

## POLICY DOCUMENT CONTROL SHEET

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### Ratification

Signature of Executive Sponsor of Ratifying Body	
Executive Sponsor of Ratifying Body:	Jeremy Cundall, Executive Medical Director
Date Ratified	23 <sup>rd</sup> October 2018
Signed Paper Copy Held at:	Corporate Records Office, DMH

## VERSION CONTROL TABLE

Date of Issue	Version Number	Status
December 2005	1.0	Superseded
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October 2018	8.2	Approved

## TABLE OF REVISIONS

Date	Section	Revision	Author
March 2008	Full	Full review to ensure document meets the needs of the NHSLA	D Wells, S Lonie
September 2010	Full	Full review to ensure document meets the needs of the 2009 NHSLA document + leaflet developed	D Wells
January 2011	Full	Full review for harmonization purposes due to integration	D Wells
January 2012	Full	Review	D Wells
February 2012	Full	Minor Changes	D Wells
May 2012	Full	Reformat – minor changes	D Wells
May 2013	Full	Full review to amend policy to include 'how' staff acknowledge apologies and explain when things go wrong, and 'how' all communication will be recorded. New process and documentation introduced taking 'duty of candour' into account.	Sandra Ross, Patient Safety Manager
27th November 2014	Full	Full review following publication of Regulation 20 Duty of Candour November 27 <sup>th</sup> Care Quality Commission  Inclusion of Letter	D Wells
January 2015	Full	Following legal information full review took place	D Wells  J Bee
March 2016	Full	Incorporating legal information and example duty of candour letter	J Bee
October 2016			C Adolph
April 2018		Update to reflect duty of candour sticker for patient notes following audit recommendation	C Adolph

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# 1 INTRODUCTION

County Durham and Darlington NHS Foundation Trust (CDDFT) is committed to the safety of all patients and to improving communication between patients and/or carers when a patient raises a complaint, makes a claim or a patient safety event occurs. This will promote a patient safety focused culture within a constant learning, improving and changing organisation.

This policy will set out how this Trust intends to ensure that Being Open is implemented, following the National Patient Safety Agency (NPSA) Framework for Being Open and Regulation 20 Duty of Candour Care Quality Commission (November 2014)

The National Patient Safety Agency (NPSA) developed a framework to demonstrate how to strengthen the culture of 'Being Open' within healthcare organisations. This framework provides best practice guidance on how to create an open and honest environment this has been reinforced within the Regulation 20 Duty of Candour document through:-

- ensuring a 'Being Open' policy is developed that clearly describes the process to be followed when a patient safety event occurs;
- committing publicly to 'Being Open' at board and senior management level;
- all staff working within a provider organisation have a responsibility to adhere to the organisation's 'Being Open' policy and procedures around duty of candour, regardless of seniority or permanency.
- identify appropriate levels of support for healthcare professionals involved in patient safety events and the patient and next of kin will be signposted to support services
- Boards, Medical Staff, senior managers within the organisations have a crucial role in ensuring the 'Being Open' framework and principles are embedded.
- committing to 'Being Open' creates an environment where:
  - patients, their families and carers receive the information they need to understand what happened, and the reassurance that everything possible will be done to ensure that a similar type of patient safety event does not recur;
  - patients, their families and carers, healthcare professionals and managers all feel supported when things go wrong;
  - the Trust promotes a culture of openness and truthfulness whilst improving safety and quality.
  - An apology will be given verbally and for any incident graded moderate harm and above a letter of apology will be sent to the patient or next of kin.

# 2 PURPOSE

The aim of this corporate policy is to ensure that County Durham and Darlington NHS Foundation Trust meet its obligations to patients, relatives, the public and all other

relevant stakeholders by being open and honest about any mistakes that are made in the way we care for and treat our patients. The policy aims to improve the quality and consistency of communication when patients are involved in a patient safety event.

The 'Being Open' Policy, in conjunction with the Supporting Staff Policy, aims to create an environment where patients and/or their carers, healthcare professionals and managers all feel properly supported when things go wrong. The policy outlines the framework to ensure we are compliant with legislative responsibilities related to Regulation 20 and implementation of the Duty of Candour.

The purpose of this policy is to:

- ensure the organisation has an agreed process to ensure compliance with our legislative responsibility related to Regulation 20 Duty of Candour which was implemented in direct response to recommendation 181 of the Francis Inquiry.
- describe the Trust's approach to communicating with patients and/or their carers following a patient safety event;
- ensure that all staff are aware of their responsibility to be open and honest with patients and/or their carers when a patient safety event has occurred;
- ensure that there is a consistent approach to communicating with patients and/or their carers in response to a complaint, claim or reported incident so that they promptly receive the information they need to enable them to understand what happened;
- ensure that patients, their families and carers, and staff all feel supported when patient safety events occur or things go wrong;
- that a meaningful apology is offered, and that patients, families and carers are informed of the action the Trust will take to try to ensure that a similar or the same event does not happen again; and to ask what questions the patient, family or carers wish to be investigated as part of the review process.
- provide information to staff on what they do when they are involved and the support available to them to cope with the consequences of what happened.
- The trust depository for duty of candour data is the Safeguard risk management system and staff must complete the process on the Safeguard system as reports are prepared from this data source

### 3 SCOPE

This policy applies to all patient safety events. Although with National Patient Safety Agency recommendations and Regulation 20 Duty of Candour, there is no requirement to inform patients or their carers of 'near miss' events (i.e. prevented patient events) or events in which no harm has been caused, County Durham and Darlington NHS Foundation Trust have developed this Being Open process for all patient safety events regardless of level of harm.

For information on definitions and levels of harm for patient safety events please see Appendix 2.

This policy is aimed at;

- all staff responsible for patient care;
- ensuring the infrastructure is in place to support openness between healthcare professionals and patients, their families and carers following an adverse event.

The requirement to be open with patients and/or their carers and to provide an apology and explanation applies to all clinical staff and managers when dealing with all patient safety events.

## 4 DEFINITIONS

### 4.1 Definitions

*Being open* refers to open communication when patients/families/carers raise a complaint, make a claim or when a patient safety event has occurred.

The 'Duty of Candour' requirements reinforce the 'being open' principles by placing more emphasis on organisational responsibility. While the Duty applies to organisations, not individuals, it is clear that individual NHS staff must cooperate with it to ensure the Duty is met.

Candour is defined in The Francis report: "The volunteering of all relevant information to persons who have or may have been harmed by the provision of services, whether or not the information has been requested and whether or not a complaint or a report about that provision has been made."

A *patient safety event* refers to an incident, complaint, PALS issue or a legal claim.

### 4.2 Being Open Principles

When mistakes are made patients/relatives/carers, other organisations and stakeholders should receive an apology and explanation as soon as a patient safety event has occurred and staff should feel able to apologise at the time of the incident. Saying sorry is not an admission of liability and it is the right thing to do.

#### **10 key principles underpinning *Being open***

1. Acknowledgement
2. Truthfulness, timeliness and clarity of communication
3. Apology
4. Recognising patient and carer expectations
5. Professional support
6. Risk management and systems improvement
7. Multidisciplinary responsibility
8. Clinical governance
9. Confidentiality
10. Continuity of care

Please refer to Appendix 1 for further details on these principles.

