Being open
Communicating patient safety incidents with patients and their carers

We recognise that healthcare will always involve risks, but that these risks can be reduced by analysing and tackling the root causes of patient safety incidents. We are working with NHS staff and organisations to promote an open and fair culture, and to encourage staff to inform their local organisations and the NPSA when things have gone wrong. In this way, we can build a better picture of the patient safety issues that need to be addressed.

www.npsa.nhs.uk
Being open

The National Patient Safety Agency’s policy on openness and honesty following patient safety incidents

“The Healthcare Commission warmly welcomes this initiative from the NPSA. Improving patient safety is a real priority for both ourselves and the NPSA. The Being open policy is rooted in sound evidence, and is supported with practical advice that will enhance learning and improvement. It has my full support.”

Anna Walker
Chief Executive
Healthcare Commission
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Executive summary

Central to the NPSA’s strategy to improve patient safety is our commitment to improving communication between healthcare organisations and patients and/or carers when a patient is moderately harmed, severely harmed or has died as a result of a patient safety incident. This also forms part of the government’s initiative to establish a safer and better healthcare service in its report *Building a safer NHS for patients*.

This communication is known as *Being open*.

*Being open* involves apologising and explaining what happened to patients and/or their carers who have been involved in a patient safety incident. It ensures communication is open, honest and occurs as soon as possible following an incident. It encompasses communication between healthcare organisations, healthcare teams and patients and/or their carers. For patients, effective communication starts from a healthcare need being identified and continues throughout their treatment. For healthcare professionals, there is an ethical responsibility to maintain honest and open communication with patients and/or carers even when things go wrong. It is only by ensuring good communication when a patient safety incident occurs that we can begin to look at ways to prevent recurrence. Promoting a culture of being open is therefore a prerequisite to improving patient safety and the quality of healthcare systems.

The effects of harming a patient can be widespread. For this reason it is essential that communication between healthcare teams and patients and/or their carers following a patient safety incident is carried out appropriately. Incidents can have devastating emotional and physical consequences for patients and their families or carers. For the staff involved too, incidents can be distressing, while members of their clinical teams can become demoralised and disaffected. Being open about what happened and discussing patient safety incidents promptly, fully and compassionately can help patients cope better with the after-effects.

Patient safety incidents also incur extra costs through litigation and further treatment; openness and honesty can help prevent such events becoming formal complaints and litigation claims. Many patients and/or their carers will often only make a litigation claim when they have not received any information or apology from the healthcare teams or organisations following the incident. Being open when things go wrong is clearly fundamental to the partnership between patients and those who provide their care.
This policy document aims to foster commitment from healthcare organisations. This includes specialist trusts, primary care organisations or independent primary care providers, private providers and prisons providing NHS care. Being open will help to:

- establish an environment where patients and/or their carers receive the information they need to enable them to understand what happened and the reassurance that everything possible will be done to ensure that a similar type of incident does not recur;
- create an environment where patients and/or their carers, healthcare professionals and managers all feel supported when things go wrong;
- ensure a Being open policy is developed and implemented in every healthcare organisation and that this policy is integrated with other risk management processes and policies – for example, incident reporting and incident analysis approaches such as root cause analysis (RCA) or significant event audit (SEA).

Being open follows the NPSA’s guidance document, Seven steps to patient safety, Step 5 – ‘Involve and communicate with patients and the public’. This outlines the NPSA’s programme to improve openness and honesty following a patient safety incident. Other elements of the Being open programme include the development of an e-learning toolkit, a video based training programme for healthcare professionals and a review of bereavement and counselling services in NHS-funded care in England and Wales. These will be available later in 2005.

The NPSA’s work on Being open is part of our wider strategy to improve patient safety and is integrated with the development of other risk management procedures – including systems of organisational responsibility such as the National Reporting and Learning System, and investigation techniques such as RCA. These are designed to promote a culture of reporting and learning from patient safety incidents to reduce levels of harm, within an overarching safety culture that is open and fair. More information can be found in Seven steps to patient safety and on the NPSA website: www.npsa.nhs.uk
Being open about patient safety incidents

Introduction
Promoting a culture of openness is a prerequisite to improving patient safety and the quality of healthcare systems. It involves apologising and explaining what happened to patients who have been harmed as a result of their healthcare treatment. It ensures communication is open, honest and occurs as soon as possible following an incident. It encompasses communication between healthcare organisations, healthcare teams and patients and/or their carers.

The basis for this policy document
As part of its scheme to test the National Reporting and Learning System (NRLS), the NPSA issued draft guidance for pilot sites on how to explain a patient safety incident or a prevented patient safety incident to patients and/or their carers. Using feedback from the pilot sites and a further review of national and international literature, the NPSA has written this policy to help healthcare organisations and their staff communicate to a patient and/or their carers what happened in an incident that led to moderate harm, severe harm or death.

What it provides
Being open provides a best practice framework for all healthcare organisations to develop a Being open policy that fits local organisational circumstances. The principles can be adapted to reflect the unique structural and resource requirements of the organisation and used to promote and disseminate information about openness.

It gives healthcare organisations guidance on creating an environment where patients, their carers, healthcare professionals and managers all feel supported when things go wrong – and subsequently have the confidence to act appropriately.

