York Hospitals NHS
NHS Foundation Trust

BEING OPEN WITH PATIENTS
Policy

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Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

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1. Introduction & Scope

This policy will apply to all staff working for York Hospitals NHS Foundation Trust and who have a role in providing patient care. Although the Trust's Risk Management Policy encourage staff to report all patient safety incidents, through the AIRS system, including those where there was no harm or it was a prevented patient safety incident (near miss), this policy relates only to those incidents which lead to moderate or serious harm or death. These are where the impact is graded as moderate, serious or catastrophic using the Trust's Risk Matrix (Appendix 1). Incidents that score as negligible or minor do not have to be dealt with using this policy.

Staff should also ensure that they are aware of their obligations detailed (*Sharing Concerns* policy). This policy should also be read in conjunction with the Trust AIRS and SUI policies (available on Horizon)

2. Definitions

DATIX data collection system used by the Trust collates data and generates reports and information

NRLS – National Reporting and Learning System is a confidential and anonymous computer based system developed by the NPSA for the collection and analysis of patient safety information

RCA – Root Cause Analysis is a systematic process whereby the factors that contribute to the incident are identified and, seeks to understand that underlying causes

Patient Safety Incident is any unintended or unexpected incident that could have or did lead to harm for one, or more, patients

PALS – Patient Advisory and Liaison Service

3 Policy Statement

Promoting a culture of openness is a prerequisite to improving patient safety and the quality of healthcare systems. It involves apologising and explaining what happened to patients who have been harmed as a result of their healthcare treatment. It ensures communication is open, honest and occurs as soon as possible following an incident. It encompasses communication between healthcare organisations, healthcare teams and patients and/or their carers.
The existence of this policy meets the requirements outlined in the NPSA Safer Practice Notice No.10 (http://www.npsa.nhs.uk/site/media/documents/1314_SaferPracticeNotice.pdf)

The Chief Medical Officer's consultation document, *Making Amends, DH 2003* also outlines processes to encourage openness in the reporting of adverse events. This would encompass:

"a duty of candour requiring clinicians and health services managers to inform patients about actions which have resulted in harm". Openness and honesty towards patients are supported and actively encouraged by many professional bodies including the Medical Protection Society, the Medical Defence Union and the General Medical Council, whose Good Medical Practice guide contains the following statement on a clinician's "duty of candour":
"If a patient under your care has suffered harm, through misadventure or for any other reason, you should act immediately to put matters right, if that is possible. You must explain fully and promptly to the patient what has happened and the likely long and short term effects. When appropriate you should offer an apology.

If the patient is an adult who lacks capacity, the explanation should be given to a person with responsibility for the patient, or the patient's partner, close relative or a friend who has been involved in the care of the patient, unless you have reason to believe the patient would have objected to the disclosure. In the case of children the situation should be explained honestly to those with parental responsibility and to the child, if the child has the maturity to understand the issues."

(General Medical Council 2001p10)

See Appendix 1 - Procedure

4. Equality Impact Assessment

The Trust aims to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that none are placed at an unreasonable or unfair disadvantage over others.

In the development of this policy, the Trust has considered its impact with regard to equalities legislation. See Appendix 4.

5. Accountability

The Medical Director is accountable for the effective implementation of this policy across the Trust. All individuals who implement this policy are responsible for ensuring that they do so according to Trust policy and other related policies, identified in Section 11 of this policy.

6 Consultation, Assurance and Approval Process

6.1 Consultation Process

Following consultation with stakeholders and relevant consultative committees, this policy will be quality assured by its approving committee.

6.2 Quality Assurance Process

Following consultation with stakeholders and relevant consultative committees, this policy has been reviewed by the Risk and Assurance Committee.

6.3 Approval Process

Following completion of the Quality Assurance Process, this policy, and any subsequent policy revisions will be approved by the Risk and Assurance Committee.

