 <b>University Hospitals of Morecambe Bay</b> NHS Foundation Trust	
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## 1. SUMMARY

This Being Open Policy deals with the University Hospitals of Morecambe Bay NHS Foundation Trust's response to both an ethical responsibility and a duty of candour requiring health care professionals and managers to inform patients about actions which have resulted in harm.

In his report into the events that occurred at Mid Staffordshire Hospital, Robert Francis QC<sup>1</sup> made a recommendation that "where death or serious harm has been or may have been caused to a patient by an act or omission ...the patient (or any lawfully entitled ...person) should be informed of the incident, given full disclosure of the surrounding circumstances and be offered an appropriate level of support, whether or not the patient or representative has asked for this information".

In his report into the events that occurred at Furness General Hospital, Dr Bill Kirkup CBE<sup>2</sup> highlighted a number of concerns about openness and candour to patients and their families and made a number of specific recommendations (Recommendation; 1, 11, 13, 24, 25, 26 & 27) for the University Hospitals of Morecambe Bay NHS Foundation Trust to implement.

The Health and Social Care Act 2008 (Regulated Activities) Regulations (SI 2014/2936)<sup>3</sup> came into force on 27th November 2014. The Regulations require NHS Trusts to act in an open and transparent way as part of their general duty of candour. Further, in relation to a 'notifiable safety incident' there is a mandatory requirement to, as soon as reasonably practicable after becoming aware that an incident has occurred, notify the 'relevant person' (the patient or their representative) in person, provide a true account of all facts (as known at the time), advise what further enquiries will be made and provide an apology. This notification must be confirmed in writing and a copy must be kept securely.

This Policy will also help to ensure that the Trust complies with the following national guidance and learning:

- NHS England: National Quality Board Guidance on Learning from Deaths, Guidance for NHS trusts on working with bereaved families and carers<sup>4</sup>
- NHS Resolution: Saying Sorry<sup>5</sup>
- Care Quality Commission: Duty of candour, Information for all providers: NHS bodies, adult social care, primary medical and dental care, and independent healthcare<sup>6</sup>
- Care Quality Commission: Report on Learning, Candour and Accountability: A review of the way NHS trusts review and investigate the deaths of patients in England<sup>7</sup>

This Policy will also help clinical colleagues to comply with the duty of candour related requirements of their personal Professional Registration, as outlined in the joint GMC and NMC publication; 'Openness and honesty when things go wrong: The professional duty of candour'<sup>8</sup> which states;

"Every healthcare professional must be open and honest with patients when something that goes wrong with their treatment or care causes, or has the potential to cause, harm or distress."

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It is recognised that a culture of openness is a precondition to improving patient safety and the quality of health care systems. This Trust is committed to the principle of openness and this policy details the meaning of openness in practice. Being Open is one of a range of measures in place to effectively manage unexpected events and support those affected by them. 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.

Being Open, is not an admission of liability, it acknowledges that something could have gone better and is the first step to learning from what happened and preventing it recurring. The Compensation Act 2006<sup>9</sup> states:

“An apology, an offer of treatment or other redress, shall not of itself amount to an admission of negligence or breach of statutory duty”.

It is recognised that a culture of openness is a precondition to improving patient safety and the quality of health care systems. This Trust is committed to the principle of openness and this policy details the meaning of openness in practice. *Being Open* is one of a range of measures in place to effectively manage unexpected events and support those affected by them.

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## 2. PURPOSE

Implementation of the policy will lead to a:

- standardised methodology for communication with patients
- statement of the information required
- statement of the record keeping required
- standardised approach to dissemination of the information process for monitoring the policy and its effectiveness
- compliance with relevant national and Professional requirements

## 3. SCOPE

This policy stipulates the mandatory arrangements and best practice for communication about a patient safety incident with patients or carers.

This Policy must be applied to all Patient Safety Incidents that have been reported as causing; ‘Moderate Harm’, ‘Severe Harm’ or ‘Catastrophic Harm’.

This Policy may also be applied to Patient Safety Incidents that have been reported as causing; ‘Low Harm’, ‘No Harm’ or being a ‘Near Miss’. Importantly it encourages the passage of other information to patients about patient safety incidents they may have been involved in. Communication with patients, and where appropriate their carers and/or family, is integral to their care and staff are encouraged to discuss matters openly. Advice for staff can be sought from Occupational Health

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The level of response in relation to the information deemed appropriate to share with patients and their family/carers requires an assessment in accordance with the grade of incident to ensure consistency of approach. There is always a requirement to be open but the legally mandated level of response is dependent upon the grading of the patient safety incident.

## 4. POLICY

### 4.1 Duties

#### 4.1.1 Senior Person responsible for the individual's care

- Responsibility for ensuring the Being Open Policy is followed in appropriate incidents.
- Responsibility for maintenance and safe storage of documentation.
- Providing patients with a letter, as detailed in Appendix 2, if appropriate.
- Ensure the details of communication with patients are recorded on the incident report
- Ensure that staff are appropriately trained and supported to enable them to effectively lead a being open discussion

#### 4.1.2 Governance Team

- Reporting information on the Being Open process and key performance indicators to the Clinical Divisions and the Trust Committees.
- Undertake quarterly audit of statutory Duty of Candour compliance.
- The Patient and Family Support Officer (PFSO) provides support to patients, families and or carers as well as staff during the investigation process for serious incidents reported through Strategic Executive Information System (StEIS)

#### 4.1.3 All other staff

- Ensure the details of communication with patients are recorded on the incident report.
- It is unacceptable for junior staff to communicate patient safety information alone or to be delegated the responsibility to lead a *Being Open* discussion unless they volunteer and their involvement takes place in appropriate circumstances (i.e. they have received appropriate training and mentorship for this role). Support should be provided by the staff member's line manager/supervisor, who should ensure that all staff are appropriately trained and supported to enable them to effectively lead a being open discussion

#### 4.1.4 Trust Board

The Trust Board will receive and discuss minutes of the Quality Committee and receive regular reports on all aspects of Governance, Risk Management and Internal Controls. Adherence to this policy will be monitored by the Quality Committee through routinely reported information.