These principles provide a framework to ensure a proactive approach to clinical negligence with the onus no longer on the patient to initiate a claim, but on risk management processes and systems identifying patient safety events which require review, and learning from them, working in partnership with all stakeholders and other organisations.

‘Being open’ about what happened and discussing patient safety events promptly, fully and compassionately can help patients cope better with the effects of a patient safety event. Litigation or complaint is often resorted to when patients or their relatives/carers feel they cannot get the information they require.

## 5 DUTIES AND RESPONSIBILITIES

### 5.1 Trust Board

- responsible for ensuring compliance with the Being open process and actively championing the process by promoting an open and fair culture that fosters peer support and discourages the attribution of blame.
- responsible for ensuring that changes identified from patient safety events are implemented and their effectiveness reviewed.
- will set the strategic context in which organisational policies and procedures are developed, and establish a scheme of governance for the formal review and approval of policies.

### 5.2 Chief Executive

- responsible for ensuring the infrastructure is in place to support openness between healthcare professionals and patients and/or their carers following a patient safety event.
- has delegated the authority to develop the Trust’s clinical governance arrangements to the Director of Nursing and the Medical Director.

### 5.3 Trust Medical Director and Director of Nursing

- have delegated responsibility for overseeing the strategic development of the Trust’s clinical governance arrangements.

### 5.4 Care Groups

- responsible for ensuring compliance with the Being open process within their Care Group Governance arrangements, through their responsibility for the culture of openness and honesty with patients, families and their carers when things go wrong.
- should ensure that their staff are offered support when things do go wrong, and are given the opportunity to have training in the Being open process.
- Care Groups should monitor their compliance regarding the statutory responsibility so reports can be prepared every 2 weeks to give assurance

the organisation is compliant with legislation. (See appendix that illustrates how the Safeguard system should be completed)

### **5.5 Care Group Leads/Senior Managers/Matrons**

It is the responsibility of the Lead Clinician, Clinical Service Manager or Matron, (or Head of Service), to ensure that the most appropriate staff are identified to contact the patient and/or relatives when patient safety events occur. In most cases this may be the Consultant or treating doctor and the Service Manager/Ward Sister. Clinical Directors/Clinical Service Managers/Matrons will give consideration to the characteristics of the person nominated to lead the Being Open process, ensuring that the lead is senior enough or has sufficient experience and expertise in relation to the type of patient safety event to be credible to patients and carers.

In the case of a complaint, the patient experience officer will make telephone contact with the complainant and an investigating manager will be identified to investigate the complaint. The investigating manager may be a Matron, Manager or Service Manager.

The Clinical Director/Clinical Service Manager/Matron will ensure that there are adequate local support mechanisms in place for the staff involved in the patient safety event and for the staff leading on the 'Being Open' process.

### **5.6 Nominated Person(s) to Lead Discussions (Being Open Leads)**

The nominated person who acts as the main link with the patient/family or carer during discussions is responsible for:

- communicating with patients involved in a patient safety event (and/or their carers) asking what they would like to be explored as part of the investigation (RCA).
- offers an apology to patient, next of kin or carers and arranges for the letter to be sent for moderate harm and above incidents
- explaining what led to the patient safety event occurring and any immediate actions if any to mitigate any similar incident
- providing the patient (and/or) carer with a contact name in the event of further queries or issues arising;
- arranging for transfer of care where the patient (and/or carer) requests this;
- documenting the details of the apology and all discussions with the patient (and/or carer) within the patients notes
- ensuring that all documentation is recorded/attached within the Safeguard risk management system.
- Keeping in close communication with the patient safety investigation leads to enable regular and informed communication with the patient and/or carer;
- Notifying the appropriate department of any patient safety event that may proceed to litigation or involve the coroner.

- Following completion of the investigation arrange for formal feedback with the patient, next of kin to share the lessons learnt and action plan to prevent any similar incident occurring.

Junior staff or those in training should not lead the 'Being Open' process except when all of the following criteria have been considered:

- The patient safety event resulted in minor harm or no harm;
- They have expressed a wish to be involved in the discussion with the patient and/or carer;
- The senior healthcare professional responsible for the care is present for support;
- The patient and/or carer agrees.

As stated above, where a junior healthcare professional who has been involved in a patient safety event asks to be involved in the 'Being Open' discussion, it is important they are accompanied and supported by a senior team member, for example their education or placement supervisor. Junior staff are not expected to communicate patient safety event information alone or to be delegated the responsibility to lead a 'Being Open' discussion unless they volunteer and their involvement takes place in appropriate circumstances (i.e. they have received appropriate training and mentorship for this role).

## 5.7 All Healthcare Staff

All staff working within the organisation will be expected to adhere to this policy. All staff have a responsibility for ensuring that patient safety events are acknowledged and reported as soon as they are identified. In cases where the patient and/or carers inform healthcare staff when something untoward has happened, it must be taken seriously from the outset. Any concerns should be treated with compassion and understanding by all healthcare staff.

All staff are responsible for accessing training on *Being Open* to improve their understanding of how to communicate effectively. *Being Open* training is available as part of the Trust Root Cause Analysis training which is lead and co-ordinated by the Patient Safety team.

