# BEING OPEN AND DUTY OF CANDOUR POLICY AND PROCEDURE (COMMUNICATING WITH PATIENTS AND / OR THEIR RELATIVES / CARERS FOLLOWING A PATIENT SAFETY INCIDENT)

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**VALIDITY** – Policies should be accessed via the Trust intranet to ensure the current version is used.

**CHANGE RECORD**

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<td>1.00</td>
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<td>This policy guides staff on the understanding of Duty of Candour to ensure both contractual and professional requirements are in place across the organisation where there is moderate harm and above.</td>
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1. INTRODUCTION

Each day more than a million people are treated safely in the NHS. Occasionally, however, something goes wrong and a patient is harmed (this is often referred to as an adverse incident or a patient safety incident). Healthcare staff may feel cautious about apologising for things that go wrong as they worry that they might say the wrong things, make the situation worse and/or may be blamed for the mistake. This policy has been designed to assist staff within Humber NHS Foundation Trust to be open with patients and/or their carers following such incidents and provides guidance on the points to consider.

‘Being open’ simply means apologising and explaining what happened to patients and/or their carers who have been involved in a patient safety incident which has resulted in harm and which may or may not result in a complaint or claim. Communicating openly and effectively with patients and/or their carers is a vital part of the process of dealing with errors or problems in their treatment and can also decrease the trauma felt. Research has shown that patients will forgive medical errors when they are disclosed promptly, fully and compassionately and such an approach can even reduce the likelihood of a subsequent complaint or claim.

Openness also has benefits for healthcare staff. These include satisfaction that communication with patients and/or their carers has been handled in the most appropriate way; developing a good professional reputation for handling a difficult situation properly; and improving their understanding of incidents from the perspective of the patient and/or their carers. Openness is also beneficial for the reputation of the healthcare organisation.

This policy is based on the National Patient Safety Agency’s (NPSA) Being Open Policy, the principles of which are fully supported by a wide range of royal colleges and professional organisations and, is consistent with the Department of Health (2003) ‘Making Amends’ consultation document, which states, “The individual who has suffered harm as a result of the healthcare they have received must get an apology”. This should be regardless of whether the patient goes on to complain or claim.

A duty of candour (to be open with patients about harm caused) is now also included as a statutory obligation in the NHS Standard Contract. This arises from the report and recommendations of Robert Francis QC into the failings at Mid Staffordshire. The contract requires NHS Trusts to ensure that ‘patients/their families are told about patient safety incidents that affect them, receive appropriate apologies, are kept informed of investigations and are supported to deal with the consequences’. The duty applies to patient safety incidents that occur during care provided under the NHS Standard Contract and that result in moderate, prolonged psychological, severe harm or death.

The Francis Inquiry report also outlined that the provision of information in compliance with this requirement should not itself be evidence or an admission of any civil or criminal liability, but non-compliance with the statutory duty should entitle the patient to a remedy.

The recommendations from the Francis Inquiry report are attached at Appendix 1.

The approach outlined within this policy is integral to the Trust’s commitment to improving patient safety and continuous quality improvement and aims to
complement existing arrangements and practices. Further, it is consistent with the Trust’s ‘fair blame’ approach following incidents which focuses on ‘what went wrong, not who went wrong’ and importantly the actions required to prevent recurrence and ensure appropriate follow-up of the affected patient(s).

The Trust is committed to being open with patients (and this is integral to the processes in place for managing incidents, complaints and claims), and a charter to this effect is proposed for agreement by the Board (see Appendix 2).

2. SCOPE

This policy applies to all staff employed by and contracted to the Trust. This policy applies to patient safety incidents involving moderate, prolonged psychological harm, severe harm or death, and which require a more formal response and is intended to ensure that all communication with patients and/or relatives and between staff/healthcare teams and, where relevant, other healthcare organisations, when things have gone wrong is open, honest and occurs as soon as possible following an incident, complaint or claim.

3. DEFINITIONS

3.1 Apology: An expression of sorrow or regret in respect of a notifiable patient safety incident

3.2 Notifiable patient safety incident: any incident that is unintended or unexpected that results in moderate harm, prolonged psychological harm, severe harm or death.

3.3 Moderate Harm: any patient safety incident that requires a moderate increase in treatment (unplanned return to surgery, an unplanned readmission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, or transfer to another treatment area (such as intensive care) and which caused significant but not permanent harm.

3.4 Prolonged psychological harm (means psychological harm which a service user has experiences, or is likely to experience, for a continuous period of at least 28 days)

3.5 Severe Harm: Any patient safety incident that appears to have resulted in permanent harm (permanent lessening of bodily functions, sensory, motor, physiological or intellectual, including removal of wrong limb or organ or brain damage)

3.6 Death: Any patient safety incident that directly resulted in the death (related to the incident rather than to the natural course of the patient’s illness or underlying condition) of one or more persons

3.7 Relevant person: this is usually the person who has been affected by the patient safety incident
4. POLICY STATEMENT

The Trust encourages staff to report patient safety incidents that were prevented i.e. ‘near misses’, no harm and low harm incidents as well as patient safety incidents that have caused moderate harm, prolonged psychological, severe harm or death. It is not, however, a requirement of this policy that prevented patient safety incidents and no harm incidents are discussed with patients. For minor or low incidents, it is anticipated that being open principles will still be applied and an apology and/or explanation will be provided at the time the incident or issue occurs.

