Being Open Policy
Incorporating Duty of Candour

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1. POLICY STATEMENT

Promoting a culture of openness is a prerequisite to improving patient safety and the quality of healthcare systems. It involves explaining and apologising to a patient/carer that has been harmed or involved in an incident as a result of their healthcare treatment. It ensures communication is open, honest and occurs as soon as possible following an incident. It encompasses communication between healthcare organisations, healthcare teams and patients and/or their carers.

This policy is based on guidance produced by the National Patient Safety Agency (NPSA) in 2009 known as The Being Open Framework.

Since the introduction of the Being Open Framework a clause has been added to the National Health Service (NHS) standard contract formally introducing ‘Duty of Candour’. From November 2014 a regulatory duty has been imposed by the Health and Social Care Regulations and is now part of the Care Quality Commission registration requirements.

1.1 What is Duty of Candour?

Duty of Candour is a new law which means that providers of healthcare across the country must be open and honest with their patients. It came into force in November 2014. One of the main aims of Duty of Candour is to make sure that patients have confidence that all NHS trusts will be honest with them about their care and treatment.

1.2 What are the Requirements?

Unfortunately, there are times when something goes wrong with a patient’s care. On these occasions the Trust is required to tell the patient what has happened as soon as is reasonably possible. In some instances the Trust may only become aware of an incident sometime after it has happened. The following actions should be taken:

- Tell the patient *in person* what has happened and apologise
- Provide the patient with a full and true account of all the known facts
- Advise what else the organisation will need to do
- Provide reasonable support to the patient
- Follow-up with a written letter which confirms the information already provided, results of further enquiries and an apology.

1.3 Being Open

Being open is a set of principles that healthcare staff should use when communicating with patients, their families and carers following an incident in which the patient was harmed. The specific delivery of “Being Open” communications will vary according to the severity grading, clinical outcome and family arrangements of each specific event.

Being Open relies initially on our staff and the rigorous reporting of patient safety incidents. The Trust endorses the Francis Report recommendation 173 and aims to promote a culture of openness, which it sees as a prerequisite to improving patient safety and experience.

Being Open can simply mean apologising and explaining what happened to a patient(s) and/or carer(s) who have been involved in a patient safety event and the principles should apply to all untoward events.
1.4 Key Principle

Every healthcare organisation and everyone working for them must be honest, open and truthful in all their dealings with patients and the public. Organisational and personal interests must never be allowed to outweigh the duty to be open, honest and truthful.

Therefore, staff who are concerned about the non-reporting or concealment of incidents, or about on-going practices which present a serious risk to patient safety, are encouraged to raise their concerns under the Trust’s Raising Concerns (Whistle blowing) Policy (Ref. 3.09).

2. PURPOSE

2.1 The purpose of this policy is to ensure that appropriate processes are in place to:

- Acknowledge, apologise and explain to patients and/or carers when things go wrong.
- Conduct a thorough investigation into the incident (whether identified from incident reporting a complaint or claim)
- Provide support to those involved, to cope with the physical and psychological consequences of what happened.
- Provide clear information to staff on what they need to do when they are involved in an incident, supporting them to communicate with patients, their families and carers in a timely and thoughtful manner.
- Ensure improved understanding of incidents from the perspective of the patient and/or their carers
- Ensure lessons are learned from incidents to help prevent them happening again
- Provide support to staff involved in an incident.
- Ensure Trust compliance with the requirements under The Being Open process, Duty of Candour and Regulation 20 of the Care Quality Commission (CQC) registration requirements.

3. SCOPE

3.1 This policy relates to communicating with the patient and/or their carers following any incident, but must be applied when an incident is rated moderate or above with reference to the Trust’s risk rating tool (Appendix 1). It does not specifically apply to minor incidents or near misses, although staff are encouraged to adhere to the principles contained within this document in all circumstances.

3.2 Although this policy is only applicable for incidents in which Trust, patients and staff are directly involved, the Trust encourages all groups of independent contractors to adopt the policy or to develop similar procedures based on the National Patient Safety Agency’s Guidance. The Trust will make this a contractual requirement in the same way as independent contractors are required to be linked into the NHS Complaints Scheme.

This policy should be read in conjunction with the:

- Incident Policy (5.01)
- Serious Incident Policy (5.32)
- Listening and Responding Policy (PALS and Complaints)(4.26)
- Procedure for Handling Claims (4.3)
- Confidentiality of Patient and Employee Information (7.1)
- Access to Health and Employee records (7.2)
- Information and Security Data Protection (7.3)
- Information security and data protection policy (7.8)
- Raising Concerns (Whistle blowing) Policy (3.09)
4. COMPLIANCE STATEMENTS

4.1 Equality & Diversity

This policy has been Equality Impact Assessed. This Trust aims to design and implement services, policies and measures that meet the diverse needs of the population it serves and its workforce ensuring that none are placed at a disadvantage over others.

5. ROLES & RESPONSIBILITIES

A comprehensive list of roles and responsibilities for individual staff and staff groups are recorded in Appendix 2.

6. FRAMEWORK

6.1 Recognising Duty of Candour

The formal requirement of Duty of Candour applies to notifiable patient safety incidents that occurred during the provision of care that in the reasonable opinion of a healthcare professional could result in or has resulted in:

- A patient death as a direct result of the incident not as a result of the underlying illness or condition.
- Severe harm, moderate harm or prolonged psychological harm (period of at least 28 days)
- Moderate is defined as requiring a moderate increase in treatment. Examples include: unplanned return to surgery, 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.

Where the degree of harm is not clear, but may fall into the above the relevant person should be informed in line with Duty of Candour requirements.

6.2 Relevant Person

This is the person who should receive the apology and explanation. In most circumstances this should be the patient. The exceptions are if the person has died, lacks capacity or is under 16.

6.3 Compliance with Duty of Candour

The Trust must notify the relevant patient and provide reasonable support as soon as reasonably practicable after the incident has been identified. The notification must include:

- All of the known detail and facts known about the incident.
- What further enquiries into the incident the Trust will take
- An apology

If verbal notification has been made to the patient this must be followed up in writing. The NHS Standard Contract states this must be done within 10 working days. Please refer to Appendix 3 for a copy of a suggested letter template.
It may also be useful to include a copy of the Trusts Duty of Candour patient information leaflet (Appendix 4) and/or The NHS Litigation Authority leaflet ‘Saying Sorry’


It is important to remember that saying sorry is not an admission of liability and is the right thing to do. For further information please refer to Appendix 5, Being Open Principles ‘Principle of Apology’.

6.4 Staff Implications

- If any member of staff is prevented from carrying out Duty of Candour requirements this will be investigated accordingly under the relevant Trust policies.

- In the event of professionally registered staff intentionally failing to comply with Duty of Candour, the Trust may refer the issue to their professional body.

The following table provides a summary of actions required to support best practice in the management of all incidents including Duty of Candour and Being Open Process.

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<th>Level of Harm caused by Incident</th>
<th>Action Required</th>
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<tr>
<td>Prevented or near miss patient safety incidents)</td>
<td>Patients will not normally be contacted or involved in investigations and these types of incidents are outside the scope of the Trust's Being Open and Duty of Candour requirements. However, through the complaints and claims investigation process it may become apparent that the Being Open/Duty of Candour principles will need to be implemented</td>
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<td>Insignificant / Minor Harm</td>
<td>Unless there are specific indications or the patient requests, the communication, investigation, analysis and implementation of changes will occur at local service delivery level. This will include the participation of those individuals directly involved in the incident. However, through the complaints investigation process it may become apparent that the Being Open/Duty of Candour principles will need to be implemented.</td>
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<tr>
<td>How will this be done?</td>
<td>Acknowledgment, apology and explanation will be communicated in the form of an open discussion between the staff providing the patient's care and the patient and/or their carers. Documentation will be in the form of patient records, letters to patients, notes of meetings with patients.</td>
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<td>Reporting will occur through standard incident reporting mechanisms, complaints &amp; claims investigation processes.</td>
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<td>Analysis of such incidents will be conducted centrally via the Trusts weekly Incident Reporting Group. 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.</td>
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<tr>
<td>Moderate, Major, Catastrophic Harm, or death (or where it is likely)</td>
<td>A higher level of response is required in these circumstances. The Patient and Organisational Safety Lead, CEO, Medical Director, Nursing Director, Clinical Director, Head of Directorate</td>
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| **DUTY OF CANDOUR** | and Head of Corporate and Legal Affairs should be notified immediately.  
The Patient and Organisational Safety Lead, Medical Director, Nursing Director and Head of Corporate and Legal Affairs will be available to provide immediate and ongoing advice and support re Duty of Candour requirements and the Being Open process.  
The Trust Weekly Incident Review Group will assist Directorates in determining if a patient safety incident has met the threshold under Duty of Candour requirements in line with its weekly review of all incidents.  