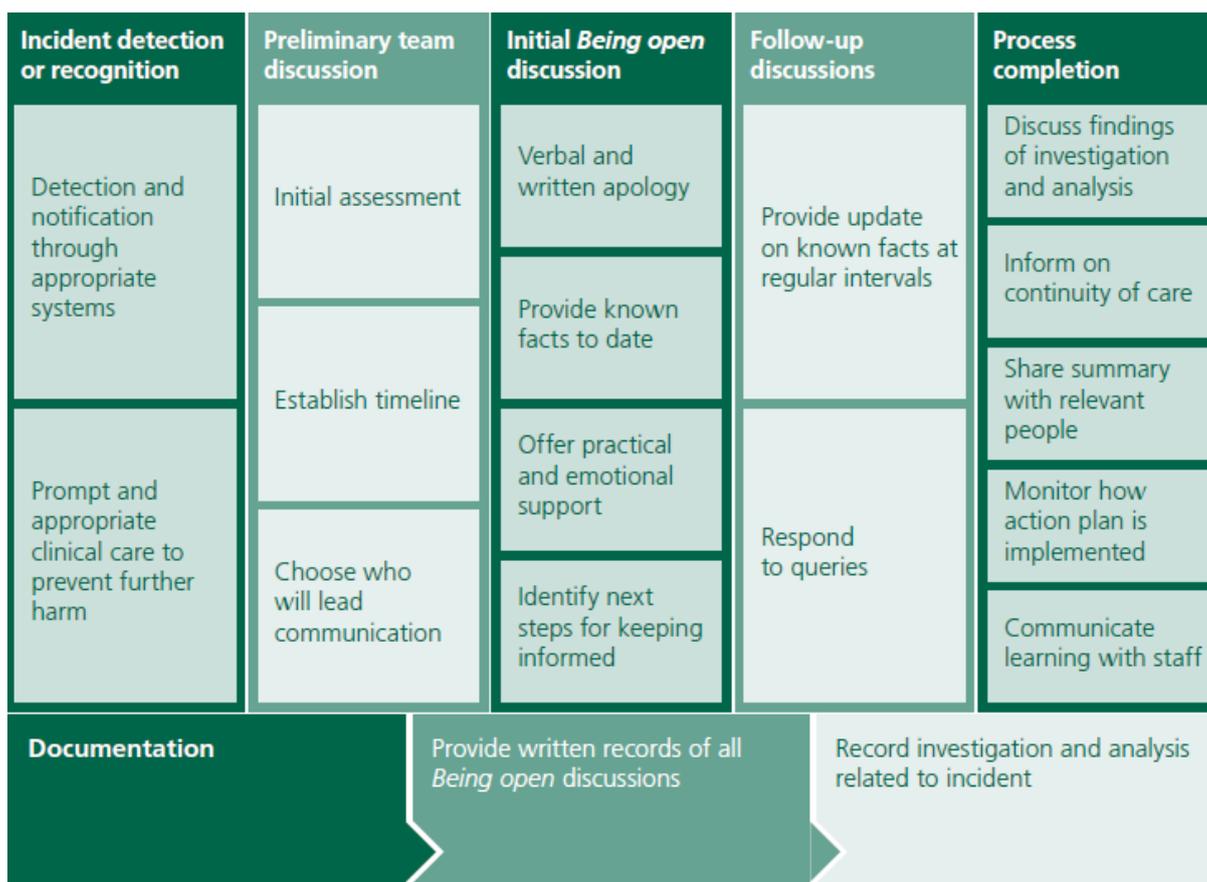
## 5.8 Other Organisations

If an incident/complaint/issue is identified and this Trust has not caused the harm our staff must give assurance that the responsible organisation is notified and made aware of the issues identified so that they can follow the duty of candour process.

# 6 MAIN CONTENT OF POLICY

## 6.1 'Being Open' Process

'Being Open' is a process rather than a one-off event. There are a number of stages in the process (Figure 1). The duration of the process depends on the patient safety event, the needs of the patient, their family and carers, and how the investigation into the patient safety event progresses.



### 6.1.1 Stage 1: Patient Safety Event Detection or Recognition

The 'Being Open' process begins with the recognition that a patient safety event has occurred.

This can be identified by any of the following mechanisms:

- Via staff at the time of the event
- Via staff retrospectively
- By the patient/ family/ carer raising a concern, either at the time, or via a complaint or claim in retrospect
- Via the incident reporting system
- Via other sources, such as the event being highlighted by another patient, visitor or non-clinical staff
- Via concerns raised following a post mortem result

As soon as a patient safety event is identified, the priority is a prompt and appropriate response to prevent further harm or a reoccurrence. Where necessary immediate clinical care should be given to prevent further harm this will be part of the reactive Safety Huddle.

Processes for reporting and then investigating and analysing the causes of patient safety events should be implemented, including the principles of acknowledgement and apology.

Once it has been identified that a patient safety event has occurred it is essential that an acknowledgment, apology and explanation is provided to the patient or their relative/carers as soon as possible. Verbal apologies allow face-to-face contact between the patient and/or relatives/carers and the healthcare team and should be given as soon as staff are aware that an event has happened. This is documented by the person completing the managers actions on the electronic 'Being Open' questionnaire attached to the specific event in the Safeguard system. Documentation in patient's notes must also take place.

It is good practice for an apology to be given whenever an event is detected, regardless of impact grade.

For events resulting in **no harm and minor harm**, at the point of detection, the team responsible for the patients care should decide if it is appropriate to inform and discuss with the patient and/or relatives/carers. The team responsible for the patient's care should determine the approach to take i.e. verbal, telephone or written communication.

For **moderate harm and above events**, the patient, family or carer should be given the opportunity to ask questions and informed that an investigation will be undertaken in line with duty of candour requirements (see section 6)

Appropriate approaches should be undertaken to assist in identifying the underlying causes of the patient safety event.

Patient safety events are almost always unintentional. However, if at any stage following a patient safety event it is determined that harm may have been the result of a criminal or intentional unsafe act, the Director of Nursing should be notified immediately.

### 6.1.2 Stage 2: Preliminary Team Discussion

All patient safety events should be initially assessed to determine the response required and then discussed with the nominated investigation lead. The level of response to a patient safety event depends on the nature of the event. Please refer to Appendix 3 for grading of patient safety events to determine level of response.

The initial 'Being Open' discussion with the patient, their family and carers should occur as soon as possible after recognition/notification of the patient safety event. In exceptional circumstances, if the healthcare professional who usually leads the 'Being Open' discussion cannot attend, they may delegate to an appropriate substitute.

Factors to consider when timing this discussion include:

- Reasonable assurance that the facts are known and understood
- Clinical condition of the patient. Some patients may require more than one meeting to ensure that all the information has been communicated to and understood by them
- Availability of key staff involved in the event and in the Being Open process

- Availability of the patient's family and/or carers.
- Availability of support staff, for example a translator or independent advocate, if required
- Patient preference (in terms of when and where the meeting takes place and who leads the discussion)
- Privacy and comfort of the patient
- Arranging the meeting in a sensitive location

Where a junior healthcare worker who has been involved in a patient safety event asks to be involved in the 'Being Open' discussion, it is important that they can be accompanied and supported by a senior team member, legal services and/or staff-side representatives.

Some patient safety events that resulted in moderate harm, severe harm or death can result from errors made by healthcare staff while caring for the patient. In these circumstances, the member(s) of staff involved may or may not wish to participate in the 'Being Open' discussion with the patient, their family and carers. Every case where an error has occurred needs to be considered individually, balancing the needs of the patient, their family and carers with those of the healthcare professional concerned. In cases where the healthcare professional who has made an error wishes to attend the discussion to apologise personally, they should feel supported by their colleagues throughout the meeting. In cases where the patient, their family and carers express a preference for the healthcare professional not to be present, it is advised that a personal written apology is handed to the patient, their family and carers during the initial 'Being Open' discussion.

### 6.1.3 Stage 3: Initial 'Being Open' Discussion

The content of the initial 'Being Open' discussion with the patient, their family and carers should cover the following:

- An expression of genuine sympathy, regret and a meaningful apology for the harm that has occurred.
- The facts that are known as agreed by the multidisciplinary team. Where there is disagreement, communication about these events should be deferred until after the investigation has been completed.
- The patient, their family and carers are informed that an investigation has been carried out or is being carried out and more information may become available as it progresses.
- The patient's, their family's and carers' understanding of what happened is taken into consideration, as well as any questions they may have.
- Consideration and formal noting of the patient's, their family's and carers' views and concerns, and demonstration that these are being heard and taken seriously.
- **Appropriate language** and terminology are used when speaking to patients, their families and carers. Avoid use of the word 'serious'.
- An explanation is provided about what will happen next in response to the investigation, analysis and findings.

