Being Open and Duty of Candour Policy

(Reference No. GR06 0217)

Version:	Version 1, February 2017
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Ratified by:	Patient Safety and Experience Group (PSEG)/ Tricia Wren, Deputy Director of Quality & Governance
Date ratified:	4th May 2017
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Name of responsible Committee/ Individual:	Healthcare Governance Committee/ Clare Hawkins, Deputy Chief Executive, Director of Quality & Governance & Chief Nurse
Name of Executive Lead	Clare Hawkins, Deputy Chief Executive/ Director of Quality & Governance & Chief Nurse
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Target audience:	All Hertfordshire Community Trust (HCT) Staff

Being Open and Duty of Candour Policy (Reference No. GR06 0217)

Version: 1

Lead Author: Christine Stock

Exec Director: Clare Hawkins

Who is this document is applicable to: All HCT Staff

Dare Issued: 25/05/17

Other policies that this policy should be read in conjunction with:

- Complaints and Concerns Policy
- Education, Training & Development Policy
- Incident Policy and Procedure
- Legality and Claims Management Policy
- Safeguarding Adults Policy and Procedure
- Safeguarding Policy for Children and young People aged 0-18 years
- Serious Incidents Policy
- Supporting Staff Involved in an Incident, Complaints or Claim Policy
- Whistleblowing/ Raising Concerns at Work Policy

Scope / Statement / Purpose:
The policy provides direction to all staff to ensure that communication with patients/ families/ carers, following a patient safety event or error of treatment that results in harm, is managed appropriately and proportionate to the harm that has occurred. Direction provided ensures that requirements associated with statutory duty of candour are met.

Key Component / Main content of the Policy:

- Explaining being open and duty of candour.
- Detailing being open actions.
- Detailing duty of candour actions.
- Providing specific guidance to ensure duty of candour requirements is met.

General Procedure guidance: It is expected that all staff communicate clearly and honestly with patients/ families/ carers at all times, including occasions when things go wrong. This policy provides guidance to ensure statutory duty of candour requirements are met on occasions when a patient safety incident causes moderate or more severe harm.

Specific procedure for individual groups: Procedures detailed in the policy apply equally to all Business Units, services and teams.

Specific training info for staff: Policy provides procedural information and guidance tools and is available for reference for all staff. The Risk Team support the management of each incident, and they, together with the Patient Safety team will provide advice and guidance on the implementation of this policy.

Specific info for equipment: N/A

Governance & Escalation: If you require any guidance about the policy refer to the policy lead. Issues should be escalated in the first instance to your line manager for review and advice.

Contents

1. Introduction

1.1 Hertfordshire Community NHS Trust (HCT) is committed to promoting a culture that assures the safety of patients, staff and visitors.

This includes promoting a culture of openness and communicating honestly with patients, families/carers and people who use HCT services especially when things go wrong and when harm has occurred.

Being open, honest and compassionate when things go wrong can help patients, families/carers and people who use our services understand and manage the distress these events may cause better.

1.2 *Being open principle:*

Evidence suggests that openness is welcomed by patients who are more likely to forgive errors when they are discussed fully in a timely and thoughtful manner and that being open can decrease the trauma felt following an incident.

Being open is a process rather than a one off event and is underpinned by 10 principles promoted in "*Saying sorry when things go wrong: Being open: Communicating patient safety incidents with patients, their families and carers"* (NPSA 2009)

The principles inform the rationale for improving communication between NHS staff and patients; Appendix 1.

1.3 *Duty of candour – an introduction*

When an incident is more serious, it is important that the being open principles are followed.

In November 2015 the duty for NHS organisations to be open and honest when a patient is harmed became statute. Duty of candour duties must be evoked when patients experience moderate or severe harm. The duty is overseen by The Care Quality Commission (CQC) and the processes detailed in this policy reflect requirements set out in CQC Regulation 20: Duty of candour.

1.4 This policy should be read in conjunction with the following HCT policies available via HCT intranet:

- *Complaints and Concerns Policy*
- Education, Training & Development Policy
- *Incident Policy and Procedure*
- *Legality and Claims Management Policy*
- *Safeguarding Adults Policy and Procedure*
- *Safeguarding Policy for Children and young People aged 0-18 years*
- *Serious Incidents Policy*
- *Supporting Staff Involved in an Incident, Complaints or Claim Policy*
- *Whistleblowing / Raising Concerns at Work Policy*

2. Aim and Purpose

2.1 The policy provides guidance to all staff working for HCT on the principles and

processes of being open and the statutory duty of candour requirements.

The Trust Board and senior managers should ensure processes are in place to support openness between healthcare professionals and patients, their families and carers when harm has occurred.

Guidance in this policy aims to improve the quality, consistency and openness when incidents involving patients and people who use HCT services occur.

2.2 The purpose of this policy is to improve the quality, consistency and speed of communication with patients/families/carers, following a patient safety event or error of treatment that results in harm, and through so doing ensure that the statutory duties associated with duty of candour are met.

3. Scope

3.1 This policy applies to all staff working for, or on behalf of HCT. Every healthcare professional must be open and honest with patients; being open principles apply to all patient safety incidents.

Duty of candour applies to all patient safety incidents which have an actual impact of moderate harm or where a patient safety incident resulted in severe harm, prolonged psychological harm or prolonged pain or death.

Incidents which come under the serious incident criteria are investigated under the serious incident policy, which adheres to the duty of candour principles.

4. Explanation of terms and definitions

4.1 ***Openness -*** Enabling concerns and complaints to be raised freely without fear and questions asked to be answered.

4.2 ***Being open -*** Communicating with patients, their families and carers, staff and visitors in a manner that is clear, honest and effective, including occasions when things go wrong.

