Title	Duty of Candour Policy
Meeting	Board of Directors
Date	31st March 2015

Executive Summary

The Trust has had a contractual Duty of Candour under the NHS Standard Contract 2013/14, issued by NHS England, to ensure that patients and their families are told about patient safety incidents that affect them, receive appropriate apologies, are kept informed of investigations and are supported to deal with the consequences. Since November 2014 there are new statutory requirements under the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014; the Duty of Candour is Regulation 20. This statutory duty applies to all health care providers and services registered with the CQC (Care Quality Commission). This statutory duty requires providers to inform all services users when a notifiable patient safety incident has occurred which has caused a harm, moderate or above. The CQC can prosecute for breaches of Regulation 20 without first serving a warning notice.

The Duty of Candour applies to all notifiable patient safety incidents that, in the opinion of a health care professional, could result in, or appear to have resulted in the death, severe harm or moderate harm (including prolonged psychological harm) to a service user or patient.

Professional regulators have also strengthened their guidance to registrants. A Joint Statement from the Chief Executives of Statutory Regulators of Healthcare Professionals sets out the expectations that registered health care professionals will be candid and honest with patients about avoidable harm and regulators will consider any health care professionals who obstruct colleagues from being candid to be in breach of their professional code.

The Duty of Candour policy sets out the expectations of Trust staff with regard to the contractual and statutory requirements of the Duty of Candour and should be implemented when notifiable patient safety incidents which cause moderate harm or above occur.The purpose of the policy is to ensure open, honest and compassionate communicaton with patients and their families occurs in a timely manner and that an apology is given and all discussions are appropriately reported and communicated.

Recommendation

That the Board of Directors approve the Duty of Candour policy which will be implemented from April 1st 2015.

Report Author	Louise Burn, Deputy Director of Nursing and Patient Safety

Executive Director/ Sponsor	Dr Bob Brown, Executive Director of Nursing, Allied Health Professions and Patient Safety.			
Purpose of paper	**Information**	√	**Discussion**	√
	Decision	√	**Assurance**	√
	Specific action			
Implications	**Staffing**		√	
	Finance			
	Legal		√	
	Public engagement		√	
	Partnership			
	Communication		√	
	Equality & Diversity		√	
	Clinical		√	
	Patient Safety		√	

Risk assessment and mitigation (include risk register reference if appropriate)	
Link to STFT Business Plan	Patient Safety, Patient experience, Safe Staffing
Link to CQC regulation	20
Link to Board Assurance Framework	Workforce requirements
Link to Strategic Risk Register	Clinical Staffing

Policy

Duty of Candour

Date Approved by	Version	Issue Date	Review Date	Executive Lead	Information Asset Owner	Author
	1	April 2015		Executive Director of Nursing and Patient Safety		Deputy Director of Nursing and Patient Safety
Policy Number						
Policy type		Risk Management				
Date Equality impact assessment completed and outcome:					Low	
CQC Regulations:				20		

DOCUMENT INFORMATION AND AMENDMENT RECORD

Document Title: Duty of Candour Policy

Executive Lead: Executive Director of Nursing and Patient Safety

Date	Amendment Details	Responsibility	Amendment No

Contents

1.0 INTRODUCTION

1.1 The *Duty of Candour* is a contractual requirement under the NHS Standard Contract 2013/14, issued by NHS England, to ensure that patients and their families are told about patient safety incidents that affect them, receive appropriate apologies, are kept informed of investigations and are supported to deal with the consequences' (2013-14 NHS Standard Contract, Technical Guidance).

1.2 From November 2014 the *Duty of Candour* is also a statutory requirement under the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. The *Duty of Candour* is Regulation 20. This statutory duty applies to all health care providers and services registered with the CQC (Care Quality Commission). This statutory duty requires providers to inform all services users when any harm, moderate or above, has arisen. The CQC can prosecute for breaches of Regulation 20 without first serving a warning notice.

2.0 PURPOSE

2.1 The purpose of this policy is to ensure that patients, their families and carers, and staff all feel supported and engaged when patient safety incidents occur or things go wrong. It provides clear information to staff on what they must do when they are involved and how to communicate with patients, their families and carers effectively.

2.2 To policy ensures that as a Trust, and therefore a CQC registered provider, we meet our statutory requirements with regard to *Duty of Candour*.

2.3 The policy provides guidance for health care staff on the requirements of *Duty of Candour* and sets out what should happen following a notifiable patient safety incident, prompting communication with patients and/or representatives which is full, open, honest and compassionate.

