patients and those who provide their care.

5.2 For UHL, Being Open involves:

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

5.3 For healthcare staff, Being Open has several benefits, including:

- Satisfaction that communication with patients and/or their carers following a patient safety incident has been handled in the most appropriate way.
- Improving the understanding of incidents from the perspective of the patient and/or their carers.
- The knowledge that lessons learned from incidents will help prevent them happening again.
- Having a good professional reputation for handling a difficult situation well and earning respect among peers and colleagues.

OVERVIEW OF THE DUTY OF CANDOUR / BEING OPEN PROCESS

5.4 Incident Detection or Recognition

The Duty of Candour / Being Open process begins with the recognition that a patient has suffered moderate harm, major harm, or has died, as a result of a patient safety incident.

A patient safety incident may be identified by:

- A member of staff at the time of the incident.
- A member of staff retrospectively when an unexpected outcome is detected.
- A patient and/or their carers who expresses concern or dissatisfaction with the patient's healthcare either at the time of the incident or retrospectively.
- Incident detection systems such as incident reporting or medical records review.
- Other sources such as detection by other patients, visitors or non-clinical staff.

As soon as a patient safety incident is identified, ensure that prompt and appropriate clinical care and prevention of further harm is in place. Where additional treatment is required, this should occur whenever reasonably practicable after a discussion with the patient and with appropriate consent.

All Patient Safety Incidents should be reported in line with the Trust Incident and Accident Reporting Policy (Including the investigation of Serious RIDDOR and Security Incidents).

5.5 Recognised complications resulting in moderate harm, major harm or death

When moderate harm, major harm or death has occurred as a result of a recognised complication, the full Duty of Candour requirements apply.

5.6 Meeting the Requirements of Duty of Candour

To meet the requirements of Regulation 20, Health and Social Care Act 2008 an NHS body has to:

- Make sure it acts in an open and transparent way with relevant individuals in relation to care and treatment provided to people who use services in carrying out a regulated activity.
- Tell the relevant individual in person as soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred, and provide support to them in relation to the incident, including when giving the notification.
- Provide an account of the incident which, to the best of the health service body's knowledge, is true of all the facts the body knows about the incident as at the date of the notification.
- Advise the relevant individual of any further enquiries the health service body believes are appropriate including:
    - Offering an apology.
    - Following this up by giving the same information in writing, and providing an update on the enquiries. (Refer to letter templates at (Appendix 3). This letter must be uploaded on to the Datix system.
    - Documenting and recording in a written record the incident which is kept securely by the health service body. (Refer to medical notes documentation example at Appendix 4).

INITIATING DUTY OF CANDOUR / BEING OPEN PROCESS

5.7 Initial Identification and Notification

Staff must report the incident via the Datix incident reporting system and to senior staff immediately.

The initial notification of the incident to the patient or family must:

- Be given **in person** by one or more representatives of the Trust or a telephone conversation if the patient is not in hospital.
- Provide an account of the facts that the Trust knows about the incident, as at the date of the notification, taking into account as little or as much information as the patient and/or family wants to hear.
- Advise the patient and/or family what further enquiries into the incident are appropriate and that new information may emerge as a result of those enquiries and that they will be kept informed.
- To provide an apology*.

A face to face meeting is to be offered to the patient/ family or other relevant person and this is to occur within 10 working days of the incident/complaint being known where possible. Further **written** notification (a summary letter) must follow and include:

- The facts as provided at the meeting or communication with the patient visit

- Details of any enquiries to be undertaken as discussed at the meeting
- The results of and further enquiries into the incident
- An apology*
- Identification of an appropriate senior staff member to be a single Trust point of contact.

*An apology is not an admission of liability, it is an apology for the distress and/or harm the person has experienced.

5.8 It may be necessary to hold further meetings with the patient and/or family as the investigation proceeds to update with further information and to ensure the necessary support is in place.

