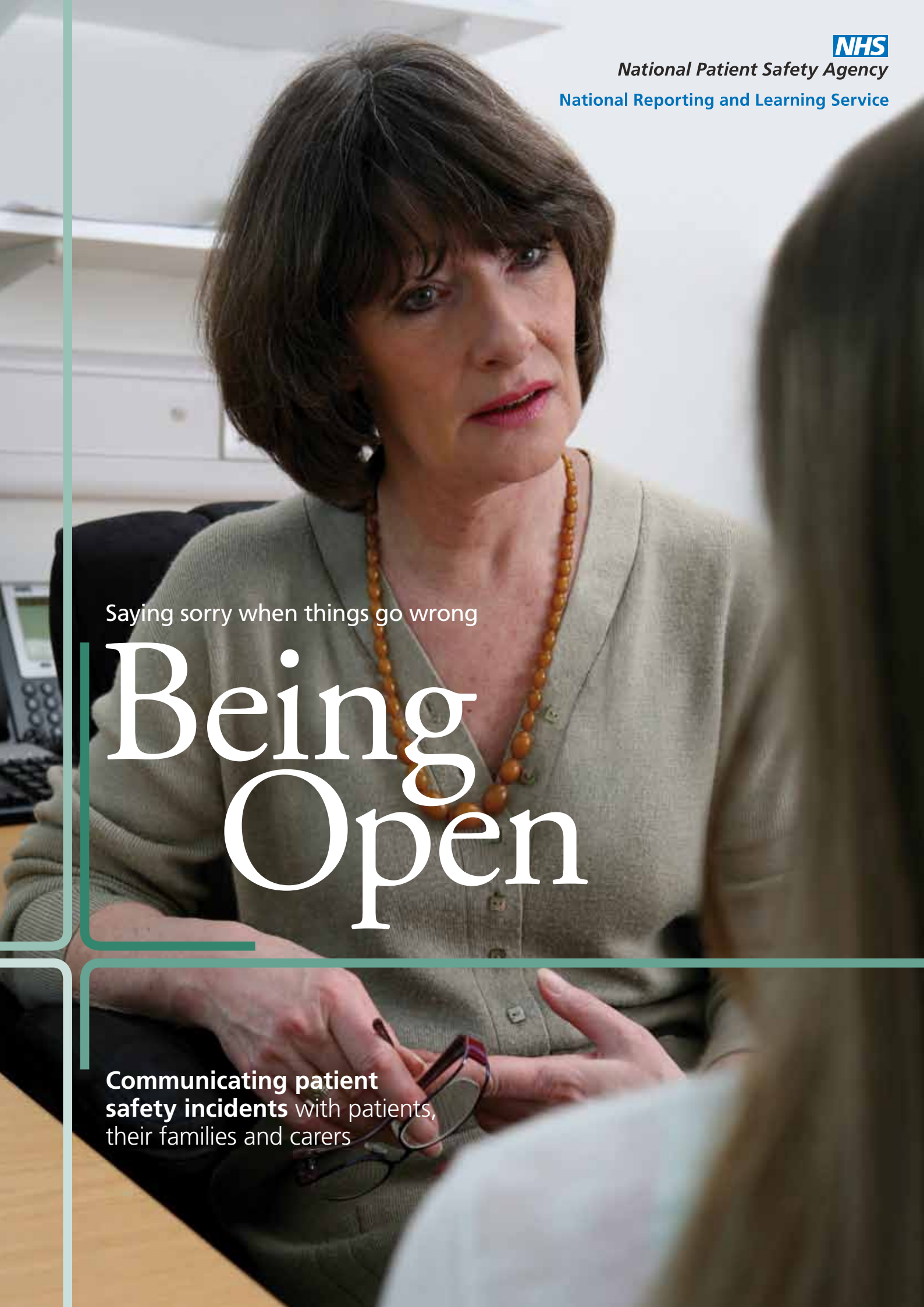


NHS
National Patient Safety Agency
National Reporting and Learning Service

Saying sorry when things go wrong

Being Open

Communicating patient safety incidents with patients, their families and carers

Contents

Being open at a glance

The effects of harming a patient can be widespread. Patient safety incidents can have devastating emotional and physical consequences for patients, their families and carers, and can be distressing for the professionals involved.

Being open about what happened and discussing patient safety incidents promptly, fully and compassionately can help patients and professionals to cope better with the after-effects[1]. Openness and honesty can also help to prevent such events becoming formal complaints and litigation claims[2].

What does *Being open* mean?

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 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 principles

The following set of principles[i] has been developed to help healthcare organisations create and embed a culture of *Being open*:

1. Acknowledgement
2. Truthfulness, timeliness and clarity of communication
3. Apology
4. Recognising patient and carer expectations
5. Professional support
6. Risk management and systems improvement
7. Multidisciplinary responsibility
8. Clinical governance
9. Confidentiality
10. Continuity of care

The process

Being open about a patient safety incident is more than a one-off event; it is a communication process with a number of stages, as outlined in the diagram opposite, and on page 18.

The duration of the process will depend on the incident, the needs of the patient, their family and carers, and how the investigation into the incident progresses.

Implementing *Being open*

The National Patient Safety Agency (NPSA) has developed this updated framework to demonstrate how to strengthen the culture of *Being open* within healthcare organisations.

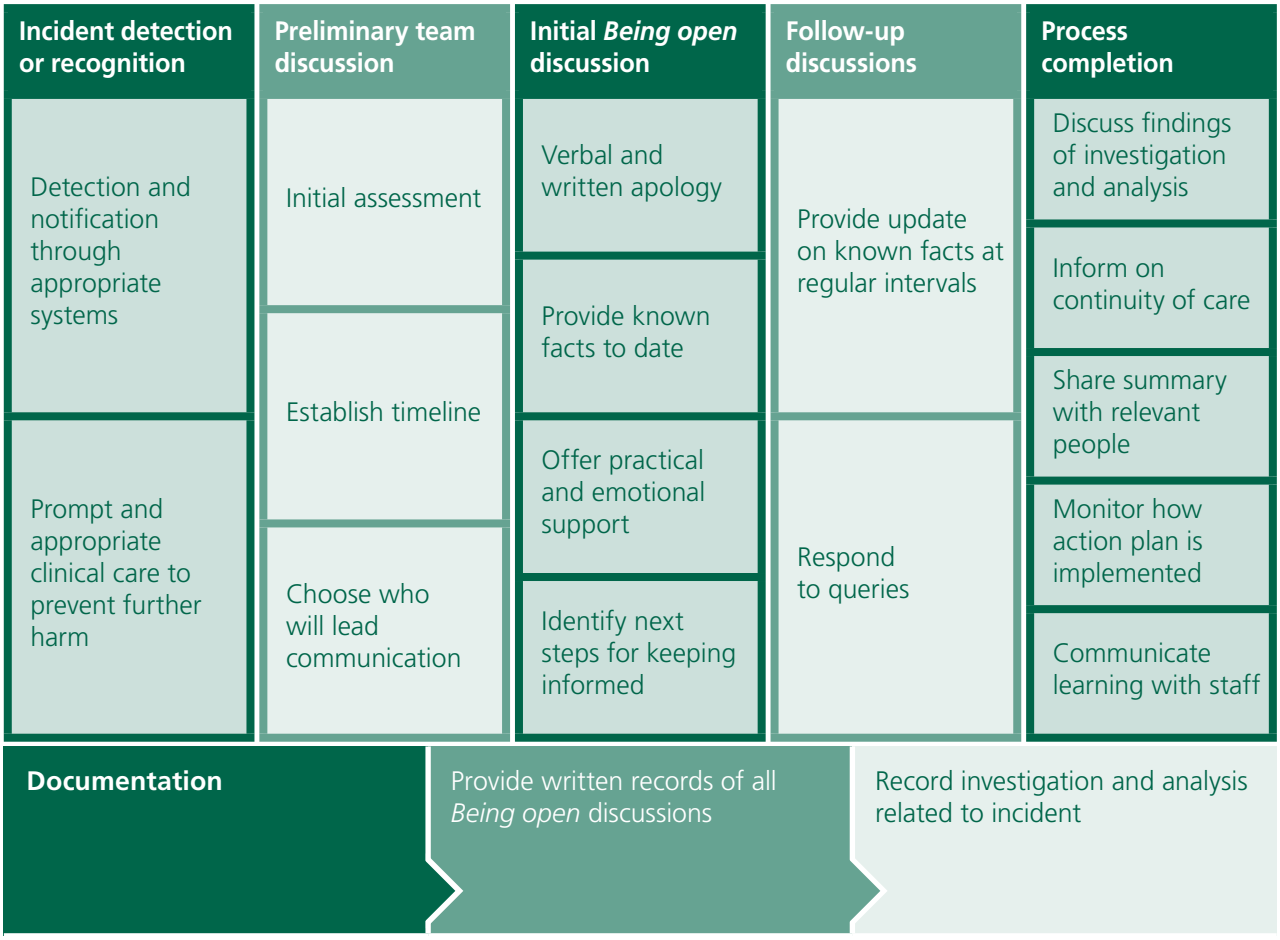
This framework provides best practice guidance on how to create an open and honest environment through:

- aligning with the *Seven steps to patient safety*[3];
- ensuring a *Being open* policy is developed that clearly describes the process to be followed when harm occurs;
- committing publicly to *Being open* at board and senior management level;
- identifying senior clinical counsellors to mentor and support fellow healthcare professionals involved in incidents.

