

Being Open and Duty of Candour Policy

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1. INTRODUCTION

1.1. Purpose

Harrogate and District NHS Foundation Trust ('the Trust') recognises and acknowledges the importance of good communication and openness between staff and patients and carers at all times, not just when things go wrong.

The purpose of this policy is to set out the arrangements for open and honest communication following an event/incident, complaint or claim in compliance with the Being Open principles and Duty of Candour requirements.

1.2. Scope

This Policy applies to all staff employed by Harrogate and District NHS Foundation Trust (HDFT) and Harrogate Integrated Facilities (HIF). It is based on the National Patient Safety Agency [Being Open](#) Framework (November 2009) and [The Health and Social Care Act 2008 \(Regulated Activities\) Regulations 2014](#).

1.3. Definitions

Being Open Principles – The 10 principles developed by the NPSA and set out in Appendix 1 – these principles require the Trust and its staff to be open and transparent in all dealings with people who use our services. This applies equally to no harm or low harm events where the statutory Duty of Candour has not been triggered, but an apology and being open with the patient is the right things to do. If felt appropriate, the Duty of Candour steps may still be followed (i.e. follow-up in writing, offer of the investigation report) for low or no harm events.

Duty of Candour Requirements – The requirement to follow the specific processes as described in sections 2.3.3 to 2.3.9 of this policy and in particular the flowchart found at Appendix 2 in all cases where a 'Notifiable Safety Incident' has occurred. These processes reflect the statutory Duty of Candour. The Duty of Candour requirements involve:

- Recognising when an event occurs that impacts on a patient in terms of harm;
- Acknowledging when things go wrong;
- Notifying the patient in person (wherever possible), explaining that something unintentional or unexpected has occurred and providing a true account of what happened;
- Apologising to the patient and/or representative;
- Conducting a thorough investigation into the event and reassuring patients, their families and carers that lessons learned will help prevent the incident recurring in accordance with the [Events and Serious Incidents Policy](#);
- Ensuring the patient, family and carers are appropriately and adequately supported and kept informed following the event and during the investigative process;

- Keeping proper records of all steps in the process and sending a written notification to the patient;
- Supporting those involved to cope with the physical and psychological consequences of what happened in accordance with the [Investigating, Learning and Supporting Guide](#).

Notifiable Safety Incident - any unintended or unexpected event that occurred during the provision of services that resulted, or could result, in:

- **Death** of the service user - where the death relates directly to the incident rather than the natural course of an illness or underlying condition
- **Severe harm** - a permanent lessening of bodily, sensory, motor, physiologic or intellectual functions, including removing 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
- **Moderate harm** - harm that requires a moderate increase in treatment, and significant, but not permanent, harm. The moderate increase in treatment could for example be an unplanned return to surgery, an unplanned re-admission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment or transfer to another treatment area (such as intensive care)
- **Prolonged 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

Patient Safety Incident - any unintended or unexpected event which could have or did lead to harm for one or more patients receiving NHS funded care.

Level of Harm – the possible levels of harm following a Patient Safety Incident as defined by the NPSA (RCA Glossary published by NPSA in August 2000):

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 (near miss). 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 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 persons receiving NHS-funded care.
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Supporting information on the grading of incidents can be found in the [Risk Assessment Matrix](#) on the intranet in the Department of Risk & Patient Experience section.

2. POLICY

2.1. Flowchart

The required process is outlined in the flowchart at Appendix 2.

2.2. Principles and how staff are encouraged to have open communication

Openness about what happened and discussing patient safety events promptly, fully and compassionately can help patients and carers cope better with the after effects. Being open is a process rather than a one-off event. The NPSA developed 10 Being Open Principles to guide organisations in how to be open. These principles are set out in full at Appendix 1 and underpin this policy. Since November 2014, the Trust has also had a legal duty to act in an open and transparent way with patients and their carers in relation to the care and treatment provided. Being open benefits patients, their families and carers, healthcare staff and healthcare organisations.

