



BEING OPEN AND THE DUTY OF CANDOUR POLICY

Version Number	2.3	Version Date	June 2015
Policy Owner	Associate Director of Patient Safety & Quality		
Author	Associate Director of Patient Safety & Quality		
First approval or date last reviewed	June 2015		
Staff/Groups Consulted	Patient Experience Team Trust Managers Associate Directors of Nursing Associate Director of Patient Safety & Quality Medical Director Safeguarding Lead Director of Nursing and Clinical Governance		
Discussed by Policy Group	Reviewed Oct 2009		
Approved by RaD	06 November 2009 Update agreed by Chair of Policy Group 5 October 2011		
Next Review Due	July 2018		
Policy Audited	July 2011, March 2015		
Equality Impact Assessment	07 October 2009, Reviewed July 2011, Reviewed 2015		

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1. RATIONALE

The National Patient Safety Agency (NPSA) Safer Practice Notice (10) and the statutory Duty of Candour aims to improve the quality and consistency of communication when patients are involved in an incident in NHS organisations. The Department of Health has directed that “The individual who has suffered harm as a result of the healthcare they have received must get an apology” (Making Amends, 2003). **An apology is not an admission of liability.**

Duty of candour (CQC regulation 20) should be applied in all serious incidents where harm is caused (moderate harm, death and prolonged psychological harm) and is a statutory requirement that has been introduced to ensure health care providers operate in a more open and transparent way when certain incidents occur in relation to the care and treatment provided to people using the service.

Being open means apologising and explaining what happened to patients and/or their carers who have been involved in a patient safety incident. Being open is also applicable when dealing with a complaint or claims process to ensure communication is effective and timely. Openness, honesty and transparency towards patients is supported and actively encouraged by many professional bodies, including Medical Defence Union, Medical Protection Society and General Medical Council.

2. AIM

This policy is designed to raise awareness amongst all healthcare staff of the need for effective communication with patients and/or their carers involved in a patient safety incident, complaint or claim as soon as reasonably practicable after becoming aware that a notifiable incident safety has occurred. It will provide a process to ensure that patients and/or carers receive the information they need to enable them to understand, and the reassurance that everything possible will be done to reduce the risk of a similar incident recurring. The policy will define systems for supporting patients, carers, healthcare professionals and managers when things go wrong.

The Being Open policy should be read in conjunction with the Incident Reporting and Investigation policy, Compliments, Complaints and Concerns policy and the Claims Management policy.

3. DEFINITIONS

The following definitions describe the terminology used:

- **Apology**
Expression of sorrow or regret in respect of a notifiable safety incident
- **Being Open Lead**
The person who leads the process of being open as a result of an incident, complaint or claim. This may be the clinical lead or a nominated person by the Trust and is likely to be the lead investigator for a complaint or incident investigation.
- **Candour**
An obligation to disclose errors that may be immediately obvious to the patient. Exercising candour narrows the gap between what the healthcare professional and the patient know about an incident

- **Claim**
As defined by the Clinical Negligence Scheme for Trust (CNST) as “any demand, however made, but usually by the patient’s legal adviser, for monetary compensation in respect of an adverse clinical incident leading to a personal injury”

- **Complaint**
Any expression of dissatisfaction with care provision, or a perceived grievance or injustice

- **Adverse Event**
Those incidents that **did** lead to harm or failure to function.

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

 - 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)

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

 - Permanent harm
Directly related to the incident and not to the natural course of the patient’s illness or underlying conditions, defined as permanently lessening of bodily functions, including sensory, motor, physiological or intellectual

 - 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.

- **Near Miss** (Preventable patient safety incident)
Any unintended or unexpected incident that was prevented, resulting in no harm to patients

- **NHS-funded services or care**
Healthcare that is partially or fully funded by the NHS, regardless of the location

- **Notifiable Safety Incident**
Any unintended or unexpected incident that occurred in respect of a service user during the provision of a regulated activity that, in the reasonable opinion of a health care professional, could result in, or appears to have resulted in:

(a) The death of the service user, where the death relates directly to the incident rather than to the natural course of the service user's illness or underlying condition, or

(b) Severe harm, moderate harm or prolonged psychological harm to the service user

- **Patient Safety 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 members of the public

- **Relevant Person:**

The service user or, in the following circumstances, a person lawfully acting on their behalf:

(a) On the death of the service user

(b) Where the service user is under 16 and not competent to make a decision in relation to their care or treatment or

(c) Where the service user is 16 or over and lacks capacity (as determined in accordance with sections 2 and 3 of the 2005 Act) in relation to the matter

- **Root Cause Analysis (RCA)**

A systematic review of an incident identifying immediate (root causes) and underlying (contributing) factors associated when an incident occurs. As a result of an RCA recommendations and lessons learned are made and action taken