**YES – DUTY OF CANDOUR APPLIES:**  
Duty of Candour requires that once an actual or suspected notifiable patient safety incident has occurred the Trust must inform the patient/and or their carers as soon as reasonably practicable.  

**ARRANGE URGENT PRELIMINARY MDT DISCUSSION**  
- Establish & clarify facts, agree plan for disclosure discussion with patient/and or their carers.  
- Notify Trust’s Performance Team ASAP (Contractual compliance)  
- Notify POST Lead, Medical and Nursing Director, CEO, Clinical Director, Matron  

**INITIAL DISCLOSURE & APOLOGY TO PATIENT / CARERS - DO NOT DELAY – Must be within 10 days of the incident occurring**  
Notification may be verbal (face to face) open discussion, expressing sincere regret, acknowledgment, apology and explanation between the staff providing the care and the patient and/or their carers where possible.  
- By Consultant/MDT/Matron/Ward Manager  
- Provide outline of investigation.  
- Identify when/if patient would like to meet.  
- A step-by-step explanation of the facts (in plain English) must be offered. This may just be an initial view, pending investigation.  

Any verbal disclosure made to the patient/carer must be followed up in writing within 10 days (letter template Appendix 3)  
Should the patient/carer decline this offer this must be recorded.  

**DOCUMENTATION IN HEALTH RECORDS**  
Record “Being Open /Duty of Candour” dates, time, names
present, issues, apology, and plan for further communication.

Documentation will be in the form of patient records; letters/leaflets issued to the patient, a formal record of any communication and meetings with the patient and where appropriate their family.

If any meetings are declined by the patient/carers this must be recorded.

MAINTAINING CONTACT WITH THE PATIENT/CARERS

- Is a second meeting required? Or Telephone call? Confirm details
- On approval of investigation report – letter and summary to be issued to family (written by CEO or Head of Directorate) before posting agree preferred method of disclosure, may prefer to meet to discuss.

The Trust’s Being Open Procedure and Duty of Candour requirements are therefore implemented – Complaints and Litigation Staff will initiate this process during the course of Complaints/Claims investigations accordingly.

7. BEING OPEN PRINCIPLES

Being Open is a process rather than a one-off event. It is a process underpinned by ten principles promoted in the NPSA’s publication ‘Being Open’: Communicating patient safety incidents with service users and their carers, NPSA (2009) which informs the rationale for improving communication between service users and staff. The principles:

1. Acknowledgement
2. Truthful, timely clear of communication
3. Apology
4. Recognition of the patient and carer expectations
5. Professional support
6. Risk management and systems improvement
7. Multidisciplinary responsibility
8. Clinical governance
9. Confidentiality
10. Continuity of care

A more detailed explanation of each principle can be found in Appendix 5.

7.1 Implementing the Being Open Process
The Being Open process begins with the recognition that a patient has suffered severe harm, or has died as a result of a patient safety incident. A patient safety incident may be identified by:

- A member of staff at the time of the incident
- A member of staff retrospectively when an unexpected outcome is detected
- A patient and/or their carers expressing concern or dissatisfaction with the patient’s healthcare either at the time of the incident or retrospectively
- Incident detection systems such as incident reporting or medical records review
- Other sources such as detection by other patients, visitors or non clinical staff.

As soon as a patient safety incident is identified the first priority is prompt and appropriate clinical care and prevention of further harm. Where additional treatment is required this should occur whenever reasonably practicable after discussion with the patient and with appropriate consent.

The Incident Reporting Policy should be implemented and the following steps taken:

**Step 1: Healthcare Professional Pre-Meeting/Preparation**

A pre-meeting / discussion amongst healthcare professionals should be held in advance of any meeting with the patient and/or their carers. The purpose of the pre-meeting is to establish and clarify facts and ensure that everyone has a clear understanding of the aims of the planned meeting with the patient/and or their carer.

**Preliminary Team Discussion**

Roles and responsibilities are set out in Appendix 2. In the first instance a multidisciplinary review team, including the most senior health professional involved in the patient safety incident, should be constituted and a meeting convened as soon as possible after the event to:

- Confirm preservation of any equipment or other materials that may need to be forensically examined
- Ensure compliance with Duty of Candour requirements
- Establish the basic clinical and other facts and prepare a chronology of events leading to the patient safety incident.
- Re-assess the incident and determine the level of immediate response
- Ensure inclusion of appropriate level of staff in the investigation process as detailed in the Incident Reporting Policy
- Ensure reporting as detailed in the Incident Reporting Policy
- Identify who will be responsible for managing the discussion with the service user and/or their carers
- Consider the appropriateness of engaging patient support which may include the use of a facilitator, a patient advocate or a healthcare professional who will be responsible for identifying the service user’s needs and communicating them back to the healthcare team
- Identify immediate support needs for the healthcare staff involved including debriefing arrangements and the involvement of the Staff Support and Counselling Service.
- Ensure there is a consistent approach by all team members concerning discussions with the service user and/or their carers and that questions are directed to the nominated Being Open Lead for detailed response
- Identify those members of staff who are required to provide statements

The need for patients and carer support should be ascertained and arranged promptly. Details and contact numbers for internal and external support organisations should be provided Appendix 6.

**Step 2: Planning the Preliminary Meeting with the Patient and or their Carers**
Any meeting with the patient and or their carers should be held as soon after the incident as possible, taking the following into consideration:

- The patients and/or their carers home and social circumstances
- Ask the patient and/or their carers who they would like to be present
- Check that the patient and/or carer is happy with the timing and venue of the meeting.
- Offer them a choice of times and confirm the chosen date in writing.
- Do not cancel the meeting unless absolutely necessary

It is acknowledged that incidents may be identified retrospectively. In the case of claims, management of meetings with patients will be at the discretion of legal teams and in the case of complaints, the complaints meeting team will need to consider these requirements.

In addition, consider the following when deciding who should attend the meeting:

There must be a lead staff member present who is normally the most senior person responsible for the patient’s care and/or someone with experience and expertise in the type of incident that has occurred. This could either be the patient’s Consultant, or any other Healthcare Professional who has a designated caseload of patients. The lead person should be experienced in patient/carer communication and have a good understanding of the patient safety incident. This person should display the following characteristics:

- Be known to and trusted by the patient and/or their carers.
- Have a good grasp of the facts relevant to the incident.
- Be senior enough or have sufficient experience and expertise in relation to the type of patient safety incident to be credible to patients, carers and colleagues.
- Have excellent interpersonal skills, including being able to communicate with patients and/or their carers in a way they can understand and avoid excessive use of medical jargon.
- Be willing and able to offer an apology, reassurance and feedback to patients and/or their carers.
- Be able to maintain a medium to long term relationship with the patient and/or their carers, where possible, and to provide continued support and information.
- Be culturally aware and informed about the specific needs of the patient and or their carers.

The person taking the lead should be supported by at least one other member of staff, for example, a member of the healthcare team treating the patient, Modern Matron or equivalent, Medical Director, Director/Deputy of Nursing, Directorate Head, Patient & Organisation Safety Lead, Complaints Lead, Clinical Director, and Directorate Governance Lead.

Where a junior healthcare professional has been involved in a patient safety incident and asks to be involved in the Being Open discussion they must be accompanied and supported by a senior team member. It is unacceptable for junior staff to communicate patient safety information alone or to be delegated the responsibility to lead a Being Open discussion until they have received support and mentorship for this role.

Ensure that those members of staff who do attend the meetings can continue to do so, continuity is very important in building relationships. In exceptional circumstances, if the healthcare professional who usually leads the Being Open discussion cannot attend, they may delegate to an appropriately trained substitute. The substitute may be the clinician responsible for risk, or someone of similar experience.

Consider each team member’s communication skills; they need to be able to communicate clearly, sympathetically and effectively.

The meeting to discuss any patient safety incident must be held in a venue appropriate to meet the needs of the person/carers
At the preliminary team meeting a forward plan of action should be agreed making clear the time-frame envisaged to completion of investigations and an outcome discussion meeting with the service user, their relatives and/or carer. The investigation process to be followed should be in line with the type of incident that has occurred.

**Step 3: Discussion with the Patient and/or their Carers:**

The initial Being Open discussion is the first part of an ongoing face to face communication process. There should be repeated opportunities for the service user and/or carer to obtain information about the incident and many of the points raised initially may be expanded on in subsequent meetings. The approach to Being Open may need to be modified according to the service user’s personal circumstances; See Appendix 7 ‘Special Circumstances’. It is essential that the following does not occur:

- Speculation
- Attribution of blame
- Denial of responsibility
- Provision of conflicting information from different individuals

The patient and/or their carers should be advised of the identity and role of all people attending a planned Being Open discussion. This should happen before the meeting takes place. This provides them with the opportunity to state their own preferences about which staff should be present. They should also be provided with contact details for the Being Open Lead.