Boards and senior managers within all healthcare organisations have a crucial role in ensuring the *Being open* framework and principles are embedded.

i See page 14 for more detail

Overview of the *Being open* process



Committing to *Being open* will help create an environment where:

- patients, their families and carers receive the information they need to understand what happened, and the reassurance that everything possible will be done to ensure that a similar type of incident does not recur;
- patients, their families and carers, healthcare professionals and managers all feel supported when things go wrong.

Supporting information and tools

In addition to this framework, supporting tools have been developed to assist healthcare organisations with implementing the actions of the NPSA's *Being open* Patient Safety Alert. Training on *Being open* is freely available through an e-learning tool. Interactive training workshops that use actors and/or video-based materials can also be commissioned by organisations.

Information on all these supporting tools can be found at: **www.nrls.npsa.nhs.uk/beingopen**

About this *Being open* framework

What is the *Being open* framework?

Being open provides a best practice framework for all healthcare organisations to create an environment where patients, their carers, healthcare professionals and managers all feel supported when things go wrong and have the confidence to act appropriately. The framework gives healthcare organisations guidance on how to develop and embed a *Being open* policy that fits local organisational circumstances.

It also identifies how organisations can strengthen existing *Being open* policies through board leadership, identifying healthcare professionals as mentors and supporters, and empowering Patient Advice and Liaison Services (PALS), or equivalents, to support patients through the process.

Another key part of the framework is the *Being open* process which provides advice on how to communicate with patients, their families and carers following harm, based on evidence in the research literature and the experience of other countries.

Underpinning *Being open* are 10 principles that can be used to promote and disseminate information about openness. These principles can be adapted to meet the structural and resource requirements of individual organisations.

Who is this framework for?

The framework is aimed at boards and healthcare staff responsible for ensuring the infrastructure is in place to support openness between healthcare professionals and patients, their families and carers when harm has occurred. This includes members of clinical governance committees or equivalent, professional ethics committees in primary care, risk managers, management boards, and medical and nursing directors.

It is accompanied by a Patient Safety Alert on strengthening *Being open* within healthcare organisations. Additional materials to support implementation of the Alert are available on the National Reporting and Learning Service (NRLS)* website at: **www.nrls.npsa.nhs.uk/beingopen**

* The NRLS is a division of the National Patient Safety Agency.

Why has the NRLS updated the *Being open* framework?

The original *Being open* guidance was issued by the NPSA in 2005. Since then, the NHS in England and in Wales have undergone significant changes that have altered the context, infrastructure and language of patient safety and quality improvement. This is demonstrated by the Department of Health publication *High Quality Care For All*,[4] the NHS Constitution and the new complaints process in England; as well as the Welsh project 'Putting Things Right' and the reorganisation of NHS organisations in Wales. Whilst progress has been made on creating a culture of openness, more needs to be done. This has been highlighted in *Safety First*[5] and by the 2009 Health Select Committee on Patient Safety[6].

An independent review of the implementation of *Being open* took place in 2008.[7] Using the findings from national implementation data, research into implementation by NHS organisations and interviews, recommendations were made to strengthen *Being open*[4].

The NRLS has updated the *Being open* framework to take account of these recommendations, demonstrate how *Being open* fits within the changed NHS context, and to strengthen *Being open* within healthcare organisations.

How did the NRLS develop the *Being open* framework?

The original *Being open* policy[8] was developed using feedback on draft guidance from NHS organisations, focus groups with patients, their families and carers, and healthcare professionals, and a review of national and international literature. The policy was released in 2005 to help healthcare organisations and their staff communicate to a patient, their family and carers when harm has occurred.

Drawing on the 2008 recommendations, the NRLS undertook a listening exercise in 2009 with healthcare professionals and patient representatives on how to strengthen *Being open*. The feedback received has informed the development of this revised edition.

An introduction to *Being open*

Open and effective communication with patients should begin at the start of their care and continue throughout their time within the healthcare system. This should be no different when a patient safety incident occurs. *Being open* when things go wrong is key to the partnership between patients and those who provide their care. Openness about what happened and discussing patient safety incidents promptly, fully and compassionately can help patients cope better with the after-effects.[1] 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.[2]

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 involved to cope with the physical and psychological consequences of what happened.

Saying sorry is not an admission of liability and is the right thing to do. Patients have a right to expect openness in their healthcare.

Being open benefits patients, their families and carers, healthcare staff and healthcare organisations – a number of these benefits are identified in Figure 1.

Figure 1: Benefits of *Being open*

Healthcare organisations and teams	Healthcare professionals	Patients
• A reputation of respect and trust for the organisation and/ or team; • Reinforces a culture of openness; • Potentially reduces the costs of litigation; • Improves the patient experience and satisfaction with the organisation; • A reputation for supporting staff when things go wrong; • Embodies the NHS Constitution for England pledge to patients around *Being open*; • Embodies the work of the 'Putting Things Right' project in Wales: • Greater opportunity to learn when things go wrong.	• Confident in how to communicate effectively when things go wrong; • Feel supported in apologising and explaining to patients, their families and carers; • Feel satisfied that communication has been handled in the most appropriate way; • Improved understanding of incidents from the perspective of the patient, their family and carers; • Know that lessons learned from incidents will help prevent them happening again; • Gain a good reputation for handling a difficult situation well.	• Receive a meaningful apology and explanation when things go wrong; • Feel their concerns and distress have been acknowledged; • Reassured that the organisation will learn lessons to prevent harm happening to someone else; • Reduce the trauma felt when things go wrong; • Have greater respect and trust for the organisation. • Reassured that they will continue to be treated according to their clinical needs.

Foundations for *Being open*

To implement *Being open* successfully, healthcare organisations need to have the following foundations:

- a culture that is open and fair;
- a local *Being open* policy and mechanisms to raise awareness about it;
- staff and patient support for *Being open*.

Open and fair culture

Promoting a culture of openness is vital to improving patient safety and the quality of healthcare systems. A culture of openness is one where[3]:

- healthcare staff are open about incidents they have been involved in;
- healthcare staff and organisations are accountable for their actions;
- healthcare staff feel able to talk to their colleagues and superiors about any incident;
- healthcare organisations are open with patients, the public and staff when things have gone wrong and explain what lessons will be learned;
- healthcare staff are treated fairly and are supported when an incident happens.

A culture of openness ensures communication is open, honest and occurs as soon as possible following an incident, or when a poor outcome has been experienced. It encompasses the communication between healthcare organisations, healthcare teams, and patients, their families and carers, and ensures that healthcare organisations support their staff in *Being open*.

Progress has been made by many organisations to introduce a culture which is open and fair. The NRLS acknowledges, however, that some staff may not feel able or confident to report or communicate patient safety incidents openly within their organisations. *Seven steps to patient safety*[3] (see Figure 2) gives an overview for leaders of healthcare organisations on how to create an open and fair culture, and have in place appropriate processes that make improved openness between staff and patients a reality. *Being open* relates directly to, and expands upon, Step 5.

Figure 2: *Seven steps to patient safety*[3]

Step 1: Build a safety culture	Create a culture that is open and fair
Step 2: Lead and support your staff	Establish a clear and strong focus on patient safety throughout your organisation
Step 3: Integrate your risk	Develop systems and processes to manage your risks, and identify and assess things that could go wrong
Step 4: Promote reporting	Ensure your staff can easily report incidents locally and nationally
Step 5: Involve and communicate with patients and the public	Develop ways to communicate openly with and listen to patients
Step 6: Learn and share safety lessons	Encourage staff to use root cause analysis to learn how and why incidents happen
Step 7: Implement solutions to prevent harm	Embed lessons through changes to practice, processes or systems

Local *Being open* policy

Staff may also be unclear about who should talk to patients when things go wrong and what they should say; there is the fear that they might upset the patient, say the wrong things, make the situation worse and admit liability. Having a local *Being open* policy that sets out the process of communication with patients, and raising awareness about this, will provide staff with the confidence to communicate effectively following an incident. This policy needs to be integrated with local and national incident reporting, risk management and concerns and complaints policies.