- **Unexpected death**

Where natural causes are not suspected

4. RESPONSIBILITIES

4.1 Chief Executive and the Board of Directors

The Chief Executive and the Board of Directors (BoD) are responsible for ensuring that an open culture of reporting in line with the iCARE principles is maintained and that systems are in place for reporting and learning from incidents, complaints and claims

4.2 Business Service Units Directors, Clinical Directors, Director of Nursing

Are responsible for:

- Ensuring that the policy and procedure are applied throughout the Trust
- Supporting Junior staff involved in any patient safety incident, complaint or claim
- Promoting a culture that is open and fair
- Establishing a clear and strong focus on patient safety throughout the organisation
- Chairing conciliation meetings with patients and/or carers
- Ensuring that staff report incidents appropriately
- Facilitating discussion about patient safety incidents at monthly rolling governance meetings

4.3 Associate Director of Patient Safety & Quality

Is responsible for:

- Maintaining a comprehensive database of all patient safety incidents and claims
- Co-ordinating the investigations into all significant untoward events
- Providing monthly reports to the Patient Safety Steering Group detailing patient safety incidents reported, outcomes of investigations, complaints and claims and any proposed actions to manage the occurrences
- Providing monthly trend reports about patient safety incidents to the Patient Safety Steering Group
- Providing quarterly trends report to the Assurance Committee and Board of Directors
- Providing ad hoc reports to the Clinical Commissioning Group
- Identifying trends and recommending appropriate changes in practice
- Updating the policy and procedure annually or when national guidance is amended
- Ensuring adequate and appropriate support is available for clinicians undertaking Root Cause Analysis (RCA) reviews, action planning and follow-up audits

4.4 Patient Experience Manager

Is responsible for:

- Maintaining a Comprehensive Database of Concerns and Complaints
- Co-ordinating the process of formal communication with patients and/or carers involved in significant patient safety incidents, ensuring that they are kept up to date with the progress of the investigation
- Managing the complaints and claims processes and providing advice and support to staff as necessary
- Preparing reports on analysis of incidents, complaints and claims
- Identifying the most appropriate senior member of staff to apologise to the patients/ carers

4.5 All Staff

All Trust staff are responsible for:

- Following the guidance outlined in this policy in line with the iCARE principles
- Reporting incidents in line with the Incident Reporting and Investigation policy

5. BENEFITS OF BEING OPEN

Effective communication with patients begins at the start of their care and should continue throughout their time within the Trust. This should be no different when a patient safety incident, complaint or claim occurs.

Openness truthfulness and transparency when things go wrong ensure that healthcare organisations and teams:

- Are satisfied that communication with patients and/or carers following a patient safety incident has been handled in the most appropriate way
- Are supported to cope with the consequences of the event
- Learn from incidents to reduce the risk of a recurrence
- Are confident when dealing with patient queries about patient safety incidents

Openness truthfulness and transparency when things go wrong ensures that patients and/or carers:

- Receive a timely apology and explanation
- Are adequately supported in dealing with the consequences of the incident
- Are advised of the actions taken to reduce the risk of a recurrence
- Understand what can be done to repair or redress the harm done

6. PRINCIPLES OF BEING OPEN

6.1 BEING OPEN PROCESS

Being Open is a process rather than a one-off event. The Trust has adopted the NPSA's 10 guiding principles and a Duty of Candour that staff should follow to encourage open communication between healthcare organisations, healthcare teams, staff and patients and/or their carers. At all times the requirement for truthfulness, timeliness and clarity of communication should be kept in mind. The following headings identify the guiding principles which can be found in greater detail at **Appendix 1**:

- Principle of Acknowledgement
- Principles of Truthfulness, Timeliness and Clarity of Communication
- Principle of Apology
- Principle of Recognising Patient and Carer Expectations
- Principle of Professional Support
- Principle of Risk Management and Systems Improvement
- Principles of Multi-Disciplinary Responsibility
- Principles of Clinical Governance
- Principle of Confidentiality
- Principle of Continuity of Care

6.2 Process for Open Communication

Refer to:

Appendix 2 - REGULATION 20: DUTY OF CANDOUR

Appendix 3 – GUIDANCE ON PARTICULAR PATIENT CIRCUMSTANCES

Annex A follow the guiding principles; describing the process with actions to take thereby ensuring staff follow the same procedure guided by best practice.

6.3 Links to Complaints and Claims Management

Patient safety incidents can incur extra costs associated with legal action and further treatment. Adopting a culture of openness honesty and transparency can help prevent such events becoming formal complaints and reduce the likelihood of litigation claims. In many cases, patients and/or carers only choose to pursue a litigation claim or complaint because they have not received an adequate explanation or apology.

