York Teaching Hospital NHS
NHS Foundation Trust

Being Open with Patients Policy

This policy and procedures may evoke safeguarding adults concerns and as such please refer to the Safeguarding Adults Policy or contact the Trust Safeguarding Adults Team for guidance. This policy and procedures may evoke the need to follow the Mental Capacity Act. Please refer to the Mental Capacity Guidance or contact the Trust Safeguarding Adults Team for guidance.

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Links to Organisational/Service Objectives, business plans or strategies	Patient Safety Strategy Risk Management Strategy

Executive Summary

This policy exists to ensure that patients and their families are told openly about patient safety incidents that affect them and receive an appropriate apology and are kept informed of investigations

This is a controlled document. Whilst this document may be printed, the electronic version is maintained on the Q-Pulse system under version and configuration control. Please consider the resource and environmental implications before printing this document.

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.

Version	Date Approved	Version Author	Status & location	Details of significant changes
1	1 May 2008	Nichola Greenwood	Withdrawn, held on Horizon Archive	New policy
2	May 2008	Nichola Greenwood	Held on Horizon	New Template Further emphasis on monitoring arrangements
3	June 2010	Elaine Miller	Horizon	RMSAT
4	May 2014	Helen Noble	Horizon	Patient circumstances
5	December 2014	Helen Noble	Staffroom	Duty of Candour

Contents

Being Open and Duty of Candour

This key policy describes a duty of Being Open when harm events occur, it incorporates the 'Duty of Candour' which is a statutory obligation since November 2014 and reinforces the fundamental obligation to be open and honest in the event of an incident where patient harm has occurred. **ALL** moderate and severe harms must be handled and reported under Being Open, the pivotal feature of which is early acknowledgement, explanation and apology.

The Act criminalises NHS bodies that fail to notify and apologise to their patients for incidents that have caused them harm. It includes "any unintended or unexpected incident that occurred in respect of a service user that, in the reasonable opinion of a health care professional, could result in, or appears to have resulted in a) 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".

Recognised complications must be notified, even where the patient has been warned in advance and there has been no failure of care.

What should be reported under the Duty of Candour

Anything unintended or unexpected if it causes or is expected to cause:

- Death or severe harm relating to an incident/action rather than a disease
- Moderate harm that is significant and requires a moderate increase in treatment and harm that is significant but not necessarily permanent
- Prolonged psychological harm for a minimum of 28 continuous days.

What is not relevant to the Duty of Candour but where an apology should be given and the incident reported and investigated internally

- Any incident which results in low harm
- Any near miss

- **Executive Summary**

All patient safety incidents causing harm should be acknowledged and reported as soon as they are identified.

Ensure confidentiality at all stages of the process.

Patients and carers should be told what happened as soon as practicable and if possible agree what further enquiries are appropriate. They should be provided directly with information relevant to the incident.

An apology should be given and clear reference made in the case notes of the discussion.

Treat patients and relatives sympathetically and with consideration and compassion throughout. Provide information on accessing the Patient Advisory and Liaison Services and other relevant support groups.

Managers should ensure staff feel supported throughout the investigation.

Root Cause Analysis (RCA) should be used to uncover the underlying causes of the patient safety incident

Ensure a multi-disciplinary discussion takes place with the patients and/or their carers following an incident that led to harm and document this including reference to any planned investigation. Inform the service user in writing of the original notification and the results of any further enquiries.

Disseminate findings to all staff so they can learn from patient safety incidents. In cases of moderate/severe harm, patients, relatives and carers should be offered a written summary of the investigation and outcomes.

1 Introduction & Scope

This policy will apply to all staff working for York Teaching Hospital NHS Foundation Trust who have a role in providing safe care.

The Trust's ultimate objective is to be trusted to deliver safe, effective healthcare to our community and this policy supports this in delivering the Trust Values.

The principles of Being Open must be applied to any incident, complaint or claim which results in harm to the patient as a result of healthcare treatment provided in the Trust.

