

Seven steps to patient safety for primary care

The full reference guide

May 2006



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A message from the Joint Chief Executive

Background and introduction

A message from the Joint Chief Executive

Every day more than a million people are treated safely and successfully within NHS-funded primary care. Advances in technology and knowledge have made this possible but they have also created an immensely complicated healthcare system. In this environment patient safety is obviously of the highest importance and taking this concept forward might seem daunting. This is especially so in primary care, given the diversity and complexity of the sector and the huge change agenda that you all face.

This complexity brings its own set of risks, and things will and do go wrong, no matter how dedicated and professional staff are. The effect of this is widespread. There can be devastating emotional and physical consequences for patients and their families. For the staff involved too, incidents can be shattering, while members of clinical and practice teams can become demoralised and disaffected. Safety incidents also incur costs through litigation and extra treatment.

In November 2003, the National Patient Safety Agency (NPSA) launched *Seven steps to patient safety*, a guide to good practice intended to offer NHS organisations practical guidance and support on improving patient safety. This was followed in early 2004 with a full reference guide detailing more of the latest thinking and evidence on patient safety.

Although the guide was aimed at staff within all healthcare settings, feedback from primary care organisations and teams told us that they wanted their own version of the guide, to acknowledge and address the different challenges that the primary care sector faces. The NPSA is committed to ensuring that the products and advice we develop for healthcare staff and organisations are effective and useful. We also place great importance on the vital role and contribution that those working in primary care can make in driving forward the patient safety agenda and have responded by developing this separate version of *Seven steps to patient safety* specifically for the sector. We hope that you will find it useful in tackling the patient safety issues that you deal with on a daily basis.

Patient safety concerns everyone in the NHS, whether you work in a clinical or a non-clinical role, as an independent contractor, or for a primary care organisation.

At the NPSA we believe that tackling patient safety collectively and in a systematic way can have a positive impact on the quality and efficiency of all NHS-funded care. 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 sectors and levels of the NHS.

Since the NPSA was 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 improve the safety of the patients in their care. In particular we would like to acknowledge the organisations that have worked with us to develop and test our National Reporting and Learning System, along with our patient safety solutions. Our thanks and gratitude goes to all these organisations for their time, dedication and enthusiasm for patient safety.

Safety in healthcare is a relatively young field internationally and it will be some time before we can understand its full potential. We still have a long way to go but we are already seeing evidence that by working together we can make healthcare safer. We hope that this version of *Seven steps to patient safety* will help all of you involved in primary care to make patient safety a reality.

Sue Osborn and Susan Williams

Joint Chief Executive

Background and introduction

Your guide to patient safety in primary care

Huge numbers of people are treated and cared for in NHS-funded primary care each day. For example, almost one million people visit their family doctor; 1.5 million prescriptions are dispensed; and district nurses make 100,000 visits. Amongst all this complex activity, the potential for risk to patients is high; things sometimes go wrong and patients are harmed as a result. When patients move between the primary and secondary care sectors, the potential for patient safety problems increases further.

Seven steps to patient safety for primary care is a best practice guide that describes the seven key areas of activity that primary care organisations and teams can work through to safeguard the patients they care for.

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

Seven steps to patient safety for primary care is your guide to patient safety. It is most relevant to staff responsible for clinical governance and risk management, but it also applies to all those who are responsible for providing care for patients in the primary care setting. This guide is equally applicable to managed staff and independent contractor staff with differing accountabilities.

These Steps are founded on a thorough review of literature from across the world, reflecting current thinking and best practice, and on experience of what works in patient safety. The guide is divided into individual Steps which can be downloaded separately and used to develop your strategies, policies and action plans, as well as for presentations to your staff.

The tools and solutions described in these Steps have been developed in conjunction with patient safety experts together with NHS staff and organisations. 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. We have tried not to be too prescriptive – there are national solutions for universal processes and procedures, but local problems require solutions tailored to the unique local environment. We hope this guide helps you identify the gains you can make within your own organisation, practice or team.

The Steps described are not exclusively one process after another. Rather, they are part of a continuing process and offer primary care organisations, staff and teams a framework on which to work towards improving patient safety. They will help you develop a culture where staff and patients are treated openly and fairly, where patient safety is a central feature of your policies and systems and is at the forefront of everyone's mind and is everyone's business. The NPSA believes that the patient experience should be at the heart of any drive to make patient care safer and that better communication between staff and patients is a key part of that effort. With this in mind, we have ensured that the principles of involving and communicating with patients are an important component of each Step.