6.4 Confidentiality

The Trust is bound by strict codes of confidentiality to protect patient information and applies strict criteria regarding the storage, disclosure and release of clinical information relating to patients. Details of patient safety incidents will be recorded on

the incident reporting system (Safeguard) and care will be taken at all times to ensure that patient and staff confidentiality is maintained within the Data Protection Act (1998) and Access to Health Records Act (1990).

6.5 Duty of candour and supporting those involved

The Trust is requires to:

- Make sure it acts in an open and transparent way with relevant persons in relation to care and treatment provided to people who use services in carrying on a regulated activity
- Tell the relevant person as soon as reasonably practicable after becoming aware that a 'notifiable safety incident' has occurred and provide support to them in relation to the incident, including when giving the notification
- Provide an account of the incident which, to the best of the Trust's knowledge, is true of all the facts the body knows about the incident as at the date of the notification:
- Advise the relevant person what further enquiries the Trust's believes are appropriate:
- Offer an apology:
- Follow this up by giving the same information in writing, and providing an update on enquiries: and
- Keep written record aof all communication with the relevant person.

Contact details for the Patient Advice & Liaison Service (PALS) should also be provided so that patients can be sign-posted to appropriate counselling or support services. Conciliation meetings may be set up to provide answers to questions that patients may have.

6.6 Support Mechanisms for Staff

It is vital that a supportive approach is adopted by managers when investigating and dealing with patient safety incidents. Staff will invariably experience a range of emotions following their involvement in a safety incident or adverse event and should be offered support. Information on procedures for supporting staff is detailed in the Incident Reporting and Investigation policy.

6.7 Being Open and Disciplinary Processes

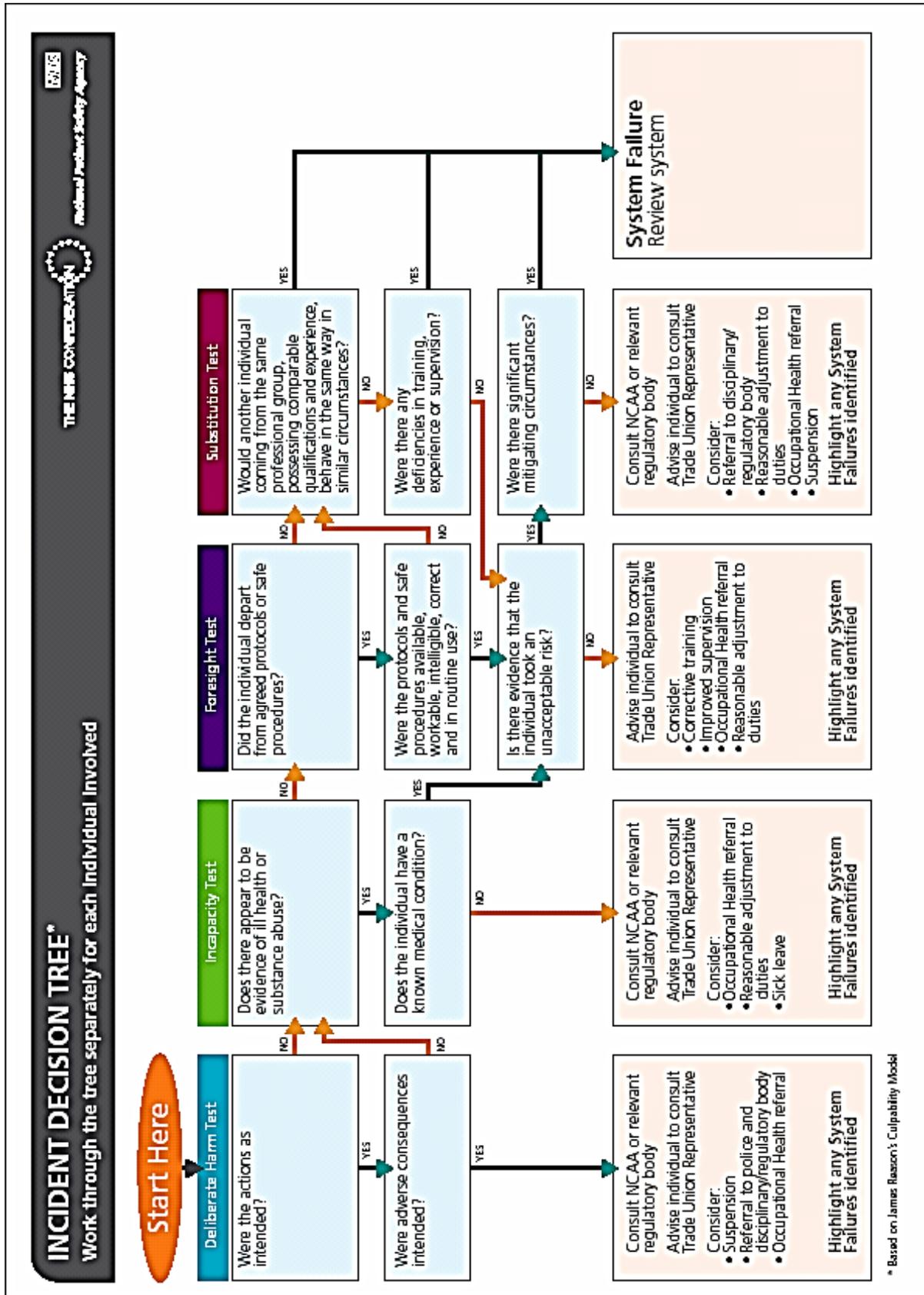
Being Open is based on concepts that should be broadly applicable in all healthcare settings. Automatic, punitive disciplinary action and inappropriate exclusion of staff from work following a patient safety incident will, in most cases, only serve to create a barrier to open reporting. Healthcare staff should therefore be encouraged to identify the underlying causes of patient incidents and system failures by employing methods such Root Cause Analysis. Managers should ensure that incident investigations focus on the causes of patient safety incidents rather than the last individual to provide care.

