Being Open and Duty of Candour Policy.

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1 Statement of Aims and Objectives

1.1. The Duty of Candour (DoC) places a requirement on providers of health and adult social care to be open with patients when things go wrong, ensuring that honesty and transparency are the norm. It is a major step towards implementing a key recommendation from the Mid Staffordshire NHS Foundation Trust Public Inquiry (the Francis Inquiry).

1.1.1. Duty of Candour became a statutory requirement for all CQC registered Trusts from 27 November 2014.

1.2. The NHS Standard Contract (Service Condition 35) also places a contractual obligation upon Trusts to comply with the Duty of Candour.

1.2.1. This Policy has been developed with reference to the National Patient Safety Agency's (NPSA) Being Open Framework.

1.2.2. Promoting a culture of openness is a prerequisite to improving patient / service user safety and the quality of healthcare systems. It ensures communication is open, honest and occurs as soon as possible following an incident between healthcare organisations, healthcare teams and patients / service users and/or their carers. It supports an ethos which adheres to the NPSA ten principles of Duty of Candour and the recommendations from CQC Learning, Candour and Accountability Review 2016.

1.3. It is a statutory obligation of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 to impose, under Section 20, the expectations of 'Duty of Candour' on a health service body. Section 20 of the legislation sets outs the face-to-face and written requirements between the appointed officer of a health service body and the patient and/or their family / representatives where a 'notifiable safety incident' has occurred.

1.4. Duty of Candour applies to all patient safety incidents under the classification of 'significant harm' in healthcare and adult social care. This classification covers the National Reporting and Learning System (NRLS) categories of 'moderate', 'severe' (major) and 'death' and includes 'prolonged psychological harm'.

1.5. The Duty will also apply in cases of death if the death relates to the incident of harm rather than to the natural course of the service user's illness or underlying condition.

1.6. **Duty of Candour Regulations**

1.6.1. The regulations outline that, where the harm threshold has been breached, specific reporting requirements must be followed.

1.6.2. In summary, the Trust needs to:

(a) notify the relevant person (which includes someone lawfully acting on their behalf where necessary) that the incident has occurred and provide reasonable support to the relevant person. This should be done within 10 working days of becoming aware of the incident, or as soon as reasonably practicable;
(b) provide the notification in person (either face-to-face or by telephone) by one or more members of staff [there may be exceptions where it is not possible to notify the relevant person in person, as per 1.6.2(b)];
(c) provide an account of all the facts known about the incident to date;
(d) advise the relevant person what further enquiries into the incident will be undertaken;
(e) ensure that in the enactment of Duty of Candour an apology is included and/or a sincere expression of regret, and;
(f) that this is recorded in writing in the notes

(g) ensure that this notification is followed up in writing to the relevant person

1.7. The aim of this policy is to ensure that the Trust is open and honest when communicating with a patient and/or their family members/ representatives following a notifiable safety incident and complies with its statutory obligations.

2 Principles

2.1. The principles of 'Being Open' and the legislation concerning 'Duty of Candour' must be followed whenever it is believed at the initial stage that a patient has suffered moderate harm, severe harm, or death as a direct result of mistakes or errors made whilst patients are in the care of Trust staff for treatment and/or transportation.

2.1.1. The Being Open and Duty of Candour Procedure describes in detail the steps to be taken following a notifiable safety incident to ensure the Trust's commitment to 'Being Open' and the 'Duty of Candour' are met. The principles the Trust have adopted are:

2.2. **Principle of Acknowledgement**

2.2.1. All notifiable safety incidents should be acknowledged and reported as soon as they are identified. The Trust target for this acknowledgement is 10 working days from the date of the incident, or as soon as is reasonably practicable once the Trust is made aware of the incident. In cases where the patient, their family or representatives inform clinical staff that something has happened, their concerns will be taken seriously from the outset. Concerns raised will be treated with compassion and

understanding by all staff members (s.20(2) Health and Social Care Act 2008 (Regulated Activities) Regulations 2014).

2.3. **Principles of Truthfulness, Timeliness and Clarity of Communication**

2.3.1. Information about notifiable safety incidents will be given in a truthful and open manner. The Trust will be proactive in its approach to providing initially known facts, explaining how incidents will be reviewed, offering an apology (see 5.2.3), providing updates, explaining the conclusions and outcomes reached and documenting the notification (s.20(3) Health and Social Care Act 2008 (Regulated Activities) Regulations 2014).

