Duty of Candour Policy and Procedure: Communicating with Patients and/or their Relatives/Carers following a Patient Safety Incident (N-053)

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Policies should be accessed via the Trust intranet to ensure the current version is used

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PATIENTS' CHARTER: 'BEING OPEN' WITH OUR PATIENTS

Staff within Humber Teaching 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 not go as expected

We make a commitment to all people using our services that if you are harmed as a result of any unintended or unexpected incident that you will be told as soon as is reasonably practicable that a notifiable incident under the duty of candour regulations has occurred.

You will be contacted to be given the opportunity to be involved in any investigation we undertake. We will ensure you are fully informed about the steps we are taking to understand what happened and why. You will receive a written and truthful account of what has happened and where errors have been made resulting in harm you will receive an apology in writing.

We will offer support to you and your family and provide details of a person as a point of contact.

We will provide you with updates of our investigation and provide full details to you both in person and in writing of the findings.

Executive Director of Nursing, Allied Health and Social Care Professionals
Humber Teaching NHS Foundation Trust

1. INTRODUCTION

Every day people are treated safely in the NHS. Occasionally however, something goes wrong with their treatment or care which causes or has the potential to cause harm or distress (this is known as a patient safety incident). This policy has been designed to assist staff within Humber Teaching NHS Foundation Trust to be open, honest and transparent with patients and/or their next of kin (nearest relative) and provides guidance on the points to consider. Staff may feel anxious about informing patients and or apologising when incidents that have caused harm or had a potential to cause harm to have occurred, worrying that they might say the wrong things, make the situation worse and/or be blamed for the mistake. Communicating openly, honestly and effectively with patients and/or their next of kin is known to decrease the trauma felt for both the patient/next of kin and the staff involved. Research has shown that patients will forgive errors when they are disclosed promptly, fully and compassionately. Being open when handled well can reduce the likelihood of a subsequent complaint.

The duty of candour is a crucial part of a positive, open and safe culture. People using any type of health or social care service have a right to be informed about all elements of their care and treatment- and all providers have a responsibility to be open and honest with those in their care

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Openness has benefits for healthcare staff. These include satisfaction that patients and/or their next of kin have been informed of the incident that has occurred which helps to build and maintain a positive relationship between the professional and patient which is built upon trust and professionalism. Openness is also beneficial for the reputation of the healthcare organisation.

The duty of candour requires registered providers and registered managers (known as ‘registered persons’) to act in an open and transparent way with people receiving care or treatment from them. The regulation also defines ‘notifiable safety incidents’ and specifies how registered persons must apply the duty of candour if these incidents occur. Refer to appendix one for the Duty of Candour regulation in full.

The approach outlined within this policy provides assurance of the Trust’s commitment to improving patient safety and continuous quality improvement therefore aims to complement existing arrangements and practices. Further, it is consistent with the Trust’s ‘just culture’ 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).

2. SCOPE

This policy applies to all permanent (clinical and non-clinical) staff, locum, agency, bank and voluntary staff and students working within the Trust and applies to:

All Patient safety incidents, require an apology, but those listed below require a formal response:

- moderate harm
- prolonged psychological harm
- severe harm
- death
- incidents that have the potential to cause significant harm in the future

A formal response ensures all communication with patients and/or relatives and between staff/healthcare teams and, where relevant, other healthcare organisations, is being open, honest and occurs as soon as reasonably practicable following an incident.

3. DEFINITIONS

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

Notifiable patient safety incident
This is a specific term defined in the duty of candour regulation. It should not be confused with other types of safety incidents or notifications.

A notifiable safety incident must meet all 3 of the following criteria:

- It must have been unintended or unexpected.
- It must have occurred during the provision of an activity CQC regulates.
- In the reasonable opinion of a healthcare professional, already has, or might, result in death or severe or moderate harm to the person receiving care.

A notifiable patient safety incident is also applicable if discovered when undertaking mortality reviews, or other retrospective audits. These could have happened some time ago or relate to care delivered by another provider. The provider who discovers the incident should work with others who are responsible for the incident that occurred in notifying the relevant person of the incident.

Definitions of Harm

Moderate harm
Harm that requires a moderate increase in treatment and significant, but not permanent, harm.

Severe 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)

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

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

Relevant person
This is usually the person who has been affected by the patient safety incident or the person acting lawfully on their behalf.

4. POLICY STATEMENT

This policy provides guidance on the statutory duty of candour to assist staff to effectively communicate with patients and/or their next of kin involved in patient safety incidents to ensure that staff feel empowered and supported to be open with patients and or next of kin when moderate harm and above has occurred within the Trust.