4.3 ***Transparency -*** Allowing information about the trust performance and outcomes to be shared with staff, patients, the public and regulators.

4.4 ***Candour -*** Any patient harmed by the provision of a healthcare service is informed and an appropriate remedy offered, regardless of whether a complaint has been made or a question asked.

4.5 ***Apology -*** A sincere expression of sorrow or regret when things go wrong is **not** an admission of guilt and should be provided by the health professional involved in the error.

4.6 ***Notifiable patient safety incident in respect to CQC Regulation 20: Duty of candour -*** Any unintended or unexpected incident that occurred during the provision of a regulated activity that, in the reasonable opinion of a health care professional, did or could result in:

- The death of the service user, where death relates directly to the incident rather

than to the natural course of the service user's illness or underlying condition, or
- Severe harm, moderate harm or prolonged psychological harm to the service user.

4.7 ***Relevant person -*** CQC Regulation 20: Duty of candour uses the term 'relevant person' when describing the person who will be informed of an incident in the duty of candour process.
Relevant person is the service user or someone acting lawfully on their behalf in the following circumstances:
- On the death of the service user,
- Where the service user is under 16 and not competent to make a decision in relation to their care or treatment, or
- Where the service user is 16 or over and lacks capacity (as determined in accordance with Sections 2 and 3 of the 2005 Mental Capacity Act) in relation to the matter.

4.8 ***Moderate harm -*** Means harm that requires a moderate increase in treatment, and significant, but not permanent harm, for example a '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).

4.9 ***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.

4.10 ***Prolonged pain -*** Means pain which the service user has experienced or is likely to experience for a continuous period of at least 28 days.

4.11 ***Severe harm -*** A permanent lessening of bodily, sensory, motor, physiologic or intellectual functions, including removal of the wrong limb or organ or brain damage that is related directly to the incident and not related to the natural course of the service user's illness or underlying condition.

5. Ownership, roles and responsibilities

The generic statement of roles and responsibilities are in line with the HCT (Trust) GR1 1215 V.4. Roles and responsibilities specific to this particular policy are defined below.

5.1 Designated Committee

5.1.1 'Healthcare Governance Committee (HGC)' is the Designated Committee for this policy.

5.2 Lead Executive Director

5.2.1 The 'Deputy Chief Executive/ Director of Quality & Governance' is the identified Lead Executive Director for this policy.

5.3 Lead Policy Author

5.3.1 The identified Lead Policy Author for this policy is the Head of Patient Safety.

5.4 General Managers/ Deputy General Managers/ Line/ Locality Managers/ Head of Services

5.4.1 Are responsible for ensuring that the policy is accessible for all of their staff and that the staff have read and understood the principles of being open and duty of candour and ensuring these principles are implemented following patient safety incidents, complaints or claims.

5.4.2 Are responsible for ensuring that all incidents and serious incidents are dealt with according to the Trust's Incident Policy and Procedure and *Serious Incident Policy* and all written complaint responses are dealt with according to the Trust's *Complaints and Concerns Policy*. This includes reviewing new incidents reported, confirming the level of harm and ensuring those incidents meeting the duty of candour requirements are managed appropriately and in line with this policy.

5.5 Senior Responsible Clinician

5.5.1 The senior clinician responsible for the episode of care during which, or as a result of which the incident happened, must liaise with their manager when a moderate or more severe incident occurs. It is appropriate for those involved in the delivery of care to give information to the patient and/or relevant person.

5.6 Specialist Groups / Individuals

5.6.1 Healthcare Governance Committee (HGC) and Patient Safety and Patient Experience Group (PSEG) - have responsibility for promoting a being open culture and for seeking assurance that this policy has been followed when reviewing incidents, serious incidents and complaints.

5.7 **All Staff**

5.7.1 All staff should comply with the principles of being open and the requirements of duty of candour as outlined in this policy.

Staff must report incidents promptly and clearly in line with the Trust Incident Policy and Procedure and ensure that appropriate actions can be taken to ensure an open and honest culture.

6. Implementation procedure

6.1 Applying the principles:

6.1.1 Being open/ candour is a process NOT an event, it should be on going and is about being open about all aspects of the care a patient has received, including when things go wrong.

6.1.2 When a patient is affected by a patient safety incident, which may include a mistake that has been made or something that has happened that was not meant to happen, the trust, and clinicians delivering care on behalf of the trust, have a duty to:

- Be open and tell patients/ their families/ carers
- Explain what has happened and answer any questions patients or their families/ carers may have
- Say sorry
- Find out why it happened
- Work to make sure it does not happen again.

6.1.3 The principles of being open apply to all incidents and events although the level of response must be proportionate to the level of harm.

The '10 Principles of Being Open' are detailed in Appendix 1. The process that must

be followed in respect to being open and duty of candour is summarised in the flowchart in Appendix 2.

6.2 Reporting incidents/ notifiable patient safety incidents:

6.2.1 When an incident occurs staff involved must follow direction provided within the Incident Policy and Procedure, including completing an incident report via the Datix incident reporting web-based system.

6.2.2 The incident report requires the reporter to summarise the nature of the incident, identify if the incident is a patient safety incident, the level of harm and impact on the patient.

6.2.3 The incident report provides links, guidance and details of whom to contact should the incident be a potential serious incident.

6.2.4 In addition, in line with expected best practice, the reporter should escalate all incidents where there has been potentially moderate or severe harm to their line manager for direction and support.

6.2.5 The line manager must prioritise incidents that are reported to have caused moderate or more severe harm; the incident must be reviewed and the degree of harm confirmed.

