

CORPORATE POLICY - Duty of Candour Policy

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Document Control / History

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5	Full review of policy and introduction of Duty of Candour SOP
6	Full review of policy including additional guidance
7	Reviewed no changes no further approval required

Consultation

Quality Improvement Committee - September 2016

Executive Committee - 21 September 2016

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Must be read in conjunction with the Duty of Candour Standard Operating Procedure
Also to be read in conjunction with any policies listed in Trust Associated Documents.

1 Introduction

- 1.1 Promoting a culture of openness is a prerequisite to improving patient safety and the quality of healthcare systems. It involves apologising and explaining what happened to patients who have been harmed as a result of their healthcare treatment. It ensures that communication is open, honest, and transparent and occurs as soon as possible following an incident. It encompasses communication between healthcare organisations, healthcare teams and patients and/or their carers (National Patient Safety Agency, 2009).
- 1.2 The Duty of Candour process is a legal duty that was introduced in November 2014 (ref: regulation 20 of the health and social care act 2008 (Regulated Activities) Regulations 2014) to ensure that providers are open and transparent with people who use services and other 'relevant persons' (people acting lawfully on their behalf) in relation to care and treatment where they have experienced significant harm.
- 1.3 A professional duty of candour also applies individually to healthcare professionals, who under GMC/NMC codes of conduct, have a responsibility to apologise and explain the facts to patients/service users when events go wrong, regardless of the severity of the incident.
- 1.4 The primary concern of Duty of Candour is to ensure that the patient and or their family/carer are told about patient safety incidents that have affected them. That they receive a genuine apology, are kept informed of investigations and are supported to deal with the consequences.

2 Purpose / Aim and Objective

- 2.1 The policy aims to improve the quality and consistency of communication when patients are involved in an incident by ensuring that, if they experience harm (moderate, severe or die unexpectedly), patients/patients relatives and/or their carers receive the prompt information they need to enable them to understand what has happened; that an apology is offered; and that patients/patients representative and/or carers are informed of the action the Trust will take to try and ensure that a similar type of incident does not recur. This policy, in conjunction with the documents listed in the Associated Documents section also aims to create an environment where patients and/or their carers, healthcare professionals and managers all feel supported when things go wrong.

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- 2.2 A further aim of this policy is to inform staff that an apology is not an admission of liability, it is however a legal expectation of the Duty of Candour.
- 2.3 This policy acts as a step by step guide to assist staff through the process; it also provides guidance on how to deliver an open and honest response.
- 2.4 Patient safety incidents can have distressing and emotional consequences for patients, families and carers but can also be distressing for the health care professionals and staff involved. Being open about what happened and discussing patient safety incidents compassionately can help both patients and staff to cope better with the aftereffects of the incident.

3 Definitions

3.1 Notifiable Patient Safety Incident

- 3.1.1 Regulatory Duty of Candour applies to patient safety incidents that result in moderate or severe harm or unexpected death. It does not apply to low harm, no harm or near miss incidents but this does not negate the requirement to inform the patient if appropriate as part of professional Duty of Candour

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:

- The death of the service user, where the death relates directly to the incident rather than to the natural course of the service users' illness or underlying condition, or
- Severe harm, moderate harm or prolonged psychological harm to the user
- Serious Incidents / Never Events regardless of level of harm

3.2 Definitions of harm:

- 3.2.1 Grade and definition of patient safety incident:

No harm

Impact prevented – any patient safety incident that had the potential to cause harm but was prevented, resulting in no harm to people receiving NHS-funded care.

Impact not prevented – any patient safety incident that ran to completion but no harm occurred.

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Low harm

Any patient safety incident that required increased observation or minor treatment and caused minimal harm, to one or more persons 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 re-admission.

Moderate harm

Any patient safety incident that resulted in a moderate increase in treatment and which caused significant but not permanent harm, to one or more persons 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, including prolonged pain and/or prolonged psychological harm which the service user has or is likely to experience for a continuous period of at least 28 days.

