

# Being Open and Duty of Candour

## **Policy Summary**

*Open, honest and transparent communication with patients, their families and carers following a patient safety event.*

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4.0	March-July 2014	Review of Policy	Head of Clinical Governance
4.1	March 2015	Review of Policy due to Duty of Candour requirements	Head of Clinical Governance
5.0	September 2018	Review of Policy and update of training and appendices	Head of Clinical Governance

<b>For more information on the status of this document, please contact:</b>	Head of Clinical Governance	
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## Executive Summary

Staff work hard to deliver the highest standards of healthcare to all patients at Moorfields Eye Hospital NHS Foundation trust. Although we provide safe and effective care to many thousands of people every year, sometimes despite our best efforts, things can and do go wrong.

Duty of Candour is defined in Sir Robert Francis' enquiry as:

*'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.'*

This is a legal duty placed on all NHS staff by virtue of the Health and Social Care Act 2008 (Regulated Activities) 2014, and the Care Quality Commission Regulation 20: Duty of Candour (November 2014).

Being Open is a set of principles that healthcare staff should use when communicating with patients, their families and carers following a patient safety event which has resulted in harm.

The trust is committed to the principles of Being Open and the Duty of Candour regulations and to improving communications with patients and/or their carers when a patient suffers harm as a result of a patient safety event. This supports a culture of openness, honesty and transparency, as well as a willingness to learn from experience.

If a patient is harmed as a result of a mistake or error during their care, we believe that they and, when appropriate, their family or those who care for them, should receive an apology, be kept fully informed as to what has happened, have their questions answered and know what is being done in response as soon as reasonably practicable after a patient safety event has occurred. By Being Open we make a commitment to our patients to:

- apologise for the harm caused;
- explain, openly and honestly, what has gone wrong;
- describe what we are doing in response to the event, and provide reassurance that lessons learned will help prevent recurrence;
- offer support and counselling services that might be able to help;
- ensure that a trust contact is available to speak to;
- give updates on the results of any investigation;
- document the action taken/information provided in the health records;
- Duty of Candour regulation includes a follow up the apology by giving the same information in writing, and providing an update on the enquiries.

Where the patient needs more detailed long-term emotional support, advice should be provided on how to gain access to appropriate counselling services.

## 1. Introduction

1.1. The promotion of a culture of openness is a prerequisite to improving patient safety and the quality of healthcare systems. This culture ensures communication is open, honest and occurs **as soon as possible** following a patient safety event, or when a poor outcome has been experienced. It encompasses the communication between healthcare organisations, healthcare teams and patients, their families and carers. In this context the term '*patient safety event*' has been used to indicate that this covers incidents, complaints and claims.

1.2. All NHS staff have a Duty of Candour as stipulated in the Health and Social Care Act 2008 (Regulated Activities) 2014, and the Care Quality Commission Regulation 20: Duty of Candour (November 2014).

[https://www.cqc.org.uk/sites/default/files/20150327\\_duty\\_of\\_candour\\_guidance\\_final.pdf](https://www.cqc.org.uk/sites/default/files/20150327_duty_of_candour_guidance_final.pdf)

The Care Quality Commission (CQC) interpret the regulations of Duty of Candour from the definitions of openness, transparency and candour used by Robert Francis in the Francis Inquiry

- Openness – enabling concerns and complaints to be raised freely without fear and questions asked to be answered
- Transparency – allowing information about the truth about performance and outcomes to be shared with staff, patients, the public and regulators
- Candour – any patient harmed by the provision of a healthcare service is informed of the fact and an appropriate remedy offered, regardless of whether a complaint has been made or a question asked about it

The Duty of Candour regulation and its implementation reflect the approach proposed by the Dalton/Williams review (see references section 18, No.5), including defining a notifiable patient safety event as one that has resulted in or could have resulted in significant harm.

1.3. Being Open involves:

- acknowledging, apologising and explaining when things go wrong;
- conducting an appropriate investigation into the patient safety event and reassuring patients, their families and carers that lessons learned will help prevent the patient safety event from recurring;
- providing support for those involved to cope with the physical and psychological consequences of what happened.

The ten principles that underpin Being Open can be found in *Appendix 5*.

***Saying sorry is not an admission of liability and is the right thing to do***  
(see *appendix 6 Saying Sorry leaflet – NHS Resolution*).

Openness and honesty towards patients are supported and actively encouraged by the General Medical Council (GMC), the Nursing and Midwifery Council (NMC), the Medical Defence Union (MDU), the Medical Protection Society (MPS) and many

other professional bodies (see section 18: supporting references). The NHS Constitution (DH 2010) also requires staff to acknowledge, apologise and put things right quickly when things go wrong. This policy has been guided by the recommendations of these bodies.

This Being Open Policy is also guided by other national initiatives and recommendations from major inquiry reports, including:

- the Francis Report into the failures of care at Mid Staffordshire NHS Foundation trust
- the 5<sup>th</sup> Shipman Inquiry Report about appropriate documentation of patient deaths
- the NHS Litigation Authority (NHS Resolution)'s 'Striking the Balance' document on providing support for healthcare professionals involved in a complaint, incident or claim

## **2. Scope**

- 2.1. All patient safety events that could result in, or have resulted in moderate, major or extreme/catastrophic harm, including prolonged psychological harm or death should be subject to a Duty of Candour.
- 2.2. It is not a requirement of this policy that '*prevented*' patient safety events (near misses) and patient safety events resulting in '*no harm*' are discussed with patients / carers; however in some cases where obvious error has been noted by both patient and staff, discussion may be beneficial. Reasons for this include:
  - added stress to patients and potential loss of confidence in the standard of care;
  - negative effects on staff confidence and morale;
  - decreased public confidence in the NHS.

Patient safety events resulting in '*Low/Minor*' harm should be considered by the staff involved as to whether disclosure would be detrimental to the health and wellbeing of the patient. The principles of Being Open should be followed where possible (*see appendix 5*) and communication should take the form of an open discussion between the staff providing the patient's care and the patient, their family and carers.

- 2.3. The policy applies to both clinical and non-clinical patient safety events and applies equally at all sites at which Moorfields provides services.
- 2.5 Informed consent and disciplinary processes are outside the scope of the Being Open framework.
- 2.6 The scope of this policy, focuses on being open with patients and, in some cases, their families and carers; however if staff, visitors or contractors are harmed as a result of trust action or inaction, the principles of Being Open should also be followed.

## **3. Purpose**

- 3.1. The purpose of this document is

- to ensure that patients, their families and carers, and staff, all feel supported when patient safety events occur
- to improve the quality and consistency of communication with patients, their families and carers when patient safety events occur
- to ensure that patients, their families and carers receive prompt and accurate information to allow them to understand what happened
- to ensure that a meaningful apology is offered
- to ensure that patients, their families and carers are informed of the action the organisation will take to try and ensure that a similar type of patient safety event does not recur
- to provide clear information to staff on what they should do when they are involved in a patient safety event, and the support available to them to cope with the consequences of what happened
- to promote an open, honest and transparent culture across the trust
- to support divisions as to how best to communicate with patients, families and carers following a notifiable patient safety event and maintain a written record

#### 4. Explanation of Terms Used

- 4.1. **Patient safety event:** a reported event that has been highlighted as an incident, complaint or claim.
- 4.2. **Incident:** an event or circumstance that could have resulted, or did result in, unnecessary damage, loss or harm such as physical or mental injury to a patient, staff, visitor or member of the public.
- 4.3. **Serious Incident (SI):** SIs are events in health care where the potential for learning is so great, or the consequences to patients, families and carers, staff or organisations are so significant, that they warrant using additional resources to mount a comprehensive response. The definition described in the trust's Incident and Serious Incident (including Never Events) Reporting Policy and Procedure sets out circumstances in which a serious incident must be declared. Every incident must be considered on a case-by-case basis
- 4.4. **Never Event (NE):** Never Events are a particular type of serious incident that meet all the following criteria:
- they are wholly preventable where guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and have been implemented by healthcare providers;
  - each Never Event type has the potential to cause serious patient harm or death. However, serious harm or death is not required to have happened as a result of a specific incident occurrence for that incident to be categorised as a Never Event;
  - there is evidence that the Never Event has occurred in the past and that the risk of recurrence remains;
  - must be able to be clearly defined and its occurrence easily recognised;
- Full details of the list of NEs can be found in the trust's Incident and Serious Incident (including Never Events) Reporting Policy and Procedure*
- 4.5. **No Harm:** refers to any incident that occurred and had the potential to cause harm, but did not result in harm.

- 4.6. **Harm:** refers to any injury, damage or loss that may arise from a hazard and may include for example, physical injury, mental distress, financial losses and damage to material.
- 4.7. **Significant Harm:** a patient safety event that could result in or has resulted in moderate, major or catastrophic harm, including prolonged psychological harm and death.
- 4.8. **Notifiable Patient Safety Event:** Any unintended or unexpected incident that occurred in respect of a service user during the provision of a regulated activity that, in the reasonable opinion of a health care professional, could result in, or appears to have resulted in:
- a) The death of the service user, where the death relates directly to the incident rather than to the natural course of the service user's illness or underlying condition, or
  - b) Severe harm, moderate harm or prolonged psychological harm to the service user
- 4.9. **Prolonged Psychological Harm:** Psychological harm which a service user has experienced or is likely to experience for a continuous period of at least 28 days
- 4.10. **Moderate Harm:**
- a) Harm that requires a moderate increase in treatment, and
  - b) Significant, but not permanent, harm
- "moderate increase in treatment" means an unplanned return to surgery, an unplanned re-admission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, or transfer to another treatment area (such as intensive care)
- 4.10 **Investigation:** an authorised, systematic and detailed examination or inquiry to uncover facts and determine the truth of a matter. This may include collecting, processing, reporting, storing, recording, analysing, evaluating, producing and disseminating the authorised information.
- 4.11 **Health Record:** A single record with a unique identifier containing information relating to the physical or mental health of a given patient who can be identified from that information and which has been recorded by, or on behalf of, a health professional, in connection with the care of that patient. This may comprise text, sound, image and/or paper and must contain sufficient information to support the diagnosis, justify the treatment and facilitate the ongoing care of the patient to whom it refers.
- 4.12 **Confidentiality:** The Confidentiality: NHS Code of Practice is a guide for those who work within or under contract to NHS organisations concerning confidentiality and patients' consent to use their health records.
- 4.13 **Caldicott Guardian:** The Caldicott Guardian is a senior person responsible for protecting the confidentiality of patient and service-user information and enabling appropriate information-sharing. The Guardian plays a key role in ensuring that the NHS, Councils with Social Services responsibilities and partner organisations satisfy the highest practicable standards for handling patient identifiable information.

- 4.14 **Being Open:** A process of honest communication and support with individuals involved in, or following a patient safety event.
- 4.15 **Duty of Candour:** The contractual and statutory Duty of Candour applies to all NHS staff and requires openness, transparency and honesty is given to all relevant people following a patient safety event that has resulted in or could result in significant harm. This Duty of Candour should be made as soon as reasonably practicable after becoming aware that a notifiable patient safety event has occurred. It is suggested that 10 working days at most is 'reasonable' to undertake this discussion. A decision to exceed this, because the patient has an appointment imminently and therefore disclosure may be made face to face, is acceptable but should be documented. Disclosure may be made over the phone where it would not be reasonable to expect the patient to attend purely to facilitate disclosure (e.g. geographical or health reasons). Disclosure should be made by a consultant, or a nominated senior clinician (e.g. Clinical Director) in the event that it is not appropriate for the patient's consultant to make the disclosure, and must be documented;
- The 2017-19 (May 2018 Edition) specific contractual requirements can be found in section 35 of the NHS standard contract service conditions  
<https://www.england.nhs.uk/wp-content/uploads/2018/05/2-nhs-standard-contract-2017-19-particulars-service-conditions-may-2018.pdf>
- 4.16 **Apology:** an expression of sorrow or regret in respect of a notifiable patient safety event. It is not an admission of guilt.
- 4.17 **Near Misses:** Near misses are prevented patient safety events.
- 4.18 **Clinical Audit:** A quality improvement process to measure and seek improvement in patient care.