6.2.6 Patient safety incidents reported via Datix are submitted to the National Reporting and Learning System (NRLS) in line with the required frequency. Through sharing patient safety incidents the trust meets its requirements to notify the CQC of certain incidents, including for example those that meet the serious incident criteria.

6.2.7 Occasionally an incident may not be discovered at the time it happens. A delay in discovering an incident does not mean that duty of candour requirements do not apply.

6.2.8 Should an incident be identified that meets the duty of candour requirements, but which relates to care delivered by another provider, that provider is responsible for implementing duty of candour. A Datix incident report should be completed, and the Risk team alerted who will then inform the other provider.

6.3 Being open actions:

6.3.1 For all incidents it must be acknowledged to the service user that an incident has occurred, verbally and face to face where possible, unless the person cannot be contacted or declines notification.

6.3.2 A sincere verbal apology should be made and the service user provided with information about what happened relevant to the incident.

6.3.3 If further actions are indicated the service user must be advised of these and an agreement made regarding if and what further enquiries are appropriate.

6.3.4 Reasonable support must be provided to the patient or service user, their families or carers.

6.4 Duty of candour actions:

6.4.1 Some patient safety incidents trigger the duty of candour statutory requirements.

6.4.2 A notifiable safety incident that will trigger the duty of candour statutory requirements is one which, in the reasonable opinion of a healthcare professional, could result in, or appears to have resulted in moderate or severe harm or death or prolonged psychological harm. The definitions of moderate and severe harm are consistent with those used within the NHS for reporting under the NRLS and as defined within CQC Regulation 20; Duty of candour, March 2015

6.4.3 Grade and definition of patient safety incident:

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.

Low harm

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

Minor treatment is defined as first aid, additional therapy, or additional medication. It does not include any extra stay in hospital or any extra time as an outpatient, or continued treatment over and above the treatment already planned. Nor does it include a return to surgery or re-admission.

Moderate harm

Any patient safety incident that resulted in a moderate increase in treatment and which caused significant but not permanent harm, to one or more persons receiving NHS-funded care.

Moderate increase in treatment is defined as a 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 area such as intensive care as a result of the incident, including prolonged pain and/or prolonged psychological harm which the service user has or is likely to experience for a continuous period of at least 28 days.

Severe harm

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

Permanent harm directly related to the incident and not related to the natural course of the patient's illness or underlying condition is defined as permanent lessening of bodily functions, sensory, motor, physiologic or intellectual, including removal of the wrong limb or organ, or brain damage.

Death

Any patient safety incident that directly resulted in the death of one or more persons receiving NHS funded care.

The death must relate to the incident rather than to the natural course of the patient's illness or underlying condition.

6.4.4 If the perceived actual impact (harm) caused as a result of the patient safety incident is moderate or above, then the incident has triggered the duty of candour requirements and a greater level of involvement and being open is required.

6.4.5 Duty of candour applies to occasions when a service user has or is likely to experience psychological harm as a result of an incident for a continuous period of at least 28 days. On occasions this may not be recognised at the time of the incident and may not be recognised until after the 28 day period. On these occasions a new

incident report is required that documents the presence of psychological harm and duty of candour actions are required.

6.4.6 Those incidents meeting the serious incident criteria are investigated under the Serious Incident policy and the duty of candour requirements for these incidents are met within the Serious Incident process.

6.5 Practical examples of applying the principles of being open and duty of candour:

6.5.1 Appendix 3 provides two examples of possible incidents and responses that should be made:

The first example is of an incident that resulted in low harm and demonstrates how this should be managed in a way that supports the principles of being open.

The second example is of an incident where the patient suffered moderate harm and demonstrates how the statutory duty of candour should be met.

7. Specific Guidance

7.1 Giving an apology:

7.1.1 Following any patient safety incident, the patient and/or other relevant person should receive a sincere expression of sorrow or regret for any harm as early as possible.

7.1.2 An apology is **not** an admission of liability, but acknowledgements of the person's distress at that time which may mitigate the trauma suffered and potentially avoid any complaint or claim being made.

7.1.3 The apology should be made by the member of staff involved in the error, but may be made by any member of staff if it is decided this is more beneficial.

7.1.4 The NHS Litigation Authority leaflet 'Saying sorry when things go wrong: Being open: Communicating patient safety incidents with service users and their carers', gives guidance on the "saying sorry" process.

7.2 Within 10 working days of the incident:

7.2.1 If the duty of candour applies a further apology must be provided as detailed below and within the flow chart in Appendix 2.

7.2.2 An initial verbal apology should be made by an appropriate manager from within the service where the incident occurred, delivered in person, providing all facts known at the time and explaining what actions are being taken and next steps.

7.2.3 The decision about who is most appropriate to provide the notification and/or apology will take into account seniority, their relationship to the service user and their experience and expertise in the type of notifiable incident that has occurred.

7.2.4 The verbal apology should be followed by written notification (letter). Example letter templates are provided in Appendix 4.

7.2.5 That an apology has been made in line with duty of candour requirements should be recorded in the appropriate section on the Datix incident report.

7.2.6 Support should be provided to the patient, their families or carers after the incident, throughout the investigation and on-going as required including providing the patient or their family with the contact details of an identified person who will coordinate communication and be a single point of contact.

7.2.7 Commence an investigation into the incident.

7.2.8 The patient/family should be informed if the incident meets the criteria and is being investigated as a serious incident. Whilst duty of candour requirements apply to serious incidents, timescales for investigation may vary and the patient /family should be informed of expectations and that investigation may take up to 60 days.

7.3 Within 28 working days of the incident

7.3.1 An investigation into the incident must be progressed to determine why the incident happened, and an explanation of the events and circumstances which resulted in the incident including identifying learning.

7.3.2 During the course of the investigation the patient/relevant person must be kept informed of progress, especially if agreed timescales are likely to slip; written records should be maintained of communication and interactions.