The Trust encourages staff to report patient safety incidents that have occurred or were prevented, i.e. ‘near misses’, 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 or low harm incidents are discussed with patients. However, for incidents where no or low harm has occurred, staff should offer an apology and explanation of what has happened at the time the incident occurs in line with their professional codes under their professional duty of candour. If a patient has died whilst under the trust's services, there is a requirement that the appropriate service makes contact with the family by telephone or sends a letter of condolence to the family of the deceased. If a more in-depth investigation is required, the family will also receive a letter from the Director of Nursing.

5. ROLES AND RESPONSIBILITIES

The Board
Responsible for promoting a culture of openness to improve patient safety and the quality of healthcare systems within the Trust.

Chief Executive
The Chief Executive is responsible for ensuring that 'Being Open' is integral to the Trust's commitment and approach to the duty of candour. The chief executive and the Trust Board hold ultimate accountability for ensuring the provision of high quality, safe and effective services within the Trust, ensuring robust systems and processes are in place when adverse incidents or patient safety incidents occur. The Chief Executive and Trust Board are also accountable for ensuring compliance with duty of candour and ensuring learning to prevent reoccurrence.

Director of Nursing, Allied Health and Social Care Professionals
The director of nursing, allied health and social care professionals is responsible for the periodic review and implementation of this policy and for ensuring that suitable training programmes for staff are in place.

Chief Operating Officer
The chief operating officer is responsible for ensuring that the statutory responsibilities regarding compliance with duty of candour are met by operational services.

Divisional Clinical Leads
The divisional clinical leads are responsible for ensuring the implementation of this policy within their areas and will ensure:

- All staff are open, honest and transparent with patients and/or their next of kin following patient safety incidents and or near misses that have occurred or have the potential to cause significant harm. This approach is also integral to the processes for responding to complaints, and including those that have the potential to become a claim.

Agreement is reached regarding who will make the initial contact with those involved, or their relatives/carers in complex situations to ensure compliance with the requirements for duty of candour.

Service Managers/Matrons/Team Leaders/Charge Nurses/Ward Managers
Responsible for:

- Mentoring and supporting their staff, within their sphere of responsibility, in being open and honest throughout the duty of candour process (following patient safety incident investigations /mortality reviews/complaints and claims), for incidents where moderate harm and above have occurred.
- Reviewing all incidents and moderating the level of harm to ensure that the statutory duty of candour is considered for all incidents that have occurred for harm caused.
- Reviewing all incidents to ensure that any incidents that have the potential to cause significant harm, staff are aware that this meets the statutory duty of candour.

- Reviews with the service that contact has been made with the family by telephone or a letter sent of condolence to the family if the patient is deceased.

Senior clinicians
Will mentor and support healthcare colleagues in 'being open' and support colleagues in their duty of candour responsibilities 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 debriefing 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

Staff
Staff involved in the incidents, investigation or follow-up of patient safety incidents, complaints and claims 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 3.

Clinical Risk Management Group (CRMG)
CRMG, on behalf of the Quality and Patient Safety Group (QPaS) is the group that monitors compliance with duty of candour.

Patient Safety Team
Monitors compliance with duty of candour for all harms that have caused moderate, severe and significant harm on a weekly basis moderating harm in discussions with the reporter as required.

Quality Committee
The Quality Committee on behalf of the Trust Board, is responsible for monitoring compliance with this policy.

6. PROCEDURE

What you must do when you discover a reportable incident:

6.1. Inform the Patient or Relevant Person

The patient or relevant person (see definitions in section 3.4) must be informed of the patient safety incident that has occurred. 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 a patient
- Where the patient 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 policy on the Mental Capacity Act
- Where the patient is under 16 and not competent to make a decision in relation to their care and treatment

Where the patient is under 16 considerations should be given to whether the child has the maturity to make their own decisions and to understand the implications of decisions. This is referred to as Gillick competence. This can be discussed supportively with parents/carers.

a. Inform the relevant person, face-to-face, that a notifiable patient safety incident has taken place.
b. Apologise, a personalised apology will be more meaningful. People are sometimes uncertain about how to apologise when an incident is still being investigated. But from the start, simple straightforward expressions of sorrow and regret can and should be made for the harm the person has suffered. Apologising to a patient / carer does not mean that you are admitting legal liability, it's just the right thing to do.
c. Provide a true account of what happened, explaining whatever you know at that point.
d. Explain to the relevant person what will happen now and in the coming weeks as we investigation the incident.
e. Follow up by providing this information, and the apology, in writing, and providing an update on any enquiries.
f. Keep a secure written record of all meetings and communications with the relevant person.

If the relevant person cannot be, or refuses to be, contacted, you may not be able to carry out all of the regulation (the parts relating to notifiable safety incidents), but you must keep a written record of all attempts to make contact. You must still report the incident through the appropriate notifications system and investigate it in order to prevent harm occurring to others, this encourages a learning culture.

