# DUTY OF CANDOUR POLICY

<table>
<thead>
<tr>
<th>Document reference:</th>
<th>COR 019</th>
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<tbody>
<tr>
<td>Version:</td>
<td>1.1</td>
</tr>
<tr>
<td>Ratified by:</td>
<td>Gloucestershire Care Services NHS Trust Board</td>
</tr>
<tr>
<td>Date ratified:</td>
<td>March 2016</td>
</tr>
<tr>
<td>Originator/author:</td>
<td>Head of Clinical Governance</td>
</tr>
<tr>
<td>Responsible committee/individual:</td>
<td>Gloucestershire Care Services NHS Trust Board</td>
</tr>
<tr>
<td>Executive lead:</td>
<td>Director of Nursing</td>
</tr>
<tr>
<td>Date issued:</td>
<td>April 2016</td>
</tr>
<tr>
<td>Review date:</td>
<td>April 2018</td>
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## DOCUMENT CONTROL SHEET

<table>
<thead>
<tr>
<th>Purpose of document:</th>
<th>To ensure the infrastructure is in place to support openness between healthcare professionals and service users/families following an incident, complaint or claim.</th>
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<tr>
<td>Dissemination:</td>
<td>Implementation of the policy is embedded within the document</td>
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<tr>
<td>Scope:</td>
<td>All colleagues who provide care to service users and carers</td>
</tr>
<tr>
<td>Review:</td>
<td>3 years or before if changes required</td>
</tr>
<tr>
<td>This document supports:</td>
<td>Any relevant governance documents, standards and legislation are embedded within the document</td>
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<td>Key related documents:</td>
<td>All related Trust policies or other control documents are embedded within the document</td>
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<td>Equality and diversity:</td>
<td>An Equality Impact Assessment has been completed</td>
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<td>Quality:</td>
<td>A Quality Impact Assessment has been completed</td>
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<tr>
<td>Consultation:</td>
<td>Consultation of this policy will be found within the document</td>
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<td>Financial implications:</td>
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### Version Control Information

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**Appendix 1**

| The 10 Principles of Being Open | 19 - 20 |

### Abbreviations

<table>
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<th>Abbreviation</th>
<th>Full Description</th>
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<tr>
<td>GCSNHST</td>
<td>Gloucestershire Care Services NHS Trust</td>
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<td>CQC</td>
<td>Care Quality Commission</td>
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<td>RCA</td>
<td>Root Cause Analysis</td>
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<td>IO</td>
<td>Investigating Officer</td>
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Duty of Candour Action Card

1. Incident occurs – Report on Datix Immediately
   • Ensure patient is safe
   • Document clearly in patient record
   • Inform senior clinician/line manager

2. In cases of Moderate / Severe Harm / Death, Duty of Candour applies
   • Discuss with Quality and Safety Team
   • Verbal apology given as soon as possible by Senior Clinician

3. Operational Lead appoints investigator to undertake quick RCA (Root Cause Analysis) to be completed within 72 hours and sent electronically to Quality and Safety Team

4. Patient receives a written apology within 10 days of incident
   • Letter written by Matron / Senior Clinician with support from Quality & Safety Team and sign off by Chief Executive Officer
   • If incident is a SIRI / Complaint is handled through SIRI / complaints process

5. Record communication on S1 / Datix “Being Open – Duty of Candour” – Date, time, persons involved, issues, apology, plan for further communication

6. Maintain contact, as agreed with patient / family if incident is SIRI / Complaint in line with GCS Complaints policy

7. Ensure that all Duty of Candour cases/SIRIS/complaints have action plans and are shared for learning at relevant Clinical Governance groups. Wider learning across Trust communicated via monthly quality and Safety report

January 2016
1. Introduction
1.1 Regulation 20 of The Health and Social Care Act 2008 (Regulated Activity) Regulations 2014, introducing the statutory Duty of Candour for the NHS, came into force on 27th November 2014. The introduction of Regulation 20 is a direct response to recommendation 181 of the Francis Inquiry report into Mid Staffordshire NHS Foundation Trust, which recommended that a statutory Duty of Candour be imposed on healthcare providers. The regulations can be found here:

Subsequently the CQC issued a guidance document addressing the Duty of Candour:
http://www.cqc.org.uk/sites/default/files/20141120_doc_fppf_final_nhs_provider_guidancev1-0.pdf

The intention of this regulation is to ensure that providers are open and transparent with people in relation to care and treatment, and specifically when things go wrong with care and treatment, and that they provide people with reasonable support, truthful information and an apology.

Gloucestershire Care Services NHS Trust (the Trust) wants to make this duty a reality for people who come into contact with our services. We want to ensure there is clear, strong organisational support for staff to follow their ethical responsibility in being open and honest with patients. This policy is a reinforcement of our development of a wider culture of safety, learning and improvement.