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

It is essential that the following does not occur, i.e., never state that it's likely it will be reported as a 'serious' incident during the 'Being Open' discussion:

- speculation;
- attribution of blame;
- denial of responsibility;
- provision of conflicting information from different individuals

#### 6.1.4 Stage 4: Follow-up Discussions

Follow-up discussions with the patient, their family and carers are an important step in the 'Being Open' process. Depending on the patient safety event and the timeline for the investigation there may be more than one follow-up discussion.

#### 6.1.5 Stage 5: Process Completion

After completion of the investigation, feedback should take the form most acceptable to the patient. Whatever method is used, the communication should include:

- the chronology of clinical and other relevant facts;
- details of the patient's, their family's and carers' issues;
- a repeated apology for the harm suffered and any shortcomings in the delivery of care that led to the patient safety event;
- a summary of the factors that contributed to the patient safety event;
- information on what has been and will be done to avoid recurrence of the patient safety event and how these improvements will be monitored.

When a patient has been harmed during the course of treatment and requires further therapeutic management or rehabilitation, they should be informed, in an accessible way, of the on-going clinical management plan.

Any recommendations for systems improvements and changes implemented should be monitored for effectiveness in preventing a recurrence.

## 6.2 Duty of Candour process

This policy takes into account the 'statutory duty of candour' in the NHS Commissioning Board 2015/2016 standard contract, reflecting the requirements set out in Everyone Counts: Planning for Patients 2013/14. Openness and honesty towards patients are supported and actively encouraged by many professional bodies, including the Medical Defence Union (MDU), Medical

Protection Society (MPS), General Medical Council (GMC) and Nursing and Midwifery Council (NMC). The Care Quality Commission Standard 20 is very clear in its outline on how the process should take place: The Health and Social Care Act 2008 (Regulated Activities) Amendment Regulation 2015 extend the fit and proper person requirement for directors and the duty of candour to all providers from 1<sup>st</sup> April.

**For moderate harm and above events**, 'the statutory 'duty of candour' must be implemented. If the patient is still an inpatient this should be undertaken by the most senior clinician available responsible for the patient's care as soon as possible after the event being identified. We must ensure the following is undertaken to meet statutory regulation 20 requirements.

- **An apology must be given as soon as possible following identification of a patient safety event that is considered moderate or above harm.**
- **A written apology must be sent or given to the patient and/or relatives/carers next of kin aim for within 10 days of event being identified.**
- **All information must be documented in the patient notes which includes that a verbal apology has been given and letter of apology is being prepared to be sent within the 10 day framework.(See appendix 10 for sticker template to record duty of candor in patients notes)**

This data is also documented by staff completing the manager's actions on the electronic 'Safeguard risk management system i.e. a copy of the letter of apology should be attached to the system with all fields completed which illustrates compliance with the duty of candour process.

Please refer to Appendix 13.8 for full duty of candour flowchart

### Exceptions

There will be exceptions to implementing the Duty of Candour; there must be very sound reasons, which must be clearly recorded within the Safeguard Management System, for not having the Duty of Candour principles applied.

For example:-

- For those cases subject to child death reviews are exempt from sending a formal duty of candour letter as this being open is covered through the child death process.
- If the patient/family/carer refuse a written letter to be sent following verbal apology.

### 6.3 Documentation and Communication

*Refer to Appendix 6 for procedure for how to communicate with patients and/or their carers when a moderate harm or above event has occurred.*

Throughout the 'Being Open' process it is important to record discussions with the patient, their family and carers as well as the investigation. The Safeguard Risk Management System is the corporate repository for all correspondence relating to incident investigation and management, complaints and legal

services. The 'nominated lead' for the Being Open process is responsible for ensuring that all discussions are recorded and uploaded onto the Safeguard system with the incident, complaint or claim file. This includes uploading the completed Being Open Report Discussion Template (Appendix 5) following a Being Open meeting, recording verbal apologies and phone calls on the Safeguard Being Open Template (when no face-to-face meeting has taken place), and uploading written correspondence and action plans. Under no circumstances should Being Open Process records be stored in the patient health records.

In addition to the Being Open records above, for all patient safety events, a 'Being Open' questionnaire in the Safeguard Risk Management System should be completed by managers following all grades of event.

Refer to Appendix 7 for 'Being Open' process flowchart.

#### **6.4 Provision of Additional Support**

The 'Being Open' process can be traumatic for staff and support must be offered from senior staff and/or from Trust Occupational Health Department. A specific 'Supporting Staff policy is available.

Line Managers must support team members during the investigation or discussion with relatives.

The patient must have an on-going Care Plan developed in consultation with them together with assurances that their care will not be affected.

The 'Being Open' process must interface with the Incident Reporting Process.

The 'Being Open' process may lead to informal/formal complaints and necessary documentation must be completed.

Help in this process is readily available from the Patient Safety Team.

Provision of counselling services should be offered to the patient/carer if required.

#### **6.5 Implementation & Training**

Being Open is included on the Trust Root Cause Analysis Training. See the Trust Education and Development Intranet Site for information on these courses and a number of other courses for staff which are provided that help provide communication skills and encourage openness

Training on the implementation of this policy will be provided to Care Groups via People and Organisational Development, and bespoke training from Patient Safety team.

The Director of Nursing is responsible for ensuring that this document is reviewed and, if necessary, revised in the light of legislative, guidance or organisational change.

Review shall be at intervals of no greater than 3 years. Any revisions to this document shall be agreed through the approval process indicated on the title page.

A copy of this policy will be placed with all other policies on the Trust's intranet and internet site. All clinical staff will be required to read the policy. This policy is subject to annual audit of compliance.

Attendance at Essential Training is recorded by People & Organisational Development and entered onto the Trust Training Management System, OLM. Monitoring of non-attendance will be in line with the Training Needs Analysis, Monitoring and Evaluation Policy and carried out by People & Organisational Development. Please refer to this policy for detailed information.

## 7 MONITORING

### 7.1 Compliance and Effectiveness Monitoring

Compliance with this policy will be monitored as outlined in the table below.

### 7.2 Compliance and Effectiveness Monitoring Table

Monitoring Criterion	Response
Who will perform the monitoring?	Patient Safety Lead and Care Group Associate Directors
What are you monitoring?	How communication between healthcare organisations, teams, staff, patients, relatives and carers is encouraged. How staff acknowledges apologies and explains when things go wrong. Truthfulness, timeliness and clarity of communication. How additional support is provided. How communication is recorded.
When will the monitoring be performed?	Monthly for all moderate harm and above via the Safety Report. Care Group Governance reports quarterly and annually and Patient Safety Forum every 2 weeks.
How are you going to monitor?	Review patient safety event documentation via audit, KPI's, committees, review, monitoring of action plans. Audit of Risk Management Reporting System via the completion of the 'Being Open' questionnaire following an event and the Being Open Report/Duty of Candour template
What will happen if any shortfalls are identified?	Raise with appropriate staff members within Care Groups that the Being Open process is not being adhered to and provide further support and education to ensure this does not reoccur. Within Incident/CLIPS Report highlight any area that has failed to comply with Policy and ensure remedial action will address will address the shortfalls. It is the Care Group Leads responsibility to ensure Being Open Culture and Process is in place. Escalated via appropriate committee.
Where will the results of the	Patient Safety Forum Safety Committee

monitoring be reported?	Quality and Healthcare Governance Committee
How will the resulting action plan be progressed and monitored?	Action Plans will be monitored via the Quality and Healthcare Governance Committee. Care Group Governance meetings
How will learning take place?	Outcomes will be discussed at various meetings (as above) and appropriate changes or awareness will be raised with the relevant department. Bulletins, One Liners, Intranet, Newsletters.