Please link into the Engaging Patient and Families policy for more information around supporting patients and families. Engaging with Patient and Families Policy N-074.pdf (humber.nhs.uk)

6.2. Providing Support to the Patient/Relevant Person

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

- Treating the person 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 wish
- Providing support to complain

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

6.3. Report the incident

These include any notifiable patient safety incidents that either have caused harm or have the potential to cause harm. This also includes incidents that have been discovered when undertaking patient safety incidents, mortality reviews or retrospective record keeping audits.

All incidents must be reported via the Datix incident reporting system within 24 hours following the incident or as soon reasonably practicable after they are identified.

Where appropriate, incidents may need to be reported to external agencies such as the police, Health and Safety Executive or the local authority (safeguarding incidents). Please contact the Trusts Patient safety Team for guidance in relation to reporting incidents to external agencies.

6.4. Determining level of response and whether the incident is notifiable

The level of response to patient safety incidents will depend on the seriousness and nature of the incident. If you are unclear, seek immediate advice from your line manager or manager on call if out of hours

When a notifiable patient safety incident is discovered following any investigation or review, a discussion should be held immediately with the divisional clinical lead and senior staff in the Patient Safety Team to agree the approach.

All incidents will be reviewed in the corporate safety huddle which is held daily Monday to Friday. Following the incident being reviewed it may require a further investigation. Patient Safety Incident Response Policy N-075.pdf (humber.nhs.uk)

6.5. Offering a meaningful apology

Saying sorry:

- is always the right thing to do
- is not an admission of liability
- acknowledges that something could have gone better
- is the first step to learning from what happened and preventing it recurring.

People who have been harmed and/or their carer's (if the person lacks the capacity to consent) must receive a truthful notification that an incident affecting them has occurred, along with a sincere expression of sorrow or regret, as soon as reasonably practicable after the incident has been identified. Patients 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. Apologising and explaining when patients have been harmed can be very difficult. This guidance aims to help ensure that you follow best practice.

A verbal apology should be made by the most appropriate person, giving consideration to seniority, relationship to the patient, experience and expertise in the type of notifiable incident that has occurred. Within inpatient services this could be the charge nurse or the matron of the services, or within primary care or community services, the clinical lead or the team manager or service manager of the services.

Factors which will be taken into account will include:

- Nature of the patient safety incident or complaint
- Degree and nature of harm sustained (physical or psychological)
- Needs and wishes of the patient and/or carers
- Capacity of the patient, and whether this is likely to change
- Involvement of any carers or relatives
- Confidentiality issues
- Assistance with communication e.g. interpreters, advocates, or communication aids

Alongside the apology the patient and/or their next of kin should be provided with an explanation of what you know about the incident at the time, what further enquiries will be made and agreeing

how they wish to receive feedback regarding the outcome. A written record should be kept of the notification and apology to the patient or their next of kin.

The patient and/or their next of kin should be offered the opportunity to be involved in any investigation into the circumstances regarding the incident including working together to agree the areas for review or questions to ask.

6.6. Timescales

CQC states - As soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred see appendix 1

Any information given is based solely on the facts known at the time. The healthcare professional providing the information should explain that the patient, 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.

If the notifiable patient safety incident is discovered following a mortality review or retrospective audit, staff involved should seek support from their immediate line manager in consultation with the divisional clinical lead in meeting with the family to discuss the incident.

6.7. Meeting with the patient and or next of kin

6.7.1. 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.
- Staff should not attend being open discussions alone. The person taking the lead should be supported by at least one other senior member of staff
- Ensure that those members of staff who do attend the meetings can continue to do so; continuity is very important in building relationships
- 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

6.7.2. When should it be held?

- As soon after the incident as possible. A letter should be sent to the patient, family / carer.
- Consider the patient's and/or their relatives'/carer's home and social circumstances
- Check that they are happy with the timing of the discussion.
- Offer them a choice of times and confirm the chosen date in writing
- Do not cancel the meeting unless absolutely necessary

6.7.3. 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
- Where appropriate, secure online meeting platforms can be used adhering to the Electronic Communications and Internet Acceptable Use Procedure.
- Home visits can be arranged and this might be most suitable for the patient / family.

6.7.4. How should you approach the patient and/or their relatives/carers?

- Speak to the patient and/or their next of kin 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 people with learning disabilities

Staff should also ascertain if the patient has a Lasting Power of Attorney (LPA) in place and consult with them in line with the MCA 2005, where a patient lacks capacity to make decisions.