It is a requirement under the NHS Standard Contract, 2013/14, to ensure that patients and their families are told openly about patient safety incidents that affect them. The Trust must ensure those patients and their families:

- Receive appropriate apologies
- Are kept informed of investigations
- Are supported to deal with the consequences

This policy should also be read in conjunction with the Trust Adverse Incident Reporting Policy and Serious Incident policy (available on Staffroom).

2 Definitions / Terms used in policy

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 National Patient Safety Agency 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 the underlying causes

Patient Safety Incident - 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

Being open involves:

- Acknowledging, apologising and explaining when things go wrong
- Conducting a thorough investigation into the incident and reassuring patients, their families and carers that lessons learned will help prevent the incident recurring
- Providing support for those patients, their families/carers and staff involved, to cope with the physical and psychological consequences of what happened.

It is important to remember that saying sorry is not an admission of liability and is the right thing to do.

The existence of this policy meets the requirements outlined in the NPSA Safer Practice Notice No.10 and the NHLSA (2013) “Saying sorry is the right thing to do” guidance.

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”:

You must be open and honest with patients if things go wrong. If a patient under your care has suffered harm or distress, you should:

- *Put matters right (if that is possible)*
- *Offer an apology*
- *Explain fully and promptly what has happened and the likely short-term and long-term effects*

"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 2001 p10)

4 Training

There is no formal training associated with this policy. Section 8 describes the process that should be used. Where further clarification is required this should be obtained from the policy author.

5 Trust Associated Documentation

- Risk Management Policy & Procedure
- Adverse Incident Reporting Policy
- Serious Incident Policy
- Claims Policy and Procedure
- Concerns and Complaints Policy
- Disciplinary Policy
- Consent Policy
- Information Governance Policy
- Discharge Policy
- Health and Safety Policy
- Resuscitation Policy
- Whistle blowing Policy
- Safeguarding Policies.

6 External References

- National Patient Safety Agency (2004),Seven Steps to patient safety: A guide for NHS staff, NPSA, London
- National Health Service Litigation Authority (2009) Apologies and Explanations, Letter to all Chief Executives, and Finance Directors all NHS bodies, NHSLA, London
- General Medical Council,Good Medical Practice (2013), Protecting patients guiding doctors (3rd edition),General Medical Council, London
- Being Open – Communicating Patient Safety Incidents to patients and their carers,NPSA 2009
- NPSA Safer Practice Notice, No 10.
- Building a Culture of Candour: a review of the threshold for the duty of candour and of the incentives for care organisations to be candid, March 2014
- A promise to learn-a commitment to act, Improving the Safety of Patients in England. National Advisory Group on Safety of Patients in England. August 2013
- Mental Capacity Act 2005
- Both the revised (2013) NHS constitution and a guidance handbook are available to download at www.england.nhs.uk/2013/03/26/nhs-constitution/
- The Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry, February 2013
- NPSA(2007) Definitions of degrees of harm
- Further information and e-learning module can be found at www.npsa.nhs.uk/

7 Ten Principles of Being Open (NPSA 2009)

The following set of principles has been developed to help healthcare organisations create and embed a culture of *Being Open.*

i. Acknowledgement

- All patient safety incidents, complaints and claims 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. 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 should be given a step-by-step explanation of what happened, that considers their individual needs and that is delivered openly and clearly.
- 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.
- 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. 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.
- 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.
- **An apology is not an admission of liability.**

iv. 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
- 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. Professional Support

- The Trust's Open and Just 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.
- Staff should not be **unfairly** exposed to punitive disciplinary action, increased medico-legal risk or any threat to their registration.
- 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.

vi. Risk Management and Systems Improvement

- The principles of Root Cause Analysis (RCA) should be applied 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. 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. 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. 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, Patient Safety Group, Health Safety and Non-Clinical Risk Group and Board of Directors.

ix. Confidentiality

- Full respect must be given to the patient's and/or their carer's and staff's privacy and confidentiality.
- Details of a patient safety incident, complaint or litigation 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 the SI Group, Risk Review meetings, Directorate meetings. 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. 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, by the relevant clinicians and managers, if possible.

8 The Being Open Process

8.1 Incident Detection or Recognition

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.