7 Review and Revision Arrangements

This policy will be reviewed by the Medical Director two years following implementation or earlier should new guidance be issued.

8 Dissemination and Implementation

8.1 Dissemination

This policy is available in alternative formats, such as Braille or large font, on request to the author of the policy.

8.2 Implementation of Policies

This policy will be implemented through communication with all Clinical Directors, Directorate Managers, Lead Investigators, Risk Reviewers, Matrons and Consultants. It will be published on Horizon as a Corporate policy.

A training programme is being developed by the Medical Governance Directorate and all staff will have access to it. However, all staff who are in discussions with the patient/carer or family will be required to undergo this training as part of their mandatory training programme.

9 Document Control including Archiving Arrangements

9.1 Register/Library of Policies

The Compliance Unit will maintain a Register of all Policies

9.2 Archiving Arrangements

The Compliance Unit will be responsible for the archiving arrangements of all policies

9.3 Process for Retrieving Archived Policies

To retrieve a former version of this policy from Horizon, the Compliance Unit should be contacted.

10 Monitoring Compliance With and the Effectiveness of Policies

This policy will be monitored for compliance with the minimum requirements of Criterion 1.5.10 of the NHSLA Risk Management Standards For Acute Trusts.

10.1 Process for Monitoring Compliance and Effectiveness

Monitoring the effectiveness of this policy will provide assurance to the Trust that the specified risks are being managed appropriately.

The aim will be to prioritise monitoring of the most important aspects of the policy initially based on previous experience of risk incident data and NHSLA standards. The processes which ensure effective feedback of the results of monitoring and audit into the Trust will be clearly identified. These processes will ensure that the evidence for the effectiveness of this policy is appropriately assessed and reported, that further monitoring and audit is planned based on previous findings and, that recommendations and action plans are produced and monitored appropriately.

The Head of Risk and Legal Services will be responsible for ensuring that the monitoring and audit of this policy takes place as detailed below:

a) process for encouraging open communication between healthcare organisations, healthcare teams, staff and patients and their carers.	Internal Audit of two SUIs per quarter reported to the SUI Committee and Risk and Assurance Committee. Ten randomly selected claim files per year reported to Risk and Assurance Committee. Twenty randomly selected complaint files per year report to Risk and Assurance Committee. Review of DATIX incidents reports identifying communication issues; 500 per year randomly selected and reported to Risk and Assurance Committee. All this will be undertaken by the use of Audit Checklists and will be undertaken by the Risk and Legal Services Senior Managers.
b) process for acknowledging, apologising and explaining when things go wrong	As per the above monitoring.
c) Requirements for truthfulness, timeliness and clarity of communication	As per the above monitoring.
d) Provision of additional support as required	As part of reviewing the documentation it should also document whether additional support has been provided to support either staff involved in the incident or, as part of the investigation into the circumstances for it, and by whom. This will be recorded within the file and will be audited in line with the above.
e) Requirement for documenting all communication	As per (a)

10.2 Standards/Key Performance Indicators

NHSLA Risk Management Standards for Acute Trusts, standard 5, criterion 9

Standards for Better Health, Core Standards C1, C7, C8 and, C14

Standards for Better Health, Development Standards D1 and D4.

11 Trust Associated Documentation

- Risk Management Strategy, York Hospitals NHS Foundation Trust
- Adverse Incident Reporting Policy, York Hospitals NHS Foundation Trust
- Serious Untoward Incident Policy, York Hospitals NHS Foundation Trust
- Disciplinary Policy, York Hospitals NHS Foundation Trust
- Consent Policy, York Hospitals NHS Foundation Trust
- Information Governance Policy, York Hospitals NHS Foundation Trust
- Discharge Policy, York Hospitals NHS Foundation Trust
- Health and Safety at work Policy, York Hospitals NHS Foundation Trust
- Resuscitation Policy, York Hospitals NHS Foundation Trust
- Complaints Policy, York Hospitals NHS Foundation Trust
- Sharing Concerns Policy, York Hospitals NHS Foundation Trust