6.7.5. What should be discussed?

- Introduce and explain the role of everyone present to the patient and/or their next of kin and ask them if they are happy with those present
- Acknowledge what happened and apologise on behalf of the team and the organisation. Apologise and express regret (this 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
- Offer the opportunity to be involved in the incident investigation including working together to agree the areas for review or questions to ask.
- 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

Agree timescales with the person as to when a written record will be completed and available.

6.8. Follow up in writing within the timescales agreed with the person

Clarify in writing the information and apologies given in the discussion or face to face meeting held. Reiterate the key points of the discussion record the 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 next of kin 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 an apology given to patients and/or their next of kin 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 next of kin receive a meaningful apology. An apology does not constitute an admission of liability. It is recognised that the provision of an apology decreases the chances of litigation claims. Patients and their next of kin 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. Be open and honest with regards to information known at the time.

6.9. 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. In some instances the patient safety team can make contact with the coroner to access next of kin details they may hold and file.

6.10. Documenting communications

Documentation of discussions should include (as appropriate):

- the time, date and place, as well as the names and job titles of attendees
- what the discussion covered and any actions agreed
- the plan for providing further information to the patient and/or their next of kin 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 next of kin
- questions raised and answers given
- plans for any follow-up meetings
- offer of any independent advice
- progress notes relating to the clinical situation and an accurate summary of all the points explained to the patient and/or next of kin

Any investigation reports to be shared with the patient/next of kin within ten days of being signed off as complete, by the director of nursing, medical director or chief operating officer.

The patient and/or relevant person should be provided with a written record of the meeting.

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.

6.11. Support for staff in relation to Duty of Candour

Staff may be understandably anxious about this process. 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 the Trust:

The Trust has in place a just culture' approach 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 divisional clinical lead and clinical director to mentor and support colleagues in being open and honest throughout the being open process. Alternatively, please contact a member of the Nursing and Quality Team.

Arrangements are in place within the divisions for debriefing 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 receives feedback following the incident investigation. Counselling and support services are available via Occupational Health.

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 that produces an adverse result, for whatever reason, to express sorrow or regret at the outcome.

Communicating a notifiable safety incident may lead to an angry reaction from patients, 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:

- General managers can also provide advice and support to staff in relation to duty of candour issues.
- The Nursing and Quality Team and the Complaints Team will also be sources of support and advice.

All staff should be issued with the 'Navigating Difficult Events at Work' booklet for reference and support.

6.12. Confidentiality

Consideration must be given to the confidentiality of all patients, 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 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

6.12.1. 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.

7. EQUALITY AND DIVERSITY

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

This has been completed and does not highlight any concerns.

8. MENTAL CAPACITY

The Trust supports the following principles, as set out in the Mental Capacity Act (2005) 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.

Lasting Powers of Attorney (LPA)
Any person aged 18 or over with capacity can appoint an attorney (or more than one attorney) to make decisions about their personal welfare and/or their property and affairs if they lose capacity to make such decisions themselves in the future. Under a Lasting Power of Attorney, the appointed person (known as the' Attorney' or 'Donee') can make decisions that are as valid as one made by the person granting the Power of Attorney (the 'Donor'):

- Property and affairs (including financial matters)
- Personal welfare decisions (including healthcare and consent to medical treatment)

Even where the LPA include healthcare decisions, Attorneys do not have the right to consent to or refuse treatment in situations where:

- The Donor still has capacity to make the particular healthcare decision
- The Donor has made an Advance Decision to refuse the proposed treatment - unless the Donor made the LPA giving the Attorney the right to consent to or refuse the treatment after the Advance Decision was made
- A decision relates to life sustaining treatment unless the LPA document expressly authorises the Attorney to consent to or refuse life sustaining treatment
- The Donor is detained under the MHA 1983, in which case an Attorney cannot consent to or refuse treatment for a mental disorder for a patient detained under the Mental Health Act 1983 (although there is an exception for ECT treatment – see section 58A of the MHA 1983)
- LPAs cannot give Attorneys the power to demand specific forms of medical treatment that healthcare staff do not believe are necessary or appropriate

9. IMPLEMENTATION

This policy will be disseminated by the method described in the Policy and Procedural Documents Development and Management Policy.

Training will be provided via the incident management training, as part of the Systems based approach training and as part of complaints/claims awareness sessions

10. MONITORING AND AUDIT

Monitoring of the Duty of Candour policy is undertaken by the Clinical Risk Management Group and the daily corporate safety huddle.

All incidents will be reviewed by the line manager of the service and moderated up or down to ensure that the statutory requirements of duty of candour is fulfilled for all incidents that have caused moderate harm and above.

Incidents that trigger the statutory duty of candour will be monitored within the patient safety team on a weekly basis. All incidents that trigger duty of candour will be reviewed and verified; confirming meets the statutory requirement for duty of candour or moderated down.