2. Purpose
2.1 Clinicians already have an ethical Duty of Candour under their professional registration to tell patients about errors and mistakes. This policy builds on individual professional duty and places an obligation on the organisation - not just individual healthcare professionals - to be open with patients when harm has been caused.

The impact and consequences of mistakes or errors can affect everyone involved and this policy aims to ensure there is unequivocal, sustained support for staff in reporting incidents and in being open.

GCSNHST’s approach to Candour underpins a commitment to providing high quality care, understanding and sharing the truths about harm at an organisational as well as an individual level, and learning from them. It is about our organisational values being rooted in genuine engagement of staff, our clinical leadership building on professional accountability, and on every member of staff’s personal commitment to the safety of patients.

Local Trust “Freedom to Speak Up Guardians” was a recommendation by Sir Robert Francis QC ‘Freedom to Speak Up Review’ (2015). The Trust’s Ambassador for Cultural Change incorporates the Guardian role and such a role can make a huge contribution to developing trust within an organisation and improving the culture and the way cases [of raising concerns] are handled.

The processes contained within this policy reflect those set out in Regulation 20 and in the associated CQC guidance.

2.2 Conversations between patients, families and staff about risk and the potential for harm are essential for fostering a culture of Candour, both as a means of preparing patients should something happen, and in encouraging clinicians and healthcare staff to do the right thing when errors occur.

This policy underpins the Trust’s values and aims to ensure:
- The patient's right to openness from the Trust is clearly understood by all staff;
- That this right is integrated into the everyday business of the Trust;
- The Trust learns from mistakes with full transparency and openness;
3. Definitions
3.1 Duty of Candour (as defined in The Francis report):

"The volunteering of all relevant information to persons who have or may have been harmed by the provision of services, whether or not the information has been requested and whether or not a complaint or a report about that provision has been made."

Unlike the existing professional and ethical duty which applies to all circumstances where a patient is harmed when something goes wrong, the statutory Duty of Candour only applies to incidents where a patient suffered unintended harm resulting in moderate or severe harm or death or prolonged psychological harm (Table 1 – page 10 provides harm definitions).

The requirements of the Duty of Candour as set out by the regulations are as follows.

As soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred a health service body must—
(a) notify the relevant person that the incident has occurred
(b) provide reasonable support to the relevant person in relation to the incident, including when giving such notification.

The notification to be given must:
(a) be given in person by one or more representatives of the health service body,
(b) provide an account, which to the best of the health service body’s knowledge is true, of all the facts the health service body knows about the incident as at the date of the notification,
(c) advise the relevant person what further enquiries into the incident the health service body believes are appropriate,
(d) include an apology, and
(e) be recorded in a written record which is kept securely by the health service body.

This notification must be followed up in writing.

Patients should always be informed when adverse incidents occur in line with being open, but the emphasis for the Duty of Candour is on incidents that result in moderate harm, severe harm or death (see Action Card).

3.2 Being Open

Being open was described by the National Patient Safety Agency in 2009 as ‘discussing patient safety incidents promptly, fully and compassionately’ adding that this ‘can help patient and professionals to cope better with the after effects’. The Being Open principles are contained in Appendix 1.

3.3 Patient Safety Incident

A patient safety incident is defined as ‘Any unintended or unexpected incident that could have or did lead to harm for one or more patients receiving NHS-funded healthcare.

3.4 Serious Incident

A serious incidents requiring investigation is defined in the NHS England (2015)
Serious Incident Framework and is an incident that occurred during NHS funded healthcare which resulted in one or more of the following:

- Unexpected or avoidable death or severe harm of one or more patients, staff or members of the public;
- A never event - all never events are defined as serious incidents although not all never events necessarily result in severe harm or death;
- A scenario that prevents, or threatens to prevent, an organisation’s ability to continue to deliver healthcare services, including data loss, property damage or incidents in population programmes like screening and immunisation where harm potentially may extend to a large population;
- Allegations, or incidents, of physical abuse and sexual assault or abuse;
- Loss of confidence in the service, adverse media coverage or public concern about healthcare or an organisation.

Further guidance in relation to Serious Incidents is available in the Trust's Incident Governance Policy. It is important to note that a Serious Incident is not necessarily the same as a Duty of Candour notifiable incident, although there will be some cases where a serious incident is also a notifiable incident.

3.5 Notifiable Incident
This is an incident that needs to be notified to the patient and/or their carer/family under the Duty of Candour. A notifiable incident and a serious incident are not necessarily one and the same; however all notifiable incidents will be investigated using Root Cause Analysis methodology. The nature of the incident will determine the scope of the investigation and this should be discussed with the Quality and Safety Manager.