2.4. **Principle of Apology**

2.4.1. If mistakes are made patients, their families and representatives should receive a meaningful apology – one that is a sincere expression of sorrow for regret for the harm that has resulted from a notifiable safety event or for the poor patient experience suffered.

2.4.2. Staff should feel able to apologise at the earliest opportunity. Saying sorry is not an admission of liability and it is the right thing to do (Saying sorry when things go wrong; Being Open, NPSA, 2009).

2.5. **Principle of Recognising Patient and Carer Expectations**

2.5.1. Patients, their families, and representatives can reasonably expect to be fully informed of the issues surrounding a notifiable safety incident, and its consequences, in a face-to-face meeting with representative(s) from the Trust in accordance with s.20 (3)(a) Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. They should be treated sympathetically, with respect and consideration. They should also be provided with support in a manner appropriate to their needs.

2.5.2. The initial face-to-face meeting should additionally be followed by a written notification covering the elements cited in 5.2.2.1 (s.20(4) Health and Social Care Act 2008 (Regulated Activities) Regulations 2014).

2.6. **Principle of Professional support**

2.6.1. The Trust has taken steps to create a patient safety focused environment in which all staff, contractors and volunteers are encouraged to report notifiable safety incidents. Staff involved in notifiable safety incidents will also be supported as the Trust recognises that they may also be adversely affected by the event.

2.7. **Principle of Risk Management and Systems Improvement**

2.7.1. The underlying causes of notifiable safety incidents should be identified through the process of investigation. The investigations into notifiable safety incidents will focus on improving systems of care and service delivery. ‘Being Open’ and the ‘Duty of Candour’ are an integral part of the Trust’s incident reporting / investigation and risk management processes.

2.8. **Principle of Multi-Disciplinary Responsibility**

2.8.1. The 'Being Open' and 'Duty of Candour' requirements apply to all staff. Most of the services the Trust provides are delivered though multidisciplinary teams / departments. This multi-disciplinary responsibility should be reflected in the way that patients, their families, and representatives are communicated with when things go wrong. This ensures 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.

2.9. **Principle of Clinical Governance**

2.9.1. Being open involves the support of patient safety and quality improvement through the Trust's clinical governance framework in which notifiable safety incidents are investigated and analysed to identify what can be done to prevent their recurrence. Outcomes should be shared with staff and the wider health economy to enable shared learning. Changes enacted as a result of investigations should be monitored to assess impact.

2.10. **Confidentiality**

2.10.1. The 'Being Open' and 'Duty of Candour' requirements should give full consideration of, and respect for, the patient's and their family's privacy and confidentiality, as such, details of patient safety incidents should be considered confidential.

2.11. **Continuity of care**

2.11.1. Patients should be confident that they will continue to receive our usual high standard of service delivery and continue to be treated with dignity, respect, and compassion after raising a concern.

3 Definitions

3.1. **Notification:** The initial point when a relevant person(s) [which includes someone lawfully acting on their behalf where necessary] is made aware that an incident has occurred. (Refer to section 1.6.2. of this procedure).

3.2. **Notifiable Safety Incident**: 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 a 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

(S.20(7) Health and Social Care Act 2008 (Regulated Activities)

Regulations 2014)

3.1.1. A Notifiable Safety Incident is the overarching term for an incident occurring which has resulted in negatively affecting patient safety and has been required to be appropriately reported. The Trust may identify such instances from pre-existing incident terms which may include:

3.2. **Patient Safety Incident**: Any unintended or unexpected occurrence that could have or did lead to harm for one or more patients receiving NHS-funded healthcare.

3.3. **Serious Incident (SI)**: SIs are events in health care where the potential for learning is so great, or the consequences to patients, families and carers, staff or organisations are so significant, that they warrant using additional resources to mount a comprehensive response. SIs can extend beyond incidents which affect patients directly and include incidents which may indirectly impact patient safety or an organisation's ability to deliver ongoing healthcare (SI Framework, March 2015). The following definitions cover the grade of harm an investigating officer of an Incident or Complaint may identify pre or post investigation which have been the direct result of the Trust's involvement:

3.3.1. **Near Miss**: An incident which may have negatively affected patient safety but did not occur due to the specific circumstances of the event, resulting in no harm to the patient, but had the potential to cause harm in another event if the actions of Trust's were the same.

3.3.2. **No Harm**: An incident raised due to concerns patient safety had been negatively affected but following review and/or investigation has considered no harm was experienced by a patient.