Who is it for?
The policy is aimed at any healthcare staff responsible for ensuring the infrastructure is in place to support openness between healthcare professionals and patients and/or their carers following an incident that led to moderate harm, severe harm or death. This includes clinical governance committees, professional ethics committees in primary care, risk managers, management boards, and medical and nursing directors. It is accompanied by a safer practice notice on being open with patients, aimed specifically at healthcare teams. This document gives advice on the ‘dos and don’ts’ of communicating with patients and/or their carers following harm, based on evidence in the research literature and the experience of other countries.
NPSA and other recommendations on being open with patients

Step 5 of *Seven steps to patient safety*, ‘Involve and communicate with patients and the public’, gives an overview of the NPSA’s work on being open with patients. Our stance on openness is consistent with previous recommendations by other agencies, including the National Health Service Litigation Authority (NHSLA) circular 02/02 and Welsh Risk Pool (WRP) technical note 23/2001. Both circulars encourage healthcare staff to apologise to patients harmed as a result of healthcare treatment and explain that an apology is not an admission of liability: ‘It seems to us that it is both natural and desirable for those involved in treatment which produces an adverse result, for whatever reason, to sympathise with the patient or the patient’s relatives and to express sorrow or regret at the outcome. Such expressions of regret would not normally constitute an admission of liability, either in part or in full, and it is not our policy to prohibit them, nor to dispute any payment, under any scheme, solely on the grounds of such an expression of regret.’ The importance of openness is also emphasised in the Clinical Negligence Scheme for Trusts (CNST) 2.1.2 and Risk Pooling Schemes for Trusts (RPST) 4.9 standards.

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

‘a duty of candour requiring clinicians and health services managers to inform patients about actions which have resulted in harm’.

Openness and honesty towards patients are supported and actively encouraged by many professional bodies including the Medical Protection Society (MPS), the Medical Defence Union and the General Medical Council (GMC), whose *Good Medical Practice* guide contains the following statement on a clinician’s ‘duty of candour’:

‘If a patient under your care has suffered serious harm, through misadventure, or for any other reason, you should act immediately to put matters right, if that is possible. You should explain fully to the patient what has happened and the likely long and short-term effects. When appropriate, you should offer an apology. If the patient is under 16 and lacks the maturity to consent to treatment, you should explain the situation honestly to those with parental responsibility for the child.’

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

- recommendations in the 5th Shipman Inquiry Report about appropriate documentation of patient deaths;
- the NHSLA’s *Striking the Balance* initiative on providing support for healthcare professionals involved in a complaint, incident or claim.
Effective communication with patients begins at the start of their care and should continue throughout their time with the healthcare organisation. This should be no different when a patient safety incident occurs. Openness about what happened and discussing patient safety incidents promptly, fully and compassionately can help patients cope better with the after-effects. Patient safety incidents also incur extra costs through litigation and further treatment; openness and honesty can help prevent such events becoming formal complaints and litigation claims. Openness when things go wrong is fundamental to the partnership between patients and those who provide their care.

1 For healthcare organisations and teams

Being open involves:
- acknowledging, apologising and explaining when things go wrong;
- conducting a thorough investigation into the incident and reassuring patients and/or their carers that lessons learned will help prevent the incident recurring;
- providing support to cope with the physical and psychological consequences of what happened.

It is therefore essential that each healthcare organisation has a Being open policy and that this is integrated with local and national incident reporting and risk management policies. Openness can help to build a reputation of respect and trust for the organisation and/or team.

2 For healthcare staff

Being open has several benefits for healthcare staff including:
- satisfaction that communication with patients and/or their carers following a patient safety incident has been handled in the most appropriate way;
- improving the understanding of incidents from the perspective of the patient and/or their carers;
- the knowledge that lessons learned from incidents will help prevent them happening again;
- having a good professional reputation for handling a difficult situation well and earning respect among peers and colleagues.
3 For patients

There is evidence to show that openness is supported by patients. A MORI survey commissioned for the Department of Health's consultation document *Making Amends* interviewed 8,000 people in the UK. Results showed that nearly 400 of the respondents reported that they had experienced a patient safety incident. These people wanted the NHS to respond in the following ways after a patient safety incident:

- 34% wanted an apology or explanation;
- 23% wanted an enquiry into the causes;
- 17% wanted support in coping with the consequences;
- 11% wanted financial compensation;
- 6% wanted disciplinary action;
- 9% provided another response, or didn't respond.

Additionally, the Australian National Open Disclosure Project\(^1\) – which consulted a wide range of consumers and their representatives – found that patients would like:

- to be told about patient safety incidents that affect them;
- acknowledgement of the distress the patient safety incident caused;
- a sincere and compassionate statement of regret for the distress they are experiencing;
- a factual explanation of what happened;
- a clear statement of what is going to happen from then onwards;
- a plan about what can be done medically to repair or redress the harm done.

Other 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\(^3\).
Laying the foundations for *Being open* in your organisation

We acknowledge that at present some staff may not feel able or confident to report or communicate patient safety incidents openly within their organisations. Leaders of healthcare organisations need to follow the guidance in *Seven steps to patient safety* to create an open and fair culture and have in place appropriate processes that make improved openness between staff and patients a reality.