## 8 GLOSSARY OF TERMS

NPSA –National Patient Safety Agency  
 PALS - Patient Advisory and Liaison service  
 RCA – Root Cause Analysis  
 MDU – Medical Defense Union  
 MPS - Medical Protection Society  
 GMC - General Medical Council  
 NMC- Nursing and Midwifery Council

## 9 ASSOCIATED DOCUMENTATION

Policy for the Development and Management of Procedural Governance Documents  
 Trust Equality/Diversity policy, strategy and action plan  
 Data Protection Policy  
 Confidentiality/Disclosure Policy  
 Incident Management Policy  
 Risk Management Strategy  
 Induction Policy  
 Training Needs Analysis, Monitoring and Evaluation Policy  
 Clinical Audit Policy  
 Complaints Handling Policy  
 Claims Handling Policy

### References

Health & Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015  
 Health & Safety At Work Act 1974  
 Human Rights Act 1998  
 Rights and freedoms protected under the European Convention on Human Rights  
 Freedom of Information Act 2000  
 Trust policies and procedures are subject to disclosure under the Freedom of Information Act 2000 (FOI)  
 Mental Capacity Act 2005  
 Equality Act 2006  
 Disability Discrimination Act 1995  
 Data Protection Act 1998

Department of Health "Records Management: NHS Code of Practice" 2006.  
Department of Health "Confidentiality: NHS Code of Practice" 2003  
NHS Litigation Authority "Standard for Primary Care Trusts": guidance on minimum policy and procedure requirements.  
NPSA November 2005 'Being Open'  
NPSA November 2009 'Being Open Framework'  
Patient Briefing, Being Open – 'Saying sorry when things go wrong', Sep 05  
NPSA 7 Steps to Patient Safety, Feb 04  
'Making Amends' DOH 2003  
DOH Better NHS response for patients harmed by healthcare 13th October 2005  
[www.dh.gov.uk](http://www.dh.gov.uk)  
NHS Redress DOH Improving the response to patients November 2005  
(LASSL 94) 4) Independent investigation of adverse events in mental health services, DoH, 15th June 2005. [www.dh.gov.uk](http://www.dh.gov.uk)  
Circular 02.2002, NHS Litigation Authority [www.nhsla.com](http://www.nhsla.com)  
NHSLA Risk Management Standards 2007, 1.5.10. [www.nhsla.com](http://www.nhsla.com)

Department of Health - Building a Safer NHS for Patients (2001) [www.dh.gov.uk](http://www.dh.gov.uk)  
National Health Service Litigation Authority (2002) Circular No: 02/02.  
NHS Commissioning Board 2013/2014 standard contract  
[Everyone Counts: Planning for Patients 2013/14](#)

## 10 APPENDICES

Appendix 1 - The Ten Principles of Being Open  
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## 10.1 Appendix 1: The Ten Principles of Being Open

### 1. ***Principle of Acknowledgement***

- All patient safety events should be acknowledged and reported as soon as they are identified in keeping with the trust's Incident Management policy.
- Were the patient, their family and carers inform healthcare staff that something has happened; concerns must be taken seriously and 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 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. Using medical jargon which they may not understand should be avoided.

### 3. ***Principle of Apology***

- Patients, their families and carers should receive a meaningful apology/expression of sympathy – one that is a sincere expression of sorrow or regret for the patient safety event (refer to Section 5- Being Open process-stage 1).
- Verbal or written apologies can be given (refer to Section 5- Being Open process-stage 1). 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, may also be provided.

### 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. 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. Contact details of the Patient Experience Team and relevant support groups should be given as soon as possible.
- Confidentiality must be maintained at all times.

## **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 Incident Decision Tree (IDT) – (found in Root Cause Analysis toolkit on Patient Safety team intranet site), can help to ensure a robust and consistent approach to patient safety event investigation. Where there are concerns about the performance of an individual, professional advice can be sought from their professional regulatory body.

## **6. *Principle of Risk Management and Systems Improvement***

- Various methodological approaches are used to investigate patient safety events, e.g. Root Cause Analysis (RCA) to find the underlying cause.
- 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. *Principles of Multi-Disciplinary Responsibility***

- The 'Being Open' document applies to all staff that have key roles in patient care. Communication with patients and/or carers following a patient safety event should reflect the multidisciplinary nature of the care and treatment received. 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.

## **8. *Principles of Clinical Governance***

- 'Being Open' requires the support of 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.
- Action plans 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 investigations before it takes place, and give them the opportunity to raise any objections.

## 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.

## 10.2 Appendix 2: Definitions for Levels of Harm/Patient Safety Levels

**Patient safety event:** refers to an incident, complaint, PALs issue or a legal claim.

**Patient safety incident:** Any unintended or unexpected incident that could have or did lead to harm for one or more patients receiving NHS-funded healthcare. It does not include harm caused as a result of the natural course of a patient's illness.

**Harm:** injury (physical or psychological), disease, suffering, disability or death

**Minor Harm:** Any patient safety event that required extra observation or minor treatment such as first aid, additional therapy, or additional medication, and caused minimal harm to one or more patients receiving NHS-funded care. 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 readmission.

**Moderate Harm:** Any patient safety event that resulted in a moderate increase in treatment and that caused **significant but not permanent harm** to one or more patients receiving NHS-funded care. Moderate increase in treatment is defined as a return to surgery, an unplanned readmission, 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 event (this particular definition is also applicable to Acute and Tertiary Care).

**Severe Harm:** Any patient safety event that appears to have resulted in permanent harm to one or more patients receiving NHS funded care. Permanent harm means directly related to the patient safety event and not related to the natural course of the patient's illness or underlying condition is defined as permanent lessening of bodily function, sensory motor, physiological or intellectual, including removal of the wrong limb or organ or brain damage.

**Death:** Any patient safety event that directly resulted in the death of one or more patients receiving NHS-funded care. The death must be related to the patient safety event rather than to the natural course of the patient's illness or underlying condition.

**Near Miss:** Any unexpected or unintended event that was prevented, resulting in no harm to one or more patients receiving NHS-funded healthcare.

### 10.3 Appendix 3: Grading of Patient Safety Events to Determine Level of Response

All events should be assessed initially by the healthcare team to determine the level of response required and then discussed with the Care Group Manager, Clinical Governance Leads/ACOO's and/or Director of Nursing if considered to require a high level of response. The level of response to a patient safety event depends on the nature of the event.

