Oxfordshire NHS
Primary Care Trust

Master ID	**141**	**Version**	**2**

Document Name	**Being Open Policy**
Type	General (non-clinical)
Date adopted	01 November 2010
Review Date	18 November 2013
Responsibility for Review	Clinical Quality and Standards Facilitator
Equality Impact Assessment Performed	Yes

Approved by

Executive Board

Oxfordshire NHS
Primary Care Trust

Being Open Policy

Contents

		Page No.
1.0	Introduction	**3**
2.0	Scope of this Policy	**4**
3.0	Key Elements of Being Open	**4**
4.0	Links to other Policies	**5**
5.0	Ten Principles of Being Open	**6**
6.0	The Being Open Process	**9**
7.0	Documentation	**17**
8.0	Follow-up Discussions	**18**
9.0	Completing the process	**19**
10.0	Training and Support	**20**
11.0	Monitoring and Feedback	**21**
12.0	References	**22**
	Appendix A - **Special Circumstances**	**23**
	Appendix B – **Overview of the Being open process**	**26**
	Appendix C- **10 Principles of Being open**	**27**

1.0 Introduction

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 the PCT/CHO and other healthcare organisations, healthcare teams and patients and/or their carers.

The policy is aimed at any healthcare staff responsible for ensuring the infrastructure is in place to support openness between healthcare professionals and patients and/or their carers following an incident. This document gives advice on the 'dos and don'ts of communicating with patients and/or their carers following harm.

In the same way that staff who report incidents are treated fairly after reporting an incident, then patients should be treated fairly if they have been involved in one. If a staff member does not report an incident, then nothing can be done to redress either its consequences, or to prevent its reoccurrence and it can escalate into something far more serious. In the same way, not informing a patient that has been involved in an incident, who then finds out later, will have removed all trust from that patient, they will be angry and upset and may be caused additional stress. All this can be avoided by Being Open

This policy is based on guidance from the National Patient Safety Agency, *Being Open, Saying Sorry When Things Go Wrong, Communicating patient safety incidents with patients, their families and cares*, 2009. These encourage healthcare staff to apologise to patients harmed as a result of healthcare treatment and explain that an apology is not an admission of liability:

The Chief Medical Officer's consultation document, *Making Amends,* 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 serious harm, through misadventure, or for any other reason, you should act immediately to put matters right, if that is possible. You should explain fully 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 under 16 and lacks the maturity to consent to treatment, you should explain the situation honestly to those with parental responsibility for the child. Further information on how to deal with specific circumstances is described in appendix A.

Elements of the *Being Open* policy are also related to other government initiatives and recommendations from major inquiry reports, including:

- recommendations in the 5th Shipman Inquiry Report about appropriate documentation of patient deaths
- the NHS Litigation Authority's *Striking the Balance* initiative on providing support for healthcare professionals involved in a complaint, incident or claim

2.0 Scope of this Policy

Although the PCT's Incident and Near Miss Reporting and Management Policy encourages staff to report all patient safety incidents, including those where there was no harm or it was a prevented patient safety incident (near miss), this policy only relates to those incidents that are Moderate (3), Major (4) or Catastrophic (5) on the PCT's Risk Consequence Grading Scale (Risk Management Strategy). Incidents that score as Insignificant (1) or Minor (2) do not have to be dealt with using this policy.

Although this policy is only applicable for incidents in which PCT patients and staff are directly involved, the PCT encourages all groups of independent contractors to adopt the policy or to develop similar procedures also based on the National Patient Safety Agency's guidance.

3.0 Key Elements of Being Open

Effective communication with patients begins at the start of their care and should continue throughout their time with the PCT. This should be no different when a patient safety incident occurs. Openness about what happened and discussing patient safety incidents promptly, fully and compassionately can help patients cope better with the after-effects. Patient safety incidents also incur extra costs through litigation and further treatment; openness and honesty can help prevent such events becoming formal complaints and litigation claims. Openness when things go wrong is fundamental to the partnership between patients and those who provide their care.