The Trust encourages open communication through numerous avenues. As part of this the Trust Board of Directors has issued a statement of commitment on Being Open. Staff are encouraged to have open communication through clarification in this policy and other risk management policies such as the [Events and Serious Incidents Policy](#) and the [Investigating, Learning and Supporting Guide](#).

An information leaflet outlining the principles of Duty of Candour was circulated to all staff in June 2015 and is also now given during Trust Induction for new starters. Information is provided on Being Open/Duty of Candour via the eLearning packages for Quality Governance and for investigations of incidents, complaints and claims. Training is also provided within the three clinical directorates by Quality Assurance Leads and supported by Risk Management.

2.3. An explanation of the process for acknowledging and explaining when things go wrong

This section should be read in conjunction with the flowchart found at Appendix 2.

2.3.1. Step 1: Event is identified and reported

In accordance with the Trust's [Events and Serious Incidents Policy](#), when any Patient Safety Incident occurs staff are required to complete an event report using Datix.

If the Duty of Candour is triggered in a complaint or a claim, Datix will be checked to see if there is a corresponding event report. If one has not been made previously, a Datix report should be completed and the following process will be considered.

2.3.2. Step 2: Verification

Once a Datix report has been made, the Risk Management Department will verify the level of harm attributed to the event by the reporter. If a level of harm has not been attributed, the Risk Management Department will attribute one in consultation with the Consultant of Care. The various levels of harm are set out in section 1.3 above and briefly are as follows:

- No harm
- Low harm
- Moderate harm
- Severe harm
- Death

The next steps will depend on the level of harm identified and the grading of the event. The following table summarises the possible outcomes:

Level of Harm	Action needed
No Harm or Low Harm	Follow the Being Open Principles (Appendix 1)
Moderate Harm or Severe Harm or Death	Follow the Being Open Principles (Appendix 1) and the Duty of Candour Requirements (Steps 3 – 9 below and Appendix 2)

Steps 3 to 9: The Duty of Candour Requirements

2.3.3. Step 3: Identify Responsible Duty of Candour Lead

The event owner assigned to the Datix report is deemed to be the responsible Duty of Candour lead initially. In conjunction with Risk Management the event owner will consider if this should be changed to the Consultant of Care or another appropriate clinician.

2.3.4. Step 4: Duty of Candour Conversation

The responsible Duty of Candour lead must hold a face-to-face Duty of Candour conversation with the patient and/or their carers (as appropriate to the individual case). The following factors should be considered:

Timing

The initial Duty of Candour discussion with the patient and/or their carers should occur as soon as is practicably possible after recognition of the event, or at the latest within 10 days of the incident. Factors to consider when timing this discussion include:

- The clinical condition of the patient;
- Patient preference (in terms of when and where the meeting takes place and which healthcare professional leads the discussion);
- Privacy and comfort of the patient;
- Availability of key staff involved in the event and in the candour process;
- Availability of the patient's family and/or carers;
- Availability of support staff, for example Patient/Family Liaison Officer;
- The need for a translator;
- Arranging the meeting in a sensitive location;
- Offering a choice of times for a meeting, and confirming the chosen date in writing;
- Not cancelling the meeting unless absolutely necessary.

Location

- Use a quiet room where there are no distractions from work, and where there will be no interruptions;
- Do not host the meeting near to a place where the event occurred as this may be difficult for the patient, their family and carers.

Who should you have the candour discussion with?

- In the normal course of events, the candour conversation should take place with the patient.
- In some cases, the patient may be incapacitated due to their physical or mental condition. Unfortunately, in some cases the patient may have died. In such cases, the candour discussion should be held with a person lawfully acting on behalf of the patient. In practical terms, this will be the next of kin or the person named by the patient as someone to consult with about their care. Care must be taken to protect the confidentiality of the information about the patient and discussions should not be held with people who have been identified as people with whom the patient expressly did not want information shared. Where information is shared then this should be restricted to that which is necessary and proportionate to enable the candour discussion to take place.

What if the patient cannot be contacted or declines to speak to staff about the incident?

In the event that the patient cannot be contacted or does not wish to speak to staff about the event, then, provided reasonable attempts have been made to have the candour discussion, a written record must be kept of the attempts to contact or speak to the relevant person. This record should be made in the patient's notes.