2.4 The policy is also aimed at any Trust staff responsible for ensuring that robust processes are in place to support openness between healthcare professionals, patients and/or their carers following an incident and includes the requirements of the statutory duty of the Trust to meet the expected standards detailed in CQC regulation 20.

3.0 AIM

3.1 The aim of this policy is to ensure that Trust staff are fully equipped to understand and fulfil the requirements of the Trust in carrying out CQC Regulation 20 with regard to our *Duty of Candour*.

4.0 SCOPE OF POLICY

4.1 The scope of this document is Trust wide and applies to all notifiable patient safety incidents.

A notifiable safety incident is defined under the Health and Social Care Act 2008(Regulated Activities) Regulations 2014 as, "*any unintended or unexpected incident that occurred in respect of a service user during the provision of regulated activity that, in the reasonable opinion of a health care professional, could result in, or appears to have resulted in";*

- *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*
- *Severe harm(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),*
- *Moderate harm (harm that requires a moderate increase in treatment such as an unplanned return to surgery, an unplanned readmission, a prolonged period of care, extra time in hospital or as an outpatient, cancelling treatment, or transfer to another treatment area such as intensive care and a significant but not permanent harm),*
- *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)*

4.2 All patient safety incidents should be reported through the Datix Incident Reporting System. Serious incident reporting requirements also include harm to visitors/staff and data security breaches which are wider than the scope of this policy.

4.3 In the case of near miss, no or low harm incidents there are no regulatory requirements with regard to the *Duty of Candour* and these are therefore outside the scope of the Duty of Candour policy. The Being Open Policy (2014) should be followed by Trust staff with regard to these types of incidents.

Incident	Action
No harm.	• *There are no regulatory requirements for "no harm or near miss incidents" with regard to the Duty of Candour therefore they are outside the scope of this policy.* • *Reporting to the risk management team will occur through standard incident reporting mechanisms.*
Low harm	• *There are no regulatory requirements for "low harm" with regard to the Duty of Candour therefore they are outside the scope of this policy.* • *Unless there are specific indications (e.g. a patient fall) or the patient requests it, the communication, investigation, analysis and the implementation of changes will occur at local service delivery level with the participation of those directly involved in the incident.* • *Communication will take the form of an open discussion between the staff providing the patient's care and the patient and/or their carers.* • *Reporting to the risk management team will occur through standard incident reporting mechanisms and be analysed centrally to detect high frequency events/trends.* • *Where the trend data indicates a pattern of related events, further investigation and analysis may be needed.* • *Communication may take the form of an open multi-disciplinary discussion at an "Uncle Ed" meeting and other Trust forums.*
Moderate harm, severe harm or death	• *A higher level of response is required in these circumstances with regard to notifiable patient safety incidents. The Duty of Candour Policy must be implemented to ensure that the statutory requirements under CQC Regulation 20 are met.* • *An Executive Director will be notified immediately and be available to provide support and advice* • *The Executive Director will notify the Chief Executive and the Medical Director* • *The Clinical Incident Review Group will meet to further investigate and analyse the incident*

5.0 EQUALITY, DIVERSITY AND HUMAN RIGHTS STATEMENT

5.1 The Trust is committed to promoting human rights and providing equality of opportunity, not only in our employment practices but also in the way we provide services. The Trust also values and respects the diversity of our employees and the communities we serve. In applying this policy, the Trust will have due regard for the need to:

- Promote human rights
- Eliminate unlawful discrimination
- Promote equality of opportunity
- Provide for good relations between people of diverse groups
- Consider providing more favourable treatment for people with Disabilities

5.2 This policy aims to be accessible to everyone regardless of age, disability (physical, mental health or learning disability), gender (including transgender) race, sexual orientation, religion or belief or any other factor which may result in unfair treatment or inequalities in health or employment.

6.0 DUTIES AND RESPONSIBILITIES

6.1 The Chief Executive has overall responsibility for ensuring that incidents are fully investigated and that the Trust requirements under the statutory requirements of the *Duty of Candour* are fulfilled ensuring that patients receive a timely, conciliatory and honest response following a notifiable patient safety incident.

6.2 The Medical Director and Executive Director of Nursing and Patient Safety will act as the designated leads to oversee the *Duty of Candour* process, ensuring that timely communication with patients, carers and families takes place following an incident that an apology is offered and an investigation takes place with lessons learned from investigations fed into service improvement. Timely communication with the patient or their representative will continue throughout the investigation.