- Delay in disclosure must be avoided. The initial communication must occur, even if details are not yet clear. This communication can occur by any appropriate means – face-to-face is best, but it can be a telephone call or invitation to a meeting. Reference should be made to the investigation which may provide different or further information.
- This initial communication must be recorded in the medical records and include date, time, people present (including patient and family names), apology, what was discussed, concerns raised by the family, and arrangements for further communication/support etc. (For an example of written documentation for medical notes see Appendix 4).
- The communication is to disclose that an incident has occurred, offering an apology and sympathetic support. It is important to avoid giving too much detail about the incident until the incident investigation has been completed. The patient/family can be told that they will be invited to a meeting to discuss details either during or after the investigation, as preferred by the patient/family. Patient/family concerns, preferences etc. should be recorded and considered in the investigation.
- An offer to meet is made to the family. This is usually at the end of the investigation so the findings can be shared and discussed, but may also occur before the investigation starts or during the process. The approach is agreed with the patient/family. The patient/family may require meetings at any stage during the investigation.

5.9 Preliminary Team Discussion

The multidisciplinary team, including the most senior health professional involved in the patient safety incident, should meet as soon as possible after the event to:

- Establish the basic clinical details and other facts.
- Assess the incident and determine the level of immediate response.
- Identify who will be responsible for discussion with the patient and/or their carers.
- Consider the appropriateness of engaging patient support at this early stage.
- Identify immediate support needs for the healthcare staff involved.
- Ensure there is a consistent approach by all team members around discussions with the patient and/or their carers.

In addition to this, it will be advantageous to provide facilities for formal and informal debriefing of the clinical team involved in the patient safety incident, where appropriate, and separate from the requirement to provide statements for the investigation. Staff may also benefit from individual feedback about the final outcome of the patient safety incident investigation.

5.10 Initial assessment to determine level of response

- All incidents should be initially assessed by the Healthcare Team to determine the level of response required and then discussed with the Corporate Patient Safety Team for clarification and guidance.
- The level of response to a patient safety incident depends on the severity of the incident. (Ref Policy for Incident and Accident Reporting Policy (Including the investigation of Serious RIDDOR and Security Incidents) (A10/2002))

5.11 Timing

The initial Duty of Candour / Being Open discussion with the patient and/or their carers should occur as soon as possible after recognition of the patient safety incident. Factors to consider when timing this discussion include:

- Clinical condition of the patient. Some patients may require more than one meeting to ensure that all the information has been communicated to and understood by them
- Availability of key staff involved in the incident and in the Duty of Candour / Being Open process.
- Availability of the patient's family and/or carers.
- Availability of support staff, for example a translator or independent advocate, if required.
- Patient preference (in terms of when and where the meeting takes place and who leads the discussion).
- Privacy and comfort of the patient.
- Arranging the meeting in a sensitive location.

5.12 Identifying the individual to communicate with the patient and/or their carers

The healthcare professional who informs the patient and/or their carers about a patient safety incident should be the most senior person responsible for the patient's care and/or someone with experience and expertise in the type of incident that has occurred. This could either be the patient's consultant or a senior member of nursing staff known to the patient, and/or Corporate Patient Safety Lead or Co-ordinator (if being investigated by the Corporate Patient Safety team). Consideration also needs to be given to the characteristics of the person nominated to lead the Duty of Candour / Being Open process.

They should:

- Be known to, and trusted by, the patient and/or their carers.
- Have a good grasp of the facts relevant to the incident.
- Be senior enough, or have sufficient experience and expertise, in relation to the type of patient safety incident to be credible to patients, carers and colleagues.
- Have excellent interpersonal skills. This includes the ability to communicate with patients and/or their carers in a way they can understand. It is important to avoid excessive use of medical jargon.
- Be willing and able to offer an apology, reassurance and feedback to patients and/or their carers.
- Be able to maintain a medium- to long-term relationship with the patient and/or their carers, where possible, and to provide continued support and information.
- Be culturally aware and informed about the specific needs of the patient and/or their carers.
- Be supported by the Corporate Patient Safety Team.
- If for any reason it becomes clear during the initial discussion that the patient and/or carers would prefer to speak to a different health care professional, the patient's wishes should be respected. A substitute with whom the patient is satisfied should be provided.