The desired outcome of any investigation should be improved safety for patients (and staff) and the identification of safe and best working practices; apportioning blame rarely achieves these outcomes. However, in cases where the discovery of serious performance concerns occur (i.e. a breach of law; professional or gross misconduct; failure to report or attempt to conceal etc) disciplinary action may not be avoided and will be handled in accordance with HR policies relating to disciplinary proceedings.

In these cases reference will be made to the NPSAs Incident Decision Tree and/or the National Clinical Advisory Service. The Associate Director of Patient Safety & Quality and Divisional triumvirate will complete this assessment.

APPENDIX 1A

APPENDIX 1A



* Based on James Reason's Culpability Model

6.8 Recording and Documenting Communication

All communication with patients, carers or relatives whether verbal or written must be recorded and maintained for the purpose of accountability. The responsibility of recording any apology *and* contact with patients, carers or relatives lies with the individual who identifies that the harm or a mistake has occurred. The incident reporting system should be used primarily to record that a patient safety incident has occurred.

Clinical Governance receives notification of incidents through the 'Safeguard' system. Complaints and notification of Claims are also recorded through this system. Dates of meetings and relevant information should be updated in 'Safeguard'. Incident investigations, complaints and legal claims will be maintained within case files managed by Clinical Governance and the Patient Experience Team

Written records of the Being Open discussion should be maintained as outlined in **Annex A**.

7. LEARNING AND COMMUNICATING

Most incidents, complaints and claims have learning that should be fed back into the organisation to prevent reoccurrence. This is carried out through committee review and meetings. Communicating externally is also a requirement of sharing investigations and lessons learned. Refer to the Incident Reporting and Investigation policy and Clinical Governance Protocol for Aggregating Data and Learning from Incidents, Complaints and Claims.

8. IMPLEMENTATION, MONITORING AND EVALUATION

This policy will be implemented, monitored and evaluated in line with the Policy on Procedural documents.

The Associate Director of Patient Safety & Quality will produce a monthly dashboard view of incidents, complaints and claims, including the current RCA's under investigation which identify the duty of candour process. This is reviewed by the Patient Safety Steering Group and actions from decisions made on the meeting are recorded and placed into an action plan if deemed appropriate.

9. APPLICABILITY

This policy applies to all staff employed by the Trust, whether on a permanent or temporary basis

10. FURTHER ADVICE & SUPPORT

Further advice can be obtained from the Associate Director of Patient Safety & Quality.

11. REFERENCES

- Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 20
- NHSLA (May 2009) 'Apologies and Explanations' available via www.NHSLA.com
- NPSA/2009/PSA003 19th November 2009 'Being Open'
- NPSA (2009) 'Saying Sorry when things go wrong'. 'Being Open - communicating patient safety incidents with patient their families and Staff' NPSA/NRLS
- Department of Health 'Building a Safer NHS for Patients' (2001)
- NPSA 'Being Open – Communicating patient safety incidents with patients and their carers' (2005)

- National Health Service Litigation Authority (2002) Circular No: 02/02. 'Apologies and Explanations'
- General Medical Council (2001) 'Good Medical Practice'
- NPSA Patient Safety Notice (2005) 'Being Open – saying sorry when things go wrong'
- Incident Reporting and Investigation Policy'
- Complaints Management Policy
- Claims Management Policy
- NHS England serious incident framework March 2005

12. **EQUALITY IMPACT ASSESSMENT**

This policy has been assessed and implemented in line with the policy on procedural documents and an equality impact has been carried out to ensure the policy is fair and does not discriminate any staff groups. A completed Equality Impact Assessment can be found at **Annex B**.