While it is essential that a *Being open* policy meets the needs of the local organisation, a number of legal and regulatory requirements must also be taken into account. The standards of openness outlined in this framework must be built into the organisational accreditation and external assessment processes, and local policies should reflect the requirements of the judicial system in England and Wales and of the following bodies:

- National Health Service Litigation Authority (NHSLA);
- Welsh Risk Pool (WRP);
- Care Quality Commission (CQC);
- Healthcare Inspectorate Wales.

This will help ensure there are no potential organisational barriers to openness.

Please note that where it is likely that a patient safety incident occurred due to negligence on the part of the healthcare organisation, and/or there is an indication that legal proceedings will be brought against it, the NHSLA or Welsh Health Legal Services (WHLS) should be involved.

Staff and patient support

To ensure both staff and patients support the implementation of *Being open*, it is vital that:

- patients, their families and carers feel confident in the openness of the communication following a patient safety incident, including the provision of timely and accurate information;
- healthcare professionals understand the importance of openness and feel supported by their healthcare organisation in delivering it.

There is evidence to show that openness is supported by patients: when things go wrong patients often want a meaningful apology, explanation, and to get an understanding of how it happened and that it will not happen to others.[9,10] Further research has shown that patients are more likely to forgive medical errors when they are discussed fully in a timely and thoughtful manner,[2] and that being open can decrease the trauma felt by patients following a patient safety incident[11].

Other recommendations on *Being open* with patients

Being open is consistent with recommendations by other national organisations and NHS commitments. Below are details of how other organisations encourage a culture of *Being open* in the NHS.

Policy makers

In January 2009, the Department of Health launched *The NHS Constitution for England*.[12] This represents a major vehicle for improving candour in the NHS and incorporates the principles of *Being open* as:

- a pledge to patients in relation to complaints and redress:

  "The NHS also commits when mistakes happen to acknowledge them, apologise, explain what went wrong and put things right quickly and effectively."

- an expectation of staff responsibility:

  "You should aim to be open with patients, their families, carers or representatives, including if anything goes wrong; welcoming and listening to feedback and addressing concerns promptly and in a spirit of co-operation. You should contribute to a climate where the truth can be heard and the reporting of, and learning from, errors is encouraged."

In addition, the new approach for dealing with complaints in England is based upon the six principles of Good Complaint Handling,[13] which are consistent with *Being open*.

In Wales, *Being open* has formed part of the 'Putting Things Right' project which has been looking at how the NHS in Wales handles and investigates concerns. It also forms a central part of the interim guidance on the handling of concerns issued to the NHS in Wales on 12 October 2009.[14]

Regulators

The CQC's guidance about compliance with the section 20 regulations of the *Health and Social Care Act* 2008 *'A quality service, a quality experience'* states, in relation to complaint handling, that service providers encourage and support a culture of openness that ensures any comments or complaints from service users, or others acting on their behalf, are listened to and acted upon.

Litigation bodies

Both the NHSLA circular, released in May 2009, and WRP technical note 23/20016[15], encourage healthcare professionals to apologise and provide explanations to patients harmed as a result of healthcare treatment, and explain that an apology is not an admission of liability:

"It is both natural and desirable for clinicians who have provided treatment which produces an adverse result, for whatever reason, to sympathise with the patient or the patient's relatives; to express sorrow or regret at the outcome; and to apologise for shortcomings in treatment. It is most important to patients that they or their relatives receive a meaningful apology. We encourage this, and stress that apologies do not constitute an admission of liability. In addition, it is not our policy to dispute any payment, under any scheme, solely on the grounds of such an apology.

"Patients and their relatives increasingly ask for detailed explanations of what led to adverse outcomes. Moreover, they frequently say that they derive some consolation from knowing that lessons have been learned for the future.

"In this area too, the NHSLA is keen to encourage both clinicians and NHS bodies to supply appropriate information whether informally, formally or through mediation."[16]

The importance of openness is also emphasised in the NHSLA's Clinical Negligence Scheme for Trusts (CNST) and Welsh Risk Pooling scheme (WRPS) standards. For example, NHS organisations who have a *Being open* policy in place gain a level one assessment. To gain a level three assessment, NHS organisations need to demonstrate they are monitoring compliance with the policy and demonstrate how the policy is implemented.

Professional bodies and indemnity organisations

Openness and honesty towards patients are supported and actively encouraged by many professional bodies, including the Medical Defence Union (MDU), the Medical Protection Society (MPS) and the General Medical Council (GMC), whose *Good Medical Practice*[17] 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."

Reports

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

- recommendations in the Fifth Shipman Inquiry Report about appropriate documentation of patient deaths;[18]
- the NHSLA's *Striking the Balance* initiative on providing support for healthcare professionals involved in a complaint, incident or claim.[19]

Being open policy

The NRLS recommendations on *Being open* are that all healthcare organisations in England and Wales:

- acknowledge, apologise and explain what happened to patients, their families and carers when a patient is harmed or has died as a result of a patient safety incident;
- are not required to discuss prevented or 'no harm' patient safety incidents with patients, their families and carers;
- have a local *Being open* policy that reflects the principles and process outlined in this framework;
- ensure their local *Being open* policy is integrated with incident reporting, risk management and concerns and complaints policies;
- create an environment where patients, their families and carers, healthcare professionals and managers all feel supported when things go wrong.

Prevented and 'no harm' incidents

The NRLS encourages staff to report patient safety incidents that were prevented (i.e. 'near misses'), no harm and low harm incidents, as well as patient safety incidents that caused moderate harm, severe harm or death. It is not however a requirement that prevented patient safety incidents and 'no harm' incidents are discussed with patients. Feedback (from a range of healthcare staff, government agencies, professional bodies, patients and the public) identified several problems if these were discussed with patients, their families and carers, including:

- added stress to patients and potential loss of confidence in the standard of care;
- negative effects on staff confidence and morale;
- decreased public confidence in the NHS.

In addition, it was widely believed that communicating prevented and 'no harm' patient safety incidents was impractical, adding to staff workload and potentially interrupting their ability to provide patient care. However, the NRLS believes that where an incident led to moderate harm, severe harm or death, the benefits outweigh these problems.

Healthcare organisations should consider discussing 'no harm' incidents with patients, their families and carers on an individual patient basis. It is within the jurisdiction of each healthcare organisation to decide whether these incidents should be communicated to the patient, their family and carers, depending on local circumstances and what is in the best interest of the patient.

Informed consent and disciplinary processes

Being open is based on concepts that should be broadly applicable to all healthcare settings. The following are outside the scope of this framework but are critical to its successful implementation:

Informed consent

Effective communication includes the provision of health information and discussion with patients of potential outcomes. There is already extensive guidance in this area from the Department of Health,[20] the Welsh Assembly Government[21,22] and the NHS Executive[23]. Informed consent is an essential element in providing high quality services.

Disciplinary processes

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 organisations should strive to identify the underlying causes of patient safety incidents (i.e. systems failures or latent conditions) by using methods such as Root Cause Analysis (RCA)[i]. They should ensure incident investigations do not focus exclusively on the last individual to provide care.

To facilitate systematic assessment of the actions of staff, and to determine the appropriate immediate action following a patient safety incident, healthcare organisations are encouraged to use the NRLS's Incident Decision Tree (IDT).[i]