Support for the patient and or their or carer at the meeting may be offered through the Trust’s Patient Experience Team. Patients and or their carers should be made aware that they may bring a friend or community representative or independent advocate to ask questions on their behalf.

With the patient’s agreement, their carers and or people close to them may be included in the discussions and decision making. If the patient is unable to participate or has died, then the carers or people closely involved with the patient may be provided with limited information in order to make decisions.

The sharing of information requires due regard to patient confidentiality and any advance direction given by the patient concerning non-disclosure of information should be taken into account. Carers and people close to the patient can be referred to other external support organisations for more information and the service user/carer should also be given the leaflet on the Being Open process so that they know what to expect.

The Being Open Lead must arrange for notes of any meeting to be taken including details of questions asked by the patient/carer and responses made. This is important as the investigation team needs to be made aware of any specific questions raised by the patient/carer so that these can be included where possible in the scope of the investigation.

This policy does not prescribe a rigid format for Being Open discussions but, as a guide, the following may assist as to the issues which should be addressed:

The patient and or their carers

- Should be offered a sincere verbal acknowledgement and apology for distress that may be caused
- Should be asked to outline their concerns, understanding of the incident and specific questions
- Should have the incident investigation process explained
- Should be made aware of any revised arrangements made for continuity of care, and the likely consequences in terms of any alteration of treatment /care plans following the incident (if relevant)
• Should be offered a clear explanation with respect to their continued entitlement to receive all usual treatment and continue to be treated with respect and compassion. If a service user expresses a preference for their healthcare needs to be taken over by another team, the appropriate arrangements should be made for them to receive treatment elsewhere
• Should be advised about how they will be kept informed of the progress being made with investigation and the arrangements for responding to their unanswered questions including details of further meeting(s) and arrangements for providing on-going information
• Should be made aware of the known facts agreed by the multidisciplinary team. Where there is disagreement, communication about these events should be deferred until after the investigation has been further progressed or completed. The service user and/or their carers should be informed that an incident investigation is being carried out and more information will become available as it progresses
• Should be informed that new facts may emerge as the incident investigation proceeds, their understanding of what happened should be taken into consideration as well as any questions they may have
• Views and concerns should be formally noted, and acknowledged as being heard and taken seriously
• Should expect appropriate language and terminology to be used throughout. For example, using the terms ‘patient safety incident’ or ‘adverse event’ may be at best meaningless and at worst insulting to a service user and/or their carers. If a patient carer’s first language is not English, or they have other communication difficulties, their language needs should be addressed as well as providing information in both verbal and written formats
• Should expect an explanation as to the likely short and long term effects of the incident (if known). The latter may have to be delayed to a subsequent meeting when the situation becomes clearer. Some service users may not wish to know every detail of an incident. They should be reassured that if they change their minds, then this information will be made available to them
• Should expect an offer of practical and emotional support. This may involve giving the service user’s/carer’s information to third parties such as charities and voluntary organisations, as well as offering more direct assistance and a list of support groups
• Should be asked whether they wish contact to be made on their behalf with third party organisations and whether they will consent to sharing of information about the incident with others.
• Should have an explanation regarding the Trust’s need to report the incident to statutory and other bodies
• Should be given information about the Trust’s complaints procedure and offered assistance if they wish to make a formal complaint
• May be anxious, angry and frustrated, even when the Being Open discussion is conducted appropriately due consideration should be given to provide them with the opportunity and time to air their concerns. However, it should be noted that the Trust will not tolerate violence and aggression towards staff in any circumstances. If necessary the meeting should be closed and arrangements made to reconvene when those affected by the incident have had opportunity to reflect, adjust and proceed constructively. In some circumstances mediation maybe a more appropriate means of providing a resolution.
• Should be informed of the steps that will be taken to ensure the incident will not be repeated.

Written Records of the Being Open Process

There should be a written record to include:

- The time, place, date (as minimum) as well as the name and relationships of all attendees at Being Open discussion meetings.
- The plan for providing further information to the patient and/or their carers;
- Offers of assistance and the patient’s and/or carers response
- Questions raised by the family and/or carers or their representatives and the answers given.
• Follow up arrangements agreed.
  • Changes of staff involved in the Being Open process

• Progress notes relating to the clinical situation and an accurate summary of all the points explained to the patient and or their carers
• Copies of letters sent to the patient, carers, GP and any others
• Copies of letters to the patient and or their statements taken in relation to the patient safety incident.
• A copy of the incident report.
  A copy of the investigation report and any agreed actions/plans.

These records will be stored in the most appropriate area depending on the nature of the incident. This may include:

• Patient and Organisational Safety Department
• Complaints Department
• Medical Records
• Claims Department

Detailed records of all communication with service user/carer should be kept for reference. All records kept will be held for the appropriate time period as instructed under the Records Management Policy (Ref. 7.07)

A summary of the preliminary Being Open discussion should be shared with the service user/relative and/or carer and with staff involved in the Being Open process.

**Principle of Confidentiality**

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 patients. Where this is not practicable or an individual refuses to consent to the disclosure, disclosure may still be lawful if justified in the public interest or where those investigating the incident have statutory powers for obtaining information.

Communications with parties outside of the clinical team should also be on a strictly need-to-know basis and, where practicable, records should be anonymous. In addition, it is good practice to inform the patient and/or carers about who will be involved in the investigation before it takes place, and give them the opportunity to raise any objections.

**Step 5: Follow Up:**

**Follow-Up Meeting with Service user/Relative and/or Carer**

A follow-up discussion with the service user and/or their carers is an important step in the Being Open process. The following guidelines should assist in making the communication effective:

• The discussion should occur at the earliest practical opportunity, once there is additional information to report
• Consideration should be given to the timing of the meeting, based on both the service user’s health and personal circumstances
• Consideration should be given to the location of the meeting e.g. the service user’s home.
  Feedback should be given on progress to date and information provided on the investigation process
• There should be no speculation or attribution of blame. Similarly, the healthcare professional communicating the incident must not criticise or comment on matters outside their own experience
• The service user and/or their carers should be offered an opportunity to discuss the situation with another relevant professional where appropriate
• A written record of the discussion should be kept and shared with the service user and/or their carers
• All queries should be responded to appropriately
• If completing the process at this point, the service user and/or their carers should be asked if they are satisfied with the investigation and a note of this made in the service user’s records
• The service user should be advised that if further issues arise later, they may be raised with their nominated contact or substitute.

**Step 6: Completing the Process:**

**Communication with the service user and/or their carers**

• After completion of the incident investigation, it is expected that in most cases there will be a frank discussion of the findings of the investigation and analysis of any action required. In some cases information may be withheld or restricted, for example: where:

  • Communicating information will adversely affect the health of the patient
  • Where investigations are pending coronial processes;
  • Where specific legal requirements preclude disclosure for specific purposes (Take advice from the Head of Corporate and Legal Affairs)

In these cases the patient and or their carer will be informed of the reasons for the restrictions.

• After completion of the incident investigation, it is expected that arrangements will be made to provide feedback to the patient, relative or carer face to face although if acceptable to the patient relative or carer this feedback may be provided in writing. Whatever method is used, the communication should include:

  • The chronology of clinical and other relevant facts
  • Details of the patient’s and/or their carer’s concerns and complaints
  • A repeated apology for the harm suffered and any shortcomings in the delivery of care that led to the patient safety incident
  • A summary of the factors that contributed to the incident
  • Information on what has been and will be done to avoid recurrence of the incident and how these improvements will be monitored

• Where a patient has been harmed the Chief Executive or Head of Directorate should write to the patient and or their carer providing a formal apology and explanation. This letter should contain details of the discussions that have taken place, details of the investigation (if available) and details of any steps being taken to reduce the risk of a similar incident recurring. The Being Open Lead may prepare the letter with the assistance of the Trust’s Head of Corporate and Legal Affairs if an admission of liability is to be made with implication that the patient or their carer may seek payment of compensation.

• The letter should offer the patient and or their carer the opportunity of a follow-up meeting if desired.

It is expected that in most cases there will be a complete discussion of the findings of the investigation and analysis. In some cases, information may be withheld or restricted, for example, where investigations are pending a coroner’s inquest, or where specific legal requirements preclude disclosure for specific purposes. In these cases the patient will be informed of the reasons for the restrictions.
7.2 Continuity of Care:

When a patient has been harmed during the course of treatment and requires further therapeutic management or rehabilitation, they should be informed, in an accessible way, of the ongoing clinical management plan. This may be encompassed in discharge planning policies addressed to designated individuals, such as the referring GP.

Patients and or their carers should be reassured that they will continue to be treated according to their clinical needs even in circumstances where there is a legal dispute between them and the healthcare team. They should also be informed that they have the right to continue their treatment elsewhere if they have lost confidence in the healthcare team involved in the patient safety incident.