#### 4.1.5 Weekly Patient Safety Summit

Incidents initially thought to cause moderate or greater harm are reviewed each week by the Weekly Patient Safety Summit and the requirement for the completion of Duty of Candour confirmed.

#### 4.1.6 Patient and Family Support Officer (PFSO)

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The role of the Patient and Family Support Officer (PFSO) is to provide a main point of contact for all patients and families involved in a Serious Incident investigation within the Trust. Serious Incident is defined as those investigations that meet the definition of a patient safety incident that is reportable on the Strategic Executive Information System (StEIS).

The contact with the family is dictated by the wishes and needs of the patient/family involved. They will be offered the opportunity to meet at the start of an investigation so that their concerns, if appropriate, can be incorporated into the Root Cause Analysis (RCA) investigation process, as well as receiving draft copies of the Terms of Reference and the RCA report for them to review and feedback on if necessary. The PFSO supports the patient and family throughout this process and keeps them up to date at each stage of the investigation. The PFSO also works closely with the Care Group RCA Lead/Team to ensure that the information provided to the family is accurate and timely.

## 4.2 Key considerations for all Being Open discussions

### Do's

- Remember that the patient has a right to know what has occurred to them
- Remember that an apology is not an admission of negligence
- Remember that an apology is not intended to be a complete and accurate explanation of what occurred
- Ensure, as far as possible, that the patient is able to understand and retain the information given to them
- Ensure, as far as possible, that the patient's privacy and dignity are maintained
- Ensure, as far as possible, that the patient has a family member, friend or carer present to support them
- Contact the Dementia Matron, Learning Difficulties Matron or Safeguarding Team for advice, if patient has mental capacity issues or learning difficulties
- Be open and clear about what has and what has yet to be established and what the consequences are likely to be
  - What happened
  - What can be done to deal with any harm caused
  - What will be done to prevent someone else being harmed (if known at the time)
- Ask the patient if they need any further clarification
- Ensure, as far as possible, that the patient knows who to contact in the Trust to ask any further questions or raise any concerns
- Record the details of your apology in the patient's clinical record
- Be personal, not general – say 'I', rather than 'We' or 'The Trust'
  - Do Say; I am sorry this happened
  - Do Say; I am sorry, we have learned that....
  - Do Say; I am truly sorry for the distressed caused
  - Do Say; It was a problematic/difficult procedure
  - Do Say; There were some issues that were difficult to anticipate in advance
- Avoid using 'double negatives' as they can be confusing
  - e.g. I did not anticipate that I would not have considered that to have been a possibility

### Don'ts

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- Assume that the patient does not want to be, or need to be, made aware - you must not make this decision on behalf of the patient
- Make the patient feel unnecessarily uncomfortable, vulnerable or confused
- Wait until the outcome of any investigation to speak to the patient
- Provide conflicting or contradictory information
- Speculate on the outcome of any investigation or the causes of the incident
- Deny any personal or organisation responsibility, but also do not take personal responsibility for system failures or other people's mistakes
- Apportion blame or criticism to other colleagues before the outcome of an investigation
- Discourage or prevent the patient from seeking further support from the Trust or external organisations
- Disregard or dismiss concerns or issues raised by the patient
  - Do Not Say; I am sorry, but....
  - Do Not Say; I am sorry you feel like that
  - Do Not Say; I am sorry if you are offended
  - Do Not Say; I am sorry you took it that way
  - Do Not Say; You were a problematic/difficult patient/case
  - Do Not Say: The severity/complexity of your condition was worse than I thought
- Use 'double negatives'

### 4.3 Initial Being Open discussion

#### 4.3.1 Timing

The initial *Being Open* discussion with the patient and/or their carers should occur as soon as possible after the patient safety incident. When an incident of 'moderate harm', or greater, occurs the relevant person must be informed as soon as reasonably practicable. Where it is unclear whether the degree of harm has triggered the statutory duty of candour (whether it a 'notifiable safety incident') the 'relevant person' must be informed in line with Regulation 20: Duty of Candour<sup>6</sup>. The Trust defines reasonably practicable as within 10 working days of the incident being reported

#### 4.3.2 Content of the initial discussion

Factors to consider for the discussion include:

- clinical condition of the patient;
- availability of key staff involved in the incident and in the *Being Open* process;
- availability of support staff, for example a translator or independent advocate, if required;
- patient preference (in terms of when and where the meeting takes place and which healthcare professional leads the discussion);
- privacy and comfort of the patient; arranging the meeting in a sensitive location.