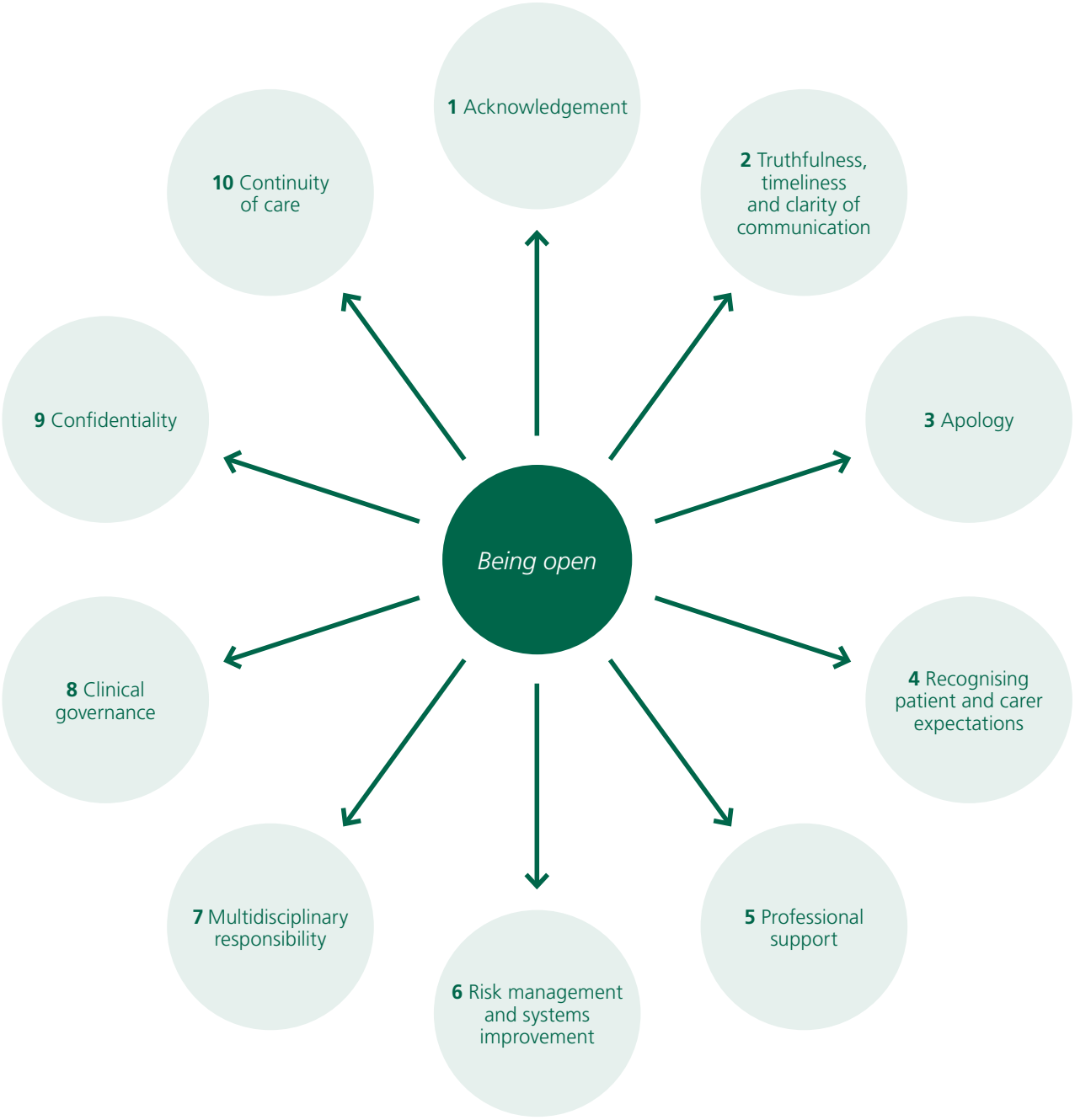
Where concerns are identified about the performance of individual doctors, dentists or pharmacists the National Clinical Assessment Service (NCAS) can be contacted for advice on handling the concern and whether an assessment of the individual's practice would be helpful.[ii]

i For Root Cause Analysis tools and the Incident Decision Tree go to: **www.nrls.npsa.nhs.uk/clinicalriskmanagers**

ii **www.ncas.npsa.nhs.uk**

10 principles of *Being open*

The following principles underpin *Being open*. They can be adapted to meet the needs of individual healthcare organisations as a criteria for developing local policies and procedures on openness.



1. Acknowledgement

All patient safety incidents should be acknowledged and reported as soon as they are identified. In cases where the patient, their family and 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 professionals.

2. Truthfulness, timeliness and clarity of communication

Information about a patient safety incident must be given to patients, their families and carers in a truthful and open manner by an appropriately nominated person. Patients should be provided with a step-by-step explanation of what happened, that considers their individual needs and is delivered openly. Communication should also be timely; patients, their families and 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 professionals should explain that new information may emerge as an incident investigation is undertaken, and that patients, their families and carers will be kept up-to-date with the progress of an investigation.

Patients, their families and carers should receive clear, unambiguous information and be given a single point of contact for any questions or requests they may have. They should not receive conflicting information from different members of staff, and the use of medical jargon, which they may not understand, should be avoided.

3. Apology

Patients, their families and carers should receive a meaningful apology – one that is a sincere expression of sorrow or regret for the harm that has resulted from a patient safety incident. This should be in the form of an appropriately worded and agreed manner of apology as early as possible.

Based on local circumstances, healthcare organisations should decide on the most appropriate member of staff to give both verbal and written apologies to patients, their families and carers. The decision 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, their family and carers and the healthcare team. This should be given as soon as staff are aware an incident has occurred. A written apology, which clearly states the healthcare organisation is sorry for the suffering and distress resulting from the incident, must also be given.

It is important not to delay giving a meaningful apology for any reason, including: setting up a more formal multidisciplinary *Being open* discussion with the patient, their family and carers; fear and apprehension; or lack of staff availability. Delays are likely to increase the patient's, their family's and their carers' sense of anxiety, anger or frustration. Patient and public focus groups reported that patients were more likely to seek medico-legal advice if verbal and written apologies were not delivered promptly.

4. Recognising patient and carer expectations

Patients, their families and carers can reasonably expect to be fully informed of the issues surrounding a patient safety incident, and its consequences, in a face-to-face meeting with representatives from the healthcare organisation. They should be treated sympathetically, with respect and consideration. They 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.

Where appropriate, information on PALS in England, the Community Health Councils (CHC) in Wales, and other relevant support groups like Cruse Bereavement Care and Action against Medical Accidents (AvMA), should be given to the patient as soon as it is possible.

5. Professional support

Healthcare organisations must create an environment in which all staff, whether directly employed or independent contractors, are encouraged to report patient safety incidents. Staff should feel supported throughout the incident investigation process because 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, healthcare organisations are advised to use the NRLS's Incident Decision Tree.

It should be remembered that NCAS can be contacted for advice on handling the concern and whether an assessment of the individual's practice would be helpful.

Where there is reason for the healthcare organisation to believe a member of staff has committed a punitive or criminal act, the organisation should take steps to preserve its position, and advise the member(s) of staff at an early stage to enable them to obtain separate legal advice and/or representation.

Healthcare organisations should also encourage staff to seek support from relevant professional bodies such as the GMC, royal colleges, the MDU, the MPS and the Nursing and Midwifery Council.

6. Risk management and systems improvement

Root Cause Analysis, Significant Event Audit (SEA) or similar techniques should be used to uncover the underlying causes of a patient safety incident. These investigations should focus on improving systems of care, which will then be reviewed for their effectiveness.

Every healthcare organisation's *Being open* policy should be integrated into local incident reporting and risk management policies and processes. *Being open* is one part of an integrated approach to improving patient safety following a patient safety incident. It should be embedded in an overarching approach to risk management that includes local and national incident reporting, analysis of incidents using Root Cause Analysis or Significant Event Audit, decision-making about staff accountability using the Incident Decision Tree and an organisational approach that follows *Seven steps to patient safety*[3].

7. Multidisciplinary responsibility

Any local policy on openness should apply to all staff that have key roles in the patient's care. Most healthcare provision is through multidisciplinary teams. This should be reflected in the way that patients, their families and carers are communicated with when things go wrong. This will ensure that the *Being open* process is consistent with the philosophy that incidents usually result from systems failures and rarely from the actions of an individual.

To ensure multidisciplinary involvement in the *Being open* process, it is important to identify clinical, nursing and managerial opinion leaders who will support it. Both senior managers and senior clinicians who are local opinion leaders must participate in incident investigation and clinical risk management.

8. Clinical governance

Being open requires the support of patient safety and quality improvement processes through clinical governance frameworks in which patient safety incidents are investigated and analysed to find out what can be done to prevent their recurrence. These findings should be disseminated to healthcare professionals so that they can learn from patient safety incidents.

It also involves a system of accountability through the chief executive to the board to ensure these changes are implemented and their effectiveness reviewed. Practice-based risk systems should be established within primary care. Continuous learning programmes and audits should be developed that allow healthcare organisations to learn from the patient's experience of *Being open*, and that monitor the implementation and effects of changes in practice following a patient safety incident.

9. Confidentiality

Policies and procedures for *Being open* should give full consideration of, and respect for, the patient's, their family's and carers' and staff privacy and confidentiality in line with the CQC's guidance for Outcome 19[24]. 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 the CQC's guidance for Outcome 20[24]. Where this is not practical, or an individual refuses to consent to the disclosure, it 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, their family and carers about who will be involved in the investigation before it takes place, and give them the opportunity to raise any objections.