## 5. Policy

- 5.1. To facilitate open and effective communication around patient safety events the trust will:
- Identify which patient safety events have resulted in harm to patients
  - Ensure that patient safety events that result in harm/potential harm to patients are discussed at the appropriate meeting (e.g. service meeting, Clinical Governance meeting, SI panel)
  - Provide opportunities for the patient and/or their carer to obtain information about the patient safety event
  - Provide information to patients in verbal and written format as appropriate
  - Provide contact details should any questions or concerns arise

- Provide assurance that the patient will continue to be treated according to their clinical needs and that the prospect of, or an actual dispute between, the patient and/or their carer and the healthcare team will not affect their access to treatment
  - Facilitate inclusion of the patient's carer or significant others in discussions about a patient safety event where the patient wishes
  - Ensure carers are provided with known information, care and support if a patient has died as a result of a patient safety incident (PSI). The carer should also be referred to the coroner for more detailed information
  - Ensure that discussions with patients and/or their carer are fully documented in the patient health records, and that information is shared with them on request
  - Ensure the patient and/or their carer are provided with information on the patient safety event, and the trust process that will follow
  - Ensure the patient's account of the patient safety event are included as part of the investigation, where appropriate
  - Ensure patients and/or their carer are fully informed of the findings and recommendations from investigations
  - Ensure that the patient has been offered a meeting to discuss the patient safety event and/or findings from the investigation with an appropriate senior clinician
  - Ensure that a process for achieving the Duty of Candour and Being Open objectives can be implemented and that the effectiveness of these objectives can be monitored
  - Discuss if questioned the scope for financial redress following patient safety events (this may simply involve explanation of the litigation process)
- 5.2. Patients and/or their carers may need considerable practical and emotional help and support after experiencing a patient safety event. The most appropriate type of support may vary widely between patients and/or their carers. It is therefore important to discuss their individual needs with the patient and/or their carer. Support may be provided by patients' families, social workers, religious representatives, and information and advice can be given by healthcare organisations such as Patient Advice and Liaison Service (PALS). Where the patient needs more detailed long-term emotional support, advice should be provided on how to gain access to appropriate counselling services (see *Appendix 3* for a non-exhaustive list of contact details).
- 5.3. The trust will offer (if requested or appropriate):
- Information on services offered by all the possible support agencies (including their contact details) that can give emotional support, help the patient identify the issues of concern, support them at meetings with staff and provide information about appropriate community services

- Contact details of a staff member who will maintain an ongoing relationship with the patient, using the most appropriate method of communication from the patient's and/or their carer's perspective
- Details of the complaints procedure, providing details on how to make a formal complaint and/or any other available means of giving positive or negative feedback to healthcare staff involved in their care

## **6. Duties**

### **6.1. Trust Board**

The Trust Board have a crucial role in demonstrating trust commitment to the Duty of Candour and ensuring that the Being Open framework is effective and in use throughout the organisation.

Staff should be aware of the principles of the *Being Open* policy framework, their professional code of conduct with respect to protecting patients, reporting and disclosing patient safety events and the Duty of Candour.

### **6.2. Chief Executive Officer**

The Chief Executive Officer is responsible for:

- setting a standard for the entire organisation
- demonstrating commitment to a culture of openness and to the trust's non-punitive approach
- ensuring that all trust Directors demonstrate the same commitment through their own actions, and champion Being Open, honesty and transparency in their own areas

### **6.3. All Board Directors**

All Board Directors have a responsibility for this policy, including its implementation, and to promote an open and transparent culture.

### **6.4. Heads / Managers / Directors**

(Head of Service/ General Manager/ Divisional Director/ Deputy Divisional Director / Deputy Divisional Manager/ Service Director/ Service Manager/ Head of Nursing)

The NPSA Alert NPSA/2009/PSA003 (*see hyperlink in section 1.2, and appendix 7*) requires trusts to nominate 'Senior Clinical Counsellors'. Their primary role is to provide support to colleagues in implementing the Being Open process. The trust has nominated the above Heads of Service, Directors and Managers to undertake this role.

The role of 'Senior Clinical Counsellor' will be to offer support to fellow healthcare professionals with Being Open by:

- Mentoring colleagues during their first Being Open discussion
- Advising on the Being Open process
- Discussions where required

- Facilitate debriefing meetings following Being Open discussions where these have been identified as necessary
- Assisting with any subsequent investigation

Heads / Managers / Directors should ensure that staff undertake the trust's purpose built e-learning tool for Duty of Candour described in section 11.0 (training), which is mandatory for all clinical staff.

Where events take place and investigations are not considered SI or NEs at SI Panel, the divisional leads will initiate the Duty of Candour requirements, including:

- Openness, honesty and candour with the patient at the earliest convenience
- Apologise to the patient
- Document all discussions fully in the patient's health records
- Investigate as necessary
- Write to the patient (cc the GP) confirming the apology and all discussions, decisions and findings

#### 6.5 **The Medical Director / Clinical Lead for Quality and Safety**

Following confirmation of SI/NE's at a SI panel, or where significant harm or death has resulted from a patient safety event, the Medical Director / Clinical Lead for Quality and Safety (or allocated individual) will:

- Nominate appropriate senior clinical staff to initiate the Being Open discussion with patients, their families or carers (if this has not already taken place)
- Check and authorise letters drafted by the Head of Risk and Safety or nominated divisional lead informing patients or their next of kin of the patient safety event investigation progress (*following incidents only, this process would be different for complaints and claims as responses will follow agreed internal processes*)

#### 6.6 **Consultants / Clinical Directors /Senior Clinician**

To promote the Being Open culture and lead on the relevant processes in their area.

As soon as reasonably practicable following a patient safety event that has resulted in significant harm, the patient's consultant (or nominated senior clinician e.g. Divisional Director) should inform the patient (or carer where applicable) of the event and offer support. The discussion with the patient should include a true and honest reflection of what happened, an apology, plans to address the issue and a full investigation into how and why this happened. **This discussion must be fully documented in the medical records and an incident form should be completed.** Follow up the apology by giving the same information in writing, and providing an update on the enquiries.

If significant harm has been determined at a SI panel, the patient's consultant / senior clinician will be nominated by the Medical Director to have the discussion with the patient at the earliest opportunity. The nominated member of staff will receive support from the Senior Clinical Counsellors (Heads of Service, Directors and Managers).

The consultant / senior clinician must document all attempts to contact the patient and inform the Risk and Safety team once contact has been made / attempted.

## 6.7 Junior Healthcare Professionals

Junior staff or those in training should not lead the Being Open process and may only participate when all of the following criteria have been considered:

- The patient safety event resulted in low/minor harm
- They have expressed a wish to be involved in the discussion with the patient/family/carer
- The senior healthcare professional responsible for the care is present for support

It is unacceptable for junior staff to communicate patient safety information alone, or to be delegated the responsibility to lead a Being Open discussion.

## 6.8 The Head of Risk and Safety and Head of Clinical Governance

The Risk and Safety team should review all reported incidents and be informed of all patient safety events resulting in significant harm, and subsequent discussions.

The Head of Risk and safety will collate all information centrally relating to significant harm patient safety events.

The Head of Risk and Safety and Head of Clinical Governance (in consultation with the Risk and Safety Advisor) will ensure that patient safety events resulting in significant harm/unknown harm are included for discussion at SI panel.

Following confirmation of SIs or where significant harm has resulted from a patient safety event, the Head of Risk and Safety should:

- Draft letters to the patient or their next of kin (to be checked and signed by the Medical Director / Clinical Lead for Quality and Safety), informing them of the patient safety event and the investigation process and asking the patient if there are any issues they would like to be raised as part of the investigation (copying the patients GP in correspondence). All letters should include an apology, a true and honest reflection of what happened and any progress made, contact details and plans to address the issues and fully investigate the event.
- On completion of the SI investigation, draft a follow-up letter to the patient (to be checked and signed by the Medical Director / Clinical Lead for Quality and Safety and cc to GP), informing the patient of the completion of the investigation and the findings, and including a copy of the completed SI report (unless the patient has expressed a wish not to receive it)
- Monitor all letters sent as a result of SI/NE's/notifiable patient safety events

There may be exceptional cases where it is inappropriate, or staff are unable, to contact the patient or next of kin. This will be at the discretion of the Head of Risk and Safety, Head of Clinical Governance and Medical Director.

There may also be situations whereby contact with the patient or next of kin is performed by a specific or more suitable member of staff.

All patient safety events where significant harm is suspected should be discussed at the trust's SI panel, where both SI status and the level of harm will be confirmed.

## 6.9 The SI panel

A weekly SI meeting, chaired by the Clinical Lead for Quality and Safety (or a nominated deputy) will take place to facilitate the prompt consideration of events that are considered to be possible or actual SI/NE's or patient safety events that it is believed would benefit from multi-disciplinary discussion and involvement. The meetings will be co-ordinated and administered by the Risk & Safety Department. The distribution list will be amended to reflect the nature of the patient safety event to be discussed. The meeting will not proceed if there are no patient safety events to be discussed.

The SI Panel will be minuted, will note the outcome of discussions and will grade patient safety events to determine whether each should be considered a Serious Incident (SI) or Never Event (NE).

The SI panel will also nominate leads for investigations, and identify staff best placed to lead Being Open discussions where this has not yet taken place.

#### **6.10 The Complaints Manager**

Following patient safety events that are identified through the complaints/PALS process, the role of the Complaints Manager is to:

- Ensure that appropriate correspondence is undertaken with the complainant in the timeframe stipulated in the Complaints Policy
- Monitor all correspondence with the complainant, including all discussions and attempts to contact the complainant. Correspondence will be held centrally and not included in any medical records due to the confidential nature of complaints
- Following receipt of the complaint, ensure that the complainant has been contacted within 3 working days acknowledging their complaint.
- Liaise with the divisional teams to determine the risk level of each complaint
- Ensure that all discussions and correspondence includes an apology, a true and honest reflection of what happened and the findings of any investigation and changes made or plans to address the issues raised.
- Liaise with the Head of Risk and Safety where suspected harm has occurred to ensure that the complaint (if appropriate) is discussed at the SI panel
- If aspects of the complaint indicate significant harm/notifiable patient safety event, these should be addressed by the Duty of Candour and Being Open principles, (*see appendix 8 -Duty of Candour & Being Open Process for incidents*)

#### **6.11 The Head of Legal Services**

Following patient safety events that are identified through the claims process, the role of the Head of Legal Services is to:

- Ensure that appropriate correspondence is undertaken with the claimant in the timeframe stipulated in the Claims Policy;
- Monitor all correspondence with the claimant and the claimant's solicitors (if instructed)
- Ensure that claimants are provided with a full and honest response to their claim;
- Liaise with the Head of Risk and Safety where suspected harm has occurred to ensure that the claim (if appropriate) is discussed at the SI panel;

- If aspects of the claim indicate significant harm/notifiable patient safety event, these should be addressed by the Duty of Candour and being open principles, (*see appendix 8 Duty of Candour & Being Open Process for incidents*)

#### 6.12 **All senior healthcare professions (band 6 and over) and all managers (band 7 and over)**

These staff are expected to:

- Support the Duty of Candour culture
- Practice and promote the principles of Being Open
- Advise their staff on the Duty of Candour and Being Open processes
- Provide the patient/carer/family with the immediate and initial acknowledgement, apologise and provide brief information that there will be a fact finding investigation (no/low harm patient safety events where indicated)
- Participate where appropriate in the initial team and Being Open meetings to discuss the patient safety event
- Take part in debriefing meetings following Being Open discussions where appropriate
- Direct colleagues involved in patient safety events to the support services provided by the trust
- Be accessible to colleagues prior to initial and subsequent Being Open discussions

#### 6.13 **Trust Staff Who Have Made Mistakes**

In these circumstances, the member(s) of staff involved may or may not wish to participate in the Being Open discussions with the patient/family/carers. Each case where an error has occurred needs to be considered individually. Staff may also wish to seek advice and support from their trade unions or defence unions.

