STEPS

NHS

National Patient Safety Agency

Seven steps to patient safety
The full reference guide

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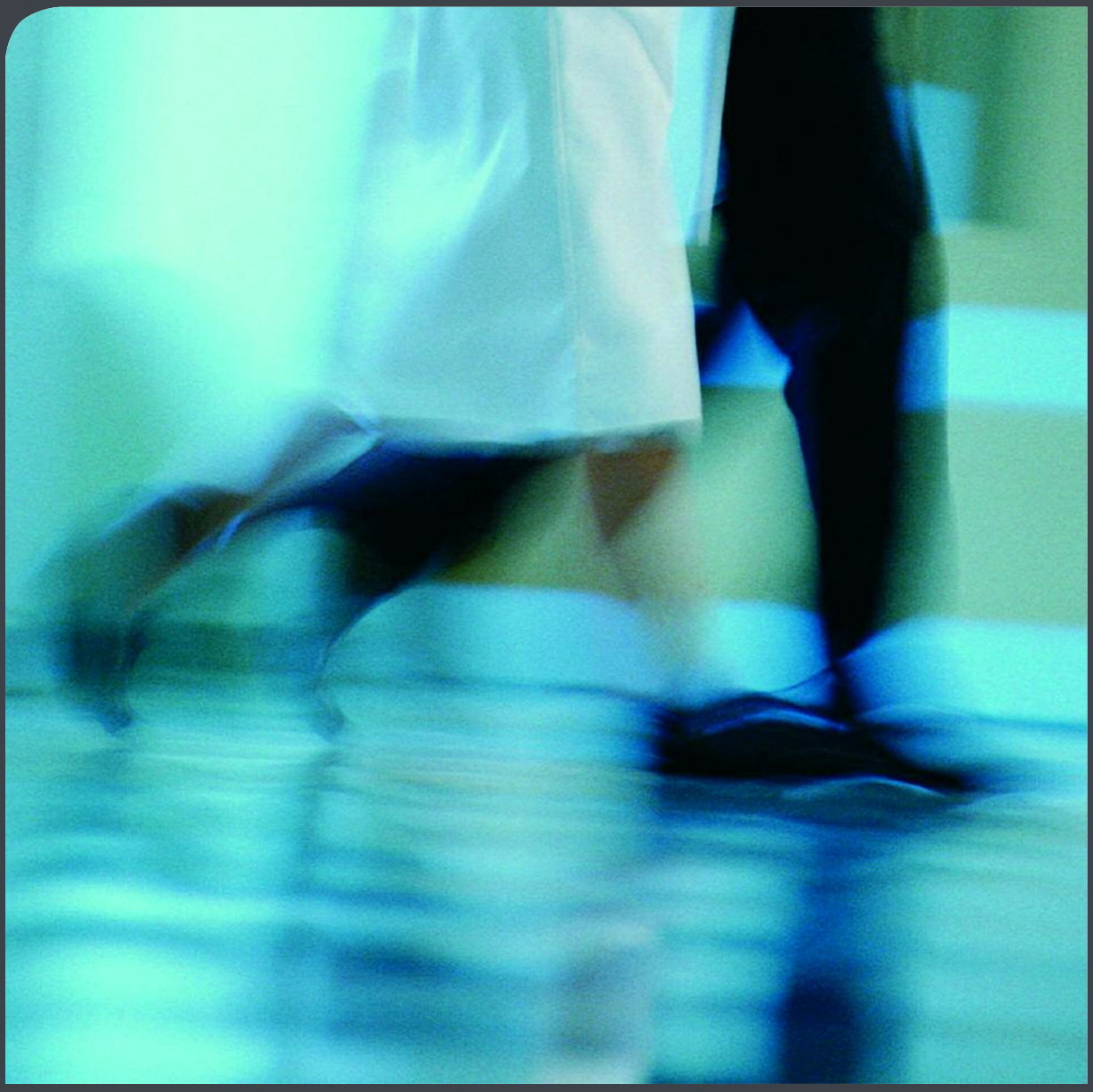

Summary introduction

Every day more than a million people are treated safely and successfully in the NHS. However, the advances in technology and knowledge in recent decades have created an immensely complex healthcare system. This complexity brings risks, and evidence shows that things will and do go wrong in the NHS; that patients are sometimes harmed no matter how dedicated and professional the staff.

Your guide to patient safety

Seven steps to patient safety describes the steps that NHS organisations need to take to improve safety. They provide a checklist to help you plan your activities and measure your performance in patient safety. Following these steps will help ensure that the care you provide is as safe as possible, and that when things do go wrong the right action is taken. They will also help you meet your clinical governance, risk management and controls assurance targets.

The seven steps to patient safety

Step 1	Build a safety culture
Step 2	Lead and support your staff
Step 3	Integrate your risk management activity
Step 4	Promote reporting
Step 5	Involve and communicate with patients and the public
Step 6	Learn and share safety lessons
Step 7	Implement solutions to prevent harm

Seven steps to patient safety is published by the National Patient Safety Agency (NPSA) and is available in full and in summary form at www.npsa.nhs.uk/sevensteps

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Introduction

A message from the Joint Chief Executive

Every day more than a million people are treated safely and successfully in the NHS. However the advances in technology and knowledge in recent decades have created an immensely complex healthcare system. This complexity brings risks, and evidence shows that things will and do go wrong in the NHS; that patients are sometimes harmed no matter how dedicated and professional the staff.

The effects of harming a patient are widespread. There can be devastating emotional and physical consequences for patients and their families. For the staff involved too, incidents can be distressing, while members of their clinical teams can become demoralised and disaffected. Safety incidents also incur costs through litigation and extra treatment.

Patient safety concerns everyone in the NHS, whether you work in a clinical or a non-clinical role. At the National Patient Safety Agency (NPSA) we believe that tackling patient safety in the NHS collectively and in a systematic way can have a positive impact on the quality of care and efficiency of NHS organisations.

Your guide to patient safety

Seven steps to patient safety describes the steps that NHS organisations need to take to improve safety. These steps are founded on a thorough review of literature from across the world (on patient safety, clinical governance, change management and risk management) and on experience of what works in patient safety. The guide builds on recommendations made in the Department of Health publication *An organisation with a memory*[1] and replaces the draft guidance 'Doing Less Harm'[2] to reflect current thinking and best practice. It also updates NHS organisations on the tools that the NPSA is developing to support the drive towards safer healthcare.

The objectives of this guide are to:

- provide specific information on:
- patient safety definitions;
- resources such as the safety culture assessment tool, the Incident Decision Tree (IDT), the introduction to patient safety e-learning toolkit and induction video, and the root cause analysis (RCA) toolkit and proposed training programmes;
- guidance on being open with patients and the public;
- the National Reporting and Learning System (NRLS);
- examples of safety solutions;

- provide information on good practice;
- highlight what the NPSA is doing to help NHS organisations improve patient safety.

It is vital that NHS staff can assess the progress they make towards delivering this safety agenda. In this guide we have set out seven steps that can be applied at both an organisational and departmental level. They provide a checklist to help you plan your activities and measure your performance in patient safety. Following these steps will help ensure that the care you provide is as safe as possible, and that when things do go wrong the right action is taken. They will also help you meet your current clinical governance, risk management and controls assurance targets.

Some organisations are already well advanced along the route to patient safety but many are right at the beginning of their journey. We have therefore tried to provide practical hints and techniques as well as examples of local best practice and toolkits for the management of patient safety.

We have made every effort to pilot each NPSA initiative first. While this may have slowed our progress we felt that it was crucial before any national roll out across the NHS. And we have tried not to be too prescriptive – there are national solutions for universal processes and procedures but local problems require local solutions tailored to the unique local environment. We hope this guide helps you identify the gains you can make within your own organisation, department or team.

Who should read this guide?

Seven steps to patient safety is most relevant to staff responsible for clinical governance and risk management, including executive and non-executive leads. We also encourage all staff who provide care in the NHS to use it as a patient safety manual. This includes those working in any care setting (primary, secondary and tertiary care, acute care, ambulance services, mental health services, the independent sector) that provides care for NHS patients. It may also be a helpful resource for patients, their representatives and the public.

The guide is primarily intended for NHS organisations in England and Wales but it may also apply to organisations in other countries.

Acknowledgments

The NPSA recognises that improving patient safety depends not only on our work nationally but also on the vital work that is taking place at a local level. We have benefited greatly from the passion and steadfast work of numerous individuals (staff, patients and the public) across all levels of the NHS. Since we were established in 2001 we have encountered a high level of commitment to patient safety from a diverse range of NHS and non-NHS staff. Hundreds of organisations are already working with us to drive forward the patient safety agenda.

In particular we would like to acknowledge the organisations that have worked with us to develop and test the NRLS. We would also like to recognise the organisations that volunteered to pilot our solutions work and that helped us to develop our patient safety tools. Our thanks and gratitude go to all these organisations for their time, commitment and enthusiasm for patient safety.

Safety in healthcare is a relatively young field internationally and it will be some time before we understand its full potential. We still have a long way to go. But we are already seeing evidence that by working together we can all make healthcare safer.

Sue Osborn and Susan Williams

Joint Chief Executive

Acknowledgments:

- Authors/editorial support: Suzette Woodward, Susannah Randall, Amanda Hoey and Rachel Bishop
- Advisors: NPSA staff and Board members, the Department of Health policy advisors, Chief Medical Officers (England and Wales), the National Health Service Litigation Authority, Clinical Risk and Clinical Governance Staff in the NHS, Professor J Reason, Professor R Lilford, Professor C Vincent.

Introduction

Patient safety – our starting point

It is important first to explain the rationale for the increased focus on patient safety in the UK and how this relates to previous safety guidance.

The Department of Health publication *An organisation with a memory* mobilised the patient safety movement in the NHS. The report reviewed the growing body of international evidence on patient safety. It drew attention to the scale and pattern of potentially avoidable patient safety incidents [a] and the devastating consequences these can have on patients, their families and the healthcare staff involved. The report also acknowledged that, as in many other countries, there has been little systematic learning from these patient safety incidents and service failure in the NHS.

It is difficult to accurately estimate the extent of unintended harm to patients across the NHS from the current studies. There is likely to be significant under-reporting and inadequate documentation of patient safety incidents within medical records (the usual source of information on unintended harm for most studies).

On the best available data in England, extrapolating from a small study in two acute care trusts based in London, it is estimated that around 10% of patients (900,000 using admission rates for 2002/3) admitted to NHS hospitals have experienced a patient safety incident, and that up to half of these incidents could have been prevented [3]. This study also estimated that 72,000 of these incidents may contribute to the death of patients, although it is unclear what proportion of this number would die as a direct result of the incident*.

In the US [4, 5], studies have found that between 44,000 and 98,000 incidents are estimated to contribute to patient deaths. This is viewed by many commentators as under-estimating the extent of the problem. Studies in Australia [6], New Zealand and Denmark [1, 7] have suggested similar findings.

The analysis of international evidence in the United States led to two important conclusions [8]:

1 The potential for error in healthcare systems represents a significant and serious challenge that needs concerted effort to manage.

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a **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 'patient safety incident (prevented)' will be used to describe 'adverse events' / 'clinical errors' and 'near misses' respectively.

* **Note:** the NPSA has revised these figures to reflect increased admission rates.

2 The best way of improving reporting and reducing error rates is to target the underlying systems failures rather than take action against individual members of staff.

An organisation with a memory proposed solutions based on developing a culture of openness, reporting and safety consciousness within NHS organisations[b]. The report identified four key areas that need to be addressed if the NHS is to modernise successfully its approach to learning from failure:

1 Unified mechanisms for reporting, and analysis when things go wrong;

2 A more open culture in which incidents or service failures can be reported and discussed;

3 Systems and monitoring processes to ensure that where lessons are identified the necessary changes are put into practice;

4 A much wider appreciation of the value of the systems approach in preventing, analysing and learning from patient safety incidents.

In response to *An organisation with a memory*, the Government report *Building a safer NHS for patients*[9] described how to implement these recommendations. It outlined a blueprint for a national incident reporting system (described in **Step 4**) and discussed the role of the National Patient Safety Agency (NPSA).

There are many examples of initiatives around the world that have successfully demonstrated that patient safety can be improved. However none has been translated to a whole healthcare system. The NHS is uniquely placed to pioneer improvements in patient safety across a single system and *Seven steps to patient safety* provides a framework for NHS organisations to achieve this.

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

The Seven steps to patient safety

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 management activity**
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

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Step 1
Build a safety culture

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Step 1

Build a safety culture

Improving patient safety[c] in the UK requires change in many different areas, including a change in the culture within the NHS. Evidence from other industries shows that if the culture of an organisation is safety conscious and people are encouraged to speak up about mistakes, then safety is improved [1 2 3].

In this first Step we focus on changing the culture of the NHS to improve safety for patients. We explain what the NPSA means by a 'safety culture', which includes being open and fair and subsequently the systems approach to safety. We identify how NHS organisations can assess and change their current culture, and how the NPSA can provide support in building a safety culture in healthcare at national and local level.

The key principles

A safety culture is where staff within an organisation have a constant and active awareness of the potential for things to go wrong. Both the staff and the organisation are able to acknowledge mistakes, learn from them, and take action to put things right.

Being open and fair means sharing information openly and freely, and fair treatment for staff when an incident happens. This is vital for both the safety of patients and the well-being of those who provide their care.

The systems approach to safety acknowledges that the causes of a patient safety incident cannot simply be linked to the actions of the individual healthcare staff involved. All incidents are also linked to the system in which the individuals were working. Looking at what was wrong in the system helps organisations to learn lessons that can prevent the incident recurring.

What is a safety culture?

The culture of an organisation is the pattern of beliefs, values, attitudes, norms, unspoken assumptions and entrenched processes that shape how people behave and work together. It is a very powerful

c **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.

force and something that remains even when teams change and individual staff move on.

There isn't a universally accepted definition of a safety culture in healthcare [4] but it is essentially a culture where staff have a constant and active awareness of the potential for things to go wrong. It is also a culture that is open and fair and one that encourages people to speak up about mistakes. In organisations with a safety culture people are able to learn about what is going wrong and then put things right [5].

In these organisations patient safety is at the forefront of everyone's minds not only when delivering healthcare but also when setting objectives, developing processes and procedures, purchasing new products and equipment, and redesigning clinics, wards, departments and hospitals. It influences the overall vision, mission and goals of an organisation.

Why is a safety culture important?

There is evidence that when open reporting and even-handed analysis of what went wrong are encouraged in principle and by example, this can have a positive and quantifiable impact on the performance of an organisation [6].

A safety culture will help NHS organisations to achieve improvements within their clinical governance [d] agenda. A key part of achieving good clinical governance is recognising that it is not always possible to achieve the perfect outcome clinically and that lessons learned are an important and integral part of a continuous programme for quality improvement [7].

A safe organisation is also an informed organisation [3]. The key benefit of this for the NHS is that each organisation is aware of what can go wrong and what has gone wrong. And as more errors and incidents are reported on a regular basis, each organisation can analyse them according to a variety of factors. If the analysis demonstrates significant themes and clusters of incidents in relation to specific factors, limited resources can then be targeted at the areas that require further investigation.

Other important benefits of a safety culture in the NHS are:

- a potential reduction in the recurrence and in the severity of patient safety incidents through increased reporting and organisational learning;
- a reduction in the physical and psychological harm patients can suffer

d **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.

because people are more aware of patient safety concepts, are working to prevent errors and are speaking up when things go wrong;

- a lower number of staff suffering from distress, guilt, shame, loss of confidence and loss of morale because fewer incidents are occurring;
- an improvement in waiting times for treatment through a higher turnover of patients. This is because patients who experience a safety incident require, on average, an extra seven to eight days in hospital over and above the time their treatment would normally require [6];
- a reduction in the costs incurred for treatment and extra therapy [8 9 10];
- a reduction in resources required for managing complaints and claims;
- a decrease in wider financial and social costs incurred through patient safety incidents including lost work time and disability benefits.

What can health providers do?

Changing values, beliefs and attitudes is not easy [11]. Developing a safety culture in an organisation needs strong leadership and careful planning and monitoring. It also requires changes at all levels of the NHS. It is vital that not only clinical staff but all those who work in NHS organisations, as well as patients and carers, ask themselves how *they* can help to improve the safety of patients.

Seven steps to patient safety describes in practical terms what NHS organisations need to do to build a safety culture. Each Step explains how to implement specific actions, as outlined below:

Step 1	Promote a safety culture that is open and fair for sharing information and ensuring lessons are learned
Step 2	Demonstrate that patient safety is a top leadership priority and fostering effective teamwork
Step 3	Implement integrated risk management processes and routinely conduct organisation-wide assessments of the risk of error and incidents. Evaluate clinical care, procedures, processes and the working environment
Step 4	Report patient safety incidents and identify trends. Give recognition for reporting incidents and safety-driven decision-making

Step 5 Engage patients and families in their safety and providing feedback

Step 6 Undertake systematic investigations following incidents to guide continuous learning and system improvements [3]

Step 7 Implement patient safety improvements that avoid reliance on memory and vigilance

Safety culture assessment

The first stage in developing a safety culture is to establish the culture of your organisation at present. A number of tools are already available to help determine underlying beliefs, attitudes and behaviour. Most are in the form of checklists or questionnaires for staff to complete. They address a variety of issues, including:

- senior management visibility and commitment to safety;
- communication between staff and managers;
- attitudes to incident reporting, blame and punishment;
- factors in the work environment that influence performance (for example, fatigue, distractions, equipment design or usability).

When choosing a tool to assess safety culture it is important to be aware that it will provide a snapshot of the culture at one point in time, and you need to repeat the assessment regularly to check your progress.

To give organisations a sense of how a safety culture assessment works, some examples of the tools available are explained below. They fall broadly into two types:

Typological tools	Dimensional tools
These are checklists of the features an organisation with a safety culture should exhibit. They allow staff to assess whether the safety features exist in their organisation or not. Typological tools provide a single statement on the organisation's safety culture ranging from 'unsafe' to 'very safe'.	These define an organisation by its position on a number of continuous variables. Data is usually collected by using a scale (i.e. a 1–5 response scale) in which staff rate how far they agree or disagree with a set of statements.
Checklist for Assessing Institutional Resilience (CAIR)[12]	**Safety Attitudes Questionnaire (SAQ)[18 19]**
The checklist comprises 20 points based on a variety of research evidence[13 14 15 16 17].	The SAQ was designed to study the attitudes of pilots in the cockpit and used as a baseline for assessing the effects of airline industry training programmes. It was tailored for use in healthcare in the late 1990s by Professor Robert Helmreich [e] as the Operating Room or Operating Theatre Management Attitudes Questionnaire (ORMAQ and OTMAQ respectively). The questionnaire compares attitudes to safety across professional groups and between hospitals.
Manchester Patient Safety Assessment Tool[20] (MaPSaT)	**Stanford Patient Safety Centre of Inquiry Culture Survey[22]**
Resulting from collaboration between the National Primary Care Research and Development Centre and Manchester University's psychology department, and based on Westrum's[21] theory of organisational safety, MaPSaT aims to help staff in primary care trusts measure the safety culture in their organisation.	The Stanford Survey collects data on 16 topics important to a culture of safety in healthcare, including: • whether reporting incidents is rewarded or punished; • senior management commitment and attitude towards patient safety; • how risks are perceived among different staff; • how safety data is handled; • time pressures on staff; • whether staff stick to policies and procedures; • how well safety is resourced and the training staff received; • the quality of communication in the team.
Advancing Health in America (AHA) and Veterans Health Association (VHA): Strategies for Leadership. An Organisational Approach to Patient Safety[23]	
This checklist helps organisations assess which areas of its practice promote a patient safety culture and which areas it needs to improve on.	

e Professor of psychology at the University of Texas, Austin and director of a research project funded by the Federal Aviation Administration to study human error and develop strategies to manage it

Details of the NPSA safety culture assessment tool can be found in the section 'How can the NPSA help?' further in this Step.

Being open and fair

A fundamental part of any organisation with a culture of safety is to ensure that is it open and fair. For NHS organisations this means that:

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

The Department of Health's publication, *An organisation with a memory*[5] highlighted how in the past the NHS has operated in a culture of blame rather than promoting openness. When things went wrong the response was often to seek one or two frontline workers to blame, who may then have faced disciplinary measures or professional censure[24] and media attention. The National Audit Office report on suspensions of clinical staff[25] following patient safety incidents also found that several staff were suspended despite evidence of systemic failures rather than individual shortcomings.

The Kennedy Report[f] recommended that every effort should be made to create an open and non-punitive environment in the NHS in which it is safe to report and admit incidents. The Government has since made it clear that being open and fair must become a top priority in healthcare.

To create an open and fair environment we need to dispel two key myths[26]:

- **The perfection myth:** if people try hard enough, they will not make any errors.
- **The punishment myth:** if we punish people when they make errors, they will make fewer of them; that remedial and disciplinary action will lead to improvement by channelling or increasing motivation.

Being open and fair does not mean an absence of accountability. It is essential in a public service that our actions are explained and that responsibility is accepted. Along with increased public awareness of

f The Kennedy Report was the public enquiry into children's heart surgery at Bristol Royal Infirmary 1984–1995, which also analysed the flaws and failures of the organisation and culture of the NHS at that time.

patient safety issues, there is increasing public interest in the performance of the health service and therefore an increased expectation around accountability.

The many different forms of accountability influence the decisions healthcare staff make on a daily basis, including when a patient safety incident occurs. Accountability for patient safety means being open with patients, explaining the actions taken and providing assurance that lessons will be learned. NHS organisations need to demonstrate the right balance between both accountability and openness.

Why is it important to be open and fair?

Staff will not report incidents if they believe that they are going to place themselves or their colleagues at risk of being disciplined or punished. An open and fair environment will therefore help ensure the reporting of incidents, from which lessons can be learned and patient safety improved.

Furthermore, the process of adopting a safety culture that is open and fair across the NHS has some very positive implications beyond the patient safety agenda. It could help facilitate modernisation and clinical governance by providing a practical example of what is meant by cultural change and what it means at an operational level.

What can health providers do?

- Organisations need to understand their existing culture before they can change it. The safety culture assessment process referred to earlier, and the tool described in the section 'How can the NPSA help?' further in this Step, will assist organisations in a **baseline assessment** of their safety culture, including whether it is open and fair.
- Changes in attitudes and behaviour can take time to develop and they require an understanding and willingness to adjust. Organisations therefore need to **raise the level of understanding** around patient safety and the systems approach to error and incidents (described in the next section of this Step). The benefits of reporting incidents should be made explicit to individual staff, patients and the organisation, and should be included in all induction and development programmes.
- The **leadership** of any organisation is central to setting the values and beliefs of an organisation's culture. The chief executive, the board and directors therefore have a vital role to play in building a safety culture that is open and fair. They need to establish an environment where the whole organisation learns from safety incidents and where staff are encouraged to report and proactively assess risks[g]. In addition senior managers and

clinicians can set the tone for their departments and teams by promoting and shifting the change in culture. They can ensure that incidents are dealt with fairly and that the appropriate learning and action takes place. An NPSA tool, the Incident Decision Tree (IDT), can help organisations assess incidents and the actions of the individuals involved. This is described in the section 'How can the NPSA help?' further in this Step.

- Being open and fair highlights a need for local NHS disciplinary **policies** that clearly describe how organisations will manage staff involved in incidents, complaints and claims [6 27] to ensure that they are not detrimental to improving patient safety.
- Organisations should also ensure that staff receive **feedback** and are informed of what action has been taken as a result of an incident being reported. Staff are more likely to foster an open attitude if they feel they have been listened to and that by reporting an incident they have made a positive difference to patient safety.
- Being open and fair is also the basis of the relationship between **patients** and their clinicians. Patients should also be encouraged to take greater responsibility for the safety of their care. This is described further in **Step 5**.
- Finally, incidents should be reviewed and **investigated fairly**, free from bias over the outcome of the incident or from hindsight. Disciplinary action tends to relate to the result of the incident. If the outcome is serious for the patient, the individuals involved are more likely to be disciplined than if the incident caused no harm [h] to the patient [28]. This is where the systems approach to safety comes in.

The systems approach to safety

Having a safety culture encourages a working environment where many components are taken into account and recognised as contributing to an incident or to the events leading up to it. This moves the investigator away from focusing blame on individuals and looks at what was wrong with the system in which the individuals were working. This is called the systems approach [1].

It is widely acknowledged that the term 'error', when investigating an incident and attributed to humans, implies blame and responsibility. But research around patient safety has highlighted that the majority

g 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.

h Harm: Injury, suffering, disability or death.

of staff try to create a safe environment, preventing things from going wrong. Despite some high profile cases the overwhelming majority of incidents are not caused by malicious intent or even lack of competence on the part of the individual delivering the care[1, 3] – the best people can make the worst mistakes[2].

Effective error management therefore requires an understanding of the varieties of human error and the conditions likely to promote them. And if human error factors (such as administering the wrong dose of a prescribed drug) are identified organisations can start to find solutions that predict or prevent it and make changes that maximise performance rather than set people up to fail.

In addition the causes of any patient safety incident extend far beyond the actions of the individual healthcare staff directly involved, and are often out of their control. And while human error might immediately precede an incident, in a technically and socially complex system like healthcare, there are usually entrenched systemic factors at work [5].

All patient safety incidents have four basic components. Each of these components should be considered in the systems approach to safety:

1 **Causal factors**: these factors play a significant part in any patient safety incident. Removing them can prevent or reduce the chance of a similar incident happening again. Causal factors are classified into the following groups [3]:

- **Active failures:** these are actions or omissions that are sometimes called 'unsafe acts'. They are actions by frontline healthcare staff who are in direct contact with patients, and include slips, lapses, mistakes or violations of a procedure, guideline or policy. Usually short lived and often unpredictable, they are influenced by latent system conditions and contributory factors (see below) such as stress, inadequate training and assessment, poor supervision or high workload. Examples of active failures include:

– an infusion bag with added potassium is incorrectly stored on the first shelf (for saline only) rather than the normal place on the second shelf. In an emergency a staff member picks up the bag from the first shelf assuming it is saline and gives the patient the wrong bag;

– a heart monitor used in an ambulance constantly alarms. When checked there appear to be no problems with either the patient or the monitor. As this continues and the crew are distracted, they ignore the alarm when in fact the patient has had a cardiac arrest;

- **Latent system conditions:** These are the underlying rather than

immediate factors that can lead to patient safety incidents. They relate to aspects of the system in which people work. They are usually actions or decisions taken at the higher levels of an organisation, which seem well thought out and appropriate at the time but can create potential problems within the system. These factors can lie dormant and unrecognised for some time. Alternatively they may be recognised but changing them is not a priority. The latent conditions combined with local conditions (active failures and contributory factors) create the potential for incidents to happen. Examples of latent system factors include decisions on:

– **Planning:** fixed staffing levels may be adequate until extreme situations occur, such as more than the usual numbers of staff are on sick leave, or there are more than the usual number of critically ill patients;

– **Designing:** designing a new clinic, practice, ward or diagnostic centre without considering vulnerable groups, such as children or mental health patients, and leaving dangerous equipment within their reach;

– **Policy-making:** having a strict take-home policy for drugs, which doesn't take into account difficult times to get to a pharmacy (holidays such as Christmas) or rare drugs that may not be local stock items;

– **Communicating:** having only a limited reporting structure for patient safety incidents, which means vital lessons are not learned across the organisation.