7.3 General Practitioner and Other Healthcare Organisations:

When the patient leaves the care of the Trust a discharge letter should be forwarded to the GP or appropriate community care service. It should contain summary details of:

- Any incident that has occurred that impacts on the person's long term health and on-going treatment
- The current condition of the patient
- Key investigations that have been carried out to establish the patient's clinical condition
- Recent results
- Prognosis

It may be valuable to consider including the GP in one of the follow-up discussions, either at discharge or at a later stage.

7.4 Special Circumstances:

For further information around special circumstances please refer to Appendix 7

7.5 Linking with External Stakeholders:

7.6 Commissioners / NHS England

In line with the Trust’s Serious Incident Policy (Ref. 5.32) the Trust is required to report all incidents that meet the threshold for under the Strategic Executive Information System (StEIS) criteria to the Commissioners. In some cases the Regional Director of Public Health, via the (StEIS) will also need to be informed. The Patient and Organisation Safety Lead will facilitate reporting via StEIS in line with current guidelines. Please refer to Trust Incident Reporting Policies (Ref. 5.32 and 5.01) for further guidance.

7.7 Coroner

All cases of untimely, unexpected or unexplained death and suspected unnatural deaths need to be reported to HM Coroner. A Coroner may request that the case is not discussed with other parties until the facts have been considered.

If necessary, the Coroner will advise on whether an apology should proceed. **However, this should not preclude fulfilment of Duty of Candour requirements**; a verbal and written apology or expression of regret should be made where appropriate.

In this situation it should be made clear to the family that a full discussion of the circumstances and any residual concerns will be arranged at a date to suit both parties after the coroner’s assessment is finished. It should also be recognised that Coroners’ investigations are stressful for patients’ family, their carers and healthcare professionals. Bereavement counselling and advice on professional support groups should be offered at the outset of a Coroner’s investigation.
7.8 Communicating Lessons Learned

Any recommendations for system improvements and changes implemented should be detailed in an action plan appended to the investigation report. This will be linked to the incident report via the incident database.

The progress, final completion and effectiveness of the action plan will be monitored and reported to the Trust Clinical Services Improvement Group (CSIG) by the Patient and Organisational Safety Lead. Examples of good practice will be passed to the NPSA for sharing with the rest of the NHS.

The NPSA will publish patient safety alerts, safer practice notices and patient safety information notices through the Safety Alert Broadcast system to highlight common factors that cause patient safety incidents, and to publicise its advice and solutions to the service. The primary aim will be to help reduce the risk of such incidents recurring. It will also use its website, www.npsa.nhs.uk plus a number of specialist web resources, to share this and supporting background information with healthcare staff throughout the NHS.

A Flow chart outlining Duty of Candour requirements can be found in Appendix 8.

8. TRAINING AND IMPLEMENTATION

- Staff are encouraged to access the NPSA’s e-learning package which provides an interactive resource for training on the management of patient safety investigations including Being Open.

- The Being Open Process and Duty of Candour requirements feature as part of the Trust induction and principle investigator training. Regular features will also be included within the Trust Plenary and publications; Learning Lessons and Communication briefings.

- Being Open principles and Duty of Candour requirements will be included within the Trust’s suite of Leadership Development programmes and Clinical Skills Leaders programme. Clinical Leaders will have operational responsibility of alerting their teams to the Being Open / Duty of Candour Policy.

- Current in-house training including: Listening and Responding, Safeguarding, Equality and Diversity, Health and Safety and the People Management Programme will include a slide raising awareness of the Being Open/ Duty of Candour Policy and Trust expectations.
This policy will be reviewed annually or earlier in light of new national guidance / other significant changes. Compliance with this policy will be monitored through the mechanisms detailed in the table below:

Where compliance is deemed to be insufficient and the assurance provided is limited an Action plan will be developed to address the gaps; progress against the action plan will be monitored at the specified group / committee.

<table>
<thead>
<tr>
<th>Minimum requirement to be monitored</th>
<th>Process / Method</th>
<th>Responsible individual / group / committee</th>
<th>Frequency of monitoring</th>
<th>Responsible individual / group / committee for review of results</th>
<th>Responsible group / committee for monitoring action plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Process for encouraging open communication between healthcare organisations, healthcare teams, staff, patients and / or their carers</td>
<td>Review</td>
<td>Policy Lead</td>
<td>Annually</td>
<td>Quality Committee</td>
<td>Quality Committee</td>
</tr>
<tr>
<td>Process for acknowledging, apologising and explaining when things go wrong</td>
<td>Review</td>
<td>Policy Lead</td>
<td>Annually</td>
<td>Committee</td>
<td>Quality Committee</td>
</tr>
<tr>
<td>Requirements for truthfulness, timeliness and clarity of communication</td>
<td>Review</td>
<td>Policy Lead</td>
<td>Annually</td>
<td>Quality e Committee</td>
<td>Committee</td>
</tr>
<tr>
<td>Provision of additional support as required</td>
<td>Review</td>
<td>Policy Lead</td>
<td>Annually</td>
<td>Quality Committee</td>
<td>Quality Committee</td>
</tr>
<tr>
<td>Requirements for documenting all communication</td>
<td>Review</td>
<td>Policy Lead</td>
<td>Annually</td>
<td>Quality Committee</td>
<td>Quality Committee</td>
</tr>
</tbody>
</table>
10. REFERENCES & ASSOCIATED DOCUMENTS

References

NPSA Patient Safety Alert: Being Open, Communicating with patients, their families and carers following a patient safety incident (2009) http://www.nrls.npsa.nhs.uk/resources/?entryid45=65077&q=0%c2%acbeing+open%c2%ac


Seven Steps to Patient Safety NPSA (2004) www.NPSA.nhs.uk

NHSLA Letter to Trusts 02/03 Explanations and Apologies www.nhs la.com

General medical Council, Good Medical Practice 2006


Healthcare Commission Report: Spotlight on Complaints (February 2009)


Disclosure of Audit results in cancer screening-advice on good practice, Jullietta Patnick Cancer Screening Service No 3 April 2006


Chapter 2 Risk Management: Patient Safety and a Medical Protection Organisation. John Hickey

Beyond Breaking Bad News: Michael W Rabow, Stephen J McPhee, Division of General Internal Medicine, University of California, San Francisco, San Francisco, California student BMJ 2000;08:45-88 March ISSN 0966-6494


Department of Health (2014)

**Appendix 2 – Risk Grading Tool**

### Guidance for Managers:

- Use this form for activities / situations which have been identified as general.
- You can rate all hazards on the form but not as a specialised form for Manual Handling, Display Screen Equipment & COSHH.

1. Identify the hazards associated with the activity / situation. (Not a definitive list)
   - Fall of person from height
   - Fall of object from height
   - Slips, trips & falls
   - Fire inc. static electricity
   - Operation of vehicles
   - Chemicals / substances
   - Violence / aggression
   - Sharp / needle stick
   - Mechanical lifting ops
   - Drowning / deep water
   - Explosion (chemical / dust)
   - Ionising radiation
   - Non Ionising radiation
   - Contact with hot / cold surface
   - Contractor operations on site
   - Contact with machinery

2. Identify Persons at Risk in Consultation with Staff?

3. Evaluate the Risk Based on your Responses in the Worst Case Outcome X Likelihood Sections. (Use the Matrix Table to Decide on the Level of Risk)

### Worst Case Outcome

**INSIGNIFICANT**


**MINIMUM**

Lost time injury, injury requiring medical intervention, bites, failure to meet internal standards & some national performance standards. Low financial loss £11k - £50k. Claim: minor civil action, local press coverage. Environmental damage spread to local community.

**SIGNIFICANT**

> 3 day injury, or additional hospital stay, over 24 hours, minor reportable accidents leading to permanent disability, moderate financial loss £100k - £250k. Repetition failure to meet internal standards, prosecution some success. International press notice, civil action, national press interest, lawsuits. Environmental damage spread to region (midlands).

**SEVERE**

Fatality, high financial loss £200k - £1m < 10% of project budget. Intermittent failure to meet professional standards and / or statutory requirements, prosecution no defences, HSE prosecutions, major civil action, national press interest. Environmental damage nationally (UK).

**CATASTROPHIC**

Multi-fatality, financial > £1m in year. Sustained failure to meet all standards, commons select committee, executive director prosecuted / imprisoned. Global environmental damage.

### Evaluate The Risk (Using Matrix)

<table>
<thead>
<tr>
<th>Consequences</th>
<th>No/ Low Risk</th>
<th>Moderate Risk</th>
<th>High Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Likelihood</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **No/ Low Risk**: Ward / department to determine whether risk treatment plan is required or manage the situation by routine procedures.
- **Moderate Risk**: Local management to develop risk treatment plan within 1 month, copy to director general manager. Risk entered on directorate risk register. Implementation of the risk treatment plan monitored by the directorate management board.
- **Significant Risk**: Senior management to ensure immediate action where necessary. Risk treatment plan produced within 2 weeks, copy to risk management committee. Risk entered on both Trust and Directorate risk registers. Implementation of the risk treatment plan monitored by Operational Board.
- **High Risk**: Immediate directorate management action where necessary. Risk treatment plan developed within 7 days, copy to risk management committee. Risk entered on both Trust and Directorate risk registers. Implementation of the risk treatment plan monitored by Operational Board.