Staff involved in a patient safety event should not lead any subsequent formal investigation.

All clinical staff involved in a SI/NE or significant harm patient safety event should discuss the event at their annual appraisal with their appraiser. For medical staff, this is a requirement for revalidation.

Trust staff involved in patient safety events may seek support from their line managers, nominated trust support staff and the trust counselling service, 'Validium'. Details can be found on the intranet at [REDACTED] or can be contacted by telephone on 0800 358 4858, or visit the website at [www.validium.com](http://www.validium.com)

Staff that have made a mistake must ensure that it has been reported via the trust's incident reporting system.

#### 6.14 **All Staff**

All staff have a duty to promote and work to support a culture of openness which is vital to improving patient safety and the quality of healthcare that we provide.

A culture of openness is one where:

- Healthcare staff are open about patient safety events they have been involved in
- Healthcare staff and organisations are accountable for their actions
- Healthcare staff feel able to talk to their colleagues and superiors about any patient safety event
- Healthcare organisations are open with patients, the public and staff when things have gone wrong, and explain what lessons will/have been learned
- Healthcare staff are treated fairly and are supported following an event

All staff are expected to report patient safety events as per the trusts '*Incident and Serious Incident (including never events) Reporting Policy and Procedure*'. All staff should comply with this Being Open and Duty of Candour Policy and related policies.

**All staff must document fully any Duty of Candour / Being Open discussions with the patient, in the patient's health record.**

#### **6.15 Clinical Governance Committee**

The Duty of Candour and Being Open processes will be monitored through the Clinical Governance Committee.

The level of disclosure to patients, their families and carers following a patient safety event will be dependent on the level of harm caused by the event. Please refer to section 7.1.3 for advice on disclosure following patient safety '*incidents*'.

### **7.0 The Process to Support 'Being Open'**

#### **7.1 Incidents, complaints and claims**

Duty of Candour and Being Open should be considered a process rather than a one off event, and applies to complaints, claims and patient safety incidents. All complaints, claims and incidents are stored on the trust's 'Safeguard Risk Management System.'

##### **7.1.1 Concerns and complaints**

It is necessary to acknowledge, apologise and explain when a concern or complaint is raised. All staff within the organisation have a responsibility to immediately respond to concerns and complaints raised directly with them, apologise that the complainant is upset or has been inconvenienced while not presuming that the complainant is correct prior to the outcome of an investigation, and try to provide a resolution. Complaints should be escalated to senior management for local resolution. Where issues cannot be resolved locally staff should direct the complainant to PALS.

Formal complaints are managed by the Complaints team who are responsible for ensuring that all responses to formal complaints contain an acknowledgement, an apology, an explanation of the facts and any changes being made as a result of the complaint.

Should any aspect of a concern/complaint raised indicate a significant level of harm, this should be raised with the Risk and Safety team and the Duty of Candour process should be followed.

The Complaints Policy is available on the trust's intranet for guidance.



### 7.1.2 Claims

When a letter of claim has been received by the trust it is the responsibility of the PA to the CEO to ensure the principles of Being Open are followed, and that an apology where appropriate and explanation are included in the trust's response to the claim. Following acknowledgement of the claim, the Head of Legal Services will notify the trust solicitors / NHS Resolution for comment and advice. Staff who are asked questions about a claim should refer these on to the Head of Legal Services.

Should any aspect of a claim raised indicate a significant level of harm, this should be raised with the Risk and Safety team and the Duty of Candour process should be followed.

The Policy & Procedure for the Management of Clinical Negligence, Third Party Liability and Property Expenses Claims is available on the trust's intranet for guidance, and includes the responsibilities of those staff involved with responding to claims.



### 7.1.3 Patient safety incidents

#### **No Harm / Near Miss**

Patients are not routinely informed about events that do not cause harm / near misses. These types of incidents are outside the scope of the Duty of Candour and Being Open Policy, (see section 2); however in some cases where obvious error has been noted by both patient and staff, discussion may be beneficial. Should it be felt necessary on a case by case basis to discuss a no harm incident with patients, their families or carers, the process for low / minor harm incidents should be followed. Specific near miss / no harm incidents may also be discussed at the SI panel on request.

#### **Low / Minor Harm**

Unless there are specific indications or the patient requests otherwise, the communication, investigation and analysis, and the implementation of change following low / minor harm incidents will occur at a local service delivery level with the participation of those directly involved in the incident.

Communication should take the form of an acknowledgement, an apology and a full and honest explanation. Being Open discussions should then take place between the staff providing the patient's care and the patient/family/carers. This should be led by the clinical member of staff in charge of the patient's care, and supported by other members of the multidisciplinary team as appropriate. All discussions should be documented in the patient's health record.

Local management of the incident should be in line with the trust's policies for reporting and investigating a patient safety incident. The principles of Being Open should be applied (see *appendix 5*)

**Significant Harm (a patient safety event that could result in or has resulted in moderate, major or catastrophic harm, including prolonged psychological harm and death - including SIs and NEs)**

Such incidents should be managed in line with trust's 'Incident, Serious Incident (SI) and Never Event Policy and Procedure', and the Risk and Safety team should be notified immediately and be able to provide support and advice during the Being Open process if required.

Duty of Candour processes should be applied as soon as reasonably practicable after becoming aware of the significant harm, including the completion of an incident report form.

Duty of Candour / Being Open discussions should be undertaken by the patient's consultant or a nominated senior clinician (e.g. Divisional Director) within the service and, if appropriate, supported by a Senior Clinical Counsellor (Head of Service/ Manager / Director / see section 6.4). The discussion between consultant and patient should take place as soon as possible either face-to-face, or via the telephone. Discussion should include an apology, a true and honest reflection of what happened and plans to address and fully investigate the event. The patient, (or where relevant their family or carer) should be informed that such an incident will be discussed at a serious incident panel, and a formal investigation to learn lessons from such an incident will take place. **All discussions with the patient, their family or carer should be documented clearly and fully in the patient's health records.** All attempts to contact the patient should also be fully documented in the health records including where the patient may decide they do not wish to be told. The apology and full discussion should be supported in writing, providing the same information and any update on the enquiries (see below).

Team discussions should be held where necessary to ascertain the facts and any urgent or immediate actions put in place to prevent repetition. Additional healthcare or managerial staff may be called upon to provide information during the discussions.

Incidents involving moderate, major and extreme harm should be reported at the earliest convenience to the Risk and Safety team, and escalated as appropriate. Where the level of harm is unknown, incidents will be discussed at the weekly SI panel to agree the actual harm caused, and determine whether each incident should be considered a SI / Never Event status. If not already agreed, the SI panel will decide on whom, how and when further communication with the patient should take place.

If an incident is considered a SI / Never Event, it will be reported externally by the Risk and Safety team to the National Reporting and Learning System (NRLS), StEIS (Strategic Executive Information System), and to the trust commissioners as appropriate.

Following the Duty of Candour discussion with the patient, the patient will be formally contacted by letter from the appropriate trust Director (in most cases the Medical Director), confirming the discussion and asking if the patient should have any specific questions that a subsequent investigation should cover. The letter will also include an apology, a true and honest reflection of what happened and plans to address and fully investigate the event. Correspondence should be copied to the patient's GP for information.

Within 10 working days of the investigation completion and sign off by the Medical Director, a formal letter will be sent to the patient (or their next of kin) summarising

the findings together with a copy of the full report (unless previously indicated by the patient that it was not required).  
*(see flowchart to illustrate the Duty of Candour and Being Open process, Appendix 8).*

**All incidents, complaints and claims must be reported onto the trust's Incident Reporting System via the appropriate incident reporting tool.**

## 7.2 Stages of the Being Open process

There are a number of stages in the Being Open process; the duration of the whole 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. The table below provides an overview of the process:

### Overview of the Being Open process

Event detection or recognition	Preliminary team discussion	Initial Being Open discussion	Follow-up discussions	Process completion
Detection and notification through appropriate systems	Initial assessment	Verbal and written apology	Provide update on known facts at regular intervals	Discuss findings of investigation and analysis
		Provide known facts to date		Inform on continuity of care
	Establish timeline	Offer practical and emotional support		Share summary with relevant people
Prompt and appropriate clinical care to prevent further harm	Choose who will lead communication	Identify next steps for keeping informed	Respond to queries	Monitor how action plan is implemented
				Communicate learning with staff
<b>Documentation</b>		<b>Provide written records of all Being open discussions</b>		<b>Record investigation and analysis related to incident</b>

*A flowchart of the Duty of Candour and Being Open Processes specific to incidents, complaints and claims can be found in appendices 8, 9 and 10.*

### 7.2.1 Stage 1: Event detection or recognition

As soon as a patient safety event is identified, the top priority is prompt and appropriate clinical care and prevention of further harm. Where additional treatment is required, this should occur whenever reasonably practicable, after a discussion with the patient/parent and appropriate consent obtained.

An acknowledgement, an apology and a true and honest reflection of what happened, including that there will be a fact finding investigation should be given as soon as possible. Discussions following significant harm should be undertaken by the patient's consultant or nominated senior clinician and for events that have resulted in low/no harm, this should be the most senior person responsible for the patient's care and/or someone with experience and expertise in the type of patient safety event that has occurred. This could either be the patient's consultant, senior nurse, or any other senior healthcare professional.

The patient safety event must be reported as soon as possible using the Safeguard Risk Management System. The trust's 'Incident and Serious Incident (including Never Events) Reporting Policy and Procedure' for reporting an incident should be followed. The Risk and Safety team accepting the incident report will decide who else needs to be informed.

If the patient safety event meets the criteria for a SI/NE or significant harm investigation, Being Open discussions should be detailed within the serious incident investigation report.

Patient safety events are almost always unintentional. However, if at any stage following an event it is determined that harm may have been the result of a criminal or intentional unsafe act, the Head of Risk and Safety and/or the Chief Executive Officer should be notified immediately. The trust will act in accordance with the instruction given in the Memorandum of Understanding and the trust Incident and Serious Incident (including Never Events) Reporting Policy and Procedure.

## 7.2.2 Stage 2: Preliminary Team Discussions

### Preliminary team discussion

The multidisciplinary team, including the most senior health professional involved in the patient safety event, should meet as soon as possible after the event to:

- establish the basic clinical and other facts;
- assess the event to determine the level of immediate response;
- identify who will be responsible for discussion with the patient and/or their carers and recognise issues of confidentiality;
- consider the appropriateness of engaging patient support at this early stage. This may include the use of a facilitator, a patient advocate or a healthcare professional who will be responsible for identifying the patient's needs and communicating them back to the healthcare team;
- identify immediate support needs for the healthcare staff involved;
- ensure there is a consistent approach by all team members around discussions with the patient and/or their carers.

Membership of the multidisciplinary team, dependent on the grade of patient safety event, should contain staff who have attended the appropriate level of training, (see *section 11*).

### Initial Assessment 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 Head of Risk and and/or local Director/ Manager/ Head of Service if considered to require a high level of

response. This should be done in accordance with the Incident and Serious Incident (including Never Events) Reporting Policy and Procedure.

#### Establish a timeline

The initial discussion with the patient/carers should occur as soon as possible after recognition of the patient safety event. Factors to consider when timing this discussion include:

- Clinical condition of the patient;
- Availability of key staff involved in the patient safety event and Being Open process;
- Availability of the patient's family and/or carers;
- Availability of support staff, e.g. translator/independent advocate, if required;
- 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;
- Arranging the meeting in a sensitive location.