12 External References

- National Patient Safety Agency (2004), Seven Steps to patient safety: A guide for NHS staff, NPSA, London
- National Health Service Litigation Authority (2002) Apologies and Explanations, Circular 02/02, NHSLA, London

- DH (2003), Making Amends, A consultation paper setting out proposals for reforming the approach to clinical negligence in the NHS: A report by the Chief Medical Officer, DH, London
- General Medical Council (2001), Good Medical, Protecting patients guiding doctors (3rd edition), General Medical Council, London
- Shipman Enquiry, fifth report: Lessons from the past – Proposals for the future:http://www.the-shipman-inquiry.org.uk/5r_page.asp?id=4817
- Being Open – Communicating Patient Safety Incidents to patients and their carers, NPSA 2005
- NPSA Safer Practice Notice, No 10. http://www.npsa.nhs.uk/site/media/documents/1314_SaferPracticeNotice.pdf
- NHSLA "Striking the Balance"

Further information and e-learning module can be found at www.npsa.nhs.uk

13. Appendices

1. Procedure
2. Risk Matrix
3. Criteria for Implementation
4. Equality Impact Assessment

Appendix 1 – Procedure

1.1Ten Principles of Being Open

Being Open is a process rather than a one-off event. With this in mind, the following principles have been drawn up to support the policy.

i. Principle of Acknowledgement

All patient safety incidents should be acknowledged and reported as soon as they are identified. In cases where the patient and/or their carers inform healthcare staff when something untoward has happened, it must be taken seriously from the outset. Any concerns should be treated with compassion and understanding by all healthcare staff. Denial of a patient's concerns will make future open and honest communication more difficult.

ii. Principle of Truthfulness, Timeliness and Clarity of Communication

Information about a patient safety incident must be given to patients and/or their carers, (with appropriate consent), in a truthful and open manner by an appropriately nominated person. Patients want a step-by-step explanation of what happened, that considers their individual needs and is delivered openly.

Communication should also be timely: patients and/or their carers should be provided with information about what happened as soon as practicable. It is also essential that any information given is based solely on the facts known at the time. Healthcare staff should explain that new information may emerge as an incident investigation is undertaken, and patients and/or their carers should be kept up-to-date with the progress of an investigation.

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. They should not receive conflicting information from different members of staff. Medical jargon, which they may not understand, should be avoided.

iii. Principle of Apology

Patients and/or their carers should receive a sincere expression of sorrow or regret for the harm that has resulted from a patient safety

incident. A worded apology should reinforce the verbal apology which would have been given when the incident became known.

Both verbal and written apologies should be given. The decision on which staff member should give the apology should take into consideration seniority, relationship to the patient, and experience and expertise in the type of patient safety incident that has occurred.

Verbal apologies are essential because they allow face-to-face contact between the patient and/or their carers and the healthcare team. This should be given as soon *as* staff are aware an incident has occurred. It is important not to delay for any reason, as delays are likely to increase the patient's and/or their carer's sense of anxiety, anger or frustration.

A written apology, which clearly states the Trust is sorry for the suffering and distress resulting from the incident, must also be given. **An apology is not an admission of liability.**

iv. 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. They should be treated sympathetically, with respect and consideration. Confidentiality must be maintained at all times. Patients and/or their carers should also be provided with support in a manner appropriate to their needs. This involves consideration of special circumstances that can include a patient requiring additional support, such as an independent patient advocate or a translator.

When appropriate, information on accessing the Patient Advisory and Liaison Services (PALS) and other relevant support groups like Cruse Bereavement Care, the Independent Complaints Advisory Service (ICAS) and Action against Medical Accidents (AvMA) should be given to the patient as soon as it is possible.

v. Principle of Professional Support

The Trust's Open and Fair Culture creates an environment in which all staff, whether directly employed or independent contractors, are encouraged to report patient safety incidents. Managers should ensure that staff feel supported throughout the incident investigation process as they too may have been traumatised by being involved. They should not be **unfairly** exposed to punitive disciplinary action, increased medico-legal risk or any threat to their registration.