Compliance with duty of candour will be monitored by the Quality Committee.

11. RELEVENT POLICIES/PROTOCOLS/GUIDELINES

This document should be read in conjunction with the following:

- Risk Management section of the Trust intranet
- Complaints and Feedback Policy
- Claims Management Policy
- Freedom to Speak Up Procedure
- Safeguarding Adults Policy
- Safeguarding Children Policy
- Mental Capacity Policy
- Electronic Communications and Internet Acceptable Use Procedure
- Interpreter Services (Hull & ER)
- Interpreter Services Guidelines (Scarborough & Ryedale and Whitby)
- Patient Safety Incident Response policy
- Engaging with patients and family's policy
- Patient Safety Incident Analysis Using Swarm Huddle Methodology

12. REFERENCES

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GMC (2014) Joint statement from Chief Executives of statutory regulators of healthcare professionals "Openness and honesty – the professional duty of candour". London, GMC.

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Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 20. Updated March 2021

Appendix 1: Duty of Candour: The Regulation in Full

1. Registered persons 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.

2. As soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred a registered person must:
   a) notify the relevant person that the incident has occurred in accordance with paragraph (3), and
   b) provide reasonable support to the relevant person in relation to the incident, including when giving such notification.

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

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.

5. But if the relevant person cannot be contacted in person or declines to speak to the representative of the registered person:
   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.

6. The registered provider must keep a copy of all correspondence with the relevant person under paragraph (4).

7. In this regulation:
   "apology" means an expression of sorrow or regret in respect of a notifiable safety incident;
   "moderate harm" means:
      a) harm that requires a moderate increase in treatment, and
      b) significant, but not permanent, harm;
   "moderate increase in treatment" means an unplanned return to surgery, an unplanned re-admission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, or transfer to another treatment area (such as intensive care);
   "notifiable safety incident" has the meaning given in paragraphs (8) and (9);
   "prolonged pain" means pain which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days;
   "prolonged psychological harm" means psychological harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days;
   "relevant person" means the service user or, in the following circumstances, a person lawfully acting on their behalf:
      a) on the death of the service user,
      b) where the service user is under 16 and not competent to make a decision in relation to their care or treatment, or
      c) where the service user is 16 or over and lacks capacity in relation to the matter;
   "severe harm" means a permanent lessening of bodily, sensory, motor, physiologic or intellectual functions, including removal of the wrong limb or organ or brain damage, that is

related directly to the incident and not related to the natural course of the service user's illness or underlying condition.

8. In relation to a health service body, “notifiable safety incident” means any unintended or unexpected incident that occurred in respect of a service user during the provision of a regulated activity that, in the reasonable opinion of a health care professional, could result in, or appears to have resulted in:
    a) the death of the service user, where the death relates directly to the incident rather than to the natural course of the service user's illness or underlying condition, or
    b) severe harm, moderate harm or prolonged psychological harm to the service user.

9. In relation to any other registered person, “notifiable safety incident” means any unintended or unexpected incident that occurred in respect of a service user during the provision of a regulated activity that, in the reasonable opinion of a health care professional:
    a) appears to have resulted in:
        i) 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,
        ii) an impairment of the sensory, motor or intellectual functions of the service user which has lasted, or is likely to last, for a continuous period of at least 28 days,
        iii) changes to the structure of the service user's body,
        iv) the service user experiencing prolonged pain or prolonged psychological harm, or
        v) the shortening of the life expectancy of the service user; or
    b) requires treatment by a health care professional in order to prevent:
        i) the death of the service user, or
        ii) any injury to the service user which, if left untreated, would lead to one or more of the outcomes mentioned in sub-paragraph (a).