Being Open involves:

- acknowledging, apologising and explaining when things go wrong
- conducting a thorough investigation into the incident and reassuring patients and/or their carers that lessons learned will help prevent the incident recurring

- providing support to cope with the physical and psychological consequences of what happened

For healthcare staff, Being Open has several benefits, including:

- satisfaction that communication with patients and/or their carers following a patient safety incident has been handled in the most appropriate way
- improving the understanding of incidents from the perspective of the patient and/or their carers
- the knowledge that lessons learned from incidents will help prevent them happening again
- having a good professional reputation for handling a difficult situation well and earning respect among peers and colleagues
- gain confidence in how to communicate when things go wrong
- feel supported in apologizing and explaining to patients, their families and carers

Being Open benefits for patients include:

- will receive meaningful apology and explanation when things go wrong
- Feel that their concerns and distress have been addressed
- Feel reassured that the organization will learn lesions to prevent harm happening to someone else
- Reduce the trauma felt when things go wrong
- Have greater respect and trust for the organization
- Feel reassured that they will continue to be treated according to their clinical needs

Being Open benefits for the organizations and teams include:

- The organization and/or the team will gain reputation of trust and respect
- The open culture will be reinforced
- It could potentially reduce the cost of litigation
- It will improve the patients experience and satisfaction with the organization
- Gain reputation for supporting staff when things go wrong
- Has a greater opportunity to learn when things go wrong
- Embodies the NHS Constitution for England pledge to patients around Being open

4.0 Links to other Policies

The Being Open Policy links with:

- Capability Policy and Procedure
- Complaints Policy
- Complaints Procedure for Primary Care Practitioners

- Disciplinary Policy and Procedure
- Incident and Near Miss Reporting and Management Policy
- Information Governance Policy
- Process for Investigation and Root Cause Analysis of Adverse Incidents, Near Misses, Claims and Complaints
- Risk Management Strategy
- Consent Policy

5.0 Ten 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 in a truthful and open manner by an appropriately nominated person. This person can be anyone that the patient is familiar with, or a senior member of staff on duty. Care must be taken to ensure that patients do not have to wait for one particular member of staff to become available before being told of the incident (see 6.4.1). 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 might 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. This

should be in the form of an appropriately worded apology, as early as possible.

Both verbal and written apologies should be given. The decision on which staff member should give the apology should consider 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, including: setting up a more formal multidisciplinary *Being Open* discussion with the patient and/or their carers, fear and apprehension, or lack of staff availability. 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 PCT 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 Service (PALS) and other relevant support groups such as Bereavement services should be given to the patient as soon as it is possible.

v. Principle of professional support

The PCT'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) 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

Where there is reason for the PCT to believe a member of staff has committed a **punitive or criminal act**, the PCT 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.

The PCT's Open and Fair Culture statement is detailed in Appendix A.

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. Only staff who have undertaken training in RCA should be asked to undertake investigations of this nature

vii. Principle of multidisciplinary responsibility

This policy applies to all staff who have key roles in the patient's care. Most healthcare provision involves multidisciplinary 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 clinical 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 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 through manager's feeding back locally.

These actions are monitored to ensure that the implementation and effects of changes in practice following a patient safety incident.

ix. Principle of confidentiality

Full respect should be given to the patient's and/or their carer's and staff's privacy and confidentiality, in line with the CQC's guidance for outcome 19.

Details of a patient safety incident should at all times be considered confidential. The consent of the individual concerned should be sought prior to disclosing information beyond the clinicians involved in treating the patient, in line with CQC's guidance for Outcome 20. Where this is not practicable or an individual refuses to consent to the disclosure, disclosure may still be lawful if justified in the public interest or where those investigating the incident have statutory powers for obtaining information. Communications with parties outside of the clinical team should also be on a strictly need-to-know basis and, where practicable, records should be anonymous. 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.

6.0 The Being Open Process

6.1 Incident Detection or Recognition

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

A patient safety incident may be identified by:

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

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. The "Incident and Near Miss Reporting and Management Policy and Procedure - appendix 5 SUI process" should be implemented. This would include:

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

6.1.1 Patient safety incidents occurring elsewhere

A patient safety incident may have occurred in another organisation, not the PCT. The individual who first identifies the possibility of an earlier patient safety incident should notify the Quality and Clinical Standards Team who will then contact their equivalent at the organisation where the incident occurred and establish whether:

- the patient safety incident has already been recognised;
- the process of *Being Open* has commenced;
- if incident investigation and analysis is underway.

The *Being Open* process and the investigation and analysis of a patient safety incident should normally occur in the organisation where the incident took place.

6.1.2 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 Quality and Clinical Standards Team and/or the Chief Executive should be notified as soon as possible. If independent contractors operating within primary care are involved then the Primary Care Contract Manager should also be informed.