To ensure a robust and consistent approach to incident investigation, the NPSA's Incident Decision Tree (IDT) (available on Horizon), has been developed as an aid to improve the consistency of decision-making about whether human error or systems failures contributed to an incident. It is designed for use by anyone who has the authority to exclude a member of staff from work following a patient safety incident (including medical and nursing directors, chief executives and human resources staff). More details can be found in *Seven Steps to Patient Safety* and on the NPSA website: www.npsa.nhs.uk and in the Trust's SUI policy.

Where there is reason for the Trust 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. Staff will also be encouraged to seek support from relevant professional bodies such as the General Medical Council, Royal Colleges, the Medical Protection Society, the Medical Defence Union and the Nursing and Midwifery Council.

vi. Principle of Risk Management and Systems Improvement

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

vii. Principle of Multi-disciplinary Responsibility

Most healthcare provision involves multi-disciplinary teams and communication with patients and/or their carers following an incident that led to harm should reflect this. This will ensure that the *Being Open* process is consistent with the philosophy that incidents usually result from systems failures and rarely from the actions of an individual.

viii. Principle of Clinical Governance

Being Open has the support of patient safety and quality improvement processes through the governance framework, in which 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 these changes are implemented and their

effectiveness reviewed. The findings are disseminated to staff so that they can learn from patient safety incidents.

These actions are monitored to ensure that the implementation and effects of changes in practice following a patient safety incident by the Trust's Risk Review Group, Clinical Risk Group, Non-Clinical Risk Group, Governance Committee and Board of Directors.

ix. Principle of Confidentiality

Full respect should be given to the patient's and/or their carer's and staff's privacy and confidentiality. Details of a patient safety incident should at all times be considered confidential. Staff should adhere to the Trust's confidentiality policy, Caldicott principles and relevant Codes of Conduct. However in order to learn from incidents it will be necessary for discussions to take place in forums such as SUI Sub-group, Risk review meetings, Directorate fora. However in all of these discussions, the identity of the patient concerned should be on a need-to-know basis and, where practicable, reports should be anonymous. In addition, it is good practice to inform the patient and/or their carers about who will be involved in the investigation before it takes place and give them the opportunity to raise any objections.

x. 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, by the relevant clinicians and managers, if possible.

1.2 The Being Open Process

1.2.1 Incident Detection or Recognition

The *Being Open* process begins with the recognition that a patient has suffered moderate harm, serious harm, or has died as a result of a patient safety incident. These would be categorized as a yellow or red incident on the Trust Risk Matrix.

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.

As soon as a patient safety incident 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 and with appropriate consent. Where incidents are graded as yellow or red, as defined in the Adverse Incident (AIRS) and Serious Untoward Incident (SUI) Policy the following should be implemented.

- acknowledgement and apology
- *an AIRs form being completed*
- a Root Cause Analysis being undertaken.

1.2.2 Patient Safety Incidents Occurring Elsewhere

A patient safety incident may have occurred in another organisation, not the Trust. The individual who first identifies the possibility of an earlier patient safety incident should ensure that contact is made with other organisation to establish whether the matter has been recognized and whether the incident is being investigated. In all circumstances, the Trust's Head of Risk and Legal Services should be notified who will ensure that this organisation is kept informed of the outcome of the investigation.

1.2.3 Criminal or Intentional Unsafe Act

Patient safety incidents are almost always unintentional. However, if at any stage following an incident it is determined that harm may have been the result of a criminal or intentional unsafe act, the line manager, the Head of Risk and Legal Services, the Medical Director and the Chief Executive should be notified immediately.