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Staff may also be unclear about who should talk to patients when things go wrong and what they should say; they fear they might say the wrong things, make the situation worse and admit liability. Developing a local policy that sets out the process of communication with patients will provide staff with the confidence to communicate effectively following an incident.

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

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

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 policy 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;
- Welsh Risk Pool.

This will help ensure there are no potential organisational barriers to openness.
The scope of this policy document

Prevented and ‘no harm’ incidents
The NPSA 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. This is done through local reporting and analysis systems and through the NRLS so that other healthcare staff can learn from them.

It is not however a requirement of this policy that prevented patient safety incidents and ‘no harm’ incidents are discussed with patients. Feedback on a draft version of Being open – from a range of healthcare staff, government agencies, professional bodies, patients and the public – identified several problems if these were discussed with patients and/or their 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, we believe that where an incident led to moderate harm, severe harm or death, the benefits outweigh these problems.

Therefore the NPSA is currently not recommending discussion with patients or carers following prevented patient safety incidents or incidents that did not lead to harm. We leave it to the jurisdiction of each healthcare organisation to decide whether these incidents should be communicated to the patient and/or their carers, depending on local circumstances. Healthcare organisations should consider the benefits and problems associated with discussing ‘no harm’ incidents with patients and/or their carers.
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 policy document 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 recent guidance in this area from the Department of Health, the Welsh Assembly Government and the NHS Executive. 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. 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 NPSA’s incident decision tree (IDT). More information on the IDT can be found in *Seven steps to patient safety* and on the NPSA website: www.npsa.nhs.uk/idt
How to communicate patient safety incidents: key principles, issues and procedures

Section A: the ten principles of Being open

Being open is a process rather than a one-off event. With this in mind the following principles have been drawn up to underpin the policy. They can be adapted to meet the needs of individual healthcare organisations as a framework for developing local policies and procedures on openness. Some of the principles listed below are discussed in more detail in subsequent sections of this policy document.

1 Principle of acknowledgement

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

2 Principle of truthfulness, timeliness and clarity of communication

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

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

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

3 Principle of apology

Patients and/or their carers should receive a sincere expression of sorrow or regret for the harm that has resulted from a patient safety incident. This should be in the form of an appropriately worded and agreed manner of apology, as early as possible.
Both verbal and written apologies should be given. Based on local circumstances, healthcare organisations should decide on the most appropriate member of staff to issue these apologies to patients and/or their 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 and/or their carers and the healthcare team. This should be given as soon as staff are aware an incident has occurred. It is important not to delay for any reason, including: setting up a more formal multidisciplinary *Being open* discussion with the patient and/or their carers; fear and apprehension; or lack of staff availability. Delays are likely to increase the patient’s and/or their carer’s sense of anxiety, anger or frustration. Three patient and public focus groups, which reviewed the draft version of the *Being open* policy, reported that patients were more likely to seek medico-legal advice if verbal and written apologies were not delivered promptly.

A written apology, which clearly states the healthcare organisation is sorry for the suffering and distress resulting from the incident, must also be given.

### 4 Principle of recognizing patient and carer expectations

Patients and/or their carers can reasonably expect to be fully informed of the issues surrounding a patient safety incident, and its consequences, in a face-to-face meeting with representatives from the healthcare organisation. They should be treated sympathetically, with respect and consideration. Confidentiality must be maintained at all times. Patients and/or their carers should also be provided with support in a manner appropriate to their needs. This involves consideration of special circumstances that can include a patient requiring additional support, such as an independent patient advocate on a translator.

Where appropriate, information on the Patient Advisory and Liaison Service (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 Principle of 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 NPSA’s incident decision tree (IDT). The IDT has been developed as an aid to improve the consistency of decision making about whether human error or systems failures contributed to an incident. It is designed for use by anyone who has the authority to exclude a member of staff from work following a patient safety incident (including medical and nursing directors, chief
executives and human resources staff). More details can be found in *Seven steps to patient safety* and on the NPSA website: www.npsa.nhs.uk

Where there is reason for the 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 General Medical Council, Royal Colleges, the Medical Protection Society, the Medical Defence Union and the Nursing and Midwifery Council.

6 **Principle of risk management and systems improvement**

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

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 RCA or SEA, decision making about staff accountability using the IDT and an organisational approach that follows *Seven steps to patient safety*.

7 **Principle of multidisciplinary responsibility**

Any local policy on openness should apply to all staff who have key roles in the patient's care. Most healthcare provision involves multidisciplinary teams and communication with patients and/or their carers following an incident that led to harm, should reflect this. This will ensure that the *Being open* process is consistent with the philosophy that incidents usually result from systems failures and rarely from the actions of an individual. To ensure multidisciplinary involvement in the *Being open* process, it is important to identify clinical, nursing and managerial opinion leaders who will champion it. Both senior managers and senior clinicians who are local opinion leaders must participate in incident investigation and clinical risk management.

8 **Principle of 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. It also involves a system of accountability through the chief executive to the board to ensure these changes are implemented and their effectiveness reviewed. These findings should be disseminated to healthcare workers so that they can learn from patient safety incidents. 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 Principle of confidentiality

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

10 Principle of continuity of care

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

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

1 Communication

As stated earlier, healthcare organisations need to create an environment that facilitates open and effective communication. Each organisation should identify a member of staff who is appropriate in seniority, expertise and experience to be responsible for implementing, overseeing and reviewing the local Being open policy. This may be the medical or nursing director, clinical governance lead, or risk manager for example. See ‘Section F: initiating the Being open process’ for information on choosing the individual to communicate with patients and/or their carers.