Notifiable Safety Incident
The regulations state that a “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; “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."

In the regulations the judgment as to whether an incident is notifiable is decided by the healthcare professional. Any decision made regarding notification by the healthcare professional must be clearly documented in the clinical notes demonstrating clear rationale for decisions made.

3.6 Determination of whether a notifiable incident has occurred
It is a matter of judgment from a healthcare professional that needs to be exercised on a case by case basis to determine whether a notifiable incident has occurred. What may or may not appear to be an incident at the outset may look very different once more information comes to light, and may therefore mean an incident becomes notifiable under the Duty of Candour.

Once an incident has been reported via the Trust's Incident Reporting system (Datix) and moderate or severe harm has been caused by this organisation, the incident is reviewed by the Clinical Safety Improvement Lead, Quality & Safety Manager and the Duty of Candour Lead to confirm that the incident is notifiable under the Duty of Candour. The Duty of Candour Lead will the contact the Service involved to provide Duty of Candour advice and support.
3.7 Relevant Person
The Relevant Person is the person who will be informed of an incident in the Duty of Candour process. This may be the service user or patient or the person 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 (as determined in accordance with sections 2 and 3 of the 2005 Act) in relation to the matter.

3.8 Level of Harm
The regulations state that the Duty of Candour applies to incidents as follows:
(a) the death of the service user, where the death relates directly to the incident rather than to the natural course of the service user’s illness or underlying condition, or
(b) severe harm, moderate harm or prolonged psychological harm to the service user; “prolonged psychological harm” means psychological harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days;

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);

4. Roles and Responsibilities
4.1 This policy applies to all colleagues including permanent and temporary staff employed by the Trust, students, bank and locum staff, contracted staff and volunteers. Every healthcare professional in the Trust must be open and honest with patients when something goes wrong with their treatment or care which causes, or has the potential to cause, harm or distress.

The Being Open principles and ethical duty of openness applies to all incidents and any failure in care or treatment. The Duty of Candour applies to incidents whereby moderate harm, severe harm or death has occurred.

There will be exceptions to implementing the Duty of Candour; there must be very sound reasons, which must be clearly recorded, for not having the Duty of Candour principles applied. These cases must be discussed with the Quality Team for advice.

4.2 Trust Board
The Board fully endorses the principles of Being Open and actively promotes an open, honest and fair culture. The Trust Board will seek assurances that the principles and processes set out in this policy work effectively to support the commitment to implementing the Duty of Candour.

Employees involved in patient safety incidents in which a patient has been harmed can be traumatised by the event. The Board ensures that systems are in place to provide support to employees in these circumstances.

4.3 Chief Executive
The Chief Executive is ultimately responsible for the process of managing and responding to the Being Open/Duty of Candour process and for the delegation of this role as required.

4.4 Executive Directors and Senior Management Team
The Executive Directors and Senior Management Team are responsible for actively supporting the Chief Executive with being open and the Duty of Candour principles and process.
4.5 The Clinical Reference Group
The Clinical Reference Group is chaired by the Director of Nursing and the Medical Director. The Clinical Reference Group will review all Serious Incident investigation Root Cause Analysis (RCA) reports to ensure the quality of the investigation is of a high standard, and that associated action plans are comprehensive. The group will monitor Root Cause Analysis reports to determine whether the principles of Being Open and the Duty of Candour have been followed appropriately in each case. The Complaints Overview Group will review and monitor these incidents and provide information other groups.

4.6 Professional Bodies and Trade Union Organisations
The above bodies accept the responsibility of working with the Trust on issues with the shared intention of investigating and learning from incidents. Trade Unions can play a vital role in representing employees in individual matters and supporting them through difficult and stressful situations.

4.7 The Director of Nursing and the Medical Director
The Director of Nursing and the Medical Director are jointly responsible for ensuring the effective implementation of the Being Open and the Duty of Candour is reported to the Quality and Performance Committee and Trust Board.

4.8 Quality Team
Quality & Safety Manager, Clinical Safety Improvement Lead and Duty of Candour Lead receive all incidents where moderate or severe harm has been caused by this Trust to establish whether it is a Duty of Candour case

4.9 Ambassador for Cultural Change
The Freedom to Speak Up Guardian component of the role will complement all other channels by which staff can raise concerns, and will provide confidential support and advice to individuals raising concerns regarding safety, quality or wrongdoing, ensuring that there are no repercussions for the person who in good faith drew attention to it.

4.10 Line Managers’ Responsibility
It is the responsibility of all Trust managers to support employees to comply with this policy and to ensure members of their teams are aware of this duty. It is the line managers responsibility to liaise with the Quality Team.