The discussion must include:

- reasonable support to the patient (relevant person – see section 4.5);
- what will happen next in terms of the long-term treatment plan
- how and when families may be contacted about investigations
- what support is available from the Trust
- the patient views and concerns are important and will be respected

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- If an in-depth investigation is required, the patient:
  - can be involved to the extent that they wish
  - will be informed of the progress of an investigation (if they wish)
  - will be offered an opportunity to shape the investigation report (if they wish)
  - will be updated on how this leads to improvements in care (if they wish)
- confirmation of any further enquiries to be undertaken;
- an apology

A record of the discussion must be documented in Ulysses Risk Management System, the patient's records and confirmed to the patient (relevant person) in writing. This should be completed in 10 working days. The duty of candour section in the manager's form must be completed and a copy of any written communication must be attached to the clinical incident in Ulysses Risk Management System.

**Please see Appendix 1, which gives guidance on the discussion and documentation process**

## 4.4 Discussions with patients

### 4.4.1 Choosing the individual to communicate with patients and/or their carers

This should be the most senior person responsible for the patient's care and/or the investigation lead. The individual(s) should ideally:

- be known to, and trusted by, the patient and/or their carers;
- have a good understanding of the facts relevant to the incident;
- have credibility associated with the level of seniority, or have sufficient experience and expertise in relation to the type of patient safety incident, for patients, carers and colleagues to feel confident that matters will be appropriately addressed; and
- have excellent interpersonal skills, including being able to communicate with patients and/or their family/carers in a way they can understand and avoiding excessive use of medical jargon.

If the relevant person cannot be contacted in person or does not want to meet or hear from anyone about the incident there is no requirement to have a meeting or send a letter. However, there must be a clear record kept (on the Trust's Ulysses Risk Management System) of the attempts to contact or speak with the relevant person. Where a relevant person has confirmed that they don't want any information about the incident, they should be given the option of changing their mind at a later date or identifying someone else to be the point of contact on their behalf.

Some patient safety incidents that result in 'moderate harm', or more, may result from errors made by healthcare staff while caring for the patient. In these circumstances, the patient (or family/carers) may not wish to speak with the member(s) of staff involved and/or the member(s) of staff may or may not wish to participate in the *Being Open* discussion with the patient and/or their family/carers.

It is recognised that staff involved may be upset and distressed and require support during the process. Details of support provision are contained in the Trust policy for supporting staff involved in traumatic or stressful incidents.

Patients, family and/or their carers should be reassured that they would continue to be

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treated according to their clinical needs even in circumstances where there is a 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. Every case where an incident has occurred needs to be considered individually, balancing the needs of the patient and/or their family/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.

The role of the Patient and Family Support Officer (PFSO) is to liaise between the patient, family and or carer (for StEIS incidents) to ensure that they are involved and can input into the incident investigation. This also allows impartiality and support to be offered throughout the process.

The Duty of Candour conversation must be clearly recorded in the patient's health record and on Ulysses Risk Management System Safeguard. A letter summarising the discussion (Duty of Candour letter; Appendix 2) must be sent to the patient or relevant person and again this must contain a meaningful apology that expresses regret at the occurrence of the patient safety incident, along with details of the agreed process for providing updates to the patient and/or family/carers. The letter should also provide the details for a lead contact and the PFSO (for StEIS incidents) to enable the patient and/or family/carers to raise specific questions that they may have around the incident following this initial discussion. It may also be advantageous at this point to try and book a provisional date for sharing the findings of the investigation (if appropriate). The date of the verbal discussion, name of the person who made the verbal contact and resultant letter sent, must be recorded in Ulysses Risk Management System, in the appropriate fields. Letters must be attached in the incident record.

#### **4.4.2 Content of the meeting following the being open discussion with the patient, family and/or their carers**

The patient and/or their carers should be advised of the identity and role of all people attending the *Being Open* meeting before it takes place. This allows them the opportunity to state their own preferences about which healthcare staff should be present.

There should be an expression of genuine sympathy, regret and an apology for the harm that has occurred.

The facts that are known and agreed by the multidisciplinary team should be stated. However, where there is disagreement, communication about these events should be deferred until after the investigation has been completed.

Information on likely short and long-term effects of the incident (if known) should be shared. An explanation should be given about:

- what will happen next in terms of the long-term treatment plan
- how and when families may be contacted about investigations
- what support is available from the Trust
- the patient views and concerns are important and will be respected
- If an in-depth investigation is required the patient:
  - can be involved to the extent that they wish

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- will be informed of the progress of an investigation (if they wish)
- will be offered an opportunity to shape the investigation report (if they wish)
- will be updated on how this leads to improvements in care (if they wish)

The patient, family and/or their carers should be informed that an incident investigation is being carried out and more information will become available as it progresses. It should be made clear to the patient and/or their family/carers that new facts may emerge as the incident investigation proceeds.

The patient's (family's and/or carer's) understanding of what happened should be taken into consideration, as well as any questions they may have. The patient's wishes (right to confidentiality) must of course be considered before information is shared with the patient's family/carers. Further, appropriate language and terminology must be used when speaking to patients and/or their family/carers.

The patient, family and/or carers should be offered an opportunity to discuss the situation with another relevant professional where appropriate.

There should be consideration and formal noting of the patient's/family and/or carer's views and concerns, and demonstration that these are being heard and taken seriously.

A verbal explanation should be followed up with an accompanying letter.

An offer of practical and emotional support should be made to the patient, family and/or their carers. This may involve getting help from third parties such as charities and voluntary organisations as well as offering more direct assistance. Information about the patient and the incident should not normally be disclosed to third parties without consent.

The patient (relevant person) should be provided with contact details so that if further issues arise later there is a conduit back to the relevant healthcare professionals.