- **Violations:** these are when individuals or groups deliberately do not follow a known procedure or choose not to follow a procedure for a number of reasons, including:

– they may not be aware of the procedure;

– the situation dictates a deviation;

– it has become habit;

– the procedure has been found not to work;

– the procedure has been surpassed by a new one but it has yet to be rewritten.

- **Contributory factors:** these are factors that can contribute to an incident in relation to:

– **Patients:** these are unique to the patient(s) involved in the incident, such as the complexity of their condition or factors such as their age or language;

– **Individuals:** these are unique to the individual(s) involved in the incident.

They include psychological factors, home factors, and work relationships;

- **Tasks:** these include aids that support the delivery of patient care, such as policies, guidelines and procedural documents. They need to be up to date, available, understandable, useable, relevant and correct;
- **Communication:** these include communication in all forms: written, verbal and non-verbal. Communication can contribute to an incident if it is inadequate, ineffective, confusing, or if it is too late. These factors are relevant between individuals, within and between teams, and within and between organisations;
- **Team and social factors:** these can adversely affect the cohesiveness of a team. They involve communication within a team, management style, traditional hierarchical structures, lack of respect for less senior members of the team and perception of roles;
- **Education and training:** the availability and quality of training programmes for staff can directly affect their ability to perform their job or to respond to difficult or emergency circumstances. The effectiveness of training as a method of safety improvement is influenced by content, delivery style, understanding and assessment of skill acquisition, monitoring and updates;
- **Equipment and resources:** equipment factors include whether the equipment is fit for purpose, whether staff know how to use the equipment, where it is stored and how often it is maintained. Resource factors include the capacity to deliver the care required, budget allocation, staffing allocation and skill mix;
- **Working conditions and environmental factors:** these affect ability to function at optimum levels in the workplace, and include distractions, interruptions, uncomfortable heat, poor lighting, noise and lack of or inappropriate use of space.

There may be more than one causal factor in any incident. In **Step 6** we will describe root cause analysis (RCA), a fundamental component of which is to understand and identify the casual factors that influence risk and safety.

2 **Timing:** this is the point at which the causal factors combine with failures in the system (defences or controls) that lead to an incident happening [3].

3 **Consequences:** these are the impact an incident can have, ranging from no harm to the patient to various levels of severity of harm: low, moderate, severe and death [3].

4 **Mitigating factors:** some factors, whether actions or inaction such as

chance or luck, may have mitigated or minimised a more serious outcome. It is important that these factors are also drawn out during any investigation so that the lessons can be used to support and promote good safety practice.

Why is the systems approach to safety important?

A difficult but essential aspect of a safety culture is the need to accept the fact that people, processes and equipment *will* fail. By doing this organisations can focus on change and develop defences and contingency plans to cope with these failures. Finding out about systems failures in an incident, in addition to the actions of individuals, will help organisations learn lessons and potentially stop the same incidents recurring[30].

The NPSA[i] has created the Incident Decision Tree (IDT) to help NHS organisations adopt the systems approach after a patient safety incident. This is described in the following section.

How can the NPSA help?

By 2005 the NPSA aims to have measures in place to help the NHS assess its progress in developing a safety culture that is open and fair. The following tools and resources are currently in development or at pilot stage.

Organisational safety culture assessment tool

The NPSA has reviewed safety culture surveys currently available, and will be developing an assessment tool that is tailor made for use across the NHS[4]. This will enable organisations to undertake a baseline assessment of their safety culture, against which they can measure progress over time. The tool can be used to evaluate the degree of cultural change following the implementation of local and national NPSA initiatives, such as the Incident Decision Tree (IDT) and root cause analysis (RCA) training (described later in this Step and in **Step 6** respectively).

Creating the virtuous circle: patient safety, accountability and an open and fair culture[28]

In February 2003 the NPSA and the NHS Confederation co-launched this report exploring how to support a culture in which the NHS will encourage open reporting of incidents and determine system-wide accountability. It is already available on the NHS Confederation website: **www.nhsconfed.org**

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i in conjunction with the NHS Confederation, the National Clinical Assessment Authority, Royal Colleges, Trade Unions and patient representatives.

The report is accompanied by a CD-ROM and the package is designed for NHS executives and non-executives, clinical governance, risk management[j], health and safety and human resources leads, as well as clinical managers and patient group representatives.

Incident Decision Tree (IDT)

The Incident Decision Tree is an interactive web-based tool for NHS managers and organisations dealing with staff who have been involved in an incident. It helps to identify whether the action(s) of individuals were due to systems failures or whether the individual knowingly committed a reckless[k], intentional unsafe[l] or criminal act. The tool changes the focus from asking 'Who was to blame' to 'Why did the individual act in this way?'

Based on a model developed by Professor James Reason[30] for the aviation industry, the IDT prompts the user with a series of questions about the incident to help them take a systematic, transparent and fair approach to decision-making.

The IDT and the following guidance notes apply only to individual actions during a patient safety incident and do not supersede the need for a full investigation. They can be used before, during and/or after an investigation. In fact as new information becomes available it may be appropriate to reconsider any earlier decision.

The flow chart format is simple to use – staff can learn how to use it in around half an hour. Examples of the kind of questions the IDT asks include:

- **whether the individual's behaviour was reckless, or inappropriate.** This is probably the most complex area to consider. There could be mitigating factors that suggest a system-induced error, such as protocols not existing, being unworkable or unintelligible, but some form of individual recklessness may still be evident. Similarly the individual may feel they have taken a 'necessary risk' given a particular set of circumstances.
- **why the individual was involved in repeated patient safety incidents.** The individual may be performing a particular job that is

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

k The term '**reckless**' in this context is recognised by law. There are two categories of recklessness:

i The individual knows that there is a risk, is willing to take that risk, and takes it deliberately.

ii The individual performs an act that creates an obvious risk, and when performing the act has either given no thought to the possibility of such a risk, or having recognised that the risk existed, goes on to take it.

l **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.

prone to incidents, in which case the design of that particular job or task needs to be improved. The design of a system may even lead individuals to make repetitive 'errors'. Again it is critical to look at the system in which these happened. There may be repeated errors because of events in the individual's life, such as bereavement, stress or fatigue. Alternatively it may be because they have been involved in a previous patient safety incident, which may increase their chances of being involved in another one.

- **why the individual did not follow the correct process or policy.** If an organisation introduces a process or policy and expects 100% compliance (with sanctions for non-compliance), it has to be workable. If not the practitioner is placed in an impossible position of adherence to the process or policy, knowing that on the one hand it is unworkable and on the other that they will be disciplined if they do not follow the process.

  In the vast majority of cases the incident will have been the result of a system-induced error. If this is identified, all the component causes (as described in the systems approach to safety earlier in this Step) need to be understood. The systems approach is therefore a fundamental part of the IDT training and must be included.

  If the action in the incident was found to be **intended** one or more of the following options may apply:

- referral to occupational health;
- referral to the appropriate disciplinary or regulatory body;
- referral to the police;
- suspension. (Note: The National Clinical Assessment Authority should be consulted before any doctor is suspended.)

  If the evidence suggests that a medical condition or substance abuse is a contributory factor and this has not been previously identified, the organisation would consider an immediate referral to occupational health or the equivalent agency. The appropriate outcome will depend on that assessment.

  As IDT is more widely used across the NHS, it will:

- encourage open reporting of patient safety incidents;
- encourage a fair and consistent approach by all NHS organisations and across different professional groups;
- act as a quick decision-support tool for chief executives, human resources, medical and other directors;

- prompt NHS decision-makers to think about systemic and organisational issues in patient safety;
- encourage a fair response to incidents prior to a full investigation and when an immediate review may be needed;
- be adaptable to local circumstances;
- help reassure patients and the public that there is a formal framework for assessing the culpability of individuals involved in patient safety incidents. In support of this approach the NPSA has developed a toolkit on root cause analysis, described in **Step 6**.

  We have piloted the IDT in the acute sector of the NHS and it is now available on the NPSA website (**www.npsa.nhs.uk/idt**) the tool is currently being adapted for primary care.

  Visit **www.npsa.nhs.uk/newsletter/newsline.asp** to subscribe to our newsletter for updates on this and other NPSA work.

Good practice in building a safety culture

Case study: South Manchester University Hospitals NHS Trust

Three years ago an in-house team developed a web-based incident reporting system for all frontline staff, as part of a pilot to test and develop the NPSA's National Reporting and Learning System (NRLS) at 39 sites.

When a report is filed the system sends an email alert to corporate managers and the risk management team within two seconds. They receive a summary of the report with a web link to the full text.

The trust deals with around 69,000 admissions a year, so might expect 7,000 adverse events in that time. It is currently logging around 4,500.

'We see success of the system as an increase in reporting and a decrease in severity,' says clinical governance manager Paul Moore. 'We have trebled the number of reports in the past eight months.'

Staff at South Manchester can report anonymously if they wish; 3% to 7% of reports are unnamed. But staff are encouraged to identify themselves to facilitate support and feedback.

In a bid to boost staff confidence in reporting patient safety incidents and maximise learning, the trust plans to formally clarify the relationship between incident reporting and disciplinary action.

Patient safety forms part of induction courses for all staff. Training is held on the wards so staff can learn in their own environment.

Other measures include a clinical risk website, incorporating the latest patient safety newsletter, details of medical alerts and archived safety material. Information about the importance of reporting patient safety incidents is also distributed with wage packets.

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Step 2
Lead and support your staff

Contents

Step 2

Lead and support your staff

Patient safety affects everyone in the NHS. Building a safer culture depends on strong leadership [1 2 3] and an organisation's ability to listen to and support all members of the healthcare team [4].

The evidence available indicates that the level of patient safety of an organisation can be improved if there is strong leadership from the top of an organisation with clarity of vision and clear policies in relation to safety, balanced by demonstrable implementation of best practice at service level. However, a lack of clinical leadership and poor multidisciplinary working within NHS organisations are among the common factors that emerge from the Commission for Health Improvement (CHI) reviews [5].

In this Step we explain how good leadership can help establish a clear and strong focus on patient safety throughout an organisation. We provide direction on the sorts of actions needed to lead the safety agenda and describe the NPSA support and tools available to assist this process.

The key principles

Delivering the patient safety agenda requires motivation and commitment from the top of each NHS organisation and from leaders throughout the service.

Staff should feel able to say if they do not feel that the care they provide is safe, irrespective of their position.

To show that safety is a priority and that the management of the organisation is committed to improvement, executive staff must be visible and active in leading patient safety improvements.

Why is good leadership and support important?

NHS organisations can improve patient safety when leaders are visibly committed to change. Leaders at the top of each organisation and throughout the service need to facilitate a change in culture, listen to and support staff when they report patient safety incidents and demonstrate the importance of safety in principle and through example [6].

Good communication and feedback is also vital. It's important that all staff know how well healthcare is being provided, understand their contribution to safety and can identify opportunities for improvements.

The NPSA recognises that patient safety may be perceived by some as yet another initiative to add to an already busy workload. But it's not about doing more – it's about doing things differently.

A vibrant, motivated and skilled workforce is critically important to continuous improvement and a key ingredient to the delivery of high quality safe care [7].

What can NHS leaders [m] do?

To help staff achieve success in patient safety, leaders within local NHS organisations need to work towards a number of objectives, as outlined in the respective Steps. A checklist designed for chief executives and their senior managerial staff is set out below.

Chief executive patient safety check list

Step 1
Build a safety culture that is open and fair

1.1 Undertake a baseline assessment of the patient safety culture within your organisation.

1.2 Review the handling of the suspension of staff following an incident, using the NPSA's Incident Decision Tree.

Step 2
Provide strong leadership and support for your staff

2.1 Appoint an operational lead for patient safety, e.g. a risk or patient safety manager.

2.2 Nominate a non-executive and executive board member with specific responsibility for patient safety.

2.3 Identify patient safety champions in every directorate, division, department or practice.

2.4 Conduct executive walkabouts.

2.5 Ensure staff carry out team briefings.

2.6 Build awareness by incorporating patient safety into the staff induction programme.

2.7 Provide general training programmes in patient safety.

2.8 Make specialist patient safety training available for the staff with specific responsibility for the safety agenda.

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m **NHS leaders:** any member of staff working in NHS-funded healthcare who is responsible for leading an organisation, a department, a team or a project.

Step 3
Integrate your risk management activity, develop systems and processes to manage risks and identify and assess things that could go wrong

3.1 Integrate structures and systems for health and safety, clinical risk (patient safety), controls assurance, complaints and clinical negligence.

3.2 Develop patient safety clinical indicators:

The Institute of Health Improvement (IHI) has developed a trigger tool and clinical indicators that will begin to give you an indication of how safe your organisation is. An example of a trigger tool can be found on the Institute's web site, **www.qualityhealthcare.org**. It is suggested that the chief executive regularly receives reports which include the following information, benchmarking themselves against similar organisations:

Undertake an assessment of key clinical indicators of safety within the organisation:

- surgical site infections;
- ventilator related acquired respiratory infections;
- deep vein thrombosis (DVT) and embolisms;
- medication errors;
- blood transfusion incidents;
- mortality rates.

3.3 Undertake an assessment of key clinical indicators of safety within the organisation.

3.4 Ensure care is based on the best available evidence.

Step 4
Promote patient safety incident reporting

4.1 Link your local risk management system to the national reporting and learning system for reporting patient safety incidents.

4.2 Provide regular safety reports for the staff and for the board.

Step 5
Involve and communicate with patients and relatives

5.1 Obtain board level support for a policy on being open with patients and relatives following a patient safety incident.

Step 6
Learn and share safety lessons, and encourage staff to learn how and why incidents happen

6.1 Ensure that the introductory root cause analysis (RCA) training course is available to all staff.

6.2 Ensure access to the advanced RCA training course for staff with specific responsibility for developing the patient safety agenda.

6.3 Chief executives to undertake at least one review of a patient safety incident per annum.

Step 7
Implement solutions to prevent harm, through changes to practice, processes or systems

7.1 Review practice in relation to NPSA's patient safety alerts, solutions and safe practice advice.

7.2 Establish links with chief executives that have participated in the NPSA's safety solutions pilots and implemented changes as a result.

Key objectives of the checklist outlined in Step 2 are described below

Provide strong leadership and support for your staff

Although the issue of safety needs to be integrated into all working practices, due to the size of the agenda, there needs to be dedicated support for chief executives in focusing on and delivering this work programme. We would recommend that every organisation should **appoint a very senior person**, directly responsible to the chief executive, with specific responsibility for this agenda, together with nominating an executive and non executive board member to lead on patient safety.

Appoint an operational lead for patient safety

The value of an operational lead for patient safety cannot be underestimated. Traditionally referred to as the risk manager or patient safety manager, they are dedicated to patient safety and are responsible for training staff and implementing patient safety tools. However, it is important that the designated operational lead is not seen as the sole person responsible for safety. We would also suggest that chief executives personally review the experiences of one patient per year, where the treatment has not gone according to plan due to a patient safety incident, by talking to the staff and patients concerned.

The patient safety lead/risk manager should:

- have a senior position in the organisation;
- have the authority to act and make decisions that improve patient safety;
- have a direct link to the chief executive;
- provide training and induction sessions;
- be seen as the organisational expert in relation to all risk management;
- ensure there are adequate resources for improving patient safety;
- be valued and respected by all professions and levels of staff within the organisation.

Designate an executive and non-executive board member to lead on patient safety

Integrated risk management systems [n] (described in **Step 3**) need to build on the structures and frameworks established for clinical governance [8 9 10]. Local NHS organisations should have board-level executive and non-executive leads for clinical governance who also take the lead for patient safety and risk management.

Patient safety needs to be led from the top of an organisation with leaders driving the risk management agenda, making key judgements, providing clear direction and prioritising risks [o] for action. The appointed board leads should ensure that effective policies and clear accountability for managing risks are in place, and that managers and staff are equipped with patient safety skills, guidance and tools. They need to establish and maintain an open culture of multidisciplinary team communication, to capture and use the contributions of any team member whose knowledge could help improve patient safety and patient care.

Appoint patient safety champions in every unit

To ensure that safety is not one person's job, each department, directorate or division needs to appoint a lead or 'champion' for patient safety. This demonstrates an organisation-wide commitment to safety.

Unit leaders need to:

- raise awareness of patient safety and develop an ethos where patient safety is seen as a priority and not as an additional burden;

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n **Integrated risk management:** the process of identification, assessment, analysis and management of all risks and incidents for every level of an organisation, and aggregating the results at a corporate level. This facilitates priority-setting and improved decision-making to reach an optimal balance of risk, benefit and cost. It is an integral component of good management and a focus for building improved organisational resilience and flexibility in the face of uncertainty.

o **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.

- be trained in integrated risk management (described in **Step 3**), patient safety issues, what is meant by a safety culture that is open and fair, human factors in relation to patient safety and the systems approach to error (described in **Step 1**);
- have the resources and authority to make decisions on patient safety locally;
- understand the risks within their unit and how they relate to the organisational risks that can affect patient safety;
- ensure integrated risk management, quality and patient safety are incorporated with clinical governance processes and are followed;
- support and guide staff, and create a culture where staff feel respected and able to be open and honest about an incident they are involved in;
- promote the organisation's 'being open policy' (described in **Step 5**) to patients and their carers;
- provide training and support to staff on patient safety and communication skills;
- establish processes for learning lessons and implementing changes to improve patient safety;
- implement appropriate monitoring and review mechanisms to measure success;
- Local patient safety champions should also meet to share patient safety information and issues across the organisation.

Conduct executive walkabouts

To show that safety is a priority and that the management of an organisation is committed to improvement, executive staff must be visible and active in leading patient safety improvements.

They can demonstrate their commitment to patient safety by conducting 'executive walkabouts' [11]. Members of an organisation's board, including executive directors as well as the chief executive, should set aside up to an hour a week to visit different areas of the organisation to discuss safety and clinical governance issues with staff – for example the types of patient safety incidents that have occurred and any action taken to reduce the chance they will happen again.

We recognise that making such a time commitment to executive walkabouts can be extremely difficult to juggle with other pressures. However, it is worth stating that many patient safety leaders in the United States have identified regular walkabouts as the key critical factor in developing a safer culture.

Discussions should remain focused on safety, of which follow-up and feedback is an essential component. Communication should also be two way, with staff able to raise safety issues and share their concerns with executive directors, and executive directors demonstrating that they are taking those concerns seriously. Executive directors should have an 'open door policy' so that staff can raise patient safety issues directly with them.

The benefits of executive walkabouts are:

- an increased awareness of safety issues and patient safety concepts among all staff;
- a demonstration that safety is a high priority for senior management;
- fostering an open and fair culture by encouraging staff to discuss incidents openly;
- a way of gathering information and ideas from staff to make patient care safer;
- a way of sharing information gathered across different parts of the organisation.

Conduct team briefings

A safety culture is dependent on a high awareness of safety issues at all levels. Leaders therefore need to raise awareness and understanding of patient safety among all staff and promote effective teamwork.

The NHS depends on the work of teams from board level to the frontline. An effective and safe team is one where members share the same set of values, where staff can trust and rely on their colleagues, can challenge each other and express any concerns they may have. There should be mutual respect for everyone's contribution no matter what their position or level. A guiding principle is 'you're not sure it's safe, then it's not safe' and to tell your colleagues by whatever means are available [12]. This could be through team briefings, incident reporting systems, one-to-one meetings, through a third party or during a root cause analysis (described in **Step 6**).

Team briefings are a simple way for staff to share information about potential patient safety issues on a daily basis [13]. They are ideal for departments where particular groups of staff form a team for the day, shift or session (for example operating theatre, outpatient department, ward, ambulance teams etc).

Staff need to be able to share patient safety issues in an environment where they can be open and are treated fairly (described in **Step 1**).

Team briefings should:

- have a clear remit, i.e. patient safety;
- be open and fair – all staff are valued and respected and everyone has a chance to speak;
- be brief – limited to a maximum of 15 minutes at the beginning of a day, shift or operating session;
- frequent enough to maintain a safety culture, i.e. teams that are small or do not change very often may not meet as frequently as larger teams or teams that regularly involve different individuals;
- be easy to facilitate – this can be achieved through facilitator training to understand what team briefing is, and what are the objectives and success criteria;
- be balanced by debriefings at the end of the shift, day or session.

Because training works well when it involves multidisciplinary teams that work together on a regular basis, team briefing provides opportunities for training on patient safety and on how to report incidents. This can help facilitate behaviour change, encourage reporting and boost morale [14 15 16]. Over time, team briefings will improve both patient care and patient safety.

To put team briefings into practice, local NHS organisations first need to identify an area on which to test the process and explain the concept. The briefings could be tested on one shift or session a week. Facilitators should be identified and given training on how to conduct a team briefing.

Team briefing agenda

- Meet at the beginning of the day, shift or session and introduce new team members.
- Understand the expectations of the day – identify potential patient safety issues, such as: complex cases; equipment needs e.g. patient identification – make it known that there are patients with the same or similar last names; any new equipment being used – are all staff familiar with the equipment; are there any training needs?
- Identify any opportunities for improvements.
- Follow up or give feedback from previous meetings.
- Mention the debriefing meeting at the end of the day, shift or session, i.e. when and where.

Debriefing agenda

- Meet at the appointed time and place.
- Discuss the events of the day, any patient safety incidents that occurred, how and why they happened and if any potential incidents were identified and how they were prevented from causing harm .
- Incident forms could be completed at this stage, including how the incidents will be investigated or how any changes identified will be taken forward.
- Follow up or give feedback from the morning's meeting.

How can the NPSA help?

The following are key NPSA tools for raising awareness of patient safety and for supporting patient safety leaders and staff. They are designed to complement the NPSA tools for developing a safety culture that is supportive, open and fair (described in **Step 1**).

Safety checklist for patient safety leads and champions

The NPSA has developed the safety checklist for patient safety leads and champions [2] in the form of a self-assessment tool. It can be used by all patient safety leads and champions to give individual or groups of leaders a range of choices to consider, periodically revisit and use to trigger action.

Actions ✔

Introduction

Familiarise yourself with the NPSA goals and objectives and who your local NPSA patient safety manager is. For details on NPSA patient safety managers visit **www.npsa.nhs.uk/static/contacts.asp**	☐

Step 1 Build a safety culture

Assist your local risk/patient safety lead with a safety culture assessment survey of your organisation.	☐
Familiarise yourself with the organisational risk management strategy.	☐
Ensure that patient safety matters are discussed in your organisation and unit.	☐
Review budgets, business planning and services developments to ensure they take into account patient safety issues.	☐
Promote a safety culture that is open and fair by establishing an environment of trust and a systems approach to incidents. Establish organisational policies that reflect this.	☐
Promote the use of the NPSA's Incident Decision Tree (IDT) (described in **Step 1**).	☐

Actions	✔
Ensure that articles and papers on patient safety are regularly communicated throughout your organisation.	☐
Continuously promote the business case for patient safety, ensuring resources are available for priority safety issues.	☐

Step 2 Lead and support your staff

Meet with the executive and non-executive board member with responsibility for patient safety; ensuring patient safety is discussed routinely at board level.	☐
Meet with the other patient safety champions in each directorate, division or department to share patient safety lessons.	☐
Build patient safety into all staff induction and ongoing training.	☐
Raise awareness of patient safety using the NPSA's induction video, described later in this Step.	☐
Use the NPSA's web-based e-learning toolkit – Introduction to Patient Safety, described later in this Step.	☐
Establish leadership training in patient safety.	☐
Promote team briefing and debriefing.	☐
Promote an ethos where all individuals within your team are respected and feel able to challenge when they think something may be going wrong.	☐
Join regular executive walkabouts in your area.	☐
Ensure you are up to date with patient safety initiatives and participate in local networks, education programmes, external seminars or conferences on patient safety issues.	☐

Step 3 Integrate your risk management activity

Review your structures and processes to ensure they integrate patient and staff safety, complaints and clinical negligence and financial and environmental risk.	☐

Actions	✔
Set up local forums to discuss risk management and patient safety issues and provide feedback to relevant groups.	☐
Develop performance indicators for your risk management system.	☐
Identify your key patient safety issues through risk assessments [p].	☐
Asses the risk to individual patients in advance of treatment.	☐
Have a regular process for assessing your risks, for defining the acceptability of each risk and its likelihood, and take appropriate actions to minimise them.	☐
Integrate unit risk assessments with the organisations risk register.	☐

Step 4 Promote reporting

Encourage patient safety incident reporting locally.	☐
Encourage patient safety incident reporting nationally to the National Reporting and Learning System (NRLS).	☐
Ensure a local implementation plan is completed which describes how and when your organisation will begin reporting to the NPSA.	☐
Ensure feedback is given to staff to show the benefits of reporting.	☐

Step 5 Involve and communicate with patients and the public

Develop a 'being open' policy with patients on patient safety issues and ensure patients and/or carers are notified promptly when an incident has caused harm.	☐
Make sure that patients and their families receive an immediate apology, and are dealt with in a respectful and sympathetic way.	☐

p **Risk assessment:** the process that helps organisations understand the range of risks they face – both internally and externally, the level of ability to control those risks, their likelihood of occurrence and their potential impacts. It involves a mixture of quantifying risks and using judgement, assessing and balancing of risks and benefits and weighing them, for example, against the cost.

Actions	✔
Set up support systems for patients and carers involved in patient safety incidents.	☐
Ensure executive walkabouts include patients.	☐
Familiarise yourself with tools that help patients become involved in their safety.	☐
Develop a communications policy for communicating risk.	☐
Involve patients and families as part of the multi-disciplinary team to help improve, change and design services.	☐
Involve patients and their families in patient safety.	☐
Involve patients in safety solutions.	☐

Step 6 Learn and share safety lessons

Set the expectation for timely and multidisciplinary incident investigations with the emphasis on the systems approach to incidents and involvement of patients and their carers.	☐
Encourage staff to use root cause analysis (RCA) or significant event audit (SEA) to learn how and why incidents happen.	☐
Ensure staff are openly supported through the RCA/SEA process.	☐
Promote the e-learning tool for RCA training (**www.npsa.nhs.uk/rca**).	☐
Identify which staff should undertake RCA training delivered by the NPSA.	☐
Encourage executive involvement in incident investigation and personally participate in RCA.	☐
Designate staff to an RCA team.	☐

Actions ✔

Step 7 Implement solutions to prevent harm

Use the information generated from incident reporting systems, risk assessments and incident investigation, audit and analysis to identify local solutions.	☐
Assess the risks for any changes you plan to make.Embed lessons through changes to practice, processes or systems.	☐
Promote a proactive stance on patient safety design, assessment and improvement. Include all NHS staff and patients.	☐
Monitor changes made through incident reporting and root cause analysis.	☐
Work with your NPSA patient safety manager to implement national solutions.	☐

Team checklist

A significant amount of evidence suggests that teams that work well together create a safer environment [17 18 19 20 21].

