University Hospitals of Derby and Burton NHS Foundation Trust

TRUST POLICY FOR BEING OPEN AND DUTY OF CANDOUR

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The policy will be published on the Trust intranet.
There will be no specific formal training on the policy; however, the following training will include the culture and requirements of the Duty of Candour:

• Incident Reporting within the Trust Induction training
• Complaints and PALS management training</td></tr>
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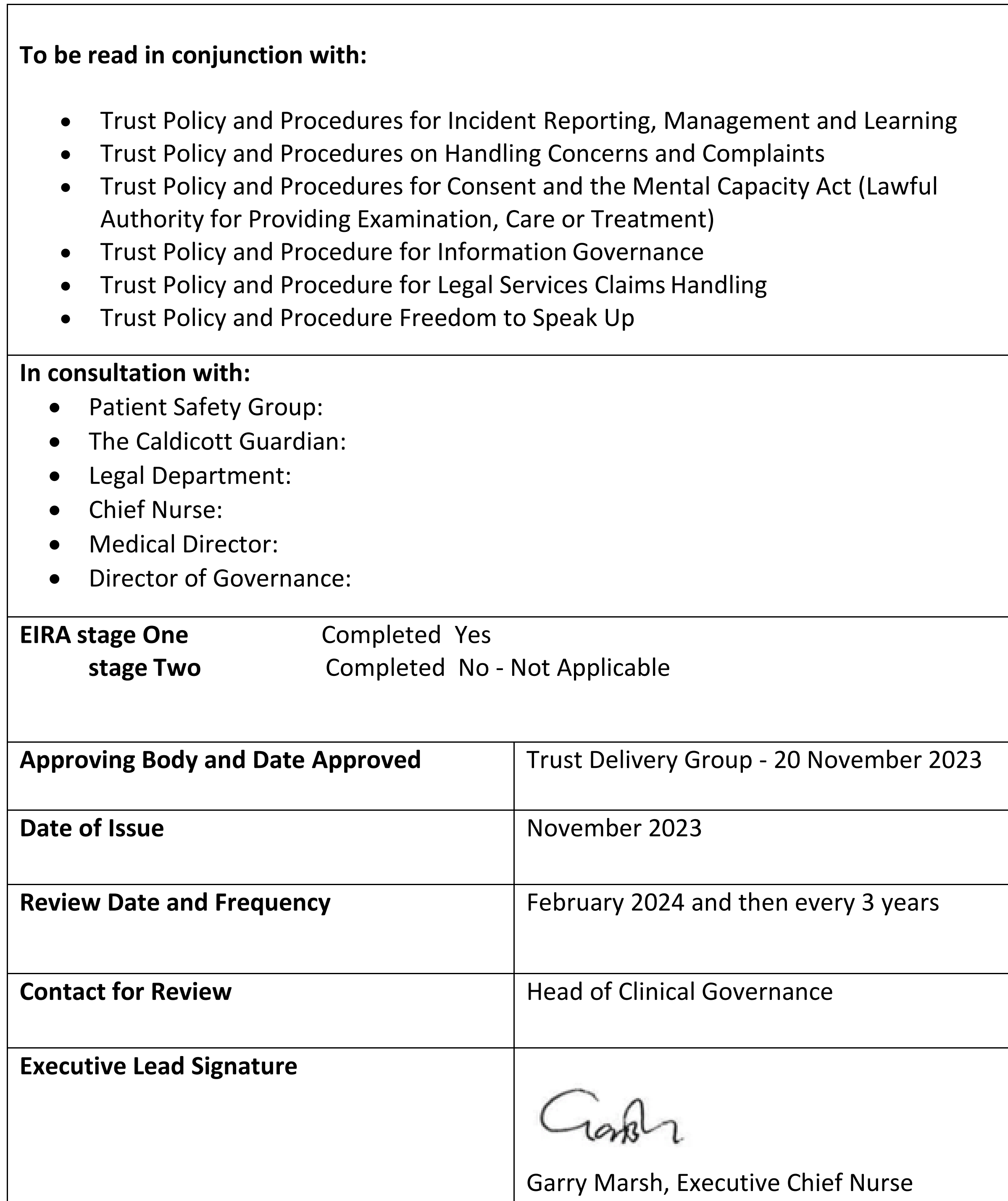

To be read in conjunction with:

- Trust Policy and Procedures for Incident Reporting, Management and Learning
- Trust Policy and Procedures on Handling Concerns and Complaints
- Trust Policy and Procedures for Consent and the Mental Capacity Act (Lawful Authority for Providing Examination, Care or Treatment)
- Trust Policy and Procedure for Information Governance
- Trust Policy and Procedure for Legal Services Claims Handling
- Trust Policy and Procedure Freedom to Speak Up

In consultation with:

- Patient Safety Group:
- The Caldicott Guardian:
- Legal Department:
- Chief Nurse:
- Medical Director:
- Director of Governance:

EIRA stage One Completed Yes
stage Two Completed No - Not Applicable

Approving Body and Date Approved	Trust Delivery Group - 20 November 2023
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Contact for Review	Head of Clinical Governance
Executive Lead Signature	Garry Marsh, Executive Chief Nurse

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TRUST POLICY AND PROCEDURE FOR BEING OPEN AND DUTY OF CANDOUR

1. Introduction

University Hospitals of Derby and Burton NHS Foundation Trust is committed to the provision of high quality health care. Promoting a culture of openness and truthfulness is a prerequisite to improving the safety of patients, staff and visitors as well as the quality of healthcare systems.

It involves apologising and explaining what happened to patients who have been harmed as a result of their (NHS) healthcare whilst an in-patient or outpatient. This Policy also covers harm caused to staff and visitors to the Trust. It encompasses communication between healthcare organisations, healthcare teams and patients and/or their carers, staff and visitors and makes sure that openness, honesty and timeliness underpins responses to such incidents.

The culture of 'Being open' should be fundamental in relationships with and between patients, the public, staff and other healthcare organisations. Duty of Candour is a statutory requirement under Care Quality Commission regulation 20 (2015). When a patient safety incident results in/or may go on to result in moderate harm, severe harm or death it is a contractually binding requirement under the Commissioner's contact with the Trust (NHS Commissioning Standards 2015/16) that we fulfil our Duty of Candour

Being open relies initially on staff and the rigorous reporting of patient safety incidents.
The Trust endorses the Francis Report Recommendation 181:

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

Therefore, staff who are concerned about the non-reporting or concealment of incidents, or about ongoing practices which present a serious risk to patient safety, are encouraged to raise their concerns under the Trust's Freedom to Speak up Policy.

The Being Open elements of this policy are based on:

- Guidance from the National Patient Safety Agency (NPSA), '*Seven steps to patient safety-An overview guide for NHS staff (2004)*.
- "Being Open" Communicating patient safety incidents with patients, their families and carers" re-launched November 2009
- In May 2009 the National Health Service Litigation Authority (NHSLA) wrote to all Trusts to outline "Apologies and explanations" and how they should be adopted.
- Hard Truths: The Journey to Putting Patients First volume 1 and 2 (2014) Government Response to the Mid Staffordshire NHS Foundation Trust Public Inquiry: Response to the Inquiry's Recommendations
- The GMC and NMC released a joint guidance document in 2015 called 'Openness and Honesty' - when things go wrong: the professional duty of candour.