Severe harm

Any patient safety incident that appears to have resulted in permanent harm to one or more persons 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, physiologic 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 persons receiving NHS funded care. *The death must relate to the incident rather than to the natural course of the patient's illness or underlying condition.*

Psychological harm

Duty of candour applies to occasions when a service user has or is likely to experience psychological harm as a result of an incident for a continuous period of at least 28 days.

On occasions psychological harm may not be recognised at the time of the incident or until after the 28 day period. On these occasions a new incident report is required that documents the presence of psychological harm and duty of candour actions are required.

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4 Implementation and procedure

- 4.1 Once a notifiable patient safety incident is reported on Datix this will trigger the duty of candour statutory requirements.
- 4.2 Where the patient has died, lacks mental capacity or is under 16, and is not competent to make treatment decisions, the notification must be given to a “relevant person”, who can be anyone lawfully entitled to act on their behalf. If the relevant person has died and there is nobody who can lawfully act on their behalf, a record of this should be kept.
- 4.3 If the relevant person does not wish to communicate with the provider, their wishes must be respected and a record of this must be kept.
- 4.4 Occasionally an incident may not be discovered at the time it happens. A delay in discovering an incident does not mean that duty of candour requirements do not apply. (*Refer to section 5.0 Special Circumstances*)
- 4.5 Should an incident be identified that meets the duty of candour requirements, but which relates to care delivered by another provider, that provider is responsible for implementing duty of candour. A Datix incident report should be completed, and the Central Quality and Patient Safety Team alerted who will then inform the other provider.

5 Special circumstances

- 5.1 The approach to Duty of Candour/ Being Open may need to be modified according to the relevant person’s personal circumstances.
- 5.2 On occasions incidents meeting the Duty of Candour threshold may be identified a significant period of time post the event, on these occasions there should be a decision made on a case by case basis. There will need to be a thorough review of all patient records, previous documentation and previous communications with the patient/next of kin/family/carer to aid with decision making, including whether or not completing Duty of Candour would cause further harm.
- 5.3 Decision making on a case by case basis will be made by the Senior Divisional Leadership team who will be required to seek approval with the decision from a member of the Executive Team. A formal decision must be documented by the Division within the patient records and reflected on the incident report form. Although these incidents may be identified a significant period of time after the event the 10 working day timeframe still applies from the date the incident was discovered.

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When Patient/Service User Dies

- 5.4 When a patient safety incident has resulted in a death it is crucial that communication is sensitive, empathic and open. It is important to consider the emotional state of bereaved relatives or carers and to involve them in deciding when it is appropriate to discuss what has happened. The relevant person's family and/or carers will probably need information on the processes that will be followed to identify the cause(s) of death. They will also need emotional support. Establishing open channels of communication may also allow the family and/or carers to indicate if they need bereavement counselling or assistance at any stage.

Usually, the Duty of Candour/Being Open discussion and any investigation occur before the coroner's inquest. But in certain circumstances the healthcare organisation may consider it appropriate to wait for the coroner's inquest before holding the Duty of Candour/Being Open discussion with the relevant person's family and/or carers. The coroner's report on post-mortem findings is a key source of information that will help to complete the picture of events leading up to the relevant person's death. In any event an apology should be issued as soon as possible after the relevant person's death, together with an explanation that the coroner's process has been initiated and a realistic timeframe of when the family and/or carers will be provided with more information.

Children

- 5.5 The legal age of maturity for giving consent to treatment is 16. It is the age at which a young person acquires the full rights to make decisions about their own treatment and their right to confidentiality becomes vested in them rather than their parents or guardians. However, it is still considered good practice to encourage competent children to involve their families in decision making.