The following NPSA checklist picks out the key criteria that improve multidisciplinary teamwork. Used as a team survey, it can help local NHS organisations address any gaps they identify and improve the effectiveness of their teams:

Criteria	✓	✗
Are the team members clear about their roles and responsibilities?	☐	☐
Are there identified leaders?	☐	☐
Are those leaders happy with the type of leadership and direction?	☐	☐
Are the team members happy with the type of leadership and direction?	☐	☐
Is each team member valued and respected for their expertise and views?	☐	☐

Criteria	✓	✗
Can any member of the team challenge any other member of the team without fear?	☐	☐
Are experts used appropriately?	☐	☐
Is there a formal process of getting together and planning objectives and goals?	☐	☐
Are there effective communications systems within and between teams?	☐	☐
Is there a shared understanding of what is required and is this actively checked?	☐	☐
Is the right information passed to the right people at the right time?	☐	☐
Does the team anticipate, discuss and prepare for potential problems, challenges and risks that may occur through a system of briefing and debriefing?	☐	☐
Is feedback given to team members on their performance?	☐	☐
Are there mechanisms for identifying and managing working conditions, such as stress or fatigue within the team?	☐	☐
Is patient safety promoted?	☐	☐

Patient safety induction video

This 20-minute film provides a practical introduction to patient safety and its relevance to NHS staff. Hosted by Channel 4's Krishnan Guru-Murthy, the film explores the reasons why patient safety incidents happen, what we can learn from them and how to minimise the risk of them happening again. It also explains the new definitions of a patient safety incident and a prevented patient safety incident and describes the role of the NPSA.

It is ideal for corporate staff inductions and as a training aid for all NHS staff, and is best used alongside a short presentation by the local risk or clinical staff on how to report incidents locally. To request a copy for your organisation please call the NHS response line on 08701 555 455.

Induction training

The NPSA is now part of the national NHS induction programmes in England for new chairs and non-executive directors, including regular

training for current chairs, non-executive directors and chief executives. Work will be undertaken with the NHS in Wales with a view to extending this programme.

Introduction to patient safety e-learning toolkit

We have developed an interactive web-based e-learning toolkit for NHS staff who want to learn more about patient safety. The tool can be adapted for different users depending on their area of interest, healthcare setting and professional role. It contains resources, case studies and modules of training material. It is now available on the NPSA website: **www.npsa.nhs.uk/ipsel**

Undergraduate and postgraduate training

The NPSA aims to ensure that safety and risk are uppermost in people's minds when delivering or receiving healthcare. We will be working with educational establishments to develop patient safety modules for undergraduate and postgraduate training curricula for all staff, including in the contractor professions. The NHS University is also committed to helping improve patient safety.

The NPSA aims to develop training programmes in 2004 to support board-level staff and local champions with their role in leading patient safety.

Visit **www.npsa.nhs.uk/newsletter/newsline.asp** to subscribe to our newsletter for updates on our work.

Good practice in leading and supporting your staff

Case study: Royal Cornwall Hospitals NHS Trust

Lessons from the airline industry were used to make members of an operating theatre team more aware of the way they work. Aircrews have a framework of how to work with each other, which allows them to question staff further up the hierarchy. This promotes passenger safety – it is not about 'who is right' but 'what is right'.

The theatre team worked with psychologists from QinetiQ's Centre for Human Sciences' organisational effectiveness group. Formerly part of the Ministry of Defence, this organisation is experienced in managing team debriefing sessions. Together they worked on a toolkit of 15 different debriefing techniques.

Theatre staff in one theatre block have now started running regular team self-review sessions. The overall performance – including patient safety, workload and staff stress levels – will be compared with another theatre block that is not using team debriefs.

The five-to ten-minute briefing session at the start of a theatre list is conducted by the surgeon or the anaesthetist. It concentrates on the technical aspects of the work and involves talking about the patients on the list and ensuring that the staff know each other and their roles. An A4 laminated sheet is used as a prompt card. The briefing enables the team to:

- introduce each other – teams often have a core set of members and a number of others who enter and exit the team structure;
- discuss the plans for the day, the order of the list in theatres or the order of the patients at the beginning of outpatients etc;
- discuss specific anticipated problems;
- discuss issues such as overbooking or time-related issues;
- share values and beliefs.

It also enhances the debriefing at the end of the day, list or clinic. The debriefing sessions can be led by any member of the team. They conduct a non-judgemental debrief to look at team cooperation, communication, equipment use and dispute resolution. A series of flash cards are used as triggers and help give the briefing a structure.

An important element of the debrief is that any issues identified can be converted into practical modifications to alter the way the team

works and packaged so that the lessons learned can be shared with other teams in the same department.

The reporting of 'near misses' in the operating theatre was also adapted from the airline industry. Royal Cornwall Hospitals NHS Trust is planning to add the reporting of what they call 'close calls' to the reporting of patient safety incidents.

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Step 3
Integrate your risk management activity

Contents

Step 3
Integrate your risk management activity

It is now well recognised that healthcare involves a wide range of risks and that any change or innovation brings new risks as well as rewards [1,2,3,4,5]. Many people regard patient safety incidents as random occurrences or unpredictable events beyond effective control. But although chance does play a part, and human error can never be eliminated entirely, the majority of incidents fall into systematic and recurrent patterns [6].

If healthcare organisations systematically identify, assess, learn from and manage all risks and incidents at *every* level, they will be able to reduce potential and actual risks, and identify opportunities to improve healthcare and patient safety – across the whole organisation.

In this Step we define how local NHS organisations can integrate risk management systems, how this can improve patient safety, and how the NPSA can support local NHS organisations in achieving this. We also provide practical guidance on how organisations can incorporate integrated risk management into their current systems, including tools for risk assessment.

The key principles

It is no longer sufficient to manage risk at the individual activity level or in functional silos. Integrated risk management means lessons learned in one area of risk can be quickly spread to another area of risk.

Integration of all risk will assist NHS organisations in complying with controls assurance standards, as well as clinical governance, Clinical Negligence Scheme for Trusts, Risk Pooling Scheme for Trusts, Welsh Risk Pool and Health and Safety Executive requirements.

A central team should be responsible for pulling together the systems and processes for risk management and ensuring all staff across the organisation feed information into this.

All risks together

Risk management in healthcare originated in health and safety. This developed with the introduction of the Clinical Negligence Scheme for Trusts (CNST), which focused NHS organisations on clinical risk management. It required each organisation to recruit a risk manager and set up a local risk management system for the detection of incidents.

These incidents and risks have since been divided into clinical (directly related to patient care) and non-clinical categories (administrative, technological, human resources, staff safety, health and safety, financial, environmental and those affecting public perceptions and reputation). However they all have the potential to affect patient safety, and by dividing risk in this way, the systems and processes created to identify and manage different risks within healthcare are patchy and fragmented [7].

It is therefore no longer sufficient to manage risk at the individual activity level or in functional silos. Organisations across the world are benefiting from a more comprehensive approach, looking across *all* aspects of the organisation to manage all their risks more effectively [8]. And by integrating risk management in this way, they are more likely to achieve their objectives and desired outcomes.

The National Audit Office recently reported [9] that improvements have been made across NHS organisations in recording, collating and reviewing risk data. These have largely been due to the self-assessments [10] from the controls assurance [q] unit (CASU) and the requirements of the Clinical Negligence Scheme for Trusts (CNST), Risk Pooling Scheme for Trusts (RPST), the Welsh Risk Pool (WRP) and the Health and Safety Executive (HSE). But their report also advises further improvements are needed to integrate risk management systems, particularly for clinical and non-clinical risk.

What is integrated risk management?

Integrated risk management is the process of identification, assessment, analysis and management of all risks and incidents for every level of an organisation, and aggregation of the results at a corporate level. This facilitates priority-setting and improved decision-making to reach an optimal balance of risk, benefit and cost.

In practice, integrated risk management in healthcare organisations means:

- integrating all risk management functions such as patient safety, health and safety, complaints, clinical litigation, employment litigation, financial and environmental risk;
- integrating all risk management functions with modernisation and clinical governance activity to unite strategies and improve outcomes

q **Controls assurance / Welsh Risk Management Standards:** The system of management which informs NHS boards about significant risks within the organisation for which they are responsible. It is designed to assist NHS staff, including chief executives and board members, to identify risks, help determine unacceptable levels of risk, and decide where best to direct limited resources to eliminate or reduce those risks.

and safety for patients. This includes integrating information about risks with service and workforce redesign and new technologies;

- integrating all sources of information related to risk and safety, for example 'reactive data', such as patient safety incidents, clinical litigation claims, complaints and health and safety incidents, as well as 'proactive data', such as the results of risk assessments;
- integrating risk assessments of all types of risks for an organisation at every level (described further in this Step);
- a consistent approach to the training, management, analysis and investigation for all risks;
- incorporating all risks into an organisation's risk assessment programme and risk register [r], using risk assessment tools to identify all potential risks to organisational strategy, policy, healthcare practices and care. This will mean organisations can plan more effectively and develop controls to reduce the effects of the risks identified;
- integrating processes and decisions about all risks into future business and strategic plans.

Why is integrated risk management important?

Integrated risk management shapes an organisation's safety culture and helps reveal the sum of the risks and the interdependence of the parts. It not only focuses on the reduction or mitigation of risk but supports and fosters innovation so the greatest returns can be achieved with acceptable results, costs and risks. It strives for the optimal balance of risk.

Integrated risk management is also an integral component of good management and provides a focus for building improved organisational resilience [s] and flexibility in the face of uncertainty [11].

It is intended to support better decision-making through a solid understanding of all risks and their likely impact.

Without effective integrated risk management processes the weakness and vulnerability of procedures, practices or major policy changes are not identified. And care is delivered without well-considered contingency plans.

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r **Risk register:** A database where results of all the organisation's risk assessments are collated. It is used as a form of audit to monitor how organisations manage their risks. It should be updated on a regular basis to show the effects of this management and reviewed on a regular basis by the board-level risk management committee.

s **Organisational resilience:** The positive side of safety, defined as the system's intrinsic resistance to its operational risks.

Benefits of integration for local NHS organisations:

- Organisations to improve information around their risks so the scale and nature of risk to patients can be properly assessed.
- Lessons learned in one area of risk, for example through clinical audit, complaints management, health and safety assessments and litigation and claims handling, can quickly be spread to other areas of risk.
- The organisational approach to the identification, analysis and investigation for all risks will be consistent; root cause analysis (RCA; described in **Step 6**) can be used for complaints and claims as well as incidents.
- It will assist organisations in complying with all controls assurance standards, as well as clinical governance, CNST, RPST, WRP and HSE requirements.
- It will help organisations plan for uncertainty, cope with the impact of unexpected events and increase patient and public confidence.

What can healthcare providers do?

All local NHS organisations need to establish an integrated risk management function. This means setting up corporate infrastructure to enhance understanding and communication of risk issues, and involves:

- balancing innovation with risks and benefits, ensuring the organisation has clear aims and ways of measuring change;
- spreading good practice;
- supporting staff;
- developing sustained and continuous improvement.

To achieve this NHS organisations can adjust their existing systems and processes in relation to:

- structure;
- staffing;
- risk assessment;
- and risk assessment tools.

Structure

To be most effective integrated risk management must be woven into the normal working processes of an organisation and into existing decision-making structures and processes [1]. Risk management and patient safety need to be incorporated into the organisation's objectives, corporate focus, strategic direction, operational systems and day-to-day practice [7].

Decisions about risk need to be balanced so the potential benefits are worth more to the organisation than it costs to address the risk. How risks are currently managed and who is responsible for this process varies across the NHS. In part this is because different organisations are at different stages of developing their risk management activity. Therefore each NHS organisation should have a clear reporting structure for all risk, which describes lines of accountability, committee structure, terms of reference, frequency of meetings and communication channels.

The evaluation and reporting mechanisms for all risk management activities should fall to multidisciplinary groups responsible for risk management in the organisation, which feed up to and receive feedback from corporate groups. Creating a structure for effective risk management includes:

- **a board-level risk management committee.** Creating a single point of coordination for the overall policy and strategy, this should be closely linked to the organisation's clinical governance committee and led by board-level executive and non-executive leads for clinical governance, who are also explicitly responsible for risk and patient safety. (This is described further in **Step 2**.)
- **local risk management groups.** Groups at local level are needed to review aggregated risk management data and review RCA investigations. These should consist of multidisciplinary teams who discuss, understand and address their risks, receive reports from RCAs, risk assessments and failure modes and effects analyses (FMEA; described later in this Step) to help forecast possible problems and contingency planning. Each local group should report to the central risk management committee.

Staffing

As described in **Step 2** the suggested optimum staffing for effective risk management and patient safety includes an executive and non-executive board member with responsibility for risk management and patient safety; a designated operational lead for patient safety such as a risk/patient safety manager; and champions for patient safety in every area.

A central team of risk experts

Local NHS organisations also need a central team of experts in all types of risk to pull together the risk management systems and processes, and ensure all staff across the organisation feed information into this. Support from those with expertise in risk management processes will enable staff at all levels to judge and manage risks successfully and undertake risk assessments of the care they deliver.

The role of a central team includes:

- responsibility for all risk, both clinical and non-clinical, and linking directly with all clinical governance leads (audit, effectiveness, information, public and patient involvement, human resources, training and development);
- promoting an open and fair culture (as described in **Step 1**) ;
- ensuring staff responsible for delivering care are also accountable for identifying and assessing risks associated with that care, and have access to relevant external training courses to develop their knowledge and skills in risk and patient safety;
- providing a central resource of expertise, training and development to support local departments and having access to external support networks in their area or nationally;
- developing a range of tools and sources of information in line with current guidance from external stakeholders;
- identifying and handling risks that cut across departments; managing potential risks or risks that have already become a major crisis for the organisation; and coordinating risk communication and learning;
- taking an overview of organisational risks and providing the strategic context for decisions made at a local level;
- reporting quarterly to the board to ensure risks are identified and are being managed effectively.

If the next phase of the patient safety movement is to succeed, it must be grounded in widespread and in-depth education of all healthcare professionals, especially clinicians. The clinical and managerial champions for patient safety should be linked to the central team within each division, department or directorate to raise awareness, undertake risk assessments, and act as trained investigators using RCA or significant event audit (SEA)[t]. Having a central team and local champions should ensure:

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t **Significant event audit:** A similar process to root cause analysis, often used in primary care and in particular in general practice. NPSA guidance on SEA as an investigation technique for primary care will be published in 2004.

- the organisation and its staff have a common understanding of risk and all refer to it using a common language;
- expert risk staff can use more advanced, sophisticated risk assessment techniques;
- local staff are able to use simple tools to identify, evaluate and manage risks; teach essential elements of risk management to their colleagues; and undertake investigations using RCA or SEA.

Education must include systems evaluation, RCA, human factors, teamwork, safety culture and improvement tools. The educational tools should include multimedia, small-group facilitated discussion, problem-based learning and simulation-based exercises. Only through innovative methods that encompass active learning, role modelling and feedback can changes in patient safety be fully realised.

Risk assessment

The Department of Health's report, *Building a Safer NHS for Patients* [12], highlighted that it is as important to identify factors that could affect patient safety and take steps to reduce these risks, as it is to report and learn from incidents that have already happened [6, 13, 14].

When decisions are made within an organisation they must take into account any potential risks that could directly or indirectly affect patient care. These risks can be environmental, financial, economic, political, and those affecting public perceptions and reputation. Although decisions taken across an organisation will involve different types of risks, a systematic approach to assessing and managing risk can still be adopted. This ensures all risks are managed in a coordinated and consistent way and the process is transparent.

Risk assessment is the process that helps organisations understand the range of risks they face (both internally and externally), the level of ability to control those risks, their likelihood of occurrence and their potential impacts. It is one of the key activities that needs to be in place for an integrated risk management system to improve patient safety.

An integrated risk assessment helps NHS organisations to:

- gain an overview of their risk management capacity, practices and culture;
- develop an open and fair culture;
- plan and establish processes;
- refine practices so they become safer and more resilient;
- achieve strategic and operational targets set by external stakeholders;
- ensure lessons are shared within and across organisations.

Risk assessments should be conducted with staff for whom the risks are relevant. For example, board and management teams will need to advise on strategic risks, while clinical teams will need to be involved when assessing an individual patient's care or a procedural risk in their department. All parties affected by risks, including patients and the public, should also be involved in the decision process. Each directorate or division should take ownership of their own risks and feed these into the organisation's risk register. The risk assessment process is then used to develop local business plans and used as evidence for service development.

Risk tolerance is another important consideration in the risk assessment process. Staff need to understand the minimal levels of permissible risk, those that should be managed at a local level, and those that should be managed at a corporate level. In general there is low risk tolerance for patient safety issues where patients are likely to be harmed and high risk tolerance for issues such as project delays or situations where people feel in more control, for example with processes that have checking systems to prevent error occurring[8]. Improved communication of an organisation's individual risk tolerance through their risk management strategy can form the basis for induction and ongoing education and training.

Risk assessment tools

There is a growing awareness that interventions, knowledge and expertise used to improve safety in other industries will help the healthcare sector understand how we can deal with similar incidents and risks to improve patient safety. A number of tools currently used in industry are now being used in healthcare to identify potential failures. They include:

- probabilistic risk assessment;
- risk matrix;
- failure modes and effects analysis;
- risk assessment checklist.

Probabilistic risk assessment (PRA)

PRA involves a mixture of quantifying risks and using judgement. The assessment defines the nature and size of the risks and weighs these up against the benefits of reducing or eliminating them and the costs of achieving this. A judgement is then made on how best to manage the risk.

The probabilistic aspect of this tool is a way of quantifying the potential risk. It evaluates the likelihood of a particular risk or incident actually happening, including a consideration of the frequency with which it may arise. It is assessed using collated incident data and by estimating how often a process can fail by observation and audit.

Example: Checking patient identification when administering medication [15]

It is usually nurses who administer medication to patients. During long shifts they get to know their patients, their diagnoses and their needs, including their medication. Despite policies that state all patients' identification must be checked before the administration of medication, nurses admit that, in practice they often fail to do so for a variety of reasons. This is rarely recorded as an incident. A probabilistic estimation could be gained by asking a team of nurses to estimate whether this failure is 1 in 100 administrations, 5 in 100, 50 in 100 and so on. This will produce a cultural norm that can be used in the risk assessment process.

There are many ways to quantify probability. The table below shows one example.

Example of a risk probability framework [16]

Probability	Criteria
Very low	0–5% – extremely unlikely or virtually impossible
Low	6–20% – low but not impossible

Medium	21–50% – fairly likely to occur
High	51–80% – more likely to occur than not
Very high	81–100% – almost certainly will occur

How will probabilistic risk assessment improve patient safety?

Fundamentally an organisation-wide PRA will mean 'fewer surprises'. It will provide evidence of the key risk areas and therefore steer prioritisation for improvement and risk management activity. In turn this can help ensure lessons are learned without having to suffer a crisis or a major incident. It will also enable organisations to target their limited resources more efficiently.

All NHS organisations must have a formal annual organisation-wide local probabilistic risk assessment programme, as indicated in the controls assurance programme and by standards set by the CNST, RPST, WRP and HES. This should be used to identify and assess all risks at three levels of the organisation: strategic, policy and operational [17].

The information collected through this annual risk assessment programme should be incorporated into the organisation-wide risk register with:

- potential risks identified from all ad hoc risk assessments throughout the year;
- information gained about potential and actual risks identified from patient safety incidents, litigation claims and complaints, coroners inquests, internal and external investigations and enquiries, confidential enquiries, external assessments and accreditations;
- information gained about potential and actual risks identified following incident investigations using RCA and SEA.

Risk matrix

A commonly used tool in risk assessment is a risk matrix. It is used to map risks against likelihood of occurrence and severity of impact, combining judgements with numerical analysis [1]. A risk matrix can be used to assess patient safety incidents that have already happened, those that have been prevented and potential risks. It should be used by both clinical and managerial staff together to assess local incidents and risks.

Once a risk has been identified the matrix is used to estimate the chances of an incident occurring or recurring, taking into account the measures in place to prevent it. The chances are rated from highly unlikely to very likely, helping an organisation to think about ways to reduce risk further.

The matrix is then used to assess the actual or potential consequence of the risk to patients. Incidents that have no impact on patients are

registered as 'not harmful' or 'low risk'; the most serious incidents could potentially cause death and are ranked 'high risk'.

Most NHS organisations currently use one of two types of risk matrix: a scoring system advocated by CASU [2] or a traffic light system, similar to that outlined in the Department of Health draft document *Doing Less Harm* [18].

Considerations when choosing a risk matrix

For a risk matrix to be effective it should:

- be simple to use and understand;
- have clear guidance for use;
- have consistent likelihood ranges that cover the full spectrum for each consequence range;
- have detailed descriptions and definitions;
- explain how the risks can be mitigated to a tolerable level on the matrix.

When considering which matrix to use locally, each NHS organisation should take the following into account:

- **Training implications:** Each local organisation will need to decide who carries out the assessment of likelihood and consequence for both risks and incidents, and place this information on the local risk matrix. If this is carried out at departmental level there will be resource implications for specific training to ensure consistency.
- **Estimating probability:** Assessing the chances of an incident happening again can be highly subjective. When estimating probability the assessor needs to take into account the fact that memorable events seem more common and constant feedback is necessary to ensure accuracy of predictions;
- **Effectiveness of estimated potential impact for prevented incidents:** There is the potential to over- or underestimate the possible impact of a prevented incident, which can then bias the organisation's risk register and future actions.
- **Balance of analysis:** The chosen system should not concentrate exclusively on the most serious incidents while ignoring the low-to-moderate incidents, which occur much more frequently. If these are reported the lessons learned could prevent the serious incidents from occurring. The NPSA believes there is something to learn from all patient safety incidents, including those that have been prevented. Local teams should decide the level to which an incident should be investigated.

- **Resources:** Each organisation must have the capacity to act on any criteria set around the risk matrix. For example if an organisation states that all incidents that led to harm must be investigated using RCA, the organisation must ensure there are enough staff with the expertise and resources to do this.

The NPSA is not currently advocating any particular risk matrix tool because:

- patient safety incidents reported by local NHS organisations via the National Reporting and Learning System (NRLS; described in **Step 4**) can only be graded according to severity of actual harm (ranging from 'no harm' to 'death'), and not according to potential likelihood of recurrence or potential consequence. And assessing the likelihood of recurrence can only be based on local demographics and knowledge, which would be meaningless nationally. We aim to review a system for assessing national likelihood of recurrence when the NRLS is fully functioning;
- the NPSA is concerned about using local data on consequence and likelihood for national purposes because of the current variation of practice, and potential inconsistency and subjectivity.

We will however be undertaking an extensive review to develop best practice, but local NHS organisations need to choose the tool that best suits their needs.

Failure modes and effects analysis (FMEA)

FMEA is widely used in industry and has been adapted as a tool for risk assessments in healthcare in the US [19, 20]. It is a proactive tool for evaluating a process to identify potential failures and the effects these failures could have on individuals and/or the organisation. The actions that need to be taken to prevent an incident can then be prioritised.

FMEA identifies the following factors:

- **Process:** How is care is expected to be delivered (e.g. a particular care pathway such as the medication delivery system, the flow through outpatients, or a surgical procedure)?
- **Failure mode:** What could go wrong?
- **Contributory factors:** Why would the failure happen?
- **Effect:** What are the consequences of the failure?

FMEA can be applied to the processes that make up a system. A medication delivery system for example is made up of a number of different clinical processes: initial diagnosis, prescribing, preparation, dispensing, administering and follow-up. Each Step in these processes could potentially result in failure.

Seven stages of an FMEA:

1 Identify a high-risk system from the organisation's risk register and incident reporting system. Break it down into various processes for analysis. This can be conducted on a system but the most effective way is to perform a separate analysis on each process within the system and then integrate the results.

2 Recruit a multidisciplinary team to chart the process in the form of a flow chart to identify all the steps that are taken.

3 Identify as a team where that process can go wrong or fail and what controls and barriers are in place to prevent those failures.

4 Identify what the effects could be if the failures occurred. Existing evidence of incidents and departmental risk assessments can be used to inform the process.

5 Assign priority scoring or rating to each failure and effect. This is normally done by using a risk matrix on the following questions:

- How likely is it that this failure mode will occur?
- If the failure mode occurs, how likely is it that the failure will be detected?
- If the failure mode occurs, how likely is it that harm will occur?

6 Evaluate the results and either reduce the probability of the failure to an acceptable level or add controls and safety mechanisms to mitigate or minimise the effects of the failure.

7 Complete an action plan for improvements.

How will FMEA improve patient safety?

FMEA can help healthcare organisations correct potential problems by making procedures safer and more efficient. It can be used to evaluate the potential impact of changes over time. While RCA is usually undertaken following an incident, FMEA can identify potential process failures *before* they happen. The emphasis is on prevention of risk for both patients and staff. It is particularly useful in evaluating a new process prior to implementation and in assessing the impact of a proposed change to an existing process.

The benefits of FMEA are:

- improved design of care processes;
- it provides a systematic, thorough and consistent tool to identify potential root causes and enable corrective actions before an incident happens;
- it ensures that care is fit for purpose and delivered according to expected outcomes.

Findings of the results of FMEA should be shared across NHS organisations to ensure national learning about potential errors and risks, and about how these risks can be reduced.

Risk assessment checklist

The Department of Health's concise guidance document, *Building the Assurance Framework: A Practical Guide for NHS Boards* [21], gives advice on how boards and senior managers can bring together the existing fragmented risk management activity. A checklist is provided in the box below.

The board and/or organisation must:

- establish its principal strategic and directorate objectives;
- identify the principal risks that may threaten the achievement of these objectives (the Department of Health suggests a range of 75–200 depending upon the complexity of the organisation [13]);
- identify and evaluate the design of key controls intended to manage the principal risks and ensure they are underpinned by core controls assurance standards;
- set out the arrangements for obtaining assurance on the effectiveness of key controls across all areas of principal risk;
- evaluate the controls assurance programme across all areas of principal risk;
- identify areas where the controls are working well and areas where there are gaps in controls;
- put plans in place to take corrective action where gaps have been identified;
- establish sound, dynamic risk management arrangements including, crucially, a well-founded risk register.

How can the NPSA help?

A comprehensive programme of change is required to improve risk management across the NHS. A priority for the NPSA is to integrate guidance based on best practice, create a common language and adopt simple tools as a basis for widespread improvement.