Being open and the *Duty of Candour* involve:

- Acknowledging, apologising and explaining when things go wrong.
- Conducting a thorough documented investigation into the patient safety event and

reassuring patients, their families and carers that lessons learned will help prevent the patient safety event recurring.
- Providing support for those involved (both patients and staff) to cope with the physical and psychological consequences of a patient safety event.

Elements of the *Being Open and Duty of Candour* policy reflect other government initiatives and recommendations from major inquiry reports such as the 6th Shipman Inquiry Report (2005), and the Francis Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry (2013).

2. Purpose and Outcomes

This policy aims to improve the quality and consistency of communication when incidents involving patients, staff or visitors occur resulting in moderate harm or above. The policy will guide staff to ensure that, if an incident occurs, the patient and/or their carer, staff member or visitor will be given an opportunity to discuss what went wrong, that they will receive an apology and be informed of the findings of the review and subsequent actions the Trust will take to reduce the risk of it happening again.

Adherence to this policy will ensure the Trust's compliance with the CQC's statutory reporting requirements of paragraphs 8 and 9 Regulation 20 and the contractually binding requirements within the NHS Standard Contract 2016/16.

This policy relates to incidents, including those which have been identified through complaints and claims, and details the process for communicating with patients and/or their carers who have suffered harm whilst under the care of the Trust. The same principles and process should be applied if a member of staff or visitor suffers harm as a result of an incident within the Trust's premises.

The Trust Policy and Procedure for Incident Reporting, Management and Learning, requires staff to report all patient safety incidents, including those where there was no harm or if it was considered to be a 'near miss'.

This policy relates to those incidents that cause moderate harm, severe harm or death (including prolonged psychological harm) on the risk consequence grading scale in appendix 2 (Being Open Response Required In Relation To Level Of Harm) incidents that are no harm/near miss are not within the scope of this policy unless we go on to investigate as part of National Patient Safety Investigation or Local priority as identified within the Trust Patient Safety Incident Response Plan (PSIRP).

It should however be noted that Being Open remains best practice and there are some instances e.g. over exposure to radiation where no harm was caused but may leave the patient with an increased risk - and it would be appropriate to inform the patient of the incident. University Hospitals of Derby and Burton NHS Foundation Trust encourages open and honest communication in all circumstances.

If an incident reaches the stage of a litigation claim, the documentation which will have been prepared in relation to the Being open and Duty of Candour process as part of the original investigation will be disclosed in accordance with the due legal process. The principles of Being open and Duty of Candour also apply to open communication between healthcare

organisations, healthcare teams, staff and patient's carers/relatives.

3. Definitions Used

- **'Being open'** refers to the process for communicating adverse events with patients and their carers, staff and visitors.
- **Openness** – enabling concerns to be raised and disclosed freely without fear, and for questions to be answered.
- **Transparency** – allowing information about the truth about performance and outcomes to be shared with service users, the public and regulators.
- **Candour: Honesty,** *"Any patient harmed by the provision of healthcare service is informed of the fact and an appropriate remedy offered, regardless of whether a complaint has been made or a question asked."* (Francis 2013)
- **Apology:** An expression of sorrow or regret in respect of a notifiable patient safety incident
- A **claim** is a request for compensation.
- A **complaint** is an expression of dissatisfaction received by the Trust verbally or in writing either directly from or on behalf of service users, their families and carers.
- **Relevant Person:** 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;
    c) Where the service user is 16 or over and lacks capacity (as determined in accordance with the mental capacity act 2005) in relation to the matter
- **Notifiable Safety Incident**: "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, moderate or prolonged psychological harm to the service user." (Care Quality Commission 2015)

Note that the key measure is the level of harm that has occurred and not on the scale of any incident. The duty also now applies to "prolonged psychological harm" as well as physical harm.

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

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

The term Near Miss is any patient safety incident where an incident was prevented, resulting in no harm to people.

The NPSA definitions of **levels of harm** are: - (See **Appendix A)**

- **No harm:** Impact prevented – any patient safety incident that had the potential to cause harm but was prevented, resulting in no harm to people receiving NHS-funded care. Impact not prevented – any patient safety incident that ran to

completion but no harm occurred to people receiving NHS-funded care.

- **Low harm:** Any patient safety incident that required extra observation or minor treatment and caused minimal harm, to one or more persons receiving NHS-funded care.

- **Moderate harm:** Any patient safety incident that resulted in a moderate increase in treatment (e.g. Increase in length of hospital stay by 4-15 days) which caused significant but not permanent harm, to one or more persons receiving NHS-funded care.

- **Severe harm:** Any patient safety incident that appears to have resulted in permanent harm to one or more persons receiving NHS-funded care.
- **Death:** Any patient safety incident that directly resulted in the death of one or more persons receiving NHS-funded care.

4. Key Responsibilities/Duties

The roles and responsibilities must be read and considered in conjunction with the appropriate policies relating to incident reporting, management of complaints and claims handling.

Trust Board

University Hospitals of Derby and Burton NHS Foundation Trust is committed to the provision of high quality health care in all aspects of its services to patients, visitors, local community and staff; promoting a culture of openness is a prerequisite to improving patient safety and the quality of healthcare systems. The Trust Board therefore supports this policy and culture of openness and honesty and discourages the attribution of blame

Non-Executive Director

As suggested in "Being Open "2009, a non-executive director is identified to support the implementation of this policy throughout the organisation.

Chief Executive

The Chief Executive is responsible for making sure that the infrastructure is in place to support openness between healthcare professionals and patients and/or their carers, staff and visitors. In conjunction with the Trust Board, the Chief Executive is responsible for actively championing the Being Open and Duty of Candour culture and process by promoting an open, honest and fair culture that fosters peer support. The Chief Executive will send a personal apology when there has been severe Harm or death as a result of an incident.

Medical Director / Chief Nurse and Director of Patient Experience

The Medical Director **/** Chief Nurse and Director of Patient Experience are the identified leads for the development, implementation and promotion of the Being Open and Duty of Candour culture within the organisation.

Executive Directors

Executive Directors are responsible for promoting an open, honest and fair culture within the organisation.

Head of Clinical Governance

The Head of Clinical Governance is responsible for ensuring there is a policy, which supports staff and the Trust to meet their statutory obligations in respect of duty of candour and "being open". They are also responsible for ensuring that the duty of candour and being open framework is integrated in governance processes.

They are responsible for informing external agencies, e.g., CQC. They are responsible for sharing the lessons learned across the Trust and will provide guidance and support to staff across the Trust with the implementation of the duty of candour process.

They will act as champion for the Being open and Duty of Candour culture and for leading the implementation of the policy, providing support and advice for staff, including any training required. The compliance with this will be monitored through the Datix system for National Patient Safety Investigation or Local Priority as identified within the Trust Patient Safety Incident Response Plan (PSIRP) and incidents that have an actual impact of 3 moderate, 4 severe or Death.