The courts have stated that younger children who understand fully what is involved in the proposed procedure can also give consent. To do this a Fraser competence assessment will need to be undertaken. Where a child is judged to have the cognitive ability and the emotional maturity to understand the information provided, he/she should be involved directly in the Duty of Candour/Being Open process after a patient safety incident. The opportunity for parents to be involved should still be provided unless the child expresses a wish for them not to be present.

Where children are deemed not to have sufficient maturity or ability to understand, consideration needs to be given to whether information is provided to the parents alone or in the presence of the child. In these instances the parents' views on the issue should be sought. More information can be found on the Department of Health's website: www.dh.gov.uk

When a child is referred to Children's Services by Trust staff when there are child protection concerns, sometimes parents/children complain about this or refuse to

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give consent for the referral to be made. A child is afforded protection under the Children Act 1989 until they are 18 years of age. The Children Act 2004 now places a duty on staff to respond appropriately in order to safeguard children. Where there is reason to believe a child may be suffering, or is likely to suffer significant harm, a referral will be made to Children's Services. In most cases consent will be obtained from the parent/young person prior to referral. If consent is refused and the professional still believes the child to be at risk, the referral will be made without consent where it is deemed in the best interests of and in order to protect the child.

Patient/Service User with Mental Health Issues

- 5.6 Duty of Candour/Being Open for patients/service user with mental health issues should follow normal procedures, unless the relevant person also has cognitive impairment (see below). The only circumstances in which it is appropriate to withhold patient safety incident information from a mentally ill patient is when advised to do so by a consultant psychiatrist who feels it would cause adverse psychological harm to the relevant person. However, such circumstances are rare and a second opinion (by another consultant psychiatrist) would be needed to justify withholding information from the relevant person. Apart from in exceptional circumstances, it is never appropriate to discuss patient safety incident information with a carer or relative without the express permission of the relevant person. To do so is an infringement of the relevant person's human rights.

Patients/Service User with Cognitive Impairment

- 5.7 Some individuals have conditions that limit their ability to understand what is happening to them. They may have authorised a person to act on their behalf by an enduring power of attorney. In these cases steps must be taken to ensure this extends to decision making and to the medical care and treatment of the patient. The Duty of Candour/Being Open discussion would be held with the holder of the power of attorney. Where there is no such person the clinicians may act in the relevant person's best interest in deciding who the appropriate person is to discuss incident information with, regarding the welfare of the relevant person as a whole and not simply their medical interests. However, the relevant person with a cognitive impairment should, where possible, be involved directly in communications about what has happened. An advocate with appropriate skills should be available to the patient to assist in the communication process.

Patients/Service User with Learning Disabilities

- 5.8 Where a relevant person has difficulties in expressing their opinion verbally, an assessment should be made about whether they are also cognitively impaired (see above). If the relevant person is not cognitively impaired they should be supported in the Duty of Candour/Being Open process by alternative communication methods (i.e., given the opportunity to write questions down). An advocate, agreed on in consultation with the relevant person, should be appointed. Appropriate advocates

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may include carers, family or friends of the patient. The advocate should assist the patient during the Duty of Candour/Being Open process, focusing on ensuring that the patient's views are considered and discussed.

Patients/service User who do not Agree with the Information Provided

- 5.9 Sometimes, despite the best efforts of care staff or others, the relationship between the relevant person and/or their carers and the care professional breaks down. They may not accept the information provided or may not wish to participate in the Duty of Candour/Being Open process. In this case the following strategies may assist:
- Deal with the issue as soon as it emerges.
 - Where the relevant person agrees, ensure their carers are involved in discussions from the beginning.
 - Ensure the relevant person has access to support services.
 - Where the senior professional is not aware of the relationship difficulties, provide mechanisms for communicating information, such as the relevant person expressing their concerns to other members of the team.
 - Offer the relevant person and/or their carers another contact person with whom they may feel more comfortable. This could be another member of the team or the individual with overall responsibility for risk management.
 - Use a mutually acceptable mediator to help identify the issues between the organisation and the relevant person, and to look for a mutually agreeable solution.
 - Ensure the relevant person and/or their carers are fully aware of the formal complaints procedures.
 - Write a comprehensive list of the points that the relevant person and/or their carer disagrees with and reassure them you will follow up these issues.