Raising awareness of patient safety

A key aim of the NPSA is to raise the profile of patient safety, which includes risk management. We are promoting this in the form of guidance, presentations, articles, an induction video, and induction programmes for NHS leaders, new organisational chairs and non-executive directors.

Training programmes

Although risk management is developing as a professional discipline there is currently no common core framework for training risk management in healthcare. NHS risk managers and patient safety managers in local organisations play a vital role in training to improve patient safety. The NPSA will help ensure they are supported in doing their work by providing expertise and access to training tools and programmes.

Current programmes include an interactive web-based e-learning tool for all NHS staff who want to learn more about patient safety (described in **Step 2**). This will help risk management staff achieve their objectives required for training by CNST, RPST, WRP and HSE. Our RCA e-learning and training programme (described in **Step 6**) covers techniques for investigating incidents. These will be available on the NPSA website: **www.npsa.nhs.uk/rca**

We are also developing leadership programmes in conjunction with the King's Fund for Senior NHS Leaders. These will include the systems approach to error, leadership needed to drive patient safety, what a safe organisation looks like and how you can measure success in patient safety.

Development of risk assessment tools for healthcare

A review of risk assessment tools, including risk matrices and FMEA techniques, is underway with a view to developing a model tool for use across the NHS. This should be completed at the end of 2004.

Partnership for patient safety

Improving patient safety is part of the work of all national organisations and groups working in the NHS. Collaboration therefore lies at the heart of the NPSA's work. We aim to encourage healthcare organisations to put patient safety on their agenda and are liaising at a national level with

key organisations to help local-level implementation. The NPSA meets regularly with CASU, the Department of Health, Welsh Assembly Government, Strategic Health Authorities (StHAs); review bodies such as the Healthcare Commission (CHAI), the National Health Service Litigation Authority (NHSLA) and risk pooling schemes. Through partnership we aim to improve consistency in the approach to patient safety across the NHS.

National patient safety managers (PSMs)

To support NHS organisations in making NHS care safer the NPSA has set up a network of patient safety managers. There are currently 32 PSM's, each based within a Strategic Health Authority in England and Region in Wales.

It is acknowledged that local risk managers, clinical governance leads, and health and safety staff have progressed a long way in risk management and patient safety. The role of the patient safety manager is not to undermine this activity but to enhance it where they are needed. Patient safety managers are to support local development, mirroring the Strategic Health Authority and Welsh NHS Region boundaries. Essentially their aim is to provide two-way communication between the NPSA and local NHS organisations in England and Wales.

Their remit is to:

- provide leadership and expertise in a designated locality;
- support and coordinate the implementation of the NRLS;
- support and coordinate RCA training;
- support and advise NHS staff on patient safety issues, in particular with developing an open and fair culture; patient safety training; and advising local staff on the identification and investigation of patient safety incidents;
- provide assistance with achieving performance indicators and national targets, and with external reviews and accreditations;
- bring patient safety concerns and solutions ideas from local NHS organisations to the attention of the NPSA and in turn help local organisations test and implement solutions developed by the NPSA.

Good practice in integrating risk management activity

Case study: Milton Keynes General Hospital

Patients with any sort of allergy at the hospital now wear a bright red bracelet as well as their normal identification tag.

The idea for the red allergy bracelets was sparked by an incident when a patient, who was allergic to penicillin, was given the drug prophylactically in theatre. Although her allergy had been recorded in her notes, prescribing staff failed to notice this.

The red bracelet immediately alerts staff to a patient with an allergy irrespective of whether their notes are available.

This idea came out of a risk forum called the Risk Identification and Information Group (RIIG), which brings together all those involved in patient risk issues, such as those dealing with incident reporting, complaints, claims and drug errors.

The group gathers once a month for a confidential but informal meeting to discuss areas of concern, and to discover whether similar incidents are occurring in their differing areas of responsibility. This helps to highlight cross-boundary risks and promote the sharing of good practice.

As part of the ensuing investigation into this particular incident, it was discovered that the notes, which had recently been redesigned, no longer contained an area inside the front cover for documenting allergies and other permanent risk factors.

In the interim a florescent green sensitivity chart has been inserted into the front of patients' notes if they have a drug sensitivity, allergy or some other permanent risk factor. This has proved so effective that it may be kept as an extra alert.

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Step 4
Promote reporting

Contents

Step 4

Promote reporting

The Department of Health publication *An organisation with a memory* emphasised the importance of collecting incidents nationally to ensure that lessons are learnt across the NHS [1]. Not only do lessons need to be learnt but a proactive approach to the prevention of recurrence is fundamental to making improvements in patient safety . The NPSA has been set up to improve patient safety for all NHS patients, wherever they are treated, and an important part of the work of the NPSA is to ensure that incidents are reported nationally. This Step is concerned with the importance of both local and national reporting, whilst the actual implementation of local risk management systems is detailed in Step 3.

The national system will provide a core of reliable information on which to base analysis and recommendations. This is a new system, with no existing international models that can be adapted to our purpose, and has been designed by the NPSA based on international experience and best practice[2, 3, 4, 5]. This will require staff who provide care for NHS-funded patients – including the contractor professions, patients and, in time, the public – to have the ability and confidence to report patient safety incidents. For this system to work it needs to be embedded in an open and fair reporting culture. The NPSA needs to work with local organisations to ensure that potential barriers to reporting are addressed.

Reporting patient safety incidents and prevented incidents nationally gives the opportunity to ensure that the learning gained from the experience of a patient in one part of the country is used to reduce the risk of something similar happening elsewhere. It is important to note, however, that national reporting should be seen as complementary to robust local reporting systems rather than as a replacement for them.

In this Step we explain the importance of creating a reporting culture, the benefits of reporting, the national reporting and learning system, and what this means for local organisations. We also highlight what local NHS organisations can do to encourage reporting – e.g. using a common safety language – and see how the NPSA can provide support and help.

The key principles

Reporting patient safety incidents and prevented incidents nationally provides the opportunity to ensure that the learning gained from the experience of a patient in one part of the country is used to reduce the risk of something similar happening to future patients elsewhere.

All reports entered onto the National Reporting and Learning System (NRLS) will have the names of the patients and staff removed, together with other identifying data not required for the purposes of learning.

The statistical analysis of the NRLS will identify themes, patterns and clusters in the data. This will form the basis for further work to determine the scale and general severity of the issues highlighted. The output of this work will support local and national learning significantly.

Why is promoting reporting important?

It is important that all staff know *what* patient safety incidents to report and *how* to report them. Incident reporting systems need to be well-defined and easy to use. The key to success of both local and national systems, however, will be ensuring the presence of a reporting culture in local NHS organisations.

An organisation with a memory identified an NHS culture in which people are swift to blame or seek retribution[1]. To encourage reporting it is necessary to promote an open and fair culture where reporting is congratulated and individuals are not blamed or penalised if they speak out. This is discussed in detail in **Step One**.

To be most effective, local systems and the national system will require the reporting of all incidents which lead to harm, whatever level of severity, and not just the most serious. This includes the reporting of those incidents which:

- did not lead to harm because, e.g. an error took place but it did not harm the patient; and
- those which did not lead to harm because an incident was prevented from reaching the patient, e.g. an intervention was made to stop this happening. Reporting these means that we can learn about what actions prevent incidents from occurring and how these can be shared in different circumstances.

Research has shown that the more incidents are reported, the more information is available about what is going wrong, and the more action can be taken to make healthcare safer. That is why it is important that all staff, both clinical and non-clinical, have the confidence and knowledge to report all patient safety incidents. Analysis at a national level will enable service-wide action where patterns, clusters or trends reveal the scope to reduce risk or prevent recurrence for future patients.

Benefits of reporting

- **Resources targeted more effectively:** reported incidents provide evidence to better target resources. They identify areas for change and improvement in both patient care and patient safety.
- **Increased responsiveness:** timely reporting can help increase responsiveness, particularly when undertaking investigations. It also enables staff to be open with patients and their carers at an earlier stage.
- **Pre-empting complaints:** organisations can prepare proactively for potential complaints and litigation cases. More detailed information on a patient safety incident given to patients and their carers at an early stage may lead to fewer complaints and litigation claims, saving time and resources.
- **Reducing costs:** financial benefits arise from reduced severity of incidents, e.g. reduced costs of treatment, reduced length of stay [6].

If organisations are to improve the reporting culture in the NHS, and therefore gain the confidence of staff, there are a number of barriers to reporting that the NHS must overcome [2]. For example, clinical staff are anxious about: being blamed; the time reporting will take; what will happen to the information they provide; and whether the process is worthwhile, i.e. will the incident report make a difference to practice?

Barriers to reporting

- **Sense of failure:** there is a professional culture that personalises error and seeks and expects perfection. Healthcare professionals are trained to expect very high standards of performance from themselves at all times, and some find it difficult to acknowledge and learn from things that have not gone as well as expected.
- **Fear of blame:** public and media attitudes to accountability of healthcare professionals result in a tendency to seek someone to blame if things go wrong. There is a perception that reporting is seen as 'telling tales' about other staff, either within or across teams and care settings; it can be used as a way of passing the blame to others. An open and fair culture is addressed in **Step One**.

- **Reports being used out of context:** healthcare professionals are concerned that safety and quality information may be incorrectly interpreted by the public or the media, without full account being taken of such factors as the severity of the patient's illness or the complexity of the care provided.
- **Fear of increased medico-legal risk:** the potential for legal action to result from the discussion, review, analysis and exposure of information generated through safety and quality improvement activities is a source of concern to healthcare professionals.
- **Benefits of reporting are unclear:** a lack of acknowledgement and feedback from reported incidents means that staff do not see any positive results. Changes can take too long for staff, particularly those who regularly change jobs within the NHS, to see any benefits. Minor incidents are an everyday occurrence, so staff feel they would spend more time completing forms than caring for patients. Reporting something that has not affected the patient (i.e. patient safety incidents which were prevented) is seen as pointless and time consuming.
- **Lack of resources:** lack of staff to handle the work involved, lack of time to report and complete a form and lack of funding to feed into solution development.
- **'Not my job':** incident reporting can be seen as the role of the nursing staff only.
- **Lack of clear definitions:** this leads to confusion of *what* to report and *when* to report.
- **Difficulty in reporting:** incident reporting can be seen as complicated and time consuming, e.g. involve reporting detailed information to multiple systems for different types of incident.

  The NPSA aims to work on national solutions. Changes can then be made which help to design out the potential for error, e.g. working with manufacturers and designers to make changes to packaging, labelling, equipment and process design. The NPSA will also regularly inform NHS staff of the lessons being learned and the recommended changes to prevent errors or systems failures recurring. It is extremely important that staff receive feedback and understand how important incident reporting is to enable these changes to happen.

What is the National Reporting and Learning System (NRLS)?

The NPSA has developed the NRLS to promote comprehensive national learning about patient safety incidents. The NRLS will receive incident reports from NHS organisations, staff and contractor professions and, in time, patients and their carers. These reports will be based on a dataset developed with wide input from NHS organisations and clinicians involved in developing and testing the system. Reports will either be received via a technical link to local risk management systems already in use in NHS organisations, or direct reporting to the NPSA through an electronic reporting form (eForm).

Patient safety incident reports will be entered into a specially designed, confidential and anonymous national database. They will be aggregated and analysed with expert clinical input; to help understand the frequency of types of patient safety incidents, patterns and trends and underlying contributory factors.

By doing this, 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.

How to report incidents to the NPSA

1. Through the local risk management system

Around 90% of NHS organisations are currently using commercial local risk management systems (LRMS). To minimise duplicate data entry and enable local organisations to act on the information, staff will mainly report via their existing LRMS and the NPSA is currently working with these suppliers to develop technical solutions which make this possible. Once the NRLS dataset has been integrated with the LRMS, organisations will be able to submit data to the NPSA without duplicate entry.

Around 6% of NHS organisations are using systems which have been developed 'in-house'. They may seek to report via their existing system or may migrate to a commercial LRMS. Bespoke systems compliant with the LRMS integration standards specified by the NPSA will be able to integrate with the NRLS.

2. Directly to the NPSA via an electronic form (eForm)

Around 4% of NHS organisations have no LRMS in place. These are mainly in primary care. These organisations may seek to report via the eForm or migrate to a commercial LRMS.

When reporting directly to the NPSA via the NPSA's eForm, staff will be encouraged to share the information with their local organisation to maximise local learning as well as national learning. The reporter will be given various choices to make:

- to share the information with their local NHS organisation – this is particularly pertinent for independent contractors such as GPs, pharmacists, dentists and optometrists when sending to their primary care organisation;
- if they wish the incident to be shared with their local organisation they can do this either with or without their own personal details being shared;

  or

- they do not wish to share the information with their local organisation – so staff will continue to be offered full anonymity in reporting, not having to identify either themselves or their organisation, if this is the only way they feel able to report an incident.

The NPSA encourages incident reporters to share details with their local organisation. However, the anonymous route is intended to act as a 'safe alternative to silence', ensuring that national learning is obtained even if, at this stage, local learning is not. The NPSA will monitor trends in the number of incidents reported by the different routes and will share lessons learned in the feedback information.

What are the benefits for local organisations and their staff in reporting to the NRLS?

- Local NHS organisations will help build a comprehensive national picture of patient safety in the NHS. Over time, the analysis will be available so they can benchmark themselves against other similar organisations – for training and raising awareness.
- Research has shown that some staff welcome a national system because they feel it will give greater weight to local reporting and that incidents will be taken more seriously at management and board level [2].
- Root cause analysis investigations can help individuals and organisations

learn lessons about why incidents happen. Local investigations will help develop national solutions in order to reduce the chances of reccurrence and severity of incidents locally. The NPSA is considering developing its NRLS to receive RCA reports of serious incidents and themed incidents in order to learn and share lessons on causal factors, and where preventative action has been successfully taken.

- The data analysis undertaken will be used as part of the NPSA's prioritisation process to inform its work plan and solutions development. This analysis will then be shared with local organisations and, in turn, increase patient and public confidence that action is being taken to improve patient safety.
- Additionally, reporting to the NPSA will help NHS organisations to demonstrate that they have developed appropriate systems for collecting and reporting data on patient safety [7, 8, 9] also enabling learning and action.

The following key issues were considered by the NPSA in developing the NRLS:

- dataset content;
- confidentiality and anonymity;
- feedback.

Dataset content

Local risk management data capture and national incident reporting needs are very different. Originally, each profession and care setting wanted the national dataset to meet their unique requirements. However, the resulting dataset would have been unwieldy, inconsistent and incomparable statistically.

The NRLS dataset has been developed with the help of 39 English and Welsh NHS organisations and reflects a range of healthcare settings. It has achieved a number of goals by being:

- simple;
- timely (it ensures that the reporting form does not take too long to complete);
- applicable to all types of incident;
- capable of addressing the unique requirements of individual care settings, as well as those of a national reporting system;
- representative of the latest thinking in patient safety.

The NRLS' reporting needs may change over time. Where these changes are reliant on local risk management systems (LRMS), they will be negotiated with the LRMS suppliers. Some of the key changes to the dataset that came about as a result of the NPSA's work with NHS organisations (described further in Appendix Four A) are as follows:

- the dataset will collect reports about patients only. It will not collect incidents where staff or third parties such as visitors are harmed;
- users will be able to capture information about groups of patients as well as details of specific individuals affected;
- only factual information should be given in answers to free text questions rather than opinion. The NPSA will, however, be asking reporters to make considered judgements, particularly on causal factors;
- patient date of birth will not be stored by the NPSA but will be used to calculate the age at the time of the incident or the report. This mitigates any Caldicott issues of patient identifiability. NHS organisations should consider the requirements of the Caldicott principles in advising patients that patient safety incidents will be shared with the NPSA, but reassuring them that no patient identifiable information will be held [u, 10]. The dataset consists of high-level generic categories applicable for the whole service. These categories will provide the NPSA with sufficient information to detect patterns in the incidents reported; other information from the form, especially that within the free text, will provide the narrative from which the NPSA can learn. The core dataset will then form the basis of the LRMS, which can be customised and expanded to meet local organisations' needs.

  The data will be even further enhanced by the use of keywords in the free text which local reporters will be asked to use. Guidance on how to use keywords will be disseminated via the extranet system for local reporters, the intranet, training, presentations and communication

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u The Caldicott Committee's report on a 'Review of Patient-Identifiable Information' was published in 1997. This report highlighted concerns that compliance with the full range of confidentiality and security requirements was patchy across the NHS. The report established the role of a Caldicott Guardian in each NHS organisation including special health authorities. Caldicott requirements therefore cover the NPSA.

The report developed a set of general principles regarding the protection and use of patient information which are outlined below:

- justify the purpose;
- do not use patient-identifiable information unless it is absolutely necessary;
- use the minimum necessary patient-identifiable information;
- access to patient-identifiable information should be on a strict 'need to know' basis;
- everyone should be aware of their responsibilities;
- there is a need to understand and comply with the law.

Information sent to the NPSA from local risk management systems will have any patient-identifiable data sent in error removed prior to storage on the NPSA database Consequently only anonymous patient data will be held on the national reporting and learning system.

documents. This partnership role of NHS staff will be fundamental to the success of the NRLS.

Confidentiality and anonymity

A review of incident reporting systems in other industries and other countries illustrates the very high importance they have placed on protecting the confidentiality of incident data to ensure the integrity of their reporting system. The importance of confidentiality has also been recognised by the Department of Health in relation to other reporting systems, for example, the National Confidential Enquiries.

The NPSA needs to maximise the trust of NHS staff, contractors and the public to encourage spontaneous, accurate, timely and complete reporting of patient safety incidents. Clinical staff may be anxious about reporting because they are unsure of what the NPSA will do with the information, or they may be concerned that the information will go into a 'black hole'. Therefore, all reports entered onto the NRLS will have the names of the patients and staff removed, together with other identifying data not required for the purposes of learning. The information removed will not be stored.

To enable effective feedback and improve the quality of the NRLS the database will record the identity of the organisation submitting the reports. This information will be entered in the NRLS database, unless the report comes directly to the NPSA via the eForm and the reporter chooses not to identify the organisation involved. Retaining the organisational identifier will enable the NPSA to achieve its purpose of national learning. For example, we will have the capacity to work with NHS organisations directly where we have a pattern of concern emerging from our data analysis.

In order to ensure the anonymity of individual staff and patients is maintained the NPSA will take the following steps:

Remove all information which could identify individual staff or patients: ideally, the NPSA will receive reports in a form which does not identify the staff or patients involved. In cases where these data are included within the incident report received via LRMS or the eForm, they will be removed by cleansing software, prior to storing in the NRLS database. Any identifiable data which passes through this section will be removed by data-cleansing staff.

Provide anonymous analysis: when information is placed in the public domain, information and statistics will be presented and aggregated to ensure individual units or people cannot be identified inadvertently.

Limit disclosure: the NPSA will not be a primary data source except for incidents reported via the eForm (LRMS data will be received at the NPSA via each NHS organisation). This is important when considering disclosure issues. When reports are submitted by the eForm, and the reporter agrees to sharing the information with the local organisation, it will be forwarded on to that organisation. This will return the information to its primary data source. Where the reporter does not want to share with the local organisation, the organisational identity will not be retained. Therefore the NPSA will refer requests for disclosure to the primary data source, i.e. the local organisation.

The benefits of retaining organisational identity are:

- improved analysis with the ability to view incidents in the context of the type of organisation (including size, complexity and so on);
- feedback to organisations reporting via the LRMS;
- ability to request focused root cause analysis for key incidents;
- national and regional forums to link and enable wider learning from focused root cause analyses;
- targeted specific data collections from organisations;
- targeted rather than generic solutions;
- if reporters choose to share the incident with the local organisation – the data will be shared with the local organisation.

Feedback, learning and sharing information

The importance of feedback cannot be underestimated. When staff submit a report to the NPSA, there will be instant acknowledgement and information sharing. This is known as 'bounceback'.

For example, reporters may be guided to the NPSA website where the latest information about lessons learned and safety solutions relevant to their incident can be found. Over time, the NPSA will also make de-identified routine reports available on the website; showing general trends, issues and solutions generated.

The NPSA will establish mechanisms to analyse the reported data and to prioritise, review and advise on patterns. Where a pattern is of serious concern, the NPSA will further examine its causes in consultation with the relevant organisations. The output of this work will support local and national learning.

The NRLS data will be analysed by software that aggregates and recognises clusters of underlying features. Themes, patterns or clusters

that are identified in the data will form the basis for further work to determine the scale and general severity of any issue(s) highlighted.

The success of the software depends on consistent reporting; local organisations and individuals will also need to describe the incident using keywords, which the software can then pick out from the descriptive text. Completion of the free text sections will therefore be a vital part of the local training required for the implementation of the NRLS. The NPSA will be seeking the advice and expertise of its Clinical Specialist Advisers, as well as from professional bodies and other clinicians to help the development of this analysis and reporting. This will enable actionable learning for the NHS.

Why is a national approach to local reporting important?

The NRLS will, in most cases, take information from local reporting systems. Therefore local reporting of patient safety incidents is essential for both local and national learning.

Currently, there is a great deal of variability in risk management practices, incident reporting structures and processes across healthcare organisations. There are different levels of organisational maturity in supporting a reporting culture both within and between organisations. For instance, most NHS reports are from nursing staff and many primary care trusts and local health boards are at an early stage of developing clinical governance, risk management and incident reporting frameworks. Also, there is a lack of integration across risk management processes including controls assurance, patient safety, complaints, litigation and health and safety – as discussed in **Step Three**.

NHS staff who move around the service have to become familiar with different systems in different local organisations. There is often a lack of clarity about what issues to report, how to report them and to whom. Also, multiple reporting systems can exist within single organisations – e.g. highly specialist reporting of complex medical and technical issues versus generic risk management reporting of systems problems.

Currently, reporting of patient safety incidents to external bodies often requires duplicate entry of data by staff involved. The number of reporting systems in use across the NHS continues to grow. This has a significant administrative impact for both clinical and managerial staff in most NHS organisations.

There are currently over 30 other bodies (shown in Appendix Four D) that either are directly reported to from local NHS organisations or are interested in the incident data collected. The main ones are:

- the Strategic Health Authorities and Welsh Assembly for Serious Untoward Incidents (SUIs);
- the Health and Safety Executive (RIDDOR) for health and safety incidents;
- the Serious Hazards of Transfusion (SHOT) reporting system for transfusion incidents;
- the Medicines and Healthcare products Regulatory Agency (MHRA) – formed from the merger of the Medicines Control Agency and the Medical Devices Agency on 1 April 2003 – for all medicine and medical device related incidents.

The NPSA has been considering the implications of these multiple reporting routes and the opportunity for the development of a common route for reporting patient safety incidents in order to make reporting easier for all staff. However, the reporting information needed by each organisation is different and used for different purposes. Initial work with the MHRA highlighted the complexities that a common route creates.

Following this joint working and the NPSA's testing and development phase, it has been decided that incidents involving medical devices, adverse drug reactions and defects with medicine products should be reported directly to the MHRA in the first instance. The MHRA will then share the learning gained through their reporting mechanisms with the NPSA. All reports submitted to the NPSA that relate to these issues, however, will be shared on an aggregate basis with the MHRA.

What do healthcare providers need to do?

In this section we outline some of the things that need to happen at a local level to promote reporting and a reporting culture. We have also highlighted how the NPSA is working to help this process.

1 Adopt a common language for reporting

Clear and standardised definitions relating to patient safety are critical to the success of any incident reporting system. They provide consistency and mean that data can be aggregated at a national level.

Currently there are a large number of different terms and definitions in the patient safety literature. These can cause confusion among staff and create a barrier to incident reporting.

How can the NPSA help?

The NPSA has been working with local NHS organisations, risk managers, patients and the public, to develop a common lexicon

around patient safety that local organisations can use for reporting. Table 1 sets out the NPSA's preferred terms, their meaning, and the terms they are designed to replace.

The NPSA has also developed a standardised dataset for patient safety reporting. This will enable consistent analysis and reporting at the national level for the first time in the NHS. The dataset is available in full from the NPSA website. Local risk management system vendors are integrating this dataset into their products. Consequently, if staff choose to report through their local risk management system, they will automatically be reporting to the NPSA, without any additional burden on the reporter or their NHS organisation.

Table 1

NPSA's preferred terms for patient safety reporting

Old terms	New terms
Clinical risk	**Patient safety:** The identification, analysis and management of patient-related risks and incidents, in order to make patient care safer and minimise harm to patients.
Adverse incident Adverse event Clinical incident Critical incident Medical error Clinical error Medical mistake Sentinel event	**Patient safety incident:** Any unintended or unexpected incident(s) that could have or did lead to harm for one or more persons receiving NHS-funded healthcare [v 2]. 'Patient safety incident' is an umbrella term which is used to describe a single incident or a series of incidents that occur over time. Terms such as adverse, error or mistake suggest individual causality and blame. Medical error in particular suggests the main cause is the medical profession.
No harm event	**Patient safety incident** (level of severity no harm): A patient safety incident that caused no harm but was not prevented ('impact not prevented') or a patient safety incident that was prevented.
Near miss/close call	**Patient safety incident** (prevented): Any patient safety incident that had the potential to cause harm but was prevented, resulting in no harm to patients receiving NHS-funded healthcare.

The term 'near miss' was introduced into healthcare in the mid 1990s, however:

- research has shown that near misses are rarely reported because staff do not understand what they are [11];

v **NHS-funded healthcare:** this includes all patients who are treated in any setting which includes: NHS establishments or services; independent establishments including private healthcare; the patient's home or workplace, where either all or part of their care is funded by the NHS. It includes all incidents which affect patient care, including incidents in relation to research, which should be reported in accordance with the research governance framework.

- a near miss is usually associated with a near-catastrophic event or death but the NPSA is interested in having *all* prevented patient safety incidents, at all levels of potential severity, reported;
- patients and the public view a near miss in relation to aviation or road traffic accidents and usually associate it with the near crash of two aeroplanes or cars. Consequently, patients and the public feel that it is an inappropriate term in the healthcare context.

  To improve reporting of near misses and to clarify their definition, the NPSA has chosen to change the terminology from 'near miss' to 'prevented patient safety incident'.

  A prevented patient safety incident could be an incident that was prevented, e.g. a surgeon almost amputating the wrong limb but being stopped by a colleague before the mistake was made.

  It could also be something that almost happened but didn't – e.g. a diathermy pad, which ignites seconds after being removed from a patient. This caused no harm, but if it had gone up in flames *before* being removed it would have done.

  (There are further examples of prevented patient safety incidents, along with examples of all incident grades, in Appendix Four F.)

  It is vital that prevented incidents are reported and analysed in the same way as for other incidents. It is less distressing to learn from an incident that did not cause patient harm and lessons can be learned about the barriers or controls that worked, or the actions taken to prevent the incident from impacting.