They are responsible for informing external agencies, e.g., CQC of notifiable incidents. They are responsible for sharing the lessons learned across the Trust and will provide guidance and support to staff across the Trust with the implementation of the duty of candour process.

Divisional Medical Directors / Divisional Nursing Directors / Director of Midwifery / Director of Allied Health Professionals and Healthcare Scientists

Divisional Medical Directors / Divisional Nursing Directors are responsible for promoting an open, honest and fair culture within the organisation making sure that the Being Open and Duty of Candour policy is implemented throughout their sphere of responsibility and also responsible for ensuring compliance.

Corporate and Divisional Clinical Governance Facilitators

The Clinical Governance Facilitators will act as champion for the Being open and Duty of Candour culture and for leading the implementation of the policy, providing support and advice for staff, including any training required.

Consultant Medical Staff

Consultant medical staff are responsible for promoting an open, honest, and fair culture within the organisation and for supporting doctors in the training grades in embracing the concept of Being Open and Duty of Candour, when any patient under their care is harmed, and in line with this policy they will lead the Being Open and Duty of Candour process. They will be active in apologising to patients under their care and support any investigations as required.

Lead Investigators

A lead will be identified for all incidents and will be responsible for liaising with patients, their relatives and carers on an individual basis. This will usually be a manager from the business unit, or an alternative senior member of the team supported by the clinician who was responsible for the patient when the incident occurred. The Lead Investigator will be responsible for managing the process in relation to that individual case including relevant

communications with the patient, their relatives and carers, other NHS staff and organisations, providing support and documenting the process in line with the process detailed within this policy.

All Staff
All staff working within the Trust will be expected to adhere to this policy and promote an open, honest and fair culture within the organisation. All staff have a responsibility for making sure that incidents are acknowledged and reported as soon as they are identified. In cases where the patient and/or carers inform healthcare staff when something untoward has happened, it must be taken seriously from the outset. Any concerns should be treated with compassion and understanding by all healthcare staff. In addition to the above, and when required, the following personnel will be involved in the process. All registered staff are responsible for delivering duty of candour. All staff must cooperate with investigations as requested.

Associate Director for Legal Services
The Head of Legal Services is responsible for promoting an open, honest and fair culture within the organisation as well as advising and providing support on the implementation of the policy and is responsible for highlighting any patient harm identified as a result of an inquest or a claim

Head of Complaints
The Head of Complaints is responsible for promoting an open, honest and fair culture within the organisation when dealing with complaints / concerns and reporting any incidents (which become apparent during the course of a complaint / concern) to the risk management team.

5. The Being Open and Duty of Candour Process (Appendix B & C)

This policy reflects the 'Ten Principles of Being Open' as identified in the National Patient Safety Agency's document "Being open": communicating patient safety incidents with patients and their carers' (NPSA, 2005) which are described at **Appendix D** and the revised 'Being Open' framework issued in November 2009. It also reflects the requirements of the NHS Standard Contract 2015/16 and CQC Regulation 20.

5.1 Stage 1 - The Detection and Recognition of Patient Safety Events
The being open and duty of candour process begins with the recognition that a service user and / or relevant other has been involved in a patient safety event. A patient safety event may be identified by:

- A member of staff at the time of the incident;
- A member of staff retrospectively when an unexpected outcome is detected;
- A service user and / or relevant other who expresses concern or dissatisfaction with the service user's healthcare either at the time of the patient safety event or retrospectively;
- Incident detection systems such as incident reporting or medical records review, such as mortality review;
- Or other sources such as detection by other service users, visitors, or non- clinical staff.

As soon as a patient safety event is identified, the priority is to provide prompt and appropriate clinical care and prevent further harm. An incident form should be completed on Datix in accordance with the Trust Incident Reporting, Management and Learning Policy. Key staff will then receive an automatic incident alert. This notification system ensures that key staff quickly become aware of an incident and enables a preliminary discussion to establish the facts of the case and to identify the timely and planned response to the service user and / or relevant others.

For all incidents where no harm has occurred, unless it is locally deemed in the best interest of the patient, the incident need not be discussed with the patient. Incidents resulting in low levels of harm as described in the definitions above require the application of the principles of Being Open and will usually be investigated at a local level. Discussions held must be documented within the patient records and uploaded to Datix. Where harm is caused resulting in moderate, severe harm, death or if we review the care as part of the National Patient Safety Investigation or Local priority as identified within the Trust Patient Safety Incident Response Plan (PSIRP), the process of Being Open must be applied, in order to meet the requirements of the Duty of Candour.

Where an incident is reported on Datix and identified with an Actual Impact as below, this will require escalation to the line manager/most senior person as soon as possible of the incident: -

- Death
- Severe
- Moderate
- Prolonged pain
- Prolonged psychological harm

An initial review (stop moment) will be carried out by the Business Unit if required to validate the harm caused prior to informing the patient or their relatives/Next of Kin or relevant person.

If the degree of harm is not yet clear, but may fall into the above categories the patient/NOK/relevant person (with consent as appropriate) **must be informed,** by handing a Duty of Candour Patient information Leaflet (**Appendix E**) and formal letter, as soon as possible, but within a maximum of **10 working days** from the incident being reported, and evidence uploaded on Datix.

5.2 Stage 2 – Notification of the incident to the relevant person

- The initial notification of the incident must be verbal (face-to-face, where possible) unless the patient or their family/carer decline notification or cannot be contacted in person.
- Provide a true account
- Advise about appropriate further enquiries
- A sincere apology / expression of regret that the incident has happened, must be provided verbally.
- This must be recorded in the Healthcare record and on Datix.

The approach to “Being Open” may need to be modified according to the patient’s personal circumstances e.g. children or patient’s with mental health issues, further advice is available

for “Special Circumstances” see **Appendix F**

5.3 Stage 3 – Written notification (initial letter)

- The patient and/or carer must be offered written notification (including a sincere apology) of the incident **within 10 working days** of the incident being reported on Datix. The offer must be recorded whatever the outcome. (Please see **appendix G** for template letters which **must be amended** to suit individual circumstances).
- A full record of discussions and meetings must be maintained, it does not need to be a verbatim record of the discussions but evidence needs to be held on Datix and in the patient’s Healthcare record as appropriate. The response of the patient/carers should also be recorded. If meetings are offered but declined this must be recorded. Any record of letters sent and discussions held need to be attached and populated on Datix for evidence of compliance.
- Any emerging information (whether during the investigation or after the investigation) must be shared with the patient / relatives.

The 10 principles of “Being Open is attached see **Appendix D**

5.4 Stage 4 - Final Stage (Final letter)

- **Within 10 working days** of the investigation report being signed off as complete and confirmation sent to Division, arrangements should be made to share the report with the patient/relatives. This should be by means of a letter and or meeting. If a meeting is agreed, wherever possible should include the Consultant and the named staff identified from the incident.
- At the conclusion of the meeting the patient / relatives should be given a copy of the final report
- It is important that patients and/or their relatives receive a meaningful apology. An apology does not constitute an admission of liability. Patients and their relatives increasingly ask for detailed explanations of what led to adverse outcomes and they frequently say that they derive some consolation from knowing that lessons have been learnt for the future.
- *NB. Not all incidents will require a meeting e.g... Pressure ulcers, falls – however a meeting should be offered.*
- Should the patient/relatives wish, or, if additional actions are agreed at the meeting, this should be confirmed in writing.