APPENDIX 1 – NPSA 10 GUIDING PRICIPLES PROCESS

1. **Principle of Acknowledgement**

All patient safety incidents should be acknowledged and reported in line with the incident reporting procedure as soon as they are identified. In cases where the patient and/or carers inform healthcare staff when something has happened, their concerns must be taken seriously and should be treated with compassion and understanding by all staff.

2. **Principles of Truthfulness, Timeliness and Clarity of Communication**

Information about a patient safety incident must be given in a truthful and open manner by an appropriately nominated person. Communication should also be timely informing the patient and/or their carers what has happened as soon as is practicable, based **solely on the facts** known at that time. Patients and/or their carers should receive clear, unambiguous information and be given a single point of contact for any questions or requests they may have.

3. **Principle of Apology**

Saying sorry is not an admission of liability and it is the right thing to do. Patients and/or carers should receive a sincere expression of sorrow or regret for the harm that has resulted from a patient safety incident. This should be in the form of an appropriately worded agreed manner of apology, as early as possible. 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 incident, must also be given to follow on from the verbal apology.

4. **Principle of Recognising Patient and Carer Expectations**

Patients and/or their carers can reasonably expect to be fully informed of the issues surrounding a patient safety incident, and its consequences, in a face to face meeting with representatives from the Trust. They should be treated sympathetically, with respect and consideration. Confidentiality must be maintained at all times. Patients and/or their carers should also be provided with support in a manner 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.

5. **Principle of Professional Support**

The Trust creates an environment in which all staff are encouraged to report patient safety incidents. Staff should feel supported throughout the incident investigation

process; they too may have been traumatised by the incident. Where there is reason to believe a member of staff has committed a punitive or criminal act, the Trust will 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.

6. Principle of Risk Management and Systems Improvement

The Trust adopts a system of Root Cause Analysis (RCA) for the investigation of Serious Untoward Incidents with a grading matrix to assess the level of seriousness to uncover the underlying causes of patient safety incident. Investigation should focus on improving systems of care, which will be reviewed for their effectiveness.

7. Principles of Multi-Disciplinary Responsibility

The Being Open policy applies to all staff that have key roles in patient care. Most healthcare provision involves multi-disciplinary teams and communication with patients and/or their carers following an incident should reflect this. Both senior managers and senior clinicians must participate in the incident investigation and clinical risk management. A Being Open lead will be identified to support the patient/carer, to ensure a consistent approach to information sharing.

8. Principles of Clinical Governance

Being open requires the support of Clinical Governance processes to ensure patient safety incidents 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 of Directors 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 incidents. Audits should be developed to monitor the implementation and effects of changes in practice following a patient safety incident.