2 Grade incidents according to harm

The effects of patient safety incidents go beyond the impact of the physical injury itself. Patients and their families may feel let down by those they trusted. The incident may also lead to unnecessary pain, additional therapy or operations and additional time being cared for in the community or in hospital.

Psychological injuries such as shock, anxiety, depression, uncertainty about recovery, fear of future treatment and disruption to work and family life are just some of the possible effects following a patient safety incident [12].

By grading patient safety incidents or prevented incidents according to the impact or harm they cause patients, local organisations can ensure consistency and comparability of data. This consistent approach locally will enable the NPSA to compare and analyse data nationally.

As described in **Step Three**, the NRLS does *not* require a patient safety incident to be graded for the following (although local organisations may still want to grade incidents in this way):

- potential impact (the NPSA would not be able to guarantee the consistency of the reporter's interpretation);
- likelihood of reoccurrence (the NPSA will be capturing the actual occurrence on a national level);
- impact on organisations, such as adverse publicity or loss of public confidence (this is difficult to quantify);
- cost of litigation damages (already captured by the NHS Litigation Authority).

How can the NPSA help?

When incorporated with the local risk management system, the NRLS dataset will automatically enable local organisations to grade in accordance with national guidelines.

The NPSA has arrived at the terms given in Table 2 for grading the level of harm caused by patient safety incidents. The different levels of harm do not include time limits, so an incident is not defined by the length of time it takes for the patient to recover. This is because patient recovery following incidents can be hard to predict accurately. Harm is defined as injury, suffering, disability or death.

Table 2

NPSA terms and definitions for grading patient safety incidents

Old terms	New terms
None/ insignificant	No harm: • **Impact prevented** – Any patient safety incident that had the potential to cause harm but was prevented, resulting in no harm to people receiving NHS-funded care. • **Impact not prevented** – Any patient safety incident that ran to completion but no harm occurred to people receiving NHS-funded care.
Low/minor	**Low:** Any patient safety incident that required extra observation or minor treatment [w] and caused minimal harm, to one or more persons receiving NHS-funded care.
Moderate	**Moderate:** Any patient safety incident that resulted in a moderate increase in treatment [x] and which caused significant but not permanent harm, to one or more persons receiving NHS-funded care.
Severe/major	**Severe:** Any patient safety incident that appears to have resulted in permanent harm [y] to one or more persons receiving NHS-funded care.
Death/ catastrophic	**Death:** Any patient safety incident that directly resulted in the death [z] of one or more persons receiving NHS funded care.

Mitigating circumstances

When reporting to the NRLS, local organisations and reporters will be asked to determine what mitigating factors or actions were taken to reduce the level of harm and impact to the patient.

Every patient safety incident may have an element of risk reduction. Even a severe incident, for example, may have involved an action or a partial recovery which prevented the incident from leading to the death of a patient. In some incidents even 'death' could be mitigated, in terms of the number of patients who died (i.e. one person died as opposed to 10 because of actions taken at the time).

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w 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 re-admission.

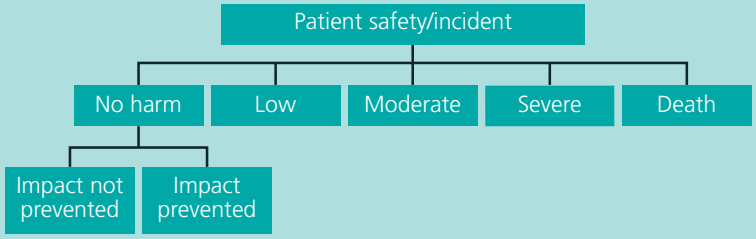
x Moderate increase in treatment is defined as a return to surgery, an unplanned re-admission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, or transfer to another area such as intensive care as a result of the incident.

y 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, physiologic or intellectual, including removal of the wrong limb or organ, or brain damage.

z The death must relate to the incident rather than to the natural course of the patient's illness or underlying condition.

The NPSA's dataset will enable the collection of information on contributory factors, action taken to minimise the incident and preventative actions. Evidence from the aviation industry has shown that these data are a valuable source of safety information because they facilitate learning about the recovery strategies people use in response to problems.

Figure 1: Levels of severity of harm



3 Develop a local implementation plan for national reporting

Implementation of the NRLS is taking place throughout 2004. For the national implementation targets to be met by December 2004, the programme management arrangement must allow for NRLS to be implemented in approximately 50 trusts/local health boards per month from January 2004 onwards. Rolling out the NRLS dataset and/or eForm will provide a significant opportunity to raise awareness of both the patient safety agenda and the range of tools available from (and being developed by) the NPSA.

Rolling out the NRLS may require NHS organisations to change the way that they record and report patient safety incidents internally. There are many different approaches currently in use to collect data about patient safety incidents. It is estimated that around 90% of NHS organisations are currently using commercial local risk management systems (LRMS), around 6% are using systems which have been developed 'in-house' and around 4% of sites have no automated data system in place at the present.

The electronic form devised by the NPSA (eForm) will be used as a data capture mechanism only in NHS organisations that do not have an LRMS application. The eForm would be used in those sites that either do not have a commercial LRMS application or have developed their own local system which cannot transmit the required data to the NRLS.

Core elements of the implementation process

Although there will be variation in how NHS organisations report to the NRLS, the following are three core foundation stones for successful implementation of the NRLS.

1 **Awareness and understanding:** NHS organisations will need to know about the NPSA and in particular the NRLS. They need to understand what is being asked of them – in particular, what is required locally, what the NRLS will be doing nationally, and how these two levels of activity link up.

2 **Readiness and planning:** NHS organisations will need to assess their own readiness for implementation of the NRLS; in particular their preferred approach to reporting patient safety incidents to the NPSA. They will then need to develop an implementation plan for establishing their agreed approach to data capture.

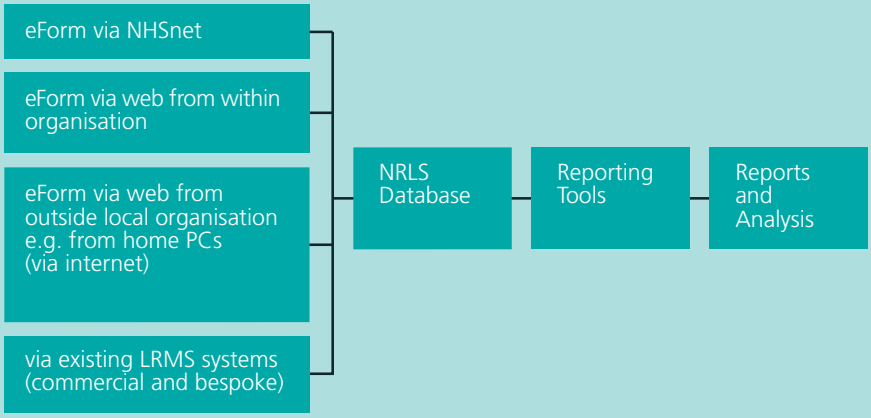
3 **Installation and connectivity:** NHS organisations will need to access technical support from the NPSA (and the LRMS vendor where appropriate) to ensure successful establishment of data capture facilities. They will also need support for data mapping; whether from their own staff, vendors and/or NPSA support. The key steps involved in implementation are as follows:

- all NHS organisations will need to appoint a local lead contact for NRLS implementation within a specified timeframe (in many cases this contact is likely to be the organisation's risk manager);
- the local lead contact will need to work with their local NPSA patient safety manager to agree an implementation plan;
- the local lead contact will decide their preferred reporting route to the NPSA. If they intend to report via the eForm they will need to complete an implementation plan with agreed dates for installation. If they intend to report via their LRMS system they will need to liaise with their LRMS vendor about availability of the NPSA-compliant upgrade. If they intend to report via their bespoke risk management system they will need to:
- review their current system against NPSA technical standards;
- decide if they have the expertise to develop a solution which is NPSA-compliant;
- complete an implementation plan with agreed dates for technical work, installation, data mapping and RCA learning set training.
- the local lead contact will need to complete an implementation plan

with agreed dates for installation (in conjunction with their LRMS vendor) and data mapping.

Once completed each local organisation will then be able to sign up to the root cause analysis network training for up to eight members of their staff, described in **Step Six**.

Figure Two: Data capture pathways for NRLS staff reporting



How can the NPSA help?

To help organisations develop their local implementation plans, and support roll out of the NRLS, the NPSA will:

- **support** NHS organisations to understand the NRLS and decide their preferred reporting pathway using information leaflets and face to face discussions – patient safety managers will take the lead in much of this work with an implementation team for backup and support;
- **develop and agree** an overall implementation plan based on the local implementation plans and vendor agreement/liaison in conjunction with the patient safety managers;
- **coordinate and schedule** agreed data mapping, technical installation and root cause analysis training dates;
- **run data mapping workshops** (described below) involving primarily the NPSA staff and the local risk managers mapping their local dataset with the national dataset and then validating agreed data mapping to NPSA standards;
- **support technical installation,** involving primarily the NPSA IT team;
- **approve successful connectivity,** involving primarily the NPSA IT team.

Data mapping

The correct mapping of data is essential to ensure NRLS data quality and consistency of reporting and analysis. At its simplest level, data mapping is tracking and recording how the organisation's dataset can 'fit' into the NRLS dataset. The NHS organisation dataset is likely to have far greater depth than the NRLS dataset.

The data mapping exercise will involve a local representative (risk manager or clinical governance lead) and a member of the NPSA information team. The NPSA will support the mapping process and review the results of the mapping exercise once it has been completed.

The time that is required for mapping will depend on the size of the NHS organisation (and its corresponding dataset) and the knowledge and experience of the local staff involved.

Support functions

Help desk: it is planned that, wherever possible, the queries of NHS organisations will be dealt with in the first instance by the relevant patient safety manager. However, it will also be necessary to operate an NRLS implementation help desk to ensure that calls are dealt with appropriately and directed when they come to the NPSA's central office. The help desk will also maintain a contact database and coordinate the resolution of any queries with IT, communications, patient safety managers and so on.

Regional and Welsh implementation forums: these will coordinate and manage the overall scheduling and timetable for data mapping workshops, technical installation, site visits and connectivity to the NRLS.

Detailed guidance on how to get connected: guidance on the roll out of the NRLS will be available from NPSA patient safety managers.

NRLS readiness review checklist: the role of the checklist is two-fold. It will help NHS organisations to review their incident reporting processes – guiding them through the technical, reporting, change management and workflow issues. The checklist will also help the NPSA to find out more about the NHS organisations (e.g. risk management processes, software used and key contacts). This will be used by the patient safety manager as a structured tool to work through with NHS organisations.

NRLS implementation planning template: this will provide a consistent template for NPSA's overall project and performance management of the NRLS implementation. Sites can also use it to develop their own local plan for NRLS implementation. Key content

will include the method of data capture, dates for NPSA (and LRMS) installation where appropriate, dates for data mapping workshop, dates for RCA training and agreed participants. This local implementation plan would need to be agreed with the NPSA (and the LRMS vendor where appropriate) and would form the basis of the formal relationship between an NHS organisation and the NPSA.

eForm templates: These are for use by NHS organisations if they want to adapt their existing paper-based reporting systems to provide all required NRLS data. It is suggested that this is provided by the patient safety manager on request.

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Appendix Four A

The National Reporting and Learning System (NRLS)

Developing the NRLS dataset and eForm

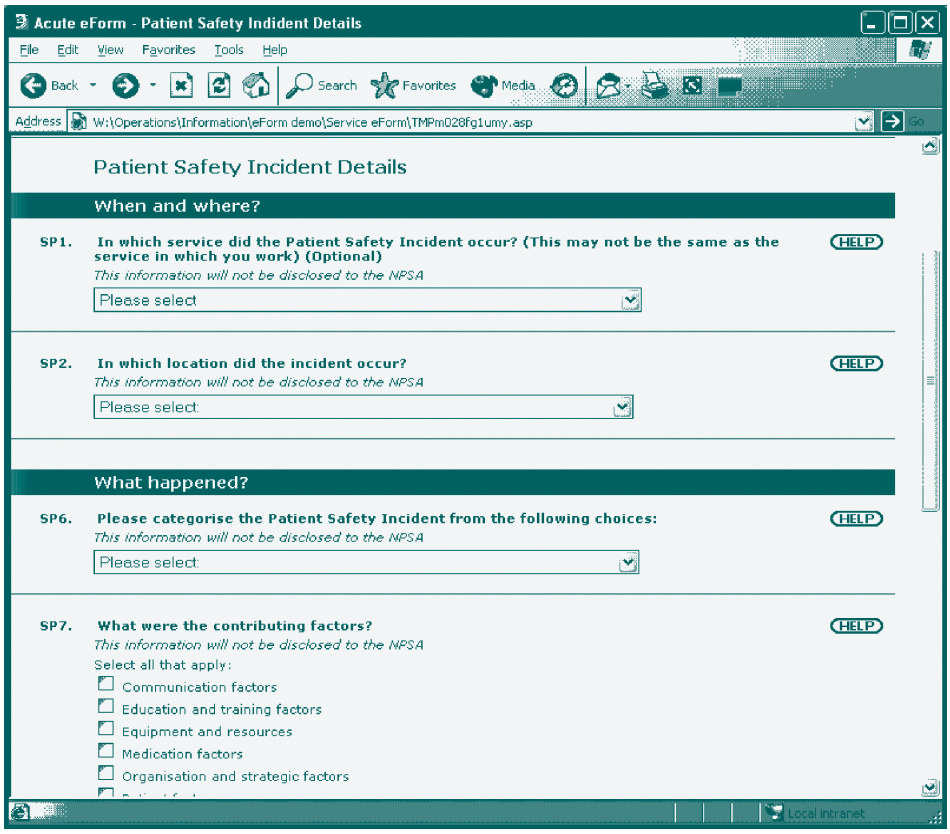
Information gathered by the NRLS will be analysed and, where lessons can be learned, these will be fed back into practice. It is therefore important that the dataset supports the information needs of users reporting to the NPSA, as well as users within the NPSA who will be working on safety solutions. The NPSA aims to increase reporting of patient safety incidents while, over time, seeing a decrease in the severity of those incidents.

The NPSA was assisted in the development of the electronic form (eForm) for the NRLS by an initial 28 pilot sites and then 39 testing and development sites. These were taken from a cross-section of NHS organisations, including primary, secondary and tertiary care settings. A version of the eForm was used from January 2003 in the testing and development sites. NHS organisations submitted live patient safety incident data to the NPSA and in doing so helped to test the dataset, the usability of the eForm, the online guidance material, and the technical viability of the solution.

Based on the data received and on qualitative feedback sent directly to the NPSA from the sites (e-mail, phone, issue logs) during site visits and telephone interviews by NPSA staff a revised dataset was released at the end of March 2003. This was built into a new version of the eForm for use in formal usability testing. During April 2003, the NPSA ran a series of intensive workshops with representatives from the testing and development sites, NHS risk managers, and NPSA staff. A major revision of the dataset was produced as a result.

Appendix Four B

An example of the eForm



Appendix Four C

The essential fields collected by the NRLS include:

- the service (acute, mental health, primary care) where the patient safety incident occurred;
- the location;
- the specialty or service area;
- date and time;
- contributing factors (e.g. communication, education and training, equipment and resources, patient, task);
- description of what happened;
- actions planned or taken to date to prevent a reccurrence;
- patient details: age range, date of birth, sex, ethnic group, disability;
- degree of harm to the patient (severity) – e.g. no harm, low, moderate, severe, death;
- actions taken to prevent the incident from reaching the patient(s);
- actions taken to minimise the impact of the incident on the patient(s);
- effect of the incident on the patient (e.g. physical, psychological etc).

Appendix Four D

Examples of categories and triggers of incident types for reporting nationally

Dataset headings	Subheadings
Access, admission, transfer (including missing patient)	Delay or failure to access care Unexpected re-admission Difficulty in obtaining clinical assistance Delay or failure to discharge
Clinical Assessment (including diagnosis, scans, tests, assessments)	Wrong diagnosis Failure to receive test results Missing test results Consent, communication, confidentiality
Consent, communication, confidentiality	Breach of confidentiality Failure to communicate outside of team Patient incorrectly identified
Disruptive, aggressive behaviour	Physical Verbal
Documentation (including records, identification)	Delay in obtaining healthcare record/card Missing healthcare record Missing scans
Implementation of care and ongoing monitoring/ review	Delay in recognising a complication of treatment Extended stay/episode of care
Infection control incident	Failure of sterilisation or contamination of equipment Cross-infection

Dataset headings	Subheadings
Infrastructure (including staffing, facilities, environment)	Exposure to cold/heat Lack of suitably qualified staff Inadequate equipment Lack of beds
Medical device/ equipment	Failure of device Unavailability of device
Medication	Wrong drug Overdose of drug
Patient abuse (by staff/third party)	Physical Verbal
Patient accident	Contact with sharps Slips, trips and falls
Self-harming behaviour	Suspected suicide
Treatment, procedure	Delay or failure to monitor Illegible healthcare record Failure to discontinue treatment Inappropriate use of control and restraint Theatre list details incorrect

Appendix Four E

Examples of external systems with an interest in patient safety and incident reporting

- Medical Devices Agency (MDA) and Medicines Control Agency (MCA) are now merged to form the Medicines and Healthcare products Regulatory Agency (MHRA) – which operates separate reporting systems, one for medical devices and one for medication incidents
- Health and Safety Executive (HSE)
- Environmental Health Agency
- Health Professions Council (registration board for paramedics and allied health professionals such as physiotherapists)
- General Medical Council (GMC)
- General Dental Council (GDC)
- Nursing and Midwifery Council (NMC)
- H. M. Coroners
- National Institute for Clinical Excellence (NICE)
- Royal Pharmaceutical Society of Great Britain (RPSGB)
- Royal College of Nursing (RCN)
- National Clinical Assessment Authority (NCAA)
- Purchasing and Supply Agency (PASA)/Welsh Health Supplies
- NHS Estates/Welsh Health Estates
- NHS Information Authority (NHSIA)
- NHS Litigation Authority
- The Prison Health Service
- The NHS Modernisation Agency
- Serious Hazards of Transfusion (SHOT)
- The Police
- Strategic Health Authorities (STEIS and SUI)
- Human Fertilisation & Embryology Authority (HFEA)
- Royal College of Anaesthetists (anaesthetic reporting system)
- Health Protection Agency (HPA)
- Counter-fraud and Security Agency
- National Newborn Screening Programme
- Healthcare Commission (CHAI)
- Welsh Assembly Government
- Clinical Negligence Scheme for Trusts
- Risk Pooling Scheme for Trusts
- Welsh Risk Pool

This list is not comprehensive; it is an assessment of the reporting systems that the NPSA has identified in its work to date.

Appendix Four F

Examples of events according to severity

1. No harm: Impact not prevented	
General	A patient is prescribed one 'painkiller' (e.g. paracetemol) and given two instead. This has not been prevented in any way but has not caused any harm in this particular case. Problems with blood taking bottles – causing false readings and irregular results with the potential for wrong diagnosis – blood re-tested. Two patients with the same name have their records amalgamated; this is picked up when the patient is seen again (either in outpatients, inpatients or GP clinic) before any incorrect diagnosis or treatment.
Acute	Very small perforation of the bowel during surgery, no content leakage; the perforation is repaired quickly and abdominal area appropriately washed out; no further operations or therapy required. Normal saline infused in two hours rather than four hours due to the wrong setting of the infusion pump, causing no harm to the patient. Two patients who require a blood transfusion both with the same blood type, patient A receives patient B's transfusion and vice versa, with no ill effects.
Mental health	A patient is given someone else's medication; however, the medication was identical to their own prescribed medication so this caused no ill effects.
Primary care	A patient is receiving warfarin as an outpatient and the GP surgery fails to monitor clotting levels according to protocol. The patient mentions this at a later date and when they are finally checked, they are found to be within normal limits. A patient is on medication that requires regular blood tests; the hospital discharge letter fails to mention this to the GP which results in the patient not being followed up appropriately. However, it is noted when the patient visits the GP for a further prescription. The patient's results are then found to be normal.
Ambulance	Ambulance crew is called to a patient at home with chest pain and gives the patient an aspirin, without asking if they are on any other medication. They are then informed that the patient is on warfarin. There are no adverse effects for the patient.

1. No harm: Impact prevented	
Acute	A porter collects a patient to go to theatre. As he is leaving the ward a nurse recognises that the porter has collected the wrong patient and another patient with the same name should be taken. This is corrected and the right patient goes to theatre.
Mental health	A patient is nearly given someone else's medication; however, the nurse double checking the patient's identification realises the mistake and does not give the patient the medication.
Primary care	A patient rings their GP practice for a follow up appointment to monitor warfarin levels, an appointment letter is sent, but would have been forgotten if the patient had not rung. A GP prescribes an inappropriate dose which the local community pharmacy picks up when dispensing the prescription.
Ambulance	An ambulance crew is called to a patient at home with chest pain and want to give the patient an aspirin; just before administration they are informed by the patient's relative that the patient is on warfarin. The aspirin is not given.

2. Low	
General	A patient trips and falls in the hospital corridor, resulting in a wound which requires stitches and a dressing. A child receives out of date feeds causing slight vomiting.
Acute	Perforation of the bowel during surgery, repaired at the time and area appropriately washed out, only antibiotic therapy required. A patient's operation is cancelled as a result of poor pre-admission assessment (e.g. clotting status) but this has minor consequences. Patient receives a small bruise from a 'towel clip' being clipped to the patient's skin as well as the towel during surgery.
Mental health	A patient is given someone else's medication; the medication was the same as the patient normally takes but a slightly higher dose, which resulted in the patient needing to go to bed earlier than normal because of drowsiness.
Primary care	Continuing treatment with warfarin without monitoring clotting levels; this results in prolonged clotting times, causing bruising. A patient's home visit is missed; the terminally ill patient required a pain assessment; this was picked up the following day resulting in the patient continuing to be in pain until the medication was altered.
Ambulance	An ambulance crew is called to a patient at home with chest pain. On arrival the crew decides to administer oxygen to the patient and is then informed that the patient has had a laryngectomy. There are no laryngectomy masks on the vehicle so the crew have to attempt to oxygenate the patient using a face mask over the stoma. On arrival in A&E the patient's oxygen saturation levels have dropped from 92% to 85%.

3. Moderate	
Acute	Perforation of the bowel during surgery not picked up at the time, which results in septicaemia and a return to theatre for repair. Patient eats prior to surgery, causing urgent operation to be cancelled, which leads to deterioration and longer stay in hospital. Wrong blood is given resulting in emergency dialysis. However, there are no long-term effects. A patient's broken foot is not detected on x-ray and the patient is sent for extensive physiotherapy which causes further pain and damage.
Mental health	A patient is given someone else's medication; the medication is stronger than their own and the patient suffers prolonged drowsiness. The patient needs frequent observations of their respiratory rate.
Primary care	Continuing treatment with warfarin without monitoring clotting levels which results in an overdose and bleeding problems. Patient with external infusion line (e.g. Hickman line) gets an infection while at home following repeated disconnections, requiring a hospital admission for antibiotic therapy.
Ambulance	An ambulance crew is conveying a patient from the ambulance to A&E on a trolley bed. The patient is left unattended for a short period and the trolley bed tips over. The patient suffers short-term loss of consciousness and needs to be admitted to hospital for observation.

4. Severe	
Acute	Perforation of the bowel during surgery, requiring a temporary colostomy and subsequent major operations. Problems with blood transfusion (e.g. transportation) resulting in the blood not arriving in time, patient suffers brain damage following haemorrhage. Wrong blood given to a young woman, who then develops anti-D antibodies which will affect any future pregnancy. Removal of wrong organ or wrong limb due to mis-identification.
Mental health	A patient is given someone else's medication which they are allergic to. The patient suffers an adverse reaction, has a cardiac arrest and suffers brain damage as a result of receiving this medication.
Primary care	Continuing treatment with warfarin without monitoring clotting levels which results in a brain haemorrhage and brain damage. A newborn baby with an inborn error of metabolism fails to be screened for phenylketonuria resulting in irreversible brain damage. A patient incurs an extravasation injury (soft tissue burn) from an intravenous line at home, causing irreversible scarring and bone damage. Failure to diagnose meningitis by GP or A&E department, child is discharged home, then collapses which leads to permanent brain damage.
Ambulance	An ambulance is called to a patient who has fallen from scaffolding. On arrival the patient is conscious but lying awkwardly, his leg is clearly fractured. Before undertaking a full assessment on the patient the ambulance crew repositions the patient to straighten his leg, without undertaking any immobilisation to the cervical spine. After repositioning, the patient is unable to move any of his limbs and investigations later identify that he had a cervical fracture and spinal cord damage. The cervical spine was, however, immobilised immediately after repositioning. He is likely to suffer long term with paralysis from the neck down.

5. Death	
Acute	Death as a direct consequence of perforation of the bowel during surgery. Pacemaker battery change is undertaken by a person with no expertise – causing the patient to have a cardiac arrest and then die. Wrong blood is given resulting in multi-organ failure and death. Death as a direct result of a hospital-acquired infection.
Mental health	A patient is given someone else's medication which they are allergic to. The patient suffers an adverse reaction, has a cardiac arrest and dies as a result of receiving this medication. A suicide or homicide on healthcare premises.
Primary care	Continuing treatment with warfarin without monitoring clotting levels which results in a brain haemorrhage and death. A patient suffering from chest pains is asked to wait for a free slot; he goes for a walk, collapses and dies in the GP car park.
Ambulance	An ambulance is responding to an emergency call on blue lights and is going through traffic lights which are on red at a crossroads. A car travelling on the road crossing which has got a green light does not see the ambulance and carries on over the crossroads. The ambulance is unable to stop in time and hits the car on the driver's side. The driver of the car has multiple injuries and later dies in hospital.

Step 5
Involve and communicate with patients and the public

Contents

Step 5

Involve and communicate with patients and the public

Involving and communicating openly with patients, their relatives, their carers and the public is essential to improving patient safety. Experience shows patients' definitions of harm and error sometimes differ from the definitions used by clinicians. And if a patient is harmed when things go wrong, they can offer insight into the reasons for the problem and inform solutions to prevent the incident recurring. To enable this to take place, the NHS must be open and receptive to engaging with patients.

At the NPSA we have developed a policy around patient involvement to ensure their interests and welfare are at the centre of our work. In this Step we outline NHS guidelines for patient and public involvement to date, describe some of the initiatives the NPSA is undertaking (including a model 'being open' policy on how to communicate patient safety incidents) and look at how local NHS organisations can encourage openness and engage with patients to help make the service safer. The Step discusses three areas of involvement:

1 involving patients and the public in developing safer services;

2 involving patients in their own care and treatment;

3 encouraging an open, two-way dialogue between health professionals and patients when things go wrong.

The key principles
Many patients are experts in their own condition and this expertise can be used to help identify risks and devise solutions to patient safety problems.