5.5 Meetings with the Patient their Relatives and/or their carer

NB. Not all incidents will require a meeting e.g... Pressure ulcers, falls – however a meeting should be offered.

5.5.1 Organising the Initial Information Sharing Meeting

The following factors should be taken into account when organising a meeting with a patient and/or their carer.

Timing:

- Within 10 days of the incident, bearing in mind the clinical and emotional condition of the patient;
- The patient should be asked if they are happy with the timing and if possible offered a choice of times and confirm the arrangements in writing; Do not

cancel the meeting unless absolutely necessary.

Who should attend?

- The patient's **Consultant at the time of the incident**, or a senior person responsible for the patient's care at the time of the incident, in the absence of the Consultant;
- If it becomes apparent that the patient would prefer to speak to a different healthcare professional, the patient's wishes should be respected. A substitute with the appropriate seniority and skills and with whom the patient is satisfied should be provided.
- Care should be taken to make sure that those members of staff attending can continue to care for the patient as continuity is very important in building relationships;
- The person taking the lead should be supported by at least one other member of staff. This could be the Divisional Medical or Nursing Director or Clinical Governance Facilitator or Matron;
- The patient should also be asked who they would like to be present;
- Consider the diverse needs of all patients, for example linguistic or cultural needs or reasonable adjustments for people with disabilities. Some people may like an interpreter or advocate present;
- The communication skills of each of the team members should be considered as they need to be able to communicate clearly, sympathetically and effectively;
- When the most senior person is unknown to the patient, a healthcare professional, such as their named nurse, should be present if possible, to provide support and to promote an environment of trust;
- A pre-meeting of healthcare professionals should be held so that everyone knows the facts and understands the aims of the meeting.

Where:

- A quiet room should be used where you will not be distracted by work or interrupted;
- Consider holding the meeting in the patient's home if this would be more helpful and acceptable for the patient;
- Do not host the meeting near to the place where the incident happened if this may be difficult for the patient and/or their carers.

5.5.2 Discussion and Communication

The following factors should be taken into account when communicating at the meeting(s) with a patient and their carer.

- Speak to the patient and/or their carers as you would want someone in the same situation to communicate with you or a member of your own family;
- Do not use jargon or acronyms: use clear straightforward language;
- Introduce everyone present at the meeting and confirm that they are happy with those present;
- Acknowledge what happened and apologise on behalf of the team and the organisation. Expressing regret is not an admission of liability;
- Describe the review of care process;
- Explain what led to the adverse outcome;

- Information on likely short and long-term effects of the incident (if known) should be shared with an explanation of what happens next;
- 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, attribute blame or provide conflicting information;
- Do not comment outside your own experience;
- Check they have understood what you have told them and offer to answer any questions;
- Patient / relative should be invited to contribute to the investigation;
- Offer practical and emotional support. This may involve giving information on third parties such as charities, voluntary organisations or support/help lines to the patient/carer, as well as offering more direct assistance. Information about the patient and the incident should not normally be disclosed to third parties without the patient's consent;
- Give the contact details of one member of staff who will act as a contact point for them, to provide both practical and emotional support;
- If a patient expresses a preference for their healthcare needs to be taken over by another team, they should be referred for treatment elsewhere;
- Give written and verbal information on the complaints procedure and offer assistance if they wish to make a complaint.
- Certain patient types or circumstances will require a different approach (see Appendix 4 Special Circumstances).
- Advise the patient's GP of the adverse event as it may have an effect on continuing care;

5.6 Duty of Candour Compliance/Non compliance

Appendix H details the requirements, responsibilities and timescales applicable to the *Duty of Candour.* These processes are monitored and non-compliance may result in:

The commissioners withholding the cost of the episode of care or implementing a fine of £10,000 if the cost is not known. In addition, they can do any/all of the following:

- Send a report to the CQC who have the option of fining the Trust
- Require that the Chief Executive send an apology and an explanation of the breach to the patient/relatives
- Publish details of the breach on the Trust web-site
- Risk of Reputational damage

KPI's will be reported monthly, figures being pulled on the 10th of each month for the previous months data.

During any CQC inspection process, the Trust's adherence to the duty of candour requirements is assessed under both the safe and well-led domains

5.7 Involving Healthcare Staff Who Have Made a Mistake

Every case where an error of this type has occurred needs to be considered individually, balancing the needs of the patient, their family or carers, with those of the healthcare professional(s) concerned.

In cases where the healthcare professional(s) who has made the error wishes to attend the discussion to apologise personally, they should feel supported by their colleagues

throughout the meeting.

In cases where the patient, their family or carers express a preference for the healthcare professional(s) not to be present, consideration should be given to a personal written apology being handed to the patient, their family or carers.

5.8 Continuity of Care

When a patient has been harmed during the course of treatment and requires further therapeutic management or rehabilitation, they should be informed of the ongoing clinical management plan. This may be included in discharge documentation addressed to designated individuals such as the referring GP, attending district nursing service or healthcare organisation if the patient is being transferred.

Patients and/or their carers should be reassured that they will continue to be treated according to their clinical needs even in circumstances where there is a 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.

Where treatment is required as a result of the Patient Safety Incident this should be managed on a case by case basis; however the patient should not wait for routine appointments; all effort should be made to appropriately expedite care. This may need to be discussed with the Medical Director.

5.9 External Communications

The GP, other community care service providers and NHS organisations Wherever possible, it is advisable to send a brief communication to the patient's GP, before discharge, describing what happened.

When the patient leaves the care of the Trust, a discharge letter should also be forwarded to the GP or appropriate community care service (a copy being sent with the patient should they be transferred) with a brief summary of:

- the nature of the patient safety incident and the continuing care and treatment requirements; and
- the current condition of the patient, key investigations with results and prognosis.

6. <u>Training</u>

There will be no specific formal training on the policy however; the following training will include the culture and statutory requirements of 'Being open' and the Duty of Candour:

- Incident Reporting within the Trust Induction training
- Complaints and PALS management training

There will also be ad hoc specialised 'Duty of Candour' training sessions available at request from the Corporate Clinical Governance and Risk office.

Patient Information Leaflets are available on the Trust Intranet **Appendix E**

Staff information leaflets and guidance on making an apology are available on Trust Intranet (See **Appendix I & J**)

7. Equality and Diversity

The Trust is committed to ensuring that, as far as is reasonably practicable, the way we provide services to the public and the way we treat our staff reflects their individual needs and does not discriminate against individuals or groups on any grounds.

This policy aims to develop an open and truthful culture and in this way it seeks to adopt an approach that promotes human rights.
The policy has been appropriately assessed.