4. Record Findings (Remedial action to Risk Action Plan) as appropriate.

5. Review assessments / annually / change to activity / situation / near miss / accident.
ROLES AND RESPONSIBILITIES

Trust Board
The Trust Board is committed to ensuring that there is an infrastructure in place to support openness between healthcare professionals and service users and/or their relatives/carers following an incident. This also applies to compliance with the requirements under the Duty of Candour. The Trust Board is also committed to ensuring support and assistance is in place for all those affected and that the Trust learns from these incidents.

Being Open Lead
Following an incident that results in moderate or severe harm to a service user or an incident where a high level response is considered likely to be needed or has been requested, it is the responsibility of the most immediate senior member of staff present, who will generally be the Consultant for the patient and/or Matron, the Ward Manager or Department Head, to ensure that:

- The patient's immediate needs are met by appropriate member(s) of staff, and appropriate support is also provided to the carer/relative.
- Relevant items of equipment which may need to be independently forensically examined are isolated and preserved for inspection.
- Detailed, accurate and contemporaneous notes are recorded.
- the Directorate Clinical Director and/or Head of Directorate (out of hours the senior on-call manager) is informed, and involved in determining an immediate action plan
- a member of staff is nominated to act as the service user, relative/carer contact
- an incident report form is completed
- those involved are noted and contacted to ensure prompt facilitation of a multidisciplinary team meeting
- A list of external organisations that may need to be involved is drawn up.

Unless otherwise directed the most senior person at the scene will be designated the Being Open Lead and is responsible for co-ordinating the Being Open process and operationally co-ordinating front-line investigations in liaison with the Directorate Leads.

In exceptional circumstances, if the healthcare professional charged with leading the Being Open process cannot attend, then they may delegate to an appropriate senior substitute with the approval of the Director of Nursing and/or the Medical Director.

It is essential that the Lead is able to effectively communicate with the service user and/or their carers without jeopardising the rights of the healthcare professional, or their relationship with the service user.

Patient and Organisational Safety Lead
The Patient and Organisational Safety Lead will be responsible for the overall co-ordination of incidents ensuring liaison with the Head of Directorate to ensure that incidents meeting the DoC threshold are investigated in line with DoC requirements following the processes described in the Policy for the Management of Incidents, Including the Management and Investigation of Serious Incidents. The Lead will be responsible for ensuring that there is a system in place to notify the Trust Performance Team of all candour incidents to ensure a clear audit trail in line with contractual requirements.
The Patient and Organisational Safety Lead should liaise promptly with the nominated member of staff appointed as the Being Open Lead, to ensure that a meeting with the service user to gather all relevant information is arranged in a timely manner. The Patient and Organisational Safety Lead may also assist the investigation and provide support regarding root cause analysis methodology.

The Patient and Organisational Safety Lead will notify the Director of Nursing of the need for investigation and the Director of Nursing will make a decision on a case-by-case basis as to the extent of the enquiry and content of the incident report to be disclosed when completed.

**Chief Executive**
The Chief Executive must be informed of all incidents that result in major or catastrophic harm, where patient and/or their carers have been consulted and ensure that appropriate action is being taken.

**Director of Nursing**
In accordance with major incident and serious investigation processes the Director of Nursing will carry overall responsibility for keeping the Chief Executive, and Board informed, and for managing external communications.

**Medical Director**
The Medical Director will be informed by the Director of Nursing and if necessary, be involved in determining an immediate action plan to ensure the person(s) nominated to meet with the service user, relative/carer have the relevant expertise to answer questions about the incident that has occurred and the possible consequences of the incident.

**Head of Directorate**
The Head of Directorate, if not the Being Open Lead, will be informed by the Patient and Organisational Safety Lead of the initiation of this process and will co-ordinate support for staff.

**Complaints Lead**
Must ensure the Trust policy and procedure for complaints and claims handling supports a culture of Being Open. Complainants should be actively encouraged to attend a meeting with senior members of Trust staff to discuss their complaint in the spirit of 'Being Open' and Duty of Candour. All meetings will be documented to the Being Open minimum standard.

**Head of Directorates / Clinical Directors / Directorate Governance Leads**
Should be involved and informed in advance of the patient and/or their carer being notified of all incidents leading to moderate, major or catastrophic harm or death (or where it is likely to lead to future harm or death). The Directorate Head and Clinical Director will confirm the way forward for liaising with the patient/carer in line with Duty of Candour requirements and the Being Open Procedure.

**Healthcare Professionals/Clinicians/Nurse Leads**
All Clinicians must be aware of the procedure of “Being Open” and Duty of Candour requirements and the need to inform and discuss adverse events with patients and carers, ensuring compliance with the required standards. Any member of staff, who believes that a colleague is not following this procedure after an incident, should immediately discuss with their line-manager.

**All Staff**
To take action in line with the Being Open Procedure and Duty of Candour requirements and ensure that incidents leading to moderate, major or catastrophic harm or death (or where it is
likely to lead to future harm or death) are reported to the key officers described in this procedure in order for the Duty of Candour requirements and Being Open procedure to be implemented.

**Nominated Patient /Relative or Carer Contact**

A member of staff will be nominated by the Being Open Lead, to be the patient /relative/carer main point of contact. This will be in agreement with the Medical Director and the Nursing Director. The person nominated should be the most senior person responsible for the patient's care who has experience in the investigation of patient safety incidents and the relevant expertise to answer questions about the incident that has occurred and the possible consequences of the incident.

Consideration needs to be given to the characteristics of the person nominated as the service user’s contact. They should:

- have received and read the Being Open Policy including the requirements under the Duty of Candour
- Be known to, and trusted by, the patient and/or their carers
- Be senior enough or have sufficient experience and expertise in relation to the type of patient safety incident to be credible to service users, carers and colleagues
- Have excellent interpersonal skills. This includes the ability to communicate with service users and/or their carers in a way they can understand. It is important to avoid excessive use of medical jargon
- Be willing and able to offer an apology, reassurance and feedback to patient’s and/or their carers
- Be able to maintain a medium to long term relationship with the patient and/or their carers, where possible, and to provide continued support and information
- Be culturally aware and informed about the specific needs of the patient and/or their carers

The nominated Being Open Lead will be responsible for ensuring the patient /carer or relatives understand the process that will be followed in accordance with this policy, and other related policies to ensure that they are kept informed of progress, are well supported and assured of receiving a truthful account of the outcome of investigations. More details are provided below concerning the steps to be taken by the Being Open Lead.

The Being Open Lead should be able to nominate a colleague to assist him or her with meetings. Ideally this should be someone with experience or training in communication and Being Open policy awareness.

If for any reason it becomes clear during the initial discussion that the patient would prefer to speak to a different healthcare professional, the patient’s wishes should be respected. A substitute, with whom the patient is satisfied, should be provided following discussion with the Being Open Lead.

**Staff involved in the Incident**

Some patient safety incidents that resulted in moderate harm, severe harm or death will result from errors made by healthcare staff while caring for the patient. In these circumstances the member(s) of staff involved may or may not wish to participate in the Being Open discussion with the patient and/or their carers. Every case where an error has occurred needs to be considered individually, balancing the needs of the patient and/or their carers with those of the healthcare professional concerned.

In cases where the healthcare professional, who has made an error, wishes to attend the discussion to apologise personally, they should feel supported by their colleagues throughout the meeting. By the same token the Being Open Lead should discuss the attendance and intentions of this professional with the service user, relative or care and ensure their agreement to meeting with the professional.
No admission of liability should be made verbally or in writing without the involved professionals being informed and having had an opportunity to consult with their professional representative and without the Head of Legal Affairs having obtained the NHSLA’s approval of the terms of any admission.

General Practitioner
Consideration should be given to contacting the referring GP where the incident may have implications for continuity of care or the welfare of persons in the community related to the service user. By informing them they can offer their support to the patient and/or their relatives/carers.

The Coroner
All cases of untimely, unexpected or unexplained death or suspected unnatural deaths need to be reported to the coroner. The contact point for the Coroner in the Trust is the Head of Corporate and Legal Affairs.

The Coroner may request that the case is not discussed with other parties until the facts have been considered. However, this should not preclude a verbal and written apology or expression of regret where appropriate. In this situation it should be made clear to the family that a full discussion of the circumstances and any residual concerns will be arranged at a date to suit both parties after the coroner’s assessment is finished. Please take advice from the Head of Corporate and Legal Affairs. It should also be recognised that Coroner investigations are stressful for service users, families, carers and staff. Bereavement counselling and advice on professional support groups should be offered at the outset of a coroner’s investigation. Details of various bereavement support groups are set out in Appendix 7.