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 defined as Adverse Incidents, Critical Incident or Serious Incidents (SI) the following should be undertaken:

- acknowledgement and apology
- completion of Datix incident form
- incident investigation.

8.2 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 the 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.

8.3 Criminal or Intentional Unsafe Act

- Patient safety incidents are almost always unintentional.

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.

8.4 Initiating the Being Open Process

Initial Assessment to Determine Level of Response

All incidents should be initially assessed to determine the level of response required. The level of response to a patient safety incident depends on the nature of the incident (see Appendix 1).

Preliminary Team Discussion

- A decision will be made by the Trusts SI decision makers in accordance with the Trust's SI Policy, as to whether the patient safety incident should be declared as an SI/CI. If so, a Lead Investigator will be appointed to lead the investigation.
- If an SI/CI 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 agree their response to the incident.
- Managers should also provide information on the support systems currently available for professionals distressed by patient safety incidents. These include counseling services offered by their professional bodies, stress management courses for staff that have the responsibility for leading *Being Open* discussions and mentoring for staff who have recently taken on a *Being Open* leadership role.
- Managers should also be mindful of the Trust's responsibilities under the Stress Management policy (available on Staffroom).

8.5 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.

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

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. The individual should have received training in communication and should:

- preferably be known to the patient and/or their carers
- have a good grasp of the facts
- be senior enough or have sufficient experience and expertise in relation to the type of patient safety incident
- avoid excessive use of medical jargon
- should offer an apology, reassurance and feedback to patients and/ or their carers
- be culturally aware and informed about the specific needs of the patient and/ or their carers.

In exceptional circumstances if the healthcare professional cannot attend the meeting they may delegate an appropriate substitute. The qualifications, training and scope of responsibility of this person should be clearly defined. This is essential for effective communication with the patient, their family and carers without jeopardizing the rights of the healthcare professional, or their relationship with the patient.
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 from within the same clinical specialty.

Responsibilities of junior healthcare professionals

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

- the incident resulted in low harm
- they have expressed a wish to be involved in the discussion with the patient, their family and carers
- the senior healthcare professional responsible for the care is present for support
- the patient, their family and carers agree.

However trainees should be offered the opportunity to give an apology where appropriate.

8.7 Patient safety incidents related to the environment

In such cases a senior manager of the relevant service will be responsible for communicating with the patient and/or their carer. Where injury has occurred related to the environment, the Consultant may be present at the initial *Being Open* discussion to assist in provide information on the likely effects of the injury.

8.8 Involving healthcare staff who made mistakes

Some patient safety incidents that resulted in moderate/severe harm, or death will arise from errors made by healthcare staff. 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.

Initial *Being Open* discussion

This is the first part of an ongoing communication process. Many of the points raised should be expanded on in subsequent meetings with the patient, their family and carers.

- There should be an expression of genuine sympathy, regret and an apology for the harm that has occurred.
- 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 interpretation and translation
- 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.

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

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

8.9 To be recorded in the case notes:

- The chronology of clinical and other relevant facts.
- Details of the patient's, their family and carers' questions and responses given.
- A record of the apology and discussion between the family/carers and lead clinician.
- A summary of known factors that contributed to the incident.
- Information on what has been and will be done in response to this event in order to avoid recurrence of the incident and how these improvements will be monitored.

8.10 Particular patient circumstances

The approach to *Being Open* may need to be modified according to the patient's personal circumstances.

When a patient dies:

- consider information needed on the processes that will be followed to identify the cause of death
- consider open channels of communication, ensuring where appropriate contact details are given to family and carers should any further information be required.

Usually the *Being Open* discussions and any investigations occur before the Coroner's inquest. In certain circumstances the Trust may consider it appropriate to wait for the Coroner's inquest before holding the discussion with the family. 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 carers will be provided with more information.

Patient 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 incident information is when advised to do so by a consultant psychiatrist who feels it would cause adverse psychological harm.