Monitoring Compliance and Effectiveness

What will be monitored i.e. measurable policy objective	Method of Monitoring	Monitoring frequency	Position responsible for performing the monitoring/ performing co-ordinating	Group(s)/committee(s) monitoring is reported for action plans and changes in practice as a result
Breaches of the requirements of Duty of Candour: - A – verbal communicatio n Within 10 working	Compliance provided for monthly Scorecard to advise on compliance Divisions to provide information on	Monthly	Head of Clinical Governance	Performance Reviews for Divisions
Breaches of the requirements of Duty of Candour: - B – written communication with the Patient/family Within 10 working days of incident reported date	Compliance provided for monthly Scorecard to advise on compliance Divisions to provide information on breaches to Information	Monthly	Head of Clinical Governance	Performance Reviews for Divisions
Breaches of the requirements of Duty of Candour: - C – written communication with the outcome of the investigation Within 10 working days of the agreed Final Investigation	Compliance provided for monthly Scorecard to advise on compliance Divisions to provide information on breaches to Information	Monthly	Head of Clinical Governance	Performance Reviews for Divisions

9 Policy Implementation

This policy will be implemented in accordance with policy "Policy for the development, management and authorisation of policies and procedures"

10 References

- The Mid Staffordshire NHS Foundation Trust Public Inquiry (2013) Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry: executive summary. London: Stationery Office (Chair: R Francis). Available at: www.midstaffspublicinquiry.com/sites/default/files/report/Executive%20summary.pdf (accessed 24/06/13)
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Appendix A

NPSA Levels of Harm

No harm:
Impacted prevented – any patient safety incident that had the potential to cause harm but was prevented, resulting in no harm to people receiving NHS-funded care. Impact not prevented – any patient safety incident that ran to completion but no harm occurred to people receiving NHS-funded care.

Low harm:
Any patient safety incident that required extra observation or minor treatment and caused minimal harm, to one or more person's receiving NHS-funded care.

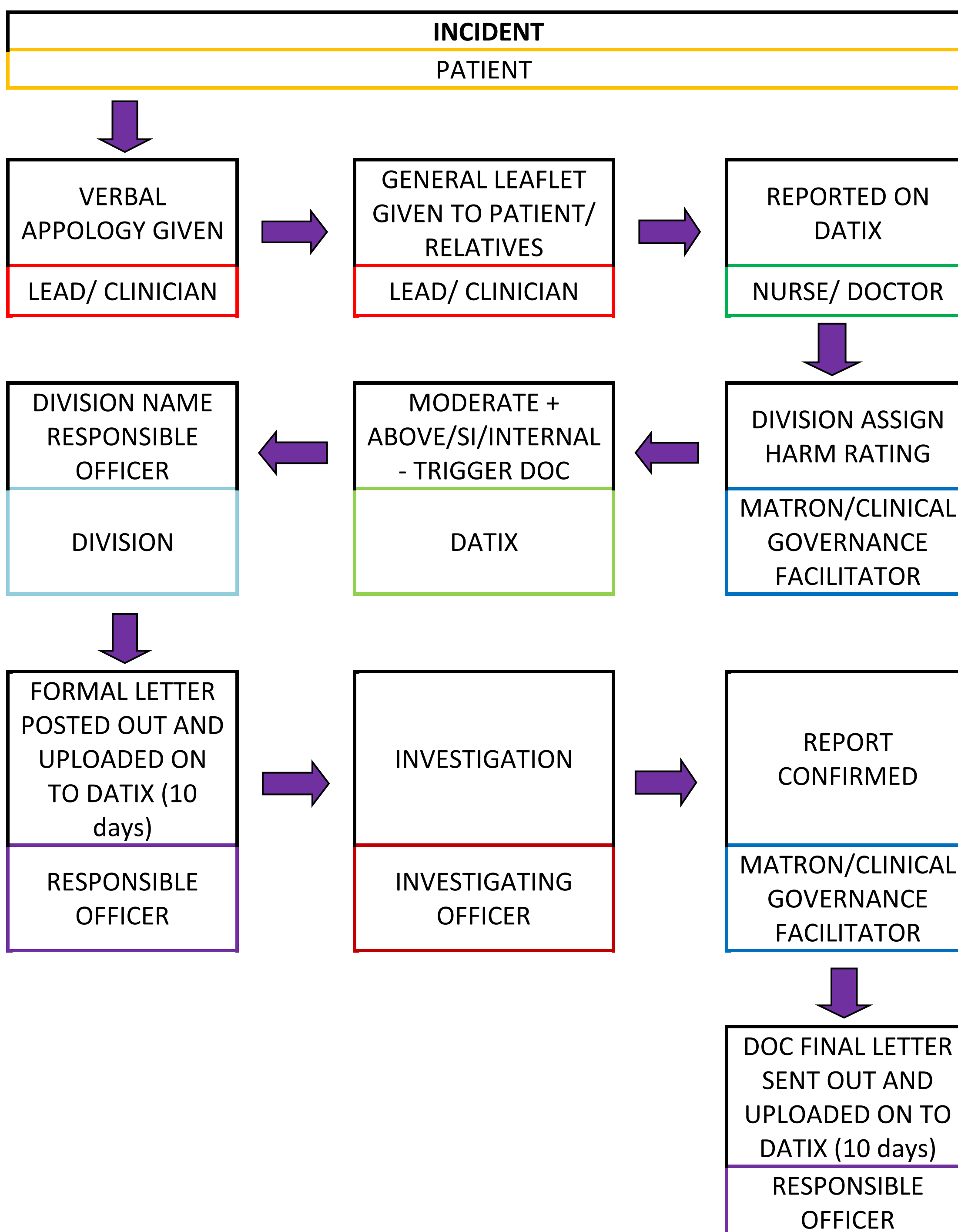
Moderate harm:
Any patient safety incident that resulted in a moderate increase in treatment (e.g. increase in length of hospital stay by 4-15 days) and which caused significant but not permanent harm, to one or more persons receiving NHS-funded care.

Severe harm:
Any patient safety incident that appears to have resulted in permanent harm to one or more persons receiving NHS-funded care.