Content of the initial Duty of Candour discussion

Inform the patient, their family and their carers of all the people (including their role) who will be attending the candour discussion in advance. This allows them the opportunity to state their own preferences about which healthcare staff should be present.

The core elements of the candour discussion

- A face to face meeting should be held where the patient and/or their representative will be provided with the following information:
 - There should be an expression of genuine sympathy, regret and an apology for the harm that has occurred.
 - The patient should be provided with a true account and explanation of the facts as they are known at that time. Staff should stick to the facts that are known and agreed by the multidisciplinary team.
 - An explanation should be given about what will happen next in terms of the further enquiries which will be carried out into the incident, the short through to long-term treatment plan and incident analysis findings.
- The patient must be provided with reasonable support in relation to the incident, including support during the face-to-face discussion. Support may need to be provided on an on-going basis (see below).

Practical tips and points to note

- It should be made clear to the patient, their family and their carers that new facts may emerge as the incident investigation proceeds. Assure them that if more information becomes available it will be shared with them and agree a plan of how this will be done.
- Check that the information given to the patient, their family and carers has been understood, and offer to answer any questions.
- The patient's, their family and carer's understanding of what happened should be taken into consideration, as well as any questions they may have.
- There should be consideration and formal noting of the views and concerns of the patient, their family and carer, and it should be made clear that these are being heard and taken seriously.
- Appropriate language and terminology should be used when speaking to patients, their family and carers. If a patient's, their family or their carer's language is not English, it is also important to consider their language needs and then make the necessary arrangements. See the protocol for translators – [Booking a translation](#)
- Information on likely short and long-term effects of the incident (if known) should be given. The long-term effects may have to be presented at a subsequent meeting when more is known.
- An offer of practical and emotional support should be made to the patient and/or their carers. This may involve getting help from third parties such as counselling service, charities and voluntary organisations as well as offering more direct assistance.
- A record of offers of support to the patient/family should be made, including maintaining a record of letters sent to the patient/family in compliance with the Duty of Candour, which include details of support arrangements.

- Appointment of a Patient/Family Liaison Officer in the case of Serious Incidents (SIs) and Significant Events (SEs), as appropriate, to ensure the patient/family receive adequate support and updated information and have a point of contact.
- Information about the patient and the event should not be disclosed to third parties without the consent of the patient.
- It should be recognised that patients, their family and carers may be anxious, angry and frustrated even when the candour discussion is conducted appropriately.
- It is essential that the following **do not** occur:
 - Speculation;
 - Attribution of blame;
 - Denial of responsibility;
 - Provision of conflicting information from different individuals.
- The initial candour discussion is the first part of an ongoing communication process. Many of the points raised here should be expanded on in subsequent meetings or via correspondence sent if the patient/representative indicate they wish to receive a copy of the investigation report.
- Advice or guidance can be sought from the Quality Assurance Lead in each clinical Directorate or the Risk Management Department.
- Staff members involved in the incident may also be traumatised and if so, should be fully supported by their line manager. The HR team, and Occupational Health are additional sources of support if required.

Documentation

The candour conversation and outcomes must be documented in a letter to the patient/representative, in the patient notes and on Datix, including what support is required and if a copy of the investigation report is requested.

2.3.5. Step 5: Written Apology and Notification

A written summary of the candour discussion must be forwarded to the patient or family/carers (as appropriate), as soon as is practicably possible. This will usually be from the Consultant of Care or Head of Nursing depending on the type of incident. In the case of concise SIs (i.e. pressure ulcer and falls investigations), this will come from the Head of Nursing and in the case of comprehensive SIs or SEs, these letters will come from the Chief Executive, Medical Director or their deputy.

The written notification should include:

- Confirmation of the face to face discussion,
- An outline of the facts of the event,
- An open apology,
- Confirmation of the investigation process and individual contact details for the investigation team,
- The results of any enquiries carried out into the event to date.

A written apology notification should also include details of how the investigation findings will be shared as agreed, if known at that time (via the Patient Liaison Officer in the case of comprehensive SIs).