Patients with cognitive impairment

Some individuals have conditions that limit their ability to understand what is happening to them. They may have authorized a person to act on their behalf by a Lasting Power of Attorney. In these cases, steps must be taken to ensure that this extends to decision making and to the medical care and treatment of the patient.
The *Being Open* discussion would be conducted with the holder of the power of attorney. Where there is no such person, the clinicians may act in the patient's best interest in deciding who the appropriate person is to discuss incident information with, regarding the patient as a whole and not simply their medical interests. However, patients with cognitive impairment should, where possible, be involved directly in communications about what has happened. Where appropriate, a referral to the Safeguarding Team should be considered.

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.
If the patient is not cognitively impaired they should be supported in the *Being Open* process by alternative communication methods (e.g. 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.

Patients with specific communication requirements

A number of patients will have particular communication difficulties, such as hearing impairment. Please ensure you meet attendees specific requirements for example book an interpreter, information available in preferred format e.g. large print.

Patients who do not agree with the information provided

Sometimes the patient, their family and carers may not accept the information provided or may not wish to participate in the *Being Open* process. In this case, the following should be considered:

- Look for a mutually agreeable solution.
- Write a comprehensive list of the points that the patient, their family and carers disagree with and reassure them you will follow up these issues.
- Ensure the patient, family and carers are fully aware of the formal complaints procedure.

8.11 Documentation

The incident report and record of the investigation and analysis process will be recorded on the incident database (Datix). Staff should ensure completion of the tick box on the Datix form to indicate that the patient/family have been informed.

9 Equality Analysis

In the development of this policy the Trust has considered evidence to ensure understanding of the actual / potential effects of our decisions on people covered by the equality duty. A copy of the analysis is attached at Appendix 2.

10 Accountability

Operational implementation, delivery and monitoring of the policy reside with:-

- The Medical Director is accountable for the effective implementation of this policy across the Trust.

11 Consultation, Assurance and Approval Process

11.1 Consultation Process

The Trust will involve stakeholders and service users in the development of its policies.

Consultation has taken place with the following stakeholders:

- Medical Director
- Chief Nurse
- Patient Safety Group
- Risk and Legal
- Internal Audit

11.2 Quality Assurance Process

Following consultation with stakeholders and relevant consultative committees, this policy has been through quality assurance checks prior to being reviewed by the authorising committee to ensure it meets the standards for the production of policy and equalities legislation and is compliant with the Development and Management of Policies policy.

11.3 Approval Process

The approval process for this policy complies with that detailed in section 6.3 of the Development and Management of Policies Policy. The approving body for this policy is the Patient Safety Group.

The Checklist for Review and Approval has been completed and is included as Appendix 3 .

12 Review and Revision Arrangements

On reviewing this policy, all stakeholders identified in section 6.1 will be consulted. The persons responsible for review are:

- Patient Safety Team

Subsequent changes to this policy will be detailed on the version control sheet at the front of the policy and a new version number will be applied.

Subsequent reviews of this policy will continue to require the approval of the Patient Safety Group.

13 Dissemination and Implementation

13.1 Dissemination

Once approved, this policy will be brought to the attention of all relevant staff working at and for York Hospital NHS Foundation Trust following the completed Plan for dissemination of the policy (See Appendix 4)

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

13.2 Implementation of Policies

This policy will be implemented throughout the Trust by communication with all Clinical Directors, Directorate Managers, Lead Investigators, Risk Reviewers, Matrons and Consultants.

In addition to this the Policy Author will collate the following evidence to demonstrate compliance with this policy:

- Annual Audit of Serious Incidents, complaints and other adverse incidents
- Patient Safety Group Agendas, minutes and other papers

14 Document Control including Archiving Arrangements

14.1 Register/Library of Policies

This policy will be stored on Staffroom, in the policies and procedures section and will be stored both in an alphabetical list as well as being accessible through the portal's search facility and by group. The register of policies will be maintained by the Healthcare Governance Directorate.

If members of staff want to print off a copy of a policy they should always do this using the version obtainable from Staffroom but must be aware that these are only valid on the day of printing and they must refer to the intranet for the latest version. Hard copies must not be stored for local use as this undermines the effectiveness of an intranet based system.