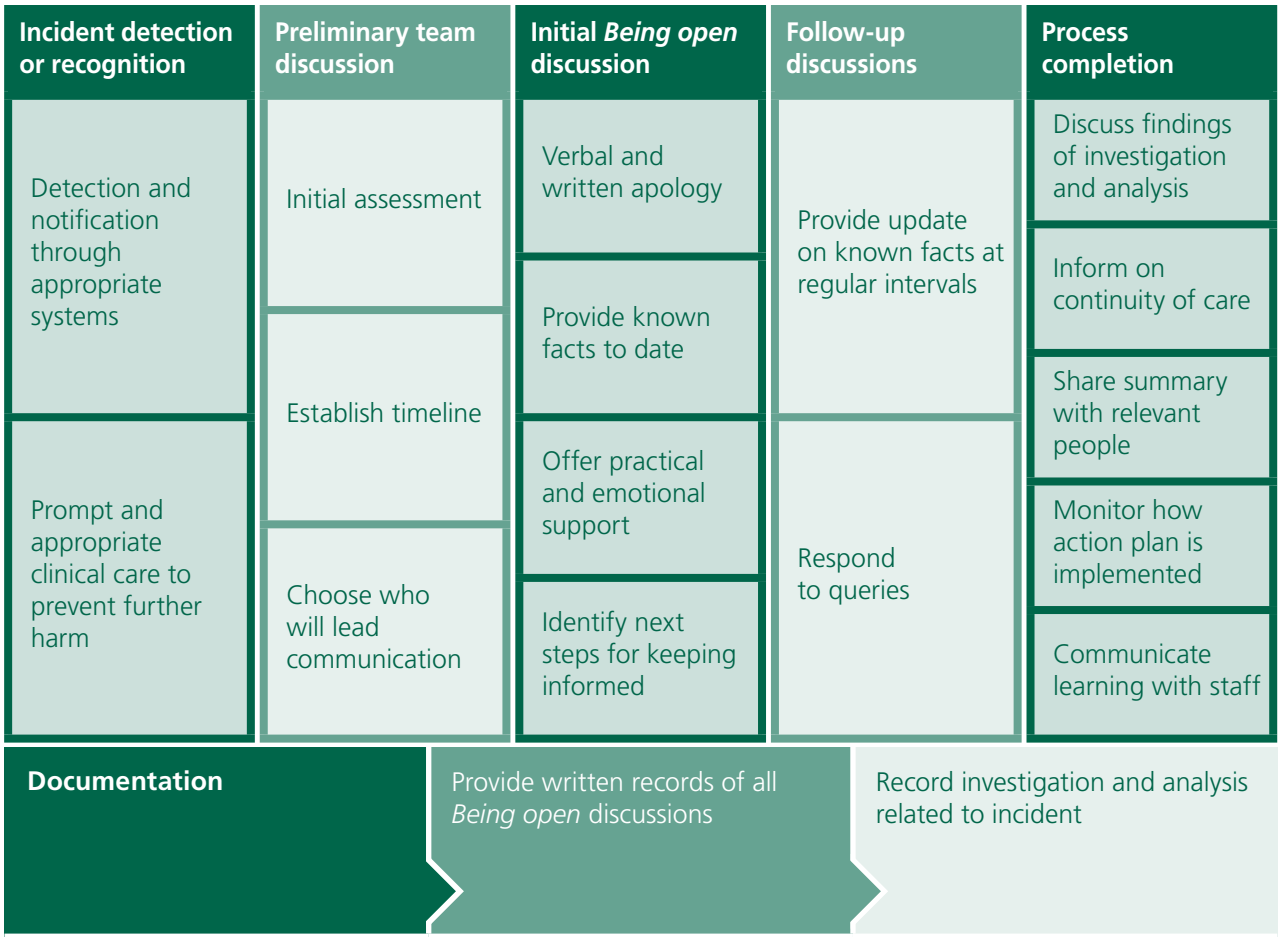
10. Continuity of care

Patients are entitled to expect that they will continue to receive all usual treatment and continue to be treated with dignity, respect and compassion. If a patient expresses a preference for their healthcare needs to be taken over by another team, the appropriate arrangements should be made for them to receive treatment elsewhere.

Being open process

Being open is a process rather than a one-off event. There are a number of stages in the process (Figure 3). The duration of the process depends on the incident, the needs of the patient, their family and carers, and how the investigation into the incident progresses.

Figure 3: Overview of the *Being open* process



Stage 1: Incident detection or recognition

The *Being open* process begins with the recognition that a patient has suffered harm or has died as a result of a patient safety incident. Healthcare organisations should develop appropriate mechanisms to identify patient safety incidents through local incident reporting.

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, their family or carers who express 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 (for example, researchers observing healthcare staff as part of ethnographic studies).

1. Priority

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 healthcare organisation's processes for reporting and then investigating and analysing the causes of incidents should be implemented, including the principles of acknowledgement and apology. An incident reporting form should be completed and sent to the person responsible for leading clinical risk management. In particular circumstances, the organisation may feel it is more appropriate to employ the services of an expert in Root Cause Analysis or Significant Event Audit to assist in identifying the underlying causes of a patient safety incident.

2. Patient safety incidents occurring elsewhere

A patient safety incident may have occurred in an organisation other than the one in which it is identified. The individual who first identifies the possibility of an earlier patient safety incident should notify the risk manager. The same individual, or a colleague, should 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;
- 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 healthcare organisation where the incident took place.

3. Criminal or intentional unsafe act

Patient safety incidents are almost always unintentional. However, if at any stage following an incident it is determined that harm may have been the result of a criminal or intentional unsafe act, the risk manager and/or the chief executive should be notified immediately. This also applies to independent contractors operating within primary care.

4. Additional notification

In addition to the organisation's incident notification systems, the following should be considered (if appropriate):

- 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, their family and carers.
- All cases of untimely, unexpected or unexplained death, and suspected unnatural deaths, need to be reported to the coroner. A coroner may request the case not be discussed with other parties until the facts have been considered. However, this should not preclude a verbal and written, meaningful 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 coroners' investigations are stressful for patients, their families and carers, and healthcare professionals. Bereavement counselling and advice on professional support groups should be offered at the outset of a coroner's investigation.
- Healthcare organisations need to ensure that they comply with the national notification requirements, such as the Serious Incident Management process or the Welsh Assembly Government's Serious Incident Reporting Requirements.

Stage 2: Preliminary team discussion

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, their family and 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 who will be responsible for identifying the patient's needs and communicating them back to the healthcare team;
- identify immediate support needs for the healthcare staff involved;
- ensure there is a consistent approach by all team members around discussions with the patient, their family and carers.

1. Initial assessment to determine level of response

All incidents should be assessed initially by the healthcare team to determine the level of response required and then discussed with the designated risk manager or equivalent if considered to require a high level of response (see Figure 4). The level of response to a patient safety incident depends on the nature of the incident.

As stated previously, it is not a requirement of this policy to communicate prevented patient safety incidents and 'no harm' incidents to patients, their families and carers. Local healthcare organisations should decide 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.

Figure 4: Grading of patient safety incidents to determine level of response*

Incident	Level of response
No harm (including prevented patient safety incident)	Patients are not usually contacted or involved in investigations and these types of incidents are outside the scope of the *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. **Apply the principles of *Being open***
Moderate harm, severe harm 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**

* See Appendix B for NRLS terms and definitions for grading patient safety incidents

2. Timing

The initial *Being open* discussion with the patient, their family and 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;
- patient preference (in terms of when and where the meeting takes place and which healthcare professional leads the discussion);
- privacy and comfort of the patient;
- availability of the patient's family and/or carers;
- availability of key staff involved in the incident and in the *Being open* process;
- availability of support staff, for example a translator or independent advocate, if required;
- arranging the meeting in a sensitive location.

3. Choosing the individual to communicate with patients, their families and carers

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:

- ideally be known to, and trusted by, the patient, their family and 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, their families and carers, and colleagues;
- have excellent interpersonal skills, including being able to communicate with patients, their families and carers in a way they can understand, and avoiding excessive use of medical jargon;
- be willing and able to offer a meaningful apology, reassurance and feedback to patients, their families and carers;
- be able to maintain a medium to long-term relationship with the patient, their family and carers, where possible, and to provide continued support and information;
- be culturally aware and informed about the specific needs of the patient, their family and carers.

3.1 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 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 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.

3.2 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 would be someone with experience or training in communication and *Being open* procedures.

3.3 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.

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 that 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).

3.4 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, their family and 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.

3.5 Involving healthcare staff who made mistakes

Some patient safety incidents that resulted in moderate harm, severe harm or death can 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, their family and carers.

Every case where an error has occurred needs to be considered individually, balancing the needs of the patient, their family and 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, their family and 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, their family and carers during the initial *Being open* discussion.

Stage 3: Initial *Being open* discussion

The initial *Being open* discussion is the first part of an ongoing communication process. Many of the points raised here should be expanded on in subsequent meetings with the patient, their family and carers.

The patient, their family and carers should be advised of the identity and role of all people attending the *Being open* discussion before it takes place. This allows them the opportunity to state their own preferences about which healthcare staff they want to be present.

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.