Possible breaches of the *Duty of Candour* by staff who are professionally registered, including the obstruction of another in their professional duty will be investigated and may lead to referral to their professional regulator or other relevant body.

6.3 Professional regulators have strengthened their guidance through the NMC Professional Code (2015) and the GMC Good Medical Practice guide (updated 2014) to reflect the expectations with regard to Duty of Candour. A Joint statement from the Chief Executives of statutory regulators of healthcare professionals sets out the expectations that registered health care professionals will be candid and honest with patients about avoidable harm and regulators will consider any health care professionals who obstruct colleagues from being candid to be in breach of their professional code. Professional regulators will review their guidance to professional misconduct panels as to whether professionals have raised concerns promptly

6.4 All Senior Managers and Clinical Leads have a duty to cooperate fully in the investigation of patient safety incidents and are responsible for responding promptly to requests for information, producing reports and action plans in addition to attending meetings with patients, carers and families during *Duty of Candour* discussions. Senior Managers and Clinical Leads are also responsible for ensuring that staff involved in incidents have access to necessary help and support throughout the *Duty of Candour* process.

6.5 All staff are responsible for communicating with colleagues and their line manager to establish safe systems and to learn and improve clinical systems when things go wrong. All staff are responsible for cooperating with any investigation into incidents where patient safety has been compromised and will be required to provide written witness statements and evidence in person where necessary.

7.0 DUTY OF CANDOUR PROCESS

7.1 Notifiable patient safety event with moderate harm (including prolonged psychological harm), severe harm or death identified

7.1.1 The *Duty of Candour* process begins with the recognition that a patient has suffered **moderate harm**, **severe harm**, or has **died** as a result of a patient safety incident. Recognition may happen 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 carer(s) 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.

7.1.2 As soon as reasonably possible after becoming aware that a notifiable patient safety incident has occurred a member of Trust staff must:-

- Notify the patient or, if not possible, a relevant person in person that the incident has occurred and include an apology. An apology is defined as an expression of sorrow and regret in these circumstances.
- In making the decision about who is the most appropriate person to notify a patient or relevant person about an incident there needs to be consideration of seniority, relationship with the patient and family as well as the experience and expertise of the member of staff in the type of incident that has occurred.
- Provide an honest account, to the best of their knowledge at the time, of all the facts with regard to the incident.
- Advise the patient or their representative of what further enquiries into the incident are appropriate
- Provide reasonable support to the patient or relevant person during the notification to help overcome the physical, psychological and emotional impact of the incident.
- A written record of the discussion must be recorded and kept securely by the Trust.
- The face to face discussion must be followed up by a letter containing all of the information provided in the discussion the results of any further enquires and an apology, must be sent to the patient or, if not possible, a relevant person
- The outcome of any further enquires or investigations must also be provided in writing to the patient or relevant person through further written notification, if they wish to receive them.

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7.1.3 If the patient or relevant person cannot be contacted, or declines to speak to a member of Trust Staff a written record must be kept of all attempts to speak to them and any correspondence must be kept.

7.1.4 The service user or patient is the person to whom all discussion and written correspondence with regard to the notifiable incident should be addressed or, in the following circumstances, a relevant person acting lawfully on their behalf;

- On the death of a patient or service user
- Where the patient or service user is under 16 and not competent to make a decision in relation to their care or treatment
- Where the service user is 16 or over and lacks capacity in relation to the matter.

Other than in the situation outlined above information should only be disclosed to family members or carers where the patient or service user has given their express or implied consent.

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7.2 Incident Investigation

7.2.1 An investigation into the incident must be conducted in accordance with the Trust Incident/Near Miss Reporting Policy(2014) using a Root Cause Analysis process. For Serious Incidents patients/relatives/carers should be offered regular updates in line with Duty of Candour requirements.

7.2.2 Throughout the *Duty of Candour* process it is important to record all discussions with the patient and carers as well as the incident investigation. The documentation should include:-

- The time, place, date, as well as the name and relationships of all attendees at meetings.
- The plan for providing further information to the patient and/or their carers.
- Offers of assistance and the patient's and/or carer's response
- Questions raised by the family and/or carers or their representatives and the answers given.
- Plans for follow-up as discussed.
- 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 any letters sent to patients and their families.
- Copies of any statements taken in relation to the patient safety incident.
- A copy of the incident report.