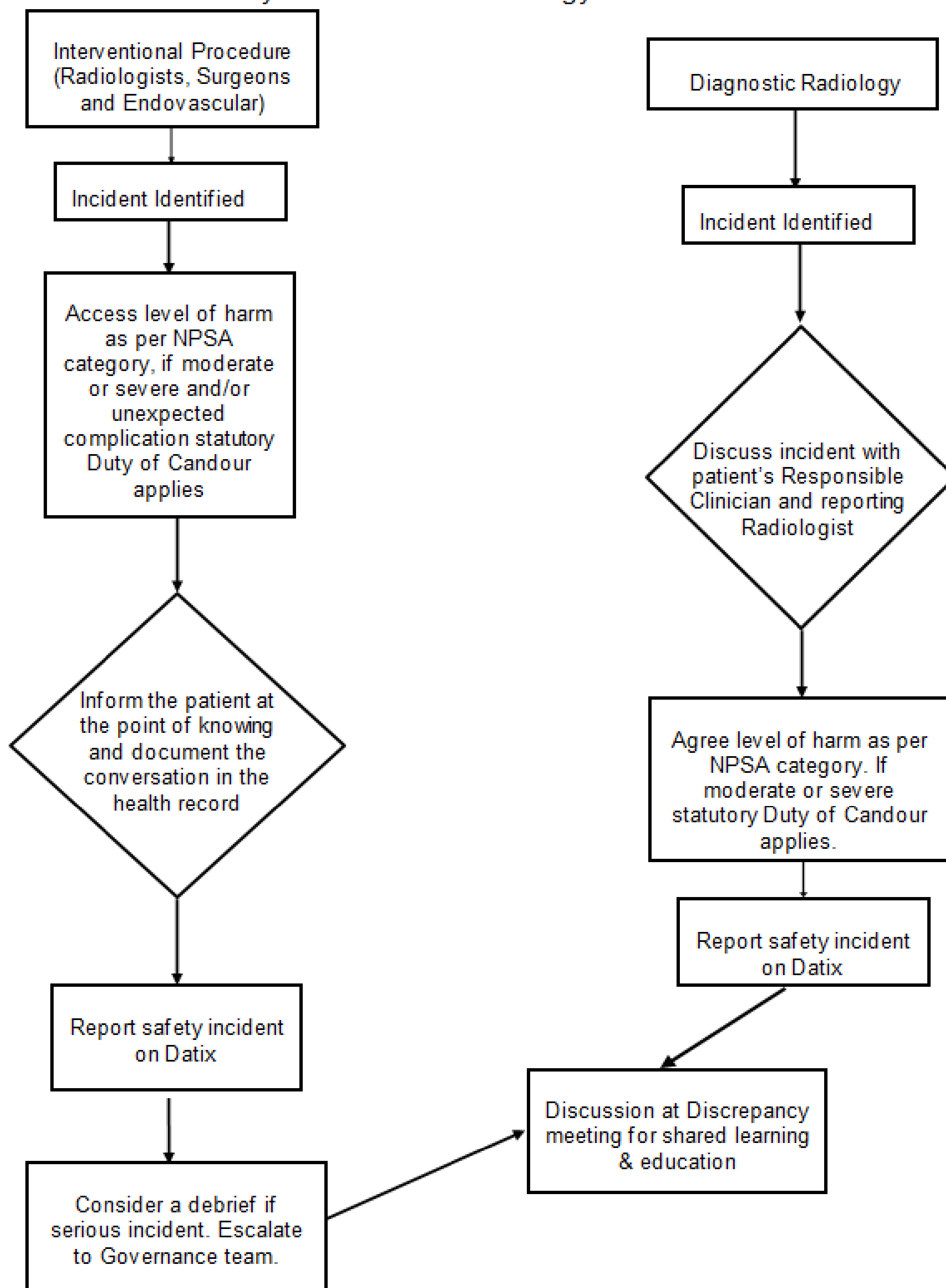
Death:
Any patient safety incident that directly resulted in the death of one or more person's receiving NHS-funded care.

Appendix B

DUTY OF CANDOUR PROCESS



Appendix C



Appendix D - The Ten Principles of Being Open

1. Principle of acknowledgement

All patient safety events should be acknowledged and reported as soon as they are identified. The concerns of those involved must be taken seriously and should be treated with compassion and understanding by staff. Denial of a person's concerns will make future open and honest communication more difficult.

2. Principle of truthfulness, timeliness and clarity of communication

Information about a patient safety event must be given in a truthful and open manner by an appropriately nominated person. Communication should be timely, informing the service user and / or relevant others what has happened as soon as is practicable, based solely on the facts known at that time. Explain that new information may emerge as an incident investigation takes place and that they will be kept up to date. Service users and / or relevant others should receive clear, unambiguous information and be given a named point of contact for any questions or requests they may have.

3. Principle of apology

Service users and / or relevant others should receive a meaningful apology – one that is a sincere expression of sorrow or regret for the harm that has resulted from a patient safety event. This should be in the form of an appropriately worded apology as early as possible. Both verbal and written apologies should be given. Verbal apologies are essential because they allow face-to-face contact. A written apology, which clearly states the organisation, is sorry for the suffering and distress resulting from the patient safety event must also be given.

4. Principle of recognising service user, family and carer expectations

Service users and / or relevant others can reasonably expect to be fully informed of the issues surrounding a patient safety event, and its consequences, in a face-to-face meeting with representatives of the Trust. They should be treated sympathetically, with respect and consideration. Confidentiality must be maintained at all times. Service users and / or relevant others should also be provided with support in a manner to meet their needs. This may involve an independent advocate or interpreter. Information on the Patient Advice and Liaison Service (PALS) and other relevant support groups should be given as soon as possible.

5. Principle of professional support

Staff are encouraged to report patient safety incidents and should feel supported throughout the investigation process. Further information about the support given to staff is contained in the Policy for Supporting Staff Involved in Incidents, Complaints and Claims. Where there is reason for the Trust to believe a member of staff has committed a punitive or criminal act, steps will be taken to preserve its position and advise the member of staff at an early stage to enable them to obtain separate legal advice and / or representation. Staff should be encouraged to seek support from relevant professional bodies.

6. Principle of risk management and systems improvement

The Trust uses systematic investigation techniques and tools to assist in uncovering the underlying causes of patient safety events. The investigation will focus on learning and improving systems of care.

7. Principle of multi-disciplinary responsibility

The Being Open and Duty of Candour Policy applies to all staff responsible for the care of service users. Most healthcare provision involves multi-disciplinary teams and communication with service users and / or relevant others following a patient safety event should reflect this. This will ensure that the Being Open process is consistent with the philosophy that patient safety incidents usually result from system failures and rarely from the actions of an individual. Managers will champion the Being Open process to help ensure multidisciplinary involvement and the identification of staff who are able to undertake the role of the named point of contact for service users and / or relevant others.

8. Principle of clinical governance

Being Open requires the support of patient safety and quality improvement through clinical governance frameworks to learn what can be done to prevent their recurrence. It also involves a system of accountability through the Trust Chief Executive to the Trust Board to ensure these changes are implemented and their effectiveness reviewed.

These findings should be disseminated to staff so they can learn from patient safety incidents. Some of the mechanisms through which this is achieved are outlined below:

- Trust wide committees
- Audits undertaken to monitor the implementation and effects of key changes in practice following a patient safety investigation.

9. Principle of confidentiality

Details of a patient safety event should always be considered confidential. The consent of the individual concerned should be sought prior to disclosing information beyond the clinicians involved in treating the service users. Where this is not practicable or an individual refuses consent to the disclosure, disclosure may still be lawful if justified in the public interest or where those investigating the incident have statutory powers for obtaining information. Communications with parties outside of the clinical team should also be on a strictly need to know basis and where practicable records should be anonymous. It is good practice to inform the service user and / or relevant others about who will be involved in the investigation before it takes place, and give them the opportunity to raise any objections.

10. Principle of continuity of care

Service users are entitled to expect they will continue to receive all usual treatment and continue to be treated with respect and compassion. If a service user expresses a preference for their healthcare needs to be provided by another team there should be serious consideration of this request.

Appendix E - Patient Information

Being open

The need to be open and honest with patients and families goes without question, even if something has gone wrong, and is a requirement of all healthcare professionals. We are committed to this principle in all aspects of the care we provide. We would like to share information with you as much as you want to know and respect that you may not want to know certain things. In our experience, people may be ready to ask for or be given information at different times after something has happened, particularly if there has been bereavement, and we will do our best to respond to your needs.