Patient/Service User with a Different Language or Cultural Considerations

The need for translation and advocacy services, and consideration of special cultural needs (such as for patients/service user from cultures that make it difficult for a woman to talk to a male about intimate issues), must be taken into account when planning to discuss patient safety incident information. It would be worthwhile to obtain advice from an advocate or translator before the meeting on the most sensitive way to discuss the information. Avoid using 'unofficial translators' and/or the relevant person's family or friends as they may distort information by editing what is communicated.

With Different Communication Needs

A number of patients/service users will have particular communication difficulties, such as a hearing impairment. Plans for the meeting should fully consider these needs.

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Knowing how to enable or enhance communications with a patient is essential to facilitating an effective Duty of Candour/Being Open process, focusing on the needs of individuals and their families and being personally thoughtful and respectful.

6 Duty of Candour process

6.1 Within 10 working days of the incident:

- An initial verbal apology should be made by an appropriate manager from within the service where the incident occurred, delivered in person, providing all facts known at the time and explaining what actions are being taken and next steps.
- The decision about who is most appropriate to provide the notification and/or apology will take into account seniority, their relationship to the service user and their experience and expertise in the type of notifiable incident that has occurred.
- The verbal apology should be followed by written notification (letter)
- Evidence that an apology has been made in line with duty of candour requirements should be recorded in the appropriate section on the Datix incident report.
- Support should be provided to the patient, their families or carers after the incident, throughout the investigation and on-going as required including providing the patient or their family with the contact details of an identified person who will coordinate communication and be a single point of contact.
- Commence an investigation into the incident.
- The patient/family should be informed if the incident meets the criteria and is being investigated as a serious incident. Whilst duty of candour requirements apply to Serious incidents, timescales for investigation may vary and the patient /family should be informed of expectations and that investigation may take up to 60 days.

6.2 Within 5 working days of the investigation report being closed by the CCG:

- Final reports must be reviewed and approved for release and suitably redacted if required.
- Approved, final reports must be shared with the patient/relevant person and a copy made available in a manner of their choosing, for example email or printed copy. Example letter templates are provided.

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- The patient/ relevant person must be provided with an opportunity to discuss the findings.
- The service must commence actions to implement recommendations identified through the investigation.