Following an awareness of the patient safety event, within 10 working days at most, is assumed to be a 'reasonable' time period to have contacted and discussed the event with the patient. A decision to exceed this, because the patient has an appointment imminently and therefore disclosure may be made face to face, is acceptable but should be documented. Disclosure may be made over the phone where it would not be reasonable to expect the patient to attend purely to facilitate disclosure (e.g. geographical or health reasons). For significant harm events, disclosure should be made by a consultant or a nominated senior clinician (e.g. Clinical / Divisional Director) in the event that it is not appropriate for the patient's consultant to make the disclosure. This must be documented.

#### Choosing the individual to communicate with patients/carers

For no/low harm events, the healthcare professional who informs the patient and/or their carers about a patient safety event should be the most senior person responsible for the patient's care and/or someone with experience and expertise in the type of patient safety event that has occurred. This could either be the patient's consultant, nurse manager / nurse practitioner, or any other healthcare professional who has a designated caseload of patients. Staff undertaking this role should have received training in communication of patient safety events (*see training section 11*).

For significant harm events the discussion should be given by the patient's consultant or nominated senior clinician.

The person nominated to lead the Being Open process should:

- be known to, and trusted by, the patient/carers;
- have a good grasp of the facts relevant to the incident;
- be senior enough or have sufficient experience and expertise in relation to the type of incident to be credible to patients/carers and colleagues;
- have excellent interpersonal skills, including being able to communicate with patients and/or their carers in a way they can understand and avoiding excessive use of medical jargon;
- be willing and able to offer an apology, reassurance and feedback to patients and/or their carers.
- be able to maintain a medium to long term relationship with the patient and/or their carers, where possible, and to provide continued support and information;

- be culturally aware and informed about the specific needs of the patient and/ or their carers.

The healthcare professional communicating information about a patient safety event can nominate a colleague to assist them with the meeting. Ideally this should be someone with experience or training in communication and Being Open procedures.

If for any reason it becomes clear during the initial discussion that the patient would prefer to speak to a different healthcare professional, the patient's wishes should be respected. A substitute with whom the patient is satisfied should be provided.

### 7.2.3 Stage 3: The initial Duty of Candour / Being Open discussion

The initial discussion with the patient, their family or carer should only cover the facts, an apology that they have had a bad experience, and an explanation as to the type of investigation the trust is going to undertake to identify the causes and prevent recurrence. This initial discussion should be non-judgmental and should not be critical of colleagues or describe any speculative detail or attribute blame.

- The patient and/or their carers should be advised of the identity and role of all people attending the Being Open discussion before it takes place. This allows them the opportunity to state their own preferences about which healthcare staff should be present;
- There should be an expression of genuine sympathy, regret and an apology for the harm and distress that has occurred;
- The facts that are known to date and are agreed by the multidisciplinary team should be shared. Where there is disagreement, communication about these events should be deferred until after the investigation has been completed. The patient and/or their carers should be informed that an investigation is being carried out and more information will become available as it progresses;
- The patient, and carer should be given the opportunity for questions that they would like included in the investigation
- It should be made clear to the patient and/or their carers that new facts may emerge as the incident investigation proceeds;
- The patient's and/or 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 patient's and/or carer's views and concerns, and demonstration that these are being heard and taken seriously;
- Appropriate language and terminology should be used when speaking to patients and/or their carers. For example, using the terms 'patient safety incident' or 'adverse event' may be at best meaningless and at worst insulting to a patient and/or their carers. If a patient's and/or their carer's first language is not English, it is also important to consider their language needs – if they would like the Being Open discussion conducted with a translator, this should be arranged;

- An indication of how long the formal investigation may take should be given to the patient and/or carer and their preferred method of communication;
- Information on likely short and long term effects of the event (if known) should be shared together with a treatment plan. The long term effects may have to be delayed to a subsequent meeting when the situation becomes clearer;
- 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 charities and voluntary organisations as well as offering more direct assistance. Information about the patient and the incident should not normally be disclosed to third parties without consent;
- It should be recognised that patients and/or their carers may be anxious, angry and frustrated even when the Being Open discussion is conducted appropriately;

**It is essential that the following does *not* occur:**

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

All discussions with the patient or attempts to contact the patient should be documented fully in the medical records. Following Duty of Candour discussion with the patient, a letter should be sent to the patient (cc their GP) summarising and reinforcing the previous discussions, apology and plans. This should be sent by the Head of Risk and Safety (for SI/NEs) or the appropriate Divisional Lead on behalf of the relevant Director.

For cases where it has not been possible to communicate with the patient, family or carer in the hospital, the flowchart to illustrate the Being Open process specific to incidents, complaints and claims (*appendices 8, 9 & 10*) should be followed.

Further guidance on the preliminary discussions can be found in *appendix 4*.

#### **7.2.4 Stage 4: Follow-Up Discussions**

Patients, their carers or relatives should be communicated with throughout the investigation process as necessary, continuing the points raised in stage 3.

Any further discussions should be clearly documented.

#### **7.2.5 Stage 5: Process Completion**

In cases where a more serious event has occurred, for example a Serious Incident (SI) / significant harm event, it will be necessary for a letter to be sent by the Clinical Lead for Quality and Safety / Medical Director / Chief Executive Officer / appropriate

Divisional Director along with the findings of the investigation and what the trust is doing to prevent recurrence. Patients should also be offered a copy of the investigation report within 10 days of its sign off.

All relevant community healthcare providers will also be informed of the investigation upon completion for shared learning. Recommendations and actions as a result of SI investigations are monitored at the Clinical Governance Committee to ensure progress and implementation.

All relevant staff groups should be informed of appropriate investigations in order to share learning from the patient safety event.

## **8 Documentation**

### **8.1 General**

The communication of patient safety events involving 'incidents' must be recorded. Required documentation includes:

- Any and all discussions with patients their families or carers concerning the patient safety event should be documented clearly in the patient's health record;
- Any failed attempt to contact the patient, or if the patient declines to speak to the member of staff should be documented in the health records;
- An incident report form should be completed at the earliest convenience;
- A record of the investigation and analysis process should be held (centrally by the Head of Risk and Safety for SI/NEs, or locally by the Divisional Leads).
- All correspondence should be held by the appropriate teams (Risk and Safety, Complaints, Claims and local divisional teams).

The incident report, complaint or claim, and record of the investigation and analysis process is filed separately to the patient's health record, as a patient safety event record.

### **8.2 Written Records of the Being Open Discussion**

Any discussions within the Duty of Candour / Being Open process with the patient, their families or carers, should be clearly documented and include:

- the time, place, date, as well as the name and relationships or designation of all attendees;
- the plan for providing further information to the patient and/or their carers;
- offers of assistance and the patient's and/or carer's response;
- questions raised by the family and/or carers or their representatives, and the answers given;
- plans for follow-up as discussed;
- progress notes relating to the clinical situation and an accurate summary of all the points explained to the patient and/or their carers;
- copies of letters sent to patients, carers and the GP for patient safety incidents;
- copies of any statements taken in relation to the patient safety incident;
- a copy of the incident report.

A summary of the Being Open discussion should be shared with the patient where appropriate.

### **8.3 Incident Report**

Where the patient safety event fulfils the definition of an 'incident', an incident report form should be completed and submitted in accordance with the instructions specified in the Incident and Serious Incident (including Never Events) Reporting Policy and Procedure.

### **8.4 Complaint documentation**

All complaint documentation and correspondence will be held centrally by the Complaints Manager and entered on the Complaints section of the Safeguard Risk management System.

### **8.5 Claim Documentation**

All claims documentation will be held centrally by the Head of Legal Services. The Head of Legal will acknowledge all claims received and notify the trust solicitors and/or NHS Resolution for comments and advice.

### **8.6 Data Protection and Confidentiality**

The trust will ensure that appropriate confidentiality is maintained at all times. Only anonymous data about patient safety events will be disseminated beyond the treating clinicians and the investigating team. Where a patient makes information public it is permissible to confirm its accuracy or to make a simple statement that the information is incorrect. Where additional information is to be disclosed, for example, to correct statements made to the media, the patient and his/her representatives should be advised of any forthcoming statement and the reasons for it. Patient consent should be sought but, if it is not given disclosure may still be warranted in the public interest. Issues relating to communication and data protection should be referred to the Head of Communications and the Head of Information Governance, respectively.

## **9.0 Specific Circumstances**

A different process may be more appropriate in the following circumstances:

### **9.1 *When a patient dies***

Although extremely rare at the trust, 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 or carers and to involve them in deciding when it is appropriate to discuss what has happened. The patient's family and/or carers should be given information on the processes that will be followed to identify the cause(s) of death. They will also need emotional support and established open channels of communication may also allow the family and / or carers to indicate if they need bereavement counselling or assistance at any stage.

### **9.2 *Children and Young People***

The legal age of maturity for decision making and giving valid 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. Young people involved in the Being Open process after a patient safety event should still be offered the opportunity to involve their parents/carers unless the young person expresses a wish for them not to be present. Young people with a cognitive impairment or learning disability, where possible, should be involved directly in communications about what has happened with consideration given to alternative communication methods for example Makaton Sign Language.

The courts have stated that children 15 years and under who understand fully what is involved in a proposed procedure can give consent. This is known as Gillick competence. 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. Where a child is deemed not to have sufficient maturity or ability to understand, consideration needs to be given to whether information is provided to the parents/carers alone or in the presence of the child.

Where children or young people are looked after by Children's Social Care the Being Open process must consider involvement of the child or young person, children's social care, their foster carers and the biological parents. In these situations advice should be sought from the Trust Safeguarding Children professionals regarding who needs to be involved.

Further guidance can be sought from the Trust Safeguarding Children Professionals or the Trust's Legal Advisor.

### *9.3 Patients with mental health issues*

The Being Open process should be followed for patients with mental health issues, unless the patient also has cognitive impairment and may lack capacity (see section 9.4 below). Patients with a mental health issue may require extra support to participate in the Being Open process. We must make reasonable adjustments in terms of support and the provision of accessible information to the individual. If required an advocate, agreed in consultation with the patient, should be appointed. Advocates may include family, carers, friends, or health and social care professionals involved with the individual. The advocate can support and assist the patient during the Being Open process, and ensure that the patient's views, wishes and preferences are considered. The only circumstance in which it is appropriate to withhold patient safety event information from a patient with mental health issues is when advised to do so by a consultant psychiatrist who feels it would cause adverse psychological harm to the patient. 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 consent of the patient. To do so is an infringement of the patient's human rights.

### *9.4 Patients with cognitive impairments*

Some individuals have conditions that may mean they lack capacity regarding some or all decisions. If it appears a patient may lack capacity, a documented capacity assessment may be required. If a patient lacks capacity, a person(s) may have the

authority to make decisions for them though a court appointed health and welfare Lasting Power of Attorney (LPA) or deputy. In these cases The Being Open discussion would be held with the power of attorney or deputy. Where there is no LPA or deputy, the clinicians must act in the patient's best interest in deciding who the most appropriate person is to discuss the patient safety event information with, regarding the welfare of the patient as a whole and not simply their medical interests. Patients with a cognitive impairment, including those who lack capacity, should, where possible, be involved in communications about what has happened. An advocate should be available to the patient to support in the communication process. See 'Patients with learning disabilities' (section 9.5 below) for details of appropriate advocates.

#### *9.5 Patients with learning disabilities or dementia*

Some patients with a learning disability or dementia may have cognitive impairment and therefore the guidance in 9.4 above should be followed. Patients with a learning disability or dementia may have additional communication needs, and will require extra support to participate in the Being Open process. We must make reasonable adjustments in terms of support and the provision of accessible information to the individual. If required an advocate, agreed in consultation with the patient, should be appointed. Advocates may include family, carers, friends, or health and social care professionals involved with the individual. The advocate can support and assist the patient during the Being Open process, and ensure that the patient's views, wishes and preferences are considered and discussed.