1.2.4 Initiating the Being Open Process

1.2.4.1 Preliminary Team Discussion

The most senior health professional should, as soon as practicable consult with the Head of Risk and Legal Services. A decision will be made, in accordance with the Trust's SUI policy, as to whether the patient safety incident should be declared as an SUI. If so, a Lead Investigator will be appointed to lead the SUI investigation.

If an SUI is not declared, the most senior health professional involved in the patient safety incident, as well as the senior clinician responsible for the patient's care should meet as soon as possible after the event to:

- establish the basic clinical and other facts
- assess the incident to determine the level of immediate response
- identify who will be responsible for discussion with the patient and/or their carers (Family Liaison Officer)
- consider the appropriateness of engaging patient support at this early stage. This includes 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.

In addition to this, it will be an advantage to provide facilities for formal and informal debriefing of the clinical team involved in the patient safety incident, where appropriate, as part of the support system and separate from the requirement to provide statements for the investigation. Staff may also benefit from individual feedback about the final outcome of the patient safety incident investigation.

Managers should also provide information on the support systems currently available for professionals distressed by patient safety incidents. These include counselling services offered by their professional bodies, stress management courses for staff who have the responsibility for leading *Being Open* discussions and mentoring for staff who have recently taken on a *Being Open* leadership role and access to the staff counselling services. The Trust booklet

"When a Serious incident happens" can be given to staff. Managers should also be mindful of the Trust's responsibilities under the Stress Management policy (available on Horizon).

1.2.4.1 Initial Assessment to Determine Level of Response

All incidents should be initially assessed, using the Trust's risk matrix at Appendix 1, by the initial team to determine the level of response required and then discussed with the Head of Risk & Legal Services if it requires a high level of response. The level of response to a patient safety incident depends on the nature of the incident (see Appendix 2).

1.2.5 Timing

The initial Being Open discussion with the patient and/or their carers should occur as soon as possible after recognition of the patient safety incident. Factors to consider when timing this discussion include:

- clinical condition of the patient. Some patients may require more than one meeting to ensure that all the information has been communicated to and understood by them
- availability of key staff involved in the incident and in the *Being Open* process
- availability of the patient's family and/or carers
- availability of support staff, for example a translator or independent advocate, if required
- patient preference (in terms of when and where the meeting takes place and who leads the discussion)
- privacy and comfort of the patient
- arranging the meeting in a sensitive location.

1.2.6 Choosing the individual to communicate with patients and/or their carers

1.2.6.1 The healthcare professional who informs the patient and/or their carers about a patient safety incident

It is important to identify which member of staff is going to take responsibility for liaising with the patient and/or carers to explain the patient safety incident. This liaison person should ideally be the most senior person responsible for the patient's care or someone with experience and expertise in the type of incident that has occurred.

All these individuals should have received training in communication of patient safety incidents and should:

- be known to, and trusted by, the patient and/or their carers
- have a good grasp of the facts relevant to the incident be senior enough or have sufficient Should the lead person wish, s/he may nominate another individual to attend the meeting for support.experience and expertise in relation to the type of patient safety incident to be credible to patients, carers and colleagues
- have excellent interpersonal skills, and be able to communicate with patients and/or their carers in a way they can understand, without 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.

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.

1.2.6.2 Patient safety incidents related to the environment of care

In such cases a senior manager of the relevant service will be responsible for communicating with the patient and/or their carer. The treating Consultant should be present to assist at the initial *Being Open* discussion to assist in providing information on what will happen next and the likely effects of the injury.

1.2.7 Involving healthcare staff who made mistakes

Some patient safety incidents that resulted in moderate harm, severe harm or death will arise from errors made by healthcare staff while caring for the patient. In these circumstances the member(s) of staff involved may or may not wish to participate in the *Being Open* discussion with the patient and/or their carers. Every case where an error has occurred needs to be considered individually, balancing the needs of the patient and/or their carers with those of the healthcare professional concerned.