In some straightforward cases, where it is clear from the outset or at an early stage what has happened (e.g. injury arising from a known complication of procedure that the patient was consented for), a separate investigation may not be required. In these cases, the candour conversation should include a full explanation of what happened and this should all be included in the letter, but a separate investigation report will not be offered to the patient. The letter should also include contact details in case the patient does have further concerns or queries about the case.

Advice or guidance can be sought from the Quality Assurance Lead in each clinical Directorate or the Risk Management Department.

A copy of the written apology and notification letter should form part of the patient's medical record.

2.3.6. Step 6: Incident Investigation

An investigation into the cause of the event must be conducted in accordance with the Trust's [Events and Serious Incidents Policy](#). Templates are available for the investigation and the Duty of Candour letters in the [Duty of Candour Toolkit](#) on the intranet.

2.3.7. Step 7: Review

For comprehensive SIs and Significant Events, once the investigation has been completed and an action plan produced, it will be reviewed at the Complaints & Risk Management Group (PESH – see section 3.4) in line with the Trust Events & Serious Incidents Policy.

2.3.8. Step 8: Investigation Completion and Final Apology

Following approval, the letter and report are sent to the patient or representative from the Consultant of Care, Head of Nursing, Medical Director or Chief Executive (depending on the level of investigation), unless they have specified that they do not wish to receive a copy. The offer of follow-up discussion is usually made.

Follow-up discussions are an important step in the candour process. Depending on the event and the timeline for the investigation there may be more than one follow-up discussion.

The following factors should be considered for any follow up meeting:

- The discussion should occur at the earliest practical opportunity;
- Consideration should be given to the timing of the meeting, based on both the patient's health and personal circumstances;
- Consideration should be given to the location of the meeting, for example at the patient's home;
- Feedback should be given on progress to date and information provided on the investigation process;

- There should be no speculation or attribution of blame. Similarly, the healthcare professional communicating the incident must not criticise or comment on matters outside their own experience;
- The patient, their family and carers should be offered an opportunity to discuss the situation with another relevant professional where appropriate;
- A written record of the discussion should be kept and shared with the patient, their family and carers;
- All queries should be responded to appropriately;
- If completing the process at this point, the patient, their family and carers should be asked if they are satisfied with the investigation and a note of this made in the investigation file;
- The patient should be provided with contact details so that if further issues arise later there is a conduit back to the relevant healthcare professionals or an agreed substitute.

2.3.9. Step 9: Learning

The Trust will communicate with the wider body of Trust staff regarding learning from Serious Incidents, complaints or claims in accordance with the [Events and Serious Incidents Policy](#), [Making Experiences Count Policy](#) and [Policy on Handling Claims](#).

Further information on all of the above steps is available on the [Duty of Candour Toolkit](#) on the intranet.

2.4. **Training**

General training for staff on event reporting is set out in the [Training Programme](#). Other resources are also available from [NHS Improvement](#) and [NHS Resolution](#). An information leaflet outlining the principles of Duty of Candour was circulated to all staff in June 2015 and is also now given during Trust Induction for new starters. Information is also provided via the eLearning packages on Quality Governance and investigations of incidents, complaints and claims. Training on Duty of Candour requirements is also provided within the three clinical directorates by Quality Assurance Leads and supported by Risk Management.

3. **ROLES AND RESPONSIBILITIES**

3.1. **Board of Directors**

Members of the Board are responsible for ensuring the Being Open and Duty of Candour Policy and principles are embedded in the organisation and being open is at the core of the organisation's values and culture.

3.2. **Chief Executive**

The Chief Executive has overall accountability for ensuring that systems are in place to enable the implementation of the Being Open and Duty of Candour Policy. The Chief Executive will on behalf of the Board make a public statement endorsing the

principles of Being Open and Duty of Candour and reinforcing the Trust's full support of an open, honest and fair culture.

3.3. Medical Director and Chief Nurse

These are responsible for promoting the policy and act as nominated officers in the Being Open/Candour communication. The Chief Nurse is the Board lead for Being Open/Duty of Candour.