It should be recognised that patients, their families and carers may be anxious, angry and frustrated even when the *Being open* discussion is conducted appropriately.

The content of the initial *Being open* discussion with the patient, their family and carers should cover the following:

- An expression of genuine sympathy, regret and a meaningful apology for the harm that has occurred.
- The facts that are known as 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, their family and carers are informed that an incident investigation is being carried out and more information will become available as it progresses.
- The patient's, their family's and carers' understanding of what happened is taken into consideration, as well as any questions they may have.
- Consideration and formal noting of the patient's, their family's and carers' views and concerns, and demonstration that these are being heard and taken seriously.
- Appropriate language and terminology are used when speaking to patients, their families and carers. For example, using the terms 'patient safety incident' or 'adverse event' may be meaningless or even insulting to some patients, their families and carers. If a patient's first language is not English, it is also important to consider their language needs – if they would like the *Being open* discussion conducted in French or Urdu for example, this should be arranged.
- An explanation about what will happen next in terms of the short through to long-term treatment plan and incident analysis findings.
- Information on likely short and long-term effects of the incident (if known). The long-term effects may have to be presented at a subsequent meeting when more is known.
- An offer of practical and emotional support for the patient, their family and carers. This may involve getting help from third parties such as charities and voluntary organisations, as well as offering more direct assistance. Information about the patient and the incident should not normally be disclosed to third parties without consent.

It is essential that the following **does not** occur during the *Being open* discussion:

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

Stage 4: Follow-up discussions

Follow-up discussions with the patient, their family and carers are an important step in the *Being open* process. Depending on the incident and the timeline for the investigation there may be more than one follow-up discussion.

The following guidelines will assist in making the communication effective:

- The discussion occurs at the earliest practical opportunity.
- Consideration is given to the timing of the meeting, based on both the patient's health and personal circumstances.
- Consideration is given to the location of the meeting, for example at the patient's home.
- Feedback is 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, their family and carers should be offered an opportunity to discuss the situation with another relevant professional where appropriate.
- A written record of the discussion is kept and shared with the patient, their family and carers.
- All queries are responded to appropriately.
- If completing the process at this point, the patient, their family and carers should be asked if they are satisfied with the investigation and a note of this made in the patient's records.
- The patient is 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.

Stage 5: Process completion

1. Communication with the patient, their family and 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, their family's and carers' 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, in the rare instances where communicating information will adversely affect the health of the patient; where investigations are pending coronial processes; or where specific legal requirements preclude disclosure for specific purposes. In these cases the patient must be informed of the reasons for the restrictions.

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 in primary care.

Patients, their families and carers need to 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 prefer.

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 a healthcare organisation, the 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 include the GP in one of the follow-up discussions either at discharge or at a later stage.

4. Monitoring

Any recommendations for systems improvements and changes implemented should be monitored for effectiveness in preventing a recurrence. The risk manager or equivalent should develop a plan for monitoring the implementation and effectiveness of changes. Examples of good practice can be passed to the NRLS for sharing with the rest of the NHS.

5. Communicating changes to staff

Effective communication with staff is a vital step in ensuring that the 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*.

Documentation

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 report(s);
- records of the investigation and analysis process.

The incident report and record of the investigation and analysis process should be filed separately to the patient's medical records as a patient safety incident record, and kept as part of the healthcare organisation's clinical governance reports.

Written records of the *Being open* discussions should consist of:

- the time, place and date, as well as the name and relationships of all attendees;
- the plan for providing further information to the patient, their family and carers;
- offers of assistance and the patient's, their family's and carers' response;
- questions raised by the patient, their family and carers, and the answers given;
- plans for follow-up meetings;
- progress notes relating to the clinical situation and an accurate summary of all the points explained to the patient, their family and carers;
- copies of letters sent to the patient, their family and 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* discussions should be shared with the patient, their family and carers.

Patient issues to consider

A key part of *Being open* is considering the patient's needs, or the needs of their family or carers in circumstances where the patient is incapacitated or has died. This section identifies those needs, based on previous research and the NRLS's work with patient and public focus groups.

1. Communication

For open and effective communication around patient safety incidents, healthcare organisations should:

- Ensure early identification of, and consent for, the patient's practical and emotional needs. This includes:
  - the names of people who can provide assistance and support to the patient, and to whom the patient has agreed that information about their healthcare can be given. This person (or people) may be different to both the patient's next of kin and from people who the patient had previously agreed should receive information about their care prior to the patient safety incident;
  - any special restrictions on openness that the patient would like the healthcare team to respect;
  - identifying whether the patient does not wish to know every aspect of what went wrong; respect their wishes and reassure them that this information will be made available if they change their mind later on.
- Provide repeated opportunities for the patient, their family and carers to obtain information about the patient safety incident.
- Provide information to patients in verbal and/or written format.
- Provide assurance that an ongoing care plan will be developed in consultation with the patient and will be followed through.
- Provide assurance that the patient will continue to be treated according to their clinical needs and that the prospect of, or an actual dispute between, the patient, their family and carers and the healthcare team will not affect their access to treatment.
- Facilitate inclusion of the patient's family and carers in discussions about a patient safety incident where the patient agrees.
- Provide the patient's family and carers with access to information to assist in making decisions if the patient is unable to participate in decision making or if the patient has died as a result of an incident. This should be done with regard to confidentiality and in accordance with the patient's instructions.
- Determine whether you will need to repeat this information to the patient at different times to allow them to comprehend the situation fully.
- Ensure that the patient's family and carers are provided with known information, care and support if a patient has died as a result of a patient safety incident. The carers should also be referred to the coroner for more detailed information.
- Ensure that discussions with the patient, their family and carers are documented and that information is shared with them.
- Ensure that the patient, their family and carers are provided with information on the complaints procedure if they wish to have it.
- Ensure that the patient, their family and carers are provided with information on the incident reporting process.
- Ensure that the patient's account of the events leading up to the patient safety incident is fed into the incident investigation, whenever applicable.
- Ensure that the patient, their family and carers are provided with information on how improvement plans derived from investigations will be implemented and their effects monitored.
- Develop a system for monitoring and auditing the patient's, their family's and carers' perceptions of the *Being open* process and ensure their comments are fed back to healthcare staff.

2. Advocacy and support

Patients, their families and carers may need considerable practical and emotional help and support after experiencing a patient safety incident. The most appropriate type of support may vary among different patients, their families and carers. It is therefore important to discuss with the patient, their families and carers their individual needs. Support may be provided by patients' families, social workers, religious representatives and healthcare organisations such as PALS, Independent Complaints Advocacy Service (ICAS) and CHCs in Wales. Where the patient needs more detailed long-term emotional support, advice should be provided on how to gain access to appropriate counselling and support services, for example, from Cruse Bereavement Care and AvMA.

Healthcare organisations should provide:

- Information on services offered by all the possible support agencies (including their contact details) that can give emotional support, help the patient identify the issues of concern, support them at meetings with staff and provide information about appropriate community services.
- Contact details of a staff member who will maintain an ongoing relationship with the patient, using the most appropriate method of communication from the patient's, their family's and carers' perspective. Their role is to provide both practical and emotional support in a timely manner.
- Information on the *Being open* process in the form of a short leaflet explaining what to expect.
- Information on how to make a formal complaint and/or any other available means of giving positive or negative feedback to healthcare staff involved in their care.

3. Particular patient circumstances

The approach to *Being open* may need to be modified according to the patient's personal circumstances. The following gives guidance on how to manage different categories of patient circumstances.

3.1 When a patient dies

When a patient safety incident has resulted in a patient's death, it is even more 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 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 the healthcare organisation may consider it appropriate to wait for the coroner's inquest before holding the *Being open* discussion with the patient's family and 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 carers will be provided with more information.

3.2 Children

The legal age of maturity for giving consent to treatment is 16 years old. 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[25]. 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.

3.3 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 '3.4 Patients with cognitive impairments').

The only circumstances in which it is appropriate to withhold patient safety incident information from a patient with mental health issues is when advised to do so by a consultant psychiatrist who feels it would cause adverse psychological harm to the patient. 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.

3.4 Patients with cognitive impairment

Some individuals have conditions that limit their ability to understand what is happening to them. They may have authorised a person to act on their behalf by an enduring 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 welfare of 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.

An advocate with appropriate skills should be available to the patient to assist in the communication process. See '3.5 Patients with learning disabilities' for details of appropriate advocates.

3.5 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 '3.4 Patients with cognitive impairment'). 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 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.

3.6 Patients with different language or cultural considerations

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

3.7 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. This involves focusing on the needs of the patient, their family and carers, and being personally thoughtful and respectful.