5.13 Responsibilities of junior healthcare professionals

Junior staff or those in training should not lead the Duty of Candour / Being Open process except when all the following criteria have been considered:

- The incident resulted in no or minor harm.
- They have expressed a wish to be involved in the discussion with the patient and/or their carers and that it is considered appropriate for them to do so.
- The senior healthcare professional responsible for the care is present for support.
- The patient and/or their carers agree.

Where a junior healthcare professional, who has been involved in a patient safety incident, asks to be involved in the Duty of Candour / Being Open discussion, it is important they are accompanied and supported by a senior team member. It is unacceptable for junior staff to communicate patient safety information alone or to be delegated the responsibility to lead a Duty of Candour / Being Open discussion unless they volunteer and their involvement takes place in appropriate circumstances.

5.14 Involving healthcare staff who made mistakes

- Some patient safety incidents that resulted in moderate harm, major harm or death will result from errors made by healthcare staff while caring for the patient.
- In these circumstances the member(s) of staff involved may or may not wish to participate in the Duty of Candour / Being Open discussion with the patient and/or their carers.
- Every case where an error has occurred needs to be considered individually, balancing the needs of the patient and/or their carers with those of the healthcare professional concerned.
- In cases where the healthcare professional who has made an error wishes to attend the discussion to apologise personally, they should feel supported by their colleagues throughout the meeting.

5.15 Initial Duty of Candour/Being Open discussions with the patient and/or their carers

With the patient's agreement, carers and those close to the patient can be included in the discussions and decision making. If the patient is unable to participate or has died, then the carers or people closely involved with the patient may be provided with limited information in order to make decisions. This should be done with regard to confidentiality and any patient instructions.

- The patient and/or their carers should be advised of the identity and role of all people attending the Duty of Candour / Being Open discussion before it takes place. This allows them the opportunity to state their own preferences about which staff should be present.
- There should be an expression of genuine sympathy, regret and an apology for the harm that has occurred.
- The known facts should be agreed by the multidisciplinary team. Where there is disagreement, communication about these events should be deferred until after the investigation has been completed. The patient and/or their carers should be informed that an incident investigation is being carried out and more information may become available following the investigation.
- It should be made clear to the patient and/or their carers that new facts may emerge as the incident investigation proceeds.
- The patient's and/or carers' understanding of what happened should be taken into consideration, as well as any questions they may have.
- There should be consideration and formal noting of the patient's and/or carers' views and concerns, and demonstration that these are being heard and taken seriously.
- Appropriate language and terminology should be used when speaking to patients and/or their carers. For example, using the terms 'patient safety incident' or 'adverse

event' may be at best meaningless and at worst insulting to a patient and/or their carers. If a patient's and/or their carers' first language is not English, or they have other communication difficulties, their language needs should be addressed as well as providing information in both verbal and written formats.

- An explanation should be given about what will happen next in terms of the long term treatment plan and incident analysis findings.
- Information on likely short- and long-term effects of the incident (if known) should be shared. The latter may have to be delayed to a subsequent meeting when the situation becomes clearer. Some patients may not wish to know every detail of an incident. They should be reassured that if they change their minds, this information will be made available to them.
- The patient and/or carer should be given the contact details of one member of staff who will acts as a contact point for them. Their role will be to provide both practical and emotional support in a timely manner.
- It should be recognised that patients and/or their carers may be anxious, angry and frustrated, even when the Duty of Candour / Being Open discussion is conducted appropriately.

5.16 It is essential that the following does not occur:

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

The initial Duty of Candour / Being Open discussion is the first part of an ongoing communication process. There should be repeated opportunities for the patient and/or carer to obtain information about the incident and many of the points raised here should be expanded on in subsequent meetings.