6.3 Documenting all communication

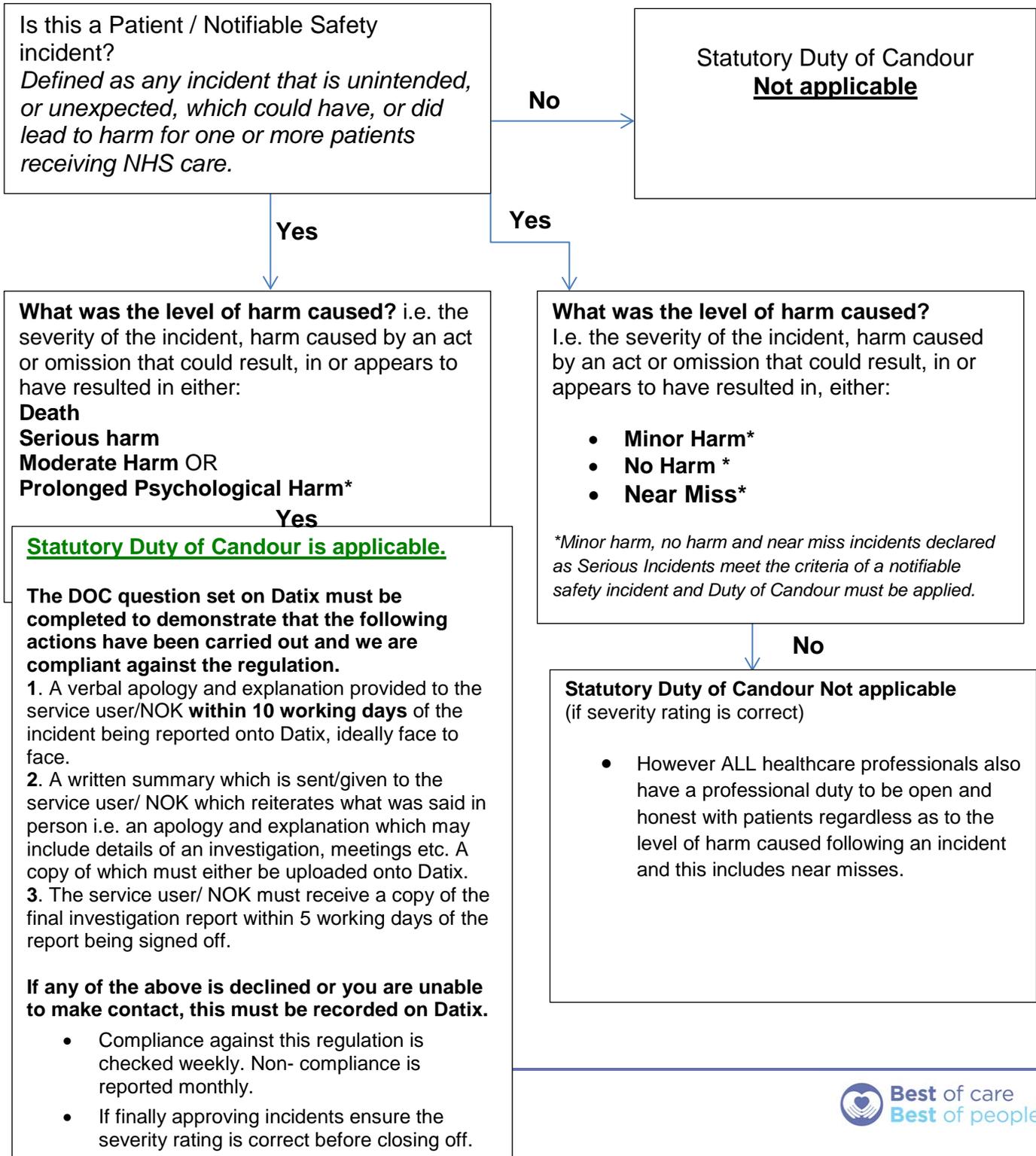
Throughout the Duty of Candour process it is important to maintain clearly documented records of:

- Dates when Duty of Candour discussions took place with the patient/family/ carers
- Dates of attempts and methods made to contact the patient/family/carers
- Time, place, date and names of who attended relevant meetings/ discussions
- Plan for providing further information and key contact for this
- Questions raised by the patient/ family/ carer to be addressed within the investigation
- Plans for follow up meetings and sharing of investigation findings
- Progress notes and accurate summary of all the points explained to the patient/ family/ carers
- Copies of letters sent to the patient/ family/ carers
- Evidence of completion of Duty of Candour and notes of meetings must be stored within the Datix incident report.

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7 Appendix 1 – Duty of Candour process

Does Statutory Duty of Candour need to be applied?



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8 (Duties) Roles & Responsibilities

This policy is aimed at all healthcare staff. The following responsibilities and accountabilities have been identified and confirmed.

8.1 Trust Board and Executive Team

The Trust Board and the wider Executive Team is responsible for:

- 8.1.1 Responsible for setting the strategic direction for the organisation, including for the implementation of the Duty of Candour.
- 8.1.2 Actively championing the “Being Open and Duty of Candour” process by demonstrating commitment to openness, honesty and transparency in all aspects of patient care and fostering a learning, supportive, fair and just safety culture.
- 8.1.3 Ensuring that recommendations and actions identified from patient safety incidents are implemented and their effectiveness reviewed.