3.4. Patient Experience & Safety Huddle (PESH)

This group has responsibility to lead and coordinate the response to any moderate or above harm, or serious near miss patient safety event identified to them. PESH will review any investigation and learning from such cases and support the directorate governance processes to address key risks and themes. Advice and review of any draft duty of candour letters or reports is always available from Risk Management. PESH also reviews the RCAs for comprehensive SIs before they are disclosed and shared more widely both to the patient/family and the organisation.

3.5. Head of Risk Management

The Head of Risk Management is responsible for the implementation of the Being Open & Duty of Candour Policy, monitoring its effectiveness, event data analysis and reporting to the Improving Patient Safety Steering Group and the Learning from Patient Experience Group.

3.6. Clinical Directors, Operational Directors, General Managers and Quality Assurance Leads

The Clinical Directors, Operational Directors, General Managers and Quality Assurance Leads supported by Consultant of Care, Senior Nurses and other clinical colleagues are responsible for the implementation of the Being Open and Duty of Candour Policy when patients are harmed within their directorates. They will also promote the policy and ensure that all staff are familiar with the policy.

3.7. All Staff

Have a responsibility to acknowledge and report any patient safety event and then to take appropriate advice from that point. Staff have a responsibility to act within their professional codes of conduct and to promote a culture within the Trust of openness, honesty and sound communication with patients, their family and carers.

4. POLICY DEVELOPMENT AND EQUALITY

This policy was developed following wide consultation. It has undergone Stage 1 Equality Impact Assessment screening. It does not require a full Stage 2 Equality Impact Assessment.

5. CONSULTATION, APPROVAL AND RATIFICATION PROCESS

This version has been shared within the Risk Management Department (patient safety and patient experience teams), Medical Director, Chief Nurse, Deputy Director of Governance and Quality Assurance Leads.

The Improving Patient Safety Steering Group (IPSSG) has also been consulted and will approve and ratify this policy.

6. DOCUMENT CONTROL

This will be an open policy and accessible via the intranet.

The author will in conjunction with the intranet administrator be responsible for ensuring archiving of replaced electronic versions within the electronic document library, as evidence of previous policy.

Copies of policy documents should not be printed unless it is absolutely necessary, to reduce the risk that out of date copies may be in circulation. Requests for this policy in an alternative language or format (such as Braille, audiotape, large print etc.) will be considered and obtained whenever possible.

7. DISSEMINATION AND IMPLEMENTATION

A “publish and point” method of communication will be used, where relevant staff are informed about the publication of a new or revised document on the intranet and pointed to the location of that document.

The directorates will also be responsible for informing staff of the policy.

This policy is a reference document. Relevant staff will be made aware of its existence and pointed to it for reference via staff induction, induction handbook, risk management training programme, case conferences and other risk management briefings.

8. MONITORING COMPLIANCE AND EFFECTIVENESS

8.1. Standards/Key Performance Indicators

CQC Regulation 20 (in force from 27 November 2014)

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

(2) As soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred a registered person must—

(a) notify the relevant person that the incident has occurred in accordance with paragraph (3), and

(b) provide reasonable support to the relevant person in relation to the incident, including when giving such notification.

(3) The notification to be given under paragraph (2)(a) must—

(a) be given in person by one or more representatives of the registered person,

(b) provide an account, which to the best of the registered person’s knowledge is true, of all the facts the registered person knows about the incident as at the date of the notification,

(c) advise the relevant person what further enquiries into the incident the registered person believes are appropriate,

- (d) include an apology, and
- (e) be recorded in a written record which is kept securely by the registered person.
- (4) The notification given under paragraph (2)(a) must be followed by a written notification given or sent to the relevant person containing—
 - (a) the information provided under paragraph (3)(b),
 - (b) details of any enquiries to be undertaken in accordance with paragraph (3)(c),
 - (c) the results of any further enquiries into the incident, and
 - (d) an apology.
- (5) But if the relevant person cannot be contacted in person or declines to speak to the representative of the registered person —
 - (a) paragraphs (2) to (4) are not to apply, and
 - (b) a written record is to be kept of attempts to contact or to speak to the relevant person.
- (6) The registered provider must keep a copy of all correspondence with the relevant person under paragraph (4).