CQC Last updated:
30 June 2022

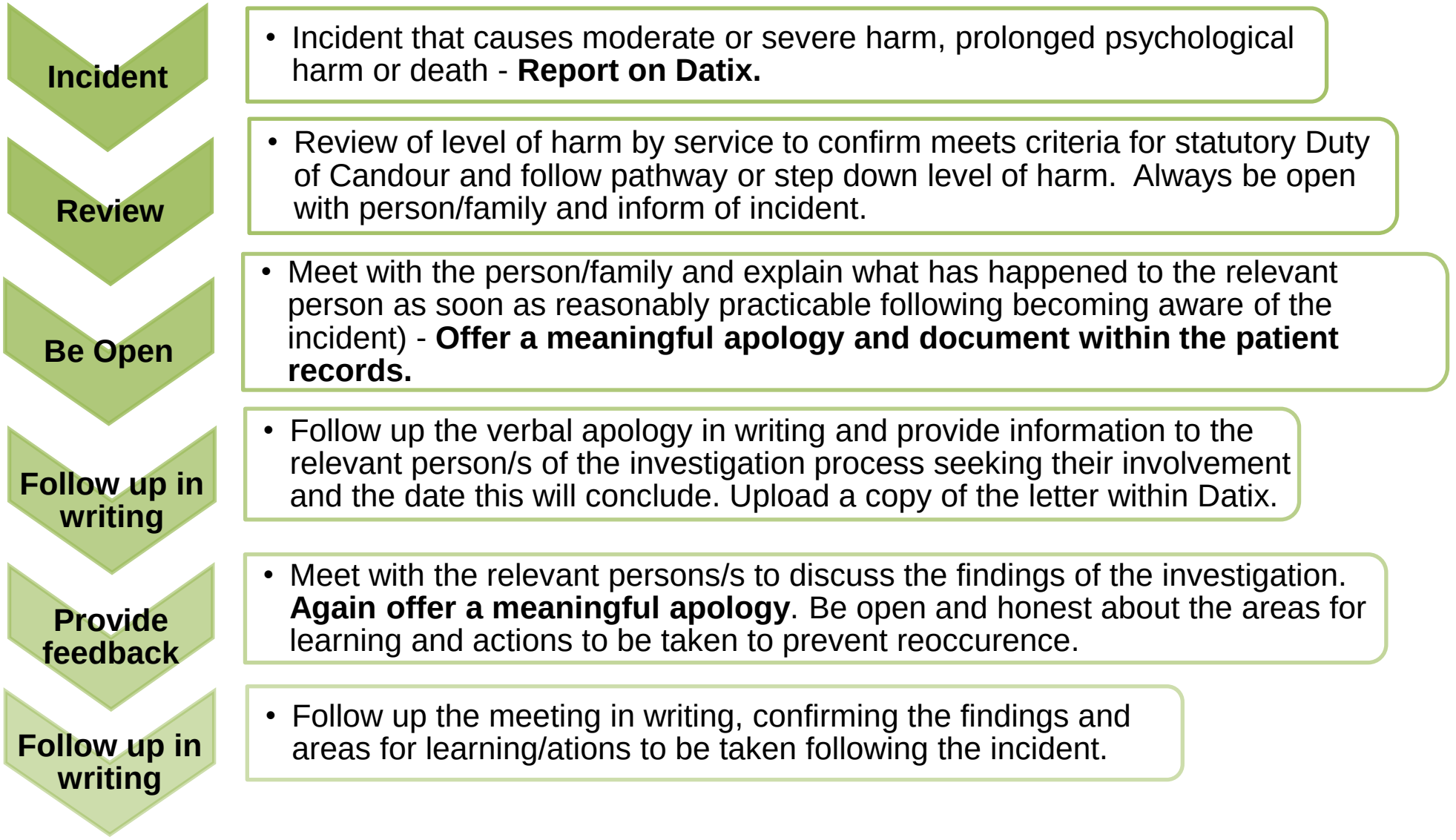
Appendix 2: Being Open Principles

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 through the datix system.
- **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 or when the incident is known to have occurred. 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 five 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 divisions' 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 patients and/or carers begins with the recognition that a patient 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.

Appendix 3: Pathway – Duty of Candour



Appendix 4: Template Letter 1

TEMPLATE LETTER 1: These are a guide only and should be personalised to address the issues raised within your communication with the initial meeting with the family

INCIDENT THAT TRIGGERS
DUTY OF CANDOUR
Letters for serious incidents are detailed within the Trust's Serious Incident and Significant Event policy with guidance and support from the Trust Risk Team

Building A,
Willerby Hill Business Park,
Willerby Court, Hull,
HU10 6FE

Tel: 01482 389135

Our Ref:

(INSERT DATE)

Private and Confidential
(INSERT NAME AND 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

Appendix 5: Template Letter 2

TEMPLATE LETTER 2: These are a guide only and must be personalised to address the issues raised within your communication following the investigation

ON COMPLETION OF THE
INVESTIGATION OF AN INCIDENT THAT TRIGGERS THE
DUTY OF CANDOUR REQUIRMENT

Building A,
Willerby Hill Business Park,
Willerby Court, Hull,
HU10 6FE

Tel: 01482 389135

Our Ref:

(INSERT DATE)

Private and Confidential
(INSERT NAME AND 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).