4.11 Employee Responsibility
All employees must comply with their relevant professional code. A joint statement on Candour has been issued by the following professional healthcare regulators:

- General Chiropractic Council
- General Dental Council
- General Medical Council
- General Optical Council
- General Osteopathic Council
- General Pharmaceutical Council
- Nursing and Midwifery Council
- Health and Care Professions Council
- College of Paramedics

All employees have a contractual duty and must understand their responsibility for being open and demonstrate the principles of being open in their work.

All employees who become aware of an incident or near miss having occurred must follow the Trust Incident Reporting Policy and apply the principles of Being Open and the Duty of Candour throughout these processes.

All employees dealing with patients or relatives should abide by the Trust’s complaints process and advise who patients or carers should write to if they wish to formalise a complaint.
Employees who are concerned about the non-reporting or concealment of incidents, or about on-going practices which present a risk to patient safety, must raise their concerns either through established governance routes or through the Trust's ‘Raising Concerns at work’ policy.

4.12 Investigating Officer
An Investigating Officer will have received training in undertaking Root Cause Analysis (RCA) and will be able to demonstrate competence with this skill. The Investigating Officer could be the point of contact throughout an investigation between the patient, the family and the Trust if it is agreed that this is most appropriate approach. This communication role can be undertaken by another person such as the lead clinician or senior manager if this is more appropriate, but whoever the contact is must be recorded in the clinical notes and the RCA documentation.

4.13 Senior Clinician
The most senior clinician in partnership with the Quality and Safety Manager will determine whether the incident is notifiable. Advice can be obtained from Senior Managers, the Deputy Director of Nursing or the Quality Team.

4.14 Notifying the Relevant Person
In making a decision about who is most appropriate colleague to lead on the notification discussion and apology, the member of staff’s seniority, relationship to the person using the service, and experience should all be considered. Issues of consent and confidentiality and will determine who will lead on the discussions with the relevant person.

4.15 Children and Young People
Young people are owed the same duties of care and confidentiality as adults. Confidentiality may only be broken when the health, safety or welfare of the young person, or others, would otherwise be at grave risk.

Where a child or young person is judged to have the mental capacity and the emotional maturity to understand the information provided (refer to the Fraser guidelines http://www.fpa.org.uk/factsheets/under-16s-consent-confidentiality), then he/she should be involved directly in the Duty of Candour process following a notifiable patient safety incident.

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’ or legal guardian’s views on the issue should be sought. More information can be found in the Trust Consent to Treatment policy.

5. Policy Details
5.1 Being Open and Duty of Candour Process
Most clinicians will find themselves in the difficult position of having to discuss harm or potential harm with a patient at some time in their career. The following guidance provides a framework for staff to work to. It is recognised however that many scenarios do not always follow predetermined processes, and staff must use their own professional judgement in deciding, for example, when is the right time to talk to patients and families/carers. There is no substitute for clinical and professional expertise and compassionate care.

Stage One
Incident Identification and Reporting
Firstly any actions that can be taken immediately to reduce the risk of harm to the patient must be implemented.
The initial facts of the incident should be established and an assessment of the level of harm that has happened to the patient as a result of the incident (see table below) should be undertaken. When considering the level of harm, it is essential to report on actual harm (not potential).

<table>
<thead>
<tr>
<th>Incident</th>
<th>Action</th>
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<td>No harm ( \text{(including prevented patient safety incidents)} )</td>
<td>o Patients are not usually contacted or involved in investigations and these types of incidents are \textit{outside} the scope of the \textit{Duty of Candour}. Openness remains best practice, but there is no requirement to follow the \textit{Duty of Candour} processes.</td>
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| Low harm | \textbullet\  Unless there are specific indications or the patient requests it, the communication, investigation and analysis, and the implementation of changes will occur at local service delivery level with the participation of those directly involved in the incident.  
\textbullet\  Communication should take the form of an open discussion between the staff providing the patient’s care and the patient and/or their carers.  
\textbullet\  Reporting to the operational managers will occur through standard incident reporting and will be analysed centrally to detect high frequency events.  
\textbullet\  Review will occur through aggregated trend data and local investigation.  
Where the trend data indicates a pattern of related events, further investigation and analysis may be needed.  
Openness remains best practice, but there is no requirement to follow the \textit{Duty of Candour} processes for incidents that result in this level of harm. |
| Moderate harm | o The \textit{Duty of Candour} policy is implemented.  
\textbullet\  It may be necessary to inform the relevant Senior Operational Manager. For Never Events senior manager must be informed immediately and for serious incidents, the Quality & Safety Team and Duty of Candour Lead will also need to be contacted as quickly as possible to ensure everyone who needs to know is informed. The Trust operates within openness principles with our commissioners and regulators, and we will inform these organisations of this. |
| Severe harm or death | \textbullet\  |

All incidents must be reported onto Datix (refer to the Trust’s Incident Governance Policy). The incident report must be completed as soon as possible after the incident has been discovered, and always within 48 hours of detecting the incident. For all moderate and greater harm incidents, Datix prompts the handler reporting the incident whether the Duty of Candour has been applied in the incident.