In cases where the healthcare professional who has made an error wishes to attend the discussion to apologise personally, they should feel

supported by their colleagues throughout the meeting. In cases where the patient and/or their carers express a preference for the healthcare professional not to be present, it is advised that a personal written apology is handed to the patient and/or their carers during the first *Being Open* discussion.

1.2.8 Content of the initial *Being Open* discussion with the patient and/or their carers

With the patient's agreement, carers and those close to the patient can be included in the discussions and decision-making. If the patient is unable to participate or has died, then the carers or people closely involved with the patient may be provided with limited information in order to make decisions, but this should be done with regard to confidentiality and any patient instructions. Also, subject to any previous expression of the patient's wishes, confidential medical information may only be disclosed to the deceased's next of kin. Carers and people close to the patient can be referred to the Coroner for more information. The patient/carer should also be given a leaflet on the Being Open process so that they know what to expect.

- 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 staff should be present
- There should be an expression of genuine sympathy, regret and an apology for the harm that has occurred
- The known facts are agreed by the multi-disciplinary team. 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 incident investigation is being carried out and more information will become available as it progresses
- 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, or they have other communication difficulties, their language needs should be addressed as well as providing information in both verbal and written formats. In these circumstances assistance can be provided by Language Line and/or interpreters. These can be accessed through the PALS team on ext 6262.

- An explanation should be given about what will happen next in terms of the long-term treatment plan and incident analysis findings, in which the patient or carer/relative will have the opportunity to be involved.
- Information on likely short- and long-term effects of the incident (if known) should be shared. The latter may have to be delayed to a subsequent meeting when the situation becomes clearer. Some patients may not wish to know every detail of an incident. They should be reassured that if they change their minds, this information will be made available to them
- An offer of practical and emotional support should be made to the patient and/or their carers. This may involve giving information on third parties such as charities and voluntary organisations to the patient/carer, as well as offering more direct assistance. Information about the patient and the incident should not normally be disclosed to third parties without the patient's consent. The patient may not wish third parties to know every detail of the incident.
- The patient/carer should be given the contact details of at least two members of staff who will act as a contact point for them, one of who will be appointed as their Family Liaison officer (FLO). Their role will be to provide both practical and emotional support in a timely manner. The Trust leaflet "What happens when a serious untoward incident happens" should be provided to the patient/carer.
- It should be explained to the patients that they are entitled to 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
- Patients/Carers should be given a complaints leaflet to read if they indicate that they wish to make a complaint. In these circumstances, the Head of Patient Experience should be advised that a complaint may be forthcoming and the name of the Family Liaison Officer (FLO).
- 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 initial *Being Open* discussion is the first part of an ongoing communication process. There should be repeated opportunities for the patient and/or carer to obtain information about the incident and many of the points raised here should be expanded on in subsequent meetings.

1.2.9 Notification

1.2.9.1 Head of Risk & Legal Services

In all cases the Head of Risk & Legal Services, or one of the Risk and Legal Services Senior managers in her absence, should be informed either by telephone, email. In all cases an AIRS form should also be completed. The NPSA will then receive anonymous notification of the incident through the National Reporting and Learning System (NRLS).

1.2.9.2 Management

The clinician who discovers the incident should report it through their line manager. When a major incident occurs or where a criminal act is suspected, the Medical Director, or if out of hours, the on-call manager must be notified immediately as per the reporting system detailed in the SUI Policy. The Medical Director should then be notified as soon as possible the next working day.

1.2.9.3 General Practitioner

Consideration should be given to contacting the referring GP for incidents that have not occurred within primary care but have implications for continuity of care. By informing them they can offer their support to the patient and/or their carers. Contact can either be by phone or by letter.