14.2 Archiving Arrangements

On review of this policy, archived copies of previous versions will be automatically held on the version history section of each policy document on Q-Pulse. The Healthcare Governance Directorate will retain archived copies of previous versions made available to them. Policy Authors are requested to ensure that the Policy Manager has copies of all previous versions of the document.

It is the responsibility of the Healthcare Governance Directorate to ensure that version history is maintained on Staffroom and Q-Pulse.

14.3 Process for Retrieving Archived Policies

To retrieve a former version of this policy from Q-Pulse, the Healthcare Governance Directorate should be contacted.

15 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.

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:

15.1 Process for Monitoring Compliance and Effectiveness

In order to fully monitor compliance with this policy and ensure effective review, the policy will be monitored as follows:-

Minimum requirement to be monitored	Process for monitoring	Responsible Individual/ committee/ group	Frequency of monitoring	Responsible individual/ committee/ group for review of results	Responsible individual/ committee/ group for developing an action plan	Responsible individual/ committee/ group for monitoring of action plan
a. process for encouraging open communication between healthcare organisations, healthcare teams, staff and patients and their carers.	Audit of two SIs Ten randomly selected claim files per year Ten randomly selected complaint files per year 20 randomly selected patient incident reports where differing degrees of harm have been identified	All this will be undertaken by the use of Audit Checklists and will be undertaken by the Risk and Legal Services Senior Managers.	Quarterly Annual	SI Group Patient Safety Group	SI Group Patient Safety Group	SI Group Patient Safety Group

Minimum requirement to be monitored	Process for monitoring	Responsible Individual/ committee/ group	Frequency of monitoring	Responsible individual/ committee/ group for review of results	Responsible individual/ committee/ group for developing an action plan	Responsible individual/ committee/ group for monitoring of action plan
b. process for acknowledging, apologising and explaining when things go wrong	See a)	See a)	See a)	See a)	See a)	See a)
c. Requirements for truthfulness, timeliness and clarity of communication	See a)	See a)	See a)	See a)	See a)	See a)
d. Provision of additional support as required	As part of reviewing the documentation the audit should consider 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	Risk and Legal Services Senior Managers	See a)	See a)	See a)	See a)

Minimum requirement to be monitored	Process for monitoring	Responsible Individual/ committee/ group	Frequency of monitoring	Responsible individual/ committee/ group for review of results	Responsible individual/ committee/ group for developing an action plan	Responsible individual/ committee/ group for monitoring of action plan
e. Requirement For documenting all communication	See a)	See a)	See a)	See a)	See a)	See a)

15.2 Standards/Key Performance Indicators

CQC Essential standards of Quality and Safety, outcome 1b,4b,16b March 2010
NHS Standard Contract
Care Act 2014

16 Appendices

Appendix 1: Harm NRLS Definition and Grading of Patient Safety Incidents to determine level of response
Appendix 2: Equality Analysis
Appendix 3: Checklist for Review and Approval
Appendix 4: Implementation Plan

Appendix 1
Harm NRLS Definition

No Harm	Impact prevented: any patient safety incident that had the potential to cause harm but was prevented, resulting in no harm to the person(s) receiving NHS-funded care. Impact not prevented: any patient safety incident that ran to completion but no harm occurred to the person(s) receiving NHS-funded care.
Low Harm	Any patient safety incident that required extra observation or minor treatment, and caused minimal harm to the person(s) receiving NHS-funded care.
Moderate Harm	Any patient safety incident that resulted in a moderate increase in treatment, and which caused significant but not permanent harm to the person(s) receiving NHS-funded care.
Severe Harm	Any patient safety incident that resulted in permanent harm to the person(s) receiving NHS-funded care.
Death	Any patient safety incident that directly resulted in the death of the person(s) receiving NHS care