It should be stressed that this policy is not intended to cover all eventualities and not all of the stages of the processes which follow will be applicable or necessary in respect of all of the incidents which are covered by this policy. This policy is intended as a guide to assist staff to effectively communicate with patients and/or their relatives/carers involved in patient safety incidents and to ensure that staff feel supported and empowered to do so.

5. DUTIES & RESPONSIBILITIES

5.1 The Chief Executive and Executive Directors are responsible for ensuring that a ‘Being Open’ Policy which outlines the Trust’s commitment and approach to the Duty of Candour is in place.

5.2 The Executive Director of Nursing, Quality and Patient Experience is responsible for the development and implementation of this policy and for ensuring that suitable training programmes for staff are in place.

5.3 The Care Group Triumvirates are responsible for ensuring the implementation of this policy within their areas and ensuring that staff are open with patients and/or their relatives/carers following patient safety incidents and integral to the processes for responding to complaints, including those which have the potential to become a claim.

5.4 Service Managers, Modern Matrons, Team leaders are responsible for mentoring and supporting their staff within their sphere of responsibility in being open and throughout the being open process (following incidents/serious untoward incidents/complaints and claims).

5.5 Senior clinicians will mentor and support healthcare colleagues in the ‘being open’ process and will practice and promote the principles of ‘being open’ and support fellow healthcare professionals with being open by:

- mentoring colleagues during their first ‘being open’ discussion
- advising on the being open process
- being accessible to colleagues prior to initial and subsequent being open discussions
- facilitating the initial team meeting to discuss the incident when appropriate
• signposting the support services within the organisation for colleagues involves in being open discussions
• facilitating de-briefing meetings following being open discussions
• support fellow healthcare professionals in dealing with patient safety incidents within the organisation by:
• signposting the support services within the organisation for colleagues involved in patient safety incident discussions
• advising on the reporting system for patient safety incidents

5.6 Staff involved in the incidents, investigation or follow-up of incidents/serious incidents, complaints and claims including being open with patients and other relatives/carers following patient safety incidents are responsible for ensuring that these discussions are managed in accordance with the principles and processes outlined within this policy. An outline of the process is provided at Appendix 4.

5.7 Organisational Risk Management Group (ORMG) on behalf of QPaS is the group that monitors compliance with Duty of Candour on a weekly basis for moderate, severe and significant harms.

5.8 The Quality and Patient Safety Committee (QPaS), on behalf of the Trust Board, is responsible for monitoring compliance with this policy.

6. EQUALITY & DIVERSITY
An Equality and Diversity Impact Assessment has been carried out on this document using the Trust approved EIA.

7. MENTAL CAPACITY
The Trust supports the following principles, as set out in the Mental Capacity Act and has applied them in the development of this policy:
1. A person must be assumed to have capacity unless it is established that they lack capacity.
2. A person is not to be treated as unable to make a decision unless all practicable steps to help him to do so have been taken without success.
3. A person is not to be treated as unable to make a decision merely because he makes an unwise decision.
4. An act completed, or decision made, under this Act for or on behalf of a person who lacks capacity must be done, or made, in his best interests.
5. Before the act is completed, or the decision made, regard must be had as to whether the purpose for which it is needed can be as effectively achieved in a way that is less restrictive of the person’s rights and freedom of action.
8. **BRIBERY ACT**

The Bribery Act 2010 makes it a criminal offence to bribe or be bribed by another person by offering or requesting a financial or other advantage as a reward or incentive to perform a relevant function or activity improperly performed.

The penalties for any breaches of the Act are potentially severe. There is no upper limit on the level of fines that can be imposed and an individual convicted of an offence can face a prison sentence of up to 10 years.


If you require assistance in determining the implications of the Bribery Act please read the Trust Bribery prevention policy available on the intranet at [http://intranet.humber.nhs.uk/bribery-prevention-policy-p183.htm](http://intranet.humber.nhs.uk/bribery-prevention-policy-p183.htm) or contact the Trust Secretary on 01482 389194 or the Local Counter Fraud Specialist on telephone 01482 866800 or fraud@humber.nhs.uk

9. **IMPLEMENTATION**

- Awareness in respect of the principles outlined in this policy will be provided via the weekly global as a practice note to all clinical staff
- Training will be provided as part of investigation and root cause analysis training and as part of complaints/claims awareness sessions

10. **MONITORING & AUDIT**

Review of the policy implementation will be monitored within the Organisational Risk Management Group of the mechanisms for being open/providing feedback and support to patients and/or their relatives/carers following patient safety incidents.