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 a 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. It is important to identify at the outset any special restrictions on openness that the patient would like the healthcare team to respect. It is also important to identify whether the patient does not wish to know every aspect of what went wrong, to respect their wishes and reassure them this information will be made available if they change their mind later on;
- provide repeated opportunities for the patient and/or their carers to obtain information about the patient safety incident;
- provide information to patients in verbal and/or written format;
- provide assurance that an 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 and/or their carers and the healthcare team will not affect their access to treatment;
• facilitate inclusion of the patient's carers or significant others in discussions about a patient safety incident where the patient agrees;
• provide carers and those very close to the patient 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 represent this information to the patient at different times to allow them to comprehend the situation fully;
• ensure 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 patients and/or their carers are documented and that information is shared with them;
• ensure the patient and/or their carers are provided with information on the complaints procedure if they wish to have it;
• ensure the patient and/or their carers are provided with information on the incident reporting process;
• ensure the patient’s account of the events leading up to the patient safety incident are fed into the incident investigation (for example, through RCA), whenever applicable;
• ensure the patient and/or their carers are provided with information on how improvement plans derived from RCA will be implemented and their effects monitored;
• develop a system for monitoring and auditing the patient's perceptions of the Being open process and ensure their comments are fed back to healthcare staff.

2 Advocacy and support
Patients and/or their carers may need considerable practical and emotional help and support after experiencing a patient safety incident. The most appropriate type of support may vary widely between patients and/or their carers. It is therefore important to discuss their individual needs with the patient and/or their carers. Support may be provided by patients’ families, social workers, religious representatives and healthcare organisations such as Patient Advisory and Liaison Service (PALS), Independent Complaints Advocacy Service (ICAS) and Community Health Councils (CHC) in Wales, among others. Where the patient needs more detailed long-term emotional support, advice should be provided on how to gain access to appropriate counselling services, for example, from Cruse Bereavement Care and Action against Medical Accidents. See Appendix C for a list of relevant organisations.

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

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

3.2 Children

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

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

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

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

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

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 this extends to decision making and to the medical care and treatment of the patient. The Being open discussion would be held with the holder of the power of attorney. Where there is no such person the clinicians may act in the patient's best interest in deciding who the appropriate person is to discuss incident information with, regarding the welfare of the patient as a whole and not simply their medical interests. However, the patient with a cognitive impairment should, where possible, be involved directly in communications about what has happened. An advocate with appropriate skills should be available to the patient to assist in the communication process. 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 above). If the patient is not cognitively impaired they should be supported in the Being open process by alternative communication methods (i.e., given the opportunity to write questions down). An advocate, agreed on in consultation with the patient, should be appointed. Appropriate advocates may include carers, family or friends of the patient. The advocate should assist the patient during the Being open process, focusing on ensuring that the patient’s views are considered and discussed.
3.6 Patients who do not agree with the information provided

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

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

3.7 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.

3.8 Patients with different communication needs

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

Knowing how to enable or enhance communications with a patient is essential to facilitating an effective Being open process, focusing on the needs of individuals and their families and being personally thoughtful and respectful.
Section C: staff issues

When a patient safety incident occurs, healthcare professionals involved in the patient’s clinical care may also require emotional support and advice. Both clinicians who have been involved directly in the incident and those with the responsibility for Being open discussions should be given access to assistance, support and any information they need to fulfil this role.

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 blame is the enemy of learning and where human error is understood to be a consequence of flaws in the healthcare systems, not necessarily the individual. More detailed advice on creating an open and fair culture can be found in Seven steps to patient safety;

• 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. The 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 box on the following page);

• provide information on the support systems currently available for professionals 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, such as staff counselling services (if these are not already in place).
NPSA training support includes:

- two e-learning training modules: ‘An introduction to patient safety’ and ‘A guide to root cause analysis from the NPSA’ (visit www.npsa.nhs.uk for more information);
- the incident decision tree (IDT);
- a national training programme for root cause analysis for up to eight staff per healthcare organisation so that by 2005 expertise will be embedded in every NHS organisation in England and Wales;
- an e-learning tool kit on Being open, due for launch in 2005;
- video-based training workshops for healthcare professionals who have to communicate with patients and/or their carers following an incident, due for launch in 2005.
Section D: organisational issues

Seven steps to patient safety explains the importance of organisational commitment to improving patient safety. This commitment is required throughout the whole healthcare organisation, from the board through to clinical and non-clinical staff. In addition to the responsibilities described in Seven steps to patient safety, healthcare organisations should consider the following legal requirements when engaging in Being open:

- appropriate confidentiality must be maintained at all times. Only anonymous data about patient safety incidents should be disseminated beyond the treating clinicians and the investigating team. Where a patient makes information public it is permissible to confirm its accuracy or to make a simple statement that the information is incorrect. Where additional information is to be disclosed, for example, to correct statements made to the media, the patient and his/her representatives should be advised of any forthcoming statement and the reasons for it. Patient consent should be sought, but if it is not given disclosure may still be warranted in the public interest;

- 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 NHS Litigation Authority or Welsh Risk Pool should be involved.