7.3 Completion of Duty of Candour Process

7.3.1 The communication of patient safety incidents must be fully and accurately recorded. Required documentation includes:

- A copy of relevant medical information, which should be filed in the patient's clinical records
- Incident report records which will be recorded and filed in the Datix system
- Records of the investigation and analysis process which will be centrally stored

7.3.2 The incident report will be recorded on the Datix incident database. A record of the investigation, analysis process and action plans will be filed and held in the Risk and Compliance Department and Complaints Department.

7.3.3 After completion of the investigation, feedback should take the form most acceptable to the patient/carer/relative. The investigation report should be shared with the patient or family within 10 working days of approval and sign off by the Trust and whatever method is used the communication should include as appropriate:

- The chronology of clinical and other relevant facts
- Details of the complaints or concerns being addressed
- 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 been and will be done to avoid recurrence of the incident and how these improvements will be monitored.
- Copy of investigation report undertaken regarding the incident
- Meeting with the patient or relevant person to receive and discuss investigation report.

The patient or relevant person should receive written confirmation by letter of any information disclosed following a face to face meeting. If this written confirmation is declined then a record should be kept to this effect. A written record of the discussion should also be kept securely by the Trust

7.5.4 Should there be reason to delay sharing the report then this should be documented.

7.5.5 Information will only be withheld in cases that are awaiting coroner review or where specific legal requirements prevent disclosure.

7.6 Continuity of Care

7.6.1 Following a notifiable patient safety event the patient should continue to receive all usual treatment and should continue to be treated with respect and compassion by staff. If the patient wishes to receive care from a different team this should be expedited as soon as possible.

8.0 PATIENT AND FAMILY SUPPORT

8.1 On most occasions the patient or service user will be the person that Trust staff communicate with directly following a notifiable patient safety incident. Sometimes a relevant person acting lawfully on behalf of the patient will be appropriate to communicate with Trust representatives for example in the case of young people under 16 or when the patient or service user lacks capacity.

8.2 The Trust must offer all reasonable support to patients and their families/carers to help overcome the physical, psychological and emotional impact of the incident this could include;

- Treating them with respect, consideration and empathy
- Offering the option of direct emotional support during meetings such as a family member or friend, a care professional or a trained advocate.
- Offering to help understand what is being said through an interpreter, non-verbal communication aids, written information, Braille etc,
- Providing access to any necessary treatment and care to recover from or minimize the harm caused where appropriate.
- Provide the patient or relevant person with details of specialist independent sources of practical advice and support or emotional support/counseling.
- Provide the patient or relevant person with information about available impartial advocacy and support services, their local Healthwatch and other relevant support groups to help them deal with the outcome of the incident.
- Arranging for care and treatment from another professional, team or provider if this is possible if the patient wishes.
- Providing support to access the complaints procedure.

9.0 STAFF CIRCUMSTANCES

9.1 The Trust actively promotes an open and fair culture that fosters peer support and discourages the attribution of blame. The Trust encourages the reporting of incidents and a non-punitive approach to those incidents it investigates is taken. Support is available for staff who have been involved in a patient safety incident such as counseling services.

9.2 Patient safety incidents are almost always unintentional. However, if at any stage following an incident it is determined that harm may have been the result of a criminal or intentional unsafe act, an Executive Director should be notified immediately who will inform the Chief Executive and the Medical Director.

10.0 EDUCATION / TRAINING REQUIREMENTS TO IMPLEMENT THE POLICY

10.1 Training and awareness of the Duty of Candour requirements will be included within;

- Induction sessions for all staff
- Awareness raising in all regular staff forums
- Statutory and mandatory training for medical staff.
- Investigation training into incidents, complaints and claims

11.0 MONITORING

Minimum requirement to be monitored (what)	**Methodology e.g. audit (how)**	**Responsible individual/ group/ (who)**	**Frequency of monitoring (when)**	**Responsible group/ committee for review of results (who)**	**Responsible individual/ group/ for development of action plan**	**Responsible individual/ group/ committee for monitoring of action plan**
1. That the process for encouraging open communication between the Trust, staff, patients and/or their carers is being implemented 2. That the process for acknowledging, apologising and explaining when things go wrong has been implemented for all notifiable patient safety incidents 3. That all communication has been documented.	Sample of incident investigations, including serious incidents, concerns and complaints will be audited	Risk Department and the Complaints Department	Annual	Choose Safer Care Sub committee	Risk Management Operational Group	Risk Management Operational Group