Incidents that trigger duty of candour will be monitored within the weekly Organisational Risk Management Committee. All incidents that trigger duty of candour will be followed up and reviewed using the tool in appendix 7. Results and findings will be shared at ORMG

Compliance with Duty of Candour will be monitored by the Quality and Patient Safety Committee.

11. **REFERENCES/EVIDENCE/GLOSSARY/DEFINITIONS**

This document should be read in conjunction with the following policies:

- Risk Management Strategy
- Incident Reporting Policy
- Serious Incident and Significant Event Policy
- Policy & Procedure for the Management of Complaints
- Claims Handling Policy & Procedure
12 References

CQC Guidance to providers on meeting the fundamental standards and on CQCs enforcement powers. July 2014.
GMC Joint statement from Chief Executives of statutory regulators of healthcare professionals “Openness and honesty – the professional duty of candour”. October 2014.
Duty of Candour Procedure

Being Open principles
The Trust promotes the Ten Principles of Being Open, which is a process rather than a one off event.

- **Acknowledgement** – all patient safety incidents should be acknowledged and reported as soon as they are identified
- **Truthfulness, timeliness and clarity of communication**; information about a patient safety incident must be shared with patients and or their relatives/carers in a truthful and open manner by a nominated person, providing clear information of what happened, taking into account their individual needs.
- **Communication** should be timely and be as soon as practicable but where possible be no longer than 10 working days from the date of the incident. Patients and or relatives/carers should be kept up to date with the investigation or review which should be agreed at the start of the investigation/review and or revisited at a later date to allow time for the person and or relative/carer to reflect upon the incident and or their level of involvement in the investigation or review
- **Apology** – patients and or their relatives/carers should receive a sincere expression of sorrow or regret for the harm that has resulted from a patient safety incident both verbally and in writing and recognising an apology is not an admission of guilt
- **Recognising patient and or carer/relatives expectations** – patients and or relatives/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.
- **Professional support** – the Trust is committed to creating an environment in which all staff are encouraged to report patient safety incidents
- **Risk management and systems improvement** – root cause analysis/use of 5 why’s will be used to uncover the underlying causes of patient safety incidents
- **Multidisciplinary responsibility** – most healthcare provision is provided by a range of professionals and communication with the patient and or relative/carers should reflect this.
- **Clinical Governance** – being open is an integral part of the approach to governance within the Care Group Triumvirates and across the Trust.
- **Confidentiality** – the patient and or relative will be assured that the details of all patient safety incidents are confidential.
- **Continuity of care** – patients are entitled to expect that they will continue to receive all usual care and treatment with respect and compassion. If a patient requests a preference for a change in healthcare worker, the appropriate arrangements should be made to facilitate this.

Being open, transparent and candid with service users and/or carers begins with the recognition that a service user has suffered harm (physical or psychological) as a result of their healthcare treatment. It could be as a result of a patient safety incident, or may be related to some other kind of adverse event.
It involves explaining and apologising for what happened to patients who have either been harmed or involved in an incident, ensuring that communication is open and honest, occurring as soon as possible following an incident. This encompasses communication between healthcare organisations, healthcare teams and patients and/or their carers.

**Key steps involved in the process are outlined in Appendix 5**

The process followed will be a case-by case decision made by the responsible manager in response to the nature of the adverse event or complaint, and the needs of the situation. In making a decision about who is most appropriate to provide the notification and/or apology, consideration should be given to seniority, relationship to the service user, experience and expertise in the type of notifiable incident that has occurred.

Factors which will be taken into account will include:

- Nature of the adverse event or complaint.
- Degree and nature of harm sustained (physical or psychological).
- Needs and wishes of the service user and/or carers.
- Capacity of the service user, and whether this is likely to change.
- Involvement of any carers or relatives.
- Diversity issues relating to delivering effective ‘being open’ communication and support to service users, carers or others.
- Confidentiality issues

On occasions, a notifiable safety incident that happened some time ago or that relates to care delivered by another provider may be discovered. The provider discovering the incident should work with others who are responsible for notifying the relevant person of the incident.

Support with decision-making can be sought from the Complaints Team, the Risk Management Team, or Care Group Directors.

If an incident is identified out-of-hours initial decisions will be made by the most senior member of the team in consultation with the on-call manager. The level of seniority of the responsible manager and the level at which decisions are taken will be dictated by the seriousness of the incident. Duty of Candour decisions following very serious incidents will be managed by the Care Group Directors or on call managers.

### 2. Duty of Candour Procedure

#### 2.1 Acknowledging and reporting adverse incidents, including notifiable patient safety incidents

All adverse incidents will be acknowledged and reported as soon as they are identified, according to the Trust incident management policies and procedures.

Where appropriate, incidents will be reported to external agencies such as the police, using the Safeguarding Adults or the Safeguarding Children policies.