Duty of Candour

Duty of candour is a formal requirement to be open and honest with a patient if they have suffered harm or a potential to be harmed by something not being done. This means that if you suffer any unexpected or unintended harm during your care we will:

- Tell you about it
- Apologise
- Investigate
- Give an explanation of what happened

Why do things go wrong?

Healthcare is very complex and things can change rapidly and unexpectedly. Occasionally things do not go to plan and a patient may be harmed or a potential to be harmed by something not being done.

We regret every case of harm or potential harm to our patients but we make sure we use the opportunity to learn and stop similar things happening again.

What can I expect?

- A member of staff will speak to you honestly and openly as soon as possible after the event to discuss what happened, your condition and your ongoing care plan.
- All of the facts may not be clear at this time so staff may not be able to answer all of your questions until we have investigated.
- If you are not in a condition to receive the information, for example if you are too ill or recovering from an anaesthetic, staff will inform your next of kin or the person named by you in your healthcare record.
- You can involve family members or carers in these discussions.
- You will be treated with dignity and respect and you will receive an apology when an apology is due
- You can expect to be involved in and contribute to decisions made about your care
- You will be given a named person to speak to. If you have any queries or concerns contact details of the designated staff member are at the end of this leaflet
- We will investigate the incident and review any lessons learnt and implement any changes necessary
- You can expect confidentiality
- You can expect to receive information regarding the outcome of the review or if you prefer you can request a meeting to explain the report findings, any recommendations made and any actions taken or planned by the service to and prevent this happening again.
- Occasionally, once initial investigation, we may find no further investigation is required. If

this is the case, we will inform you by telephone or letter.

What does this mean for you?

Should I have someone with me when staff are talking to me about what happened?
It is recommended that you do choose someone to support you during the discussion. This should be somebody that you are comfortable with, can talk to easily and who you do not mind hearing personal information.
Please let us know if you wish somebody to be with you for the discussions. An advocate can be arranged for you if required.
Please remember that when something goes wrong it is distressing for everyone involved including the members of staff.

Who will speak to me about what happened?

- One or more staff may talk to you,
- Usually the person leading the conversation will be someone from your healthcare team who knows the most about what happened and will be able to answer any questions you may have.

How should I prepare for a duty of candour conversation?
Before the conversation you may find the following advice helpful:

- Think about what questions and fears/concerns you have in relation to: what has happened, your condition and your ongoing care.
- Write down any questions or concerns you have. Please be aware that this process will only look at the incident which caused harm. If you have any other concerns you wish to raise, this can be made through the normal complaint root.
- Think about who you would like to have with you to support you.
- Think of what things may assist you moving forward.

What happens next?

- A lot of information has to be obtained to investigate the incident and to produce a report. You will be notified when the report is complete (this could take 12-20 weeks- depending on the information required to complete the investigation)
- We may not be able to provide you with answers until the whole investigation has concluded. Please be assured that we will be open and honest with you at all times.

- The investigation process is not about apportioning blame to individual staff members, but is about identifying the "root causes" and ensuring subsequent learning occurs
- Once the investigation is finished, you will be offered an explanation of the report. We will post this to you, or if preferred, a meeting can be planned to go through the findings.
- If you want a copy of the report, it is important to note that because this is a formal report, it can appear a little impersonal in how it is written. This is because the report needs to be structured and factual in order to see exactly what happened.
- The individual patient and the impact of what happened to them is always our focus throughout the investigation the report does not include the patient's name or details to protect his/her privacy. The report will not be placed in their medical records
- Sometimes even after investigation there is no clear cause found or it may be that what happened could not have been avoided. An investigation will usually find things that we

can learn from to help to improve the service that we provide.

- We want to learn from what has happened and do everything that we can to make care safer for all our patients.
- We would welcome any feedback following this process to ensure that we are reporting back relevant, meaningful information in a timely manner. This feedback can be sent through to the contact person below.

During the Investigation

If you have any concerns in relation to the process please do not hesitate to contact the person below

Name: - ……………….………………………….

Job Title: - ……………………………………………

Contact Number: - …………………….……………….

Appendix F

Special Circumstances

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

Children

The legal age of maturity for giving consent to treatment is 16. It is the age at which a young person acquires the full rights to make decisions about their own treatment and their right to confidentiality becomes vested in them rather than their parents or guardians. However, it is still considered good practice to encourage competent children to involve their families in decision-making.

The courts have stated that younger children who understand fully what is involved in the proposed procedure can also give consent. This is sometimes known as Gillick competence or the Fraser guidelines. Where a child is judged to have the cognitive ability and the emotional maturity to understand the information provided, he/she should be involved directly in the “Being open” process after a patient safety incident. The opportunity for parents to be involved should still be provided unless the child expresses a wish for them not to be present.

Where children are deemed not to have sufficient maturity or ability to understand, consideration needs to be given to whether information is provided to the parents alone or in the presence of the child. In these instances the parents’ views on the issue should be sought. More information can be found in the Consent policy.

Patients with mental health issues

“Being open” for patients with mental health issues should follow normal procedures, unless the patient also has cognitive impairment (see below). 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 rare and a second opinion (by another consultant psychiatrist) would be needed 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 human rights.

Patients with cognitive impairment

Some individuals have conditions that limit their ability to understand what is happening to them. They may have authorised a person to act on their behalf by an enduring power of attorney. In these cases steps must be taken to ensure this extends to decision-making and to the medical care and treatment of the patient. The “Being open” discussion would be held with the holder of the power of attorney.

Where there is no such person the clinicians may act in the patient’s best interest in deciding who the appropriate person is to discuss incident information with, regarding the welfare of the patient as a whole and not simply their medical interests. However, the patient with a cognitive impairment should, where possible, be involved directly in communications about what has happened. An advocate with appropriate skills should be available to the patient to assist in the communication process.

Patients with learning disabilities

Where a patient has difficulties in expressing their opinion verbally, an assessment should be made about whether they are also cognitively impaired (see above). If not cognitively impaired they should be supported in the "Being open" process by alternative communication methods (i.e., given the opportunity to write questions down). An advocate, agreed on in consultation with the patient, should be appointed. Appropriate advocates may include carers, family or friends of the patient. The advocate should assist the patient during the "Being open" process, focusing on ensuring that the patient's views are considered and discussed.

Patients who do not agree with the information provided

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

- Deal with the issue as soon as it emerges;
- Where the patient agrees, make sure their carers are involved in discussions from the beginning
- 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 and/or offer the patient and/or their carers another contact person.
- Appoint a mediator to help identify the issues between the healthcare organisation and the patient, and to look for a mutually agreeable solution.