9. Principle of Confidentiality

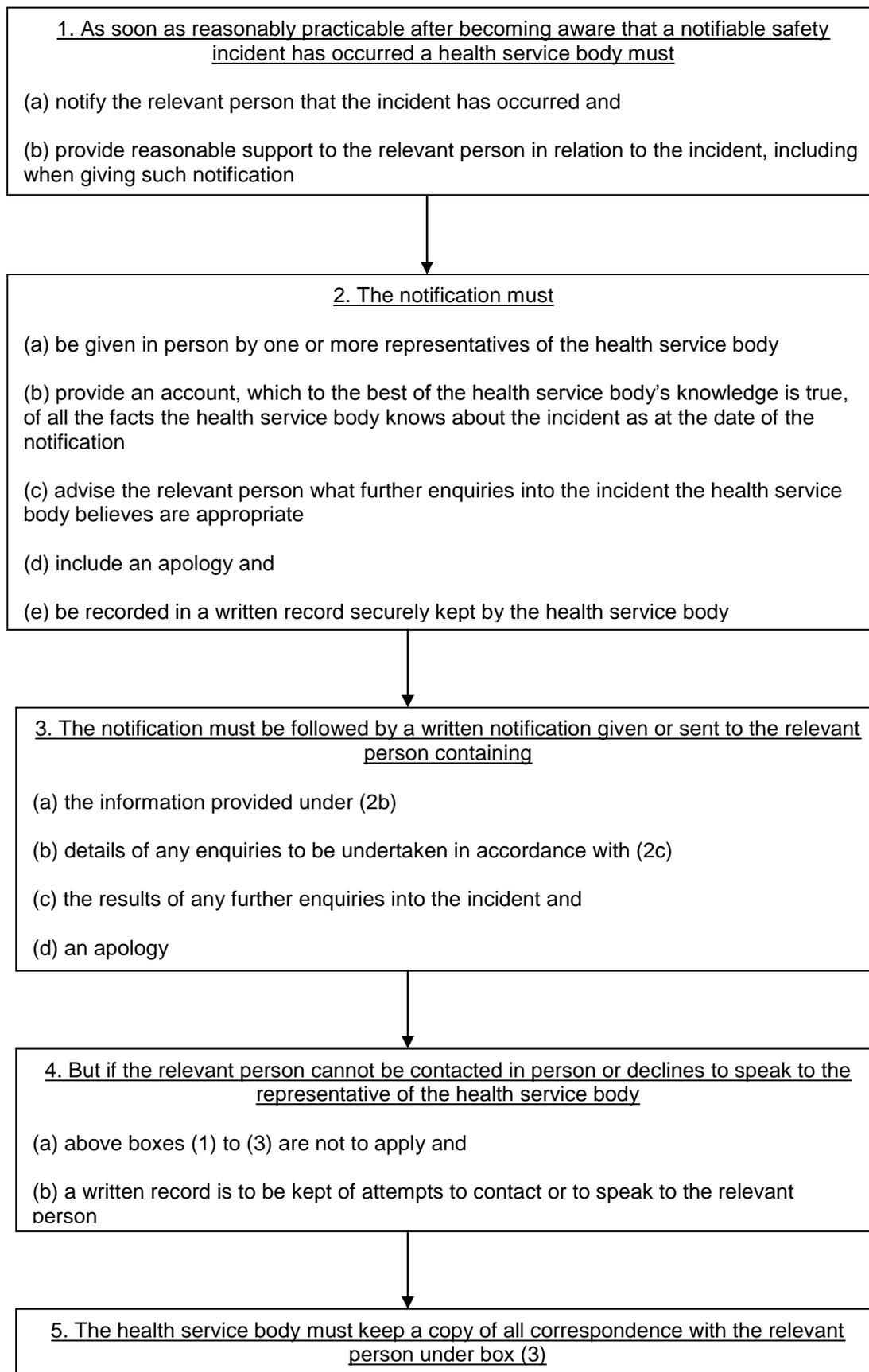
Details of a patient safety incident should at all times be considered confidential. The consent of the individual concerned should be sought prior to disclosing information beyond the clinicians involved in treating the patient. Where this is not practicable or an individual refuses consent to the disclosure,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

10. Principle of Continuity of Care

Patients will continue to receive all required treatment and will 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 will be made for this to happen.

APPENDIX 2 – REGULATION 20: DUTY OF CANDOUR

MUST ACT IN AN OPEN AND TRANSPARENT WAY WITH RELEVANT PERSONS IN RELATION TO CARE AND TREATMENT PROVIDED



APPENDIX 3 – GUIDANCE ON PARTICULAR PATIENT CIRCUMSTANCES

When a patient Dies

When a patient safety incident has resulted in a patient's death it is crucial that communication is sensitive, empathic and open. It is important to consider the emotional state of bereaved relatives and carers and to involve them in deciding when it is appropriate to discuss what has happened. The patient's family and/or carers will probably need information on the processes that will be followed to identify the cause(s) of death. They will also need emotional support. Establishing open channels of communication may also allow the family and/or carers to indicate if they need bereavement counselling or assistance at any stage (Use the Hospital Bereavement Service).

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

Children

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

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

The opportunity for parents to be involved should still be provided unless the child expresses a wish for them not to be present.

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

More information can be found on the Department of Health's website www.dh.gov.uk

Patients with Mental Health Issues

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

Patients with Cognitive Impairment

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

Patients with Learning Disabilities

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

Patients with Different Language or Cultural Considerations

The need for translation and advocacy services, and consideration of special cultural needs (such as for patients from cultures that make it difficult for a woman to talk to a male about intimate issues), must be taken into account when planning to discuss patient safety incident information. It would be worthwhile obtaining 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. The Trust has access to Translation services found through the Intranet.

Patients with Different Communication Needs

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

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

ANNEX A – PROCESS FOR OPEN COMMUNICATION

1. Identifying a Patient Safety Incident

The Being Open process begins with the recognition that a patient has suffered moderate harm, major harm, or has died, as a result of a patient safety incident.

