CONTROLLED DOCUMENT

University Hospitals Birmingham
NHS Foundation Trust

Duty of Candour (Being Open) Policy

CATEGORY:	Policy
CLASSIFICATION:	Governance
PURPOSE	To set out the framework for Duty of Candour and the principles of being open with patients in relation to patient safety incidents, complaints and claims.
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Contents

1. Policy Statement

1.1 University Hospitals Birmingham NHS Foundation Trust (the 'Trust') is committed to its values of *Honesty* and *Accountability*. It promotes a culture of openness in line with the NHS Constitution for England.

1.2 In general terms, a Duty of Candour is a duty to be open and honest with patients when things go wrong. All healthcare professionals have a professional, or ethical, duty of candour to be open and honest with patients when something that goes wrong with their treatment or care causes, or has the potential to cause, harm or distress.

1.3 In addition, The Trust has a contractual and statutory Duty of Candour, the Care Quality Commission (CQC) Duty of Candour Regulation 20 of the Health & Social Act 2008 (Regulated activities, Regulations 2014), which requires it to:

1.3.1 Encourage open communication with patients and/or their relatives/carers and between healthcare organisations ;

1.3.2 Conduct an appropriate investigation into the incident, complaint and/or claim and reassure patients, their families and carers that lessons learned will help prevent the incident recurring; and

1.3.3 Provide support for those involved to assist them to cope with the physical and psychological consequences of an incident.

1.4 The statutory Duty of Candour only applies to incidents or suspected incidents that result in moderate or severe harm (including prolonged psychological harm) or death.

1.5 The benefits of *Duty of Candour* are widely supported by policy makers, professional bodies, litigation and indemnity bodies, including the Care Quality Commission, the General Medical Council, NHS Resolution, the Medical Defence Union and the Medical Protection Society.

1.6 The NHS Constitution for England embeds the principles as a pledge to patients in relation to complaints and redress.

It states:

"The NHS pledges to ensure that when mistakes happen or if you are harmed while receiving health care you receive an appropriate explanation and apology, delivered with sensitivity and recognition of the trauma you have experienced, and know that lessons will be learned to help avoid a similar incident occurring again" (NHSE Constitution, updated 2015)

1.7 The purpose of this policy is to ensure that, when mistakes happen or if patients are harmed while receiving health care:

1.7.1 patients will receive an appropriate explanation and apology;

1.7.2 lessons will be learned to help avoid a similar incident re-occurring; and

1.7.3 openness, honesty and timeliness will underpin the standards of this policy.

1.8 It is important to remember that saying sorry need not be an admission of liability and is the right thing to do. (NHS Resolution, Saying Sorry 2018).

2. Scope

2.1 This policy applies to all areas of the Trust and all individuals providing care in the Trust including contractors, volunteers, students, locum, bank and agency staff and staff employed on honorary contracts.

2.2 This policy applies to communication by Trust staff with patients and/or their families/carers (and, where appropriate, other healthcare organisations, healthcare teams and staff) following:

2.2.1 All individual patient safety incidents which causes, or has the potential to cause, harm or distress;

2.2.2 A Serious Incident (SI) or Never Event;

2.2.3 A serious complaint and/or legal claim.

3. Framework

3.1 This section describes the broad framework for compliance with the 'Duty of Candour' (Appendix B) and the principles of being open (Appendix C). The Duty of Candour Procedure details the steps to be taken.

3.2 The associated Duty of Candour Procedure may be amended by the authority of the Chief Nurse, provided that such amendments are compliant with the policy.

3.3 The Trust encourages healthcare staff to maintain the principles as outlined in the NHS Constitution in an honest and timely fashion with clear communication.

3.4 The Trust encourages the provision of information to ensure patients/families/carers receive the information in a format they understand and

can seek reassurance from. The Trust will document all discussions of the events and make these records available to patients and/or their relatives.

3.5 Where an incident has caused low harm, staff should apologise in line with the general principles and note this in the medical record. The incident should be reported promptly on the Trust's incident reporting system.

3.6 The statutory Duty of Candour applies when a 'notifiable safety incident' (moderate harm, severe harm or death) has occurred as per the definition in Appendix B.

3.7 The Duty of Candour extends to instances where the patient is appropriately consented for the risks of a treatment or procedure but a known and consented for complication has occurred, as a result of a specific act or admission which causes moderate harm, severe harm or death. (refer to the CQC Duty of Candour Information for all Providers 2015). An example where the Duty of Candour would apply is where a blood vessel is nicked during surgery and the subsequent blood loss leads to a stroke. Conversely, an example of where the Duty of Candour would not apply would be the correct prescription of medication resulting in an unanticipated adverse drug reaction.