NPSA Being Open Alert (November 2009)

- 1) Local policy: Review and strengthen local policies to ensure they are aligned with the Being open framework and embedded with your risk management and clinical governance processes.
- 2) Leadership: Make a board-level public commitment to implementing the principles of Being open.
- 3) Responsibilities: Nominate executive and non-executive leads responsible for leading your local policy. These can be leads with existing responsibilities for clinical governance.
- 4) Training and support: Identify senior clinical counsellors who will mentor and support fellow clinicians. Develop and implement a strategy for training these staff and provide ongoing support.
- 5) Visibility: Raise awareness and understanding of the Being open principles and your local policy among staff, patients and the public, making information visible to all.
- 6) Supporting patients: Ensure Patient Advice and Liaison Services (PALS), and other staff have the information, skills and processes in place to support patients through the Being open process.

8.2. Process for Monitoring Compliance

8.2.1. Monitoring

Data analysis using Datix will be used to monitor the Being Open and candour process for individual events (which will also cover any complaints and claims triggering the Duty, as discussed in section 2.3.1). This will also be monitored quarterly within the patient safety report. Other opportunities for relevant monitoring will be considered as required. Please see Appendix 4 for further detail.

8.2.2. Audit

Specific audits will be identified and undertaken as required in order to identify compliance with the requirements of this policy and to evaluate the effectiveness of the policy.

8.2.3. Feedback

The results of monitoring and audit will be presented to the IPSSG in the quarterly patient safety reports and as specific audit reports where appropriate. Interim reports may be required if results indicate that urgent action is needed. This process will ensure that the compliance with this policy and the management of the relevant risks are considered within the governance framework of the Trust.

Reports and action plans will be cascaded to the directorates who will be responsible for following up outstanding cases and implementing required actions.

9. REFERENCE DOCUMENTS

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- NHS Standards Contracts April 2003 – contractual Duty of Candour
- The 2014 regulations; Health & Social Care Act, Statutory Duty of Candour
- CQC guidance: **Regulation 20: Duty of candour** (Information for all providers: NHS bodies, adult social care, primary medical and dental care, and independent healthcare – March 2015)

10. ASSOCIATED DOCUMENTATION

[Events and Serious Incidents Policy](#)
[Investigating, Learning and Supporting Guide](#)
[MEC Policy](#)
[Policy on Handling Claims](#)

11. GLOSSARY OF TERMS

PESH	Patient Experience & Safety Huddle
NPSA	National Patient Safety Agency (superseded by NHS Improvement)
Datix	Reporting and management system used by the Trust that collates data on events, complaints and claims, and generates reports and information
IPSSG	Improving Patient Safety Steering Group
NRLS	National Reporting and Learning System – a confidential and anonymous computer-based system developed by the NPSA for the collection and analysis of patient safety information
RCA	Root Cause Analysis - a systematic process whereby the factors that contribute to an incident are identified, and seeks to understand the underlying causes
PSI	Patient safety incident – any unintended or unexpected incident that could have or did lead to harm for one or more patients
SI	Serious Incident
SE	Significant Event

12. APPENDICES

Appendix 1: Principles of Being Open
Appendix 2: HDFT Duty of Candour Process – summary flowchart
Appendix 3: Consultation Summary
Appendix 4: Monitoring, audit and feedback summary

12.1. Appendix 1: Principles of Being Open (NPSA)

The following ten principles underpin this policy and should be followed in all patient safety events, regardless of the level of harm:

1. Principle of Acknowledgement

All patient safety events should be acknowledged and reported as soon as they are identified. In cases where the patient, their family and carers inform healthcare staff that something has happened, their concerns must be taken seriously and should be treated with compassion and understanding by all staff. Denial of a person's concerns will make future open and honest communication more difficult.

2. Principles 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 also be timely, informing the patient, their family and carers what has happened as soon as is practicable, based solely on the facts known at that time. Explain that new information may emerge as the patient safety event investigation takes place and that they will be kept up-to-date. Patients, their families and carers should receive clear, unambiguous information and be given a single point of contact for any questions or requests they may have.