**Stage Two**

**Being Open**

There are a set of principles for being open that colleagues should refer to when communicating with the relevant person following an incident in which the patient/service user was harmed.

**Mental Capacity**

Where the patient or service user is assessed as not having the capacity to make a decision in relation to their care or treatment, or where the patient / service user is under 16 and deemed not to have the necessary competency, then the most appropriate
relevant person should be notified of the incident.

Confidentiality
Details of a patient’s care and treatment should at all times be considered confidential. Where the Duty of Candour would include providing confidential information to family or carers, then the consent of the individual concerned should be sought prior to disclosing information. This consent or denial of consent to share should be recorded in the clinical notes and subsequent RCA documentation.

Communication with parties outside of the clinical team should be on a strictly need-to-know basis and, where practicable, records should be anonymised.

Further advice is available in the Trust’s Consent to Treatment Policy and Code of Conduct for Employees in Respect of Confidentiality.

If the Relevant Person Cannot be Contacted or Declines to Have Further Information
If, after discussion, the patient says they do not want more information, then the possible consequences must be explained to them. It should be made clear that they can change their mind and have more information at any time.

All Duty of Candour conversations must be recorded in the notes including instances when the patient has declined the offer of further information.

Where a relevant person cannot be contacted, a clear written record must be kept of the attempts made to contact or speak to the relevant person. This should evidence that every reasonable effort was made to contact the person by stating how many attempts were made, who by and when.

Stage Three
The initial ‘Being Open’/Duty of Candour communications will vary according to the individual needs of the relevant person, the severity grading of the incident, clinical outcome and family circumstances for each specific event. The most senior clinician on the clinical shift should coordinate this initial communication, ensuring that the relevant person receives clear, unambiguous explanation of the event and the next steps to be taken. It is also vital that staff involved in the incident receive appropriate support from the outset.

The following is intended as broad advice as it is recognised that the vast majority of clinical staff have extensive, highly tuned communication skills.

Apology
Where a patient safety incident has caused harm, an apology must be offered to the relevant person – a sincere expression of sorrow or regret for any possible harm and distress caused as soon as possible.

Guidance from the NHS Litigation Authority (2009) states:

“It is both natural and desirable for clinicians who have provided treatment which produces an adverse result, for whatever reason, to sympathise with the patient or the patient’s relatives; to express sorrow or regret at the outcome; and to apologise for shortcomings in treatment. It is most important to patients that they or their relatives receive a meaningful apology. We encourage this, and stress that apologies do not constitute an admission of liability. In addition, it is not our policy to dispute any payment, under any scheme, solely on the grounds of such an apology.”

Clarity of Communication
The individual communication needs of the relevant person, for example, linguistic or cultural needs, learning disabilities, or sensory impairments must be considered and taken into full account before any discussion takes place. This involves consideration of circumstances that can include a patient requiring additional support, such as an independent patient advisor or a translator.
The relevant person should be fully informed of the issues surrounding the patient safety incident and its consequences in a face to face meeting where possible. The facts that are known should be explained. When talking to the relevant person about the incident colleagues must use clear, straightforward language and be honest with responses to any questions that are raised.

The relevant person should be informed that an incident review will be carried out and more information will become available as this progresses.

It should be made clear to the relevant person that new facts may emerge as the incident review proceeds.

The relevant person’s understanding of what happened should be established from the outset, as well as any questions they may have.

There should be consideration and formal noting of the relevant person’s views and concerns, and demonstration that these have been heard and taken seriously.

An explanation should be given about what will happen next in terms of the long term treatment plan for the patient as well as the incident review findings.

Information on likely short and long-term effects of the incident (if known) should be shared. An offer of practical and emotional support should be made to the relevant person.

Patients, family and/or carers might be anxious, angry and frustrated, even when the discussion is conducted appropriately. It is essential that staff are not drawn into speculation, attribution of blame, denial of responsibility or the provision of conflicting information.

**Stage Four**

The Investigation

For Serious Incidents involving Duty of Candour, the Investigating Officer (IO) will undertake the RCA as set out in the Trust’s Incident Governance Policy. The IO will meet with the employee(s) directly involved in the incident to establish the facts.

Where an incident is notifiable but does not meet the criteria for a Serious Incident, then an RCA must be undertaken.

The actions above should be followed by a letter within 10 working days from the Service involved to the patient/relatives with an offer of a meeting, if this is appropriate. The letter should be sent from a Senior member of staff and includes their contact details as the contact lead for the duration of the investigation.