It recognised that patients and/or their family/carers may be anxious, concerned, frightened or even angry and frustrated, when the Being Open discussion is conducted. Staff are expected to use appropriate judgement and techniques to address these issues, as far as practically possible.

**It is essential that the following does not occur:**

- speculation;
- apportioning of blame;
- criticism or comment on matters outside their own experience;
- renunciation of responsibility;
- provision of conflicting information from different individuals.

The initial *Being Open* discussion is the first part of an ongoing communication process.

#### **4.4.3 Documentation regarding of meetings in relation to the Being Open Policy**

There should be documentation of:

- the time, place, date, of meetings as well as the name and relationships of all attendees;
- the plan for providing further information to the patient and/or their carers;

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- questions raised by the family and/or carers or their representatives, and the answers given;
- plans for follow-up as discussed;
- progress notes relating to the clinical situation and an accurate summary of all the points explained to the patient and/or their carers;
- A copy of the incident report form.
- A summary letter of the *Being Open* meeting should be shared with the patient or relevant person.

Documentation regarding both the investigation and discussions with the patient, family and/or carer should be kept securely and separately to the patient's medical records. However, a copy of the initial Being Open discussion with the patient can also be recorded within the patient's medical records. Details of patient contact and digitised copies of documentation should be held on Ulysses Risk Management System, linked to the incident report.

Responsibility for maintenance and safe storage of documentation lies with the investigation lead.

#### 4.4.4 Follow-up

The Being Open meeting may not be a one-off event and regular follow-up meetings/telephone contact should be arranged by the investigation lead or PFSO (for StEIS incidents) to ensure the patient, family and/or carers are kept updated. The investigation lead should also liaise with the legal and patient relations department to avoid confusion and duplication if formal procedures are to be instigated.

Where there are implications for continuity of care, it may be valuable to consider including the GP in one of the follow-up discussions either at discharge or at a later stage; the principles described for the initial meeting apply throughout.

#### 4.4.5 Completing the process

After completion of the incident investigation, feedback (where wanted by the relevant person) should be provided in the form that has been previously agreed with the patient. 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.
- Copies of incident investigations should be approved by the Director of Governance /Deputy Director of Clinical Governance prior to being disclosed.

If the patient requests a copy of the incident report form and/or investigation report, **a redacted copy which does not identify staff by name** should be given to them. In exceptional cases, information may be withheld or restricted, for example, where communicating information will adversely affect the health of the patient, where investigations are pending, or where specific legal requirements preclude disclosure for specific purposes. In these cases, the patient (relevant person) will ordinarily be informed

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of the reasons for the restrictions/delay.

#### 4.4.6 Patients who require additional support or guidance

Sometimes, despite the best efforts of healthcare staff or others, the relationship between the patient and/or their family/carers and the healthcare professional breaks down. They may disagree with, or challenge, the information provided or may not wish to participate in the *Being Open* process. The following strategies may assist:

- deal with the issue as soon as it emerges;
- where the patient agrees, ensure their family/carers are involved in discussions from the beginning;
- ensure the patient 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 and/or their family/carers another contact person with whom they may feel more comfortable. This could be another member of the team, the individual with overall responsibility for clinical risk management or a member of the patient relations team;
- 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 patient and/or their family/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 that you will follow up these issues.

### 4.5 Special Circumstances

#### 4.5.1 When a patient 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 family 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 occurs before the coroner's inquest. But in rare certain circumstances it may be appropriate to wait for the coroner's inquest before holding the substantive *Being Open* discussion with the patient's family and/or carers. The post-mortem report can be 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.

#### 4.5.2 Children and Young People

The legal age of presumed capacity (maturity) for giving consent to treatment is 16. It is

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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 (unless they are assessed as lacking mental capacity). However, it is still considered good practice to encourage competent children to involve their families in decision making.

The courts have confirmed 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<sup>10</sup>. 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 the Consent Policy or on the Department of Health and Social Care's website<sup>11</sup>.

#### **4.5.3 Patients with mental health issues**

*Being Open* for patients with mental health issues should follow normal procedures. The only circumstances in which it is appropriate to withhold patient safety incident information from a mentally ill patient is when advised to do so by a consultant psychiatrist who feels it would cause adverse psychological harm to the patient. However, such circumstances are expected to be rare and it may be appropriate to obtain a second opinion (from Senior Clinical decision maker) to justify withholding information from the patient. 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 patient. To do so is an infringement of the patient's right to confidentiality.

#### **4.5.4 Patients with cognitive impairment**

Some individuals have conditions that limit their ability to understand what is happening to them (they lack capacity). Reasonable support and adjustments should always be made to accommodate the patient's needs and optimise communication and understanding. They may have authorised a person to act on their behalf (if they previously had the necessary capacity) under a health and welfare lasting power of attorney or a court may have appointed a deputy to make decisions on their behalf (this applies for healthcare or for finances or both - it is important to check which one and require the documented proof of the POA (power of attorney) and document in the patient's notes). In these cases, steps must be taken to ensure their responsibility extends to the care and treatment of the patient. The *Being Open* discussion would be held with the responsible (relevant) person. Where there is no such person, consideration of an IMCA (Independent Mental Capacity Advocate) is best practice and in the patient's best interest.