The taking of automatic punitive disciplinary action and inappropriate exclusion of staff from work following a patient safety incident will create a barrier to open reporting. Healthcare organizations should strive to identify the underlying causes of patient safety incidents (i.e. systems failure or latent conditions) by using methods such as Root Cause Analysis (RCA). They should ensure incidents investigations do not focus exclusively on the individual to provide care.
Non-punitive approach means that disciplinary action will not be taken against a member of staff for reporting an incident, except in the rare circumstances where there is evidence of:

- *Gross professional or gross personal misconduct*
- *Repeated breaches of acceptable behaviour or protocol*
- *An incident that results in a police investigation.*

6.2 Initiating the Being Open Process

6.2.1 Preliminary team discussion

As described in the “Incident and Near Miss Reporting and Management Policy and Procedure - appendix 5 SUI process” the multidisciplinary team, including the most senior health professional involved in the patient safety incident, 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
- 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 that 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
- ensure a clear communication strategy is in place

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.

6.2.2 Initial assessment to determine level of response

All incidents should be initially assessed by the team to determine the level of response required and then discussed with the designated Risk Manager or equivalent if it requires a high level of response. The level of response to a patient safety incident depends on the nature of the incident. Definitions for the following can be found in the relevant policy

Insignificant (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. It should be decided locally whether to communicate these incidents to patients, their families and carers, based on local circumstances and what is in the best interest of the patient.

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.

Apply the principles of Being open

Moderate, Major or death

A higher level of response is required in these circumstances. The Risk Manager or equivalent should be notified immediately and be available to provide support and advice during the *Being Open* process if required.

Apply the Being Open process

6.3 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.

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

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

This should be the most senior person responsible for the patient's care and/or someone with experience and expertise in the type of incident that has occurred. This could either be the patient's consultant, nurse consultant, or any other healthcare professional who has a designated caseload of patients. They should have received training in communication of patient safety incidents. Consideration also needs to be given to the characteristics of the person nominated to lead the *Being Open* process.

They 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 experience and expertise in relation to the type of patient safety incident to be credible to patients, carers and colleagues.
- have excellent interpersonal skills, including being able to communicate with patients and/or their carers in a way they can understand and avoiding excessive use of medical jargon.
- be willing and able to offer an apology, reassurance and feedback to patients and/ or their carers.
- be able to maintain a medium to long term relationship with the patient and/or their carers, where possible, and to provide continued support and information.
- be culturally aware and informed about the specific needs of the patient and/ or their carers.
- Contact Legal Services for advice as required.

6.4.2 Use of a substitute healthcare professional for the *Being Open* discussion

In exceptional circumstances, if the healthcare professional who usually leads the *Being Open* discussion cannot attend, they may delegate to an appropriately trained substitute. The qualifications, training and scope of responsibility of this person should be clearly delineated. This is essential for effective communication with the patient and/or their carers without jeopardising the rights of the healthcare professional, or their relationship with the patient. The substitute may be the clinician responsible for clinical risk (for example, the clinical governance director) or someone of similar experience.

6.4.3 Assistance with the initial *Being Open* discussion

The healthcare professional communicating information about a patient safety incident should be able to nominate a colleague to assist them with the meeting. Ideally this should be someone with experience or training in communication and *Being Open* procedures. The Quality and Clinical Standards Team or Legal Services should be contacted for advice as required.

6.4.4 Consultation with the patient regarding the healthcare professional leading the *Being Open* discussion

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.

6.4.5 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 and/or their carers.
- the senior healthcare professional responsible for the care is present for support.
- the patient and/or their carers agree.

Where a junior healthcare professional who has been involved in a patient safety incident asks to be involved in the *Being Open* discussion, it is important they are accompanied and supported by a senior team member. It is unacceptable for junior staff to communicate patient safety information alone or to be delegated the responsibility to lead a *Being Open* discussion unless they volunteer and their involvement takes place in appropriate circumstances (i.e., they have received appropriate training and mentorship for this role).

6.4.6 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 carers. A senior member of the multidisciplinary team should be present to assist at the initial *Being Open* discussion. The healthcare professional responsible for treating the patient should also be present to assist in providing information on what will happen next and the likely effects on the patient.

6.4.7 Involving healthcare staff who made mistakes

Some patient safety incidents that resulted in moderate harm, severe harm or death will result from errors made by healthcare staff while caring for the patient. In these circumstances the member(s) of staff involved may or may not wish to participate in the *Being Open* discussion with the patient 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 initial *Being Open* discussion.

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

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.
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. Carers and people close to the patient can be referred to the Coroner for more information.