The Investigating Officer will keep the relevant Quality Safety Lead and Duty of Candour Lead fully informed on progress with the investigation.

**Stage Five**

**Communication with the Relevant Person – the Notification Meeting**

A meeting with the relevant person should be arranged as soon as possible after the incident has happened by the Investigating Officer and supported by the Duty of Candor Lead to notify them of the incident. This meeting should always take place within 10 working days of the incident being discovered.

At the meeting the Investigating Officer will follow the procedure below:

- If known, explain what went wrong and where possible, why it went wrong;
- Inform the patient and/or relative(s) and others what steps are being/will be taken to prevent the incident recurring;
- Offer an apology;
- Provide opportunity for the patient and/or relatives and others to ask any questions;
- Agree with the patient and/or relatives and others any future meetings
as appropriate;
- Suggest any sources of additional support and counselling and provide written information if appropriate.
- Inform the relevant person that a further meeting will be arranged on completion of the investigation to share the outcome, findings and recommendations. This will be followed by a letter from the Chief executive summarising the outcome, findings and recommendations.

All Duty of Candour letters will be signed off by the relevant Director and a copy retained on the Datix system to provide a robust audit trail.

If, for whatever reason, the patient cannot be contacted in person or declines to speak to anyone from the Trust in relation to the incident, then the above processes do not apply but a written record must be kept of the attempts made to contact or to speak to the relevant person.

**Stage Six**

**Investigation Closure and Learning**

Where a SIRI investigation has been conducted, where Duty of Candour applies, the report will be presented to the Clinical Reference Group.

All learning from the incidents must be cascaded via the Directorate Governance meetings, Quality and Performance Committee and Team Brief. This information will be relayed to Trust Board through the Quality and Performance Report.

The outcome of reports must also be shared with any other healthcare organisation or relevant stakeholder as appropriate to optimise learning from the incident.

### 5.2 Implications of non-compliance of the Duty of Candour requirements

As the Duty of Candour is a statutory requirement, non-compliance is a criminal offence. Commissioners can withhold the cost of the episode of care or implement a fine of £10,000 if the cost is not known. In addition, they can do any/all of the following:
- Inform the CQC
- Require that the Chief Executive send an apology and an explanation of the breach to the patient/relatives
- Publish details of the breach on the Trust web-site.

The CQC will assess whether a provider is complying with the new regulation. The CQC's key lines of enquiry will be:
1. Are lessons learned and improvements made when things go wrong?
2. Are people who use services told when they are affected by something that goes wrong, given an apology and informed of any actions taken as a result?
3. How does the leadership and culture reflect the vision and values encourage openness and transparency and promote good quality care?
4. Does the culture encourage candour, openness and honesty?

### 5.3 Incidents that are later uncovered or that have occurred within the care of another provider

On occasions, an incident that happened some time ago may be discovered. The incident should be reported in the usual way on Datix, and agreement reached by the senior clinician and the Quality and Safety Manager as to the most appropriate action to take. A delay in discovering an incident does not mean the Duty of Candour does not apply.

The processes however may require additional consideration so that the patient is informed of the incident with care to avoid unexpected shock or distress.

Incidents that are discovered which relate to care delivered by another provider will be reported to a senior manager in that organisation, and to the commissioning body. That
organisation is then responsible for implementing the Duty of Candour. The Trust will work in partnership with other providers to ensure the Duty of Candour applies as a care economy wide, patient-centred policy.

This policy deals with the information and methods of sharing of information with the relevant person. Patients and those close to them will vary in how much information they want, and when they want it. Some people will want as much detail as possible, including details of rare risks, to those who ask health professionals to make decisions for them. There will always be an element of professional judgement in determining what information should be given. However, the presumption must be that the relevant person wishes to be well informed about the risks and benefits of the various options. Where the relevant person makes clear (verbally or non-verbally) that they do not wish to be given this level of information, this should be documented.

**The potential implications of not implementing the Duty of Candour requirements**

As the Duty of Candour is a statutory requirement, non-compliance is a criminal offence.

Commissioners can withhold the cost of the episode of care or implement a fine of £10,000 if the cost is not known. In addition, they can do any/all of the following:

- Inform the CQC
- Require that the Chief Executive send an apology and an explanation of the breach to the patient/relatives
- Publish details of the breach on the Trust web-site.

The CQC in their guidance relating to the Duty of Candour explain the approach they will be taking to assess whether a provider is complying with the new regulation. The CQC’s key lines of enquiry will be:

1. Are lessons learned and improvements made when things go wrong?
2. Are people who use services told when they are affected by something that goes wrong, given an apology and informed of any actions taken as a result?
3. How does the leadership and culture reflect the vision and values encourage openness and transparency and promote good quality care?
4. Does the culture encourage candour, openness and honesty?