3.8 In the event of a notifiable safety incident, a senior member of the treating team will:

3.8.1 Meet with the patient/family/carer to acknowledge and apologise for any harm caused in line with the Duty of Candour Procedure. This will be completed within 10 working days of being aware of the incident occurring. The initial conversation should explain the facts as known at the time and identify any actions taken, or planned, to minimise the effect of the incident for the patient or to mitigate the risk of the incident occurring again.

3.8.2 Record this discussion on the Initial Conversation proforma and follow up with a letter to the patient/families/carers.

3.8.3 Ensure the incident is appropriately investigated with support from the Clinical Governance and Patient Safety Department

3.8.4 Share the outcome of the findings (with appropriate consent, where necessary) with patients/families/carers, to reassure them that lessons learned will help prevent the incident recurring. This will be completed within 10 working days of completing the review/investigation of the incident.

3.9 **Situations when information may be withheld from patients/families/carers**

3.9.1 In certain circumstances it may be necessary to withhold specific pieces of information during the Duty of Candour process. Information may be withheld or restricted where:

a) communicating a certain piece of information may adversely affect the health of the patient;

b) information is held under legal privilege;

c) specific legal requirements preclude disclosure for specific purposes, for example, where formal safeguarding proceedings are in place; or

d) disciplinary proceedings have been instigated following a Human Resources Investigation, the details will usually be precluded from sharing with patients/families/carers.

3.9.2 Where information is withheld, the patient/family will be informed of the reasons for the restrictions and when, if at all, the information will be available.

3.10 **Supporting those Involved**

3.10.1 The Trust will provide appropriate support to both patients and their family and staff involved in any incident, complaint or claim.

3.10.2 The Trust will offer reassurance to patients and carers that they will continue to be treated according to their clinical needs even where there is a dispute between them and the healthcare team.

3.10.3 The Trust promotes an open and fair culture which recognises that the attribution of blame is not conducive to openness and learning. Root Cause Analysis techniques will be used to determine if and where systems have failed and how they can be improved. Information from investigations will be used to inform organisational learning.

3.10.4 Staff involved will be offered appropriate support. This may be via a mentor, occupational health, support services teams, Trust solicitors and where detailed in the relevant Trust policies and procedures.

3.11 **Exemptions**

Whilst it is not anticipated, there will be justifiable reasons for exemptions from the process of Being Open or Duty of Candour, if a senior clinician feels there

are exceptional circumstances that necessitate it, this must be discussed with the Chief Nurse and/or the Chief Medical Officer.

3.12 Documentation

All communication with patients/families/carers must be documented in the medical record. When Duty of Candour is applied, all evidence should also be recorded on the Datix system used to manage incidents, complaints and claims.

4. Duties

4.1 Chief Nurse

The Chief Nurse is responsible for providing assurance to the Board of Directors on compliance with this policy.

4.2 Governance Facilitation Teams (part of the Clinical Governance and Patient Safety Department)

The Governance Facilitation Team will support and monitor the implementation of this policy. This includes supporting and monitoring compliance with the steps out in this policy and the Duty of Candour Procedure.

4.3 Investigations Team (part of the Clinical Governance and Patient Safety Department)

The Investigations Team will support the policy as outlined in the procedural document. This includes confirmation of investigation, notification of an investigation, and being a point of contact for the patient/relative.

4.4 Site & Clinical Delivery Group Management Team

The Site and Clinical Delivery group Management Teams are responsible for ensuring that:

4.4.1 The Duty of Candour and Being Open principles are followed in relation to incidents, complaints and claims.

4.4.2 Where appropriate, patients/families/carers are informed openly and truthfully with the facts known at the time and any immediate actions put in place. Where a report is generated, for example an After Action Review/Roundtable report or Patient Safety Serious Incident report, the patient or next of kin will be offered feedback in compliance with the procedural document.

4.4.3 Staff involved in a serious incident, complaint or claim are appropriately supported.

4.5 Specialty Management Team (including Matrons and CSLs)

The Speciality Management Teams are responsible for ensuring that:

4.5.1 The Duty of Candour and Being Open principles are followed in relation to incidents, complaints and claims.

4.5.2 Where appropriate, patients/families/carers are informed openly and truthfully with the facts known at the time and any immediate actions put in place, and the outcomes of investigations are fed back to them.

4.5.3 Staff involved in a serious incident, complaint or claim are appropriately supported.

4.6 Line Managers

Line Managers are responsible for ensuring that:

4.6.1 This policy is followed and that the patient/families/carers and other relevant persons receive timely, truthful and adequate explanations from appropriate members of staff when an incident occurs. It is important that they receive information about the incident before any media involvement.

4.6.2 All communication with patients/relatives is recorded in the patient's notes and where applicable on the Datix system.

4.6.3 Staff are supported where they are involved in a serious incident, complaint or claim by making referrals to appropriate support.

4.7 All Staff Involved in Clinical Care

All staff involved in clinical care must comply with the policy and all related procedures.