Patients want to be involved as partners in their care. Healthcare staff need to include patients in reaching the right diagnosis, deciding appropriate treatment, discussing the risks and ensuring treatment is correctly administered, monitored and adhered to.

Being open about what has happened and discussing the problem promptly, fully and compassionately can help patients cope better with the after effects when things have gone wrong.

A duty to involve

It is now widely accepted that involving patients [1] and the public in every aspect of healthcare can improve patient care, including safety. In 2000 the Department of Health set out its commitment to involving the public

and patients in The NHS Plan – A Plan for Investment A Plan for Reform [2]. The Health and Social Care Act 2001 [3] subsequently set legislation that places a duty on the NHS to engage actively with the community and service users. The Act established a new system of patient and public involvement to replace Community Health Councils (CHCs) in England as part of the modernisation programme. The new system was also designed to respond to the public enquiry into children's heart surgery at Bristol Royal Infirmary [4], which recommended representation of patient interests at every level of the NHS.

Through involvement in safety issues it is hoped that:

- risks and patient safety problems will be proactively identified by patients;
- concerns and ideas for improvement from patients and the public will be shared;
- solutions generated in partnership with patients and the public will be more realistic and achievable.

But how can local NHS organisations achieve this involvement?

1 Involving patients and the public in developing safer services

To help develop safer services it is crucial to involve users of the NHS at a strategic level. Many patients are recognised by the NHS [5] as experts in their own condition and this expertise can be used to help identify risks and devise solutions to patient safety problems.

Examples from the NPSA

The NPSA has set out a commitment to involve patients and the public in all its work. For example:

- we have involved the public, patients and the voluntary sector in workshops to discuss how we should prioritise patient safety issues to work on [6];
- we have involved patient representatives and members of the public in developing the system for reporting and learning from patient safety problems. This will complement the National Reporting and Learning System (NRLS) for NHS staff and organisations;
- patient representatives are also active members of the working groups set up to develop solutions to patient safety problems, and we are working with patients and patient groups to design products and materials and test their effectiveness.

To ensure a range of voices are heard and to enable participation in all areas of the NPSA's work, a variety of approaches is required. For

example to inform the aforementioned patient reporting system the NPSA organised:

- a usability study involving health service users, run by the Help for Health Trust – Centre for Health Information Quality (CHIQ)[7];
- meetings and a workshop between NPSA staff and members of interest groups such as Sufferers of Iatrogenic Neglect (SIN) and Action Against Medical Accidents (AvMA), as well as representatives from Patient Advice and Liaison Services (PALS) and other statutory bodies such as the Commission for Health Improvement (CHI).

This work found that patients and their representatives supported a system for allowing patients to report even though they had many questions about the relationship of organisations such as the NPSA and regulators. They asserted that such a system would enable the NPSA to learn about the experience and impact of a patient safety incident – what it felt like, how it affected a patient's life, and the emotional and psychological consequences of being harmed.

Case study: Involving patients in developing safer services

Oral methotrexate

This project was set up due to an increasing number of dosing errors with oral methotrexate. To find out about patients' experiences of using this drug the NPSA conducted 16 face-to-face and telephone interviews with patients and carers across the UK. The patients were both current and former users of methotrexate and were members of registered charity patient groups for arthritic and psoriatic conditions.

Patients, carers and voluntary organisations were also invited to join healthcare professionals at a workshop to consider possible solutions to the problems identified. The effectiveness of the proposed solutions to remove or prevent opportunities for things to go wrong was tested by patients and carers, and by healthcare professionals. Newly diagnosed patients with no previous experience of oral methotrexate were also involved in the testing by and with their specialist consultant.

What can local NHS organisations do?

All NHS organisations need to adopt a strategic approach to patient involvement in both risk management and patient safety. They need to

define what this means and how it will be implemented. Formal systems are also needed to provide the patient and their relatives or carers with a 'voice', in addition to NHS complaints procedures, so they can suggest improvements or inform someone when they think there is a potential risk. Local Authority Overview and Scrutiny Committees and Patient and Public Involvement Forums offer good access points to wider local communities.

Patients should also be represented on committees that make decisions about how risks are managed and safety issues dealt with. Patient Advice and Liaison Services can help by acting as an early warning system for NHS organisations and patients' fora by monitoring trends, highlighting gaps in services and making reports for action to NHS organisation management.

2 Involving patients in their own care and treatment

There is plenty of evidence to show that patients want to be involved as partners in their care [8,9,10]. This kind of partnership means healthcare staff need to include patients in reaching the right diagnosis, deciding appropriate treatment, discussing the risks and ensuring treatment is correctly administered, monitored and adhered to [6, 11].

Examples from the NPSA

'Ask about medicines' week

A MORI poll in 2003 showed that up to 50% of people in the UK do not take their medicines as prescribed. Almost one in three people say they do not know enough about the potential side effects of medicines. Knowing what questions to ask is key to prompting discussion and increasing awareness around medication use. To facilitate this process the NPSA has sponsored an 'ask about medicines' card in a shared effort to encourage patients and health professionals to discuss their medication. The card features five key questions and five top tips to help patients learn more about the medicines they are prescribed.

Ask About Your Medicines: questions to ask

1 What does this medicine do?

2 How long will I need to use it?

3 How and when should I take it?

4 Should I avoid other medicines, drinks, foods or activities when I am taking this medicine?

5 What are the possible risks and side effects – and what should I do if they happen to me?

Ask About Your Medicines: top tips

1 **Share** any questions or concerns about the medicines you are prescribed or buying – and ask about other options.

2 **Tell** a health professional about the medicines you are taking.

3 **Tell** them if you think the medicines you are taking aren't working or are giving you side effects.

4 **Ask** if you are unsure how to take your medicines or for how long.

5 **Ask** if you need help getting a regular supply of your medicines.

Involving patients and their relatives or carers in decisions about their medicines and informing them how to take or use their medicines correctly can help ensure patients obtain the greatest benefit from their medicines in the safest possible way.

What can local NHS organisations do?

Patients need to be sufficiently informed, given time to consider key information before making a decision, and helped to understand any information given to them [12, 13]. They need to be aware not only of the benefits care may provide but also the risks. Knowing what might go wrong can help patients play their part in managing and avoiding risks.

The main way local NHS organisations can involve individuals in their care is to encourage good two-way communication between health professionals and patients. NHS organisations may need to offer training to staff to achieve this, particularly in risk communication.

The NPSA is also assessing demand and requirements from both patients and health professionals for tools to encourage patients to play a part in preventing errors and systems failures. For example the approach known as 'speak up' [14], developed by the US Joint Commission on Accreditation

of Health Organisations (JCAHO), provides a useful framework for locally engaging patients in their safety. The following is adapted from this approach:

S peak up if you have any questions or concerns and if you don't understand.

P ay attention to the care you are receiving and make sure you are receiving the right treatment and medication.

E ducate yourself about your diagnosis.

A sk a trusted family member or friend to be your advocate.

K now what medicines you are taking and why.

U nderstand more about your local NHS organisation.

P articipate in all decisions around your treatment.

Each step could include the following advice or actions:

- **S**peak up if you have any questions or concerns and if you don't understand:
  - Don't worry about being embarrassed if you don't understand something.
  - Don't be afraid to ask about safety. If you are having surgery for example, ask your doctor to mark the area to be operated on so there is no confusion.
  - Don't hesitate to tell healthcare staff if you think you have been confused with another patient or if you think you have received the wrong medicine.
  - Tell the staff if something doesn't seem right.
- **P**ay attention to the care you are receiving and make sure you are receiving the right treatment and medication:
  - Make sure you are clear about what treatment you have agreed to and don't be afraid to ask for a second opinion.
  - Make sure you are aware of any possible risks or complications your treatment may entail.
  - Expect healthcare staff to tell you who they are and look for their identification.
  - Make sure staff confirm your identity when they give you medicines or administer treatment.
  - Notice if staff wash their hands before and after your treatment – it's OK

to remind a doctor or nurse to do this.

- **E**ducate yourself about your diagnosis:

– Ask more questions, such as: How does your condition affect you? How is your condition treated? How should your condition respond to this treatment?

– Ask if there is any written information available to back up your discussion.

– Gather information about your condition from reputable sources, such as well-researched studies, journals and books, expert groups and validated websites.

– Write down the important facts so you can easily refer to them later.

– Read all forms you are asked to sign and ask healthcare staff to explain if you don't understand anything.

– Make sure you get your test results and don't assume 'no news is good news'.

– If you have to use any equipment, make sure you understand what your role is.

- **A**sk a trusted family member or friend to be your advocate:

– Your advocate can ask questions for you if you are under stress.

– Your advocate can help remember answers to questions you asked.

– Make sure your advocate understands your preference for care.

- **K**now what medicines you are taking and why:

– Ask what the medicine or treatment is for, if there is any written information about it, and what possible side effects, complications or risks there may be.

– If you don't recognise the medicine verify that it is for you.

– If you are having an IV ask the nurse how long it is expected to last – don't be afraid to call someone if it appears to be going too quickly or too slowly.

– Tell healthcare staff about your allergies and reactions.

– If you are on multiple medicines ask staff whether they can be taken together.

– Make sure you can read your prescription – if you can't read it your pharmacist might not be able to either.

- **U**nderstand more about your local NHS organisation:

– How does your local NHS organisation perform against national targets for infection rates?

– What level of achievement does your local NHS organisation have against national targets, such as for waiting times, cancelled operations and deaths following surgery?

– What level of achievement does your local NHS organisation have for patient safety assessments, such as the clinical negligence scheme for trusts (range 1–3)?

– Read the review of your local NHS organisation by the Commission for Healthcare Improvement (**www.chi.nhs.uk**).

• **P**articipate in all decisions around your treatment:

– Agree with healthcare staff exactly what will be done during each step of your care.

– Know who will be taking care of you, how long the treatment will last and how you should feel.

– Don't be afraid to ask for a second opinion at any stage – the more information you have about the options available the more confident you will be with the decisions made.

– Ask to speak to others who have undergone the procedure you are considering.

3 Encouraging an open, two-way dialogue between health professionals and patients when things go wrong

Openness when things go wrong is also fundamental to the partnership between patients and those who provide their care¶. There is strong evidence to show that when something goes wrong with healthcare, the patients who are harmed, their relatives or carers want to be given information about what has happened. And often they want someone to say sorry.

A MORI survey commissioned for the Department of Health's consultation document, Making Amends[9], interviewed 8,000 people. Just under 5% of them considered they had suffered injury or other adverse effects

¶ Being open is not a process for admitting liability. The National Health Service Litigation Authority (NHSLA) circular no 02/02 encourages healthcare professionals, including managers, to be as honest and transparent with patients and their relatives as they would wish healthcare staff to be with them. The NHSLA state that it is both natural and desirable to sympathise and express sorrow or regret if harm has been caused. Such expressions would not normally constitute an admission of liability. In addition patients and relatives frequently ask for detailed explanations of what led to the incident. Therefore explanation and provision of information constitutes good clinical practice, providing facts are given as opposed to opinions. In any discussion the healthcare individual should not state or agree that they, another person, or the organisation is liable for the harm caused to the patient.

as a direct result of their medical care with the NHS. Of these:

- 34% wanted an apology or explanation when an incident occurred;
- 23% wanted an inquiry into the causes;
- 17% wanted support in coping with the consequences;
- 11% wanted financial compensation;
- 6% wanted disciplinary action against the staff involved.

Being open about what has happened and discussing the problem promptly, fully and compassionately can help patients cope better with the after effects when things have gone wrong [15]. Openness and honesty can also help prevent such incidents from becoming formal complaints and litigation claims [16].

The three most important elements of being open are:

1 providing an apology and explanation;

2 a thorough investigation following the incident;

3 support in coping with the physical and psychological consequences of what happened.

Examples from the NPSA

As mentioned earlier in this Step, the NPSA is developing a system to allow patients, third parties such as witnesses to incidents, organisations that receive information about harmful events, and the general public to report errors and systems failures that occur in their use of the NHS. This will allow people to provide details of their experience, how it affected them and to make suggestions for preventing future incidents. The information collected will be aggregated with information received from staff via the NRLS and fed into the NPSA's priority-setting processes to determine which safety issues it will address and develop solutions for.

What can local NHS organisations do?

When things go wrong local NHS organisations can help ensure a two-way dialogue exists between the NHS services and patients by:

- developing a local policy on being open ;
- engaging with patients during investigations;
- designating key staff to have responsibility for being open;
- providing training and support to staff in communication skills;
- providing support for patients.

Developing a local policy on being open

In the past staff have been unclear about who should talk to patients when things have gone 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.

A 'being open' policy should include:

- a description of how the information will be treated in accordance with privacy and confidentiality guidelines, and in line with data protection and freedom of information requirements;
- a description of the incident process, including how incidents are detected and reported, responded to, managed and investigated;
- defined roles and responsibilities of the healthcare team and identification of the individual who should make the explanation;
- guidance on the content of the initial discussion about the incident with the patient, their relatives or carers;
- details of external reporting requirements;
- details of the support and follow-up required for both the patient and staff.

The NPSA is developing a framework (see the section 'How can the NPSA help?' further in this Step) to help local NHS organisations develop their own policies on being open, which can be adapted to reflect the unique structural and resource requirements of the organisation and used to promote and disseminate information about openness.

While it is essential that 'being open' policies meet the needs of the local organisation, a number of legal and regulatory requirements must also be taken into account. Local policies should therefore reflect the requirements of the judicial system in England and Wales and of the following bodies:

- National Health Service Litigation Authority (NHSLA);
- Clinical Negligence Scheme for Trusts (CNST);
- Risk Pooling Scheme for Trusts (RPST) in England;
- Welsh Risk Pool (WRP) in Wales.

It also needs to be recognised that in some rare circumstances patients and their relatives or carers may reject any contact with the healthcare team. The local policy needs to describe how this will be managed and

the potential role of a key link, who may be someone from outside the team or organisation. Referral to another care provider may occasionally be required.

Engaging with patients during investigations

In line with the organisation's local 'being open' policy, patients and their relatives or carers should be involved in the investigation of what went wrong. They should be contacted as soon after the incident as feasible. This contact should:

- recognise the level of severity of the incident (see the table below);
- be made by the right person with the right skills in the right way (see the following subsection);
- be offered on more than one occasion even if initially rejected;
- be maintained for a period relevant to the incident and investigation process.

The level of involvement clearly depends on the nature of the incident. The table below summarises suggested action according to the severity of the incident:

Incident	Action
No harm (including incident prevented)	Patients are not usually contacted or involved in investigations.
Low harm	Unless there are specific indications or the patient requests it, the process and the investigation will occur at local level. This should take the form of an open discussion between the staff providing the patient's care and the patient and/or their relatives or carers.
Moderate harm **Severe harm** **Death**	A higher level of response is required in these three circumstances and the organisation's 'being open' policy should be implemented.

Once patients are involved they need to be:

- informed about the nature of the incident;
- informed about the type of investigation being undertaken and what a root cause analysis means (see **Step 6**);
- asked for their perception of the events leading up to the incident;

- advised about the progress of the investigation;
- involved in the post-investigation findings;
- informed about the final outcome and given a written report;
- told what the NHS will do to prevent the incident from happening again.

Designating key staff to have responsibility for being open

The most senior person responsible for the patient's care should inform the patient and their relatives or carers about the incident. This could either be the patient's consultant, nurse consultant, or any other healthcare professional who has a designated case load of patients. They should have received training in communication of patient safety incidents. If they are not the most senior person they should also have approval and guidance from their senior colleagues.

Ideally they should be:

- known to the patient, relatives or carers;
- have a good grasp of the facts relevant to the incident;
- be senior enough to be credible to patients, staff and any future inquiry;
- have excellent interpersonal skills, including being able to communicate with patients, their relatives or carers in a way they can understand;
- be able to offer an apology, reassurance and feedback;
- be able to provide continued support and information to the patient, their relatives or carers.

In addition local organisations should identify clinical, nursing and managerial opinion leaders who will promote the being open process across the organisation. Most healthcare provision involves multidisciplinary teams, so being open needs multidisciplinary representation (see the 'Principle of multidisciplinary responsibility' in the section 'How can the NPSA help?' further in this Step).

Providing training and support to staff in communication skills

The NPSA is developing a toolkit to help NHS staff facing the difficult task of talking to patients and their relatives or carers following a serious patient safety incident. More information can be found under 'How can the NPSA help?' in this Step.

It is also important that local organisations provide facilities and

resources for staff to discuss the incident together as well as for staff to talk to patients and their relatives or carers.

Providing support for patients

Providing support for patients and their relatives or carers is crucial. Local NHS organisations need to recognise the right of patients and their relatives or carers to seek advice and guidance from independent bodies and provide them with:

- an explanation of the support being offered and the role of the key link, and be given contact details;
- information on the organisation's bereavement or counselling services, religious support, and Patient Advice and Liaison Service/Community Health Council.
- information on external support services such as the Citizens Advice Bureau, CHCs in Wales, AvMA, and other patient support groups.

How can the NPSA help?

The NPSA is committed to helping local NHS organisations involve patients and the public in patient safety. The main ways we are supporting local organisations with involvement include:

- developing best practices for communication with patients, which incorporates being open;
- ensuring patient safety is a priority throughout healthcare by setting clear objectives in our guidance for NHS organisations and leaders (as stated in **Steps 2 and 3**), as well as in future guidance, such as *Seven steps to patient safety for Chief Executives*;
- providing advice and guidance through local NHS networks, including strategic health authority meetings, regional forums and seminars arranged by NPSA staff, and in particular by local patient safety managers;
- seeking to inform patients, the public and the media about patient safety issues in the form of information leaflets, which local organisations can use as a resource.

We are developing the following tools:

'Being open' toolkit

The NPSA's 'being open' toolkit aims to improve communication between healthcare teams, patients and their relatives or carers in the event of a patient safety incident that led to harm or death. It will contain detailed guidance on the principles of being open, how to

communicate with patients when something has gone wrong, advocacy and support for patients and staff, training issues, roles and responsibilities, and legal considerations

We plan to publish the toolkit in autumn 2004 on the NPSA website: **www.npsa.nhs.uk**

Framework for a 'being open' policy

Policies and procedures for being open should be developed by all local NHS organisations, in line with our forthcoming national guidance document, *Being Open*. It is due for launch in 2004 on the NPSA website: **www.npsa.nhs.uk**. The framework, which can be adapted to the needs of individual organisations, includes the following ten principles:

1 **Principle of acknowledgement**

All patient safety incidents should be acknowledged as soon as they are identified. In cases where the patient or their relatives or carers inform healthcare staff when an incident has happened, it must be taken seriously from the outset. Any concerns should be treated with compassion and understanding by all healthcare staff.

2 **Principle of truthfulness, timeliness and clarity of communication**

Information about a patient safety incident must be given to patients and their relatives or carers in a truthful and open manner by an appropriately nominated person. Communication should also be timely: patients and their relatives or 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. New information may emerge as an investigation is undertaken, and patients and their relatives or carers should be kept up to date with the progress. They should receive clear, unambiguous information and be given a single point of contact for any further questions or requests. They should not receive conflicting information from different members of staff, and medical jargon which they may not understand should be avoided.

3 **Principle of apology**

All patients and their relatives or carers should receive a sincere expression of sorrow and 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.

4 **Principle of recognising patient and carer expectations**

Patients and their relatives or carers may reasonably expect to be fully

informed of the issues surrounding patient safety incidents and their consequences. They should also be treated sympathetically, with respect and consideration. Confidentiality must be maintained at all times. Patients and their relatives or carers should also be provided with support in a manner appropriate to their needs. Where fitting, information on PALS in England or CHC in Wales and other relevant support groups should be given to the patient as soon as 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, any threat to their registration or increased medico-legal risk. Where there is reason for the healthcare organisation to believe a member of staff has committed a punitive or criminal act, they 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.

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.

7 Principle of multidisciplinary responsibility

Any local policy on being open should apply to all staff who have key roles in the patient's care. Most healthcare provision involves multidisciplinary teams and being open should therefore have multidisciplinary representation. This approach will ensure the being open process is consistent with the philosophy that patient safety incidents usually result from systems failures and rarely from the actions of an individual (see **Step 1**). To ensure multidisciplinary involvement it is important to identify clinical, nursing and managerial opinion leaders who will champion the being open process. 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 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. Practice-based risk systems should be established within primary care. Continuous learning programmes should be developed that allow healthcare organisations to learn from the patient's experience of being open and monitor the implementation and effects of changes in practice following a patient safety incident.

9 Principle of confidentiality

Full consideration and respect should be given to patients', relatives', carers' and staff privacy and confidentiality. Details of a patient safety incident should at all times be considered confidential. Communicating confidential patient data in an incident investigation may not require the consent of the individual to be lawful. However any discussions with parties outside the clinicians involved in treating the patient should be on a strictly need-to-know basis. In addition it is good practice to inform the patient and their relatives or 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.

Good practice in involving and communicating with patients

Case study: York Health Services NHS Trust

York Health Services NHS Trust is one of six trusts piloting the NPSA's 'clean**your**hands' campaign, which involves patients as well as staff to improve hand hygiene in hospitals.

Antiseptic hand-rub dispensers have been set up at each bedside in the two designated wards at each hospital. Where bedside dispensers might pose problems – for example in children's wards – staff have been given personal clip-on hand-rub dispensers.

Staff badges saying 'Clean**your**hands; It's OK to ask' encourage patients to question staff about their hand hygiene. Patients are also given leaflets on the campaign and can talk to Patient Advice and Liaison Service (PALS) staff and volunteers.

To encourage staff to use the hand rub before and after every patient contact, eye-catching posters have been put up around the wards. Some of these carry a photograph of a member of staff championing the project, and have proved popular with patients.

Dr Colin Jones, physician in the renal unit at York Hospital, said several patients told him they had seen 'his' poster. 'They didn't have to ask me if I had cleaned my hands as they could see me doing it at the bedside.'

Jo Allerton, PALS adviser said: 'Lots of comments have been made about how much easier it is for patients to ask, remind or check with staff in a jovial way if they have cleaned their hands when they know the consultants are on board.'

Future posters will feature a modern matron, a cleaner and a nurse.

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Step 6
Learn and share safety lessons

Contents

Step 6

Learn and share safety lessons

Reporting when things go wrong is essential in healthcare. But it is only part of the process of improving patient safety. It is equally important that organisations look at the underlying causes of patient safety incidents and learn how to prevent them from happening again. Often the underlying causes are many and in the majority of cases extend beyond the individual staff member or team involved. The benefit of the National Reporting and Learning System (NRLS) described in **Step 4** is that lessons learned in organisations in one part of the country can be shared with organisations elsewhere.

In this Step we explain how to use a chronological investigation technique – root cause analysis (RCA) – to find out what went wrong in a patient safety incident, how and why. We suggest how local NHS organisations can learn safety lessons through RCA and what the NPSA can do to help.

The key principles

When a patient safety incident occurs the important issue is not 'who is to blame for the incident?' but 'how and why did it occur?'[1]

To promote learning local NHS organisations need a systematic approach in which staff know what type of incidents should be reported, what information is needed and when, and how to analyse and act on this information.

Root cause analysis is a systematic investigation technique that looks beyond the individuals concerned and seeks to understand the underlying causes and environmental context in which the incident happened.

Why is learning and sharing safety lessons important?

When the safety of a patient has been compromised it is tempting to explain it in one of two ways: as the product of negligence, incompetence or carelessness on the part of staff; or as a rare misfortune that's neither predictable nor preventable. However, experience from other complex high technology settings, such as the aviation industry, has shown that safety incidents are not simply the result of human mistakes, such as inattention or forgetfulness[2,3,4,5]. Nor are they random or rare – in fact certain organisational and cultural factors can make them more likely to happen[6].

When a patient safety incident occurs the important issue is not 'who is to blame for the incident?' but 'how and why did it occur?' One of the most important things to ask is 'what is this telling us about the system in which we work?' [1] The root causes of incidents can be found in a broad mixture of interconnected factors within the system – a system in which the universal and inevitable human ability to make mistakes may have been left inadequately controlled.

The principle of the systems approach to error was discussed in **Step 1**. Understanding why an incident has occurred is a fundamental part of the investigation – and fundamental to ensuring that the incident is not repeated. Only by learning about the underlying causes of an incident can we implement new ways of working to minimise the risk of future harm. Given that incidents are invariably about system failures, any investigation must dissect what may be a complex chain of events and the interaction between local conditions, human behaviours, social factors and organisational weaknesses [7 8].

How is the NPSA promoting learning and sharing?

The NPSA is fostering a practical and systematic process of learning from patient safety incidents. It also seeks to enable shared learning across the health service, making progress towards improving patient safety faster and more effective.

One of the key elements of promoting learning has been to develop the technique of root cause analysis for use in the context of healthcare. RCA is not a new technique. Models based on a chronological chain of events have been in use for some time [9 10]. The NPSA has based its model for examining patient safety incidents on the work of experts in investigating organisational incidents (see Rasmussen [11 12], Reason [13], Taylor-Adams and Vincent [14], and Vincent et al [15]).

Root cause analysis explained

A root cause is the cause or causes that if addressed will prevent or minimise the chances of an incident recurring. Root cause analysis is a technique for undertaking a systematic investigation that looks beyond the individuals concerned and seeks to understand the underlying causes and environmental context in which the incident happened. Retrospective and multidisciplinary in approach, it is designed to identify the sequence of events, working back from the incident. This allows the real causes of an incident to emerge so that organisations can learn and put remedial action in place.

RCA looks at an incident from several vantage points, including in most instances that of the patient and the family. Research has shown

that an RCA approach to incident investigation will achieve a number of patient safety benefits [15 16]. These include:

- providing a structured and consistent approach to incident investigation across all care settings;
- shifting the focus away from individuals and on to the system to help build an open and fair culture;
- increasing awareness of patient safety issues;
- helping engage patients in the investigation;
- demonstrating the benefits of reporting incidents;
- focusing recommendations and change as a result of identifying the root cause(s) of an incident.

A similar process to root cause analysis – significant event audit (SEA) – is often used in primary care and in particular in general practice [17 18 19]. This will be developed further by the NPSA and detailed guidance on SEA as an investigation technique for primary care will be published in 2004.

Root cause analysis is not the same as failure modes and effects analysis (FMEA) described in **Step 3**. FMEA is a prospective evaluation, which questions how to change the process of care, the equipment used or the way things are done to minimise risks to patients [20]. In contrast RCA looks at an incident retrospectively, asking 'why did this happen and how?'

Practical support for using RCA can be found in the NPSA's web-based e-learning toolkit at: **www.npsa.nhs.uk/rca** This includes useful advice on how to document and organise evidence, guidelines on patient and staff interviews, detail and illustrations of techniques for analysing incident information, barrier analysis tools and case studies to help staff familiarise themselves with the methodology. More details on the toolkit can also be found in the section 'What can the NPSA do to help?' further in this Step.

