Duty of Candour can make an important contribution to creating a culture of openness and honesty which always places the safety and the needs of the patient and family above the reputation of the organisation.

What is needed is a culture of openness and honesty, stimulated by a duty of candour, which is wholeheartedly adopted by organisations and individuals. This will enable our patients to be reassured that when things go wrong, we will learn and we will improve. (Dalton & Williams 2014)

The commitment to candour has to be about values and it has to be routed in genuine engagement of staff building on their own professional duties and their personnel commitments to their patients.

The West Suffolk NHS Foundation Trust Board has set out a commitment to transparency and being open and this document describes how the Trust will implement and monitor adherence to this commitment.
1. Introduction

In September 2005 the National Patient Safety Agency (NPSA) issued a Safer Practice Notice calling on all NHS organisations to develop local ‘Being Open’ policies. The aim was to provide a framework for communicating patient and service user safety incidents that lead to moderate or severe harm to the patients, service users and/or their carers.

In November 2009 the NPSA updated the guidance with the issue of Patient Safety Alert NPSA/2009/PSA003. This alert required all organisations commissioning and providing healthcare to implement actions set out in the revised NPSA Being Open framework.

The National NHS Contract for 2013/14 introduced a contractual Duty of Candour for patient safety incidents that resulted in moderate harm, severe harm or death (using NPSA definition see Appendix A) that are reported to local risk management systems. This required an apology to be provided using the principles set out in ‘Being Open’ (see Appendix B).

In November 2014 a statutory Duty of Candour was introduced for all Secondary care providers registered with CQC in England as set out in Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 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 introduced for health and care providers. This is further to the contractual requirement for candour for NHS bodies in the standard contract, and professional requirements for candour in the practice of a regulated activity.

The regulation and its implementation reflect the approach proposed by the Dalton/Williams review, including explaining notifiable safety incidents across different sectors.

In April 2015 this became law for all providers registered with the CQC to achieve a verbal Duty of Candour for moderate harm and above within 10 working days. This should be followed up with a written Duty of Candour in a suitable timeframe.

2. Purpose of this Policy

2.1 Staff work hard to provide services which are safe and of a high quality. However, sometimes things go wrong.

2.2 This policy has been developed to ensure that staff are aware of the processes and steps to follow in supporting patients and carers following an incident meeting the requirements for provision of Duty of Candour. It sets out specific requirements to follow when things go wrong with care and treatment, including informing people about the incident, providing reasonable support, providing truthful information and an apology.

2.3 Health professionals have a duty to be open and honest with patients when things go wrong as set out in the joint GMC / NMC document Openness and honesty when things go wrong: the professional duty of candour supported by the Joint statement from the Chief Executives of statutory regulators of healthcare professionals.

2.4 The policy provides guidance to staff on how to undertake the Duty of Candour and support mechanisms available where staff are unsure how to proceed.

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1 Openness and honesty when things go wrong: the professional duty of candour
http://www.gmc-uk.org/static/documents/content/DoC_guidance_english.pdf

2 Joint statement on the professional duty of candour
http://www.gmc-uk.org/Joint_statement_on_the_professional_duty_of_candour_FINAL.pdf_58140142.pdf
2.5 There are some specific incident types which have a defined pathway within the remit of Duty of Candour and these are set out in Section 8.

2.6 The policy also sets out how the Trust will ensure that such events are identified, recorded, and completion monitored.

2.7 Illustrative examples of incidents that trigger the thresholds for duty of candour are provided in Appendix C.

3. Scope of this Policy

3.1 The Trust’s Incident Reporting and Management Policy (PP105) encourages staff to report all patient and service user safety incidents, including those where there was no harm or it was a ‘near miss’ event.

3.2 This ‘Being Open – The Duty of Candour’ policy only relates to those incidents where actual harm has occurred and the consequences are graded as Moderate, Major (referred to as ‘Severe’ in the NPSA framework) or Catastrophic (referred to as ‘Death’ in the NPSA framework). Implementation of this policy will be an integral part of the management and investigation of these incidents.

3.3 However, there is flexibility to discuss incidents resulting in a lower level of harm (including no harm) with patients on an individual basis depending on local circumstance and the best interest of the patient. Where this does occur details of all communication must be documented.

3.4 Other disciplinary processes are outside the scope of the Being Open policy. Immediate disciplinary action can create a barrier to open reporting. The root causes of an incident should be the focus of the investigation, rather than the last individual to provide care.