3.3.3. **Low Harm**: Harm that requires a minimal increase in treatment, extended period of pain experienced, or care required and/or minor but not permanent harm.

3.3.4. **Moderate Harm**: Harm that requires a moderate increase in treatment, extended period of pain experienced, or care required and/or significant but not permanent harm (Health and Social Care Act 2008 (Regulated Activities) Regulations 2014).

3.3.5. **Severe Harm**: Permanent lessening of bodily, sensory, motor, physiologic or intellectual functions. Additionally, notably impacting on a patient's chances of survival that is not related to the natural course of the patient's underlying condition (Health and Social Care Act 2008 (Regulated Activities) Regulations 2014).

3.3.6. **Death**: Where the death of a patient has resulted directly from the Trust's involvement rather than the patient's underlying condition. (Health and Social Care Act 2008 (Regulated Activities) Regulations 2014).

4. Responsibilities

4.1. **The Chief Executive Officer (CEO)** is ultimately accountable for the implementation of this Policy.

4.2. **The Trust Board** have the responsibility to obtain assurance that the processes described work effectively and support the board level public commitment to implementing the being open principles and Duty of Candour requirements.

4.3. **The Executive Director of Quality and Nursing** has delegated responsibility to ensure compliance with the 'Being Open' and 'Duty of Candour' process. The Executive Director of Quality and Nursing will report to the Trust Board and the Chief Executive Officer on matters relating to this Policy.

4.4. **The Senior Management Teams within the Trust** are responsible for ensuring compliance with this policy and the associated processes within their areas / stations / departments.

4.5. **All staff** employed by the Trust are required to follow the principles outlined in this policy and demonstrate the principles of 'Being Open' and adhere to the statutory requirements of 'Duty of Candour' in their interaction with patients.

5. Competence

5.1. All staff involved in care delivery require an awareness of their 'Being Open' and 'Duty of Candour' responsibilities and statutory obligations. Initial training will be delivered by the Nursing & Quality Directorate with ongoing awareness training to be delivered in line with the Training Needs Analysis.

5.2. All managers who undertake investigations into patient safety incidents, complaints, claims and SIs should receive appropriate training, in line with the Training Needs Analysis, to ensure they are competent and have a detailed knowledge of the 'Being Open' and 'Duty of Candour' processes detailed within this Policy and associated Procedure.

6. Monitoring

6.1. Monitoring compliance and effectiveness of this policy and the associated procedure (within the Being Open and Duty of Candour Procedure) will be undertaken as outline below.

Requirements to be monitored	Process for monitoring e.g. audit	Responsible individual/ group/ committee	Frequency	Responsible individual/ group/ committee (plus timescales) for:		
				Review of results	Development of action plan	Monitoring of action plan
Provision of training during staff induction for statutory obligations for 'Duty of Candour'.	Analysis of training records database.	Head of Learning and Organisation Development	Six- monthly	Clinical Sub-Group	Head of Compliance	Senior Management forum
Provision of patient safety incident investigation training for appropriate members of management team; to include 'Being Open' and 'Duty of Candour'.	Analysis of training records database.	Head of Learning and Organisation Development	Six- monthly	Clinical Sub-Group	Head of Compliance	Senior Management forum

Requirements to be monitored	Process for monitoring e.g. audit	Responsible individual/ group/ committee	Frequency	Responsible individual/ group/ committee (plus timescales) for:		
				Review of results	Development of action plan	Monitoring of action plan
Correctly identified Notifiable Safety Incidents that resulted in moderate harm, severe harm or death.	Audit of risk management database (DATIX) to assess both quantitative and qualitative data.	Patient Experience Lead & Head of Compliance	Annually	Clinical Sub-Group	Patient Experience Lead & Head of Compliance	Senior Management forum

Requirements to be monitored	Process for monitoring e.g. audit	Responsible individual/ group/ committee	Frequency	Responsible individual/ group/ committee (plus timescales) for:		
				Review of results	Development of action plan	Monitoring of action plan
Patient, or family / representative, verbally notified that a notifiable safety event is under review within 10 working days of the Investigating Manager being assigned but must be no later than 15 working days following the Trust becoming aware of a patient safety incident that resulted in moderate harm, severe harm or death (or where a SI to notify irrespective of the level of harm, with the exceptions of e.g. systems issues which do not directly relate to specific harm).	Audit of risk management database (DATIX) to identify number of days taken for notification to be made.	Patient Experience Lead & Head of Compliance	Monthly	Clinical Sub-Group	Patient Experience Lead & Head of Compliance	Senior Management forum