#### 2.2 The relevant person should be notified

The Duty of Candour regulation refers to our responsibility to notify the ‘relevant person’. This is usually the person who has been affected by the patient safety
incident, but can apply to a person acting lawfully on their behalf under the following circumstances:

- On the death of the service user.
- Where the service user is under 16 and not competent to make a decision in relation to their care and treatment.
- Where the service user is 16 or over and lacks capacity in relation to the matter in accordance with the Mental Capacity Act 2005. Please refer to the Trust’s Mental Capacity Act 2005 Protocol.

2.3 Determining level of response and whether the incident is notifiable

The level of response to adverse incidents will depend on the seriousness and nature of the incident.

The definition of what constitutes a notifiable patient safety incident is set out in Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015. It specifies that a notifiable patient safety incident means any unintended or unexpected incident that occurred in respect of a service user during the provision of a regulated activity that, in the reasonable opinion of a health care professional, could result in, or appears to have resulted in moderate harm, prolonged psychological harm, severe harm and death.

2.4 Communicating the incident and offering a meaningful apology

Service users and/or their carers must receive a truthful notification that a patient safety incident affecting them has occurred, along with a sincere expression of sorrow or regret for any harm that has resulted, as soon as reasonably practicable after the incident has been identified. A verbal apology should be made by the most appropriate person, giving consideration to seniority, relationship to the service user, experience and expertise in the type of notifiable incident that has occurred.

Factors which will be taken into account will include:

- Nature of the adverse event or complaint.
- Degree and nature of harm sustained (physical or psychological).
- Needs and wishes of the service user and/or carers.
- Capacity of the service user, and whether this is likely to change.
- Involvement of any carers or relatives.
- Confidentiality issues.

Whilst considering the need for confidentiality, staff will ensure that any required assistance with communication is available, for example interpreters, advocates, or communication aids should be used to enable effective communication and support to service users, carers or others.

Alongside the apology the service user and / or their carer should be provided with a step-by-step explanation of what happened, as soon as practicable. The NHS Standard Contract requires that the notification must be within at most 10 working days of the incident being reported to local systems and sooner where possible. Where this is not possible, a clear documented rationale must be given on the Trust DATIX system.
It is essential that any information given is based solely on the facts known at the time. The healthcare professional providing the information should explain that the service user, their families and carers (as appropriate) will be kept up-to-date with new information which emerges and with the progress of any investigation. They should be given a single point of contact for any questions or requests they may have.

### 2.5 Providing support to the service user / relevant person

It is essential to offer appropriate support to the individual(s) concerned, including when we notify them of the incident. This includes:

- Treating them with respect, consideration and empathy.
- Offering the option of direct emotional support during the notifications, for example from a family member, a friend, a care professional or a trained advocate.
- Offering access to assistance with understanding what is being said, e.g. through interpreting services, non-verbal communication aids, written information, Braille etc.
- Providing access to any necessary treatment or care to recover from or minimise the harm caused where appropriate.
- Providing details of specialist independent sources of practice advice and support or emotional support or counselling.
- Providing information about available impartial advocacy and support services, their local Healthwatch and other relevant support groups, for example Cruse Bereavement Care, to help them deal with the outcome of the incident.
- Arranging for care and treatment to be delivered by another professional, team or provider if this is possible and desirable.
- Providing support to complain.

The Being Open framework (NPSA 2009) provides further guidance on how to support patients, their families and carers when a patient safety incident has occurred.

### 2.6 Written communication and apology

The verbal communication and apology should be followed up by providing the same information in writing. Written follow-up communications should also include:

- Details of any further enquiries to be undertaken.
- The results of any further enquiries into the incident, and
- An apology.

A written record of all communication (verbal and written) with the relevant person must be kept on Datix.

Where the issue is the subject of a complaint, the Complaints Team will lead the Duty of Candour and receive copies of all documentation.

The account of the facts of the incident should:

- Include as much or as little information as the person wants to hear;
- Be jargon-free and explain any complicated terms;
• Be given in a manner that the relevant person can understand, with consideration to the need for interpreters, advocates, communication aids; while being conscious of any potential breaches of confidentiality in doing so.

The Being Open framework (NPSA 2009) provides guidance on how to ensure good communication with the patient, their families and carers.

Although meeting with service users or carers in these circumstances may be difficult for many reasons, delays are likely to increase anxiety, anger or frustration. Patient and public focus groups report that patients were more likely to seek medico-legal advice if apologies were not delivered promptly.

A further verbal apology may be offered at any subsequent meetings (such as at a meeting to provide feedback on the outcome of the Trust’s incident investigation). This will be done by the most appropriate person at the time.

2.7 If verbal and written communication are not successful

All reasonable attempts must be made to contact the affected person through all available communication means. All attempts at contact must be documented.

If the affected person does not wish to communicate with the Trust their wishes must be respected and a record of this must be kept.