Grading of Patient Safety Incidents to determine level of response

Incident	Level of Response
No harm (including prevented patient safety incidents)	Patients are not usually contacted or involved in investigations and these types of incidents are outside the scope of Being Open Policy. Individual Healthcare Organisations decide whether 'no harm' events (including prevented patient safety incidents)are discussed with patients, their families and carers, depending on local circumstances and what is in the best interest of the patient.
Low Harm	Unless there are specific indications or the patient requests it, the communication investigation and analysis, and the implementation of changes will occur at local service delivery level with the participation of those directly involved in the incident. 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. Communication should take the form of an open discussion between the staff providing the patient's care and the patient, their family and carers and formally documented. **Apply the principles of *Being Open***
Moderate harm, severe harm or death	A higher level of response is required at department or local level in these circumstances. There must be an open and documented discussion/investigation planned by the lead investigator with the patient/family/carers. A discussion/decision needs to be made as to whether external investigators are required **Apply the *Being Open* process.**

Appendix 2 Equality Analysis

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

Name of Policy	Being Open with Patients Policy
1.	**What are the intended outcomes of this work?** To ensure that patients and their families are told openly about patient safety incidents that affect them and receive an appropriate apology, support and are kept informed of investigations
2	**Who will be affected?** Patients, relatives, carers, staff
3	**What evidence have you considered?** NPSA Safer Practice Notice No.10 2005 NHLSA (2013) "Saying sorry is the right thing to do" guidance. Chief Medical Officer's consultation document, *Making Amends, DH 2003* Comments from Medical Director, Quality and Safety Team, Patient Safety Group members, Virtual Policy Review Group, Head of Risk and Legal, Internal Audit and Directorate Managers and Clinical *Leads* (May – August 2014)
a	**Disability –** No impact
b	**Sex –** No impact
c	**Race -** Interpreters would be obtained where appropriate.
d	**Age** – No impact
e	**Gender Reassignment** -
f	**Sexual Orientation** - No impact
g	**Religion or Belief** - No impact
h	**Pregnancy and Maternity**. - No impact
i	**Carers –** This policy exists to ensure that carers and relatives are supported and involved and kept informed in the event of an adverse incident, providing that the patient has given consent for information to be released to them.
j	**Other Identified Groups** – None identified

4.	**Engagement and Involvement**	
a.	Was this work subject to consultation?	Yes
b.	How have you engaged stakeholders in constructing the policy	By circulation of the document for consultation and many have provided feedback and suggestions for improvement
c.	If so, how have you engaged stakeholders in constructing the policy	As above
d.	For each engagement activity, please state who was involved, how they were engaged and key outputs The Medical Director, Quality and Safety Team, Patient Safety Group members, Head of Risk and Legal, Internal Audit and Directorate Managers and Clinical Leads have all had copies of the document circulated to them and their feedback has been used to ensure that the document is workable and fully informs and supports patients and their carers/relatives. (May – August 2014) The key outcome is a document which works in practice and ensures that staff are open, honest and compassionate with patients, carers and relatives in the event of a patient safety incident occurring.	
5.	**Consultation Outcome** *Now consider and detail below how the proposals impact on elimination of discrimination, harassment and victimisation, advance the equality of opportunity and promote good relations between groups*	
a	Eliminate discrimination, harassment and victimisation	No impact
b	Advance Equality of Opportunity	No impact
c	Promote Good Relations Between Groups	Positive impact
d	What is the overall impact?	No impact
	Name of the Person who carried out this assessment: Head of Patient Safety	
	Date Assessment Completed May 2014	
	Name of responsible Director Medical Director	

If you have identified a potential discriminatory impact of this procedural document, please refer it to the Equality and Diversity Committee, together with any suggestions as to the action required to avoid/reduce this impact.

Appendix 3 Checklist for Review and Approval

Authors need to be confident that their policy meets all of the criteria identified below before submitting this to the appropriate committee(s) for consideration and approval.