5.17 Preliminary Follow-Up

The preliminary follow-up discussion with the patient and/or their carers is an important step in the Duty of Candour / Being Open process. The following guidelines should assist in making the communication effective:

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

5.18 Documentation

Written records of the Duty of Candour/ Being Open discussion

There should be documentation of:

- The time, place, date, as well as the name and relationships of all attendees.
- The plan for providing further information to the patient and/or their carers.
- Offers of assistance and the patient's and/or carers' response.
- Questions raised by the family and/or carers or their representatives and the answers given.
- Plans for follow-up as discussed.

Follow this up by giving the same information in writing, and providing an update on the enquiries and upload the letter in to the Datix system. (Refer to letter templates at Appendix 3)

Other recorded documentation should be:

- A written record which is kept securely by the health service body (Refer to medical notes documentation example at Appendix 4)
- Progress notes relating to the clinical situation and an accurate summary of all the points explained to the patient and/or their carers.
- Copies of letters sent to patients, carers and the GP for patient safety incidents not occurring within primary care.
- Copies of any statements taken in relation to the patient safety incident.
- A copy of the incident report.

COMPLETING THE PROCESS

5.19 Communication with the patient and/or their carers

After completion of the incident investigation, feedback should take the form most acceptable to the patient. Whatever method is used, the communication should include:

- The chronology of clinical and other relevant facts.
- Details of the patient's and/or their carers' concerns and complaints.
- A repeated apology for the harm suffered and any shortcomings in the delivery of care that led to the patient safety incident.
- A summary of the factors that contributed to the incident.
- Information on what has and will be done to avoid recurrence of the incident and how these improvements will be monitored.

It is expected that in most cases there will be a complete discussion of the findings of the investigation and analysis. In some cases information may be withheld or restricted, for example: where communicating information will adversely affect the health of the patient; where investigations are pending coronial processes; where specific legal requirements preclude disclosure for specific purposes. In these cases, the patient will be informed of the reasons for the restrictions.

5.20 Continuity of Care

- When a patient has been harmed during the course of treatment and requires further therapeutic management or rehabilitation, they should be informed, in an accessible way, of the ongoing clinical management plan. It may be valuable to consider including the patients GP in discussions at any point during the process.

- Patients and/or their carers should be reassured that they will continue to be treated according to their clinical needs, even in circumstances where there is a dispute between them and the Healthcare Team. They should also be informed that they have the right to continue their treatment elsewhere if they have lost confidence in the Healthcare Team involved in the patient safety incident.

6 EDUCATION AND TRAINING REQUIREMENTS

6.1 The principles of Duty of Candour and Being Open training is provided to the CMG clinical teams by the Corporate Patient Safety Team as part of a face to face Patient Safety training programme delegates should book their place on this via HELM.

6.2 Reference to Duty of Candour has also been incorporated into the Complaints e-learning module which is on HELM for all staff.

7 PROCESS FOR MONITORING COMPLIANCE

7.1 The audit criteria for this policy and the process to be used for monitoring compliance are given in the table below:

Element to be monitored	Lead	Tool	Frequency	Reporting arrangements
Duty of Candour requirements are met 100% of time	Senior Patient Safety Manager	Datix	Monthly	Executive Quality Board

8 EQUALITY IMPACT ASSESSMENT

8.1 The Trust recognises the diversity of the local community it serves. Our aim therefore is to provide a safe environment free from discrimination and treat all individuals fairly with dignity and appropriately according to their needs.

8.2 As part of its development, this policy and its impact on equality have been reviewed and no detriment was identified.