Requirements to be monitored	Process for monitoring e.g. audit	Responsible individual/ group/ committee	Frequency	Responsible individual/ group/ committee (plus timescales) for:		
				Review of results	Development of action plan	Monitoring of action plan
Following a notifiable safety incident that resulted in moderate harm, severe harm or death an apology should be provided to the patient, or their family / representative along with initially known facts, explaining how incidents will be reviewed, providing updates, explaining the conclusions and outcomes reached. This should be provided verbally on initial notification and during a face-to-face meeting (then documented) and where applicable included in the written confirmation.	Monthly information obtained via Datix incident reporting system. Audit Complaints, Incidents, and SI investigations reports to ensure DoC is followed, as qualitative audit six-monthly.	Head of Compliance	Monthly	Clinical Sub-Group	Patient Experience Lead & Head of Compliance	Senior Management forum

Requirements to be monitored	Process for monitoring e.g. audit	Responsible individual/ group/ committee	Frequency	Responsible individual/ group/ committee (plus timescales) for:		
				Review of results	Development of action plan	Monitoring of action plan
Face-to-face meeting with appointed investigating manager offered to the patient, or their family / representative, when investigation into a notifiable safety incident that resulted in moderate harm, severe harm or death is commenced. Meeting to explain initial facts, process of investigation and offer of support.	Monthly information obtained via Datix incident reporting system. Audit Complaints, Incidents, and SI investigations reports to ensure DoC is followed, as qualitative audit six-monthly.	Head of Compliance	Monthly	Clinical Sub-Group	Patient Experience Lead & Head of Compliance	Senior Management forum

Requirements to be monitored	Process for monitoring e.g. audit	Responsible individual/ group/ committee	Frequency	Responsible individual/ group/ committee (plus timescales) for:		
				Review of results	Development of action plan	Monitoring of action plan
Face-to-face meeting with appointed investigating manager offered to the patient, or their family / representative, when investigation into a patient safety incident that resulted in moderate harm, severe harm or death is concluded. Meeting to explain conclusions reached, the outcomes and actions to prevent recurrence.	Monthly information obtained via Datix incident reporting system. Audit Complaints, Incidents, and SI investigations reports to ensure DoC is followed, as qualitative audit six-monthly.	Head of Compliance	Monthly	Clinical Sub-Group	Patient Experience Lead & Head of Compliance	Senior Management forum

7. Audit and Review

7.1. The Head of Compliance (or equivalent role) will review this policy every three years or sooner if new legislation, codes of practice or national standards are introduced. Any changes will be made in line with the Trust's Policy and Procedure on the Development and Management of Policies and Procedures.

7.2. The effectiveness of this policy will be assessed annually by the Head of Compliance (or equivalent role). Where non-compliance is identified because of the monitoring processes described in section 8.1 the policy and its associated documentation will be reviewed to ensure its aims and objectives are capable of being met.

8. References

8.1. Health and Social Care Act 2008 (Regulated Activities) Regulations 2014

8.2. Patient Briefing, Being Open – 'saying sorry when things go wrong,' NPSA. 19th November 2009

8.3. Seven steps to patient safety, NPSA, August 2004

8.4. The Mid Staffordshire NHS Foundation Trust Public Inquiry, Chair by Robert Francis QC, 2012

8.5. http://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-20-duty-candour

8.6. CQC Learning, Candour and Accountability Review 2016

8.7. NHSE National Guidance on Learning from Deaths 2017

Appendix 1

Our Commitment to a Fair and Open Culture

A clinical or non-clinical error, accident, or incident, however serious, is rarely caused willfully. It is not evidence of carelessness, neglect or a failure to carry out a duty of care. Errors are often caused by several factors including process problems, human error, individual behaviour and lack of knowledge or skills. Learning from incidents can only take place when they are reported and investigated in an open and structured way.

Determining safe practice is a vital part of successful risk management. Learning from incidents will promote a fair and open culture and ensure the best possible practice across the organisation. This will enable the Trust to identify trends and take positive action to prevent similar incidents from happening again.

To promote a fair and open culture and encourage the reporting of incidents, disciplinary action will not be taken against a member of staff for reporting an incident, except in the rare circumstances where there is evidence of:

- *Gross professional or gross personal misconduct*
- *Repeated breaches of acceptable behaviour or protocol*
- *An incident that results in a police investigation regarding the staff member*

Staff remain accountable to our service users, carers, the Trust, and their professional bodies for their actions.