	Title of document being reviewed:	Yes/No	Comments
1.	**Development and Management of Policies**		
	Is the title clear and unambiguous and meets the requirements of page 3 of the Development and Management of Policies Policy?	Y	
	Is it clear whether the document is a policy, procedure or protocol?	Y	
	Does the style and format of the policy meet the requirements of section 3.2 of the Development and Management of Policies Policy?	Y	
	Does the policy contain a list of definitions of terms used?	Y	
2.	**Rationale**		
	Are reasons for development of the document stated?	Y	
3.	**Development Process**		
	Is the method described in brief?	Y	
	Are individuals involved in the development identified?	Y	
	Do you feel a reasonable attempt has been made to ensure relevant expertise has been used?	Y	
	Is there evidence of consultation with all relevant stakeholders and users?	Y	
4.	**Content**		
	Is the document linked to a strategy?	Y	Patient Safety Strategy Risk Management Strategy
	Is the objective of the document clear?	Y	
	Is the target population clear and unambiguous?	Y	
	Are the intended outcomes described?	Y	
	Are the statements clear and unambiguous?	Y	

	Does it meet all of the requirements of external agencies/bodies where applicable?	Y	
5.	**Evidence Base**		
	Is the type of evidence to support the document identified explicitly?	Y	
	Are supporting references cited in full?	Y	
	Are local/organisational supporting documents referenced?	Y	
	Are all associated documents listed and updated?	Y	
6.	**Approval**		
	Does the document identify which committee/group will approve it?	Y	
	If appropriate, have the staff side committee (or equivalent) approved the document?	N/A	
7.	**Dissemination and Implementation**		
	Does the dissemination plan identify how this will be done and is it clear?	Y	
	Does the plan include the necessary training/support to ensure compliance?	Y	
	Does the policy detail what evidence will be collated to demonstrate compliance with it?	Y	
8.	**Document Control**		
	Does the document identify where it will be held?	Y	
	Have archiving arrangements for superseded documents been addressed?	Y	
9.	**Process for Monitoring Compliance**		
	Are there measurable standards or KPIs to support monitoring compliance of the document?	Y	
	Is there a plan to review or audit compliance with the document?	Y	
10.	**Review Date**		
	Is the review date identified?	Y	
	Is the frequency of review identified? If so, is it acceptable?	Y	

11.	Overall Responsibility for the Document		
	Is it clear who will be responsible for coordinating the dissemination, implementation, evidencing, monitoring and review of the documentation?	Y	

Policy Owner's Approval			
If you are happy to approve this document, please sign and date it and forward to the chair of the committee/group where it will receive final approval. (This can be completed electronically with an electronic signature)			
Name	Dr A Turnbull	Date	May 2014
Signature	*Dr A Turnbull*		
Committee Approval			
If the Chair or Vice Chair of the committee is happy to approve this document, please sign and date here and enter the name of the committee/group. The Policy Author will contact the secretary/administrator of the committee/group to obtain a signed copy of this checklist. The Policy Author will then submit this together with the approved policy (ensuring the "draft" watermark is removed) to the Policy Manager for logging and publication.			
Name	Dr A Turnbull	Date	3 December 2014
Signature	*Dr A Turnbull*		
Committee/ Group title	Patient Safety Group		

For Policy Manager's use only	
Is there a signed and completed Checklist for Review and Approval accompanying the policy?	Y
Is the policy logged on Qpulse?	Y
Has the old version of the policy been archived? (if applicable)	Y
Has the policy been published on Staffroom?	Y
Author notified that policy has been published?	Y

Appendix 4 Plan for the dissemination of a policy

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

Title of document:	Being Open with Patients Policy
Date finalised:	December 2014
Previous document in use?	Yes
Dissemination lead	Head of Patient Safety
Which Strategy does it relate to?	Patient Safety/Risk Management
If yes, in what format and where?	Electronic – stated departments
Proposed action to retrieve out of date copies of the document:	Healthcare Governance Directorate will hold archive

To be disseminated to:	All staff
Method of dissemination	• Article for inclusion in team brief • Published on Staffroom
who will do it?	Policy Author/Policy Manager
and when?	On approval
Format (i.e. paper or electronic)	Electronic

Dissemination Record

Date put on register / library	On approval
Review date	December 2017
Disseminated to	As above
Format (i.e. paper or electronic)	Electronic
Date Disseminated	On approval
No. of Copies Sent	As above
Contact Details / Comments	Helen Noble Extn 771 2341