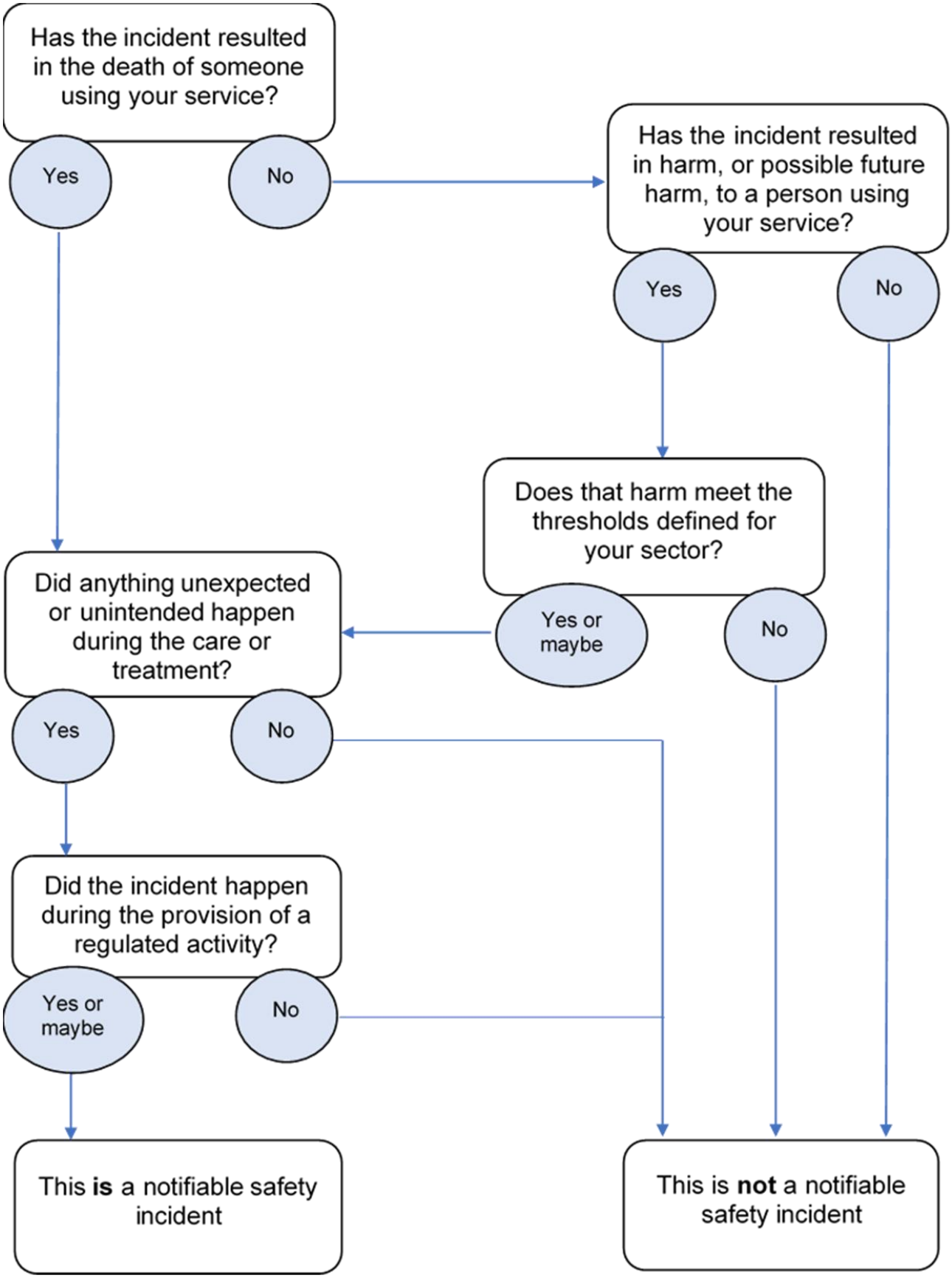
(* DELETE AS APPROPRIATE)

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/DIVISIONAL DIRECTOR/)

Appendix 6: Duty of Candour Flow Chart



Appendix 7: Equality Impact Assessment (EIA)

For strategies, policies, procedures, processes, guidelines, protocols, tenders, services

1. Document or Process or Service Name: Duty of Candour Policy
2. EIA Reviewer (name, job title, base and contact details): Su, Davis, Senior Clinical Governance Manager
3. Is it a Policy, Strategy, Procedure, Process, Tender, Service or Other? Policy

Main Aims of the Document, Process or Service

The approach outlined within this policy provides assurance of 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 'just culture ' 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).