1.2.9.4 The Coroner

All cases of untimely, unexpected or unexplained death or suspected unnatural deaths must to be reported to the coroner. Where a patient safety incident has resulted in a patient death, the Head of Risk and Legal Services will liaise with the coroner’s office to discuss whether a Being Open discussion can take place.

A coroner may request the case is not discussed with other parties until all the facts have been considered. Where this occurs, the appointed Being Open family liaison officer should carefully explained this to the family and advised that as soon as it is possible to discuss the matter further, a meeting will be arranged at a date to suit both parties. However this should not preclude a verbal and written apology, or expression of regret where appropriate. In these situations care should be given to ensuring that information is accurate and relevant and appropriate advice should be sought from Risk and Legal Services.

It should also be recognised that coroner investigations are stressful for patients, families, carers and staff. Bereavement counselling and advice on professional support groups should be offered at the outset of a coroner's investigation.

1.2.9.5 Relevant Statutory/other Bodies

The Adverse Incident Reporting Policy and Serious Untoward Incident Policy detail which external agencies should be informed of a patient safety incident and when this should occur. The Head of Risk & Legal Services is responsible for notifying these relevant agencies such as the Strategic Health Authority or, NHSLA.

1.2.10 **Documentation**

1.2.10.1 General

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

- a copy of relevant medical information, which should be filed in the patient's medical records
- AIRs form (incident report)
- records of the investigation and analysis process.

The incident report and record of the investigation and analysis process will be recorded on the incident database (Datix). **In no circumstances should the notes of a Being Open investigation be placed within a patients healthcare notes**.

The initial incident will be reported using the procedures detailed within the relevant AIRS or SUI policy and will be recorded on the Trust's incident database and reported to the NPSA through the NRLS.

1.2.10.2 Written Records of the *Being Open* Discussion

There should be documentation 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 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 not occurring within primary care
- 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.

1.2.11 **Preliminary Follow-up**

The preliminary follow-up discussion will usually involve the Family Liaison Officer and the patient's consultant and will involve a meeting with the patient and/or their carers. This is an important step in the *Being Open* process. The following guidelines should assist in making the communication effective:

- the discussion should occur at the earliest practical opportunity, once there is additional information to report
- consideration should be given to the timing of the meeting, based on both the patient's health and personal circumstances
- consideration should be given to the location of the meeting eg the patient's home. Feedback should be given on progress to date and information provided on the investigation process
- there should be no speculation or attribution of blame. Similarly, the healthcare professional communicating the incident must not criticise or comment on matters outside their own experience
- the patient 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

1.2.12 Completing the Process

1.2.12.1 Communication with the Patient and/or Their Carers

After completion of the incident 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
- answers to 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 recommendations of the investigation and analysis. 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 will be informed of the reasons for the restrictions. The meeting notes should record all the above details.

1.3 Recommendations for Improvement

Any recommendations for systems improvements and changes implemented following a Being Open incident will be detailed in an action plan which will be linked to the incident on the incident database. The progress, final completion of and effectiveness of the action plan will be monitored and reported to the Clinical or Non Clinical Risk Groups by the Head of Risk and Legal Services. Examples of good practice will be passed to the NPSA for sharing with the rest of the NHS by the Head of Risk & Legal Services.

1.4 Communication of Improvements to Staff

Effective communication of lessons learnt is a vital step in ensuring that recommended changes are fully implemented and monitored. It will also facilitate the move towards increased awareness of patient safety issues and the value of Being Open. Team meetings, newsletters and Horizon are all available to help communicate with staff.