Relevant statutory/other bodies
The Trust’s policy for incident management informs which external agencies should be notified of a patient safety incident and when this should occur.

The Head of Patient and Organisational Safety, with the Being Open Lead, is responsible for ensuring that a list of those requiring notification is completed as soon as possible after the incident.

Generally, the Director of Nursing, with the Trust’s Head of Communications, will manage all media communications. Otherwise, the Director of Nursing may delegate the preparation of reports through STEIS to the Strategic Health Authority, and to National Health Service Litigation Authority and/or Health & Safety Executive (RIDDOR) but will be involved in approving these reports before they are sent. The NPSA will receive anonymous notification of the incident through the National Reporting and Learning System.

Head of Communications
The Director of Nursing with the Trust’s Head of Communications officer will handle all external communications (other than reports required by such bodies as Strategic Health Authority, National Health Service Litigation Authority or Health & Safety Executive (RIDDOR)).

Head of Corporate and Legal Affairs
The Head of Corporate and Legal Affairs will provide advice where information may be held or restricted in certain circumstances. The Head of Corporate and Legal Affairs will also provide advice and assistance with any letters sent on behalf of the Trust. Agreement should also be sought from this post holder before any admissions of liability are made with the implication that this will result in a claim against the trust.
Performance Team
Will be responsible for returning performance related metrics for Duty of Candour incidents in line with the contractual requirements in conjunction with the Head of Patient and Organisational Safety

APPENDIX 3a

North Staffordshire Combined Healthcare
NHS Trust

DUTY OF CANDOUR - suggested letter template (initial invite to meeting)

Dear Patient/Relative (as appropriate)

Re: Duty of Candour Patient Safety Incident, Date: 

You/Your ……………………… (Insert relative/friend etc.) 

has been involved in a patient safety incident on the (Add in date). The details of which included: (describe incident) ………………………………. 

I am writing to you to acknowledge and express my sincere apology that this regrettable incident occurred. I offer you my assurance that a prompt investigation into the incident will be conducted, the findings of which will be shared with you as soon as possible. This information can be shared with you through another meeting or receipt of a written report summary being made available to you. We will be guided by your preference.

We would like to invite you and or your carers/relatives (as appropriate) to attend a meeting to fully discuss the incident, identify and arrange available support options and respond to any questions that you may have. If this is agreeable to you please would you consider the following:

• Preferred date and time of meeting
• Preferred venue, this can be held at the hospital or we can arrange to visit you at home.
• Who you would like to attend the meeting

I would be very grateful if you would contact xxxxxxxxxx as soon as possible so meeting arrangements may be confirmed.

Please feel free to bring a friend or relative with you to the meeting.

However, if you do not wish to attend any meetings please let us know. Likewise, if you would like to receive a written summary of the investigation report findings.

In the meantime should you have any queries / Staff member XXXXX has been identified as lead contact for the duration of the Being Open process they can be contacted on telephone number xxxx xxxxxxx. Email xxxxxxxxxx. Alternatively, please do not hesitate to contact me directly, my contact details can be found above.

Yours sincerely
DUTY OF CANDOUR – WRITTEN COMMUNICATION RE INVESTIGATION FINDINGS

Dear Patient/Relative

Re: Duty of Candour - Patient Safety Incident   Date xxxxx

As discussed previously, please find enclosed a copy of the written investigation report into the patient safety incident that you were involved in, on date xxxxx

- Description:
- Immediate Action Taken:
- Investigation findings:
- Lessons Learned:
- How these lessons learned will be shared across all departments:

It is regrettable that this unfortunate incident occurred and once again I would like to apologise I on behalf of the Trust.   If you would like to meet to discuss the report findings please do not hesitate to contact me (include contact details)

Yours sincerely

Mrs C Donovan   (or alternative i.e. Medical Director/Head of Directorate)
Chief Executive Officer
North Staffordshire Combined Healthcare NHS Trust
Ensuring Duty of Candour takes place

1. We ensure patients and family are supported to deal with the consequences and have a key contact identified for the incident

2. We ensure there is an appropriate level of investigation

3. We ensure the patient/family/patient representative is informed within 10 working days of the decision that the incident is a moderate/permanent harm incident

4. We ensure that the initial notification should be face to face and this is accompanied with an offer of a written notification

5. We ensure an apology is provided and documented in the patient notes

6. We ensure that a step-by-step explanation is offered as soon as possible pending the investigation

7. We ensure full written documentation of all meetings are kept with the patient/family and filed accordingly for future reference

8. We ensure full written documentation is kept of all staff interviews and meetings about the incident and filed in the incident/complaint account

9. We ensure the final investigation will be shared with the patient/family/patient representative within 10 days of approval

10. The Trust will be monitored by Commissioners as part of our monthly Quality Contract around our contractual obligations to comply with Duty of Candour

Who else is affected by Duty of Candour?

Duty of Candour applies to all providers of healthcare who are registered with the Care Quality Commission. This means that Duty of Candour also applies to dentists, GPs, commissioners, care homes, pharmacies and opticians, amongst others.

What happens if an NHS trust does not comply?

An NHS trust can be fined and the Care Quality Commission has the power to prosecute the trust.

Can I complain?

Duty of Candour does not affect your right to complain. You can make a formal complaint if you are not happy with any aspect of your care, even if your concerns are not affected by Duty of Candour. Send your complaint to the Patient Experience Team, using the details below.

Contact us

Please contact the Patient Experience Team if you would like more information.

Tel:

Email:

Address:
Why have I been given this leaflet?

You have been given this leaflet because you, or a patient you are representing, have been involved in a Duty of Candour incident. This leaflet explains what a Duty of Candour incident is and what we will do. Please contact the following person if you have any questions:

Name:

What is Duty of Candour?

North Staffordshire Combined Healthcare NHS Trust has always been committed to being open, frank and honest with patients when things go wrong, under our Being Open policy.

From November 2014, Duty of Candour become a law which means providers of healthcare across the country must be open and honest with patients. One of the main aims of Duty of Candour is to make sure patients have confidence that an NHS trust will be honest with them about their care and treatment.

Why did Duty of Candour come about?

Previously, there was a contractual Duty of Candour for healthcare organisations. This meant that NHS trusts signed up to an NHS contract and had to be open and honest with patients in order to meet the requirements of the contract.

In 2013, Robert Francis QC published his report into failings at Mid-Staffordshire NHS Foundation Trust. He made many recommendations for change throughout the NHS. One of his recommendations was for a statutory Duty of Candour, which has now come into force.

What are the requirements?

Unfortunately, there are times when something goes wrong with a patient's care. On those occasions, the organisation responsible should:

- tell the patient in person what has happened and apologise
- provide the patient with a full and true account of all the known facts
- advise what else the organisation will need to do
- provide reasonable support to the patient
- follow-up with a written letter which confirms the information already provided, results of further enquiries and an apology

The organisation should tell the patient what has happened as soon as is reasonably possible. Sometimes, we will only become aware of an incident sometime after it has happened.

In certain situations, the requirements above will apply to someone representing the patient. This is likely to be when the patient is under 16 years old or when the patient lacks capacity to make their own decisions.

What incidents are affected by Duty of Candour?

Duty of Candour starts when there has been a 'notifiable safety incident'. This is a serious incident which has resulted in either:

- a patient's death
- moderate harm to the patient
- severe harm to the patient, or
- prolonged psychological harm to the patient

Moderate harm is when there has been a moderate increase in treatment, unplanned readmission, a prolonged episode of care, extra time in hospital as an inpatient or outpatient, cancelling of treatment or transfer to another treatment area.

Severe harm is when there has been a permanent lessening of functions that is related directly to the incident. Prolonged psychological harm is psychological harm which is experienced or is likely to be experienced for a continuous period of at least 28 days.
APPENDIX 5

“BEING OPEN PRINCIPLES”

1. Principle of acknowledgement
All patient safety incidents should be taken seriously acknowledged and reported as soon as they are identified. All concerns should be treated with compassion and understanding by all healthcare staff. A bare denial of a service user’s concerns will make future open and honest communication more difficult.

2. Principle of truthfulness, timeliness and clarity of communication
Information about a patient safety incident must be given to patients and/or their carers in an open and honest manner by an appropriately nominated person.

Communication should be timely with information about what happened being provided as soon as practicable. It should be made clear that new information may emerge as a result of investigation and a step-by-step explanation of what happened will be delivered openly keeping those involved up-to-date with the progress of an investigation.

Patients and/or their carers should be given a single point of contact for any questions or requests they may have to avoid them receiving conflicting information. Medical jargon, which they may not understand, should be avoided or explained and staff should adhere to the facts avoiding speculation as to the cause of an incident in advance of the results of a more detailed investigation.