7.3.3 If the incident is not being investigated as a serious incident, the investigation should be concluded within 28 days and a report provided to the patient/relevant person outlining an explanation of the events and circumstances which resulted in the incident. A suggested report template is available in Appendix 5.

7.3.4 All final incident reports must be reviewed and agreed by the Deputy Director of Quality and Governance/Deputy Chief Nurse or the Delegated Manager as suitable and sufficient to outline the root cause of the incident.

7.4 Within 10 days of the investigation report being completed and accepted

7.4.1 Final reports must be reviewed and approved for release and suitably redacted if required.

7.4.2 Approved, final reports must be shared with the patient/relevant person and a copy made available in a manner of their choosing, for example email or printed copy. Example letter templates are provided in Appendix 4.

7.4.3 The patient/ relevant person must be provided with an opportunity to discuss the findings.

7.4.4 The service must commence actions to implement recommendations identified through investigation.

7.5 Documenting all communication

7.5.1 Throughout the being open and duty of candour process it is important to maintain clear, contemporaneous records including:

- Dates when discussions took place with the patient/family/ carers
- Time, place, date and names of who attended meetings/ discussion
- Plan for providing further information
- Offers of assistance
- Questions raised by the patient/ family/ carer
- Plans for follow up meetings

- Progress notes relating to the clinical situation and an accurate summary of all the points explained to the patient/ family/ carers
- Copies of letters sent to the patient/ family/ carers
- A summary of the 'being open' discussions

7.5.2 It is recommended that all documentation relating to the being open and duty of candour process is, as a minimum, stored within the Datix incident report, including copies of letters and notes of meetings.

8. Special considerations

The following gives guidance on how to manage different patient circumstances, it is based on guidance provided within *"Being open. Communicating patient safety incidents with patients and their carers" (National Patient Safety Agency, 2009).* When managing different patient circumstances, the over-arching principle is that each circumstance is carefully considered, to ensure that appropriate, sensitive and respectful communication occurs.

8.1 When a patient dies

8.1.1 When an incident has resulted in a patient death it is crucial that communication is sensitive, empathic and open and takes into consideration the individual circumstances of the event and the timing when to discuss what has happened with bereaved relatives or carers.

8.1.2 An incident that results in the patient death will be reported and investigated as a Serious Incident.

8.1.3 Usually the being open discussion and investigation will occur before the Coroner's inquest. Occasionally however, the Trust may consider it appropriate to wait for the outcome of a Coroner's inquest before holding being open discussions. On these occasions it is important to explain to the relatives that they will be kept informed as information is released form the Coroner's Office.

8.1.4 The circumstances surrounding the death of a patient may give rise to police enquiry. This should not prevent a being open meeting taking place with relatives or carers. It is however important to underline the need ensure that only facts known at the time are communicated.

8.2 Patients with cognitive impairment and who may lack capacity

8.2.1 Wherever possible the patient, including a patient with a cognitive impairment, will be involved in communication about what has happened. An advocate with appropriate skills should be available to the person to assist in the communication process. Referrals for an advocate can be made through PoHwer on 0300 1234044.

8.2.2 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 someone who holds a valid 'Lasting Power of Attorney' or 'Deputy of the Court of Protection'. In these cases steps must be taken to clarify the extent of this authority and the 'being open / duty of candour' discussion would be held with the holder of the power of attorney. This person would be the relevant person with regards the duty of candour requirements. Where there is no such person, the clinicians may act in the patient's best interest in deciding who the most appropriate person to discuss incident information should be with, regarding the welfare of the patient as a whole

and not simply their medical interests.

8.3 Safeguarding

8.3.1 Staff must consult the relevant safeguarding policy for guidance on information sharing when there is a patient safety incident involving concerns about a vulnerable child or adult at risk. This does not exclude safeguarding incidents from the requirements of this policy nor working to the principles of being open as per HCT Safeguarding Adults policy and HCT Safeguarding Policy for Children and Young People aged 0-18 years.

8.4 Children

8.4.1 The legal age of maturity for giving consent to treatment is 16. This is the age at which a young person acquired 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.

8.4.2 The courts have stated that younger children who understand fully what is involved in the proposed procedure can give consent (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 an incident. The opportunity for parents to be involved should still be provided unless the child expresses a wish for them not to be present.

8.4.3 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.

8.5 Patients with different communication needs

8.5.1 Some patients will have particular communication needs including for example patients with hearing impairment or those with learning disability. Plans for meeting with the patient and discussing the incident should fully consider these needs.
For example access needs may need to be taken into account when planning communication with patients and their families to ensure equity of access. This may include making adjustments to allow access to a building, or other premises or particular aids or equipment such as portable induction loop, for people with hearing aids, British sign Language interpreters, providing information in alternative formats such as Braille or audio CDs. Knowing how to enable or enhance communication with a patient is essential to facilitating an effective being open process as is focusing on the needs of the individuals and their families and being personally thoughtful and respectful.

8.6 Patients with different language or cultural considerations

8.6.1 The need for translation and advocacy services, and consideration of special cultural needs, including for example patients who may prefer discussions with people of the same gender as themselves, must be taken into account when planning to discuss patient safety information. Avoid using 'unofficial translators' and/or patient's family or friends.

8.7 Patients with mental health issues

8.7.1 Being open for patients with mental health issues should follow normal procedures,

unless the patient also has a cognitive impairment (see above). The only circumstances in which it is appropriate to withhold patient safety incident information from a patient with mental health issues is when advised to do so by a consultant psychiatrist who feels it would cause adverse psychological harm. However, such circumstances are rare.
Apart from in exceptional circumstances it is never appropriate to discuss patient safety information with a carer or relative without permission of the patient.