9 SUPPORTING REFERENCES, EVIDENCE BASE AND RELATED POLICIES

- Policy for Incident and Accident Reporting Policy (Including the investigation of Serious RIDDOR and Security Incidents) (A10/2002).
- Policy for the Management of Complaints (A11/2002).
- Policy for the Support of Staff Involved in Incidents, Inquests Complaints and Claims (B28/2007).
- https://www.cqc.org.uk/guidance-providers/all-services/regulation-20-duty-candour
- Joint GMC/NMC Guidance 'Openness and honesty when things go wrong: the professional Duty of Candour' (2015)
- Health and Social Care Act 2008 (Regulated Activities) Regulations 2014/Statutory Instrument 2014 No.2936
- NHS Standard Contract 2014/15: Updated Technical Guidance
- Definitions of levels of harm included in: National Patient Safety Agency, Seven Steps to Patient Safety
- NHS Resolution: Saying sorry
- Mental Capacity Act 2005
- CQC guidance for NHS Bodies on Regulation 20: Duty of candour (2014)
- Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry, Chaired by Robert Francis QC 2013

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10 PROCESS FOR VERSION CONTROL, DOCUMENT ARCHIVING AND REVIEW

- This document will be uploaded onto SharePoint and made available for access by staff through InSite. It will be stored and archived through this system.
- The availability of an updated policy will be communicated by the Trust's Senior Patient Safety Manager to CMGs and Corporate Directorates via email to Senior Management teams.
- The policy will be reviewed every three years unless there is reason for earlier review. Document review will be the responsibility of the document author.

Appendix 1

Duty Of Candour Quick Reference Guide

University Hospitals of Leicester NHS Trust

Caring at its best

Incident Grade	Inform	Apologise	Explain	Document	Investigate	Report	Update	Audit	Further Info. /Comment
No Harm	✓	✓	✓	✓	✗	✗	✗	✗	Local thematic review by numbers causing concern
Minor Harm	✓	✓	✓	✓	✓	✗	✗	✗	As above.
Moderate Harm (Notifiable Safety Incident)	✓	✓	✓	✓	✓	✓✗	✓✗	✓✗	Full report not always required. Corporate PS Team will advise.
Major Harm/Death (Notifiable Safety Incident)	✓	✓	✓	✓	✓	✓	✓	✓	
Never Event	✓	✓	✓	✓	✓	✓	✓	✓	May not meet moderate as major harm, but will investigate /Report required.

Appendix 2 Duty of Candour Letter templates

Example Letter to be sent to the patient affected by the incident

NB This is provided purely for guidance. All letters must be personalised and tailored to the individual needs of the person receiving the letter.

(Insert contact address and telephone number)

PRIVATE AND CONFIDENTIAL

(Insert date)

(Insert name and address)

Dear XXXX

Further to our discussion on ……. regarding the incident which occurred on the ……we write to extend a sincere apology for this incident and any failings in care.

We are genuinely sorry that this incident occurred and would be happy to discuss it with you further if you feel that would be helpful. Should you want further support, the point of contact is ……..... (Consultant, Matron, Head of Nursing, Ward Sister, Head of Service) or …….. who can be contacted on the following number ……

Yours sincerely,

Name
Title

Appendix 3 Duty of Candour Letter Templates

Example Letter to be sent to the patient affected by the incident

NB This is provided purely for guidance. All letters must be personalised and tailored to the individual needs of the person receiving the letter.

(Insert contact address and telephone number)

PRIVATE AND CONFIDENTIAL

(Insert date)

(Insert name and address)

Dear [name the person likes to be known as - based on nursing documentation]

You were recently receiving care at [site] hospital and as Dr/Nurse [name and designation] explained to you, [brief description of the incident and what has previously been discussed] whilst you were a patient on [ward]

I would like to take this opportunity to express my sincere apologies that this event has occurred while you were under our care and to assure you that the Trust aims to provide a quality service to all our patients. We are therefore, undertaking a full investigation into the incident in an effort to understand exactly what happened and to find out whether there is something that we could do differently in future to stop this happening to anyone else.