4. Definitions

NB: Definitions of openness, transparency and candour are those set out by Robert Francis in his report\(^3\). All other definitions are those set out within the CQC Regulation 20: Duty of Candour with the exception of Clinical Lead which is a local WSFT definition.

Openness – enabling concerns and complaints to be raised freely without fear and questions asked to be answered.

Transparency – allowing information about the truth about performance and outcomes to be shared with staff, patients, the public and regulators.

Candour – any patient harmed by the provision of a healthcare service is informed of the facts and an appropriate remedy offered, regardless of whether a complaint has been made or a question asked about it.

Clinical Lead – The senior clinical professional responsible for undertaking the Duty of Candour communication. This will usually be a Consultant or Matron but may on occasion be another senior person dependant on the specific incident type and location where the incident took place.

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Apology
An 'apology' is an expression of sorrow or regret in respect of a notifiable safety incident; it is not an admission of guilt.

Appropriate written records
Records are complete, legible, accurate and up to date. Every effort must be made to ensure records are updated without any delays.

Cancelling treatment
Where planned treatment is not carried out as a direct result of the notifiable safety incident.

Moderate harm
'Moderate harm' means harm that requires a moderate increase in treatment, and significant, but not permanent, harm, for example a “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).

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

Prolonged psychological harm
'Prolonged psychological harm' means psychological harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days.

Relevant person
This is the person who is receiving services or someone acting lawfully on their behalf in the following circumstances: on their death, or where they are under 16 and not competent to make a decision in relation to their care or treatment, or are 16 or over and lack the mental capacity in relation to the matter in accordance with the Mental Capacity Act 2005.

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

Written Notification
A written notification is one given or sent to the relevant person in written form containing the information provided in any initial notification made in person, details of any enquiries to be undertaken, advise of any appropriate enquiries to be undertaken by the registered person, the results of any further enquiries into the incident, and an apology (as defined above).

5. Responsibilities

5.1 All staff

- Responsible for reporting patient safety incidents on the Trust Datix incident reporting system according to the Trust's policy PP105.
- Documenting any conversation with the patient or other relevant person relating to the reported incident in the patient’s health record.
5.2 Clinical Lead

- Responsible for providing an apology to the patient or other relevant person following a reported notifiable incident according to the principles of the Duty of Candour.
- Documenting any conversation with the patient or other relevant person relating to the reported incident in the patient's health record.
- Providing a written notification to the patient or other relevant person.

5.3 Divisional Governance Manager

- Ensuring the Clinical lead is aware of the notifiable incident and their responsibility to provide an apology and written notification.
- Monitoring completion of the Duty of Candour process using the relevant section of the Trust Datix incident reporting system.
- Escalation to the Clinical Director or Head of Nursing of any instance where the Duty of Candour process has not been adhered to.

5.3 Clinical Director / Head of Nursing

- Responsible for allocation of Clinical lead where there is lack of clarity following initial reporting of the notifiable incident.
- Acting to ensure completion of the Duty of Candour process for any instance escalated by the Divisional Governance Manager where the Duty of Candour process has not been adhered to.

5.4 Head of Patient Safety & Effectiveness

- Responsible for the oversight and management of the Trust’s Duty of Candour process including reporting to the Trust Board and monitoring adherence to the policy. This responsibility is delegated to the Trust Compliance Manager.

6. Documentation

Throughout the Duty of Candour process it is important to record discussions with the patient or other relevant person in the health record.

7. Process for undertaking Duty of Candour

See flowchart overleaf
8. Specific incident types

There are some specific incident types which have a defined pathway within the remit of Duty of Candour. This section sets out the pathway for these incident types:

8.1 In cases where a complaint triggers the reporting of an amber or red incident, a separate Duty of Candour is not triggered as the complainant by definition is already aware as they have raised the complaint. However, the response must cover off all the issues raised as well as any others that are identified as part of the investigation that the complainant may not have been aware of. The complainant will also be given an opportunity to meet with staff. The complaint acknowledgment letter issue date is recorded as the ‘Notification letter’ date on the Datix incident record.