EVENT TYPE	ACTION
No harm  (including prevented Patient safety events)	<p>Feedback from a range of healthcare staff, government agencies, professional bodies, patients and the public on the NPSA's Being Open policy identified several problems if 'no harm' and prevented events were discussed with patients and/or their carers. These included added distress to patients and potential loss of confidence in the standard of care, negative effects on staff confidence and morale, and decreased public confidence in the NHS.</p> <p>Reporting to the risk management team/or Care Group governance teams will occur through standard adverse event reporting mechanisms and be analysed to detect high frequency events. Review will occur through aggregated trend data and local investigation. Where trend data indicates a pattern of related events, further investigation and analyses may be needed.</p> <p>The short Being Open questionnaire in SAFEGUARD can be completed to state if Being Open was applicable.</p>
Low harm	<p>Unless there are specific indications or the patient and relatives/carers requests it, the communication, investigation and analysis, and the implementation of changes will occur at local service delivery level with participation of those directly involved in the event.</p> <p>Communication should take the form of an open discussion between the staff providing the patient's care and the patient and/or their carers.</p> <p>Reporting to the risk management team/or Care Group governance teams will occur through standard adverse event reporting mechanisms and be analysed to detect high frequency events. Review will occur through aggregated trend data and local investigation. Where trend data indicates a pattern of related events, further investigation and analyses may be needed.</p> <p>The short Being Open questionnaire in SAFEGUARD can be completed to state if Being Open was applicable.</p>
Moderate harm, severe harm, or death	<p>A higher level of response is required in these circumstances. Senior Care Group Manager, Clinical Governance and/or Director of Nursing should be notified immediately. Advice and support will be provided during the <i>Being Open</i> process if required.</p> <p>The Being Open Report template (Appendix 5) should be completed and a copy uploaded into Safeguard against the appropriate event.</p> <p>The 'Duty of Candour' template should be completed in Safeguard. Copy of DOC letter to be attached to incident record within Safeguard.</p>

## 10.4 Appendix 4: 'Being Open' - Guidance for Staff, Particular Patient Circumstances

### *When a patient dies*

When a patient safety event has resulted in a patient's death it is crucial that communication is sensitive, empathic and open. It is important to consider the emotional state of bereaved relatives and carers and to involve them in deciding when it is appropriate to discuss what has happened. The patient's family and/or carers will probably need information on the processes that will be followed to identify the cause(s) of death, an individual should be identified and contact details given to the patient's family and/or carers so they have contact details of someone who will facilitate their inquiries and link to Trust processes. They will also need emotional support; establishing open channels of communication may also allow the family and/or carers to indicate if they need bereavement counselling or assistance at any stage.

Usually the 'Being Open' discussion and any investigation occur before the Coroner's inquest. But in certain circumstances the healthcare organisation may consider it appropriate to wait for the Coroner's inquest before holding the 'Being Open' discussion with the patient's family and/or carers. The Coroner's report on post-mortem findings is a key source of information that will help to complete the picture of events leading up to the patient's death. In any event an apology should be issued as soon as possible after the patient's death, together with an explanation that the Coroner's process has been initiated and a realistic timeframe of when the family and/or carers will be provided with more information.

### *Children*

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

The courts have stated that younger children who understand fully what is involved in the proposed procedure can also give consent. This is sometimes known as Gillick competence or the Fraser guidelines. Where a child is judged to have the cognitive ability and the emotional maturity to understand the information provided, he/she should be involved directly in the 'Being Open' process after a patient safety event.

The opportunity for parents to be involved should still be provided unless the child expresses a wish for them to be present.

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

More information can be found on the Department of Health's website [www.dh.gov.uk](http://www.dh.gov.uk)

All child deaths, before duty of candour apology or any letter sent, lead for child death audit/review must give a letter as appropriate as there is a patient safety issue.

*Patients with Mental Health Issues*

'Being Open' for patients with mental health issues should follow normal procedures, unless the patient also has cognitive impairment. The only circumstances in which it is appropriate to withhold patient safety information from a mentally ill patient is when advised to do so by a consultant psychiatrist who feels it would cause adverse psychological harm to the patient. However, such circumstances are rare and a second opinion (by another consultant psychiatrist) would be needed to justify withholding information from the patient. Apart from in exceptional circumstances, it is never appropriate to discuss patient safety event information with a carer or relative without the express permission of the patient.

*Patients with Cognitive Impairment*

Some individuals have conditions that limit their ability to understand what is happening to them. They may have authorised a person to act on their behalf by an enduring power of attorney. In these cases steps must be taken to ensure this extends to decision making and to the medical care and treatment of the patient. The 'Being Open' discussion would be held with the holder of the power of attorney. Where there is no such person the clinicians may act in the patient's best interests in deciding who the appropriate person is to discuss the event information with, regarding the welfare of the patient as a whole and not simply their medical interests. However, the patient with a cognitive impairment should, where possible, be involved directly in communications about what has happened. An advocate with appropriate skills should be available to the patient to assist in the communication process.

*Patients with Learning Disabilities*

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

*Patients with Different Language or Cultural Considerations*

The need for translation and advocacy services, and consideration of special cultural needs (such as for patients from cultures that make it difficult for a woman to talk to a male about intimate issues), must be taken into account when planning to discuss patient safety event information. It would be worthwhile to obtain advice from an advocate or translator before the meeting on the most sensitive way to discuss the information. Avoid using 'unofficial translators' and/or the patient's family or friends as they may distort information by editing what is communicated.

*Patients with Different Communication Needs*

A number of patients will have particular communication difficulties, such as hearing impairment. Plans for the meeting should fully consider these needs.

Knowing how to enable or enhance communications with a patient is essential to facilitating an effective Being open process, focusing on the needs of individuals and their families.

Prisoners – There is no difference in the process involved of the Prison authorities with full review of the incident will take place for all deaths, but apologies will only take place if there is a safety incident.

## 10.5 Appendix 5: How to communicate with patients and/or their carers following an event in which a patient has been moderately or seriously harmed or has died

### 1. PURPOSE

The purpose of this procedure is to:

- Describe the steps to be followed by staff when responding to a complaint, claim or event following a patient safety event in which a patient has been **moderately harmed, severely harmed or has died**;
- outline the mechanisms in place to support staff through this process

### 2. AIM

The aim of this procedure is to ensure that:

- staff know who is responsible for communicating with patients and/or their carers when things go wrong;
- staff are provided with information to enable them to respond effectively to patients who have been involved in a patient safety event;
- staff feel supported when things go wrong;
- staff feel confident and empowered to communicate effectively in response to a complaint, claim or incident following a patient safety event; and
- consistency of communication is achieved

### 3. MANAGEMENT OF RECORDS RELATING TO PATIENT SAFETY EVENT INVESTIGATIONS AND *BEING OPEN*/DUTY OF CANDOUR DISCUSSIONS

Documentation relating to the investigation and analysis of patient safety events should be held electronically in the SAFEGUARD system either through scanning or uploading into the attachments section of the relevant event. The patient safety event records will comprise of the following information:

- the record of the *Being Open* discussions including a summary of all the points explained to the patient and/or their carers. A template has been designed for this purpose and this is attached at Appendix 5.
- copies of letters sent to the patient and/or their carers, GP and other external/statutory bodies
- copies of statements taken in relation to the patient safety event
- progress notes relating to the clinical situation and an accurate summary of all the points explained to the patient and/or their carers
- a *Being Open* element built into the Root Cause Analysis templates within the RCA Toolkit as a standard action prior to closure of investigation.