Appendix G - Duty of Candour letter templates

Initial Stage Letters

Initial Stage Letter DOC.doc

Initial Stage Letter DOC- Following Deatl

Initial Stage Letter DOC- Following Morta

Initial Stage Letter DOCunpreventable n

Finial Stage Letters

Final Stage Letter DOC.doc

Final Stage Letter DOC- Following Deatl

Final Stage Letter DOC- Following Morta

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Appendix H - Being Open Responsibility and Timeframe Table

	Requirement under Duty of Candour	Responsible person/ department	Timeframe
1	Patient or their family/carer must be informed that a suspected or actual incident has occurred (moderate harm, severe harm or death)	Lead Investigator and Clinician* responsible for episode of care during, or as a result of which, the incident occurred. Departmental Manager and Risk Team should be made aware/	Maximum 10 working days from incident being reported on Datix
2	Initial notification of incident must be verbal (face-to-face, where possible) unless patient or their family/carer decline notification or cannot be contacted in person. Sincere expression of apology must be provided verbally.	Lead Investigator and Clinician* responsible for episode of care during, or as a result of which, the incident occurred. Departmental Manager and Risk Team should be made aware/ involved.	Maximum 10 working days from incident being reported on Datix
3	Written notification of investigation. Including sincere apology must be provided in writing. Whether declined or accepted, this must be recorded.	As Above	Maximum 10 working days from incident being reported on Datix. See template letter – Being Open Policy.
4	Step-by-step explanation of the facts (in plain English) and the process must be provided. This may just be an initial view, pending investigation. This would also	As above.	As soon as practicable.
5	Maintain full written documentation of any meetings. If meetings are offered but declined this must be recorded.	As above. All follow –up letters to patients/ relatives will be approved for release by the Medical Director	As soon as practicable.
6	Emerging information (whether during investigation or after investigation) must be offered.	As above	As soon as practicable.
7	Share incident investigation report (including action plans) in the format they were approved in. (Ensure written in Plain English, template is available within Datix for Moderate investigations)		Within 10 working days of report being signed off as complete and incident closed.
8	Once the patient / family are satisfied with the content of the report a formal written apology should be issued	Individual divisions will decide whom the letter of apology will come from.	Within 10 days of the conclusion of discussions with the patient / relative

NB*: Provide reasonable support to the relevant people in relation to the incident.*

**The clinician may be the lead doctor responsible for the patient's care but in the case of falls resulting in a fracture or Trust-acquired pressure ulcers category 3 and 4 the Ward Manager or Matron or Tissue Viability team may be more appropriate.*

Appendix I

DUTY OF CANDOUR – STAFF INFORMATION

WHAT IS DUTY OF CANDOUR?

Duty of candour is the legal duty to inform a patient and / or family where an incident has occurred involving patient care or treatment, which has led to / or the potential to harm, and to provide an apology.
This applies to all patient safety incidents that result in moderate or above harm or where there will be an investigation.
All registered staff are responsible for undertaking Duty of Candour and supporting with any investigations.

WHY WE NEED THIS POLICY?

It is a legal requirement through the CQC Regulation 20 (Duty of Candour) to be open, honest and transparent when something goes wrong whilst patients are in our care.
There are specific requirements that we must follow when things go wrong with care or treatment, including informing people about the incident, providing reasonable support, providing truthful information, provide an apology and evidence learning from the incident.

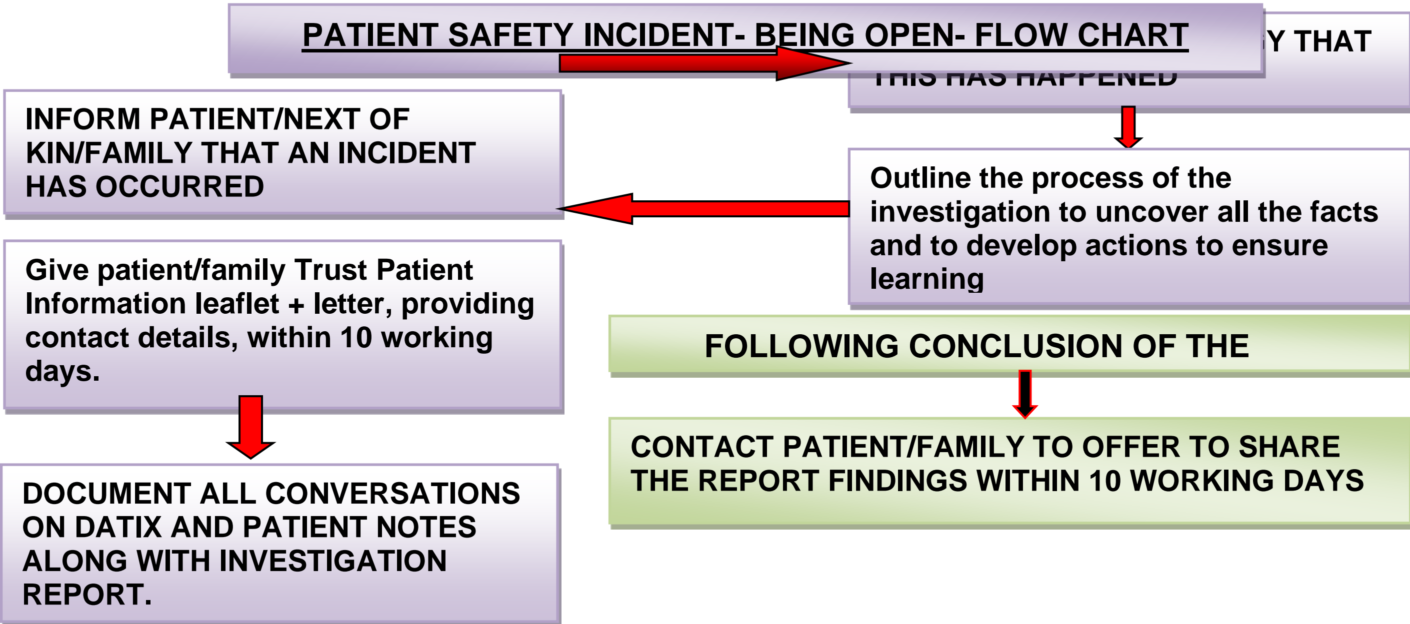
WHAT DO WE NEED TO DO?

An open and honest conversation (ideally face to face) should be held as soon as possible, with the patient and/or their family and followed up with a Patient Information leaflet / letter within 10 working days of becoming aware of the incident. An Incident Form (IR1/ Datix) should be generated as soon as possible and all details of conversation recorded within Datix system.
There will be an investigation, so keep any information that may be required.
Following the results of the investigation, this information is sent on to the patient/ family within 10 working days of report closure.

CONTACTS

It is important that we all understand our role within Duty of Candour. If you have any further questions

- Read the trust policy which can be found on Flo
- Speak to your Senior Sister/ Lead/ Matron/CGF's
- Contact Lorraine Horobin- Duty of Candour Manager on Derby 01332 786734



Appendix J

WHAT IS AN APOLOGY – GUIDANCE FOR STAFF

- ✓ Clinical staff may worry that being open with patients may compromise the ability to deal with a claim if one is subsequently made by the patient / patient's representative.
- ✓ In reality candour is all about sharing accurate information with patients and should be encouraged.
- ✓ The facts are the facts and staff should be encouraged and supported to help patients / next of kin understand what has happened

- ✓ Where staff should be more cautious is where the facts are not yet known or where they are being asked to speculate beyond what is known.
- ✓ It can be more damaging to a relationship with the patient to speculate inaccurately than to investigate and find out the facts, and then provide the extra information.
- ✓ An apology is about being sorry that something has happened to the patient and is not an admission of any guilt