What can local NHS organisations do?

Local NHS organisations should use the RCA tool developed by the NPSA to investigate patient safety incidents and promote learning. It provides a systematic approach to guide staff on what type of incidents should be reported, what information is needed and when, and how to analyse and act on this information.

Who takes part in RCA?

All NHS staff can take part in an incident investigation. Appointed by the chief executive, the investigation team should include staff who

represent a variety of groups and professions within an organisation.

Staff who lead an investigation or an investigation team will need an in-depth understanding of the NPSA RCA methodology and be able to apply the tools and techniques in a variety of settings. The NPSA will provide formal training for this (described at the end of this Step).

They should also have a relatively senior position in the organisation – typically ward sisters, registrars, consultants, general practitioners, practice managers, senior paramedics, senior managers, heads of support teams, physiotherapy and other allied health professional leads. For complex and high profile incidents the investigator should have a senior position. Expert advisers can be consulted to ensure specialist knowledge is used appropriately, depending on the incident specialty. For all incidents investigators need to be able to demonstrate competence, credibility, objectivity and a degree of independence.

Patients and their carers should also be involved in the incident investigation, for example in asking for their perception of events, and informing them about the investigation, the findings and proposed remedial action. This is detailed among the stages below.

Stages of RCA

It is important that all patient safety investigations cover all the stages and meet the 'best practice' criteria on which the NPSA RCA tool is based. These are set out below:

1 Identifying which incidents should be investigated;

2 Gathering the information;

3 Mapping the events;

4 Analysing the information;

5 Barrier analysis;

6 Developing solutions and an action plan for implementation (described in Step 7);

7 Completing a report.

1 Identifying which incidents should be investigated

Follow-up and investigation of safety incidents increases an organisation's knowledge of why incidents happen and its capacity to prevent them recurring. The following guidelines will help local NHS organisations determine which incidents should be investigated.

- Decide which incidents require more detailed investigation. There are

two main considerations here:

1 The level of severity of harm to the patient;

2 The potential for learning.

- Consider the facts and evidence of an incident to determine how detailed the investigation should be. The impact of the incident, in terms of severity of patient harm, should be a guide to the scope of investigation. Similarly the complexity of the investigation should be determined by the complexity of the incident that has triggered it.
- Prioritise the incidents earmarked for a full RCA according to resources available. The NPSA recommends that each local organisation's incident reporting policy or risk management strategy describes a standard approach for each class of patient safety incident. The table below details the level of investigation required for the different grades of patient safety incidents, and the following lists provide a suggested approach to incident investigation.
- A full RCA should be undertaken for:

– all unexpected deaths that were directly related to an incident;

– all incidents that resulted in suspected permanent injury, loss of function or loss of a body part.

RCA should be considered for:

– incidents where the patient needed further surgical intervention or transfer to intensive care;

– incidents that were prevented but considered by the investigator to be worth an in-depth review of not only what, why and how it happened but also what were the actions that prevented the incident from affecting the patient(s);

– all incidents that trigger external investigations, such as a coroner's inquest, complaints, legal claims or criminal investigations.

Level of investigation for different grades of patient safety incidents

Grade	Level of investigation
No harm • Impact prevented • Impact not prevented	Local organisations may want to pick up to 10 of these incidents each year to identify lessons learned. As described in **Step 4** these are useful for lessons in preventative measures. They can also be used as incidents for training staff in the RCA or SEA approach to investigation.
Low	A low-level investigation is required involving capture of patient demographics, type of incident, types of staff involved, factual description of what happened, details of contributory factors, action taken to minimise the incident and action after the incident. This is recorded on the local risk management system and forms the basis for the NRLS dataset. If the data identifies themes and patterns the organisation may want to undertake a focused RCA, bringing together a number of incidents. The patient should be informed by a member of staff who has been providing their care
Moderate	Organisations should assess their capacity to investigate and undertake a level of investigation accordingly. If the data identifies themes and patterns, the organisation may want to undertake a focused RCA, bringing together a number of incidents. The patient and carers should be informed and involved in any investigation. The organisation's 'being open policy' (described in **Step 5**) should be implemented.
Severe	A full RCA should be undertaken. The patient and carers should be informed and involved in any investigation. The organisation's 'being open policy' should be implemented.
Death	A full RCA should be undertaken. The patient's carers should be informed and involved in any investigation. The organisation's 'being open policy' should be implemented.

2 Gathering the information

One of the primary jobs of the incident investigator(s) is to collect evidence and retain it so that it can be easily reviewed. Here we outline the types of data needed for RCA and suggest how this can be collected efficiently.

Data collection

There is a vast array of information and data surrounding any incident. Sorting out what is relevant and what is not relevant can be difficult. The types of information required for an investigation include:

- healthcare records;
- relevant results and diagnostic aids such as X-rays and scans;

- current policies and protocols;
- relevant integrated care pathways where available;
- the incident report form;
- the list of key staff involved and written reports from staff.

Interviews

Interviews should be held by the lead investigator to find out what happened and why it happened. This should be explained in detail to the interviewees. The interview process should be supportive and non-judgemental, and should be conducted in private. Staff may require further support and counselling following a patient safety incident and this should be offered at this stage if it has not been offered already [4 21].

The interviews increase both the quantity and quality of information obtained from witnesses and patients. For staff, the interview should be used to establish the role of the person being interviewed, recording their actions and a chronology of events as they saw them. These will then be compared with other staff members' responses as they are interviewed.

Questions are typically open and may include variations on the following:

- What do you think happened?
- What knowledge did you use in making this decision?
- What were your specific goals at the time?
- What happened then?

or requests for information:

- Take me through the key stages you went through.
- Describe for me the events that took place.
- Show me how you went about doing that.
- Could you explain further?

The perspective of the patient and carer is also invaluable. Patients and carers should be involved in the incident investigation using a similar approach and should also be offered support and counselling. The level of involvement depends on the nature of the incident but includes:

- informing the patient and their carers that a patient safety incident has occurred;
- informing them of the type of investigation being undertaken and what RCA means;

- asking for their perception of the events leading up to the incident and identifying a chronology of events as they saw them;
- advising them on the progress of the investigation;
- involving them in the post-investigation meeting;
- informing them on the findings of the process and providing a written report;
- providing information of the proposed remedies that the organisation will be putting in place.

Patients' healthcare records

All patient safety incidents should be recorded in the patient's healthcare record, including GP, community and ambulance records, along with any other relevant information. Information recorded should include a factual account of the incident and details of any further treatment required by the patient. Discussions with patients and their carers should also be recorded in their healthcare record. Details of the wider investigation should be kept in the incident report file.

Equipment

Equipment that may have precipitated or caused harm should be preserved if at all possible in the state it was in at the time of the incident. For investigation of some incidents a 'mock-up' of the equipment is a useful exercise. This is especially useful for incidents involving medication.

Site visits

A site visit can help the investigator to establish whether the physical environment was a contributory factor in the incident. It can offer an insight into factors such as the line of sight between a member of staff and the patient affected by the safety incident, or the positioning of equipment.

The investigator should be escorted on a site visit by a member of staff who was present when the incident occurred. It can be useful to conduct the visit when the conditions on-site match those at the time of the incident, for example at night or on the same day as a busy clinic.

Photographs, measurements or sketches of layout are useful records of the visit and can assist with later analysis.

In some circumstances a site visit may also involve a reconstruction of the incident, i.e. placing the people and equipment as they were when the incident happened and recreating the steps that led up to the

incident. This is particularly useful for complex incidents when staff are unclear about who was doing what, or when the root causes have not been identified. The reconstruction should be a non-threatening event to enhance the investigation, not to catch people out in any way. Despite the obvious benefits reconstructions are likely to be a rare occurrence because:

- shift patterns and staff movement usually mean that the same staff are rarely working together – it may therefore take some time to bring them all together;
- the site of an incident is likely to be required on an ongoing basis for continuing patient care – it is therefore difficult either to preserve it or to render it vacant to enable the reconstruction to take place.

Other data

An investigator may decide that various other pieces of evidence need to be collected, depending on the type of incident. These could include switchboard records to check response times, audit reports, minutes of management meetings, service schedules, maintenance reports, safety accreditation information (e.g. of electrical equipment) and risk assessments .

3 Mapping the events

Once the investigator has collected the basic data about an incident, the input of the staff associated with the incident helps piece together the chain of events that led up to it. This can also be a valuable forum for developing ideas about how to adapt the system to prevent repeat incidents.

Involving the staff in this mapping exercise has been found to have a significant positive impact on the way a team works together and engenders a real sense of contributing to a workable solution. Ideally an RCA team will include all the staff involved in the incident. They should consider the incident together rather than from separate or individual sides of the story.

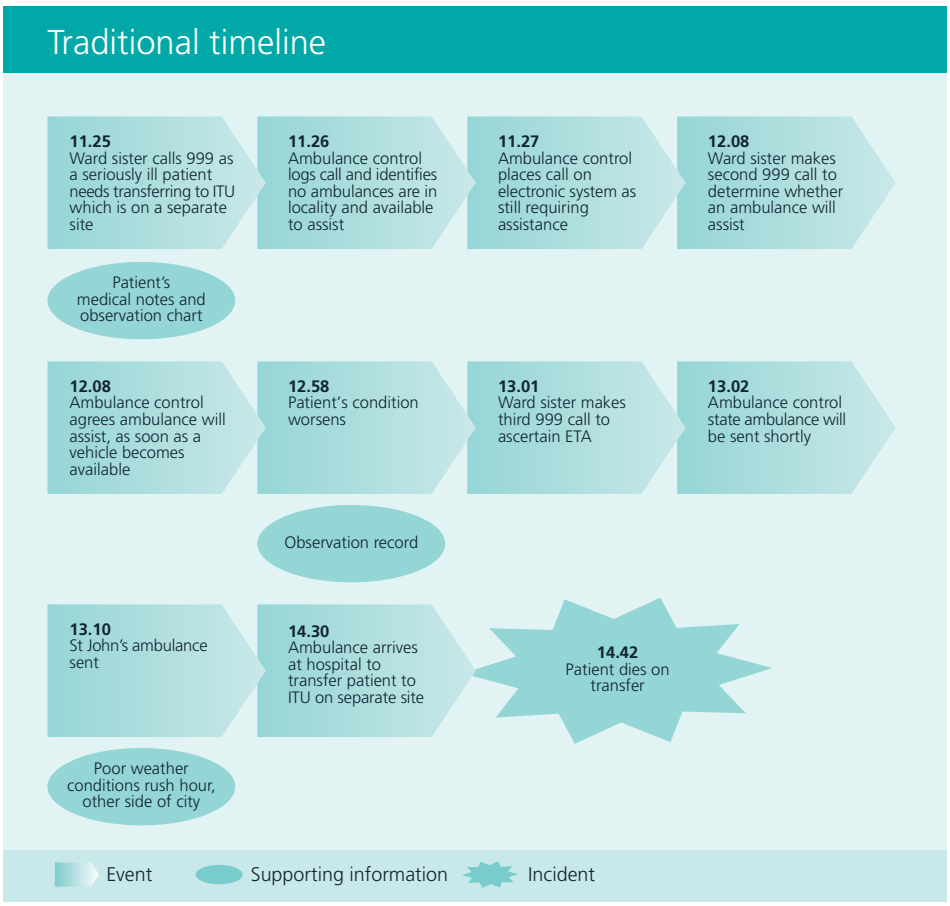
Running a multidisciplinary team review

The multidisciplinary team review offers all members of staff involved in the incident the opportunity to contribute their account of the chronology and their view of the causal factors. A multidisciplinary review is more effective than when individual professions stay in their 'silos' [4 22].

This may be the first time that staff have been able to discuss the incident in detail and to hear what others involved are saying. It is

important that they do not feel constrained from making a full and honest contribution to the review process. One way of doing this is to involve an expert facilitator, who will be able to negotiate tensions and emphasise that the review is a positive learning opportunity for everyone. Time is a precious commodity for healthcare staff so any team review should be as short as possible with an agreed agenda, a minute taker separate from the facilitator, and clear outcomes. The following tools can be used to record the information in the team review:

- **Timelines:** a timeline is a method for mapping and tracking the chronological chain of events in an incident. It allows the investigator(s) to identify information gaps as well as critical problems that arose in the process of care delivery. Different types of timeline are illustrated below:



Tabular timeline: The table allows more detail to be recorded than the traditional timeline but retains the timeline-type chronology. For each incident, as well as its nature, date and time, there are four other fields that can be completed if the team has this information. These are supplementary information, good practice, care delivery problems and contributory factors [4].

Incident date and time		
Nature of incident		
Supplementary information		
Good practice		
Care delivery problems		
Contributory factors		

Time–person grids: A time–person grid is a tabular mapping tool for tracking the movements of the people involved (staff, patients, visitors, contractors) before, during and after an incident. It therefore enables the investigator to clarify where everyone was at key points in the incident.

Staff involved	9.02am	9.04am	9.06am	9.08am
SHO	With patient	At Dr's station	At Dr's station	With patient
Ward manager	In office	In office	With patient	With patient
Nurse	With patient	With patient	With patient	With patient

4 Analysing the information

Once information about an incident has been gathered and mapped it needs to be analysed to identify underlying causes and lessons that can be learned. When carrying out this stage of the RCA the investigator should consider the circumstances that individuals faced at the time and the evidence they had before them, and not be biased by either the outcome or hindsight.

Hindsight bias is when actions that should have been taken in the time leading up to an incident seem obvious because all the facts become clear after the event. This leads to judgement and assumptions around the staff closest to the incident.

Outcome bias is when the outcome of an incident changes the way it is analysed. When an incident leads to the death of a patient it is considered very differently to an incident which leads to no harm, even when the type of incident is exactly the same. For example giving double the dose of paracetemol is the same action as giving double the dose of morphine, but the consequences are very different when other factors such as the patient's age and state of health come into play. When people are judged one way when the outcome is poor and another when the outcome is good, accountability becomes inconsistent – and unfair.

A number of analysis tools are available but the following have been shown to work well in healthcare, across different care settings. They can be used by an individual investigator or an investigation team and include:

- brainstorming;
- brainwriting;

- nominal group technique;
- five whys;
- fishbone diagrams, based on the NPSA list of contributory factors.

Brainstorming

The object of brainstorming is to generate as many ideas as possible on a subject in a short amount of time. It can be used to identify the causes of an incident or the solutions to those causes. There is no ideal group size, although between five and 15 people is a good guide. Start by allowing time for thought, and then ask for suggestions. The best way to capture the ideas is by appointing someone to write the ideas on a flipchart or on 'post-it' notes to stick on a board. Once all the ideas are written up the group discusses each issue and orders them according to priority.

There are two basic forms:

- **unstructured brainstorming:** Everyone can freely verbalise ideas. This is generally quite spontaneous but is often more confusing than a structured brainstorming, and can lead to one or more person(s) dominating the activity;
- **structured brainstorming:** Each participant offers an idea in turn. This can be more constructive and allows for more equal participation, but it is possibly less spontaneous.

A disadvantage of the open forum style of brainstorming is that some members of the group may be reluctant to volunteer ideas in the presence of certain colleagues.

Brainwriting

Brainwriting shares many features with brainstorming but ideas are proposed anonymously on slips of paper and are read only by the facilitator. The facilitator can then transcribe the points onto a flipchart or wallboard for the group to consider. Because the source of ideas is anonymous this often suits groups with a mix of senior and junior personnel. It is also preferred over brainstorming when complex ideas are expected, or to avoid one or more individuals dominating the activity.

Nominal group technique (NGT)

This is another structured method of generating a list of ideas, prioritising the ideas of the whole group or deciding which ideas to explore further. More formal than brainstorming or brainwriting, NGT is a simple consensus-building and voting tool that enables all group members to participate. It is called 'nominal' because in the process of

generating ideas the group does not interact, making it ideal for controversial issues.

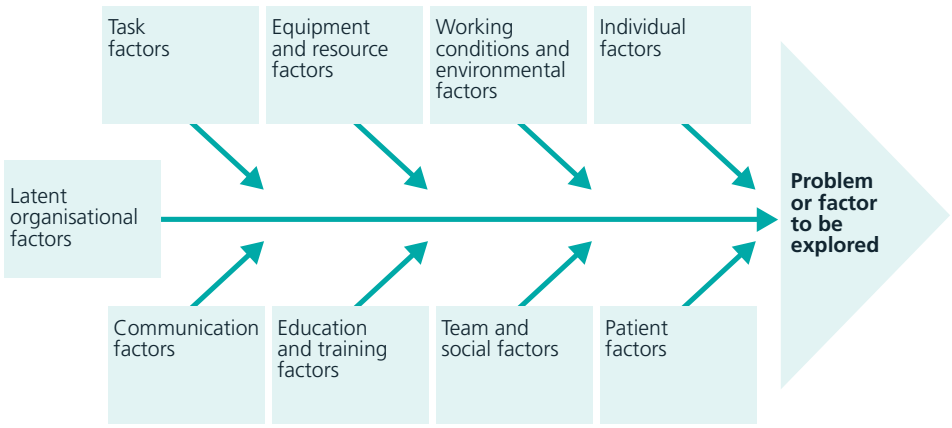
The technique is usually conducted in two stages – a focused brainstorming or brainwriting session followed by a selection process.

Five whys

This involves a process of asking 'why?' enough times in a row to detect the root cause of a particular incident[23]. Also known as the 'why-why chart' its focus is to enable the RCA investigator to penetrate more deeply into the causes of a patient safety incident[10].

The 'five whys' technique is very easy to understand and simple to teach. It is particularly useful in a busy healthcare setting and can be applied by an individual or by teams. After the gathering and mapping of information, which identifies problem areas, it asks why each problem occurred until the root cause is found. It draws out the fundamental issues by enabling staff to think beyond the immediate or obvious conclusions about who was responsible or why an incident occurred. The exact number of times to ask 'why?' depends on the complexity of the issues; five times is a useful guide.

Fishbone diagram



A way of representing contributory factor information is the fishbone diagram or cause and effect diagram. A common approach is to draw a horizontal arrow on a large sheet of paper or white board. Note down the issue or problem to be explored at the head of the arrow. Then add spines to the arrow in a fishbone arrangement, giving each spine a classification heading (from the NPSA contributory factors outlined in Step 1 and repeated below for ease of reference). These

represent the main areas in which you may want to explore the factors that contributed to the identified issue or problem.

NPSA contributory factors

Patient factors: these are unique to the patient(s) involved in the incident, such as the complexity of their condition or factors such as their age or language.

Individual factors: these are unique to the individual(s) involved in the incident. They include psychological factors, home factors, and work relationships.

Task factors: these include aids that support the delivery of patient care, such as policies, guidelines and procedural documents. They need to be up to date, available, understandable, useable, relevant and correct.

Communication factors: these include communication in all forms: written, verbal and non-verbal. Communication can contribute to an incident if it is inadequate, ineffective, confusing, or if it is too late. These factors are relevant between individuals, within and between teams, and within and between organisations.

Team and social factors: these factors can adversely affect the cohesiveness of a team. They involve: communication within a team, management style, traditional hierarchical structures, lack of respect for less senior members of the team and perception of roles.

Education and training factors: the availability and quality of training programmes for staff can directly affect their ability to perform their job or to respond to difficult or emergency circumstances. The effectiveness of training as a method of safety improvement is influenced by content, delivery style, understanding and assessment of skill acquisition, monitoring and updates.

Equipment and resources factors: equipment factors include whether the equipment is fit for purpose, whether staff know how to use the equipment, where it is stored and how often it is maintained. Resource factors include the capacity to deliver the care required, budget allocation, staffing allocation and skill mix.

Working conditions and environmental factors: these factors affect ability to function at optimum levels in the workplace and include distractions, interruptions, uncomfortable heat, poor lighting, noise and lack of or inappropriate use of space.

Each fishbone should represent just one of the contributory factors. The investigators may not find factors for each heading and should not 'force' factors to have something in every category.

5 Barrier analysis

A barrier is a defence or control measure to prevent harm to vulnerable or valuable objects (e.g. people, buildings, organisational reputation and the wider community). A barrier in healthcare is either an obstruction (e.g. locked controlled drug cupboards) or preventative action (e.g. using a checklist). The fact that a patient safety incident has taken place means that one or more of the barriers have failed.

This stage of RCA is known as 'barrier analysis'[24 25 26 27] and is designed to identify:

- which barriers should have been in place to prevent the incident;
- why the barrier failed;
- which barriers could be used to prevent the incident happening again.

It offers a structured way to visualise the events related to system failure and can be used reactively to solve problems or proactively to evaluate existing barriers.

There are four types of barriers. Examples of each type are listed below.

1 **Physical barriers** (an actual physical hindrance)

- bar coding;
- keypad-controlled doors;
- computer programmes that prevent a reporter from continuing if a field is not completed;
- controlled drugs kept in double-locked cabinets that require two keys, usually kept separately.

2 **Natural barriers** (barriers of distance, time or placement)

- the procedure for diagnosing brain dead patients involving an independent review by two doctors, which is then repeated at 12-hourly intervals;
- giving methotrexate and vincristine on different days by different persons;
- a system for checking prescriptions in a community pharmacy, i.e. a 10-minute break between the first check and the dispensing of the drug;
- pre- and post-operative swab counts.

3 **Human action barriers**

- checking the temperature of a bath before immersing an elderly patient;

- checking patients' identification with another staff member;
- checking patients' identification with the patient, carer or relative;
- surgical site marking.

4 Administrative barriers

- protocols and procedures;
- checklists;
- alert notices;
- professional registers.

Physical barriers are the most reliable in terms of providing failsafe solutions to safety problems. Natural barriers, while less effective, generally provide a more robust solution than human action and administrative barriers. These are considered the least reliable barriers because they rely on human action and behaviour, and mistakes can be made.

6 Developing solutions and an action plan for implementation

This is described in **Step 7**.

7 Completing a report

RCA concludes with an investigation report. This needs to be written as soon as possible after the investigation. When writing a report bear in mind that it needs to be accessible and understandable to all readers. Stakeholders who may expect to see an investigation report include:

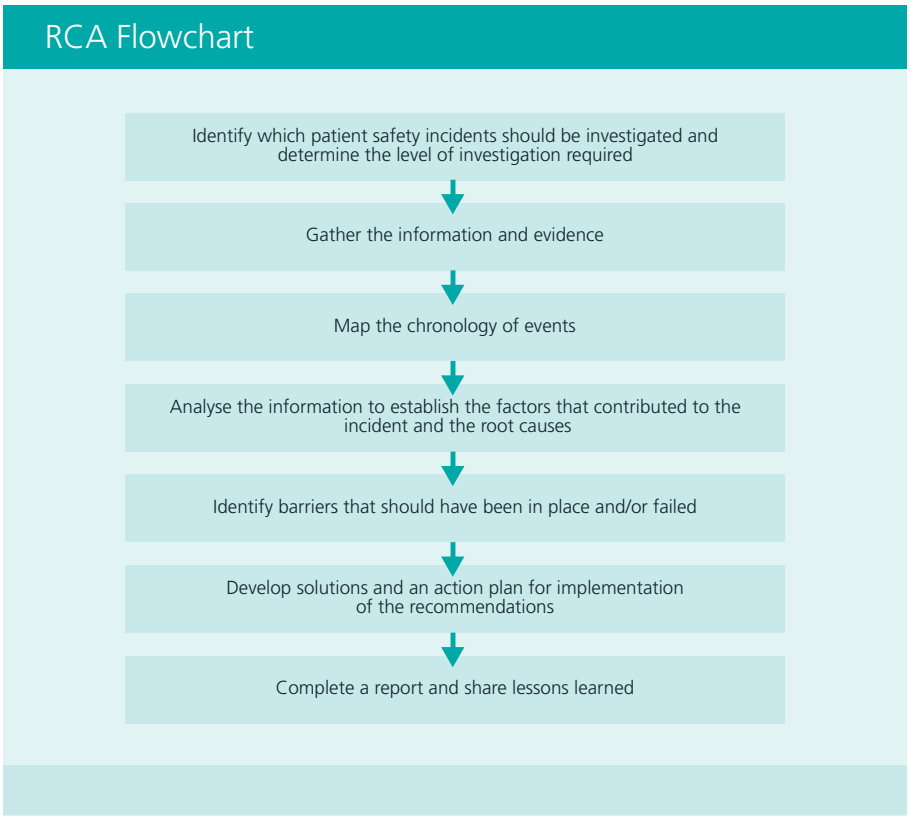
- the patient and their carers;
- organisational management committees e.g. Clinical Governance Committee;
- Trust Board/Local Health Board;
- coroner's office;
- Strategic Health Authority/Regions (Wales);
- Department of Health;
- Welsh Assembly Government;
- local and national media;
- the general public.

Basic guidelines for writing an investigation report:

- Keep it simple and easy to read.
- Start with a summary, describing in the briefest terms the incident, its consequences and the nature of the investigations, findings and recommendations.
- Use a contents list and clear headings that follow the RCA stages.
- Include the title of the document and whether it is a draft or the final version in the header.
- Include the version date, reference initials, document name, computer filepath and page number in the footer.
- Use it as a forum for learning, not for attributing blame.

  Don't use any identifying information for the members of staff involved in the incident, i.e. don't use first or second names – instead use codenames like 'Dr A' or 'Nurse Y' (the key to the code should be kept confidential by the investigator).
- Include recommendations for change and identified solutions in the conclusion. This should also incorporate an action plan with named leads to implement the solutions, and timescales for implementation.
- Include a summary list of recommendations, a list of documentary evidence, copies of evidence where necessary and any relevant diagrams (timelines, fishbone diagrams etc) in the appendices.

  All RCA reports and recommendations should be monitored by the organisation on a regular basis, at least quarterly. This can be done by the clinical governance or risk management committee. The board should also be informed and assured that remedial actions are being taken and being monitored.



How can the NPSA help?

The NPSA aims to help local NHS organisations ensure that the investigation team they create is proficient in RCA by providing both online and face-to-face training.

RCA training

We are providing RCA training for every NHS organisation in England and Wales that begins participating in national reporting. The objective is to ensure that all NHS organisations have staff with the skills to lead and take part in RCA.

Regional patient safety managers will be delivering free network training for up to eight delegates from each NHS organisation. The NPSA will help each organisation identify the most appropriate delegates. Network training is a three-day programme, conducted one day a month for three months. The time between sessions will be used to consolidate learning.

We are also offering a one-day RCA foundation course open to all NHS staff, and master classes and accreditation for more advanced training. Ultimately the training will support the wider strategy for learning from patient safety incidents, reducing their impact by targeted national safety solutions and hence improving patient safety across the NHS.