3. Principle of Apology

Patients, their families and carers 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 agreed manner of apology, as early as possible. Both verbal and written apologies should be given. Saying sorry is not an admission of liability and it is the right thing to do. 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 Patient and Carer Expectations

Patients, their families and carers 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 from the organisation. They should be treated sympathetically, with respect and consideration. Confidentiality must be maintained at all times.

Patients, their families and carers should also be provided with support in a manner to meet their needs. This may involve an independent advocate or an interpreter. Information on the Patient Experience Team and other relevant support groups should be given as soon as possible.

5. Principle of Professional Support

The organisation must create an environment in which all staff are encouraged to report patient safety events. Staff should feel supported throughout the patient safety event investigation process; they too may have been traumatised by the patient safety event. Using the [Just Culture Guide](#) developed by NHS England and NHS Improvement can help to ensure a robust and consistent approach to patient safety event investigation. Where there are concerns about the performance of individual doctors, dentist or pharmacists, the National Clinical Assessment Service (NCAS) can be contacted for advice. Where there is a reason for the healthcare organisation to believe a member of the staff has committed a punitive or criminal act, the organisation should take steps to preserve its position and advise the member(s) of staff at an early stage to enable them to obtain separate legal advice and/or representation. Staff should be encouraged to see support from relevant professional bodies.

6. Principle of Risk Management

Root Cause Analysis (RCA), Significant Event Audit (SEA) or similar techniques should be used to uncover the underlying causes of patient safety events. This investigation should focus on improving systems of care, which will be reviewed for their effectiveness. This Being Open document should be integrated into local patient safety event reporting and risk management policies and processes.

7. Principle of Multi-Disciplinary Responsibility

The Being Open document applies to all staff who have key roles in patient care. Most healthcare provision involves multi-disciplinary teams. This should be reflected in the way that patients, their families and carers are communicated with when things go wrong. This will ensure that the Being Open process is consistent with the philosophy that patient safety events usually result from system failures and rarely from actions of an individual. To ensure multi-disciplinary involvement in the Being Open process, it is important to identify clinical, nursing and managerial leaders who will support it. Both senior managers and senior clinicians must participate in the patient safety event investigation and clinical risk management.

8. Principle of Clinical Governance

Being open requires the support of patient safety and quality improvement through clinical governance frameworks, in which patient safety events are investigated and analysed, to find out what can be done to prevent their recurrence. It also involves a system of accountability through the Chief Executive to the Board to ensure that these changes are implemented and their effectiveness reviewed. These findings should be disseminated to staff so they can learn from patient safety events. Audits should be developed to monitor the implementation and effects of changes in practice following a patient safety event.