3.8 Patients who do not agree with the information provided

Sometimes, despite the best efforts of healthcare staff or others, the relationship between the patient, their family and 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 family and 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, their family and carers another contact person with whom they may feel more comfortable. This could be another member of the team or the individual with overall responsibility for clinical risk management;
- use a mutually acceptable mediator to help identify the issues between the healthcare organisation and the patient, and to look for a mutually agreeable solution;
- ensure the patient, their family and carers are fully aware of the formal complaints procedures;
- 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.

Strengthening *Being open* by supporting staff

When a patient safety incident occurs, healthcare professionals involved in the patient's clinical care may also require emotional support and advice. Professionals who have been involved directly in the incident, those with the responsibility for *Being open* discussions and those identified as senior clinical counsellors (people who can provide mentoring and support to their colleagues) should be given access to assistance, support and any information they need to fulfil their roles.

To support healthcare staff involved in patient safety incidents, organisations should:

- Actively promote an 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 systems, not necessarily the individual. See *Seven steps to patient safety.*[3]
- Educate all their healthcare staff about *Being open* and ensure they understand that apologising 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 within 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 (see Figure 5).
- Provide information on the support systems currently available for staff distressed by patient safety incidents. This includes counselling 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 a *Being open* leadership role.
- Develop specific systems of support in their own organisations through:
  - staff support services (if these are not already in place); and
  - senior clinical counsellors.

Figure 5: Training support

Training support includes:

- Training workshops on *Being open* for healthcare professionals that incorporates video and actor rol-playing methods
- An e-learning tool: *Being open*
- Training for Root Cause Analysis
- An e-learning tool: A guide to root cause analysis from the NPSA
- The Incident Decision Tree

Visit **www.nrls.npsa.nhs.uk** for more information.

Senior clinical counsellors

Senior clinical counsellors provide mentoring and support to their colleagues. Identification of these people comes from one of the recommendations for strengthening *Being open*. A few organisations have these people in place already.

A senior clinical counsellor should only be asked to lead *Being open* discussions when appropriate. Their primary role is to provide support to their colleagues in implementing *Being open*. Senior clinical counsellors should:

- Support fellow healthcare professionals with *Being open* by:
  - mentoring colleagues during their first *Being open* discussion;
  - advising on the *Being open* process;
  - being accessible to colleagues prior to initial and subsequent *Being open* discussions;
  - facilitating the initial team meeting to discuss the incident when appropriate;
  - signposting the support services within the organisation for colleagues involved in *Being open* discussions;
  - facilitating debriefing meetings following *Being open* discussions;
  - mentoring colleagues to become senior clinical counsellors.
- Support fellow healthcare professionals in dealing with patient safety incidents by:
  - signposting the support services within the organisation for colleagues involved in patient safety incident discussions;
  - advising on the reporting system for patient safety incidents.
- Practice and promote the principles of *Being open*.

For further information about this role please see the supporting resources on the NRLS website at: **www.nrls.npsa.nhs.uk/beingopen**

Strengthening *Being open* through board leadership

Seven steps to patient safety[3] explains the importance of organisational commitment to improving patient safety. This commitment is required throughout the whole of a healthcare organisation, from the board through to clinical and non-clinical staff.

Boards and senior managers have a crucial role to play in ensuring the *Being open* framework and principles are embedded in their organisations. *Being open* must not be seen as an 'add on' when something goes wrong, but should be at the core of the organisation's values and culture of working with patients, the public and staff.

To demonstrate the board's commitment, the chair or chief executive is asked to make a public statement endorsing the principles of *Being open*, setting out the duty of all staff to follow the *Being open* principles and reinforcing the organisation's full support of an open, honest and fair culture.

Staff involved in patient safety incidents in which a patient has been harmed can be devastated and traumatised by the event and need the full support of the organisation. The board must ensure that systems are in place to provide support to staff in these circumstances.

Boards can strengthen *Being open* by:

- Identifying executive and non-executive leads responsible for ensuring that the *Being open* principles and policy are embedded in the organisation. These can be those already responsible for patient safety or clinical governance.
- Ensuring that a *Being open* policy is in place and fully implemented throughout the organisation. This helps to support a process for application of the *Being open* principles to a patient safety incident. The policy must be fully integrated with other policies, especially with clinical governance, risk management and concerns and complaints policies.
- Gaining assurance that a training programme is in place to raise awareness amongst all staff of the *Being open* framework. It should provide all staff engaged in patient care with sufficient skills and knowledge to allow them to practice the *Being open* principles and feel confident in communicating with patients, their families and carers when things go wrong.
- Ensuring that the senior clinical counsellors are fully equipped with the knowledge and skills that they require in order to fulfil their role in supporting staff.

In addition, boards of commissioning primary care trusts can seek assurance that *Being open* is fully implemented and practised in provider organisations.

For further tools to assist please see the supporting resources on the NRLS website at: **www.nrls.npsa.nhs.uk/beingopen**

Supporting resources for healthcare organisations

A range of resources have been developed to help healthcare organisations strengthen *Being open* and implement the actions within the Patient Safety Alert. These include:

- Patient Safety Alert – outlines the actions healthcare organisations are required to implement to strengthen *Being open*.
- Patient Safety Alert supporting information – describes the reasons why the *Being open* Patient Safety Alert has been released.
- *Questions are the answer!* – a fact sheet with seven questions every board member should ask about patient safety, developed by the NPSA, the Appointments Commission and the NHS Confederation.
- *Being open* e-learning – a tool that healthcare professionals can use to learn about *Being open,* which includes case studies.
- *Being open* training workshops – training workshops that healthcare organisations can commission to train staff on *Being open*.

The resources are available from:
www.nrls.npsa.nhs.uk/beingopen

For enquiries regarding the *Being open* Framework, the Patient Safety Alert and suggestions for additional supporting resources, please email: **beingopen@npsa.nhs.uk**

References

1. Crane M. What to say if you made a mistake. *Med Econ*. 2001; 78: 26–8, 33–6
2. Vincent CA and Coulter A. Patient safety: what about the patient? *Qual Saf Health Care*. 2002; 11: 76–80
3. National Patient Safety Agency. *Seven steps to patient safety. The full reference guide*. 2004.
4. Department of Health. *High Quality Care for All – NHS Next Stage Review final report*. 2008.
5. Department of Health. *Safety First: A report for patients, clinicians and healthcare managers*. 2006.
6. House of Commons Health Committee. *Patient Safety – Sixth Report of Session 2008-2009*. Volumes 1 and 2. 2009.
7. Wu A. *Review of 'Being open' Final Report*. 2008 (unpublished).
8. National Patient Safety Agency. *Being open: communicating patient safety incidents with patients and their carers*. 2005.
9. Department of Health. *Making amends: a consultation paper setting out proposals for reforming the approach to clinical negligence in the NHS*. 2003.
10. Australian Council for Safety and Quality in Health Care. *When things go wrong: an open approach to adverse events*. Issues paper for the National Open Disclosure Project. Public Interest Advocacy Centre. 2002.
11. Vincent CA, Pincus T and Scurr JH. Patients' experience of surgical accidents. *Qual Saf Health Care*. 1993; 2: 77–82
12. Department of Health. *The NHS Constitution for England*. 2009.
13. Department of Health. *Listening, Responding, Improving – A guide to better customer care*. 2009.
14. Welsh Assembly Government. *Interim Guidance on the Handling of Concerns for the New NHS Wales Structure*. 2009.
15. Welsh Risk Pool. Technical Note 23, Apologies and Explanations. 2001. Updated 2009.
16. National Health Service Litigation Authority. *Apologies and Explanations*. Letter to chief executives and finance directors. May 2009.
17. General Medical Council. *Good Medical Practice*. 2001.
18. Department of Health. *Harold Shipman's clinical practice 1974-1998: a clinical audit commissioned by the Chief Medical Officer*. 2001.
19. Kaplan C and Hepworth S. Supporting health service staff involved in a complaint, incident or claim - an NHSLA initiative. *NHSLA Journal*. 2004; 3: 11–13
20. Department of Health. *Reference Guide to Consent for Examination or Treatment*. 2001.
21. Welsh Health Circular. WHC(2008)10. *Patient Consent to Examination and Treatment – Revised Guidance*. 2008.
22. Welsh Health Circular. WHC(2008)36. *Good Practice in Consent Implementation Guide: consent to examination or treatment*. 2008.
23. Department of Health. HSC 2001/023: *Good practice in consent: achieving the NHS Plan commitment to patient-centred consent practice*. NHS Executive. 2001.
24. Care Quality Commission. *A quality service, a quality experience*. In print, December 2009.
25. *Gillick v West Norfolk and Wisbech Area Health Authority*. [1985] 3 All ER 402 (HL).