We would like the opportunity to discuss and share our findings with you and therefore, I would like to invite you to come to a meeting, once the investigation has been completed, this can be arranged at a mutually convenient time. I am more than happy for you to bring a relative or friend with you if this would help. Alternatively, it may be that you do not feel a meeting would be of any help, either now or in the future and that is, of course, your decision: there is absolutely no pressure for you to come and talk to us. We just wanted to give you the opportunity, should you wish to do so.

The investigation process can take up to 60 working days to complete. xxx will be your lead contact during this time and, whether you wish to attend a meeting or not, he/she should be grateful if you would ring [his/her secretary] on the number at the top of this letter. We can then make any necessary arrangements. If you feel that you do not wish to telephone, xxx will be more than happy to hear from you by letter.

Yours Sincerely,

Name
Title

Appendix 4 Duty of Candour Letter Templates

Example Letter to be sent to relatives where patient does not have capacity

NB This is provided purely for guidance. All letters must be personalised and tailored to the individual needs of the person receiving the letter.

(Insert contact address and telephone number)

PRIVATE AND CONFIDENTIAL

(Insert date)

(Insert name and address)

Letter to be sent to relatives where patient does not have capacity

Dear [name]

Your [Mother/Father/Son etc] was recently receiving care at [site] hospital and as Dr/Nurse [name and designation] has explained to you, [enter brief description of the incident and what has previously been discussed]. Whilst Your [Mother/Father/Son etc.] was a patient on [ward}

I would like to take this opportunity to express my sincere apologies that this event has occurred while [name of patient] was under our care and to assure you that the Trust aims to provide a quality service to all our patients. We are therefore, undertaking a full investigation into the incident in an effort to understand exactly what happened and to find out whether there is something that we could do differently in future to stop this happening to anyone else.

We would like the opportunity to discuss and share our findings with you and therefore I would like to invite you to come to a meeting once the investigation is complete. I am more than happy for you to bring a relative or friend with you if this would help. Alternatively, it may be that you do not feel a meeting would be of any help, either now or in the future and that is, of course, your decision: there is absolutely no pressure for you to come and talk to us. We just wanted to give you the opportunity, should you wish to do so.

The investigation process can take up to 60 working days to complete. xxx will be your lead contact during this time and, whether you wish to attend a meeting or not, he/she should be grateful if you would ring [his/her secretary] on the number at the top of this letter. We can then make any necessary arrangements. If you feel that you do not wish to telephone, xxx would be more than happy to hear from you by letter.

Yours Sincerely,

Name
Title

Appendix 5 Duty of Candour Letter Templates

Letter to be sent to relatives where the patient has died

NB This is provided purely for guidance. All letters must be personalised and tailored to the individual needs of the person receiving the letter.

(Insert contact address and telephone number)

PRIVATE AND CONFIDENTIAL

(Insert date)

(Insert name and address)

Dear [name]

I am writing to offer you my sincere condolences on the recent death of your [Mother/Father/Son] [name of patient].

[Name of patient] was recently receiving care at [site] hospital and as Dr/Nurse [name and designation] has explained to you, [Brief description of the incident and what has previously been discussed] whilst [name of patient] was a patient on [Ward]

I would like to take this opportunity to express my sincere apologies that this event has occurred while [name of patient] was under our care and to assure you that the Trust aims to provide a quality service to all our patients. We are therefore, undertaking a full investigation into [name of patient]'s care and treatment in an effort to understand exactly what happened and to find out whether there is something that we could do differently in future to stop this happening to anyone else.

We would like the opportunity to discuss and share our findings and therefore I would like to invite you to come to a meeting, once the investigation is completed this can be arranged at a mutually convenient time. I am more than happy for you to bring a relative or friend with you if this would help. Alternatively, it may be that you do not feel a meeting would be of any help, either now or in the future and that is, of course, your decision: there is absolutely no pressure for you to come and talk to us. We just wanted to give you the opportunity, should you wish to do so.