If the affected person has died and there is nobody who can lawfully act on their behalf, a record of this should be kept.

A record of all Duty of Candour correspondence must be kept on Datix, along with any investigations and the outcome or results of the enquiries or investigations.

2.8 Documenting communications

Records of meetings should include:

• The date, time, place, the names, relationships or job roles of those who attended.

• What the discussion covered and any actions agreed.

• The plan for further communication and contact.

• A summary of agreed actions.

The service user and/or carer should be provided with a written record of the meeting.

Copies of any letters sent and file notes of any other communication such as telephone discussions with the service user and or carer must all be kept securely on the Datix system, linked to the incident record. It may also be appropriate under some circumstances to keep some relevant notes and copies of communication in the case notes or care records.

2.9 Support for staff in relation to Duty of Candour.

Staff may be understandably anxious about this process. It should be clearly understood that saying sorry following an incident or complaint does not imply liability but should be a genuine apology about something that has gone wrong. It is natural and desirable for those involved in treatment which produces an adverse result, for whatever reason, to sympathise with the patient or the patient’s relatives and to express sorrow or regret at the outcome.
Communicating a notifiable safety incident may lead to an angry reaction from service users, carers or others. Staff should be supported to manage and compassionately respond to such circumstances.

Support for staff in relation to being open will be provided through the responsible manager. Out of hours support is available through the on-call manager. Should staff members feel unable to seek support through the management route for any reason, the following alternative sources of advice and support are available:

- Care Group Directors can also provide advice and support to staff in relation to Duty of Candour issues.
- The Risk Management Team and the Complaints Team will also be sources of support and advice.

2.91 Confidentiality

Consideration must be given to the confidentiality of all service users, carers and staff (Data Protection Act 1998), and information disclosure and sharing will be subject to the usual confidentiality and information governance restrictions. Advice can be sought from the Trust’s Information Governance Manager or the Caldicott Guardian.

Details of an adverse incident or complaint should at all times be considered confidential. The consent of the individual concerned must be sought prior to disclosing identifiable information beyond the teams involved in providing care, unless safeguarding adult, child, legal or criminal concerns are raised.

Confidential information may be disclosed to a person acting lawfully on the service user’s behalf under certain circumstances.

2.92 Communication with other Trust staff, health and social care teams, external organisations and agencies.

Consideration will be given to contacting other trust teams and staff members; the GP; and other services or agencies involved in providing care to the individual, as:

- These services may be able to offer support to the service user and/or their carers at a difficult time. It may be necessary to include these services in any investigation. It may be appropriate to share outcomes and learning, providing that:
  - Information is relevant to the continuing safe delivery of care, treatment and support.
  - Information is factual, correct and does not include subjective opinions about the person.
  - Information can be shared in line with the Data Protection Act 1998 and other relevant guidance.

The Information Governance Department can provide advice in relation to Confidentiality/ Data protection concerns, in partnership with the Caldicott Guardian.
2.93 Supporting Staff Following a Patient Safety Incident

When a patient safety incident occurs, healthcare professionals involved in the patient’s clinical care may also require emotional support and advice. Both clinicians who have been directly involved in the incident and those with the responsibility for the being open discussion should be given access to assistance, support and any information they need to fulfil this role. To support healthcare staff involved in patient safety incidents, the following arrangements are in place within HFT:

- The Trust has in place a ‘fair blame’ culture that discourages the attribution of blame and, following adverse incidents, focuses on ‘what went wrong, not who went wrong’
- It is the role of the Clinical Care Group Directors and Associate Medical Director to mentor and support colleagues in being open and throughout the being open process. Alternatively, please contact a member of the Risk & Governance Team
- Arrangements are in place within the Care Groups for de-briefing of the clinical team involved in patient safety incidents, where appropriate, as part of the support system and separate from the requirement to provide statements for the investigation. Mechanisms are also in place to ensure that staff involved in adverse incidents receive feedback following the incident investigation
- Counselling and support services are available via Occupational Health

3. Meeting with the patient and or relatives following an identified patient safety incident

Service users and/or their carers should receive an apology as soon as possible after an adverse event which has affected them or when a complaint has been made. Staff should feel able to apologise on the spot. Service users have a right to expect openness in their care and treatment.

Saying sorry is not an admission of fault or liability and is the right thing to do, apologizing and explaining when patients have been harmed can be very difficult. This guidance aims to help ensure that you follow best practice.

Stage 1 – Preliminary Meeting with the Patient and/or their Relatives/Carer (within 10 days of the identified patient safety incident)

Who Should Attend?