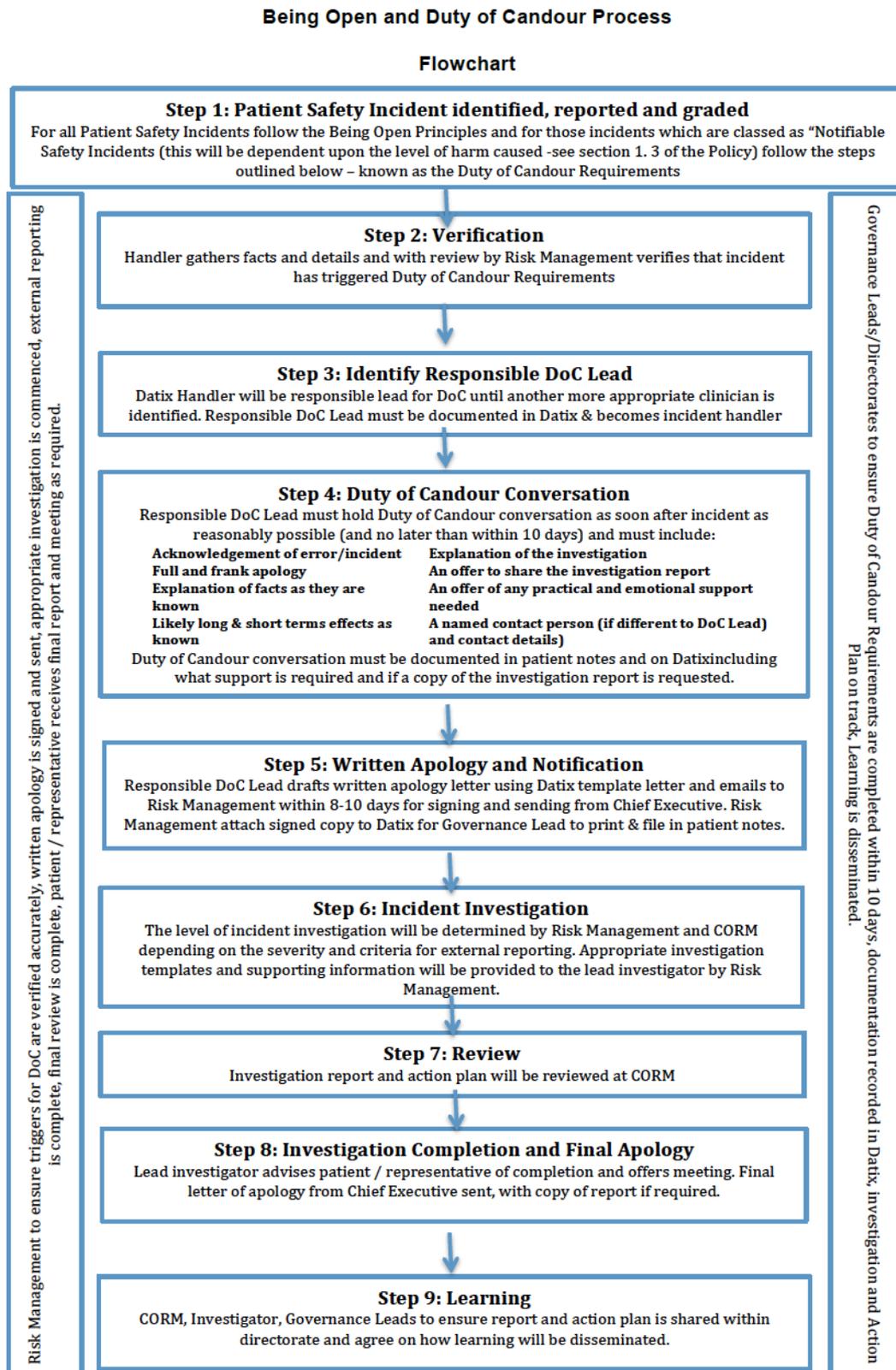
9. Principle of Confidentiality

Details of a patient safety event 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. 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 patient safety event 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 patient, their family and carers 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

Patients are entitled to expect that 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.

12.2. Appendix 2: Being Open and Duty of Candour Flowchart



12.3. Appendix 3: Consultation Summary

<p>Those listed opposite have been consulted and comments/actions incorporated as required.</p> <p>The author must ensure that relevant individuals/groups have been involved in consultation as required prior to this document being submitted for approval.</p>	<p>List Groups and or Individuals Consulted</p>
	Medical Director
	Chief Nurse
	Deputy Director of Governance
	Head of Risk Management
	Patient Safety Manager (MEC)
	Patient Safety Coordinator
	Quality Assurance Leads
	Improving Patient Safety Steering Group

12.4. Appendix 4: Monitoring, Audit and Feedback Summary

KPIs	Audit/Monitoring required	Audit/Monitoring performed by	Audit/Monitoring frequency	Audit/Monitoring reports distributed to	Concerns escalated to
Process for fulfilling being open when Duty of Candour is triggered	Number of incidents reported where Duty of Candour triggered and actioned (please note this includes complaints and claims which have triggered an incident report)	Patient Safety Co-ordinator/ Patient Safety Manager	Quarterly	Improving Patient Safety Steering Group	SMT/Quality Committee

Internal Audit and/or the Clinical Effectiveness team may be requested to undertake additional in-depth audits of the process as required as part of annual audit planning.