8.2 Medical Director and Director of Nursing

They are responsible for:

- 8.2.1 Conveying to medical, nursing and other health care professionals the importance of complying with both the regulatory and professional duty of candour; and
- 8.2.2 Raising awareness of the process, ensuring that the requirements for sharing information under both the Duty of Candour and Open & Transparent processes are met.

8.3 Associate Director of Quality and Patient Safety

The Associate Director of Quality and Patient Safety is responsible for:

- 8.3.1 Oversight of the effective systems and processes to ensure that there is timely notification and communication to patients or their representatives.
- 8.3.2 Work closely with the Medical Director and Director of Nursing to ensure regulatory compliance of the Duty of Candour is met.
- 8.3.3 Providing advice to health professionals and managers on meeting the Duty of Candour.

8.4 Quality and Patient Safety Team

- 8.4.1 Facilitate the implementation of the Duty of Candour systems and processes by working with the Division staff.

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- 8.4.2 Measure organisational compliance with regulatory Duty of Candour
- 8.4.3 Providing training or arranging for training to be provided on the Duty of Candour.
- 8.4.4 Ensuring that the Being Open and Duty of Candour Policy and the Duty of Candour Guidance is kept up to date to comply with current regulation and recognised best practice

8.5 Directors of Operations, Divisional Directors of Nursing and Divisional Medical Directors

The Divisional management team is responsible for:

- 8.5.1 Ensuring that health professionals within their directorates comply with both the regulatory and professional duty of candour by following this policy.
- 8.5.2 Liaising with the Patient Safety Team regarding compliance with this policy.
- 8.5.3 Be responsible for implementing training sessions within their directorates and raising awareness of the Duty of Candour with their relevant staff

8.6 Divisional Governance Managers:

Divisional Governance Managers are responsible for:

- 8.6.1 The coordination of communication with patients and patient representatives for Duty of Candour in relation to incoming complaints and incidents.
- 8.6.2 Ensuring that a corresponding entry and documentation is made on the Incidents module of Datix and that the responsible senior clinician initiates the Duty of Candour procedure.
- 8.6.3 Ensure that relevant staff are attending Duty of Candour training sessions.

8.7 General Managers, Heads of Nursing and Clinical Directors

The Care Programme management team is responsible for:

- 8.7.1 Ensuring the principles of being open and the Duty of Candour are followed in their service
- 8.7.2 Making the initial disclosure of harm as soon as possible after the incident (usually within 48 hours of the incident and definitely no longer than 10 working days after the incident being reported onto Datix).
- 8.7.3 Apologising to the patient/family/carer, giving an initial explanation of the incident which is known at that point.
- 8.7.4 Signposting the patient/family/carer to appropriate support.

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- 8.7.5 Discussing the investigation process with the patient/family/carer and asking if they have any concerns regarding the investigation and conveying these concerns to the investigator(s) if not present.
- 8.7.6 Agreeing an ongoing point of contact with the patient/family/carer
- 8.7.7 The Duty of Candour letters must be completed by the directorate Governance Manager/lead supported by the senior clinician involved in the patients care within 48 hours of the incident and filed in the patient's notes; they must also be attached to the relevant Datix report to evidence compliance. The first letter is completed after the verbal meeting. The second letter is completed following the meeting where the investigation results are discussed.
- Letter one is to inform the patient/patient representative of the incident and to apologise and inform them that an investigation will be taking place, providing them with a key contact and opportunity to raise questions to be including within the investigation
 - Letter two is to provider a further apology and inform the patient/patient representative of the findings from the investigation and how lessons will be learnt
- 8.7.8 Ensuring all staff involved in an incident, including non-clinical staff, staff from other teams and locum staff are debriefed and signposted to further sources of support if required for example counselling.