Healthcare organisations should also educate all their healthcare professionals about the aims of the Being open policy and ensure they understand that saying sorry to patients and/or their carers is not an admission of liability.
Section E: incident detection or recognition

1 General
The Being open process begins with the recognition that a patient has suffered moderate harm, severe 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.

2 Detection
A patient safety incident may be identified by:

- a member of staff at the time of the incident;
- a member of staff retrospectively when an unexpected outcome is detected;
- a patient and/or their carers who expresses concern or dissatisfaction with the patient’s healthcare either at the time of the incident or retrospectively;
- incident detection systems such as incident reporting or medical records review;
- other sources such as detection by other patients, visitors or non-clinical staff (for example, researchers observing healthcare staff as part of ethnographic studies).

3 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 (RCA) or significant event audit (SEA) to assist in identifying the underlying causes of a patient safety incident. See ‘Section C: staff issues’ for details of the NPSA’s RCA training programme. More information is also available at: www.npsa.nhs.uk
4 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.

5 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.
Section F: initiating the Being open process

1 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 and/or their carers;
- consider the appropriateness of engaging patient support at this early stage. This includes the use of a facilitator, a patient advocate or a healthcare professional who will be responsible for identifying the patient’s needs and communicating them back to the healthcare team;
- identify immediate support needs for the healthcare staff involved;
- ensure there is a consistent approach by all team members around discussions with the patient and/or their carers.

2 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 if considered to require a high level of response. The level of response to a patient safety incident depends on the nature of the incident. See suggested matrix below (NPSA definitions of levels of harm can be found in Appendix B).
Table 1: grading of patient safety incidents to determine level of response

<table>
<thead>
<tr>
<th>Incident</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>No harm (including prevented patient safety incident)</td>
<td>Patients are not usually contacted or involved in investigations and these types of incidents are outside the scope of the <em>Being open</em> policy. Individual healthcare organisations decide whether ‘no harm’ events (including prevented patient safety incidents) are discussed with patients and/or their carers, depending on local circumstances.</td>
</tr>
<tr>
<td>Low harm</td>
<td>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. Communication should take the form of an open discussion between the staff providing the patient’s care and the patient and/or their carers. Reporting to the risk management team will occur through standard incident reporting mechanisms and be analysed centrally to detect high frequency events. Review will occur through aggregated trend data and local investigation. Where the trend data indicates a pattern of related events, further investigation and analysis may be needed.</td>
</tr>
<tr>
<td>Moderate harm, severe harm or death</td>
<td>A higher level of response is required in these circumstances. The risk manager should be notified immediately and be available to provide support and advice during the <em>Being open</em> process if required. The organisation’s <em>Being open</em> policy is implemented.</td>
</tr>
</tbody>
</table>

As stated previously, it is not a requirement of this policy to communicate prevented patient safety incidents and ‘no harm’ incidents to patients and/or carers. We leave it to the jurisdiction of local healthcare organisations to decide whether to communicate these incidents to patients and/or their carers, based on local circumstances.

3 Timing

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

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

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

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

• be known to, and trusted by, the patient and/or their carers;
• have a good grasp of the facts relevant to the incident;
• be senior enough or have sufficient experience and expertise in relation to the type of patient safety incident to be credible to patients, carers and colleagues;
• have excellent interpersonal skills, including being able to communicate with patients and/or their carers in a way they can understand and avoiding excessive use of medical jargon;
• be willing and able to offer an apology, reassurance and feedback to patients and/or their carers;
• be able to maintain a medium to long term relationship with the patient and/or their carers, where possible, and to provide continued support and information;
• be culturally aware and informed about the specific needs of the patient and/or their carers.

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

The healthcare professional communicating information about a patient safety incident should be able to nominate a colleague to assist them with the meeting. Ideally this should be someone with experience or training in communication and *Being open* procedures.

4.4 **Consultation with the patient regarding the healthcare professional leading the Being open discussion**

If for any reason it becomes clear during the initial discussion that the patient would prefer to speak to a different healthcare professional, the patient's wishes should be respected. A substitute with whom the patient is satisfied should be provided.

4.5 **Responsibilities of junior healthcare professionals**

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

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

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

4.6 **Patient safety incidents related to the environment of care**

In such cases a senior manager of the relevant service will be responsible for communicating with the patient and/or their carers. A senior member of the multidisciplinary team should be present to assist at the initial *Being open* discussion. The healthcare professional responsible for treating the injury should also be present to assist in providing information on what will happen next and the likely effects of the injury.