9. Implementation and training

9.1 This policy will be available as reference for all staff at all the times and the Trust will ensure all staff implementing this policy have access to appropriate implementation tools and advice.

9.2 There are no mandatory training needs in relation to implementing this policy.

9.3 However, training delivered associated with risk management, incidents, complaints and Patient Advice and Liaison service (PALS) management, undertaking investigations and serious incident management will include the principles of being open and the requirements of duty of candour.

9.4 Senior managers including deputy general managers and general managers, ward/line managers and locality/service managers are responsible for ensuring implementation of the policy including that all relevant staff receive appropriate training both at induction and thereafter, annual competence assessment and three yearly update training.

10. Monitoring compliance and effectiveness of policy

10.1 The compliance and effectiveness of this policy has to be tested primarily through audit of key performance indicators (KPIs) as shown in attached Appendix 6. This will be undertaken by the Lead Policy Author in accordance with the timescales identified.

11. Review, Revision and Governance

11.1 The review, updating and archiving process for this policy shall be carried out in accordance with the Trust (HCT) GR1 Policy for Procedural Documents, V.4 by the identified Lead Policy Author.

11.2 The version control table as listed in Appendix 7 enables appropriate control of the policy with listed personnel responsible for its implementation as well as the date assigned/ approved/ circulated.

12. Equality Impact Analyses (EIA)

12.1 It is the responsibility of the Lead Policy Author to complete the EIA form (Appendix 8) before submitting the policy for ratification.

13. References

- The National Reporting and Learning website provides further information and resources in relation to 'Being open': http://www.nrls.npsa.nhs.uk/site-map/ This includes:
- National Framework for Reporting and Learning from Serious Incidents Requiring Investigation. (2009)
- National Reporting and Learning Service (NRLS) Data Quality Standards: Guidance for Organisations Reporting to the Reporting and Learning System (RLS)
- Medical Error: What to do if things go wrong: A guide for junior doctors. (2010)
- Patient Safety Alert. Being Open: Communicating with patients, their families and carers following a patient safety incident. (2009)
- Department of Health. (1999). *HSC 1999/198. The Public Disclosure Act 1998: Whistle blowing in the NHS.* London: Department of Health. Available at: www.dh.gov.uk
- Department of Health. (2009). *Listening, Responding, Improving: A guide to better customer care.* London: Department of Health. Available at: www.dh.gov.uk
- General Medical Council (GMC). (2009 [1995]). *Good Medical Practice*. London: GMC. Available at: www.gmc-uk.org
- Nursing & Midwifery Council (NMC). (2009 [2008]). '*The Code: Standards of conduct, performance and ethics for nurses and midwives*'. NMC website page. NMC. Available at: www.nmc-uk.org
- Saying sorry when things go wrong: Being Open: Communicating patient safety incidents with patients, their families and carers. NPSA 2009
- Care Quality Commission (CQC) – Regulation 20: Duty of candour (March 2015)

14. Appendices

The following appendices are attached to support this policy:

Appendix 1 – The ten principles of being open
Appendix 2 – Flow chart - Duty of candour process
Appendix 3 – Practical examples
Appendix 4 – Example template letters
Appendix 5 – Example investigation report template
Appendix 6 – Monitoring compliance for the policy
Appendix 7 – Version control table
Appendix 8 – Equality impact analyses form

APPENDICES

Appendix 1: The ten principles of being open

"Saying sorry when things a go wrong: Being open: Communicating patient safety incidents with patients, their families and carers", (NPSA 2009).

The National Patient Safety Agency being open framework has 10 guiding principles which the Trust has adopted and will follow to ensure a proactive approach to being open.

1. Principle of acknowledgment

- All patient safety incidents should be acknowledged and reported as soon as they are identified. In cases where the patient and/or their 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.

2. Principle of truthfulness, timeliness and clarity of communication

- Information about a patient safety incident must be given to patients and/or their carers in a truthful and open manner by an appropriately nominated person.
- Communication should also be timely: patients and/or their carers should be provided with information about what happened as soon as practicable.
- Patients should receive clear information and be given a single point of contact for any questions they may have. They should not receive conflicting information from different members of staff, and medical jargon which they may not understand should be avoided.

3. Principle of apology

- Patients and/or their carers should receive a sincere expression of sorrow or regret for harm that has resulted from a patient safety incident. This should be in the form of an appropriately worded and agreed manner of apology, as early as possible.
- Both verbal and written apologies should be given. Organisations should decide on the most appropriate member of staff to issue these apologies. The decision should consider seniority, relationship to the patient, and experience and expertise in the type of patient safety incident that has occurred.
- Verbal apologies are essential because they allow face-to-face contact between the patient and/or their carers and the healthcare team. This should be given as soon *as* staff are aware that an incident has occurred.
- A written apology, which clearly states the healthcare organisation is sorry for the suffering and distress resulting from the incident, must also be given.

4. Principle of recognising patient and carer expectations

- Patients and/or their carers can reasonably expect to be fully informed of the issues surrounding a patient safety incident in a face-to-face meeting with representatives from the healthcare organisation. They should be treated sympathetically, with respect and consideration.
- Confidentiality must be maintained at all times.
- Patients and/or their carers should also be provided with support in a manner appropriate to their needs including considering special circumstances such as a patient requiring additional support, such as an independent patient advocate or a translator.

5. Principle of professional support for staff

- Staff should feel supported throughout the investigation process. They should not be unfairly exposed to punitive disciplinary action, increased medico-legal risk or any threat to their registration.
- Where there is reason for the healthcare organisation to believe a member of staff has committed a punitive or criminal act, the organisation should take steps to preserve its position, and advise staff at an early stage to enable them to obtain separate legal advice and/or representation. They should be encouraged to seek support from relevant professional bodies such as the General Medical Council, Royal Colleges, the Medical Protection Society, the Medical Defence Union and the Nursing and Midwifery Council.