#### **4.5.5 Patients with learning disabilities or Autism**

Where a patient has learning difficulties or Autism, an assessment should be made about whether they are also cognitively impaired using the Mental Capacity Assessment. Reasonable support and adjustments must always be provided to a patient (the relevant person) during the *Being Open* process including by alternative communication methods (i.e. given the opportunity to write questions down or consideration of an IMCA) where

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appropriate. This obligation will require particular consideration where a patient has learning disabilities. It may be appropriate to appoint an advocate, in consultation with the patient. An appropriate advocate may be a carer, a family member, a friend or other person significant to the patient. The advocate can then assist the patient during the *Being Open* process, helping to ensure that the patient's views are considered and discussed.

#### 4.5.6 Patients with different communication needs

A number of patients will have communication difficulties, such as a hearing impairment, which must be taken into consideration with reasonable support and adjustments being provided. Knowing how to enable or enhance communications with a patient is essential to facilitating an effective *Being Open* process, focusing on the needs of individuals and their families and being personally thoughtful and respectful.

#### 4.5.7 Patients with a different language or cultural considerations

The need for translation and advocacy services, and consideration of special cultural needs (such as for patients from cultures that make it difficult for a woman to talk to a male about intimate issues), must be taken into account when planning to discuss patient safety incident information. It would be worthwhile to obtain advice from an advocate or translator before the meeting on the most sensitive way to discuss the information. Further advice, including approved arrangements for translation services, can be provided by the Trust's customer care team.

5. ATTACHMENTS	
Number	Title
1	Duty of Candour Flow chart
2	Template Letter
3	Values and Behaviours Framework
4	Equality and Diversity Impact Assessment Tool

6. OTHER RELEVANT / ASSOCIATED DOCUMENTS	
The latest version of the documents listed below can all be found via the <a href="#">Trust Procedural Document Library</a> intranet homepage.	
Unique Identifier	Title and web links from the document library
Corp/Proc/057	Consent to Examination or Treatment – Adults and Children
Corp/Pol/201	Reporting and Management of Safety Events including Serious Incidents
HR2	Supporting Staff following Traumatic or Stressful Incidents
Corp/Pol/033	Mental Capacity Act (2005)
Corp/Proc/081	Interpretation Services Procedure

7. SUPPORTING REFERENCES / EVIDENCE BASED DOCUMENTS	
References in full	
No	References
1	Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry (2013). Available from: <a href="https://www.gov.uk/government/publications/report-of-the-mid-staffordshire-nhs-foundation-trust-public-inquiry">https://www.gov.uk/government/publications/report-of-the-mid-staffordshire-nhs-foundation-trust-public-inquiry</a> (accessed 27.8.19)
2	Morecambe Bay Investigation: Report. Available from: <a href="https://www.gov.uk/government/publications/morecambe-bay-investigation-report">https://www.gov.uk/government/publications/morecambe-bay-investigation-report</a> (accessed 27.8.19)

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3	The Health and Social Care Act 2008 (regulated Activities) Regulations 2014 (SI2014/2936) Available from: <a href="https://www.legislation.gov.uk/ukdsi/2014/978011117613/contents">https://www.legislation.gov.uk/ukdsi/2014/978011117613/contents</a> (accessed 27.8.19)
4	NHS England (2018) National Quality Board. Guidance on learning from deaths, guidance for NHS trusts on working with bereaved families and carers. Available from: <a href="https://www.england.nhs.uk/publication/learning-from-deaths-guidance-for-nhs-trusts-on-working-with-bereaved-families-and-carers/">https://www.england.nhs.uk/publication/learning-from-deaths-guidance-for-nhs-trusts-on-working-with-bereaved-families-and-carers/</a> (accessed 27.9.19)
5	NHS Resolution (2017) Saying sorry. Available from: <a href="https://resolution.nhs.uk/wp-content/uploads/2017/07/NHS-Resolution-Saying-Sorry-Final.pdf">https://resolution.nhs.uk/wp-content/uploads/2017/07/NHS-Resolution-Saying-Sorry-Final.pdf</a> (accessed 27.8.19)
6	CQC (2017) Regulation 20: Duty of candour. Available from: <a href="https://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-20-duty-candour#full-regulation">https://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-20-duty-candour#full-regulation</a> (accessed 27.8.19)
7	CQC (2016) Learning, candour and accountability. Available from: <a href="https://www.cqc.org.uk/sites/default/files/20161213-learning-candour-accountability-full-report.pdf">https://www.cqc.org.uk/sites/default/files/20161213-learning-candour-accountability-full-report.pdf</a> (accessed 27.8.19)
8	GMC and NMC (2015) Openness and honesty when things go wrong: The professional duty of candour'. Available from: <a href="https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/candour---openness-and-honesty-when-things-go-wrong">https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/candour---openness-and-honesty-when-things-go-wrong</a> (accessed 27.8.19)
9	Great Britain (2006) The Compensation Act 2006. Available from: <a href="https://www.legislation.gov.uk/ukpga/2006/29/section/3">https://www.legislation.gov.uk/ukpga/2006/29/section/3</a> (accessed 27.8.19)
10	NSPCC. A child's legal rights: Gillick competency and Fraser guidelines. Available from: <a href="https://learning.nspcc.org.uk/research-resources/briefings/gillick-competency-and-fraser-guidelines/">https://learning.nspcc.org.uk/research-resources/briefings/gillick-competency-and-fraser-guidelines/</a> (accessed 27.8.19)
11	Department of Health website. Available from: <a href="https://www.gov.uk/government/organisations/department-of-health-and-social-care">https://www.gov.uk/government/organisations/department-of-health-and-social-care</a> (accessed 27.8.19)