The investigation process can take up to 60 working days to complete. xxx will be your lead contact during this time, whether you wish to attend a meeting or not, he/she should be grateful if you would ring [his/her secretary] on the number at the top of this letter. We can then make any necessary arrangements. If you feel that you do not wish to telephone, xx would be more than happy to hear from you by letter.

Yours Sincerely,

Name
Title

Appendix 6

Medical record documentation examples

As per Duty of Candour, I have discussed this incident with the patient and explained what happened, what are the likely consequences of the incident and any new treatment, care instigated. I have apologised to the patient and told them that they will be kept informed of any actions taken as a result of this incident.

We all sincerely apologised as a team for the events on xxx. I fully explained the sequence of events to the patient and discussed the plan of care now which is xxxxx, which is to xxxx. All questions were answered and we offered the patient and family our full support. I have advised that they will be kept informed as agreed of any actions taken as a result of this incident. We have agreed that we will meet with them to share our findings from the investigation.

NB This is provided purely for guidance. All documentation must be personalised and tailored to the individual needs of the case.

Appendix 7

Useful contacts

AvMA	Action against Medical Accidents	http://www.avma.org.uk/
Cruse	Bereavement Care	www.crusebereavementcare.org.uk
GMC	General Medical Council	http://www.gmc-uk.org/
HPC	Health Professions Council	http://www.hpc-uk.org/
MDU	Medical Defence Union	http://www.the-mdu.com/
MPS	Medical Protection Society	http://www.medicalprotection.org/uk
NHS	NHS Resolutions	resolution.nhs.uk
NMC	Nursing and Midwifery Council	http://www.nmc-uk.org/
RCN	Royal College of Nursing	www.rcn.org.uk
RCGP	Royal College of General Practitioner	http://www.rcgp.org.uk
RCP	Royal College of Physicians	www.rcplondon.ac.uk

Appendix 8

The Ten Principles of Being Open

Being Open is a process rather than a one-off event. With this in mind, the following principles have been drawn up to support the policy.

i. Principle of acknowledgement

- All patient safety incidents should be acknowledged and reported as soon as they are identified.
- In cases where the patient and/or their carers inform healthcare staff when something untoward has happened, it must be taken seriously from the outset.
- Any concerns should be treated with compassion and understanding by all healthcare staff. Denial of a patient's concerns will make future open and honest communication more difficult.

ii. Principle of truthfulness, timeliness and clarity of communication

- Information about a patient safety incident graded as moderate or major must be given to patients and/or their carers in a truthful and open manner by an appropriately nominated person. Patients want a step-by-step explanation of what happened, that considers their individual needs and is delivered openly. A Being Open leaflet should be provided for the patient or relative in all cases of moderate and major harm.
- Communication should also be timely: patients and/or their carers should be provided with information about what happened as soon as practicable. This should be logged on Datix and documented within the medical records to confirm it has happened.
- It is also essential that any information given is based solely on the facts known at the time.
- Healthcare staff should explain that new information may emerge as an incident investigation is undertaken, and patients and/or their carers should be kept up-to-date with the progress of an investigation.
- Patients and/or their carers should receive clear, unambiguous information and be given a single point of contact for any questions or requests they may have. They should not receive conflicting information from different members of staff. Medical jargon, which they may not understand, should be avoided.

iii. Principle of apology

- Patients and/or their carers should receive a sincere expression of sorrow or regret for the harm that has resulted from a patient safety incident. This should be in the form of an appropriately worded and agreed manner of apology, as early as possible.
- Both verbal and written apologies should be given. The decision on which staff member should give the apology should consider seniority, relationship to the patient, and experience and expertise in the type of patient safety incident that has occurred. This will be dependent on the individual circumstances and seriousness of the incident.
- Verbal apologies are essential because they allow face-to-face contact between the patient and/or their carers and the healthcare team. This should be given as soon as staff are aware an incident has occurred.
- It is important not to delay for any reason, including: setting up a more formal multidisciplinary Being Open discussion with the patient and/or their careers, fear and apprehension, or lack of staff availability. Delays are likely to increase the patient's and/or their carer's sense of anxiety, anger or frustration. A written apology, which clearly states the healthcare organisation is sorry for the suffering and distress resulting from the incident, must also be given. *__An apology is not an admission of liability.__ *see section 8.1