6. Principle of risk management and systems improvement.

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

7. Principle of multidisciplinary responsibility

- Most healthcare provision involves multidisciplinary teams and communication with patients and/or their carers following an incident that led to harm, should reflect this.
- Senior managers and clinicians must participate in incident investigation and clinical risk management and champion the being open process.

8. Principle of clinical governance

- *Being open* requires the support of patient safety and quality improvement processes through clinical governance frameworks, in which patient safety incidents are investigated and analysed, to find out what can be done to prevent their recurrence.

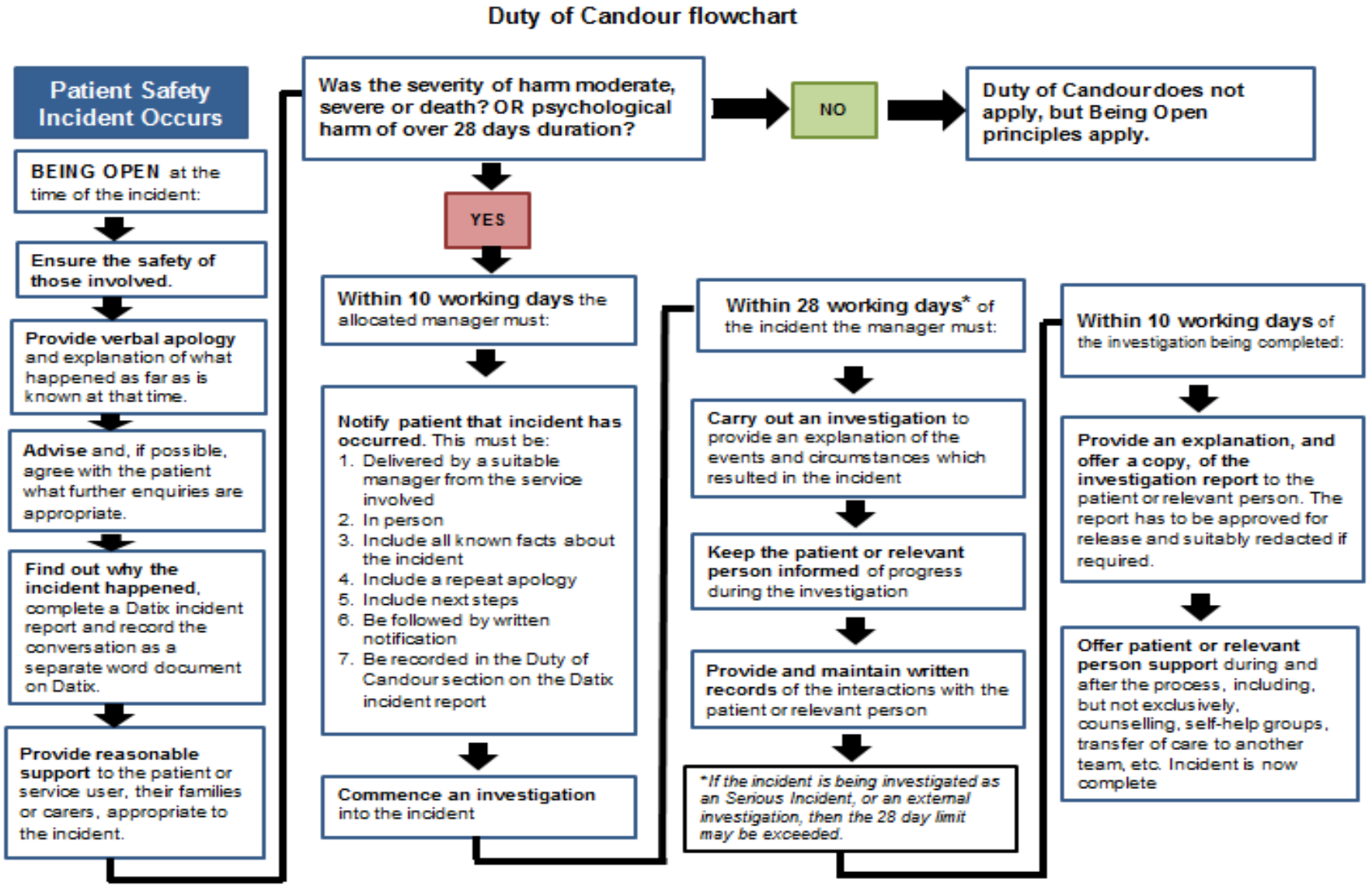
9. Principle of confidentiality

- Policies and procedures for being open should give full consideration of, and respect for, the patient's and/or their carer's and staff privacy and confidentiality.
- Details of a patient safety incident should at all times be considered confidential. The consent of the individual concerned should be sought prior to disclosing information beyond the clinicians involved in treating the patient.
- 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.

10. Principle of continuity of care

- Patients are entitled to expect they will continue to receive all usual treatment and continue to be treated with respect and compassion.
- If a patient expresses a preference for their healthcare needs to be taken over by another team, the appropriate arrangements should be made for them to receive treatment elsewhere.

Appendix 2: Duty of candour flowchart



Appendix 3: Practical examples - being open and duty of candour in practice

<table>
<tr><th colspan="2">What does BEING OPEN look like in practice?</th></tr>
<tr><td colspan="2">A patient with dementia fell on one of the wards; they fell whilst in their room and the fall was unwitnessed.

When the nurse arrived after hearing the fall, the patient was on their knees and was attempting to stand.