3. Principle of apology. ¹
A plain expression of sympathy and acknowledgement of the facts need not express an admission of liability, but will show an understanding that there seems to have been an unexpected consequence of the incident. ²

Patients and/or their carers should receive a verbal apology acknowledging the occurrence of a patient safety incident as early as possible. Preferably the apology should be given by a senior staff member who has been involved with the patient’s care, and who has experience in handling patient safety investigations.

Verbal apologies are essential because they allow face-to-face contact between the patient and/or their carers and the healthcare team. It is important not to delay the giving of an apology pending setting up a more formal multidisciplinary meeting as delays are likely to increase the patient’s and/or their carers sense of anxiety, anger or frustration.

A written apology, which clearly states that the Trust is sorry for any suffering and distress resulting from the incident, should be given as soon as possible after a verbal apology has been provided.

1 Refer to NHSLA Letter to Trusts 02/03 Explanations and Apologies www.nhsla.com: Seek assistance and advice from the Litigation Manager if planning on making an admission of liability

2 Refer to NHSLA Letter to Trusts 02/03 Explanations and Apologies www.nhsla.com: Circular No: 02/02 Apologies and Explanations – Seek assistance and advice from the Litigation Manager if planning on making an admission of liability
An apology is not an admission of liability. However, if the investigation has revealed a standard of care below that which the patient could reasonably have expected which has caused him significant harm then an admission of liability will need to be made. In such circumstances, the Being Open Lead must involve the Head of Legal Affairs who will contact the NHSLA for advice, and seek this organisation's approval of any further correspondence to be sent to the patient, relative and/or carer.

The purpose of this approach is not to avoid making a necessary admission but to ensure that the Trust’s insurer is provided with advance notification, and has approved this course. This approach provides for objective external review of the Trust’s findings. This ensures that internal judgment as to the quality of care, is benchmarked against national standards, and the causal analysis, as well as issues of contribution between organisations/independent contractors is subject to an accuracy check before being shared. Otherwise, there is a risk that an admission may later require retraction which may undermine the patient, relative and/or carer’s confidence in the Being Open process, and make the legal process of resolving any dispute more difficult and costly.

4. Principle of recognizing patient/carer expectations

Patients and/or their 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 as soon as possible after the event.

Relatives should be treated sympathetically, with respect and consideration and provided with support in a manner appropriate to their needs. This involves consideration of any special circumstances that may require additional support, from, for example, an independent patient advocate, a translator or member of the Chaplaincy staff.

Information on accessing support via the Trust’s Patient Experience Team should be given to the patient and or their relatives/carers) as soon as possible. Patients may also benefit from information and support of local or national community voluntary organisations like Cruse Bereavement Care and Action against Medical Accidents (AvMA) or from the involvement of a member of chaplaincy staff. Up to date information on such groups and appropriate referral advice can be obtained from the PALS service (see the Trust’s Listening and Responding Policy – PALS and Complaint ) A contact list in respect of support organisations is set out in Appendix 6.

5. Principle of professional support

The Trust encourages an open and fair blame culture in which all staff, whether directly employed or independent contractors, are encouraged to report patient safety incidents without fear of reprisal. Managers should ensure that staff are supported throughout the incident investigation process as they too may have been traumatised by being involved. Staff should not be unfairly exposed to punitive disciplinary action, increased medico-legal risk or any threat to their registration.

Where there is reason to believe a member of staff has committed a punitive or criminal act, the Trust will take steps to preserve its position, and will advise member(s) of staff at an early stage to enable them to obtain separate legal advice and/or representation. Staff will also 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.

6. Principle of risk management and systems improvement.

3 Note other organisations ICAS Independent Conciliation and Advisory Service, Chaplaincy Service, IMCAS-Independent Mental Capacity Advisory Service

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Root cause analysis (RCA) should be used to uncover the underlying causes of a patient safety incident. Investigations should focus on improving systems of care, which will then be reviewed for their effectiveness.

The NPSA’s Incident Decision Tree (IDT) has been developed to ensure a robust and consistent approach to incident investigation. This aims to improve the consistency of decision making about whether human error or systems failures contributed to an incident. More details can be found in Seven Steps to Patient Safety and on the NPSA website: www.npsa.nhs.uk.

7. Principle of multidisciplinary responsibility
Most healthcare provision involves multidisciplinary teams and communication with service users and/or their carers should reflect a multidisciplinary approach to investigations following an incident based on an understanding that most incidents result from systems failures rather than the actions of an individual. Consequently, there is an expectation that there will be a corporate or collective acceptance of any blame and that individuals will not be singled out or criticised inappropriately by any other member of the multi-disciplinary team.

8. Principle of clinical governance
It is fundamental to good clinical governance that patient safety incidents are investigated and analysed, to find out what can be done to prevent recurrence. This involves adhering to a reporting system which will ensure accountability, through the Chief Executive, to the Board and disseminated to staff information about valuable lessons learned from patient safety incidents through managers feeding back locally the outcome of investigations. It is key that follow-up actions are monitored to ensure that the effective changes in practice following a patient safety incident are implemented.

9. Principle of confidentiality
It is good practice to inform the patient and/or their carers about who will be involved in the investigation before it takes place and give them the opportunity to raise any objections - careful consideration needs to be given to the breadth of discussion of patient safety incidents. Service users and/or their carer’s and staff have a right to respect for their privacy. Details of a patient safety incident should at all times be considered confidential. The consent of individuals concerned should be sought prior to disclosing information beyond the clinicians involved in treating the patient. Where this is not practicable or an individual refuses to consent to the disclosure, disclosure may still be lawful if justified in the public interest or where those investigating the incident have statutory powers for obtaining information. However, communications with parties outside of the clinical team should also be on a strictly need-to-know basis and, investigation reports should always be anonymised before wider distribution.

10. Principle of continuity of care
Service users are entitled to expect they will continue to receive all usual treatment and continue to be treated with respect and compassion. If a patient expresses a preference for their healthcare needs to be taken over by another team, consideration should be given and where appropriate arrangements should be made for them to receive treatment elsewhere.

Access to the Being Open National Patient Safety Document can be downloaded from: www.nrls.npsa.nhs.uk/beingopen
PATIENT SUPPORT ORGANISATIONS

Find out more about local services at Patient UK – www.patient.co.uk

Local Organisations:

North Staffordshire User Group
6 THE DUDSON CENTRE
HANLEY
STOKE-ON-TRENT ST1 5DD
United Kingdom
mainoffice@nsug.co.uk
http://www.nsug.co.uk/

North Staffordshire Carers Association
UNIT 2
BURSLEM ENTERPRISE CENTRE
MOORLAND ROAD
BURSLEM
STOKE-ON-TRENT ST6 1JQ
United Kingdom

ASIST
WINTON HOUSE
STOKE ROAD
STOKE-ON-TRENT ST4 2RW
United Kingdom
enquiries@asist.co.uk
http://www.asist.co.uk/

Beth Johnson Foundation
Advocacy, mentoring & Community Development
PARKFIELD HOUSE
64 PRINCES ROAD
HARTSHILL
STOKE-ON-TRENT ST4 7JL
United Kingdom
betty@bjf.org.uk
http://WWW.BJF.ORG.UK

Changes 12 Steps to Mental Health
Victoria Court
Booth Street
STOKE-ON-TRENT ST4 4AL
United Kingdom
stoke@changes.org.uk

The Dove Service
The Dudson Centre
Hope Street
Hanley
Stoke on Trent ST1 5DD
United Kingdom
info@thedoveservice.org.uk

REACH
Winton House
Stoke Road
Stoke on Trent ST4 2RW
United Kingdom
reach@asist.co.uk
http://www.asist.co.uk/#

National organisations:

The Child Bereavement Trust
National UK charity providing specialised training and support for professionals to help them respond to the needs of bereaved families. Resources and information for bereaved children and families as well as the doctors, nurses, midwives, teachers, police, emergency services and voluntary sector support services
Aston House, West Wycombe, High Wycombe, Bucks HP14 3AG
Information and support service line: 0845 357 1000
enquiries@childbereavement.org.uk
www.childbereavement.org.uk

Cruse Bereavement Care
Charity providing information to anyone who has been affected by a death. Also offers education, support, information and publications to anyone supporting bereaved people. A national charity with over 6,000 trained counsellors.
Cruse Bereavement Care, Cruse House, 126 Sheen Road, Richmond TW9 1UR
Tel: 0870 167 1677
www.crusebereavementcare.org.uk

Supportline
A helpline providing confidential emotional support to children, young people and adults on any issue - referring callers to sources of help in their immediate area.
PO Box 1596, Ilford, Essex, IG1 3FW
Helpline: 020 8554 9004 (opening hours vary)
www.supportline.org.uk

British Association for Counselling and Psychotherapy
The 'Seeking a Therapist' section of the website gives lists of qualified counsellors and psychotherapists available in your area. This service is also available over the phone.
1 Regent Place, Rugby, Warwickshire CV21 2PJ
Tel: 0870 443 5252
www.bacp.co.uk