- A lead staff member 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. N.B. Staff should not attend being open discussions alone
- Ensure that those members of staff who do attend the meetings can continue to do so; continuity is very important in building relationships
- The person taking the lead should be supported by at least one other senior member of staff.
- Ask the patient and/or their carers who they would like to be present
• Consider each team member’s communication skills; they need to be able to communicate clearly, sympathetically and effectively
• Hold a pre-meeting amongst healthcare professionals so that everyone knows the facts and understands the aims of the meeting

When should it be held?
• As soon after the incident as possible (must be held within 10 days of the incident)
• Consider the patient’s and/or their relatives/carer’s home and social circumstances
• Check that they are happy with the timing
• Offer them a choice of times and confirm the chosen date in writing
• Do not cancel the meeting unless absolutely necessary

Where should it be held?
• Use a quiet room where you will not be distracted by work or interrupted
• Do not host the meeting near the place where the incident occurred as this may be difficult for the patient and/or their relatives/carers

Stage 2 – Discussion:

How should you approach the patient and/or their relatives/carers?
• Speak to the patient and/or their carers as you would want someone in the same situation to communicate with a member of your own family
• Do not use jargon or acronyms: use clear, straightforward language
• Consider the needs of patients with special circumstances, for example, linguistic or cultural needs, and those with learning difficulties

What should be discussed?
• Introduce and explain the role of everyone present to the patient and/or their relatives/carer and ask them if they are happy with those present
• Acknowledge what happened and apologise on behalf of the team and the organisation. Apologising and expressing regret is not an admission of liability
• Agree what will be discussed
• Stick to the facts that are known at the time and assure them that if more information becomes available, it will be shared with them
• Do not speculate or attribute blame
• Suggest sources of support and counselling
• Check they have understood what you have told them and offer to answer any questions
• Provide a named contact who they can speak to again
• Agree next steps in terms of investigation, care of the patient, process for feeding back
• As per the note below, full written documentation of meetings must be maintained
Stage 3 – Follow-Up

- Clarify in writing the information and apologies given, reiterate key points, record action points and assign responsibilities and deadlines
- The patient’s notes should contain a complete, accurate record of the discussion(s) and apologies given including the date and time of each entry, what the patient and/or their relatives/carers have been told, and a summary of agreed action points
- Maintain a dialogue by addressing any new concerns, share new information once available and provide information on support and counselling, as appropriate
- It is essential that written records are maintained of any discussion with and apology given to patients and/or their carers following patient safety incidents – either at the time the incident occurs whilst the patient may be still on the ward/in the clinic etc. or at any time subsequent to the incident. This will include appropriate entries in the patient’s notes and as part of the incident investigation, complaint or claim file. In respect of the latter, incident, complaint and claim information is held electronically on DATIX, therefore, all written communications should be saved to the relevant entry.
- It is important that patients and/or their relatives receive a meaningful apology. An apology does not constitute an admission of liability. Patients and the relatives increasingly ask for detailed explanations of what led to adverse outcomes and they frequently say that they derive some consolation from knowing that lessons have been learned for the future. Explanations should not contain admissions of liability.

3.1 Documentation

Documentation of being open discussions should include (as appropriate):

- the time, date and place, as well as the names and job titles of attendees
- the plan for providing further information to the patient and/or their carers or other nominated representative or the GP in relation to the incident
- apologies given
- offers of assistance and the response of the patient and/or carer
- questions raised and answers given
- plans for any follow-up meetings
- progress notes relating to the clinical situation and an accurate summary of all the points explained to the patient and/or carer

Any investigation reports will have to be shared with the patient/relative/carer within ten days of being signed off as complete
Appendix 1

Francis Inquiry Recommendations – Duty of Candour

Recommendation 181

A statutory obligation should be imposed to observe a duty of candour:

- On healthcare providers who believe or suspect that treatment or care provided by it to a patient has caused death or serious injury to a patient to inform that patient or other duly authorised person as soon as is practicable of that fact and thereafter to provide such information and explanation as the patient reasonably may request;

- On registered medical practitioners and registered nurses and other registered professionals who believe or suspect that treatment or care provided to a patient by or on behalf of any healthcare provider by which they are employed has caused death or serious injury to the patient to report their belief or suspicion to their employer as soon as is reasonably practicable.

The provision of information in compliance with this requirement should not of itself be evidence or an admission of any civil or criminal liability, but non-compliance with the statutory duty should entitle the patient to a remedy.”

Recommendation 183

It should be made a criminal offence for any registered medical practitioner, or nurse, or allied health professional or director of an authorised or registered healthcare organisation:

- Knowingly to obstruct another in the performance of these statutory duties;

- To provide information to a patient or nearest relative intending to mislead them about such an incident;

- Dishonestly to make an untruthful statement to a commissioner or regulator knowing or believing that they are likely to rely on the statement in the performance of their duties.”