4.7 **Involving healthcare staff who made mistakes**

Some patient safety incidents that resulted in moderate harm, severe harm or death will result from errors made by healthcare staff while caring for the patient. In these circumstances the member(s) of staff involved may or may not wish to participate in the *Being open* discussion with the patient and/or their carers. Every case where an error has occurred needs to be considered individually, balancing the needs of the patient and/or their carers with those of the healthcare professional concerned. In cases where the healthcare professional who has made an error wishes to attend the discussion to apologise personally, they should feel supported by their colleagues throughout the meeting. In cases where the patient and/or their carers express a preference for the healthcare professional not to be present, it is advised that a personal written apology is handed to the patient and/or their carers during the first *Being open* discussion.
5 Content of the initial Being open discussion with the patient and/or their carers

- The patient and/or their carers should be advised of the identity and role of all people attending the Being open discussion before it takes place. This allows them the opportunity to state their own preferences about which healthcare staff should be present.
- There should be an expression of genuine sympathy, regret and an apology for the harm that has occurred.
- The facts that are known are agreed by the multidisciplinary team. Where there is disagreement, communication about these events should be deferred until after the investigation has been completed. The patient and/or their carers should be informed that an incident investigation is being carried out and more information will become available as it progresses.
- It should be made clear to the patient and/or their carers that new facts may emerge as the incident investigation proceeds.
- The patient's and/or carer's understanding of what happened should be taken into consideration, as well as any questions they may have.
- There should be consideration and formal noting of the patient's and/or carer's views and concerns, and demonstration that these are being heard and taken seriously.
- Appropriate language and terminology should be used when speaking to patients and/or their carers. For example, using the terms ‘patient safety incident’ or ‘adverse event’ may be at best meaningless and at worst insulting to a patient and/or their carers. If a patient's and/or their carer's mother tongue is not English, it is also important to consider their language needs – if they would like the Being open discussion conducted in Welsh or Urdu for example, this should be arranged.
- An explanation should be given about what will happen next in terms of the long term treatment plan and incident analysis findings.
- Information on likely short and long term effects of the incident (if known) should be shared. The latter may have to be delayed to a subsequent meeting when the situation becomes clearer.
- An offer of practical and emotional support should be made to the patient and/or their 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 should be recognised that patients and/or their carers may be anxious, angry and frustrated even when the Being open discussion is conducted appropriately.

It is essential that the following does not occur:

- speculation;
- attribution of blame;
- denial of responsibility;
- provision of conflicting information from different individuals.
The initial Being open discussion is the first part of an ongoing communication process. Many of the points raised here should be expanded on in subsequent meetings with the patient and/or their carers.

6 Notification

6.1 Risk manager
In all cases the risk manager should be informed either by telephone, electronically or by completion of the incident form. The NPSA will then receive anonymous notification of the incident through the National Reporting and Learning System.

6.2 Management
The individual responsible for clinical risk will usually notify management. However, when a major incident occurs or where a criminal act is suspected, the chief executive must be notified immediately (as per local policy) and the incident reported through the national Serious Untoward Incident (SUI) reporting system.

6.3 General practitioner
Consideration should be given to contacting the referring GP at an early time for incidents that have not occurred within primary care but have implications for continuity of care. By informing them they can offer their support to the patient and/or their carers.

6.4 The coroner
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 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’ family, their carers and healthcare professionals. Bereavement counselling and advice on professional support groups should be offered at the outset of a coroner’s investigation.

6.5 Relevant statutory/other bodies
Healthcare organisations need to ensure they comply with the national notification requirements, such as the SUI process or the Welsh Assembly Government’s Serious Adverse Incidents Policy.
Section G: documentation

1 General

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

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

2 Written records of the Being open discussion

There should be documentation of:

- the time, place, date, as well as the name and relationships of all attendees;
- the plan for providing further information to the patient and/or their carers;
- offers of assistance and the patient’s and/or carer’s response;
- questions raised by the family and/or carers or their representatives, and the answers given;
- plans for follow-up as discussed;
- progress notes relating to the clinical situation and an accurate summary of all the points explained to the patient and/or their carers;
- copies of letters sent to patients, carers and the GP for patient safety incidents not occurring within primary care;
- copies of any statements taken in relation to the patient safety incident;
- a copy of the incident report.

A summary of the Being open discussion should be shared with the patient.

3 Incident report

An initial incident report should be submitted by clinical or other staff through the means defined by the local policy and in line with the requirements of the NRLS established by the NPSA.
Section H: preliminary follow-up

The preliminary follow-up discussion with the patient and/or their carers is an important step in the Being open process. The following guidelines should assist in making the communication effective:

- The discussion should occur at the earliest practical opportunity.
- Consideration should be given to the timing of meeting, based on both the patient’s health and personal circumstances.
- Consideration should be given to the location of the meeting e.g. the patient’s home.
- Feedback should be given on progress to date and information provided on the investigation process.
- There should be no speculation or attribution of blame. Similarly, the healthcare professional communicating the incident must not criticise or comment on matters outside their own experience.
- The patient and/or their carers should be offered an opportunity to discuss the situation with another relevant professional where appropriate.
- A written record of the discussion should be kept and shared with the patient and/or their carers.
- All queries should be responded to appropriately.
- If completing the process at this point, the patient and/or their carers should be asked if they are satisfied with the investigation and a note of this made in the patient’s records.
- The patient should be provided with contact details so that if further issues arise later there is a conduit back to the relevant healthcare professionals or an agreed substitute.
Section I: completing the process

1 Communication with the patient and/or their carers

After completion of the incident investigation, feedback should take the form most acceptable to the patient. Whatever method is used, the communication should include:

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

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

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 and/or their carers should be reassured that they will continue to be treated according to their clinical needs even in circumstances where there is a dispute between them and the healthcare team. They should also be informed that they have the right to continue their treatment elsewhere if they have lost confidence in the healthcare team involved in the patient safety incident.
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, a discharge letter should also be forwarded to the GP or appropriate community care service. It should contain summary details of:

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

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

4 Monitoring

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

5 Communication of changes to staff

Effective communication with staff is a vital step in ensuring that recommended changes are fully implemented and monitored. It will also facilitate the move towards increased awareness of patient safety issues and the value of being open.