#### *9.6 Patients with different language and cultural considerations*

The need for translation and advocacy services and consideration of special cultural needs 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 (see the 'Interpreting and Translation Policy and Procedure' document for the translation options available at Moorfields).

#### *9.7 Patients with different communication needs*

Many of the patients at Moorfields may have particular communication difficulties, such as visual or 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 and being personally thoughtful and respectful.

#### *9.8 Patients who do not agree with the information provided*

Sometimes, despite the best efforts of healthcare staff or others, the relationship between the patient/family/carer and the healthcare professional breaks down. They may not accept the information provided or may not wish to participate in the Being Open process. In this case the following strategies should be considered:

- deal with the issue as soon as it emerges;
- where the patient agrees, ensure their family and carer are involved in discussions from the beginning;
- ensure the patient has access to support services;
- where the senior health professional is not aware of the relationship difficulties, provide mechanisms for communicating information, such as the patient expressing their concerns to other members of the clinical team;
- offer the patient and/or their carers another contact person with whom they may feel more comfortable. This could be another member of the team or the individual with overall responsibility for clinical risk management;
- use a mutually acceptable mediator to help identify the issues between the healthcare organisation and the patient, and to look for a mutually agreeable solution;
- ensure the patient and/or their carers are fully aware of the formal complaints procedures;
- document a comprehensive list of the points that the patient and/or their carer disagree with and reassure them you will follow up these issues.

### 9.9 *Patient safety incidents occurring elsewhere*

A patient safety 'incident' may have occurred or originated in another organisation but has been identified by trust staff. The individual who first identifies the possibility of such a patient safety incident should notify their line manager who should report the incident to the Risk and Safety team via the incident reporting procedure. The trust's Head of Risk and Safety will ensure contact is made with the appropriate colleagues in the other organisations. An acknowledgement, apology and an explanation should be given.

Communications with parties outside of the clinical team should be on a strictly need to know basis and, where practicable, records should be anonymous. In addition, it is good practice to inform the patient/family/carers about who will be involved in the investigation before it takes place, and give them the opportunity to raise any objections.

Should staff require guidance on issues related to confidentiality this should be sought in the first instance from their line manager and if further guidance is required, from the trust's Caldicott Guardian, Medical Defence Unions, Trade Unions or professional organisations.

### 9.10 *Duty of Candour / Being Open over the telephone*

Sensitivity needs to be considered if informing patients of a significant harm patient safety event via the telephone. The consultant or senior clinician undertaking the discussion must consider any language constraints prior to contacting the patient (see section 9.6 above). The consultant will also need to consider further immediate support for the patient and assess their ability to accept and understand the bad news via the telephone. Assurances should be made that is comfortable with the information given to them prior to ceasing the conversation. (see support section 10).

### 9.11 Safeguarding

Staff must consult the Safeguarding Team for guidance on information sharing when there is a patient safety incident involving concerns about a vulnerable child or young person and/or an adult at risk. Safeguarding incidents are not excluded from the requirements of this policy nor working to the principles of being open as per the Trust's Safeguarding Adults policy and Safeguarding Children and Young People (0-18 years) Policy.

## **10 Support for people involved in a patient safety event**

The trust is committed to supporting all people involved in patient safety events and seeks to meet the needs of people affected by them.

Patients, their families, carers and healthcare professionals may need considerable practical and emotional help and support after being involved in a patient safety event. The most appropriate type of support may vary, it is therefore important to discuss individual needs with the patient, their family or carer, or the staff member(s) involved.

Where the patient needs more detailed long-term emotional support, they should be directed to contact their GP regarding how to gain access to appropriate counselling and support services.

The trust will provide the contact details of a staff member who will maintain an ongoing relationship with the patient/family/carers with regard to advice and information and signposting the trust's processes for raising a concern or complaint and/or any other available means of giving feedback. Patients are entitled to expect that they will continue to receive all usual treatment and will continue to be treated with dignity, 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.

Support details can be found within the following policies:

- Incident and Serious Incident (including Never Events) Reporting Policy and Procedure

Support for people involved in / affected by an incident (*including patients, relatives, visitors, contractors, staff, trainees*) (*Section 9*)

[REDACTED]

- Policy and procedure for the management of clinical negligence, third party liability and property expenses claims policy

Support for staff (*section 10*)

[REDACTED]

- Policy for the investigation of incidents, complaints and claims

Support for staff, patients and relatives / carers (*section 9*)

[REDACTED]

Staff may wish to contact the trust counselling service, or refer themselves to Occupational Health as necessary. (*see section 6.12*)

## **11 Training**

A bespoke Duty of Candour e-learning module has been developed by the Head of Clinical Governance with support from the Head of Risk and Safety and is a mandatory training requirement for all clinical staff. The module will be completed as part of new starters induction, and will be available for resident staff to complete via the Insight module on the trust's intranet.

Training is interactive and an assessment with a pass mark of 80% is required to complete the training. Completion of the training will be required every 3 years as a minimal update for clinical staff.

Guidance and support should be provided to staff involved in a patient safety event by line managers and colleagues. Clinicians are expected to mentor and support each other through the different issues that arise from such a patient safety event, with additional support from the appropriate Service Manager / Director.

Other staff groups should seek support from their line managers.

Further support services and advice is available within the trust as discussed in *section 6.13*, or externally in *appendix 3*.

Further information on learning from Being Open and supporting tools can be found on the Archived NPSA pages at:

<http://webarchive.nationalarchives.gov.uk/search/result/?q=being+open>

Staff should ensure they have attended the trust's mandatory 'conflict resolution' training course that covers appropriate communication skills. The trust's Nurse Counsellor also provides a 'Breaking Bad News Workshop', aimed at members of the counselling network group or for staff who are specifically interested in supporting patients psychologically following a bad news break in their clinical area.

## **12 Stakeholder Engagement and Communication**

This policy was circulated to all Service Directors, Heads of Nursing, Clinical Directors, General Managers, Nurse Managers, the Complaints department the Claims team, Risk and Safety team and members of the Clinical Governance Committee prior to approval.

The Clinical Commissioning Group have also reviewed the policy and can assess compliance of the Policy at any time, reporting any problems to the CQC. Financial penalties can be awarded to the trust if the policy is not followed at all times.

## **13 Approval and Ratification**

This policy will be approved by the Clinical Governance Committee and ratified by Management Executive and the trust Management Board.

## **14 Dissemination and Implementation**

This policy will be disseminated via communications and will be available on the trust intranet. The Duty of Candour and Being Open principles will also be available on the Clinical Governance department intranet site.

A summary document will be available to all staff via a hyperlink to the full Duty of Candour and Being Open Policy. Clinical and managerial leads will be asked to read the policy in full as they will need to be able to follow the Duty of Candour and Being Open principles on a day to day basis. Service Managers/Directors will be asked to discuss the contents of the policy at their service meetings, and Nurse Managers at their senior nurse meetings. The Duty of Candour e-learning training that refers to the policy will be included as a mandatory requirement for all clinical staff.

## 15 Review and Revision Arrangements

This policy will be reviewed by the Head of Clinical Governance every 3 years. Should there be any change to legislation or a significant change in process then this policy will be reviewed to reflect the changes.

## 16 Document Control and Archiving

16.1 The current and approved version of this document can be found on the trust's intranet site. Should this not be the case, please contact the Quality and Compliance team.

16.2 Previously approved versions of this document will be removed from the intranet by the Quality and Compliance team and archived on the corporate governance shared drive. Any requests for retrieval of archived documents must be directed to the Quality and Compliance team.

## 17 Monitoring compliance with this Policy

The trust may use a variety of methods to monitor compliance with the processes in this document. The proposed audit (below) may include some or all of the following policy objectives/standards:

Measurable Policy Objective	Monitoring/ Audit method	Frequency of monitoring	Responsibility for performing the monitoring	Monitoring reported to which groups/ committees, including responsibility for reviewing action plans
Compliance with the Duty of Candour and Being Open Policy	Assess the process for acknowledging apologising and explaining when things go wrong	Ad Hoc	Head of Risk and Safety	Identified through incident reports
	Audit the process of Duty of Candour for all incidents graded as moderate harm	Annually	Head of Risk and Safety / Head of Clinical Governance	Clinical Governance Committee

	or above.			
	Audit sample of complaints to ensure Duty of Candour has been followed as appropriate	Annually	Head of Complaints and Patient Experience	Patient Participation and Experience Committee
	Audit sample of claims to ensure Duty of Candour has been followed as appropriate	Annually	Head of Legal Services	Discussed through claims reports

In addition to the monitoring arrangements described above the trust may undertake additional monitoring of this policy as a response to the identification of any gaps, or as a result of the identification of risks arising from the policy prompted by incident review, external reviews or other sources of information and advice.

## 18 Supporting References / Evidence Base

### Significant references

1. The 2017-19 (May 2018 Edition) specific contractual requirements can be found in section 35 of the NHS standard contract service conditions  
<https://www.england.nhs.uk/wp-content/uploads/2018/05/2-nhs-standard-contract-2017-19-particulars-service-conditions-may-2018.pdf>
2. CQC Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 20  
<https://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-20-duty-candour>
3. Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry, chaired by Robert Francis QC (2013)  
<http://www.midstaffpublicinquiry.com/sites/default/files/report/Executive%20summary.pdf>
4. Sir David Dalton and Prof. Norman Williams, Building a culture of candour: a review of the threshold for the duty of candour and of the incentives for care organisations to be candid (march 2014)

### Further references:

1. Vincent CA and Coulter A. Patient safety: what about the patient? *Qual Saf Health Care*. 2002; 11: 76–80
2. Vincent CA, Pincus T and Scurr JH. Patients' experience of surgical accidents. *Qual Saf Health Care*. 1993; 2: 77–82
3. Department of Health. (2009) *The NHS Constitution for England*. London, DH. Available at: [www.dh.gov.uk](http://www.dh.gov.uk)
4. NHS Litigation Authority (NHSLA) (2009) Apologies and explanations letter. London: NHSLA. Available at: [www.nhsla.com](http://www.nhsla.com)
5. Medical Defence Union. *MDU encourages doctors to say sorry of things go wrong*. MDU, May 2009. Available at: [www.the-mdu.com/Search/hidden\\_Article.asp?articleID=1982&contentType=Media%20release&articleTitle=MDU+encourages+doctors+to+say+sorry+if+things+go+wrong&userType=](http://www.the-mdu.com/Search/hidden_Article.asp?articleID=1982&contentType=Media%20release&articleTitle=MDU+encourages+doctors+to+say+sorry+if+things+go+wrong&userType=)
6. NHS Litigation Authority. *Apologies and Explanations*. NHSLA, London. May 2009. Available online at: [www.nhsla.com/NR/rdonlyres/00F14BA6-0621-4A23-B885-FA18326FF745/0/ApologiesandExplanations.pdf](http://www.nhsla.com/NR/rdonlyres/00F14BA6-0621-4A23-B885-FA18326FF745/0/ApologiesandExplanations.pdf)
7. Welsh Risk Pool. *Technical Note 23: Apologies and Explanations*. WRP, July 2001. Updated 2009. Available at <http://howis.wales.nhs.uk/sites3/docmetadata.cfm?orgid=287&id=71076>
8. Ledema RA, Mallock NA, Sorensen RJ, et al. The National Open Disclosure Pilot: evaluation of a policy implementation initiative. *Med J Aust*. 2008; 188: 397-400
9. Albert Wu, Professor of Health and Policy Management at the John Hopkins Bloomberg School of Public Health, personal communication with Geoffrey Hirst, Director of Surgical Services, Mater Health Services, South Brisbane.
10. Albert Wu, Professor of Health and Policy Management at the John Hopkins Bloomberg School of Public Health, personal communication with a hospital representative.
11. Boothman RC, Blackwell AC, Campbell DA Jr, Commiskey E, Anderson S. A better approach to medical malpractice claims? The University of Michigan experience. *J Health Life Sci Law*. 2009; 2: 125-159
12. National Quality Forum. *Safe practices for better healthcare – 2009 update. A consensus report*. Washington, DC, NQF; 2009.
13. Bayley C. Turning the Titanic: changing the way we handle mistakes. *HEC Forum*. 2001; 13: 148-159.
14. Quinn RE, Eichler MC. The 3Rs program: the Colorado experience. *Clin Obstet Gynecol*. 2008; 51: 709-718
15. Kraman SS, Cranfill L, Hamm G, Woodard T., John M. Eisenberg Patient Safety Awards. Advocacy: the Lexington Veterans Affairs Medical Center. *Jt Comm J Qual Improv*. 2002; 28: 646-650.
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18. Royal College of Surgeons of England (RSC) (2008) Good Surgical Practice. London: RCS. Available at: [www.rcseng.ac.uk/](http://www.rcseng.ac.uk/)
19. Care Quality Commission (CQC) (2009) A Quality Service, a Quality experience. London: CQC. Available at: [www.cqc.org.uk](http://www.cqc.org.uk)
20. Department of Health (2009) Listening, Responding, Improving: A guide to better customer care. London: Department of Health. Available at: [www.dh.gov.uk](http://www.dh.gov.uk)