**Incidents that are later uncovered or that have occurred within the care of another provider**

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5.4. **Documentation**

All correspondence should be held in accordance with Trust’s Records Management Policy. With specific relation to the Being Open/Duty of Candour the clinical records must:

- Record the sharing of any facts that are known and agreed with the relevant person;
- Record how it has been agreed that the relevant person will be kept informed of
the progress and results of that investigation;
- Record, where appropriate, a full apology to the patient and their family/carers;
- Record any explanation given of the likely short and long-term effects of the incident;
- Contain copies of any letters sent to the relevant person;
- Record an offer of appropriate practical and emotional support.

5.5 Performance/Disciplinary Issues
As previously described, the Trust will strive to identify the underlying causes of patient safety incidents (i.e. systems failures or latent conditions) through RCA processes. The incident decision tree [http://www.ahrq.gov/downloads/pub/advances/vol4/meadows.pdf](http://www.ahrq.gov/downloads/pub/advances/vol4/meadows.pdf) supports this process and provides a straightforward guidance tool to support a fair and just approach to patient safety incidents. The tool aims to support clinicians and managers in understanding when safety incidents should be attributed to systemic or organisational issues, as well as identifying the occasions when there may be individual culpability for an incident.

The purpose of the tool is to support building a just and fair safety culture that moves away from inappropriately blaming individual staff for safety incidents when these are more often the result a combination of human, organisational, technological and system factors.

Where concerns are identified about the performance of staff, the Trust’s Human Resources policies will be invoked.

This will particularly be the case in matters where safeguarding issues are identified. The appropriate professional body (GMC/NMC/ etc.) may also need to be notified.

6. Consultation
Complaints Oversight Group
Clinical Policy Group
Clinical Reference Group
Quality and Performance Committee

7. Resources
Staff trained to undertake RCA

8. Training
8.1 As part of the Trust’s induction programme, all new employees of the Trust are made aware of the ‘Being Open’ process and Duty of Candour.

All Investigating Officers should receive RCA training before undertaking an investigation. The Duty of Candour processes form part of this training.

Awareness of the Being Open principles will be promoted to all through Team Brief, information leaflets and existing Quality Governance structures.

8.2. Support and Advice for Staff
Staff in healthcare rarely intend to cause harm or fail to do the right thing. While risks can be minimised, it will never be possible to eliminate them fully and many ‘human factors’ can increase the risk of incidents occurring such as:
- Workload
- Distractions
- Physical environment
- Physical demands
- Device / product design.
and the Trust is committed on the learning and prevention of incidents and not to apportioning blame on staff.

Involvement in an incident and particularly a serious incident can have profound consequences on colleagues who may experience a range of reactions and support is available from Line Management, Senior Managers, Human Resources and Care First

9. Implementation
9.1 The policy will be communicated to staff via line managers following the approved process.
9.2 The policy will be made available on the organisation’s Intranet and it will also be highlighted in team meetings.
9.3 Information on who to contact for access to the policy from outside the organisation is available on the Internet. Details how the document is to be rolled out and maintained within the Trust

10. Audit
10.1 The Clinical Reference Group is responsible for the agreeing sign off and closure of the incident report and once completed, the outcome of this will be reported to the Quality and Performance Committee and Trust Board.

A questionnaire will be developed to gain feedback from colleagues who have been involved in Duty of Candour incidents in order to establish what extra support and resources need to be put in place to provide support throughout the process.

11. Equality Impact
11.1 This policy has been subject to a Quality and Equality Impact review. This concluded that this policy will not create any adverse effect or discrimination on any individual or particular group. Confirms the results of an Equality Impact Assessment

12. Quality Impact
12.1 This policy has been subject to a Quality and Equality Impact review. This concluded that the policy will not negatively impact upon the quality of health and social care services provided by the Trust. Confirms the results of a Quality Impact Assessment

13. Review
3 years or before if changes required

14. References, Bibliography and Acknowledgements
The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 No. 2936 PART 3SECTION 2 Regulation 20

The Francis Enquiry  http://www.midstaffspublicinquiry.com/


Building a culture of candour - A review of the threshold for the duty of candour and of the incentives for care organisations to be candid

Human Factors in Healthcare – National Quality Board 2013
NPSA – Being Open resources:
http://www.nrls.npsa.nhs.uk/resources/?entryid45=65077

Mental Capacity Act 2005 – Code of Practice
http://www.justice.gov.uk/protecting-the-vulnerable/mental-capacity-act

Fraser Guidelines
http://www.fpa.org.uk/factsheets/under-16s-consent-confidentiality

General Medical Council, Good medical Practice, 2006
www.gmc-uk.org/guidance/good_medical_practice/index.asp

National Patient Safety Agency, Seven Steps to Patient Safety, April 2004
http://www.nrls.npsa.nhs.uk/resources/collections/seven-steps-to-patient-safety/

NHS Litigation Authority, Litigation Circular No. 02/02 Apologies and Explanations, 11 February 2002 www.nhsla.com

NHS Litigation Authority – Saying Sorry: 2013 -

CQC Provider Guidance
Appendix 1

The 10 Principles of Being Open - Being open involves apologising when something has gone wrong, being open about what has happened, how and why it may have happened, and keeping the patient and their family informed as part of any subsequent review.