## Bibliography

Being Open – Safer Practice Notice NPSA 2005 Available from: <https://webarchive.nationalarchives.gov.uk/20171030131232/http://www.nrls.npsa.nhs.uk/resources/type/alerts/?entryid45=59792&p=4> (accessed 27.8.19)

Being Open – Patient safety Alert NPSA/2009/003 Available from: <https://webarchive.nationalarchives.gov.uk/20171030130738/http://www.nrls.npsa.nhs.uk/resources/type/alerts/?entryid45=65077&p=2> (accessed 27.8.19)

DoH (2003). Making amends: a consultation paper setting out proposals for reforming the approach to clinical negligence in the NHS. Available from: [https://webarchive.nationalarchives.gov.uk/20120809195448/http://www.dh.gov.uk/prod\\_cconsum\\_dh/groups/dh\\_digitalassets/@dh/@en/documents/digitalasset/dh\\_4060945.pdf](https://webarchive.nationalarchives.gov.uk/20120809195448/http://www.dh.gov.uk/prod_cconsum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4060945.pdf) (accessed 27.8.19)

## 8. DEFINITIONS / GLOSSARY OF TERMS

Abbreviation or Term	Definition
moderate harm	means: a) harm that requires a moderate increase in treatment, and

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	b) significant, but not permanent, harm.
moderate increase in treatment	an unplanned return to surgery, an unplanned re-admission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, or transfer to another treatment area (such as intensive care)
notifiable safety incident	any unintended or unexpected incident that occurred in respect of a patient during the provision of care that, in the reasonable opinion of a health care professional, could result in, or appears to have resulted in: <ul style="list-style-type: none"> <li>a) the death of the service user, where the death relates directly to the incident rather than to the natural course of the service user's illness or underlying condition, or</li> <li>b) severe harm, moderate harm or prolonged psychological harm to the patient.</li> </ul>
prolonged pain	pain which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days (as a consequence of the incident)
prolonged psychological harm	pain which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days (as a consequence of the incident)
relevant person	the patient or, in the following circumstances, a person lawfully acting on their behalf: <ul style="list-style-type: none"> <li>a) on the death of the patient,</li> <li>b) where the patient is under 16 and not competent to make a decision in relation to their care or treatment, or</li> <li>c) where the patient is 16 or over and lacks capacity in relation to the matter.</li> </ul>
severe harm	a permanent lessening of bodily, sensory, motor, physiologic or intellectual functions, including removal of the wrong limb or organ or brain damage, that is related directly to the incident and not related to the natural course of the patient's illness or underlying condition

## 9. CONSULTATION WITH STAFF AND PATIENTS

Enter the names and job titles of staff and stakeholders that have contributed to the document

Name/Meeting	Job Title	Date Consulted
Distribution list from the Weekly Patient Safety Summit	All on circulation list	February 2019
Stuart Bates	Deputy Director of Clinical Governance	July 2019
Carl Foulkes	Compliance and assurance manager	April 2019

## 10. DISTRIBUTION & COMMUNICATION PLAN

Dissemination lead:	Associate Deputy Director of Patient Safety
Previous document already being used?	Yes
If yes, in what format and where?	Trust Procedural document library
Proposed action to retrieve out-of-date copies of the document:	N/A
<b>To be disseminated to:</b>	
Document Library	Yes
Proposed actions to communicate the document contents to staff:	Include in the UHMB Weekly News – New documents uploaded to the Document Library

## 11. TRAINING

Is training required to be given due to the introduction of this procedural document? **No**

**If 'Yes', training is shown below:**

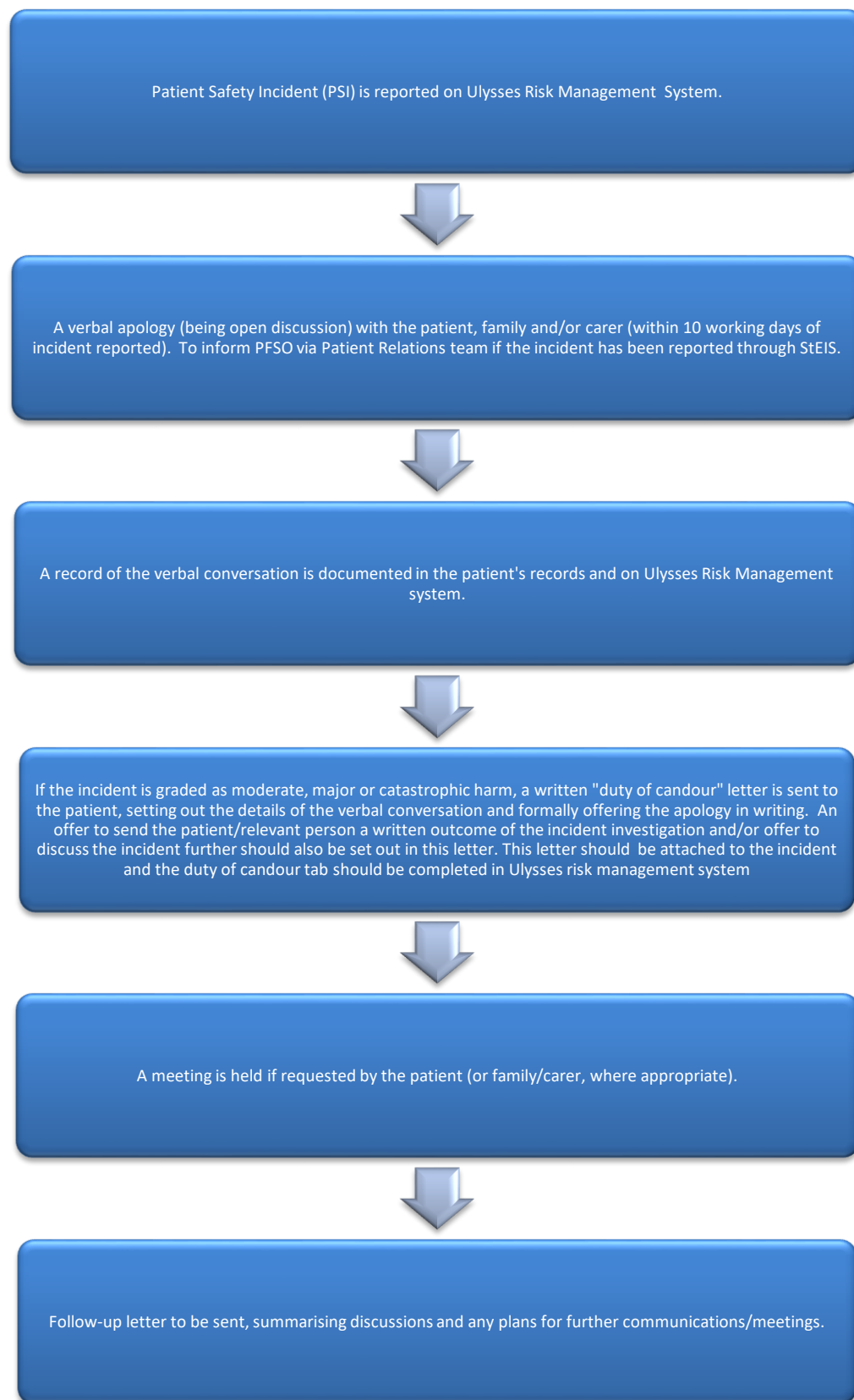
Action by	Action required	To be completed
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		<b>(date)</b>
E learning Ulysses incident management	Ongoing via TMS	Ongoing
Root cause analysis face to face training	bookable via TMS	Ongoing