6 Communication of lessons learned throughout the health service

The NPSA will publish patient safety alerts, safer practice notices and patient safety information notices to highlight common factors that cause patient safety incidents, and to publicise its advice and solutions to the service. The primary aim will be to help reduce the risk of such incidents recurring. It will also use its website (www.npsa.nhs.uk) plus a number of specialist web resources, to share this and supporting background information with healthcare staff.
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 resulted in moderate harm, severe harm or 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 primary coordination responsibility for issues of clinical risk management. See 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.

**Liability:** legal responsibility for an action or event.

**National Reporting and Learning System (NRLS):** a confidential and anonymous computer-based system developed by the NPSA for the collection and analysis of patient safety incident information. It receives incident reports from NHS organisations, staff and contractor professions and, in time, patients and carers.
Reports are received via a technical link to existing local risk management systems or direct reporting to the NPSA through an electronic reporting form (eForm). Through the system the NPSA will inform national learning about risks to patient care, establish priorities for action, and work with the NHS to develop practical solutions to improve patient safety.

**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 establishments 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.

**NPSA:** the National Patient Safety Agency 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 improve the safety of patients by promoting a culture of reporting and learning from patient safety incidents.

**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 the 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
- eForm: electronic form used to submit reports to the NRLS
- GMC: General Medical Council
- ICAS: Independent Complaints Advocacy Services
- IDT: Incident Decision Tree
- MORI: Market and Opinion Research International
- MPS: Medical Protection Society
- NHSLA: National Health Service Litigation Authority
- NPSA: National Patient Safety Agency
- NRLS: National Reporting and Learning System
- PALS: Patient Advisory and Liaison Service
- RCA: Root cause analysis
- RPST: Risk Pooling Schemes for Trusts
- SUI: Serious untoward incidents
- WRP: Welsh Risk Pool
### Appendix B: NPSA terms and definitions for grading patient safety incidents

<table>
<thead>
<tr>
<th>Grade of patient safety incident</th>
<th>Definition</th>
</tr>
</thead>
</table>
| 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. |
|                                  | *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 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. |
|                                  | *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.
<table>
<thead>
<tr>
<th>Grade of patient safety incident</th>
<th>Definition</th>
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<tbody>
<tr>
<td><strong>Severe harm</strong></td>
<td>Any patient safety incident that appears to have resulted in permanent harm* to one or more patients receiving NHS-funded care.</td>
</tr>
<tr>
<td></td>
<td>*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.</td>
</tr>
<tr>
<td><strong>Death</strong></td>
<td>Any patient safety incident that directly resulted in the death* of one or more patients receiving NHS-funded care.</td>
</tr>
<tr>
<td></td>
<td>*The death must be related to the incident rather than to the natural course of the patient's illness or underlying condition.</td>
</tr>
</tbody>
</table>
Appendix C: support and advice for those who are bereaved

Find out more about local services at Patient UK – www.patient.co.uk

**National organisations**

**The Child Bereavement Trust**
Aston House, West Wycombe, High Wycombe, Bucks HP14 3AG
Information and support service line: 0845 357 1000
enquiries@childbereavement.org.uk
www.childbereavement.org.uk

National UK charity providing specialised training and support for professionals to help them respond to the needs of bereaved families. Resources and information for bereaved children and families as well as the doctors, nurses, midwives, teachers, police, emergency services and voluntary sector support services.

**Cruse Bereavement Care**
Cruse Bereavement Care, Cruse House, 126 Sheen Road, Richmond TW9 1UR
Tel: 0870 167 1677
www.crusebereavementcare.org.uk

Charity providing information to anyone who has been affected by a death. Also offers education, support, information and publications to anyone supporting bereaved people. A national charity with over 6,000 trained counsellors.

**Supportline**
PO Box 1596, Ilford, Essex, IG1 3FW
Helpline: 020 8554 9004 (opening hours vary)
www.supportline.org.uk

A helpline providing confidential emotional support to children, young people and adults on any issue - referring callers to sources of help in their immediate area.
London Bereavement Network
356 Holloway Road, London N7 6PA
Tel: 020 7700 8134
www.bereavement.org.uk/about/index.asp
Offers information and a referral service to anyone living in Greater London who is affected by bereavement.

British Association for Counselling and Psychotherapy
1 Regent Place, Rugby, Warwickshire CV21 2PJ
Tel: 0870 443 5252
www.bacp.co.uk
The 'Seeking a Therapist' section of the website gives lists of qualified counsellors and psychotherapists available in your area. This service is also available over the phone.

Jewish Bereavement Counselling Service
PO Box 6748, London N3 3BX
Tel: 020 8349 0839/020 8343 8989
www.jvisit.org.uk/jbcs/
The service is offered to any member of the Jewish community at no charge.

Royal College of Psychiatrists
www.rcpsych.ac.uk/info/help/bereav/
In-depth information about the emotions you may feel during bereavement.

Depression Alliance
35 Westminster Bridge Road, London SE1 7JB
Textphone/Minicom: 0207 928 9992
www.depressionalliance.org
A UK charity offering information to people with depression; run by sufferers.