8.2 Within Obstetrics there are a number of ‘trigger events’ which are unexpected adverse outcomes however these may not always be as a result of failures in care. For such events there is a pathway which incorporates Being Open conversations. Where incidents are initially graded as moderate harm or above consideration should be given to undertaking Duty of Candour with the parent(s) / relevant person. See overleaf.
8.2.1 Neonatal transfers to tertiary centre for ‘cooling’

Prior to baby being transferred to a tertiary centre the Paediatric or Obstetric medical staff should ensure that they have explained to the parent(s) that, because of this unusual adverse outcome we will be reviewing the care. The parent(s) should be offered the opportunity to highlight any questions they may wish answered. This initial conversation should be confirmed in a written letter. After the investigation is complete they should also be offered the opportunity to receive feedback along with a copy of the review report.

8.2.2 Intrauterine / Intrapartum / Neonatal death

As part of the bereavement process, often during the conversation which asks for consent to post-mortem, the Paediatric or Obstetric medical staff should ensure that they have explained to the parent(s) that, because of this unexpected outcome we will be reviewing the care. The parent(s) should be offered the opportunity to highlight any questions they may wish answered. This initial conversation should be confirmed in a written letter. After the investigation is complete they should also be offered the opportunity to receive feedback along with a copy of the review report.

9. When Duty of Candour is not required

There are two circumstances in which Duty of Candour can be omitted.

1. Regulation 20(5)\(^5\) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 sets out that it is acceptable not to undertake Doc in the following circumstance:

   \(\text{If the relevant person cannot be contacted in person or declines to speak to the representative of the registered person}\)

   - The provider must make every reasonable attempt to contact the relevant person through all available means of communication. All attempts to contact the relevant person must be documented.
   - 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.
   - If the relevant person has died and there is nobody who can lawfully act on their behalf, a record of this should be kept.

2. Furthermore it is acknowledged that there will be occasions when a patient has died and the incident for which Duty of Candour applies is not causative in the death. If the senior clinician feels that it would cause further distress to the family to undertake Duty of Candour it is acceptable to decide not to undertake the conversation or written follow up. For each case where this is applicable, a formal request not to undertake Duty of Candour should be sent to the Clinical Commissioning Group (CCG) Patient safety lead. A formal documentation of this decision making will be documented within the Datix record for that incident.

   It is NOT acceptable to omit Duty of Candour where the incident is considered to be or is possibly causative in that death.

10. Monitoring

\(^{5}\) Guidance for providers on meeting the regulations Health and Social Care act 2008 (Regulated activities) Regulations 2014 (Part 3) (as amended) http://www.cqc.org.uk/content/regulation-20-duty-candour#guidance
The Trust uses the Trust Datix incident reporting system to monitor the progress of the Duty of Candour and a monthly status update is provided to the Trust board via the Quality & Performance report.

A monthly report is also provided to the Clinical Commissioning Group providing the detail of all cases identified as requiring Duty of Candour in the month.

11. Document configuration information

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<th>Author(s):</th>
<th>Head of Patient Safety &amp; Effectiveness</th>
</tr>
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Appendix A: NPSA definitions of harm

<table>
<thead>
<tr>
<th>Grade</th>
<th>Definitions</th>
<th>Average annual figure reported to NRLS rounded</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Harm</td>
<td>Impact prevented – any 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 to people receiving NHS funded care.</td>
<td>900,000</td>
</tr>
<tr>
<td>Low</td>
<td>Any patient safety incident that required extra observation or minor treatment (first aid, additional therapy, additional medication) and caused minimal harm.</td>
<td>335,000</td>
</tr>
<tr>
<td>Moderate</td>
<td>Any patient safety incident that resulted in a moderate increase in treatment (return to surgery, unplanned readmission, prolonged episode of care, extra time in hospital) and which caused significant but not permanent harm.</td>
<td>85,000</td>
</tr>
<tr>
<td>Severe*</td>
<td>Any patient safety incident that appears to have resulted in permanent harm (permanent lessening of bodily functions, sensory, motor, physiological or intellectual, including removal of wrong limb or organ or brain damage).</td>
<td>7,500</td>
</tr>
<tr>
<td>Death**</td>
<td>Any patient safety incident that directly resulted in the death (related to the incident rather than to the natural course of the patients illness or underlying condition) of one or more persons.</td>
<td>3,500</td>
</tr>
</tbody>
</table>

*Severe – The WSFT incident reporting system Datix uses the term “Major”
**Death – The WSFT incident reporting system Datix uses the term “Catastrophic”
Appendix B: Key Principles of Being Open

1. Principle of acknowledgement
   - All patient and service user safety incidents should be acknowledged and reported as soon as they are identified in accordance with the Incident Reporting and Management Policy.