iv. Principle of recognising patient and carer expectations

- Patients and/or their carers can reasonably expect to be fully informed of the issues surrounding a patient safety incident and its consequences in a face-to-face meeting which includes the appropriately nominated person from UHL.
- They should be treated sympathetically, with respect and consideration. Confidentiality must be maintained at all times.
- Patients and/or their carers should also be provided with support in a manner appropriate to their needs. This involves consideration of special circumstances that can include a patient requiring additional support, such as an independent patient advocate or a translator.
- Where appropriate, information on accessing the Patient Information and Liaison Service (PILS) and other relevant support groups egg Cruse Bereavement Care and Action against Medical Accidents (AvMA) should be given to the patient as soon as it is possible. (See Appendix 3)

v. Principle of professional support

- The Trust's Open and Fair culture creates an environment in which all staff, whether directly employed or independent contractors, are encouraged to report patient safety incidents.
- Staff should feel supported throughout the incident investigation process as they may have been traumatised by being involved. For further information regarding support, please see the UHL Policy for the Support of Staff Involved in Incidents, Inquests Complaints and Claims (B28/2007).
- Staff should not be unfairly exposed to punitive disciplinary action, increased medico-legal risk or any threat to their registration.

vi. Principle of risk management and systems improvement

- Root cause analysis (RCA) should be used to uncover the underlying causes of a patient safety incident. Investigations should focus on improving systems of care, which will then be reviewed for their effectiveness.
- To ensure a robust and consistent approach to incident investigation the Trust will use the NPSA's Incident Decision Tree (IDT). The IDT has been developed as an aid to improve the consistency of decision making about whether human error or system failures contributed to the incident. More information can be found in Seven Steps to Patient Safety and on the NPSA website : www.npsa.nhs.uk

vii. Principle of multidisciplinary responsibility

- This policy applies to all staff that have key roles in the patient's care. Most healthcare provision involves multidisciplinary teams and communication with patients and/or their carers following an incident that led to harm, should reflect this. This will ensure that the Being Open process is consistent with the philosophy that incidents usually result from systems failures and rarely from the actions of an individual alone.

viii. Principle of clinical governance

- Being open has the support of patient safety and quality improvement processes through the clinical governance framework, in which patient safety incidents are investigated and analysed to find out what can be done to prevent their recurrence. It also involves a system of accountability through the Chief Executive to the Board to ensure these changes are implemented and their effectiveness reviewed. The findings are disseminated to staff so that they can learn from patient safety incidents through managers feeding back locally.
- These actions are monitored to ensure that the implementation of changes in practice following a patient safety incident are completed.

ix. Principle of confidentiality

- Full consideration to, and respect should be given to the patient, their carers and staff's privacy and confidentiality.
- Details of a patient safety incident should at all times be considered confidential. The consent of the individual concerned should be sought prior to disclosing information beyond the clinicians involved in treating the patient.
- Where this is not practicable or an individual refuses to consent to the disclosure, disclosure may still be lawful if justified in the public interest or where those investigating the incident have statutory powers for obtaining information.
- Communications with parties outside of the clinical team should also be on a strictly need-to-know basis and, where practicable, records should be anonymous.
- In addition, it is good practice to inform the patient and/or their carers about who will be involved in the investigation before it takes place and give them the opportunity to raise any objections. Discussion should be recorded in the incident investigation file.

- The patient should be reassured that a record of the investigation will be filed separately from their medical records and that no documentation of the investigation will affect their future care at the Trust.
- Records of the investigation will be filed on Datix.

x. Principle of continuity of care

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