Appendix 1

NPSA terms and definitions for grading patient safety incidents

Grade of patient safety incident	Definition
No harm	• **Incident prevented** – any patient safety incident that had the potential to cause harm but was prevented, and no harm was caused to patients receiving NHS-funded care. • **Incident not prevented** – any patient safety incident that occurred but no harm was caused to patients receiving NHS-funded care.
Low harm	Any patient safety incident that required extra observation or minor treatment* and caused minimal harm to one or more patients receiving NHS-funded care. ***Minor treatment** is defined as first aid, additional therapy, or additional medication. It does not include any extra stay in hospital or any extra time as an outpatient, or continued treatment over and above the treatment already planned; nor does it include a return to surgery or readmission.
Moderate harm	Any patient safety incident that resulted in a moderate increase in treatment* and that caused significant but not permanent harm to one or more patients receiving NHS-funded care. ***Moderate increase in treatment** is defined as a return to surgery, an unplanned readmission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, or transfer to another area such as intensive care as a result of the incident.
Severe harm	Any patient safety incident that appears to have resulted in permanent harm* to one or more patients receiving NHS-funded care. ***Permanent harm directly related to the incident** and not related to the natural course of the patient's illness or underlying condition is defined as permanent lessening of bodily functions, sensory, motor, physiological or intellectual, including removal of the wrong limb or organ, or brain damage.
Death	Any patient safety incident that directly resulted in the death* of one or more patients receiving NHS-funded care. ***The death must be related to the incident** rather than to the natural course of the patient's illness or underlying condition.

Appendix 2

References

NHS Standard Contract, 2013-14 Technical Guidance, NHS Commissioning Board 2013

Care Quality Commission 2015 Guidance for Providers on meeting the Regulations
http://www.cqc.org.uk/sites/default/files/20150210_guidance_for_providers_on_meeting_the_regulations_final_01.pdf

Being open: communicating patient safety incidents with patients and their carers, National Patient Safety Agency 2005

Being Open Patient Safety Alert, National Patient Safety Agency 2009

Department of Health 2010, The NHS Constitution for England,
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_113613

Freedom of information Act, 2000,
http://www.legislation.gov.uk/ukpga/2000/36/contents

General Medical Council, *Good Medical Practice 2013 :* updated April 2014,
http://www.gmc-uk.org/guidance/

Joint statement from the Chief Executives of statutory regulators of healthcare professionals: Openness and honesty - the professional duty of candour
http://www.gmcuk.org/Joint_statement_on_the_professional_duty_of_candour_FINAL.pdf_58140142.pdf_58417477.pdf

Nursing and Midwifery Council 2015, *The code: Professional Standard of practice and behaviour for nurses and midwives*,
http://www.nmc-uk.org/The-revised-Code/The-revised-Code-in-full/

Department of Health, *Code of Conduct for NHS Managers*, published 9 October 2002,
http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4085904.pdf

NPSA, *Being open: communicating patient safety incidents with patients, their families and carers*, issued 19 November 2009,
http://www.nrls.npsa.nhs.uk/resources/collections/being-open/?entryid45=83726

The Health & Social Care Act 2008 (Regulated Activities) Regulations 2014,
http://www.legislation.gov.uk/ukdsi/2014/9780111117613

NHS Litigation Authority, Letter on apologies and explanations to chief executives and finance directors of all NHS bodies, 1st May 2009 http://www.nhsla.com/NR/rdonlyres/00F14BA6-0621-4A23-B885-FA18326FF745/0/ApologiesandExplanationsMay1st2009.pdf

Making Amends, Department of Health 2003

Seven steps to patient safety, National Patient Safety Agency 2004

Silence Kills: The Seven Crucial Conversations for Healthcare, VitalSmarts & the American Association of Critical Care Nurses 2005

The Compensation Act 2006, http://www.legislation.gov.uk/ukpga/2006/29/contents

The Data Protection Act 1998, http://www.legislation.gov.uk/ukpga/1998/29/contents

For example, definitions are contained in *Seven Steps to Patient Safety; a full reference guide*, http://www.nrls.npsa.nhs.uk/resources/collections/seven-steps-to-patient-safety?entryid45=59787

Signature Sheet

This sheet can be used to record the names of staff members who have read and understood the above policy document. Ward / Department Managers may use an alternative method of ensuring staff have access to and read any new policies. This should be documented system.

Name (please print)	Job Title	Date	Signature