<b>12. AMENDMENT HISTORY</b>				
<b>Version No.</b>	<b>Date of Issue</b>	<b>Page/Section Changed</b>	<b>Description of Change</b>	<b>Review Date</b>
1.0	01/09/2006		Original	19/09/2008
2.0	16/10/2007	All	Re draft	31/10/2010
3.0		All	Re draft based on latest NHSLA guidance and Trust Management structure.	June 2015
3.1	January 2013	Monitoring Section	Monitoring amended to reflect all minimum requirements	June 2015
4	April 2015	P3 and appendix 1	Included reference to statutory duty and amendment of template	Jan 2018
4.1	04/10/2017	Page 3	BSF page added	01/04/2018
4.2	11/04/2018	Page 1	Review Date extended – form 049/2018	01/09/2018
4.3	08/11/2018	Page 1	Review Date extended – form 155/2018	01/01/2019
4.4	10/07/2019	Page 1	Review date extended - form 115/2019	01/09/2019
5	24/07/2019	Document	Substantive changes	01/02/2022
5.1	27/10/2021	Appendix 2	Reference to PFSO role removed	01/02/2022
5.2	31/01/2022	Page 1	Review Date extended – extension ID #483	01/04/2022
5.3	06/05/2022	Page 1	Review Date extended – extension ID #564	01/07/2022
5.4	26/08/2022	Page 1	Review Date extended – extension ID #672	01/12/2022
5.5	21/07/2023	Page 1	Review Date extended – extension ID #901	01/10/2023
5.6	07/09/2023	Page 1	Review Date extended – extension ID #922	01/04/2024

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## Appendix 1: Flow chart



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## Appendix 2: Template Letter

Printable version: [Duty of Candour - Letter Template](#)

Please adapt this template following the initial being open discussion



### University Hospitals of Morecambe Bay NHS Foundation Trust

#### Trust Headquarters

Westmorland General Hospital  
Burton Road  
Kendal  
LA9 7RG

Tel: <insert telephone number>

Fax: <insert fax number>

Web: [www.uhmb.nhs.uk](http://www.uhmb.nhs.uk)

#### Sample letter

<insert date>

<insert reference>

#### PRIVATE AND CONFIDENTIAL

<insert name>

<insert address>

Dear <insert name>

I am writing, further to [our / X's] discussion on [date], to express my sincere apologies that (you have/your relative XXXXX has) been involved in an incident whereby .....(describe event here). As a Trust we are committed to being open with patients and carers when events such as these occur so that we gain a shared understanding of what happened, and what we can do to reduce the risk of such an incident occurring again in the future.

I would like to assure you that an internal investigation is already underway to try and establish the cause of the incident. However, we would also welcome your input in to the investigation as we feel it is extremely important to listen to the experiences and concerns of the patients and families involved.

If you would like to attend an initial meeting or to have a telephone discussion as part of the investigation process, please contact me within the next two weeks on the number below and the appropriate arrangements can be made. If you wish to attend a meeting, we would be more than happy for you to bring a friend/carer or relative with you for support. Prior to a meeting going ahead, I would appreciate your consideration as to whether you have any questions you would like addressing as part of the investigation. If we do not hear back from you within two weeks, we will assume that you would prefer not to be part of the initial investigation process.

Following conclusion of the incident investigation, we will contact you again to arrange how you would like to receive the findings of the investigation.

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I appreciate that this may be a difficult time for you/your family, and we do not wish to intrude or cause further distress, but we feel it is important to keep you informed of the process underway and ensure that communication channels remain open.