8.8 All staff

- 8.8.1 All cases of moderate harm, severe harm, death or prolonged psychological trauma (at least 28 days) must be promptly escalated to the senior clinician present at that time, for initiation of the Duty of Candour procedure.
- 8.8.2 Every member of staff has a duty to ensure all patient safety incidents are promptly reported using the Trust incident reporting system (Datix).
- 8.8.3 To report notifiable safety incidents using the trust Datix electronic incident reporting system and complete the duty of candour question set
- 8.8.4 All staff should be sensitive to peers involved in an incident and provide a supportive environment.

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9 Monitoring and Review

What will be monitored	How/Method	Frequency	Lead	Reporting to	Deficiencies/ gaps Recommendations and actions
Ensure the Trust complies with the Duty of Candour Policy following all incidents of moderate harm and more severe incidents.	Audit of Datix records for evidence of completion of Duty of Candour	Monthly	Quality and Patient Safety Team	IQPR / PRM	Where gaps are recognised actions plans will be put into place to improve compliance
Ensure the Trust complies with Regulation 20 Duty of Candour and the Professional Duty of Candour.	Compliance report as part of wider monitoring report.	Monthly	Head of Quality and Patient Safety	IQPR / PRM	Where gaps are recognised actions plans will be put into place to improve compliance
That the Being Open and Duty of Candour Policy and SOP continue to meet regulatory requirements and best practice.	Keep abreast of regulatory changes and best practice from CQC guidance	On-going	Head of Quality and Patient Safety		The policy will be updated when there is a requirement to do so following regulatory and/or best practice changes.

10 Training and Implementation

- 10.1 E-learning package directing staff through the principles and concept of Duty of Candour and Being Open.
- 10.2 Directorate Governance Managers will be responsible for implementing training sessions within their directorates and raising awareness of the Duty of Candour with their relevant staff.

11 Equality Impact Assessment Statement & Tool

All public bodies have a statutory duty under The Equality Act 2010 (Statutory Duties) Regulations 2011 to provide “evidence of analysis it undertook to establish whether its policies and practices would further, or had furthered, the aims set out in section 149(1) of the [Equality Act 2010]”; in effect to undertake equality impact assessments on all procedural documents and practices. Authors should use the Equality Impact Toolkit to assess the impact of the document.

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In the first instance this will mean screening the document and, where the screening indicates, completing a full assessment. The Toolkit can be found on the Trust website <http://www.medway.nhs.uk/our-foundation-trust/publications/equality-and-diversity/equality-impact-assessments/>

A document will not be considered approved until the author has confirmed that the screening process has been carried out and where required a full impact assessment has been completed. Where a full assessment is completed this should be submitted along with the document for approval.

12 References

Document	Ref No
References:	
Health and Social Care Act 2008 (Regulated Activities) Regulations 2014	Regulation 20
Care Quality Commission: Regulation 20: Duty of candour Information for all providers: NHS bodies, adult social care, primary medical and dental care, and independent healthcare	March 2015
CQC Provider Handbook: NHS and independent acute hospitals (KLOE)	S2 Prompt 1 W3 Prompt 9
Joint Statement from the Chief Executives of statutory regulators of healthcare professionals – Openness and honesty – the professional duty of candour	http://www.gmc-uk.org/Joint_statement_on_the_professional_duty_of_candour_FINAL.pdf
2014/15 NHS Standard Contract: Service Conditions	http://www.england.nhs.uk/nhs-standard-contract/
NPSA: Being Open Framework (2009)	http://www.nrls.npsa.nhs.uk/resources/collections/being-open/?entryid45=83726
Trust Associated Documents:	
Duty of Candour Guidance	GUCGR021
Risk Management Policy	POLCGR065
Maternity Risk Management Strategy	STRCGR006
Risk Management Standing Operating Procedure	SOP0064
Serious Incident Policy	POLCGR071
PALS & Advocacy Policy	POLCPCM018
Complaints Policy	POLCGR005
Respect Countering Bullying in the Workplace Policy	POLCHR002

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