21. National Patient Safety Agency (NPSA) (2009) Patient Safety Alert: Being Open communicating with patients, their families and carers following a patient safety incident. NPSA. (see appendix 7) Available at: [www.npsa.nhs.uk](http://www.npsa.nhs.uk)
22. National Patient Safety Agency (NPSA) (2009) Putting Patient Safety First: A compendium of patient safety in practice. London: NPSA. Available at: [www.npsa.nhs.uk](http://www.npsa.nhs.uk)
23. National Patient Safety Agency (NPSA). Incident Decision Tree: Exploring Incidents, Improving Safety. NPSA online tool. London: NPSA. Available at: [www.npsa.nhs.uk](http://www.npsa.nhs.uk)
24. National Patient Safety Agency (NPSA) (2009) Being Open: supporting information. London: NPSA. Available at: [www.npsa.nhs.uk](http://www.npsa.nhs.uk)
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28. Royal College of Surgeons of England (RCS) (2010) Openness and Transparency in Surgery. London: RCS. Available at: [www.rcseng.ac.uk/](http://www.rcseng.ac.uk/)
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30. National Patient Safety Agency (NPSA) (2010) Medical Error: what to do if things go wrong: a guide for junior doctors issue 02. London: NPSA. Available at: [www.npsa.nhs.uk](http://www.npsa.nhs.uk)
31. Public Inquiry at Mid Staffordshire NHS Foundation Trust and subsequent Francis report <http://www.midstaffspublicinquiry.com/report>
32. NHSLA Saying Sorry leaflet (see appendix 6) <http://www.nhs.uk/Claims/Documents/Saying%20Sorry%20-%20Leaflet.pdf>

## 19 Supporting Documents

Supporting Documents/References	Owner
Incident and Serious Incident (including Never Events) Reporting Policy and Procedure	Head of Risk and Safety
Complaints Policy	Complaints Manager
Policy & Procedure for the Management of Clinical Negligence, Third Party Liability and Property Expenses Claims	Head of Legal
Policy for the investigation of incidents, complaints and claims	Head of Risk and Safety
Interpreting and Translation Policy and Procedure	Facilities Manager

## Equality Impact Assessment

The equality impact assessment is used to ensure we do not inadvertently discriminate as a service provider or as an employer.

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

		YES/ NO	Comments
1	Which groups is the policy/guidance intended for? Who will benefit from the policy/guidance? (refer to appropriate data)		The Policy is intended for all staff and will benefit all staff and patients.
	<ul style="list-style-type: none"> <li>• Race</li> </ul>		
	<ul style="list-style-type: none"> <li>• Gender (or sex)</li> </ul>		
	<ul style="list-style-type: none"> <li>• Gender Reassignment</li> </ul>		
	<ul style="list-style-type: none"> <li>• Pregnancy and maternity</li> </ul>		
	<ul style="list-style-type: none"> <li>• Marriage and civil partnership</li> </ul>		
	<ul style="list-style-type: none"> <li>• Religion or belief</li> </ul>		
	<ul style="list-style-type: none"> <li>• Sexual orientation including lesbian, gay and bisexual people</li> </ul>		
	<ul style="list-style-type: none"> <li>• Age</li> </ul>		
	<ul style="list-style-type: none"> <li>• Disability (e.g., physical, sensory or learning)</li> </ul>		
2	What issues need to be considered to ensure these groups are not disadvantaged by your proposal/guidance?		None
3	What evidence exists already that suggests that some groups are affected differently? (identify the evidence you refer to)		None
4	How will you avoid or mitigate against the difference or disadvantage.		N/A
5	What is your justification for the difference or disadvantage if you cannot avoid or mitigate against it, and you cannot stop the proposal or guidance?		N/A

If you have identified a potential discriminatory impact of this procedural document, please refer it to the director of quality and safety, or the human resources department, together with any suggestions as to the action required to avoid/reduce this impact.

For advice in respect of answering the above questions, please contact the director of quality and safety (██████████)

Please ensure that the completed EIA is appended to the final version of the document, so that it is available for consultation when the document is being approved and ratified, and subsequently published.

### Checklist for the Review and Approval of Documents

To be completed (electronically) and attached to any document which guides practice when submitted to the appropriate committee for approval or ratification.

**Title of the document:**     **Duty of Candour and Being Open Policy**

**Policy (document) Author:**     **Head of Clinical Governance**

**Policy (document) Owner:**     **Head of Clinical Governance**

		Yes/No/ Unsure/ NA	Comments
<b>1.</b>	<b>Title</b>		
	Is the title clear and unambiguous?	Yes	
	Is it clear whether the document is a guideline, policy, protocol or standard?	Yes	
<b>2.</b>	<b>Scope/Purpose</b>		
	Is the target population clear and unambiguous?	Yes	
	Is the purpose of the document clear?	Yes	
	Are the intended outcomes described?	Yes	
	Are the statements clear and unambiguous?	Yes	
<b>3.</b>	<b>Development Process</b>		
	Is there evidence of engagement with stakeholders and users?	Yes	
	Who was engaged in a review of the document (list committees/ individuals)?	Yes	
	Has the policy template been followed (i.e. is the format correct)?	Yes	
<b>4.</b>	<b>Evidence Base</b>		
	Is the type of evidence to support the document identified explicitly?	Yes	
	Are local/organisational supporting documents referenced?	Yes	
<b>5.</b>	<b>Approval</b>		
	Does the document identify which committee/group will approve/ratify it?	Yes	

		Yes/No/ Unsure/ NA	Comments
	If appropriate, have the joint human resources/staff side committee (or equivalent) approved the document?	Yes	
<b>6.</b>	<b>Dissemination and Implementation</b>		
	Is there an outline/plan to identify how this will be done?	Yes	
	Does the plan include the necessary training/support to ensure compliance?	Yes	
<b>7.</b>	<b>Process for Monitoring Compliance</b>		
	Are there measurable standards or KPIs to support monitoring compliance of the document?	Yes	
<b>8.</b>	<b>Review Date</b>		
	Is the review date identified and is this acceptable?	Yes	
<b>9.</b>	<b>Overall Responsibility for the Document</b>		
	Is it clear who will be responsible for coordinating the dissemination, implementation and review of the documentation?	Yes	
<b>10.</b>	<b>Equality Impact Assessment (EIA)</b>		
	Has a suitable EIA been completed?	Yes	

<b><u>Committee Approval</u></b> Clinical Governance Committee			
If the committee is happy to approve this document, please complete the section below, date it and return it to the Policy (document) Owner			
Name of Chair	Director of Nursing and AHPs	Date	25 <sup>th</sup> September 2018
<b><u>Ratification by Management Executive (if appropriate)</u></b>			
If the Management Executive is happy to ratify this document, please complete the date of ratification below and advise the Policy (document) Owner			
Date: 24 <sup>th</sup> March 2015			

## **Counselling and Support**

Find out more about local services at Patient UK – [www.patient.co.uk](http://www.patient.co.uk)

### • **Eye Charities/Organisations**

- Action for blind people – [www.afbp.org](http://www.afbp.org)
- AMD alliance – [www.amdalliance.org](http://www.amdalliance.org)
- British Retinitis Pigmentosa society – [www.brps.org.uk](http://www.brps.org.uk)
- Diabetes UK – [www.diabetes.org.uk](http://www.diabetes.org.uk)
- Eye Cancer Network – [www.eyecancer.com/](http://www.eyecancer.com/)
- Eye UK – [www.eyeu.com](http://www.eyeu.com)
- International glaucoma association – [www.iga.org.uk](http://www.iga.org.uk)
- The Keratoconus Group – [www.keratoconus-group.org.uk](http://www.keratoconus-group.org.uk)
- Macular Society - [www.macularsociety.org](http://www.macularsociety.org)
- Royal National Institute for the Blind – [www.rnib.org.uk](http://www.rnib.org.uk)
- Uveitis Information Group – [www.uveitis.net](http://www.uveitis.net)
- SeeAbility - Support for people with sight loss, autism, and learning disabilities - <https://www.seeability.org>

### **National organisations**

#### **Mind**

[www.mind.org.uk](http://www.mind.org.uk)

They provide advice and support to empower anyone experiencing a mental health problem -

#### **Alzheimer's Society**

[www.alzheimers.org.uk](http://www.alzheimers.org.uk)

Support for people with, or caring for relatives or friends with Alzheimer or dementia

#### **Age UK**

Support and advice for the elderly

[www.ageuk.org.uk](http://www.ageuk.org.uk)

#### **Patients Association**

Campaigning and support group for patients

[www.patients-association.org.uk](http://www.patients-association.org.uk)

#### **POhWER**

A charity that provides free information, advocacy and advice services across England should you need to make a complaint

[www.pohwer.net](http://www.pohwer.net)

### **Cruse Bereavement Care**

Cruse Bereavement Care, Cruse House, 126 Sheen Road, Richmond TW9 1UR

Tel: 0870 167 1677

[www.crusebereavementcare.org.uk](http://www.crusebereavementcare.org.uk)

Charity providing information to anyone who has been affected by a death.

Also offers education, support, information and publications to anyone supporting bereaved people. A national charity with over 6,000 trained counsellors.

### **Samaritans**

Helpline: 08457 90 90 90 (24 hours)

[www.samaritans.org](http://www.samaritans.org)

24-hour confidential emotional support for anyone in a crisis.

### **If I Should Die**

[www.ifishoulddie.co.uk](http://www.ifishoulddie.co.uk)

This website looks at all aspects of bereavement from the practical to the emotional.

- **Support for Carers**

#### **The Princess Royal Trust for Carers**

142 Minories, London, EC3N 1LB

Tel: 020 7480 7788

[www.carers.org](http://www.carers.org)

Information, support and practical help for all carers through a network of Princess Royal Trust for Carers centres.

#### **Carers UK/ Carers National Association**

20-25 Glasshouse Yard, London EC1A 4JS

Helpline: 0808 808 7777 (freephone, 10am-12noon and 2pm-4pm, Mon-Fri)

[www.carersuk.org.uk/about/main.htm](http://www.carersuk.org.uk/about/main.htm)

Runs a helpline and provides support, encouraging carers to recognise their own needs. There is also an information officer to answer enquiries from professionals.

#### **Seniorline**

England, Scotland, Wales: 0808 800 6565 (freephone)

Northern Ireland: 0808 808 7575 (freephone)

The lines are open Mon-Fri between 9am-4pm.