The patient sustained a small skin tear to their arm and shortly after the fall bruising began to develop on the arm.</td></tr>
<tr><th>How the clinician managed the incident</th><th>Being open</th></tr>
<tr><td>The nurse asked and the patient expressed that they were not in pain. As the patient was attempting to stand, the nurse judged it appropriate to help the patient on to their bed where the patient was examined for injury.

The patient was asked, but was unable to provide full details about the fall. As the fall was un-witnessed neuro observations commenced.

The patient did not report pain and had full movement in all limbs. The decision was therefore made to alert the ward doctor but that immediate medical examination was not indicated.

The skin tear was dressed and the fall, the injuries sustained and the actions taken were summarised in the clinical records.

A Datix incident report was completed and detailed the circumstances of the fall. The injuries were correctly assessed as being ‘low harm’, as the patient required only minor treatment. The Datix report also provided a summary of the preventative care in place at the time of the fall.

The nurse phoned the patient’s daughter and informed them of the fall, expressed regret that it had happened and that the daughter’s father had bruised his arm and had a skin tear but was otherwise unharmed.

The falls risk assessment was repeated and falls care plan reviewed. Extra measures were considered to help prevent the patient falling again.</td><td>The level of harm was correctly assessed by the nurse as being ‘low harm’.

As the patient did not suffer ’moderate’ or more ‘severe’ harm the incident did not trigger formal ‘duty of candour’ requirements.

However, in line with the principles of being open the nurse contacted the family and alerted them to the fall. The nurse offered an apology, provided an explanation and gave the family an opportunity to discuss the fall.</td></tr>
</table>

What does DUTY OF CANDOUR look like in practice?

A new frame was delivered to an inpatient in a community hospital. The patient used the frame for two weeks before the incident occurred.

At time of incident the patient had been sitting on the seat of the frame when one of the front swivel wheels detached, causing the patient to fall backwards. The patient hit her head resulting in a haematoma to the head, a small open wound to left elbow and a 5cms haematoma to her right calf.

The patient was admitted to hospital because of suspected head trauma. A CT scan showed no new injuries and the patient returned to the ward the next day.

Whilst not a serious incident, the patient suffered **moderate harm** and therefore, in line with duty of candour requirements, a more involved response was needed.

The actions taken by the Lead Neurological Physiotherapist provide an example of what 'good' looks like in respect to being open and meeting duty of candour requirements.

How the clinician managed the incident	Duty of candour
"I spoke to the patient yesterday to apologise for the distress that the incident had caused. I explained the processes that are in place to escalate the incident wider and that this could include recall of other frames and medical device alerts to other organisations as necessary, should the piece of equipment be found to be faulty. I asked if the patient would like me to keep her updated on the stages of the investigation and the patient said that she would. I agreed to write down the details of our discussion today for her and also to speak to any of her family who may wish to discuss this with me. She felt her daughter-in-law may wish to talk to me and she consented to this. I have given her my contact details. I will add this information to the Datix incident report and summarise the incident and the outcome in the patient's clinical notes".	Senior clinician met with patient after the incident. Apology and explanation offered. Whilst not a serious incident, service followed up incident (including liaising with Medical Devices) and undertook local investigation. Informed patient what actions were being taken to find out why incident happened and ensure safety of other patients. Offered to provide patient with an update. Offered to write down discussion. Clinician provided her contact details. Offered to meet with patient's family. Updated clinical notes. Updated Datix to ensure information full and accurate.

Appendix 4: Letter Templates (guidance examples)

Letter templates are provided for guidance only; all final letters must be personalised and tailored to the individual situation and the individual needs of the person receiving the letter and reflect discussions that have been had and agreements that that have been reached.

Written notification/apology

Example 1
Letter of apology to be written after a patient safety incident where the patient has suffered ***moderate or more severe harm****. Letter to be written within 10 working days of the incident and after the patient has been verbally informed that the circumstances and events of the incident are being investigated.*

Dear XXX

Thank you for taking the time to talk *with me/my colleague* regarding *XX (e.g. your father's fall on 23rd June and subsequent fractured hip)*.

I would like to express my sincere apologises that this event occurred while *XX* was in our care and want to assure you that we will be investigating this incident to understand how this happened and whether there is anything that we could do differently in future to stop this happening to anyone else.

As a trust we are committed to being open when events such as this happen and I will write to you again within the next XX weeks *(i.e. 10 working days after the investigation has been completed)* once the findings of the investigation are known.

Once you have received our investigation findings we would welcome the opportunity to meet with you again to discuss the findings more personally and answer any questions that you may have.

In the meantime, should you have any questions please don't hesitate to contact me on XXX

Yours sincerely

Manager name and designation

Conclusion of investigation / offering copy of report / offering to meet

Example 2
Letter written at conclusion of the investigation within agreed timescales and reflecting agreements that have been reached with the patient/relevant person, for example the patient may have requested to receive the complete investigation report, requested a meeting, requested a summary only.

Dear XXX

As agreed during our discussion on X and subsequent letter on X, we have investigated the incident concerning your X (*e.g. father*).

Please find enclosed a copy of the investigation report.

Once you have had an opportunity to read the report, and should you find it helpful, we would be pleased to arrange a time to meet with you to talk through the findings and to answer any questions you may have. If this is something that you would find helpful please let me know.

I hope that the investigation and the findings help to assure you that we have taken appropriate steps to understand why this incident happened and to identify any lessons that may need to be learnt to help prevent a similar incident happening again.

Should you have any questions please don't hesitate to contact me on XXX

Yours sincerely

Manager name and designation

Example 3
Letter written at conclusion of the investigation within agreed timescales and reflecting agreements that have been reached with the patient/relevant person, for example the patient may have requested to receive a summary of the investigation findings.