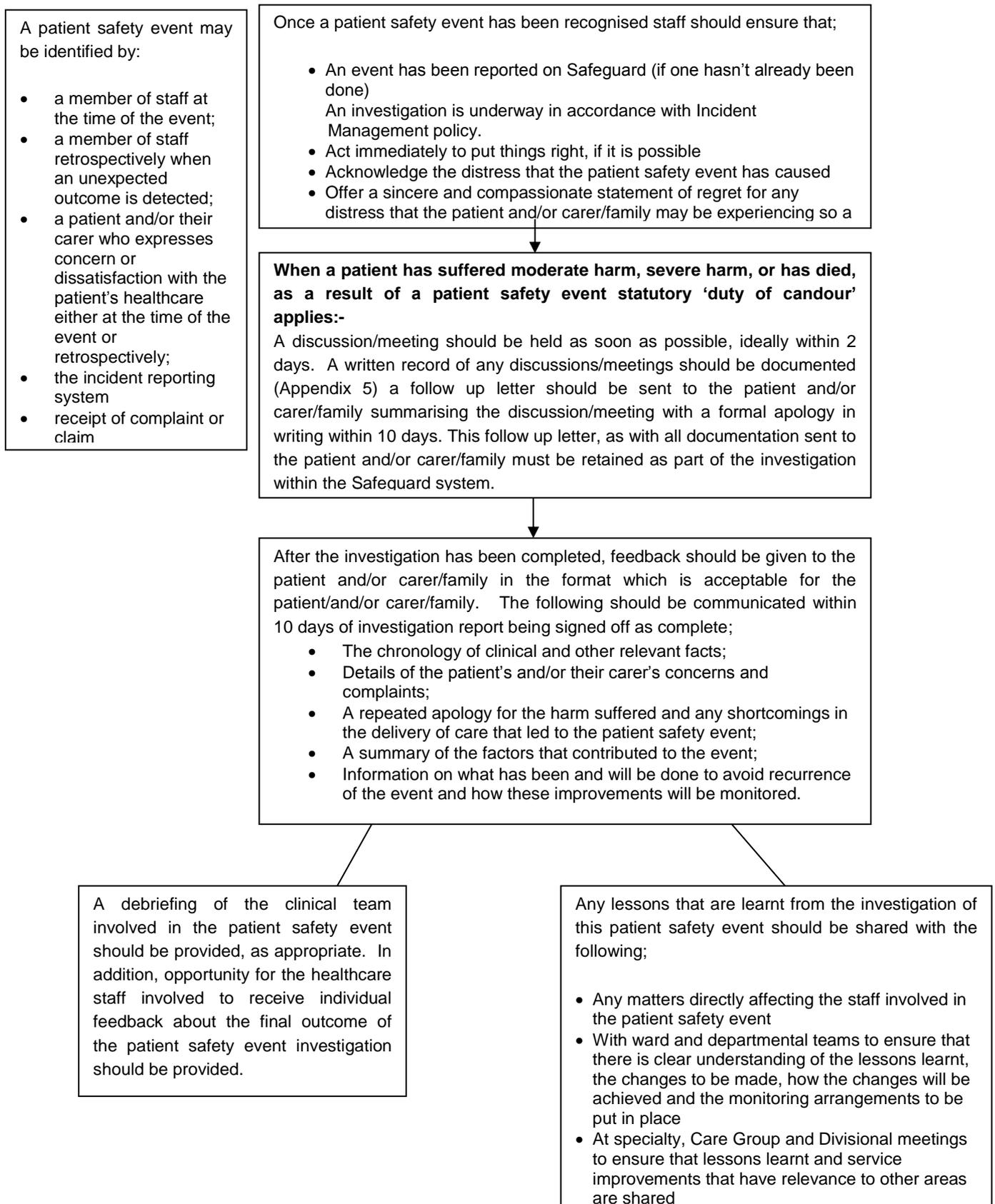
Hard copy records relating to a *Being Open* discussion held as part of the investigation and response to a serious untoward incident, complaint, claim, or coroner's inquest will be retained in the relevant investigation file by the appropriate central team e.g. Patient Safety Team for incidents, Patient Experience for Complaints, and Legal Services for Claims. When there has been an investigation under the child death review process this will be the Child death review team. Wherever possible, the template provided in SAFEGUARD should be utilised so that an electronic record is also maintained.

Records of a *Being Open* discussion should not be filed in the patient's notes. However, the plan of care developed following a patient safety event must be documented in the patient's medical records as well as being summarised in the Being Open template report (Appendix 5).

**Serious Incidents (SIs)**

If it is decided that a patient safety event should be investigated as a SI, all evidence of Being Open should be documented using the templates provided within SAFEGUARD. Upon initial declaration of a SI the patient and/or carer/family should be notified of this and informed of what the process entails. Upon completion of the investigation the patient and/or carer/family should be offered the opportunity to view the investigation report and/or be invited for a meeting to discuss the outcome of the investigation.

## 10.6 Appendix 6: The Being Open Process



## 10.7 Appendix 7: Duty of Candour Letter Template Example

Hospital Address

Dear Patient/relative (as appropriate)

You/Your .....(insert relative) have /has been involved in an incident. It concerned ..... (describe even here).....

I wish to express my sincere apologies that this incident occurred. The Trust aims to provide a quality service to patients and to explore why incidents happen and share findings with those affected by them. To support anyone involved, the Trust has a 'Being Open/Duty of Candour' Policy.

We would like to give you/your (relatives as appropriate) the opportunity, if you wish, to identify any key questions you would like answers to as part of the review. This can be shared with the lead contact, identified below, either via telephone, written letter or face to face meeting.

When our review is complete the final report will be subject to the Trust governance approval process. This process involves Care Group and Safety Committee approval, to give you the full assurance that the services have agreed actions/controls to prevent a similar incident taking place.

To provide you with a potential timeframe we can advise the next Care Group meeting will be the DD/MMM/YY.