Please indicate in the table that follows whether the document or process has the potential to impact adversely, intentionally or unwittingly on the equality target groups contained in the pro forma

Equality Target Group	Is the document or process likely to have a potential or actual differential impact with regards to the equality target groups listed?	How have you arrived at the equality impact score?
1. Age 2. Disability 3. Sex 4. Marriage/Civil Partnership 5. Pregnancy/Maternity 6. Race 7. Religion/Belief 8. Sexual Orientation 9. Gender re-assignment	Equality Impact Score Low = Little or No evidence or concern (Green) Medium = some evidence or concern(Amber) High = significant evidence or concern (Red)	a) who have you consulted with b) what have they said c) what information or data have you used d) where are the gaps in your analysis e) how will your document/process or service promote equality and diversity good practice

Equality Target Group	Definitions	Equality Impact Score	Evidence to support Equality Impact Score
Age	Including specific ages and age groups: Older people Young people Children Early years	Low	The policy is applicable across all age ranges
Disability	Where the impairment has a substantial and long term adverse effect on the ability of the person to carry out their day to day activities: Sensory Physical Learning Mental health (including cancer, HIV, multiple sclerosis)	Low	The policy is applicable to all, regardless of any disability
Sex	Men/Male Women/Female	Low	The policy is not influenced by sex/gender
Marriage/Civil Partnership		Low	The policy is applicable to all, regardless of marital state
Pregnancy/ Maternity		Low	The policy is not affected by pregnancy
Race	Colour Nationality Ethnic/national origins	Low	The policy is applicable to all, regardless of race

Equality Target Group	Definitions	Equality Impact Score	Evidence to support Equality Impact Score
Religion or Belief	All religions Including lack of religion or belief and where belief includes any religious or philosophical belief	Low	The policy equally applies to all regardless of religion or belief
Sexual Orientation	Lesbian Gay men Bisexual	Low	The policy equally applies to all regardless of sexual orientation
Gender Reassignment	Where people are proposing to undergo, or have undergone a process (or part of a process) for the purpose of reassigning the person's sex by changing physiological or other attribute of sex	Low	The policy equally applies to all regardless of gender identity

Summary

Please describe the main points/actions arising from your assessment that supports your decision. This policy is applicable to all patient safety incidents and is not influenced by any equality factors above. It is incumbent upon the staff member fulfilling the duty of candour requirements to take into account any factors that may require taking account of.	
EIA Reviewer: Michelle Ireland	
Date completed: 23.05.2024	Signature: Michelle Ireland

Appendix 8: Document Control Sheet

Document Type	Duty of Candour Policy		
Document Purpose	To reflect the process to be followed to comply with the statutory duty of candour		
Consultation/Peer Review:	Date:	Group/Individual	
List in right hand columns consultation groups and dates	July 2020	Quality and Patient Safety Group	
Approving Committee:	Quality and Patient Safety Group	Date of Approval:	16 May 2024
Ratified at:	N/A	Date of Ratification:	
Training Needs Analysis: *(please indicate training required and the timescale for providing assurance to the approving committee that this has been delivered)*		Financial Resource Impact	
Equality Impact Assessment undertaken?	Yes [✓]	No [ ]	N/A [ ] Rationale:
Publication and Dissemination	Intranet [✓]	Internet [ ]	Staff Email [✓]
Master version held by:	Author [ ]	HealthAssure [✓]	
Implementation:	*Describe implementation plans below - to be delivered by the Author:*		
	The policy has been revised to reflect the processes developed to comply with the statutory duty of candour already in operation. The policy will be uploaded to the intranet and shared through the divisional governance structures.		
Monitoring and Compliance:	Policy implementation will be monitored via CRMG		

Document Change History: (please copy from the current version of the document and update with the changes from your latest version)			
Version number/name of procedural document this supersedes	*Type of change, e.g. review/legislation*	*Date*	*Details of change and approving group or executive lead (if done outside of the formal revision process)*
1.00	*New policy*	*June 2015*	*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.*
1.01	*Review*	*Dec 2015*	*Changes following consultation with Trust Board.*
1.02	*Review*	*May 2016*	*Duty of Candour applies when an incident has the potential to cause harm and applicability when undertaking mortality reviews and or retrospective audits of care.* *Changes to review of Duty of Candour processes.*
1.03	*Review*	*May 2017*	*The Patients' Charter has been moved to the front of the document.* *Clarification regarding who should make verbal apologies.* *Addition of the Duty of Candour leaflet for patients and their families*
1.04	*Review*	*Sept 2017*	*Changes made to pathway*
1.05	*Review*	*July 2020*	*Minor amendments*
1.06	*Review*	*February 2021*	*Minor amendments – replaced care groups with divisions and changed references to Su Davis to Michelle Ireland*
1.07	*Review*	*April 2021*	*Updated to reflect latest CQC update to the Duty of Candour dated 11 March 2021. Definitions updated. DOC regulation in full added (Appendix 1).* *Removal of reference to the Pressure Ulcer Learning and Review Forum in section 5.10 as per QPaS minutes of 14 April 2021.*
1.08	*Review*	*May 2024*	*Updated to reflect the changes made to patient safety incidents following the implementation of the Patient Safety Incident Investigation Framework (PSIRF).* *Approved at QPaS (16 May 2024).*