Recommendation 28

Zero tolerance: A service incapable of meeting fundamental standards should not be permitted to continue. Breach should result in regulatory consequences attributable to an organisation in the case of a system failure and to individual accountability where individual professionals are responsible. Where serious harm or death has resulted to a patient as a result of a breach of the fundamental standards, criminal liability should follow and failure to disclose breaches of these standards to the affected patient (or concerned relative) and a regulator should also attract regulatory consequences. Breaches not resulting in actual harm but which have exposed patients to a continuing risk of harm to which they would not otherwise have been exposed should also be regarded as unacceptable.”
Appendix 2

PATIENTS’ CHARTER: ‘BEING OPEN’ WITH OUR PATIENTS

Staff within Humber NHS Foundation Trust work hard to deliver the highest standards of healthcare to all patients who use our services. We provide safe and effective care to many thousands of people every year but sometimes, despite our best efforts, things can and do go wrong.

If a patient is harmed as a result of a mistake or error in their care, in line with our culture within our services that is honest and open at all levels, that we believe that they, their family or those who care for them, should be told in a timely manner and receive a written and truthful account of the incident and an explanation about any enquiries and investigations, be kept fully informed as to what has happened, have their questions answered and know what is being done in response and should receive an apology in writing. This is something that we call ‘Being Open’ and to fulfil ‘Duty of Candour’ requirement to ensure that patients/families are informed of medical errors causing moderate, severe harm or death and are provided with support, we make a commitment to our patients to:

- apologise for the harm caused
- explain, openly and honestly, what has happened
- describe what we are doing in response to the incident
- offer support to the person and or family
- provide the name of a person to speak to
- give updates on the results of any investigation
- follow up the findings of the investigation in writing

Trust Board
Humber NHS Foundation Trust
December 2016
Appendix 3

**Regulation 20 of the CQC fundamental standards of care specifies that:**

20(1) A health service body must act in an open and transparent way with relevant persons in relation to care and treatment provided to service users in carrying on a regulated activity.

20(2) As soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred a health service body must: 20(2)(a) notify the relevant person that the incident has occurred; 20(2)(b) provide reasonable support to the relevant person in relation to the incident, including when giving such notification.

20(3) The notification to be given under paragraph (2)(a) must – 20(3)(a) be given in person by one or more representatives of the health service body; 20(3)(b) to provide an account, which to the best of the health service body’s knowledge is true, of all the facts the health service body knows about the incident as at the date of the notification; 20(3)(c) advise the relevant person what further enquiries into the incident the health service body believes are appropriate; 20(3)(d) include and apology, and 20(3)(e) be recorded in a written record which is kept securely by the health service body.

20(4) The notification given under paragraph (2)(a) must be followed by a written notification given or sent to the relevant person containing – (a) the information provided under paragraph (3)(b), (b) details of any enquiries to be undertaken in accordance with paragraph (3)(c), (c) the results of any further enquiries into the incident, and (d) an apology.

20(5) But if the relevant person cannot be contacted in person or declines to speak to the representative of the health service body – (a) paragraphs (2) to (4) are not to apply, and (b) a written record is to be kept of attempts to contact or to speak to the relevant person.
Pathway - Duty of Candour

**Incident**
- Incident that causes moderate or severe harm, prolonged psychological harm or death - **Report on Datix**.

**Review**
- Review of level of harm by Care Group to confirm meets criteria for statutory Duty of Candour and follow pathway or step down level of harm. Always be open with person/family and inform of incident.

**Be Open**
- Meet with the person/family and explain what has happened to the relevant person as soon as reasonably practicable (Within 10 working days of the incident occurring or becoming aware of the incident) - **Offer a meaningful apology and document within the patient records.**

**Follow up in writing**
- Follow up the verbal apology in writing and provide information to the relevant person/s of the investigation process and the date this will conclude. Upload a copy of the letter within DATIX.

**Provide feedback**
- Meet with the relevant persons/s to discuss the findings of the investigation. **Again offer a meaningful apology.** Be open and honest about the areas for learning and actions to be taken to prevent reoccurrence.

**Follow up in writing**
- Follow up the meeting in writing, confirming the findings and areas for learning/ations to be taken following the incident.
APPENDIX 5

TEMPLATE LETTER 1:

INCIDENT THAT TRIGGERS
DUTY OF CANDOUR (Not Serious Incident)
Letters for serious incidents will be produced by the Trust Risk Team

Our Ref:

(INsert Date)

Private and Confidential
(INsert Name & Address of Patient/Relative)

Dear (Insert Name of Patient / Relative)

I write further to the incident which occurred on (Insert Date), which was discussed with you by (Insert Name) on (Insert Date).

(Insert Details of the incident and confirm the discussion of any queries or questions that the family may want an answer to)

May I confirm that the incident is being investigated and will take approximately (Insert No) of weeks to complete; it will be completed by (Insert Date). If for any reason there is likely to be a delay in completing this, we will notify you as soon as possible.

When the investigation has been completed, I will contact you again to arrange to meet with you to discuss the investigation findings and answer an additional questions or concerns which you may have. We will confirm the actions we have taken or propose to take as a result of the investigation and harm that you suffered.

Should you wish to discuss matters further in the meantime, please do not hesitate to contact (Insert Name of Family Liaison) on (Insert Tel or Email).