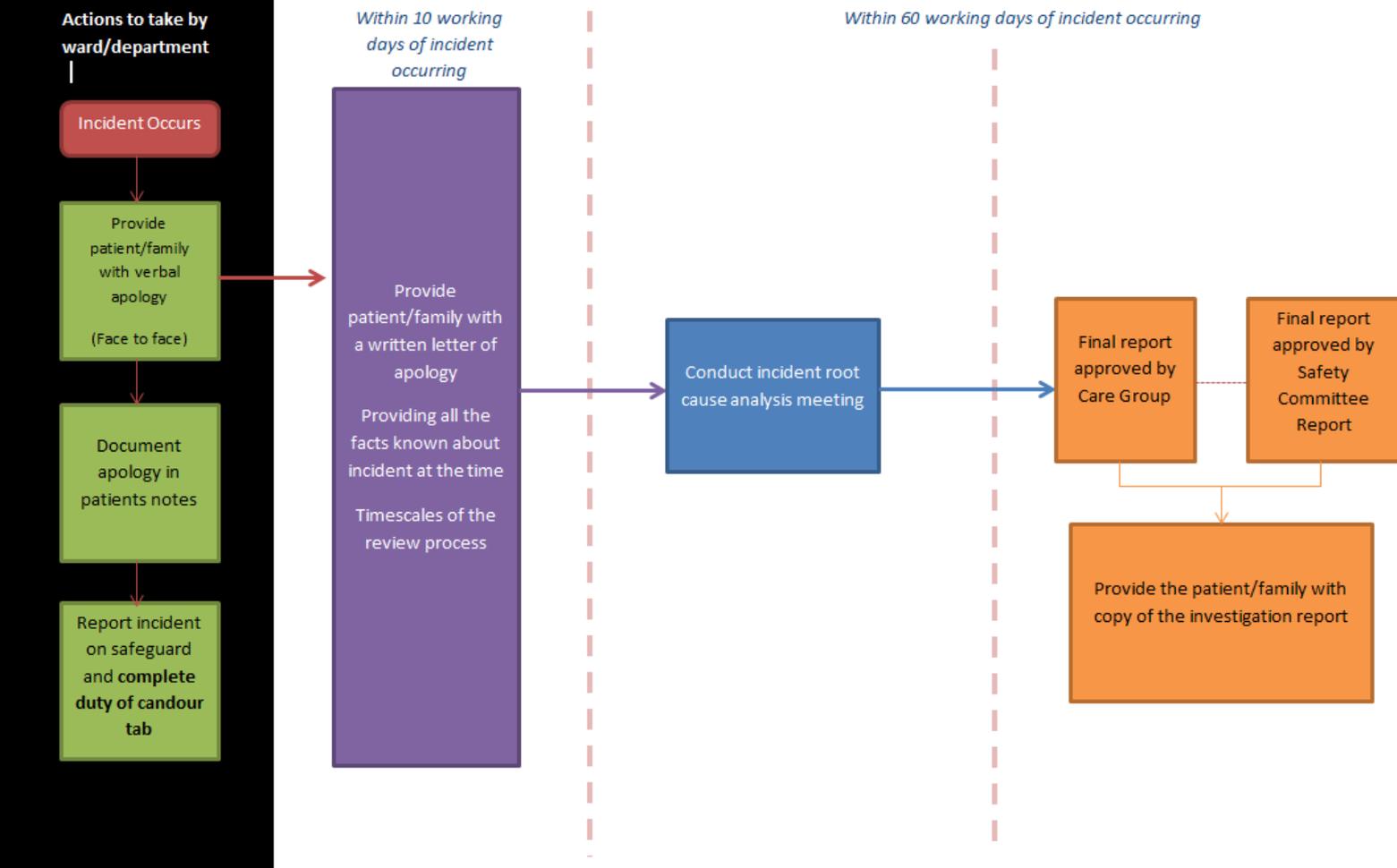
Following the approval process we will write to you arranging a date to provide you with the final report and give feedback regarding the outcome/findings.

I/Staff member xxxxx is acting as your lead contact for the duration of the being open process. I/they can be contact on telephone number xxxxx xxxxxxx

Yours sincerely

Area incident occurred

### 10.8 Appendix 8 - Duty of Candour process



**10.9 Appendix 9: Duty of Candour Notes Sticker template**

Duty of Candour

A conversation with ..... took place on ..... reference the  
..... during

(NOK/Patient/Family)                      (date)                      (Incident)

the conversation I apologised for the incident taking place and we will be reviewing the incident for any learning or recommendations/changes in practice can be taken from this. Written correspondence (if patient/family agree) will be sent out to the home address within 10 days.

Appendix 10: Equality Impact Assessment

# Equality Analysis / Impact Assessment

EIA Assessment Form

v3/2013

**Division/Department:**

Nursing - Governance

**Title of policy, procedure, decision, project, function or service:**

Being Open Policy

**Lead person responsible:**

Delcy Wells, Patient Safety Lead

**People involved with completing this:**

Delcy Wells, Patient Safety Lead, Joanne Todd, Associated Director of Nursing & Service Transformation, Maureen Grieveson, Associate Director of Patient Experience, Patient Safety Managers, Patient Experience Managers, Matrons, Director of Nursing, Medical Director

**Type of policy, procedure, decision, project, function or service:**

- Existing
- New/proposed
- Changed

**Date Completed:**

2014



## Step 1 – Scoping your analysis

**What is the aim of your policy, procedure, project, decision, function or service and how does it relate to equality?**

To ensure all staff are aware of their responsibilities regarding 'Being Open'.

**Who is the policy, procedure, project, decision, function or service going to benefit and how?**

Staff, Patients, visitors and contractors

**What barriers are there to achieving these outcomes?**

Not adhering to policies and guidelines and not attending training

**How will you put your policy, procedure, project, decision, function or service into practice?**

Monitoring patient safety events and visiting departments when patient safety events have occurred and stressing the importance of following correct procedures and attending training

**Does this policy link, align or conflict with any other policy, procedure, project, decision, function or service?**

Links to: Incident Management Policy, Supporting Staff Policy, Lessons Learnt , Complaints Handling Policy

## Step 2 – Collecting your information

### What existing information / data do you have?

Annual audit results, reports

### Who have you consulted with?

Patient Experience Department, Clinical Colleagues, Matrons, medical staff, Legal Services

### What are the gaps and how do you plan to collect what is missing?

N/A

## Step 3 – What is the impact?

Using the information from Step 2 explain if there is an impact or potential for impact on staff or people in the community with characteristics protected under the Equality Act 2010?

### Ethnicity or Race

No

### Sex/Gender

No

### Age

No

### Disability

No

### Religion or Belief

No

**Sexual Orientation**

No

**Marriage and Civil Partnership (applies to workforce issues only)**

No

**Pregnancy and Maternity**

No

**Gender Reassignment**

No

**Other socially excluded groups or communities e.g. rural community, socially excluded, carers, areas of deprivation, low literacy skills etc.**

No

**Step 4 – What are the differences?**

**Are any groups affected in a different way to others as a result of the policy, procedure, project, decision, function or service?**

No

**Does your policy, procedure, project, decision, function or service discriminate against anyone with characteristics protected under the Equality Act 2010?**

No

**If yes, explain the justification for this. If it cannot be justified, how are you going to change it to remove or mitigate the affect?**

N/A

**Step 5 – Make a decision based on steps 2 - 4**

**If you are in a position to introduce the policy, procedure, project, decision, function or service? Clearly show how this has been decided.**

Agreed at Safety Committee and approved at the Quality & Healthcare Governance Committee

**If you are in a position to introduce the policy, procedure, project, decision, function or service, but still have information to collect, changes to make or actions to complete to ensure all people affected have been covered please list:**

N/A

**How are you going to monitor this policy, procedure, project or service, how often and who will be responsible?**

Monitoring will be carried via investigation of patient safety events