2. Principle of truthfulness, timeliness and clarity of communication
   - Information about a patient or service user safety incident must be given to the individual and/or their carers in a truthful and open manner by an appropriately nominated person.
   - Communication should also be timely: patients, service users and/or their carers should be provided with information about what happened as soon as practicable.
   - Patients, service users and/or their carers should receive clear, unambiguous information and be given a single point of contact for any questions or requests they may have. They should not receive conflicting information from different members of staff, and using medical jargon which they may not understand should be avoided.

3. Principle of apology
   - Patients, service users and/or their carers should receive an apology as soon as possible.
   - Both verbal and written apologies should be given. Verbal apologies are essential because they allow face-to-face contact between the patient, service user and/or their carers and the health or social care team.
   - A written apology, which clearly states the health/social care organisation is sorry for the suffering and distress resulting from the incident, must also be given.

4. Principle of recognising patient, service user and carer expectations
   - Patients, service users and/or their carers should receive a full explanation of what led up to the patient/service user safety incident in a face-to-face meeting.
   - They should be provided with support in a manner appropriate to their needs.
   - Confidentiality should be maintained at all times.

5. Principle of professional support
   - Staff should feel supported throughout the incident investigation process.
   - Staff should be encouraged to seek support from relevant professional bodies such as the General Medical Council, Royal Colleges, the Medical Protection Society, the Medical Defence Union and the Nursing and Midwifery Council, General Social Care Council.
   - Staff should be made aware of the Whistleblowing policy and procedure.

6. Principle of risk management and systems improvement
   - Root cause analysis (RCA), significant event audit (SEA) or similar techniques should be used to uncover the underlying causes of a patient or service user safety incident.
   - Investigations should focus on improving systems of care, which will then be reviewed for their effectiveness.

7. Principle of multidisciplinary responsibility
   - Communication with patients, service users and/or carers following an adverse incident should reflect the multi disciplinary nature of the treatment received.
   - Senior managers, clinicians and health and social care leaders should champion the Being Open process.

8. Principle of clinical governance
   - Being Open is part of the overall quality and governance frameworks.
9. Principle of confidentiality

- Policies and procedures for Being Open should give full consideration to the confidentiality of the patient, service user, carer and member of staff.
- Details of a patient safety incident should at all times be considered confidential. The consent of the individual concerned should be sought prior to disclosing information beyond the clinicians involved in treating the patient.

10. Principle of continuity of care

- Patients and service users should expect to continue to receive all usual treatment / care and continue to be treated with respect and compassion.
- If a patient or service user expresses a preference for their health or social care needs to be taken over by another team, the appropriate arrangements should be made for them to receive treatment or care elsewhere.
Appendix C: Examples of incidents that trigger the thresholds for duty of candour

Taken from: Regulation 20: Duty of candour Information for all providers: NHS bodies, adult social care, primary medical and dental care, and independent healthcare (March 2015)

These examples have been developed with stakeholders to illustrate examples of notifiable safety incidents that trigger the threshold for the duty of candour regulation. The examples presented are illustrative only and not an exhaustive list. Where possible the examples used in this guidance are sourced or adapted from the following two documents: ‘Seven steps to patient safety for primary care’ (National Patient Safety Agency 2006) and ‘Duty of Candour Threshold Review Group Review of Definitions’ (Royal College of Surgeons 2014).

### Surgery

<table>
<thead>
<tr>
<th>Examples</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>A patient arrived for planned surgery but had not been given the correct advice to discontinue their Warfarin treatment. The surgery had to be postponed.</td>
<td>This would be an example where an incident appeared to have resulted in moderate harm</td>
</tr>
<tr>
<td>During a difficult appendectomy the patient’s bowel was accidentally perforated. This was recognised the day after surgery when the patient became increasingly unwell. The patient returned to theatre where the problem was fixed and the patient made a full recovery.</td>
<td>This would be an example where an incident appeared to have resulted in moderate harm</td>
</tr>
<tr>
<td>Wrong site surgery: The identities of two patients on the list are mixed up and one patient undergoes the wrong operation on the incorrect site. The patient is permanently harmed as a result.</td>
<td>This would be an example where an incident appeared to have resulted in severe harm</td>
</tr>
<tr>
<td>An elderly patient undergoes a coronary artery bypass operation. The patient is appropriately consented for the risks of the operation, including stroke and death. Unfortunately, the patient sustained a large stroke during the operation, and subsequently died as a result.</td>
<td>This would be an example where an incident resulted in death</td>
</tr>
<tr>
<td>A patient experienced pain during an elective Caesarean section due to incomplete anaesthesia from an epidural line. The patient found this experience traumatic and subsequently had an acute episode of severe anxiety and depression which lasted more than 28 days</td>
<td>This would be an example where an incident appeared to have resulted in prolonged psychological harm</td>
</tr>
</tbody>
</table>