Finally, please accept my sincere and unreserved apologies for the distress caused by this incident.

Yours sincerely

INSERT NAME
JOB TITLE

Trust Headquarters
Wllerby Hill
Beverley Road
Wllerby
East Riding of Yorkshire
HU10 6ED

Tel: 01482 389135
APPENDIX 6

Trust Headquarters
Willerby Hill
Beverley Road
Willerby
East Riding of Yorkshire
HU10 6ED
Tel: 01482 389135

TEMPLATE LETTER 2:
ON COMPLETION OF THE
INVESTIGATION OF AN INCIDENT THAT TRIGGERS THE
DUTY OF CANDOUR REQUIREMENT

Our Ref: (INSERT DATE)

Private and Confidential
(INSERT NAME & ADDRESS OF PATIENT/RELATIVE)

Dear (INSERT NAME OF PATIENT / RELATIVE0

I write further to my letter of (INSERT DATE), in respect of the incident which occurred on (INSERT DATE).

The Trust’s investigation has now been concluded. As indicated in my earlier correspondence to you, we would like to make arrangements to meet with you to discuss the investigation findings and to answer any additional questions or concerns which you may have and importantly to confirm the lessons learnt and actions we have taken or intend to take as a result of this incident in order to minimise the risk of further such incidents.

I understand that meeting arrangements have already been discussed and agreed with you OR* if you would like to take up this offer of a meeting, please contact (INSERT NAME OF AGREED FAMILY LIAISON) on (INSERT TELEPHONE NUMBER) or via email (INSERT EMAIL ADDRESS).

(* DELETE AS APPROPRIATE)

Finally and once again, please accept my sincere and unreserved apologies on behalf of the Trust for distress caused by this incident. I would like to assure you that the Trust takes seriously incidents such as this and steps are being taken to ensure that lessons are learnt not only in the area concerned but across the Trust as a whole.

Yours sincerely

(INSERT CEO/COO/CARE GROUP DIRECTOR/)

Humber NHS Foundation Trust
Duty of Candour Policy
Version 1 date October 2015
Page 26 of 29
Audit - Duty of Candour

Every day more than a million people are treated safely within the NHS. Occasionally, however something goes wrong and a patient is harmed; this is often known as an adverse incident or a patient safety incident. These incidents are recorded onto DATIX.

The Francis Inquiry recommended that there should be a statutory requirement placed upon organisations to observe a duty of candour; this simply means being open with the person about the harm caused.

The NHS Contract now stipulates Duty of Candour as a statutory requirement following any incident that has caused moderate or severe harm, where there has been prolonged psychological harm or following a death. This must be undertaken within 10 working days of the incident occurring or within 10 working days of becoming aware of the incident.

All harms that trigger Duty of Candour to be reviewed within the Care Group Triumvirate

<p>| Care Group Triumvirate - Children and Learning Disability ☐ Community and Older People ☐ Mental Health ☐ Specialist ☐ |
| WebEx Number: |
| Recording level of harm |
| 1. The level of harm is reported correctly |
|   Moderate Harm ☐ Severe Harm ☐ Prolonged Psychological Harm ☐ Death ☐ |
| 2. If the level of harm, in your opinion is not recorded correctly, what should it be? |
|   Not applicable ☐ No harm ☐ Low harm ☐ Moderate harm ☐ Severe harm ☐ Death ☐ |</p>
<table>
<thead>
<tr>
<th>Outcome of review of harm</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Level of harm changed? Yes ☐ No ☐</td>
<td>Level of harm correct and meets Duty of Candour requirement? Yes ☐ No ☐</td>
</tr>
</tbody>
</table>

### Being Open

3. There is evidence that the relevant person was verbally informed of the incident. Yes ☐ No ☐

4. How did this meeting take place? Face to face ☐ Over the telephone ☐

5. There is evidence that the incident and information known at the time was shared with the 'relevant person' within 10 days of the incident occurring or within 10 days of the staff becoming aware of the incident. Yes ☐ No ☐

6. There is evidence that this was followed up in writing to the 'relevant person'. Yes ☐ No ☐

7. There is evidence of a meaningful apology or expression of sorrow or regret being given to the relevant person that is documented in the records. Yes ☐ No ☐

### Investigation of notifiable patient safety incident

8. There is evidence that an investigation was carried out within 10 days of the incident occurring or within 10 days of becoming aware of the incident. Yes ☐ No ☐

### Follow up with the relevant person

9. There is evidence of a follow up meeting with the relevant person? Yes ☐ No ☐

10. There is evidence that the findings from the investigation were shared with the 'relevant person'? Yes ☐ No ☐

11. There is evidence that the findings were followed up in writing to the relevant person? Yes ☐ No ☐

12. There is evidence of an unreserved apology or meaningful expression of sorrow and regret being offered to the 'relevant person' following the investigation? Yes ☐ No ☐