Appendix 2 Risk Matrix

Probability					
Almost certain					
Likely					
Possible					
Unlikely					
Rare					
Severity	Negligible/ None	Minor/ Low	Moderate	Serious/ Severe	Catastrophic/ Death

Severity of incident	Injury / Illness	Patient Experience	Systems / project / targets/ objectives	Complaints / Claims	Financial Loss	Adverse Publicity
Catastrophic/ Death	Death or major and permanent incapacity or disability	Totally unsatisfactory patient outcome.	Failure of critical system/ project/targets/objectives	Multiple claims or a single major claim	£1,000,000+	Nation wide multi media coverage
Serious/ Severe	Major injuries, or long term incapacity or disability	Patient outcome or experience significantly below reasonable expectation across the board	Partial failure of critical systems, projects, objectives or target achievement.	Above excess claim, multiple justified complaints	£50,000 - £1,000,000	Extensive local coverage and widespread NHS coverage.
Moderate	Significant injury or ill health – medical intervention necessary – some temporary incapacity.	Patient outcome or experience below reasonable expectation in one or more areas.	Resolvable problem with critical system, project, target or objectives achievement Partial failure of important system, project, target or objective achievement. Failure of peripheral system/project/target or objective achievement.	Justified complaint involving the lack of appropriate care, or below the excess claim.	£5,000 - £50,000	Coverage throughout the organisation and / or some public coverage
Minor/ Low	Minor injury or ill health – first aid or self treatment – no incapacity.	Patient experience temporarily unsatisfactory – rapidly resolved.	Resolvable problem with important system, project, target or objective achievement.	Justified complaint peripheral to clinical care (e.g. Car parking / access	£500 - £5,000	Coverage limited to elements within the organisation (e.g. trade unions and /or some external stakeholders)
Negligible / None	Injury or illness not requiring intervention	Single resolvable problem in patient experience.	Resolvable problem with peripheral system, objective or project.	Low value claim handled by an ex gratia payment	£0 -£500	Awareness limited to individuals within the organisation

Appendix 3 – Criteria for when to implement the Being Open Policy

Severity of Incident	Response	Who else must be involved
Negligible (including near misses)	Patients are not usually contacted or involved in investigations and these types of incidents are outside the scope of the Being Open policy	
Minor	Unless there are specific indications or the patient requests it, the communication, investigation, analysis and the implementation of changes will occur at local service delivery level with the participation of those directly involved in the incident. Communication should take the form of an open discussion between the staff providing the patient's care and the patient and/or their carers. Reporting to the risk management team will occur through standard incident reporting mechanisms and be analysed centrally to detect high frequency events. Review will occur through aggregated trend data and local investigation. Where the trend data indicates a pattern of related events, further investigation and analysis may be needed.	AIRS form must be completed and forwarded immediately to Risk and Legal Services detailing action taken
Moderate, Serious or Catastrophic	A higher level of response is required in these circumstances. The *Being Open* policy is implemented.	*The Head of Risk & Legal Services and Medical Director* must be notified immediately and be available to provide support and advice during the *Being Open* process if required.

Appendix 4 – Equality Impact Assessment Tool

To be completed when submitted to the appropriate committee for consideration and approval.

Being Open Policy

		Yes/No	Comments
1.	**Does the document/guidance affect one group less or more favourably than another on the basis of:**	No	
	• Race	No	
	• Ethnic origins (including gypsies and travellers)	No	
	• Nationality	No	
	• Gender (incl transgender)	No	
	• Culture	No	
	• Religion or belief	No	
	• Sexual orientation including lesbian, gay and bisexual people	No	
	• Age	No	
	• Disability - learning disabilities, physical disability, sensory impairment and mental health problems	No	
2.	**Is there any evidence that some groups are affected differently?**	No	
3.	**If you have identified potential discrimination, are there any exceptions valid, legal and/or justifiable?**	N/A	
4.	**Is the impact of the document/guidance likely to be negative?**	N/A	
5.	**If so, can the impact be avoided?**	N/A	

6.	**What alternative is there to achieving the document/guidance without the impact?**	N/A	
7.	**Can we reduce the impact by taking different action?**	N/A	

If you have identified a potential discriminatory impact of this procedural document, please refer it to Brian Golding Associate Director of Estates and Facilities, 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 Brian Golding Associate Director of Estates and Facilities.