Samaritans
Helpline: 08457 90 90 90 (24 hours)
www.samaritans.org
24-hour confidential emotional support for anyone in a crisis.

If I Should Die
www.ifishoulddie.co.uk
This website looks at all aspects of bereavement from the practical to the emotional.
Support for carers
The Princess Royal Trust for Carers
142 Minories, London, EC3N 1LB
Tel: 020 7480 7788
www.carers.org
Information, support and practical help for all carers through a network of Princess Royal Trust for Carers centres.

Carers UK/ Carers National Association
20-25 Glasshouse Yard, London EC1A 4JS
Helpline: 0808 808 7777 (freephone, 10am-12noon and 2pm-4pm, Mon-Fri)
www.carersuk.org.uk/about/main.htm
Runs a helpline and provides support, encouraging carers to recognise their own needs. There is also an information officer to answer enquiries from professionals.

Caring Matters
132 Gloucester Place, London NW1 6DT
Tel: 020 7402 270
Focuses on the rights and responsibilities of everyone receiving or providing long-term care services.

Seniorline
England, Scotland, Wales: 0808 800 6565 (freephone)
Northern Ireland: 0808 808 7575 (freephone)
The lines are open Mon-Fri between 9am-4pm.
Free national information service for senior citizens, their carers and relatives.

When a baby or child dies
Child Death Helpline
Great Ormond Street Hospital for Children, London, WC1N 3JH
Tel: 0800 282 986
www.childdeathhelpline.org.uk
A telephone helpline that offers help and support to anyone affected by the death of a child. Staffed by parent volunteers who are supported by a professional team.

Compassionate Friends
53 North Street, Bedminster, Bristol BS3 1EN
Help Line: 0117 953 9639 (seven days 9.30am-10.30pm)
www.tcf.org.uk
Support and friendship for bereaved parents and their families.
SANDS - Stillbirth and Neonatal Death Society (UK)
28 Portland Place, London W1N 4DE
Helpline: 0207 436 5881
www.uk-sands.org
A national self-help organisation that provides support for bereaved parents and their families whose baby has died at or soon after birth.

The Cot Death Society
1 Browning Close, Thatcham, Berks RG13 4AU
Tel: 01635 861 771
Help and support for anyone affected by cot death.

Scottish Cot Death Trust
Tel: 0141 357 3946
www.sidscotland.org.uk
Provides support and information to parents bereaved by sudden infant deaths.

The Foundation for the Study of Infant Deaths
24-hour helpline: 0207 235 1721
Offers help to those who have lost a baby.

Babyloss.com
www.babyloss.com
An exclusively online resource for anyone whose life has been touched by pregnancy loss, stillbirth or neonatal death.

Loss in pregnancy
Miscarriage Association:
Helpline: 01924 200 799
Helpline (Scotland): 0131 331 883
www.miscarriageassociation.org.uk
Provides support for those who have suffered the loss of a baby during pregnancy.

Help for young people
rd4u
Cruse Bereavement Care, Cruse House, 126 Sheen Road, Richmond, Surrey TW9 1UR
Helpline: 0808 808 1677 (answered by trained volunteers aged between 16-25, 4pm-7pm, Mon-Wed)
www.rd4u.org.uk
The youth branch of Cruse, set up to help young people after the death of someone close.
Winston’s Wish
The Clara Burgess Centre, Gloucestershire Royal Hospital, Great Western Road, Gloucester GL1 3NN
Helpline: 0845 2030405 (9.30am-5pm, Mon-Fri; 9.30am-1pm, Sat)
www.winstonswish.org.uk
Charity that offers support to young people who have experienced bereavement.

ChildLine
Helpline: 0800 1111
www.ChildLine.org.uk
Free, 24-hour helpline for children and young people who need to talk about any problem they may have.

Childhood Bereavement Network
Huntingdon House, 278-290 Huntingdon Street, Nottingham NG1 3LY
Tel: 0115 911 8070
A new national resource for bereaved children and young people, their parents and care givers.
References

1 Department of Health (2001). *Building a safer NHS for patients*. Copies can be obtained from the Department of Health, PO Box 777, doh@prolog.uk.com Available at: www.dh.gov/assetRoot/04/05/80/94/04058094.pdf (April 2004)
11 Kaplan C and Hepworth S. *Supporting health service staff involved in a complaint, incident or claim - an NHSLA initiative*. NHSLA journal, 2004, issue 3, 11–13


**Other useful references**


Being open

The National Patient Safety Agency’s policy on openness and honesty following patient safety incidents

“The Healthcare Commission warmly welcomes this initiative from the NPSA. Improving patient safety is a real priority for both ourselves and the NPSA. The Being open policy is rooted in sound evidence, and is supported with practical advice that will enhance learning and improvement. It has my full support.”

Anna Walker
Chief Executive
Healthcare Commission
The National Patient Safety Agency

We recognise that healthcare will always involve risks, but that these risks can be reduced by analysing and tackling the root causes of patient safety incidents. We are working with NHS staff and organisations to promote an open and fair culture, and to encourage staff to inform their local organisations and the NPSA when things have gone wrong. In this way, we can build a better picture of the patient safety issues that need to be addressed.