5. Implementation and Monitoring

5.1 Implementation

5.1.1 This policy will be available on the Trust's Intranet Site. The policy will also be disseminated through the management structure within the Trust;

5.1.2 The Governance Facilitation Team will provide advice and support to clinical and managerial leads, clinicians and other Trust staff to support the implementation of this Policy.

5.2 Monitoring

Appendix C provides full details on how the policy will be monitored by the Trust.

6. Associated Policy and Procedural Documentation

Duty of Candour Procedure

Policy for the Reporting and Management of Incidents including Serious Incidents

Procedure for the Reporting and Management of Incidents including Serious Incidents

Complaints Policy

Complaints Procedure

Claims Handling Policy

Claims Handling Procedure

Appendix A Monitoring Matrix

MONITORING OF COMPLIANCE	MONITORING LEAD	REPORTED TO PERSON/GROUP	MONITORING PROCESS	MONITORING FREQUENCY
Compliance with the Duty of Candour process (10 and 10 day target met)	Head of Clinical Governance and Patient Safety	Monthly audit overseen by the Clinical Risk lead to identify compliance with the duty of candour timescales. The outcome of this will be provided in the following reports:		
		Birmingham and Solihull ICB	Integrated Quality Report	Monthly
		Site Q&S/Clinical Quality groups	Integrated Quality Report	Quarterly
		Board of Directors	Integrated Quality Report	Quarterly

Appendix B Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 20

20.—

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

2. As soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred a registered person must—

a. notify the relevant person that the incident has occurred in accordance with paragraph (3), and

b. provide reasonable support to the relevant person in relation to the incident, including when giving such notification.

3.The notification to be given under paragraph (2)(a) must—

a. be given in person by one or more representatives of the registered person,

b. provide an account, which to the best of the registered person's knowledge is true, of all the facts the registered person knows about the incident as at the date of the notification,

c. advise the relevant person what further enquiries into the incident the registered person believes are appropriate,

d. include an apology, and

e. be recorded in a written record which is kept securely by the registered person.

4. The notification given under paragraph (2)(a) must be followed by a written notification given or sent to the relevant person containing—

a. the information provided under paragraph (3)(b),

b. details of any enquiries to be undertaken in accordance with paragraph (3)(c),

c. the results of any further enquiries into the incident, and

d. an apology.

5. But if the relevant person cannot be contacted in person or declines to speak to the representative of the registered person —

a. paragraphs (2) to (4) are not to apply, and

b. a written record is to be kept of attempts to contact or to speak to the relevant person.

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

7. In this regulation—

"apology" means an expression of sorrow or regret in respect of a notifiable safety incident;

"moderate harm" means—

a. harm that requires a moderate increase in treatment, and

b. significant, but not permanent, harm;

"moderate increase in treatment" means an unplanned return to surgery, an unplanned re-admission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, or transfer to another treatment area (such as intensive care);

"notifiable safety incident" has the meaning given in paragraphs (8) and (9);

"prolonged pain" means pain which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days;

"prolonged psychological harm" means psychological harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days;

"relevant person" means the service user or, in the following circumstances, a person lawfully acting on their behalf—

a. on the death of the service user,

b. where the service user is under 16 and not competent to make a decision in relation to their care or treatment, or

c. where the service user is 16 or over and lacks capacity in relation to the matter;

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

8. In relation to a health service body, "notifiable safety incident" means any unintended or unexpected incident that occurred in respect of a service user during the provision of a regulated activity that, in the reasonable opinion of a health care professional, could result in, or appears to have resulted in—

a. the death of the service user, where the death relates directly to the incident rather than to the natural course of the service user's illness or underlying condition, or

b. severe harm, moderate harm or prolonged psychological harm to the service user.

9. In relation to any other registered person, "notifiable safety incident" means any unintended or unexpected incident that occurred in respect of a service user during the provision of a regulated activity that, in the reasonable opinion of a health care professional—

a. appears to have resulted in—

i. 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,

ii.an impairment of the sensory, motor or intellectual functions of the service user which has lasted, or is likely to last, for a continuous period of at least 28 days,

iii. changes to the structure of the service user's body,

iv. the service user experiencing prolonged pain or prolonged psychological harm, or

v. the shortening of the life expectancy of the service user; or

b. requires treatment by a health care professional in order to prevent—

i. the death of the service user, or

ii. any injury to the service user which, if left untreated, would lead to one or more of the outcomes mentioned in sub-paragraph (a).

Appendix C Principles of 'Being Open' (NPSA 2009)

1 Principle of acknowledgement

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

2 Principle of truthfulness, timeliness and clarity of communication

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

Patients, their families and 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, and the use of medical jargon, which they may not understand, should be avoided.