### Medicine

<table>
<thead>
<tr>
<th>Examples</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>A doctor causes a pneumothorax whilst placing a Central Venous Catheter (a recognised complication). The patient requires a chest drain to be inserted and a short stay on the Intensive Care Unit. The patient makes a full recovery.</td>
<td>This would be an example where an incident appeared to have resulted in moderate harm</td>
</tr>
<tr>
<td>A patient developed a small grade 2 pressure ulcer during an admission to treat an acute cardiac problem. Although they were now fully mobile, they need district nursing visits after discharge home to check and dress the ulcer until healing was complete two weeks later</td>
<td>This would be an example where an incident appeared to have resulted in moderate harm</td>
</tr>
<tr>
<td>A patient incurs an extravasation injury (soft tissue burn) from an intravenous line causing irreversible scarring and bone damage.</td>
<td>This would be an example where an incident appeared to have resulted in severe harm</td>
</tr>
<tr>
<td>A confused elderly patient was supposed to have 1:1 supervision on a medical ward. The patient was left unsupervised for a period of time whilst the shift change was occurring, and the patient fell out of bed, sustaining a severe head injury from which they later died.</td>
<td>This would be an example where an incident resulted in death</td>
</tr>
</tbody>
</table>
## Examples

<table>
<thead>
<tr>
<th>Examples</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>A patient who is normally very shy sustains an extravasation injury (soft tissue burn) from an intravenous line. This causes irreversible and extensive scarring on her arm and as a result she becomes severely socially anxious for which she needs a prolonged period of therapy.</td>
<td>This would be an example where an incident appeared to have resulted in prolonged psychological harm</td>
</tr>
</tbody>
</table>

## Maternity

<table>
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<th>Examples</th>
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</tr>
</thead>
<tbody>
<tr>
<td>A mother had significant post-partum haemorrhage after a difficult delivery, and there was some delay in obtaining blood for transfusion. As a result, she needed treatment in the high dependency unit for 24 hours before making a full recovery.</td>
<td>This would be an example where an incident appeared to have resulted in moderate harm</td>
</tr>
<tr>
<td>A pregnant woman was seen in A&amp;E at 12 weeks gestation with abdominal pain and PV bleeding. A high vaginal swab was taken by the Gynae SHO which grew Group B Streptococcus (GBS). When the woman went in to labour 28 weeks later, the midwife attending the birth did not check the laboratory results which showed the GBS growth and so the woman was not given intra-partum antibiotic prophylaxis as per national guidelines. The child then went on to develop GBS septicaemia in the days following delivery and required treatment in the Neonatal Intensive Care unit for 5 days before making a full recovery.</td>
<td>This would be an example where an incident appeared to have resulted in moderate harm</td>
</tr>
<tr>
<td>An expectant mother who rang the maternity unit to report possible blood loss and reduced foetal movements was given inappropriate reassurance rather than asked to come for assessment. The baby later born with severe disabilities.</td>
<td>This would be an example where an incident appeared to have resulted in severe harm</td>
</tr>
<tr>
<td>A woman requiring a blood transfusion for a post-partum haemorrhage received the wrong unit of blood after an error in labelling sample tubes. As a result the woman suffered a severe reaction leading to multi-organ failure and a fatal cardiac arrest.</td>
<td>This would be an example where an incident resulted in death</td>
</tr>
<tr>
<td>An expectant mother with a past history of severe mental health problems was not appropriately assessed at her antenatal appointment. As a result she was not offered NICE recommended psychological therapies, prophylactic medications or specialist follow-up. After delivery she became symptomatic, and these errors led to delays to her diagnosis and treatment. This resulted in a prolonged deterioration in her mental health for more than 28 days.</td>
<td>This would be an example where an incident appeared to have resulted in prolonged psychological harm</td>
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