Further reading

Gallagher TH. A 62 year-old woman with skin cancer who experienced wrong-site surgery: review of medical error. *JAMA*. 2009; 302: 669–677

Gallagher TH, Waterman AD, Ebers AG, Fraser VJ and Levinson W. Patients' and physicians' attitudes regarding the disclosure of medical errors. *JAMA*. 2003; 26: 1001–1007

Shannon SE, Foglia MB, Hardy M and Gallagher TH. Disclosing errors to patients: perspectives of registered nurses. *Jt Comm J Qual Patient Saf.* 2009; 35: 5–12

Small SD and Barach P. Patient safety and health policy: a history and review. *Haematol Oncol Clin North Am*. 2002; 16: 1463–1482

Vincent CA. Understanding and responding to adverse events. *N Engl J Med*. 2003; 348(11): 1051–1056

Vincent CA. Caring for patients harmed by treatment. In Vincent CA, ed. *Clinical Risk Management: Enhancing Patient Safety*. London; BMJ Publications. 2001.

Vincent C, Young M and Phillips A. Why do people sue doctors? A study of patients and relatives taking legal action. *Lancet*. 1994; 343: 1609–1615

Wu AW. Medical error: the second victim. The doctor who makes the mistake needs help too. *BMJ*. 2000; 320: 726–727

Appendix A: **Glossary of terms and list of acronyms and abbreviations**

Adverse event: see *Patient safety incident*.

Anonymous: information that has had patient identifiable features removed; without making the information of no use for its purposes.

Apology: a sincere expression of regret offered for harm sustained.

***Being open*:** open communication of patient safety incidents that result in harm or the death of a patient while receiving healthcare.

Carers: family, friends or those who care for the patient. The patient has consented to their being informed of their confidential information and to their involvement in any decisions about their care.

Clinical governance: a framework through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish.

Clinical risk manager: an officer within a trust assigned with primary coordination responsibility for issues of clinical risk management. See also *Risk management*.

Harm: injury (physical or psychological), disease, suffering, disability or death.

Healthcare professional: doctor, dentist, nurse, pharmacist, optometrist, allied healthcare professional, or registered alternative healthcare practitioner.

Healthcare organisation: organisations that provide a service to individuals or communities to promote, maintain, monitor or restore health. See also *NHS organisation*.

Injury: damage to tissues caused by an agent or circumstance.

Intentional unsafe acts: incidents resulting from a criminal act, a purposefully unsafe act, or an act related to alcohol/substance abuse by a care provider. These are dealt with through performance management and local systems.

Incident Decision Tree (IDT): 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).

Liability: legal responsibility for an action or event.

Near miss: see *Prevented patient safety incident*.

NHS-funded healthcare: see *NHS organisation*.

NHS organisation: any area where NHS-funded patients are treated, i.e. NHS providers or services, independent establishments including private healthcare or the patient's home or workplace. Either all or part of the patient's care in these settings is funded by the NHS. This may also be referred to as NHS-funded healthcare.

National Patient Safety Agency (NPSA): the NPSA was set up in July 2001 following recommendations from the Chief Medical Officer in his report on patient safety, *An organisation with a memory*. Its role is to lead and contribute to improved, safe patient care by informing supporting and influencing the health sector.

National Reporting and Learning Service (NRLS): one of three divisions of the NPSA. The NRLS works to identify and reduce risks to patients receiving NHS care, and leads on national initiatives to improve patient safety. See also *National Patient Safety Agency*.

Patient safety: the process by which an organisation makes patient care safer. This should involve risk assessment, the identification and management of patient-related risks, the reporting and analysis of incidents, and the capacity to learn from and follow-up on incidents and implement solutions to minimise the risk of them recurring. The term 'patient safety' is replacing 'clinical risk', 'non-clinical risk' and the 'health and safety of patients'.

Patient safety incident: any unintended or unexpected incident that could have or did lead to harm for one or more patients receiving NHS-funded healthcare. The terms 'patient safety incident' and 'prevented patient safety incident' will be used to describe 'adverse events'/'clinical errors' and 'near misses' respectively.

Prevented patient safety incident: any unexpected or unintended incident that was prevented, resulting in no harm to one or more patients receiving NHS-funded healthcare.

Risk: the chance of something happening that will have an impact on individuals and/or organisations. It is measured in terms of likelihood and consequences.

Risk management: identifying, assessing, analysing, understanding and acting on risk issues in order to reach an optimal balance of risk, benefit and cost.

Root Cause Analysis (RCA): a systematic process whereby the factors that contributed to an incident are identified. As an investigation technique for patient safety incidents, it looks beyond the individual concerned and seeks to understand the underlying causes and environmental context in which an incident happened.

Safety: a state in which risk has been reduced to an acceptable level.

Standard: sets out agreed specifications and/or procedures designed to ensure that a material, product, method or service is fit for purpose and consistently performs in the way it is intended.

Significant Event Audit (SEA): an audit process where data is collected on specific types of incidents that are considered important to learn about and improve patient safety.

Suffering: experiencing anything subjectively unpleasant. This may include pain, malaise, nausea and/or vomiting, loss, depression, agitation, alarm, fear, grief, or humiliation.

Systems failure: a fault, breakdown or dysfunction within operational methods, processes or infrastructure.

Systems improvement: the changes made to improve operational methods, processes and infrastructure to ensure better quality and safety.

Treatment: broadly, the management and care of a patient to prevent or cure disease or reduce suffering and disability.

Acronyms and abbreviations

AvMA	Action against Medical Accidents
CHC	Community Health Councils
CNST	Clinical Negligence Scheme for Trusts
CQC	Care Quality Commission
GMC	General Medical Council
ICAS	Independent Complaints Advocacy Service
IDT	Incident Decision Tree
MDU	Medical Defence Union
MPS	Medical Protection Society
NCAS	National Clinical Assessment Service
NHSLA	National Health Service Litigation Authority
NPSA	National Patient Safety Agency
NRLS	National Reporting and Learning Service
PALS	Patient Advice and Liaison Services
RCA	Root Cause Analysis
SEA	Significant Event Audit
WHLS	Welsh Health Legal Services
WRPS	Welsh Risk Pooling scheme
WRP	Welsh Risk Pool

Appendix B: **NRLS terms and definitions for grading patient safety incidents**

Grade of patient safety incident	Definition
No harm	Incident prevented – any patient safety incident that had the potential to cause harm but was prevented, and no harm was caused to patients receiving NHS-funded care.
	Incident not prevented – any patient safety incident that occurred but no harm was caused to patients receiving NHS-funded care.
Low harm	Any patient safety incident that required extra observation or minor treatment* and caused minimal harm to one or more patients receiving NHS-funded care.
Moderate harm	Any patient safety incident that resulted in a moderate increase in treatment† and that caused significant but not permanent harm to one or more patients receiving NHS-funded care.
Severe harm	Any patient safety incident that appears to have resulted in permanent harm‡ to one or more patients receiving NHS-funded care.
Death	Any patient safety incident that directly resulted in the death§ of one or more patients receiving NHS-funded care.

* Minor treatment is defined as first aid, additional therapy, or additional medication. It does not include any extra stay in hospital or any extra time as an outpatient, or continued treatment over and above the treatment already planned; nor does it include a return to surgery or readmission.

† Moderate increase in treatment is defined as a return to surgery, an unplanned readmission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, or transfer to another area such as intensive care as a result of the incident.

‡ Permanent harm directly related to the incident and not related to the natural course of the patient's illness or underlying condition is defined as permanent lessening of bodily functions, sensory, motor, physiological or intellectual, including removal of the wrong limb or organ, or brain damage.

§ The death must be related to the incident rather than to the natural course of the patient's illness or underlying condition.

Organisations endorsing the *Being open* principles:

avma
action against medical accidents

DH Department of Health

agic hiw
Arolygiaeth Gofal Iechyd Cymru
Healthcare Inspectorate Wales
SICRHAU
GWELLIANT
TRWY
AROLYGU ANNIBYNNOL
A GWRTHRYCHOL

EST 1885
THE
MDU

MPS

NHS
Litigation Authority

RC
GP
Royal College of
General Practitioners

Royal College
of Nursing

Royal College of
Obstetricians and
Gynaecologists
Setting standards to improve women's health

RC
PSYCH
ROYAL COLLEGE OF
PSYCHIATRISTS

Royal College
of Physicians
Setting higher medical standards

THE NHS CONFEDERATION

THE WELSH NHS CONFEDERATION
CONFFEDERASIWN GIG CYMRU

Llywodraeth Cynulliad Cymru
Welsh Assembly Government

WRP
WELSH RISK POOL • CRONFARISG CYMRU

National Reporting and Learning Service
National Patient Safety Agency
4 - 8 Maple Street
London W1T 5HD

T 020 7927 9500
F 020 7927 9501

www.nrls.npsa.nhs.uk

NPSA reference: 1097 November 2009
Gateway reference: 13015