A patient safety incident may be identified by:

- A member of staff at the time of the incident
- A member of staff retrospectively when an unexpected outcome is detected
- A patient and/or their carers who expresses concern or dissatisfaction with the patient's healthcare either at the time of the incident or retrospectively
- Incident detection systems such as incident reporting or medical records review
- Other sources such as detection by other patients, visitors or non-clinical staff
- A complaint or claim received

As soon as a patient safety incident is identified, the top priority is prompt and appropriate clinical care to prevent further harm. Where further treatment is required this should occur whenever reasonably practicable following a discussion with the patient and with appropriate consent.

The healthcare team must assess the level of response required and whether to implement the *Being Open* procedure according to the following matrix:

(ACTUAL) SEVERITY	ACTION
No or Low harm - patient requires extra observation or minor treatment	Complete an incident report form Investigate at a local level and implement changes to prevent recurrence
Moderate harm - Patient requires moderate increase in treatment and adverse event caused significant but not permanent harm	Complete an Incident report Implement <i>Duty of Candour</i> Moderate harm – Report Clinical Governance to determine if Root Cause Analysis investigation required - Report to the immediate line manager actions to be detailed in the incident report
Severe (Significant) harm - Adverse event resulted in permanent harm e.g. permanent lessening of bodily function, permanent change for the worse in their medical condition	Severe harm – As for Moderate harm but also report to the lead Clinical & General Manager Death – Immediately report to the appropriate Director (on-call Director out of hours), the Chief Executive and the Associate Director of Patient Safety and Quality Clinical Governance Department must be notified as soon as possible. Root Cause Analysis required
Death/Catastrophic (High) harm – death directly related to the adverse event	

(Actual) Severity is taken from the NPSA Terms and Definitions for Grading Patient Safety Incidents.

2. Recording the Incident

Responsibility of recording any apology *and* contact with patients, carers or relatives lies with the individual who identifies the harm or a mistake has occurred. Document an incident through the incident reporting system and record details in the patient's notes of the care provided.

3. Supporting the Patient's Immediate Needs

Following a patient safety incident the lead clinician must give consideration to the patient's immediate needs which may include the following:

- Early identification of the patient's practical and emotional needs. This includes the names of people who can provide assistance and support to the patient, and to whom the patient has agreed that information about their healthcare can be given. This person (or people) may be different to the patient's next of kin and from people who the patient has previously agreed should receive information about their care prior to the patient safety incident.
- Identify whether the patient does not wish to know every aspect of what went wrong, to respect their wishes and reassure them that this information will be made available if they change their mind later on
- Provide repeated opportunities for the patient and/or their carers to obtain information about the patient safety incident
- Provide information to patients in verbal and/or written format
- Provide assurance that an on-going care plan will be developed in consultation with the patient and will be followed through
- 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 carers and the healthcare team will not affect their access to treatment

4. Timing of the meeting with Patient and/or their carer(s)

The initial discussion with the patient and/or carer should occur as soon as possible after recognition of the patient safety incident. With an acknowledgement of the incident and related harm or event that occurred. Factors for the lead to consider when timing this discussion include:

- Clinical condition of the patient
- Availability of key staff involved in the incident
- Availability of the patient's family and-or carers
- Availability of support staff, for example a translator or independent advocate, if required
- Patient preference (in terms of when and where the meeting takes place and which healthcare professional leads the discussion – if for any reason during the initial discussion it becomes clear that the patient would prefer to speak to a different healthcare professional, the patient's wishes should be respected and a substitute with whom the patient is satisfied should be provided)
- Privacy and comfort of the patient
- Arranging the meeting in a sensitive location

5. Content of Initial Discussion with Patient and/or Carers

The lead has a number of responsibilities as detailed below:

The lead will advise the patient and/or carers 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.

The lead should express sympathy, regret and an apology for the harm that has occurred.

The lead will ensure that the facts that are known are agreed by the multidisciplinary team. Where there is disagreement, communication about these events should be deferred until after the investigation has been completed. The lead must inform the patient and/or carers that an incident investigation is being carried out and more information will become available as it progresses.

The lead should make it clear to the patient and/or carer that new facts may emerge as the incident investigation proceeds.

The lead must take into consideration the patient's and/or carer's understanding of what happened, as well as any questions they may have.

The lead should give consideration to the formal noting of the patients and/or carer's views and concerns, and demonstrate that these are being heard and taken seriously.

The lead should ensure that appropriate language and terminology is used when speaking to patients and/or 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 carer. If a patient's first language is not English, it is also important to consider their language needs – if they would like the Being Open discussion conducted in another language, this should be arranged.

The lead should provide an explanation about what will happen next in terms of the long term treatment plan and incident analysis findings.

Information on likely short and long term effects of the incident (if known) should be shared with the patient and/or carer by the lead in conjunction with other members of the healthcare team as appropriate. The latter may have to be delayed to a subsequent meeting when the situation becomes clearer.