Free national information service for senior citizens, their carers and relatives.

- **When a baby or child dies**

#### **Child Death Helpline**

Great Ormond Street Hospital for Children, London, WC1N 3JH

Tel: 0800 282 986

[www.childdeathhelpline.org.uk](http://www.childdeathhelpline.org.uk)

A telephone helpline that offers help and support to anyone affected by the death of a child. Staffed by parent volunteers who are supported by a professional team.

**Compassionate Friends**

53 North Street, Bedminster, Bristol BS3 1EN

Help Line: 0117 953 9639 (seven days 9.30am-10.30pm)

[www.tcf.org.uk](http://www.tcf.org.uk)

Support and friendship for bereaved parents and their families.

• **Help for young people**

**rd4u**

Cruse Bereavement Care, Cruse House, 126 Sheen Road, Richmond, Surrey TW9 1UR

Helpline: 0808 808 1677 (answered by trained volunteers aged between 16-25), 4pm-7pm, Mon-Wed)

[www.rd4u.org.uk](http://www.rd4u.org.uk)

The youth branch of Cruse, set up to help young people after the death of someone close.

**Childhood Bereavement Network**

Huntingdon House, 278-290 Huntingdon Street, Nottingham NG1 3LY

Tel: 0115 911 8070

A new national resource for bereaved children and young people, their parents and care givers.

### **Guidance on the Preliminary Discussions**

- The discussion should occur as soon as reasonably practicable after the event;
- Consideration should be given to the timing of meeting/discussion, based on both the patient's health and personal circumstances;
- Consideration should be given to the location of the meeting e.g. the patient's home, quiet office, via telephone;
- 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 and/or their 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 and/or their carers;
- All queries should be responded to appropriately;
- If completing the process at this point, the patient and/or their carers should be asked if they are satisfied with the investigation and a note of this made in the patient's records;
- 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.

## The following ten principles underpin Being open:

### *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.

### *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.

### *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.

### *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 Advisory and Liaison Service (PALS) and other relevant support groups should be given as soon as possible.

### *Principle of Professional Support*

Moorfields Eye Hospital NHS Foundation trust ensures it provides an environment in which all staff are encouraged to report patient safety incidents. Staff should feel supported throughout the patient safety event investigation process; they too may have been traumatised by the patient safety events. Using the Incident Decision Tree (ICT) can help to ensure a robust and consistent approach to patient safety incident investigation along with root cause analysis. Where there are concerns about the performance of individual doctors or pharmacists the National Clinical

Assessment Service (NCAS) can be contacted for advice. Where there is reason for the healthcare organisation to believe a member of staff has committed a punitive or criminal act, the organisation should take steps to preserve its position and advise 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 seek support from relevant professional bodies.

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

Root Cause Analysis (RCA) is to be used to uncover the underlying causes of patient safety event. This investigation focuses on improving systems of care, which will be reviewed for their effectiveness. This Being Open policy should be integrated into local patient safety event reporting and risk management policies and processes.

### *Principles of Multi-Disciplinary Responsibility*

This policy 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 the 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 incident investigation.

### *Principles 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.

### *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.

*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.

# Saying sorry

Saying sorry meaningfully when things go wrong is vital for everyone involved in an incident, including the patient, their family, carers, and the staff that care for them.



Advise / Resolve / Learn

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

### Why?

Not only is it a moral and right thing to do - it is also a statutory, regulatory, and professional requirement. It can also support learning and improve patient safety.

### When?

As soon as possible after you become aware something has gone wrong you should seek out the patient and or their family and say sorry and acknowledge what has happened and tell them that you will find out more. Reassure them that you will keep them informed.

### Who?

Everyone can say sorry, but you may need to be supported to do so. You may need the backing of more senior people and staff may need training but it should not stop you from simply saying

sorry. As part of an initial apology it is best practice to provide the patient and their family with a key contact wherever possible.

### What if there is a formal complaint or claim?

The Compensation Act 2006 states; 'An apology, an offer of treatment or other redress, shall not of itself amount to an admission of negligence or breach of statutory duty'. (source: [Compensation Act 2006 – Chapter 29 page 3](#))

In fact, delayed or poor communication makes it more likely that the patient will seek information in a different way such as complaining or taking legal action. The existence of a formal complaint or claim should never prevent or delay you saying sorry.

### How?

The way you say sorry is just as important as saying it. An apology should demonstrate sincere regret that something has gone wrong and this includes recognised complications referred to in the consent process. It should be confidential and tailored to the individual patient's needs.

Where possible you should say sorry in person and involve the right members of the healthcare team. It should be heartfelt, sincere, explain what you know so far and what you will do to find out more.

It is the starting point of a longer conversation; as over time this will lead to sharing information about what went wrong, what you will do differently in the future. It is vital to avoid acronyms and jargon in all communications.

You may also need to say sorry in writing where significant harm has been caused or in response to a written complaint. An example of this could be:

"I wish to assure you that I am deeply sorry for the poor care you have been given and that we are all truly committed to learning from what happened. I apologise unreservedly for the distress this has caused you and your family"

### What about the Duty of Candour?

The statutory Duty of Candour requires all NHS staff to act in an open and transparent way. Regulations governing the duty set out the specific steps healthcare professionals must follow if there has been an unintended or unexpected event which has caused moderate or severe harm to the patient.

These steps include informing people about the incident, providing reasonable support, truthful information and an apology. Saying sorry forms an integral part of this process. Process should never stand in the way of providing a full explanation when something goes wrong.

#### Don't say

- x I'm sorry you feel like that
- x We're sorry if you're offended
- x I'm sorry you took it that way
- x We're sorry, but...

#### Do say

- ✓ I'm sorry X happened
- ✓ We're truly sorry for the distress caused
- ✓ I'm sorry, we have learned that...

***“We have never, and will never, refuse cover on a claim because an apology has been given.”***

**Helen Vernon, Chief Executive, NHS Resolution**

### **For more Information**

Nursing and Midwifery Council & General Medical Council joint guidance on openness and honesty when things go wrong

[www.gmc-uk.org/guidance/ethical\\_guidance/27233.asp](http://www.gmc-uk.org/guidance/ethical_guidance/27233.asp)

Reports and consultations on complaint handling (Parliamentary and Health Service Ombudsman)

[www.ombudsman.org.uk](http://www.ombudsman.org.uk)

AvMA (Action against Medical Accidents) Duty of Candour leaflet [www.avma.org.uk/policy-campaigns/duty-of-candour/duty-of-candour-leaflet](http://www.avma.org.uk/policy-campaigns/duty-of-candour/duty-of-candour-leaflet)

Care Quality Commission - Regulation 20: Duty of Candour [www.cqc.org.uk/content/regulation-20-duty-candour](http://www.cqc.org.uk/content/regulation-20-duty-candour)

### **The NHS Constitution**

Patients: “you have the right to an open and transparent relationship with the organisation providing your care. You must be told about any safety incident relating to your care which in the opinion of a healthcare professional, has caused or could still cause significant harm or death. You must be given the facts, an apology, and any reasonable support you need”.

Staff: “you should aim to be open with patients... if anything goes wrong; welcoming and listening to feedback and addressing concerns promptly and in the spirit of cooperation.”

**If you want to get in touch**  
[safetyandlearningenquiries@resolution.nhs.uk](mailto:safetyandlearningenquiries@resolution.nhs.uk)



Alert

## Patient Safety Alert

NPSA/2009/PSA003  
19 November 2009



National Patient  
Safety Agency

National Reporting  
and Learning Service

# Being Open

## Communicating with patients, their families and carers following a patient safety incident

Being open is a set of principles that healthcare staff should use when communicating with patients, their families and carers following a patient safety incident in which the patient was harmed.

Being open supports a culture of openness, honesty and transparency, and includes apologising and explaining what happened.

In 2005, the National Patient Safety Agency (NPSA) issued a Safer Practice Notice advising the NHS to develop a local Being open policy and to raise awareness of this policy with all healthcare staff.

The guidance has now been revised in response to changes in the healthcare environment and in order to strengthen Being open throughout the NHS.

The revised Being open framework (available at [www.nrls.npsa.nhs.uk/beingopen](http://www.nrls.npsa.nhs.uk/beingopen)) should be used in conjunction with this Alert to help develop and embed Being open in each NHS organisation.

The Being open principles are fully supported by a wide range of royal colleges and professional organisations, including the Medical Defence Union, Medical Protection Society, NHS Litigation Authority and Welsh Risk Pool.

Tools to support organisations in the implementation of this Alert are available at: [www.nrls.npsa.nhs.uk/beingopen](http://www.nrls.npsa.nhs.uk/beingopen)

### Endorsed by:

Action Against Medical Accidents  
Department of Health  
Healthcare Inspectorate Wales  
NHS Confederation (England)  
NHS Confederation (Wales)  
NHS Litigation Authority  
Medical Defence Union  
Medical Protection Society

Royal College of General Practitioners  
Royal College of Nursing  
Royal College of Obstetricians and Gynaecologists  
Royal College of Physicians  
Royal College of Psychiatrists  
Welsh Assembly Government  
Welsh Risk Pool

## Action for the NHS

For action by Chief Executives of organisations commissioning and providing healthcare.

### Deadlines:

- Actions underway:  
**22 February 2010**
- Actions completed:  
**23 November 2010**

### Actions:

- 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.



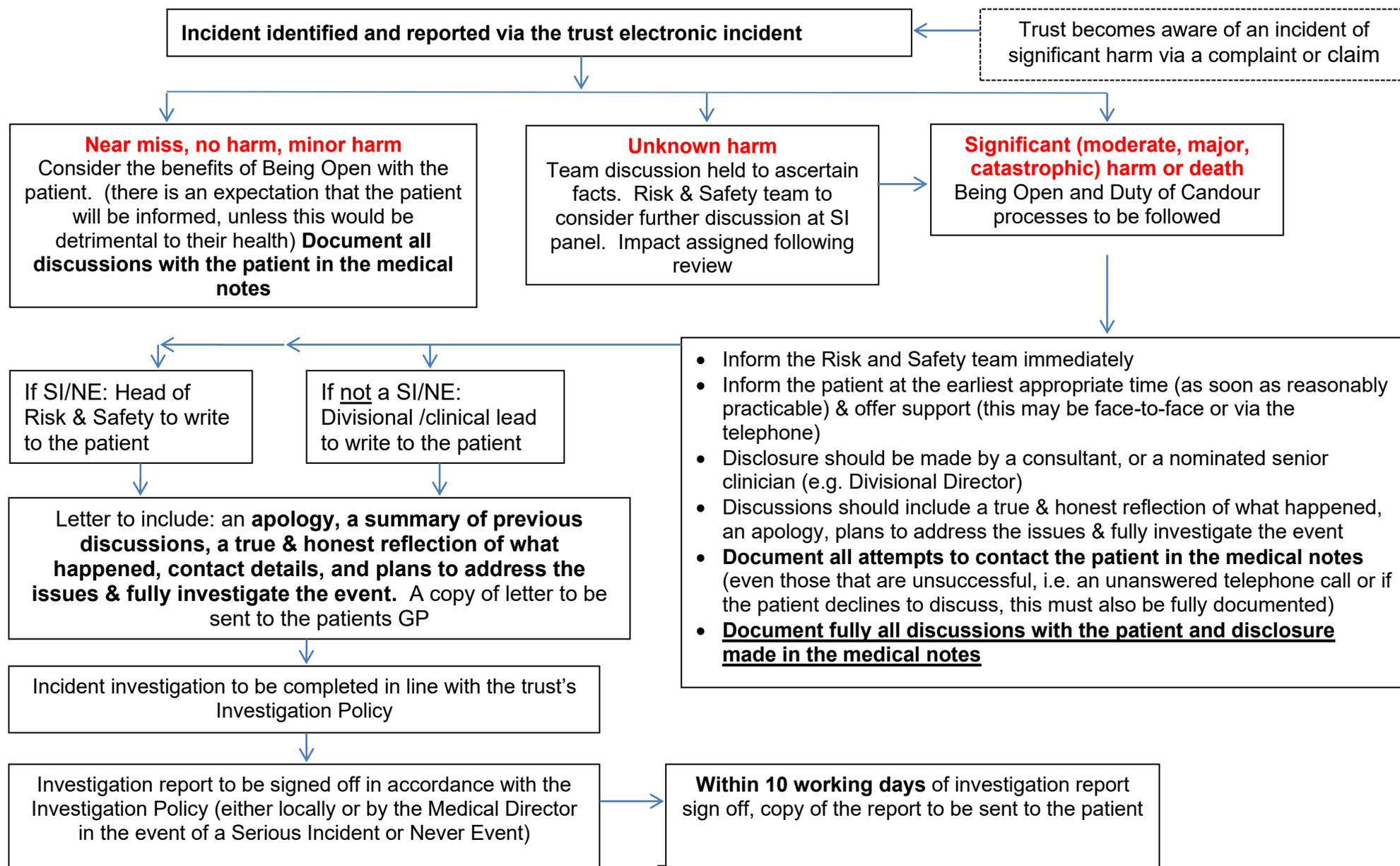
This Alert replaces the Being Open Safer Practice Notice (2005)