3 Principle of apology

Patients, their families and carers should receive a meaningful apology – one that is 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. Based on local circumstances, healthcare organisations should decide on the most appropriate member of staff to give both verbal and written apologies to patients, their families and carers. The decision should consider seniority, relationship to the patient, and experience and expertise in the type of patient safety incident that has occurred. Verbal apologies are essential because they allow face-to-face contact between the patient, their family and carers and the healthcare team. This should be given as soon as staff are aware an incident has occurred. A written apology, which clearly states the healthcare organisation is sorry for the suffering and distress resulting from the incident, must also be given. It is important not to delay giving a meaningful apology for any reason, including: setting up a more formal multidisciplinary Being Open discussion with the patient, their family and carers; fear and apprehension; or lack of staff availability. Delays are likely to increase the patient's, their family and their carers' sense of anxiety, anger or frustration. Patient and public focus groups reported that patients were more likely to seek medico-legal advice if verbal and written apologies were not delivered promptly.

4 Principle of recognising patient and carer expectations

Patients, their families and carers can reasonably expect to be fully informed of the issues surrounding a patient safety incident, and its consequences, in a face-to-face meeting with

representatives from the healthcare organisation. They should be treated sympathetically, with respect and consideration. They 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 PALS in England, the Community Health Councils (CHC) in Wales, and other relevant support groups like Cruse Bereavement Care and Action against Medical Accidents (AvMA), should be given to the patient as soon as it is possible.

5 Principle of professional support

Healthcare organisations must create an environment in which all staff, whether directly employed or independent contractors, are encouraged to report patient safety incidents. Staff should feel supported throughout the incident investigation process because they too may have been traumatised by being involved. They should not be unfairly exposed to punitive disciplinary action, increased medico-legal risk or any threat to their registration. To ensure a robust and consistent approach to incident investigation, healthcare organisations are advised to use the NRLS's Incident Decision Tree. It should be remembered that NCAS can be contacted for advice on handling the concern and whether an assessment of the individual's practice would be helpful.

Where there is reason for the healthcare organisation to believe a member of staff has committed a punitive or criminal act, the organisation should take steps to preserve its position, and advise the member(s) of staff at an early stage to enable them to obtain separate legal advice and/or representation. Healthcare organisations should also encourage staff to seek support from relevant professional bodies such as the GMC, royal colleges, the MDU, the MPS and the Nursing and Midwifery Council.

6 Principle of risk management and systems improvement

Root Cause Analysis, Significant Event Audit (SEA) or similar techniques should be used to uncover the underlying causes of a patient safety incident. These investigations should focus on improving systems of care, which will then be reviewed for their effectiveness.

Every healthcare organisations 'Being Open' policy should be integrated into local incident reporting and risk management policies and processes. 'Being Open' is one part of an integrated approach to improving patient safety following a patient safety incident. It should be embedded in an overarching approach to risk management that includes local and national incident reporting, analysis of incidents using Root Cause Analysis or Significant Event Audit, decision-making about staff accountability using the Incident Decision Tree and an organisational approach that follows

7 Principle of multi-disciplinary responsibility

Any local policy on openness should apply to all staff that have key roles in the patient's care. Most healthcare provision is through multidisciplinary teams. This should be reflected in the way that patients, their families and carers are communicated with when things go wrong. 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. To ensure multidisciplinary involvement in the Being Open process, it is important to identify clinical, nursing and managerial opinion leaders

who will support it. Both senior managers and senior clinicians who are local opinion leaders must participate in incident investigation and clinical risk management.

8 Principle of governance

Being Open requires the support of patient safety and quality improvement processes through clinical governance frameworks in which patient safety incidents are investigated and analysed to find out what can be done to prevent their recurrence. These findings should disseminated to healthcare professionals so that they can learn from patient safety incidents. It also involves a system of accountability through the chief executive to the board to ensure these changes are implemented and their effectiveness reviewed. Practice-based risk systems should be established within primary care. Continuous learning programmes and audits should be developed that allow healthcare organisations to learn from the patient's experience of Being Open, and that monitor the implementation and effects of changes in practice following a patient safety incident.

9 Principle of confidentiality

Policies and procedures for Being Open should give full consideration of, and respect for, the patient's, their family's and carers' and staff privacy and confidentiality in line with the CQC's guidance for Outcome 1924. Details of a patient safety incident should at all times be considered confidential. The consent of the individual concerned should be sought prior to disclosing information beyond the clinicians involved in treating the patient, in line with the CQC's guidance for Outcome 2024. Where this is not practical, or an individual refuses to consent to the disclosure, it may still be lawful if justified in the public interest, or where those investigating the incident have statutory powers for obtaining information. Communications with parties outside 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, their family and carers about who will be involved in the investigation before it takes place, and give them the opportunity to raise any objections

10 Principle of continuity of care

Patients are entitled to expect that they will continue to receive all usual treatment and continue to be treated with dignity, 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.