1. Principle of Acknowledgement
   All patient safety events should be acknowledged and reported as soon as they are identified. In cases where the patient, their family and carers inform healthcare employees that something has happened, their concerns must be taken seriously and should be treated with compassion and understanding by all employees. Denial of a person’s concerns or defensiveness will make future open and honest communication more difficult.

2. Principles of Truthfulness, Timeliness and Clarity of Communication
   Information about a patient safety incident must be given in a truthful and open manner by an appropriately nominated person. Communication should be timely, informing the patient, their family and carers what has happened as soon as is practicable, based solely on the facts known at that time. It will be explained that new information may emerge as the event investigation takes place. Patients, their families and carers and appointed advocates should receive clear, unambiguous information and be given a single point of contact for any questions or requests they may have.

3. Principle of an 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 event or that the experience was poor. Both verbal and written apologies should be offered. **Saying sorry is not an admission of liability and it is the right thing to do.** Verbal apologies are essential because they allow face to face contact, where this is possible or requested. A written apology, which clearly states the organisation is sorry for the suffering and distress resulting from the patient safety event, should also be given.

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 organisation and/or in accordance with the local resolution process where a complaint is at issue. They should be treated sympathetically, with respect and consideration. Confidentiality must be maintained at all times. Patients, their families and carers should also be provided with support in a manner to meet their needs. This may involve an independent advocate or an interpreter. Information enabling to other relevant support groups will be given as soon as possible and as appropriate.

5. Principle of Professional Support
   The Trust has set out to create an environment in which all employees are encouraged to report patient safety events. Employees should feel supported throughout the patient safety event investigation process; they too may have been traumatised by the event. Resources available are referred to within the respective Trust policies, to ensure a robust and consistent approach to patient safety event investigation. Where there are concerns about the practice of individual employee the Trust’s Human Resources department must be contacted for advice. Where there is reason to believe an employee has committed a punitive or criminal act, the Trust will take steps to preserve its position and advise the employee at an early stage to enable them to obtain separate legal advice and/or representation. Employees should be encouraged to seek support from relevant professional bodies. Where appropriate, a referral will also be made to the Independent Safeguarding Authority.
6. Principle of Risk Management and Systems Improvement
   Root Cause Analysis (RCA) or similar techniques should be used to uncover the underlying causes of patient safety events. Investigations at any identified level will however focus on improving systems of care, which will be reviewed for their effectiveness. Being open is integrated into patient safety incident reporting and risk management policies and processes.

7. Principles of Multi-Disciplinary Responsibility
   Being open applies to all employees who have key roles in patient care. This ensures that the Being open process is consistent with the philosophy that patient safety incidents usually result from system failures and rarely from actions of an individual. To ensure multi-disciplinary involvement in the Being open process, it is important to identify clinical and managerial leaders who will support this across the health and care agencies that may be involved. Both senior managers and senior clinicians will be asked to participate in the patient safety incident investigation and clinical risk management as set out in the respective Trust policies and practice guidance.

8. Principles of Clinical Governance
   Being open involves the support of patient safety and quality improvement through the Trust’s clinical governance framework, in which patient safety incidents are investigated and analysed, to identify what can be done to prevent their recurrence. It is a system of accountability to ensure that these changes are implemented and their effectiveness reviewed. Findings are disseminated to employees so they can learn from patient safety incidents. Audits are an integral process, to monitor the implementation and effects of changes in practice following a patient safety incident.

9. Principle of Confidentiality
   Details of a patient safety incidents 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. The Trust will anonymise any incident it publishes but still seek the agreement of those involved.
   Where it is not practicable or an individual refuses consent to disclosure, disclosure may still be lawful if justified in the public interest or where those investigating the patient safety event have statutory powers for obtaining information. Communications with parties outside of those involved in the investigation will be on a strictly need to know basis. Where possible, it is good practice to inform the patient, their family and carers about who will be involved in the investigations before it takes place, and give them the opportunity to raise any objections.
   Consent and duty to inform for incidents involving patients in Offender Health will be dealt with in accordance with the normal prison protocol.

10. Principle of Continuity of Care
    Patients will continue to receive all usual treatment and continue to be treated with respect and compassion.

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Being open: communicating patient safety incidents with patients and their carers