I will be acting as your lead contact for the duration of the investigation and can be contacted on telephone number xxxxx xxxxxxxx.. [This sentence only to be used in cases where the harm is thought to be graded as major or catastrophic harm reported through StEIS].

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## Appendix 3: Values and Behaviours Framework

To help create a great place to work and a great place to be cared for, it is essential that our Trust policies, procedures and processes support our values and behaviours. This document, when used effectively, can help promote a positive workplace culture. By following our own policies and with our **ambitious** drive we can cultivate an **open, honest and transparent culture** that is truly **respectful and inclusive** and where we are **compassionate** towards each other.

<h3>We are... Compassionate</h3>  <p><b>We will:</b></p> <ul style="list-style-type: none"> <li>• Be kind and caring to each other; our patients and families and our partners</li> <li>• Consider the feelings of others</li> <li>• Work together to deliver safe care and a safe working environment</li> <li>• Be proud of the role we do and how this contributes to patient care</li> </ul> <p><a href="http://www.uhmb.nhs.uk">www.uhmb.nhs.uk</a></p>	<h3>We are... Respectful and inclusive</h3>  <p><b>We will:</b></p> <ul style="list-style-type: none"> <li>• Show respect to and for everyone</li> <li>• Act professionally at all times</li> <li>• Communicate effectively – listen to others and seek clarity when needed</li> <li>• Value each other and the contribution of everyone</li> </ul>	<h3>We are... Ambitious</h3>  <p><b>We will:</b></p> <ul style="list-style-type: none"> <li>• Go beyond traditional boundaries; being positively receptive to change and improvement</li> <li>• Work with colleagues and system partners to improve services for our patients, families and carers</li> <li>• Support each other to listen, learn and develop</li> <li>• Collaborate with and empower each other</li> </ul>	<h3>We are... Open, honest and transparent</h3>  <p><b>We will:</b></p> <ul style="list-style-type: none"> <li>• Seek out feedback and act on it</li> <li>• Take personal responsibility and accountability for our own actions</li> <li>• Not be afraid to be challenged</li> <li>• Ensure consistency and fairness in our approach</li> </ul> <p>@UHMBT  </p>
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## Equality Impact Assessment Form

Department/Function	Governance	
Lead Assessor	Nicky Edmondson	
What is being assessed?	Being Open policy	
Date of assessment	25/07/2019	
What groups have you consulted with? Include details of involvement in the Equality Impact Assessment process.	Equality of Access to Health Network	<input type="radio"/> Yes <input checked="" type="radio"/> No
	Staff Side Colleague	<input type="radio"/> Yes <input checked="" type="radio"/> No
	Service Users	<input type="radio"/> Yes <input checked="" type="radio"/> No
	Staff Inclusion Network(s)	<input type="radio"/> Yes <input checked="" type="radio"/> No
	Personal Fair Diverse Champions	<input type="radio"/> Yes <input checked="" type="radio"/> No
	Other (including external organisations) Please give details: Clinical Director, CCS	<input checked="" type="radio"/> Yes <input type="radio"/> No

1) What is the impact on the following equality groups?		
<b>Positive:</b> <ul style="list-style-type: none"> <li>➤ Advance Equality of opportunity</li> <li>➤ Foster good relations between different groups</li> <li>➤ Address explicit needs of Equality target groups</li> </ul>	<b>Negative:</b> <ul style="list-style-type: none"> <li>➤ Unlawful discrimination / harassment / victimisation</li> <li>➤ Failure to address explicit needs of Equality target groups</li> </ul>	<b>Neutral:</b> <ul style="list-style-type: none"> <li>➤ It is quite acceptable for the assessment to come out as Neutral Impact.</li> <li>➤ Be sure you can justify this decision with clear reasons and evidence if you are challenged</li> </ul>
Equality Groups	Impact (Positive / Negative / Neutral)	Comments
<b>Race</b> (All ethnic groups)	Positive	<ul style="list-style-type: none"> <li>➤ Provide brief description of the positive / negative impact identified benefits to the equality group.</li> <li>➤ Is any impact identified intended or legal?</li> </ul>
<b>Disability</b> (Including physical and mental impairments)	Neutral	Guidance includes recommendation advice to seek support from an advocate or translator if required.
<b>Sex</b>	Neutral	
<b>Gender reassignment</b>	Neutral	
<b>Religion or Belief</b>	Neutral	
<b>Sexual orientation</b>	Neutral	
<b>Age</b>	Neutral	
<b>Marriage and Civil Partnership</b>	Neutral	
<b>Pregnancy and maternity</b>	Neutral	
<b>Other</b> (e.g. caring, human rights)	Neutral	

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2) In what ways does any impact identified contribute to or hinder promoting equality and diversity across the organisation?	
--	--

3) If your assessment identifies a negative impact on Equality Groups you must develop an action plan <b>to avoid discrimination and ensure opportunities for promoting equality diversity and inclusion are maximised.</b> <ul style="list-style-type: none"> <li>➤ This should include where it has been identified that further work will be undertaken to further explore the impact on equality groups</li> <li>➤ This should be reviewed annually.</li> </ul>
---

Action Plan Summary		
Action	Lead	Timescale

*This form will be automatically submitted for review for Policies and Procedures once approved by Policy Group. For all other assessments, please return an electronic copy to [EIA.forms@mbht.nhs.uk](mailto:EIA.forms@mbht.nhs.uk) once completed.*

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