Jewish Bereavement Counselling Service
The service is offered to any member of the Jewish community at no charge.
PO Box 6748, London N3 3BX
Tel: 020 8349 0839/020 8343 8989
www.jvisit.org.uk/jbcs/
Royal College of Psychiatrists
In-depth information about the emotions associated with bereavement
www.rcpsych.ac.uk/info/help/bereav/

Depression Alliance
UK charity offering information to people with depression; run by sufferers.
35 Westminster Bridge Road, London SE1 7JB
Textphone/Minicom: 020 7928 9992
www.depressionalliance.org

Samaritans
24-hour confidential emotional support for anyone in a crisis.
Helpline: 08457 90 90 90 (24 hours)
www.samaritans.org

If I Should Die
This website looks at all aspects of bereavement from the practical to the emotional.
www.ifishoulddie.co.uk

Support for carers
Information, support and practical help for all carers through a network of Princess Royal Trust for Carers centres.
The Princess Royal Trust for Carers
142 Minories, London, EC3N 1LB
Tel: 020 7480 7788
www.carers.org

Carers UK/ Carers National Association
Runs a helpline and provides support, encouraging carers to recognise their own needs. There is also an information officer to answer enquiries from professionals.
20-25 Glasshouse Yard, London EC1A 4JS
Helpline: 0808 808 7777 (freephone, 10am-12noon and 2pm-4pm, Mon-Fri)
www.carersuk.org.uk/about/main.htm

Caring Matters
Focuses on the rights and responsibilities of everyone receiving or providing long-term care services.
132 Gloucester Place, London NW1 6DT
Tel: 020 7402 270

Seniorline
Free national information service for senior citizens, their carers and relatives.
England, Scotland, Wales: 0808 800 6565 (freephone)
Northern Ireland: 0808 808 7575 (freephone)
The lines are open Mon-Fri between 9am-4pm.

When a baby or child dies
A telephone helpline that offers help and support to anyone affected by the death of a child. Staffed by parent volunteers who are supported by a professional team.
Child Death Helpline
Great Ormond Street Hospital for Children, London, WC1N 3JH
Tel: 0800 282 986
www.childdeathhelpline.org.uk

Compassionate Friends
Support and friendship for bereaved parents and their families
Winston’s Wish
Charity that offers support to young people who have experienced bereavement.
The Clara Burgess Centre, Gloucestershire Royal Hospital, Great Western Road, Gloucester GL1 3NN
Helpline: 0845 2030405 (9.30am-5pm, Mon-Fri; 9.30am-1pm, Sat)
www.winstonswish.org.uk

ChildLine
Free, 24-hour helpline for children and young people who need to talk about any problem they may have
Helpline: 0800 1111
www.ChildLine.org.uk

Childhood Bereavement Network
A new national resource for bereaved children and young people, their parents and care givers.
Huntingdon House, 278-290 Huntingdon Street, Nottingham NG1 3LY
Tel: 0115 911 80
SPECIAL CIRCUMSTANCES GUIDANCE

The approach to Being Open may need to be modified according to the patient’s personal circumstances.

When a service user dies

When a patient safety incident has resulted in a patient’s 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 patient’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 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 Being Open discussion with the patient’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 patient’s death. In any event an apology should be issued as soon as possible after the patient’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

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. This is sometimes known as Gillick competence or the Fraser guidelines. 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 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 in Trust’s Consent Policy and under consent on the Department of Health’s website: www.dh.gov.uk

Patient’s with mental health issues

Being Open for patients with mental health issues should follow normal procedures, unless the service user also has cognitive impairment (see below). The only circumstances in which it is
appropriate to withhold patient safety incident information from a mentally ill service user is when advised to do so by a consultant psychiatrist who believes it would cause adverse psychological harm to the service user. However, such circumstances are rare and a second opinion (by another consultant psychiatrist) would be needed to justify withholding information from the service user. 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 service user. To do so is an infringement of the service user’s human rights unless the service user is considered incompetent, and consequently unable to express his wishes, has not made an advance direction prohibiting disclosure and disclosure is considered to be in his best interests.

**Patient’s with cognitive impairment**

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 in respect of matters concerning their welfare under a Lasting 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 service user. The 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 service user’s best interest in deciding who the appropriate person is to discuss incident information with, regarding the welfare of the service user as a whole and not simply their medical interests. However, the service user with a cognitive impairment should, where possible, be involved directly in communications about what has happened. An advocate (an Independent Mental Capacity Advocate IMCA) with appropriate skills should be available to the service user to assist in the communication process.

**Patient’s with learning disabilities**

Where a service user has difficulties in expressing their opinion verbally, an assessment should be made about whether they are also cognitively impaired (see above). If the service user is not cognitively impaired they should be supported in the Being Open process by alternative communication methods (i.e., given the opportunity to write questions down). An advocate, (from the Independent Conciliation and Arbitration Service, ICAS) should be appointed in consultation with the service user. Other appropriate advocates may include carers, family or friends of the service user. The advocate should assist the service user during the Being Open process, focusing on ensuring that the service user’s views are considered and discuss

**Patient’s who do not agree with the information provided**

Sometimes, despite the best efforts of healthcare staff or others, the relationship between the service user and/or their carers and the healthcare professional breaks down. They may not accept the information provided or may not wish to participate in the Being Open process. In this case the following strategies may assist:

- Deal with the issue as soon as it emerges
- Where the patient agrees, ensure their carers are involved in discussions from the beginning
- Ensure the service user has access to support services
- Where the senior health professional is not aware of the relationship difficulties, provide mechanisms for communicating information, such as the patient expressing their concerns to other members of the clinical team
- Offer the patient user 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 clinical risk management
- Use a mutually acceptable mediator to help identify the issues between the healthcare organisation and the patient, and to look for a mutually agreeable solution
- Ensure the service user, relative and/or carer is fully aware of support services available
- Ensure the patient and/or their carers are fully aware of the formal complaints procedures
- Write a comprehensive list of the points that the patient and/or their carer disagree with and reassure them you will follow up these issues

**Service users with a different language or cultural considerations**

The need for interpretation, translation assistance and consideration of special cultural needs (such as, cultural values 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. If the patient's first or preferred language is not English you must offer the services of a trained interpreter. In the case of a child when communication with a child is necessary for the purposes of safeguarding and promoting that child’s welfare, an interpreter must be used. It would be worthwhile to obtain advice from a member of the Chaplaincy Centre team and or an interpreter before arranging any meeting so as to discuss the most sensitive way forward. Use of ‘unofficial translators’ such as members of a service users family or friends is not encouraged as they may distort information by editing what is communicated. Interpretation and translation services may be accessed by the Being Open Lead via Switchboard.

**Service users with different communication needs**

A number of patients will have particular communication difficulties, such as a hearing impairment. Plans for the meeting should fully consider these needs. Knowing how to enable or enhance communications with a patient is essential to facilitating an effective Being Open process. There should be a focus on the needs of individuals and their families, with thoughtful and respectful communication.
DUTY OF CANDOUR FLOW CHART

PATIENT SAFETY INCIDENT OCCURS

- Complete incident report immediately and submit – this will automatically go to Incident Review Group.
- Moderate/Severe harm/Death – DOES DUTY OF CANDOUR Apply?
- ASAP Contact Patient and Organisational Safety Team (POST) to alert potential Duty of Candour Incident
- Incident Review Group convenes and determines if incident meets criteria for Duty of Candour.

NO:
- Senior member of care team to meet with the patient and or carers ASAP, Apologise and explain.

YES:

ARRANGE URGENT PRELIMINARY MDT DISCUSSION
- Establish & clarify facts, agree plan for disclosure discussion with patient
- Notify Trust’s Performance Team ASAP (Contractual compliance)
- Notify POST Lead, Medical and Nursing Director, CEO, Clinical Director, Matron

INITIAL DISCLOSURE & APOLOGY TO PATIENT/CARERS - DO NOT DELAY – Must be within 10 days of the incident occurring.

Notification may be verbal (face to face), open discussion expressing sincere regret, apology and explanation between the staff providing the care and the patient and/or carers where possible.

- By Consultant/MDT/Matron/Ward Manager
- Provide outline of investigation.
- Identify when/if patient would like to meet.
- Any verbal disclosure made to the patient and or carer must be followed up in writing within 10 days.

DOCUMENTATION IN HEALTH RECORDS
• Record “Being Open /Duty of Candour” dates, time, names present, issues, apology, and plan for further communication.

If any meetings are declined by the patient and or their carers this must be recorded.

MAINTAINING CONTACT WITH PATIENT and or /Carer
• Is a second meeting required? Or Telephone call? Confirm details
• On approval of investigation report – letter and summary to be issued to family (written by CEO or Head of Directorate) before posting agree preferred method of disclosure, may prefer to meet to discuss.