The lead should offer practical and emotional support to the patient and/or carer. 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

The lead should ask the patient and/or carer if they are satisfied with the explanation and a note made of this in the patient's records.

The lead should provide the patient and/or carer with contact details so that if further issues arise later there is a conduit back to the relevant healthcare professionals or an agreed substitute.

6. Written Records of the Discussion

The lead should ensure that a separate record linked to the patient's notes is created of the Being Open process. The document should contain details of:

- The time, place, date as well as the name and relationships of all attendees
- The plan for providing further information to the patient and/or carer
- Offers of assistance and the patient's and/or carer's response
- Questions raised by the family and/or carer 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 carer
- Copies of letters sent to patients, carers and the GP

Statements taken in relation to the patient safety incident should form part of the incident investigation. For completeness, a copy of all of the above documents should be provided to the lead incident investigator for inclusion with the incident investigation report. Refer to the Incident Reporting and Investigation Policy for details of incident investigation processes.

7. Completing the Communication Process Post Investigation

After completion of the incident investigation, the Being Open lead must feedback on the results of the investigation. Feedback should take the form most acceptable to the patient. Whatever method is used, the communication should include:

- The chronology of clinical and other relevant facts
- Details of the patient's and/or their carer's concerns and complaints
- A repeated apology for the harm suffered and any shortcomings in the delivery of care that led to the patient safety incident
- A summary of the factors that contributed to the incident
- Information on what has been and will be done to avoid recurrence of the incident and how these improvements will be monitored

It is expected that in most cases there will be a complete discussion of the findings of the investigation and analysis with the patient. In some cases information may be withheld or restricted, for example, where communicating information will adversely affect the health of the patient; where investigations are pending coronial processes; or where specific legal requirements preclude disclosure for specific purposes. In these cases the patient must be informed of the reasons for the restrictions.

8. Communication with the GP and other Community Care Service Providers

Wherever possible, it is advisable to send a brief communication to the patient's GP, before discharge, describing what happened.

When the patient leaves the care of a healthcare organisation, the Being Open lead must ensure that a discharge letter is forwarded to the GP or appropriate community care service. It should contain summary details of:

- The nature of the patient safety incident and the continuing care and treatment
- The current condition of the patient
- Key investigations that have been carried out to establish the patient's clinical condition
- Recent results
- prognosis

9. Continuity of Care

When a patient has been harmed during the course of treatment and requires further therapeutic management or rehabilitation, the Being Open lead should ensure that the patient and/or carer is informed of the on-going clinical management plan. This may be encompassed in discharge correspondence to designated individuals such as the referring GP.

Patients and/or their carers should be reassured that they will continue to be treated according to their clinical needs even in circumstances where there is a dispute between them and the healthcare team. They should also be informed that they have the right to continue their treatment elsewhere if they have lost confidence in the healthcare team involved in the patient safety incident. In cases where patients and/or carers request a transfer of care, leads should seek advice and support from their Clinical Lead/Head of Service to ensure that the transfer happens as safely and promptly as possible.

10. Particular Patient Circumstances

The approach to being open may need to be modified according to the patient's personal circumstances. Please see **Appendix 1** for guidance on how to manage different categories of patient circumstances.

11. Patients Who Do Not Agree With the Information Provided

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

- Deal with the issue as soon as it emerges
- Where the patient agrees, ensure their carers 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 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 procedure
- Write a comprehensive list of the points that the patient and/or carer disagree with and reassure them you will follow up these issues
- Identify if a conciliation meeting may be appropriate

ANNEX B – EQUALITY IMPACT ASSESSMENT TOOL

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

Name of Document: **'Being Open when Patients are Harmed' Policy**

1.	Does the policy/guidance affect one group less or more favourably than another on the basis of:		
	• Race	No	
	• Ethnic origins (including gypsies and travellers)	No	
	• Nationality	No	
	• Gender	No	
	• Culture	No	
	• Religion or belief	No	
	• Sexual orientation including lesbian, gay and bisexual people	No	
	• Age	No	
	• Disability	No	
2.	Is there any evidence that some groups are affected differently?	None	
3.	If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?	None Identified	
4.	Is the impact of the policy/guidance likely to be negative?	No	
5.	If so can the impact be avoided?	Not Applicable	
6.	What alternatives are there to achieving the policy/guidance without the impact?	Not Applicable	
7.	Can we reduce the impact by taking different action?	Not Applicable	

For advice or if you have identified a potential discriminatory impact of this procedural document, please refer it to The Equality & Diversity Lead, Yeovil Academy, together with any suggestions as to the action required to avoid/reduce this impact.

Signed: (Associate Director of Patient Safety & Quality)

Date: 26/11/2014 Reviewed: November 2014