RCA toolkit

We have developed a web-based e-learning training package on RCA. The toolkit provides NHS staff with guidance on how to collect data and analyse incidents, and an interactive tool to help them develop confidence in performing RCA. Self-study modules 1–4 deal largely with RCA processes for gathering information; modules 5–6 are for staff who wish to lead the analysis. Our online resource centre contains downloadable documents covering a range of RCA tools, a glossary and key references and links. This is available at **www.npsa.nhs.uk**

Good practice in learning and sharing safety lessons

Case study: North Devon Primary Care Trust

All 22 general practices across the Primary Care Trust (PCT) meet monthly for a significant events audit (SEA). The meetings include practice nurses and district nurses.

GPs rarely chair the meetings. "This encourages contributions from all healthcare staff," says Amanda Kilby, North Devon PCT clinical governance support officer.

The meetings are a useful team-building exercise. And the SEA is a useful forum for identifying and celebrating success and sharing good practice.

The practices send quarterly reports of clinical and administrative incidents to the trust. These are coded, entered on a database and used to analyse trends.

As a result, GPs are now required to check at least two identifying details such as name, date of birth or address to prevent mistaken identity. Where appropriate, practices now delay vaccinating new patients to accommodate delays in the arrival of new notes.

"Feedback is really important," says Amanda. "People need [this] to know that something happens as a result of their reports."

A twice-yearly staff newsletter provides useful links and reports on trends, individual incidents, and good practice. It is distributed to all GP practices in the trust, the practice managers' forum and community hospitals.

The first edition covered problems with warfarin dose monitoring and highlighted The Warfarin Shared Care Guidelines. A case of anaphylactic shock after a pre-school booster prompted a reminder that anaphylaxis training can be booked with the resuscitation officer.

Good practice in learning and sharing safety lessons

Case study: Sharing Actions Following Events Reporting (SAFER), Gwent, Wales

SAFER is an anonymous reporting system for prescribing and dispensing incidents for community pharmacists and GPs.

Nuala Brennan, a pharmacist and consultant in pharmaceutical public health with the National Public Health Service in Wales, leads the project: "We want people to share their experiences and learn from each other. But a dispensing error is a criminal offence and it was felt that we would not get very many reports if individuals were identifiable."

The system, now in its second year, has been extended to all five Local Health Boards in Gwent. Gwent Healthcare Trust also contributes primary care incidents picked up by the admission pharmacists.

SAFER receives about 30 reports a month from 130 pharmacies. "We are asking people to report things that they think we can learn from, and we expect that as people get used to reporting we will learn about more incidents and near misses," says Nuala.

A monthly newsletter includes issues raised by the reports and provides a learning forum.

The main theme to emerge is that failure to follow procedures can have adverse consequences. But sometimes there was no procedure to follow. In one case prescription medicines were left with the wrong person because the pharmacy delivery service had no standard signing or checking procedures.

Another item concerned the need for entries in controlled drug registers to include the name of the actual prescriber. Some practices had no lead GP, and doctors using locum pads could not easily be identified.

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Step 7
Implement solutions to prevent harm

Contents

Step 7

Implement solutions to prevent harm

Many local NHS organisations have made important breakthroughs in the design and performance of safer systems in healthcare following patient safety incidents. But many of these successes are short lived and are not shared across the NHS.

We need local NHS organisations to help the NPSA understand the underlying contributory factors of a patient safety incident so that, over time, learning from experiences in one area will help and inform many others elsewhere. This will make the NHS an even safer service. We can capture national data about patient safety incidents (and prevented incidents) through the National Reporting and Learning System (NRLS). This learning will be aggregated with patient safety research and other data sources to enable us to find practical and sustainable solutions at national level to improve patient safety. And by sharing these across the NHS, agreed solutions can be implemented locally.

In this Step we promote the importance of translating lessons from incidents into practical long-term solutions for change and ensuring these are embedded into the culture and routine practice of NHS organisations. We give guidance on how local NHS organisations can incorporate lessons and changes into their processes and systems and provide examples of approaches and solutions being developed by the NPSA.

The key principles

Learning from patient safety incidents needs to be 'active' so changes are incorporated into the way all staff work at all levels. Any specific changes to systems and procedures need to be sustainable so they will survive once a crisis is perceived to be over.

Best practice that is developed locally can be shared at national level via the NPSA, enabling other NHS organisations to design problems out of their systems and embrace agreed safety solutions. The network of patient safety managers will act as a key link between local and national innovations.

Solutions need to be realistic, sustainable and cost effective. They also need to draw on the experience of NHS staff, patients and the public to ensure they are achievable in practice. Before implementation they must undergo risk assessment and evaluation.

The importance of 'active' and sustained learning

Currently the NHS is not learning effectively from failures and is not sharing lessons successfully across the service. Too often it falls down at the latter stage of the learning process – sustained implementation – so the benefits of experience are not actually realised. But taking action to apply safety lessons on the ground is an essential part of the learning process for each organisation and for the service as a whole.

An organisation with a memory [1] made the important distinction between two types of learning within organisations: 'passive learning' – where lessons are identified but not put into practice; and 'active learning' – where identified lessons are embedded into an organisation's culture and practices. **Step 3** describes an approach to ensuring lessons are learned, implemented and shared through integrated risk management.

One of the problems with spreading change across healthcare services is that if an incident has not happened to specific staff, they feel the change does not apply to them. Another is that staff see learning as a one-off event. To overcome these, learning needs to be 'active' so changes are incorporated into the way *all* members of staff approach their work at all levels, and any specific changes to systems and procedures need to be sustainable so they will survive once a crisis is perceived to be over. If an organisation focuses intensively on a problem for a short time but forgets about it when new priorities emerge or key personnel move on, sustained learning cannot take place.

What can local NHS organisations do?

By setting challenging but realistic targets local NHS organisations can stimulate change and innovation to improve patient safety. They need to cultivate a learning environment that identifies areas where new initiatives are necessary or desirable, and where both opportunities and risks are recognised when improving patient care and patient safety. This will provide the NPSA with best practice evidence that can be shared at a national level and implemented locally. Other NHS organisations can then design problems out of their systems and embrace agreed safety solutions.

Adopting the following procedures can help ensure lessons learned effect a change in culture and practice.

Identify changes that need to be made

NHS organisations have a wealth of information about how systems are failing to provide optimum care. These are identified through local risk management systems that collect information about incidents,

potential risks recognised in risk assessments, and areas of weakness shown by complaints and litigation claims. Integrated risk management systems should ensure this data is routinely collected and aggregated to identify areas for change. This is evidence-based patient safety.

Keep it simple

Simple changes generally spread faster than complicated ones. Following any incident review or any risk assessment, staff should work through each potential recommendation for change or each potential risk and prioritise them. It is all too easy to list over 30 recommendations following an investigation when in reality only three or four can be implemented effectively.

Draw up an action plan

The local analysis of patient safety incidents should lead to a local action plan to ensure lessons are applied throughout the organisation. This could include redesigning systems and processes, and adapting staff training or clinical practice. Actual examples include effective use of computer-based support systems such as computerised records, radiology and medication systems; new infusion devices designed to recognise the drugs they administer; new labelling techniques; and redesigning care delivery by reducing delays and improving patient flow and access. Discussing and communicating the action plans from local to board level will demonstrate that patient safety is being taken seriously. The impact of these action plans should also be measured over time as part of a core clinical governance activity review programme. This helps provide NHS organisations with a 'memory' – a record of changes recommended and action taken to implement those changes.

Show that change makes a difference

Staff are more likely to adopt a change if they think it will help them do their job. So local NHS organisations need to demonstrate the optimum balance of risks and benefits by comparing current outcomes with potential outcomes. Evidence and thorough testing are required before changes can be fully implemented. In addition, for innovation and change to diffuse rapidly, they must be compatible with the values of the organisation and the individuals who work within it[2].

Demonstrate effective leadership

The leadership of an organisation can be a catalyst for change by influencing the rate of its diffusion, and by encouraging and supporting the change. Directing change requires an investment of time and energy from NHS leaders to spread good practice, prioritise

action and ensure appropriate use of scarce resources. They need to champion the spread of innovation and be prepared for resistance[2]. Leaders can demonstrate that patient safety is a priority by ensuring recommendations from all risk-related investigations are followed up and monitored.

Involve staff and patients

Incident reporting should be encouraged from a broad spectrum of healthcare staff and patients. Any design of new solutions should therefore involve the staff and patients affected by drawing on their experiences to ensure the changes work in practice. Communicating action plans to staff and showing them changes that have made a difference can help to boost confidence that reporting incidents *is* worthwhile and *does* change practice. Feedback on how solutions are working and any changes to the way they are delivered is also vital if they are to be sustainable.

Design safety solutions around the following principles[3]

- Design tasks and processes to minimise dependency on short-term memory and attention span.
- Avoid fatigue: review working hours and workloads.
- Retraining is not always the right solution.
- Simplify tasks, processes, protocols, equipment.
- Standardise processes and equipment where relevant.
- Use protocols and checklists wisely; resist reliance on policies and protocols as task aids.

How can the NPSA help?

The NPSA recognises that to achieve change wherever NHS patients receive treatment and care we need to provide more than just guidance. Over the next few years we will be developing new ways of supporting and assisting organisations in overcoming patient safety problems.

Staff working within the safety solutions directorate and our network of patient safety managers (described in **Step 3**) will work directly with local NHS organisations to keep them informed about national solutions and help with their implementation. The patient safety managers will also act as a key link between innovations developed locally and nationally to ensure duplication of effort is minimised.

Information will also be available online (**www.npsa.nhs.uk**) so all healthcare staff can find out about solutions work and keep up to date

with progress. When staff report patient safety incidents they will receive feedback about solutions work or research already developed (or in development) to reduce the occurrence of incidents similar to the one they are reporting.

Questions can be posted on the website and the NPSA will respond to queries as well as providing access to a frequently asked questions section.

Chat rooms will also be developed around specific clinical areas. These will be moderated by experienced clinical staff to allow good practice to be shared, provide details of good practice websites, and offer discussion with NPSA staff about issues and solution development to ensure all NPSA work reflects everyday clinical practice.

The NPSA's approach to developing solutions

The solutions we develop to improve patient safety need to be realistic, sustainable and cost effective. They also need to be validated to make sure they work, especially where ideas come from experience in other sectors or organisations [1]. We are involving NHS staff, patients and the public in developing and implementing solutions to ensure they are achievable in practice.

Identifying incident trends

While acknowledging that any incident reporting system has its limitations (as discussed in **Step 4**), the NPSA will use data from the NRLS to identify trends and common themes in incidents. For example, the data will flag up:

- high-risk procedures;
- comparisons between specialties;
- incidents that have been prevented from occurring;
- incidents that require further information;
- themes that require focused root cause analysis (RCA);
- areas for further research;
- times of the day or night when patient safety incidents are more common.

The data collected through the NRLS will then be correlated with information gathered by patient safety managers, through other data collection systems and through research, to identify the priorities for action and change.

Investigating patterns of error

The NPSA's safety solutions directorate will investigate these trends and develop solutions that can be implemented nationally and locally.

The directorate includes experts from key specialty areas and a network of clinical specialty advisers who represent most of the Royal Colleges. It will validate the information from the NRLS with other research and clinical audits as well as evidence from detailed RCA undertaken locally and submitted nationally.

An organisation with a memory identified four areas (shown below) where regular patterns of error occur and which are a risk to patients. *Building a Safer NHS for Patients*[4] added timescales to the Department-of-Health-led targets in order to:

1 reduce to zero the number of patients dying or paralysed by maladministered spinal injections by the end of 2001;

2 reduce by 25% the number of instances of harm in the field of obstetrics and gynaecology that result in litigation by the end of 2005;

3 reduce by 40% the number of serious errors in the use of prescribed drugs by the end of 2005;

4 reduce to zero the number of suicides by mental health patients as a result of hanging from non-collapsible bed or shower curtain rails on wards by March 2002.

Learning from existing solutions and working in partnership

The NPSA is also working closely with other groups and organisations both in the UK and internationally to learn from solutions already identified. We are also looking into opportunities to develop solutions in partnership with other organisations. For example we are working with the NHS Purchasing and Supply Agency (PaSA) and the Medicines and Healthcare products Regulatory Agency (MHRA) to ensure evidence on patient safety incidents involving equipment is reflected in purchasing decisions at national level and in the advice given to NHS organisations.

Involvement in top-level solutions work

The NPSA is contributing to Department of Health-led solutions work. We have a representative on the Department of Health steering group to prevent the maladministration of spinal injections and are taking part in the risk assessment of spinal connector solutions.

We have been involved in the development of a chemotherapy toolkit, which includes a video for learning. This is being promoted by the patient safety managers during their visits to local NHS organisations and used in patient safety training.

We have also contributed to the Chief Pharmaceutical Officer's report,

Building a safer NHS for patients: Improving medication safety[5], which provides guidance for health professionals and NHS organisations, drawing on experience and good practice within the NHS and worldwide.

In addition we are working with the Mental Health Act Commission to monitor the causes of death of hospital patients detained under the Mental Health Act and assisting in a pilot study of using RCA for mental health homicides and suicides.

Prioritising patient safety solutions

The NPSA is prioritising its solutions development so we can concentrate on areas that make the greatest difference to patient safety. In the past resources and investigations have concentrated on serious patient safety incidents as these can have a devastating outcome for the patient, such as permanent harm caused by the removal of the wrong body part or death following overdose of medication. These incidents will remain a top priority but the NPSA will also now concentrate on developing solutions to prevent less serious incidents. Studies show that more minor incidents pose considerable cost to the NHS as they occur more often and affect a larger number of people than serious incidents[6,7].

The NPSA is currently consulting with the NHS, patients and the public in order to develop an open and transparent prioritisation process to select areas for solutions work. We aim to develop the capacity to respond to both urgent concerns that need solutions to be developed quickly and to concerns that need more complex solutions.

Learning from research

Where evidence does not exist to support solutions the NPSA is establishing research programmes to inform its work. To do this we are:

- developing a research strategy outlining the NPSA's contribution to the research agenda;
- promoting an innovative multidisciplinary environment in which the right research questions can be framed and then answered to promote improved patient safety;
- working with existing research funding bodies to ensure the NPSA priorities identified in the NRLS and other services are funded;
- beginning to develop capacity for the researchers of the future.

The Department of Health has also established the Patient Safety Research Programme to ensure the UK remains at the forefront of patient safety learning. Led by Professor Richard Lilford at the

University of Birmingham, the programme awarded its first patient safety research grants in 2002 [8].

Similarly the Medical Research Council (MRC), the Economic and Social Research Council (ESRC) and the Engineering and Physical Sciences Research Council (EPSRC) jointly held a workshop on patient safety research in January 2003. This has resulted in submissions of proposals for collaborative networks with the long-term objective of increasing and promoting high-quality multidisciplinary patient safety research. These collaborations will provide a forum for knowledge transfer between disciplines and between institutions, advance multidisciplinary working, and identify research areas where the UK might take a lead.

Assessing the risks of solutions

The NPSA's solutions will only be introduced after a careful and systematic assessment of risk. In all our work to develop solutions we build in risk assessments and in the launch of every solution we build in evaluation. It is essential that in encouraging a change in practice we do not introduce new risks. The Healthcare Commission (CHAI), the Clinical Negligence Scheme for Trusts (CNST) and other risk-pooling schemes will review the activities of NHS organisations to improve safety and minimise risk across the service.

Examples of NPSA solutions work

We have a wide range of patient safety solution development projects underway. Once fully developed and tested, these are the kind of practical solutions that will be shared throughout the NHS for implementation locally.

Determining patient safety priorities for people with learning difficulties

Information on the impact of patient safety incidents involving people with learning difficulties is limited. The NPSA is the first patient safety organisation to focus on designing solutions to reduce the risk of incidents for this client group. We are working in partnership with Speaking Up! [9] – a self-advocacy group that aims to enable people with learning difficulties to be involved in decisions affecting their own lives. The project to establish the patient safety priorities for people with learning difficulties entails:

- a review of national and international literature;
- national service user and family carer involvement sessions;
- workshops with learning disability professionals.

Speaking Up! has facilitated workshops and one-to-one interviews with people with learning difficulties across England and Wales. All of the workshops and interviews were co-facilitated by Speaking Up! leaders who have learning difficulties. Reports are available at **www.npsa.nhs.uk/learningdisabilities**

The restraint of older people

Concerns raised by nurse consultants have initiated a review to explore the existing literature and current guidelines on the use of restraint (both chemical and physical) of older people. The review will be completed in spring 2004 and will identify any gaps in the literature. These will be used to propose the way forward.

Safe medication practice for children

It is widely known that drug calculation in paediatrics is complex and risky. Joint work between the NPSA, the Royal College of Paediatrics and Child Health, and the Medicines Sub-Committee of the National Service Framework for Children is being carried out with the aim of reducing patient safety incidents involving medicines and children.

Wrong site surgery

This project explores the root causes of wrong site surgery and aims to reduce or prevent it occurring. Current literature shows that although the incidence of wrong site surgery is unknown, the most common and significant factor in the majority of the reported cases is communication breakdown between surgical team members and between teams and the patient.

The project will develop changes in practice, guidance and a checklist following consultation with:

- the Royal Colleges of Surgery, Anaesthetics, Ophthalmologists and Radiology;
- patients who have been affected by wrong site surgery;
- the US Joint Commission for the Accreditation of Health Organizations (JCAHO);
- the US National Center for Patient Safety (NCPS) for the Department of Veterans Affairs (VA).

'Right patient, right treatment'

Research evidence shows that some incidents arise when patients are misidentified or receive the wrong intervention, notably in the areas of

blood transfusion, drugs, surgery and pathology. For example, this may occur when two patients share a similar name or when a patient's sample is labelled incorrectly, and treatment is consequently based on the wrong information. The outcomes of mismatching patients and care range from no harm to patient death.

The 'right patient, right treatment' project is exploring a mistake-proof systems for ensuring a patient's identity is correctly matched with samples or specimens taken and with the treatment planned for them. It aims to identify both manual checking and technological initiatives that could be applied to the NHS, such as bar coding and radio frequency tagging.

Standardising the crash call number

The NPSA was asked to undertake a feasibility study for the standardisation of the crash call telephone number in hospitals. A range of numbers is in use across the NHS and using the wrong number creates delay and the potential for patient safety incidents. Following a survey with all acute NHS trusts in England, the NPSA published a patient safety alert advising trusts to standardise to 2222.

Team resource management

Team resource management enhances operational effectiveness and patient safety through the introduction of briefing and debriefing practices. The Royal Cornwall Hospitals' Trust (referred to in **Step 2**) carried out a project comprising team resource management training and education, debriefing, and 'near miss' reporting. Members of the operating theatre team learned to be more aware of the way they work and how this affects other team members. Feedback from prevented or potential patient safety incidents was used to refine how the team worked together. The NPSA aims to share lessons learned from this project to improve teamwork throughout the NHS.

The hand hygiene project: 'clean**your**hands'

Evidence shows that poor hand hygiene spreads infection, including methicillin resistant staphylococcus aureus (MRSA). Each year healthcare-associated infections cost the NHS around a £1,000 million and contribute to the death of some 5,000 patients [10]. It is estimated that one-third of these infections are preventable with better hand hygiene.

'Clean**your**hands' is an integrated campaign to boost hand hygiene among NHS staff and has been piloted in six acute NHS trusts. It has been reviewing:

- bedside or clip-on antiseptic hand-rub dispensers;
- posters and other promotional material;
- patient involvement. Patients are given information leaflets on healthcare infections, which also encourage them to reinforce the hand-washing message. In addition staff are wearing badges that read: 'Clean your hands. It's OK to ask';
- methods to strengthen the role of the ward housekeepers and modern matrons.

The results of the project will be used to develop solutions for roll out in 2004.

Reducing the risk of oral methotrexate dosage error

The NPSA is working with pharmacists, drug companies and patients to reduce errors associated with the use of the drug oral methotrexate. It is prescribed to treat a range of serious illnesses including cancer and rheumatoid arthritis. Errors in prescribing and administering methotrexate can be serious or fatal, such as when a patient is accidentally prescribed or administered a daily instead of a weekly dose. One of the problems found has been in the package design. Methotrexate is often dispensed in packs of 28 tablets, which patients could interpret as a month's supply and assume they should take one a day. Following widespread consultation with patients, carers, clinicians and representatives from the pharmaceutical industry and IT software suppliers, a package of practical patient safety solutions has been proposed, to be launched in 2004. It includes:

- a patient treatment diary to encourage the patient to record date-specific information about their condition, use of the drug and side effects. It also provides information on oral methotrexate, including dosage information and copies of all monitoring test results;
- changes to GP prescribing support software and pharmacy dispensing software incorporating default set dose frequency and alerts to warn the user of safety implications;
- changes to the packaging and presentation of the tablets to give clearer warnings to patients of the weekly dosage regime and reduce the opportunity to physically handle the tablets.

The infusion pump project: toolkits and e-learning

Infusion devices are used to deliver fluids and drugs at a controlled rate to thousands of hospital patients every day. However it is not

uncommon for several different models of these often complicated devices to be used on a single ward. Each year the Medical Devices Agency (MDA; now part of the MHRA) receives reports of approximately 800 patient safety incidents related to infusion pumps. Investigations conducted by the MDA suggest that in more than half of these cases no fault can be found with the device.

The NPSA sought expert advice (from manufacturers, clinical staff and pharmacists) and commissioned a literature review and patient research to inform solutions to the infusion device problem. Initial work showed that the root causes of many of these incidents relate to uncontrolled and poor purchasing practices, device management including maintenance and storage, and staff training.

We have developed a range of solutions to assist trusts to 'buy right, manage right and use right'. The purpose is to promote standardisation, centralisation and competency training in infusion devices to improve patient safety over time. Three solutions have already been tested and evaluated in six pilot sites across England and Wales, focusing on the 'buy right, manage right' issues:

1 a purchasing checklist to help organisations take a systematic approach to buying infusion devices;

2 a step-by-step guide to assist organisations to develop a business case for an equipment library or other methods of centralisation;

3 a patient information leaflet, the content of which was proposed and agreed by patients. This received a positive response in pilot sites and is signposted as part of the toolkit of supporting information at: **www.pasa.nhs.uk/infusiondevices**

A fourth solution focusing on competency-based training ('use right') is being developed separately in collaboration with the NHS University and will be ready by late autumn 2004. This will be an e-learning course to help NHS organisations train staff to use infusion devices.

A fifth solution is to embed commercially available surveillance software into infusion devices to prevent programming errors. Research methodology to evaluate identified software has been proposed following an NPSA-commissioned review involving the RAND Corporation and the Intensive Care National Audit and Research Centre (ICNARC). The NPSA is continuing this work in collaboration with Professor Richard Lilford at the University of Birmingham.

Evaluation of the infusion pump project has so far been extremely positive. Predicted common issues emerged clearly, providing evidence that infusion device management is a national issue.

To optimise the impact and sustainability of these solutions the NPSA plans to:

- **promote solutions uptake** through key implementers at national level. Staff such as clinical engineering managers, governance and risk management leads, and board members will be engaged in this process through the recommendations. Many of the solutions already form part of national inspection schemes such as Controls Assurance Standards and CNST. Other national partners, such as the MHRA, Bath Institute of Medical Engineering (BIME) and PaSA, will also be included.

Good practice in implementing solutions to prevent harm nationally

Case study: Recommended safety controls for potassium chloride

'The way to prevent tragic deaths from accidental intravenous injection of concentrated KCl [potassium chloride] is excruciatingly simple – organizations must take it off the floor stock of all units. It is one of the best examples I know of a "forcing function" – a procedure that makes a certain type of error impossible.' Lucian Leape MD, Harvard School of Public Health [11]

Evidence found in the US and UK has shown that a common category of errors in healthcare is medication errors, and that one of the most frequently implicated drugs was potassium chloride. The Joint Commission on Accreditation of Healthcare Organizations reviewed ten incidents of patient death resulting from the maladministration of potassium, eight of which were directly related to the infusion of concentrated potassium by mistake [12]. During the course of the NPSA's pilot study 33 patient safety incidents involving strong intravenous potassium solutions were reported. In both the US and UK examples, the root causes of these incidents were considered to be the availability of concentrated potassium at ward level, and that the potassium was mistaken for another medication primarily due to similar packaging and labelling. Most often potassium was mistaken for sodium chloride, heparin or frusemide.

The first patient safety alert issued by the NPSA in July 2002 advised NHS trusts to remove concentrated potassium solutions from open ward areas and to ensure they were placed in locked storage.

The alert appears to have been effective in bringing about change. Independent and NPSA evaluation of 166 NHS trusts in England and Wales has found that the number of hospitals implementing formal safety controls on potassium chloride has more than doubled since the alert. Before the alert formal written safety controls were in place in only 25% of NHS trusts. This had risen to 68% six months after the alert and is expected to continue rising. The alert also prompted a 27% drop in the use of undiluted potassium chloride, which is being replaced by safer, diluted formulations of the drug.

Good practice in implementing solutions to prevent harm locally

Case study:
Royal Liverpool and Broadgreen University Hospital Trust

The trust had already recognised intravenous potassium chloride as a potential patient safety issue before the national NPSA alert in 2002.

The pharmacy department had looked at how the drug was stored and used at the hospital. The risks associated with potassium chloride ampoules had been widely publicised yet infusions using ampoules of strong potassium chloride injection of 15% were still being prepared on wards.

After extensive consultation it became clear that a range of licensed pre-mixed potassium chloride infusions were regularly used for the prevention and treatment of hypokalaemia, and that ampoules were mixed together on wards to produce solutions of greater concentration than the maximum available commercially (40 mmol/l).

The concentrations produced were typically around 80mmol/l and were infused peripherally. In areas such as intensive care and coronary care more concentrated infusions were often used and were administered via a central line.

The risk management committee therefore devised a policy defining strict criteria for the prescription and use of intravenous potassium chloride.

Agreement was reached to commission unlicensed products of higher concentrations for routine and special uses and to reduce the range of licensed pre-mixed infusions in glucose and saline variants. A table was prepared that defined degrees of hypoglycaemia and recommended appropriate infusions.

The policy was first publicised throughout the hospital using bulletins, emails, posters and flyers. Good practice, such as changes in storage and the use of volumetric pumps for the intravenous delivery of all potassium infusions, was actively promoted. Finally potassium chloride ampoules were withdrawn from all wards and theatres.

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Creating a common language for patient safety

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.

Patient safety incident: any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving NHS funded healthcare. *This is also referred to as an adverse event/incident or clinical error, and includes near misses.*

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.

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.

Seven steps to patient safety

We have set out the seven steps that NHS organisations should take to improve patient safety.

The steps provide a simple checklist to help you plan your activity and measure your performance in patient safety. Following these steps will help ensure that the care you provide is as safe as possible, and that when things do go wrong the right action is taken. They will also help your organisation meet its current clinical governance, risk management and controls assurance targets.

Further copies

If you would like to order printed copies of *Seven steps to patient safety - the overview guide* please call the NHS response line on 08701 555455. The full guide is available on line in individual sections at www.npsa.nhs.uk/sevensteps

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