Important Points:

- 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 multidisciplinary 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.
- 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 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 one member of staff who will acts as a contact point for them. Their role will be to provide both practical and emotional support in a timely manner.
- 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 information on the complaints procedure and offered assistance if they wish to make a complaint.
- 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.**

6.6 Notification

6.6.1 The Quality and Clinical Standards Team

In all cases the Quality and Clinical Standards Team should be informed either by telephone, electronically or by completion of the incident form. The National Patient Safety Agency will then receive anonymous notification of the incident through the National Reporting and Learning System. If there is indication that legal proceedings will be brought against it, the NHSLA should be involved.

6.6.2 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 Chief Executive, or if out of hours, the on call director must be notified immediately as per the reporting system detailed in the Incident and Near Miss Reporting and Management Policy and Procedure - appendix 5 SUI process

6.6.3 General practitioner

Consideration should be given to contacting the referring GP at an early time 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.

6.6.4 The Coroner

All cases of untimely, unexpected or unexplained death or suspected unnatural deaths need to be reported to the coroner. A coroner may request the case is not discussed with other parties until the facts have been considered. However this should not preclude a verbal and written apology or expression of regret where appropriate. In this situation it should be made clear to the family that a full discussion of the circumstances and any residual concerns will be arranged at a date to suit both parties after the coroner's assessment is finished. 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.

6.6.5 Relevant statutory/other bodies

The Incident and Near Miss Reporting and Management Policy details which external agencies should be informed of a patient safety incident and when this should occur. The Quality and Clinical Standards Team, Health and Safety Adviser or Community Health Oxfordshire Quality Team are responsible for notifying these relevant agencies such as the Strategic Health Authority, National Health Service Litigation Authority or Health and safety Executive.

7.0 Documentation

7.1 General

Throughout the *Being Open* process it is important to record discussions with the patient, their family and carers as well as the incident investigation. Required patient safety incident documentation includes:

- a copy of relevant medical information, which should be filed in the patient's medical records.
- incident reports.
- 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.

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

7.2 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, their families and carers and recorded in the patient's notes.

8.0 Follow-up Discussions

The follow-up discussions with the patient and/or their carers is an important step in the *Being Open* process. Depending on the incident and the timeline for the investigation there may be more then one follow-up discussion. 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 e.g. 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 if appropriate.
- a written record of the discussion should be kept and shared with the patient and/or their carers.
- all queries should be responded to appropriately.
- if completing the process at this point, the patient and/or their carers should be asked if they are satisfied with the investigation and a note of this made in the patient's records.
- the patient should be provided with contact details so that if further issues arise later there is a conduit back to the relevant healthcare professionals or an agreed substitute.

9.0 Completing the process

9.1 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.
- details of the patient's and/or their carer's concerns and complaints.
- a repeated apology for the harm suffered and any shortcomings in the delivery of care that led to the patient safety incident.
- a summary of the factors that contributed to the incident.
- information on what has been and will be done to avoid recurrence of the incident and how these improvements will be monitored.

It is expected that in most cases there will be a complete discussion of the findings of the investigation and analysis. 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.

9.2 Continuity of care

When a patient has been harmed during the course of treatment and requires further therapeutic management or rehabilitation, they should be informed, in an accessible way, of the ongoing clinical management plan. This may be encompassed in discharge planning policies addressed to designated individuals such as the referring GP when the patient safety incident has not occurred within the PCT.

Patients and/or their carers should be reassured that they will continue to be treated according to their clinical needs even in circumstances where there is a dispute between them and the healthcare team. They should also be informed that they have the right to continue their treatment elsewhere if they have lost confidence in the healthcare team involved in the patient safety incident.

9.3 Communication with the GP and other community care service providers for patient safety incidents not occurring in primary care

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

When the patient leaves the care of the PCT/CHO, a discharge letter should also be forwarded to the GP or appropriate community care service. It should contain summary details of:

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

It may be valuable to consider including the GP in one of the follow-up discussions either at discharge or at a later stage.

9.4 System Improvements

Any recommendations for systems improvements and changes implemented 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 Integrated Quality and Clinical Standards Committee via the Community Health Oxfordshire Clinical Quality and Governance Committee. Examples of good practice will be passed to the NPSA and SHA for sharing with the rest of the NHS.

9.5 Communication of changes to staff

Effective communication with staff 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 the PCT web site are all available to help communicate with staff.