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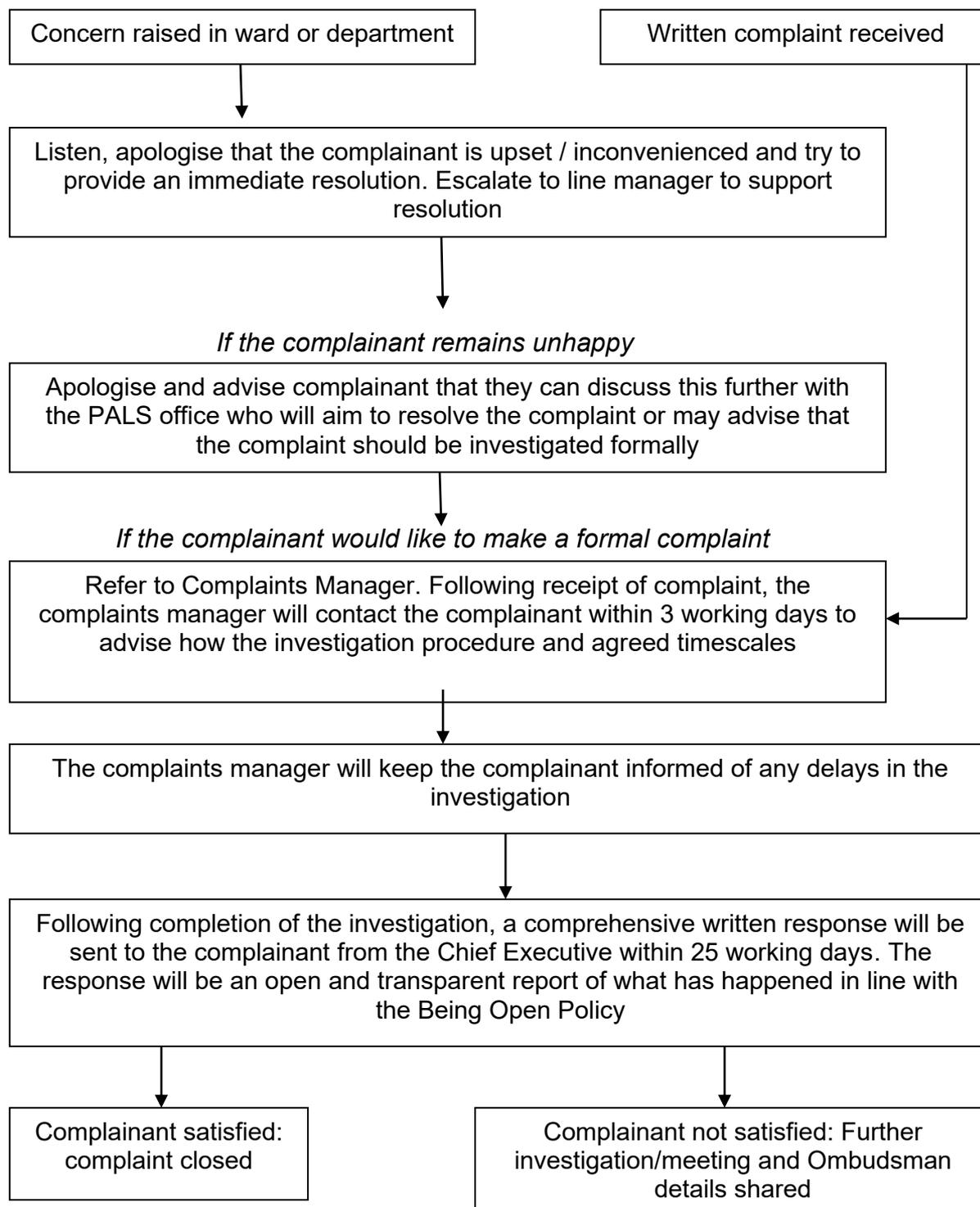
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19/11/2009

National Reporting and Learning Service  
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[www.nrls.npsa.nhs.uk](http://www.nrls.npsa.nhs.uk)

**Flowchart to Illustrate the Duty of Candour and Being Open Process (for 'Incidents')**



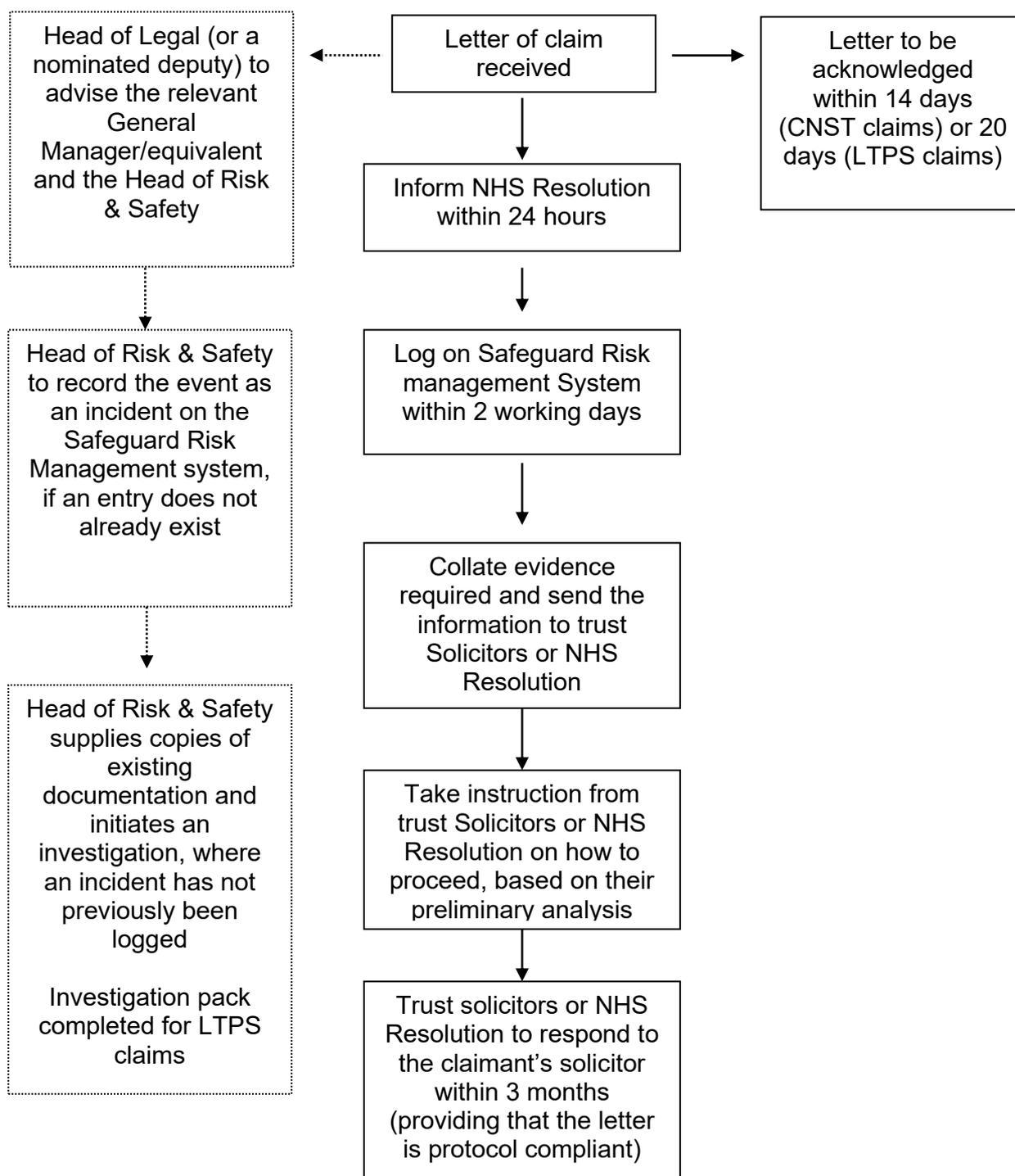
### Flowchart to illustrate the Being Open Process for 'Complaints'



**If at any time the complaint raises an issue that has resulted in or could result in significant harm, this aspect should be discussed with the Risk and Safety team and the Duty of Candour and Being Open principles followed (see appendix 8)**

For more detailed instructions of what to do following a complaint / concern raised, please see the trust Complaints Policy on the intranet.

### Flowchart to illustrate the Being Open process for 'Claims'



**If at any time the claim raises and issue that has resulted in or could result in significant harm, this aspect should be discussed with the Risk and Safety team and the Duty of Candour and Being Open principles followed (see appendix 8)**

Flowchart taken from the *'Policy & Procedure for the Management of Clinical Negligence, Third Party Liability and Property Expenses Claims'* available on the intranet.

Ways to say sorry poster

**Ways to say sorry** **hin**

I am sorry if you were offended

I am sorry for my decision

I am sorry that you were upset

I am sorry to anyone that was offended

I am sorry if you were offended

We all make mistakes in life

We sincerely apologise for the error

Even though this is the normal procedure

It is not right that you felt hurt

If I caused you upset, I apologise

On reflection, I wish I had made a different decision

It is regrettable that the decision we made has caused you upset

On this occasion we let you down

I apologise for my actions

I have agreed to apologise for the error

If we let you down, I deeply regret it

We apologise for the whole situation

We recognise mistakes were made in the operation

It certainly was not my intention to upset you

General Medical Council Supported by

## Policy Applicability to Trust sites

This document applies to premises occupied by trust staff/activities, as outlined below:

Site	Applicable (yes/no)
Arthur Steele Unit	Yes
Bedford	Yes
City Road	Yes
Community clinics	Yes
Croydon	Yes
Darent Valley	Yes
Ealing	Yes
Ebenezer Street	Yes
Homerton	Yes
John Saunders Suite/Cayton Street	Yes
Ludwig Guttman	Yes
Loxford	Yes
Mayday	Yes
Mile End	Yes
Moorfields Pharmaceuticals	Yes
Northwick Park	Yes
Potters Bar	Yes
Provost Street	Yes
RDCEC	Yes
St Ann's	Yes
St George's	Yes
Barking	Yes
Upper Wimpole Street	Yes
Watford	Yes

Where the list indicates that the policy does not apply, this implies that the trust will adhere to the policy of the host. Where a query exists then this must be referred, in the first instance, to either the:

- Divisional Manager / Head of Nursing
- Policy owner
- Accountable director
- Service director

Moorfields Dubai will adhere to their own local policies and procedures and trust wide documents will not apply unless explicitly stated otherwise.