Dear XXX

As agreed during our discussion on X and subsequent letter on X, we have investigated the incident concerning your X (*e.g. father*).

Please find below a summary of the investigation findings:

Description:
(Enter text/concise summary of incident being investigation)

Immediate action taken:
(Enter text/concise summary of actions taken immediately after the incident – could be presented as bullet points or short paragraph)

Investigation findings:
(Enter text/concise summary of findings – Why incident occurred? Root cause identified through investigation)

Lessons learned:
(Enter text/concise summary of what will be done differently/ what investigation identified)

How the lessons learned will be shared across the Trust:
(Enter text/concise summary giving assurance of how learning will be communicated)

I trust that the actions we have taken help to assure you that appropriate steps have been taken to identify care and treatment issues relevant to the incident, and that recommendations for action have been prioritised.

Yours sincerely

Manager name and designation

Appendix 5: Example Investigation report template

Investigation Report (duty of candour)					
About the Incident					
DATIX INCIDENT REF:		BUSINESS UNIT		GENERAL MANAGER	
SERVICE TEAM/AREA		DATE & TIME OF INCIDENT		LOCALITY/SERVICE MANAGER	
Summary of Incident					
Immediate actions taken					
Chronological account of events leading up to the incident, the incident itself					
Date/Time	**Details**				
Analysis					
Conclusions					
Root Cause(s)					
Lessons Learned / Recommendation / Actions					
How Lessons Learned will be shared across the Trust					
Investigation and report completed by:					
Name		Job Title		Date	

Appendix 6: Monitoring compliance of policy

This document will be used to ensure effective monitoring and to seek compliance assurance for the policy.

Policy Name	Being open and duty of candour	Policy Version	V.1		
Lead Policy Author	Christine Stock	Date of Ratification	04/05/17	Date of next review	May 2019

Requirement to be monitored (WHAT)	Lead (WHO)	Tool (HOW)	Frequency of Monitoring (WHEN)	Reporting Arrangements (WHERE)	Development of Action Plan (WHAT and WHO)	Monitoring of Action Plan and Implementation (HOW and WHEN)
Duty of candour requirements to be met for all incidents that result in patient's suffering moderate or more severe harm, in line with actions detailed in Appendix 3 (DoC flowchart)	Head of Risk	Head of Risk will ensure regular and frequent review of all incidents reporting moderate or more severe harm, to ensure grading is correct and that DoC actions and standards are evidenced within the Datix risk management system.	Daily (review of moderate or more serious incidents).	Head of Risk to be informed when moderate or more severe incidents are reported	Head of Risk to ensure systems in place to monitor incidents requiring DoC actions	Monitoring arrangements will be built into Datix teams regular review processes.
Duty of candour requirements to be met for all incidents that result in patient's suffering moderate or more severe harm, in line with actions detailed in Appendix 3 (DoC flowchart)	Head of Patient Safety	To undertake a quarterly review of all moderate or more severe incidents; data to be gathered from Datix risk management system, tool to be developed based on Appendix 3 key DoC requirements	Quarterly	To Patient Safety and Experience Group	Themes and patterns will be identified and as appropriate communicated to relevant senior managers along with actions needed to improve performance	Performance will be monitored quarterly. When actions are identified to address standards that have not been met/patterns that have been identified these will be reviewed at the Patient Safety and Experience Group.

Appendix 7: Version control table

Version No.	**Status** (Draft / Approved)	**Lead Policy Author**	**Date ratified** (dd/mm/yyyy) **and assigned Designated Committee**	**Comment** (Key points of amendments)
V.1	Consultation draft	Christine Stock		Correcting layout/grammatical errors. Developing 'Special Consideration sections 7.2,7.5,7.6
V.1	Final draft	Christine Stock	April 2017	
V.1	Approved draft	Christine Stock	04.05.17	HCT Being Open Policy is merged with Duty of Candour Policy now

Appendix 8: Equality impact analysis form

To be undertaken, completed and attached to any procedural document when submitted to the appropriate committee for consideration and ratification.

Name of the Policy	Being open and duty of candour
Date of Equality Analysis	22/03/2017
Those involved in this analysis	Christine Stock, Head of Patient Safety Monika Kalyan, Equality & Diversity Manager

Intended Outcomes What are the Desired Outcomes? What are the benefits?	**Human Rights Approach** What are the patient's core rights as part of this service / function? Are there any gaps identified? What are the risks? What action is needed to mitigate risk and / or close the gap?
The policy outcomes are to ensure that the Trust is open and transparent in response to incidents, complaints and claims and meets its statutory duty of candour in respect to notifiable patient safety incidents.	Being open recognises that everyone has the right to be treated with respect and to receive fair and dignified treatment. Being open enables the Trust to fulfil its duties to promote human rights in a practical, day-to-day level. It particularly enables the Trust to promote the right to a fair trial and the right to freedom of expression.

Evidence What evidence is being used to support and develop the service / function?	**What are the Risks?** What are the risks in providing an equitable service? How can these risks be reduced, managed or justified?
This policy outlines to staff the importance and of being open with patients, carers and others, and the process that must be followed when a notifiable patient safety incident occurs.	See below

Who will be Affected? Identify issues in relation to each of the protected groups below:	
Race: None	Gender Reassignment: None
Disability: None	Religion or Belief: None
Gender: None	Maternity & Pregnancy: None
Age: None	Marriage & Civil Partnership: None
Sexual Orientation: None	

What Workforce Issues, including job role and design, need to be considered?	**Engagement and Involvement** Who has been involved in this analysis?
None	Christine Stock and Monika Kalyan

Actions Identified: None

S. No.	What	Who	When	Cost