9.6 Communication of lessons learned throughout the health service

The NPSA will publish patient safety alerts, safer practice notices and patient safety information notices through the Safety Alert Broadcast System to highlight common factors that cause patient safety incidents, and to publicise its advice and solutions to the service. The primary aim will be to help reduce the risk of such incidents recurring. It will also use its website, www.npsa.nhs.uk plus a number of specialist web resources, to share this and supporting background information with healthcare staff throughout the NHS.

10.0 Training and support

Professionals who have been involved directly in the incident, those with the responsibility for Being open discussions and those identified as senior clinical counselors should be given access to assistance , support and any information they need to fulfill their roles.

In order to provide this support the senior management should:

- Actively promote open and fair culture that fosters peer support and discourages the attribution of blame. They should work towards a culture where human error is understood to be a consequence of flaws in the healthcare system, not necessarily the individual.
- Educate all their staff about *Being open* and ensure they understand that apologizing to patients, their families and carers is not an admission of liability.
- 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. Healthcare staff may also benefit from individual feedback about the final outcome of the patient safety incident investigation.
- Provide opportunities with the clinical schedule for healthcare staff involved in the *Being open* process to discuss their involvement and/or the circumstances leading up to the patient safety incident and what they are going to say.
- Provide advice and training on the management of patient safety incidents, including the need for practical, social and psychological support, as part of a general training programme for all staff in clinical risk management and patient safety issues.
- Provide information on the support systems currently available for staff distressed by patient safety incidents. This includes counseling services offered by 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 *Being open* leadership role.
- Develop specific systems of support in their own organization through:
    1. staff support services(if these are not already in place; and
    2. senior clinical counselors

The PCT/CHO Incident Reporting e learning package available to all staff explains the Being Open process and provides a link to this policy.

The 1 day Root Cause Analysis training gives detail of this policy to senior managers who will be expected to undertake such investigations. Further advice is available and should be sought from the PCT/CHO Legal services Department and the PCT/CHO Quality and Clinical Standards Team

E-learning is available from the NPSA's website

11.0 Monitoring and Review of the policy

The results of Being Open discussions with patients and/or carers will be fed back by the manager leading the process and to the Quality and Clinical Standards Team. Implementation of the Being Open Policy will be recorded on the Datix Incident Management System to allow audit of the process.

The policy will be reviewed on a three year cycle by the Quality and Clinical Standards Team or more frequent if required.

12.0 References

"Being Open", National Patient Safety Agency, 2005

"Being Open", National Patient Safety Agency, 2009

13.0 Consultation

Prior to finalization this policy was sent for comments to:

Mandy Mckendry	**Clinical Risk Manager**
Moira Gilroy	**Safeguarding Adults Manager**
Helen Bosley	**Infection Control Matron**
Pete McGrane; Helen Hunt and Christine Hewitt	**Urgent Care Managers**
Sandra Allen; Jackie Taylor; Maggie Webb and Wendy Corner	**Unit Mangers, Community Hospitals**
Ingrid Goodman; Amanda Jones; Marie Frizgerald and Xante Cummings	**Unit Managers, Community Nursing**
Catherine Riddle; Joy Dadswell	**Children Services**
Jacqui Connelly	**Continuing Care Manager**

Appendix A

Special Circumstances

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

When a patient dies

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

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

Children

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

The courts have stated that younger children who understand fully what is involved in the proposed procedure can also give consent. This is sometimes known as Gillick competence or the Fraser guidelines. Where a child is judged to have the cognitive ability and the emotional maturity to understand the information provided, he/she should be involved directly in the *Being Open* process after a patient safety incident. The opportunity for parents to be involved should still be provided unless the child expresses a wish for them not to be present.

Where children are deemed not to have sufficient maturity or ability to understand, consideration needs to be given to whether information is provided to the parents alone or in the presence of the child. In these instances the parents' views on the issue should be sought. More information can be found in the CHO Consent Policy or on the Department of Health's website: www.dh.gov.uk

Patients with mental health issues

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

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

Patients with learning disabilities

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

Patients who do not agree with the information provided

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

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

Patients with a different language or cultural considerations

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

Patients with different communication needs

A number of patients will have particular communication difficulties, such as a hearing impairment. Plans for the meeting should fully consider these needs. Knowing how to enable or enhance communications with a patient is essential to facilitating an effective *Being Open* process, focusing on the needs of individuals and their families and being personally thoughtful and respectful.

Appendix B

Overview of the *Being Open* process

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

Appendix C

10 Principles of *Being open*