Some organisations are already well advanced along the route to patient safety, but many are just starting to think about how best to address the patient safety problems they face. We have therefore tried to provide practical hints and techniques, examples of local best practice and tool kits for the management and promotion of patient safety. These provide a checklist to help you plan your activities and measure your performance.

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 standards or contractual obligations, risk management accreditations and the national standards for safety.¹ We encourage all staff who provide care in the NHS to use this guide as a patient safety manual and as a framework to develop your plans for improving patient safety over the next three to five years. There are many examples of initiatives around the world that have successfully demonstrated that patient safety can be improved. None, however, have been translated to an entire healthcare system. The NHS is uniquely placed to pioneer improvements in patient safety across a single system and *Seven steps to patient safety for primary care* provides a framework for primary care organisations, staff and teams to achieve this.

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Terminology

For ease of reference, throughout these Steps:

Primary care organisation(s) will be used as a collective term to describe primary care trusts (England) and local health boards (Wales).

Practice(s) will be used to include all the different types of practices; general medical practices, general dental practices, and their staff (e.g. practice nurses, practice managers, dental nurses, hygienists, receptionists), optometrists and opticians, pharmacy practices, and so on.

¹ Department of Health (2004). *National Standards, Local Action Health and Social Care Standards and Planning Framework 2005/06–2007/08*. Available at: www.dh.gov.uk/publications

Teams and staff applies to teams who are directly managed working in community settings, e.g. community children's nurses, community learning disability nurses, nursery nurses, district nurses, health visitors, community psychiatric nurses and community midwives (the latter employed by an acute trust). The term also includes 'lone' professionals working across community settings (e.g. clinics, patients' homes, respite care, day care, residential homes, nursing homes) such as specialist nurses (e.g. continence, tissue viability) as well as allied health professionals (e.g. chiropodists, podiatrists, physiotherapists, audiologists, speech and language therapists, occupational therapists, dieticians).

Leaders applies to the chief executive of a primary care trust or local health board; their board, fellow directors and senior staff; clinical and managerial leads within each practice (pharmacy leads, general medical leads, general dental leads, optometry leads, practice managers); lead nurses; and leaders of each allied health profession.

Patient safety – our national challenge

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

1 Unified mechanisms for reporting and analysis when things go wrong

The NPSA aims to collect information on patient safety incidents, collate local data (from staff and patients), review existing evidence (e.g. epidemiological, research and development), trigger original research and development and feed back data and information

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 term 'patient safety incident' will be used to describe 'adverse events' or 'clinical errors', and 'near misses'. **Step 4** describes this in more detail.

on patient safety to NHS organisations and patients. This is described further in **Step 4**.

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

The NPSA aims to focus on changing the culture in healthcare to improve safety for patients. This is through raising awareness, providing clear guidance, providing support through a network of patient safety managers, and developing the tools and techniques described in **Steps 1 and 2**. **Step 5** describes the involvement and communication with patients and their families to ensure we are more open and inclusive.

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

Step 7 promotes 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 primary care trusts, local health boards, practices and teams. We offer guidance on how to incorporate lessons and changes into processes and systems and provide examples of approaches and solutions being developed by the NPSA.

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

Step 6 explains how to use chronological investigation techniques – significant event audit (SEA) and root cause analysis (RCA) – to find out what went wrong in a patient safety incident, how and why. We suggest how primary care organisations, practices and teams can learn safety lessons through SEA/RCA and what the NPSA can do to help.

Online resources for patient safety

To access all versions of *Seven steps to patient safety*:

www.npsa.nhs.uk

Your local NPSA patient safety manager can also help with support and advice: **www.npsa.nhs.uk**

More information about safety briefings, safety culture assessments and other tools: **www.saferhealthcare.org.uk**

The NPSA developed the Incident Decision Tree for acute care to support fair decision-making, and is now adapting the tool for primary care:

www.npsa.nhs.uk/health/resources/incident_decision_tree

The NPSA's *Being open* policy encourages healthcare staff and organisations to be more honest and open with patients when things go wrong. Training tools and resources to support local policies are now available. For more information visit the *Being open* academy: **www.msnpsa.nhs.uk/boa**

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

Your patient safety manager can update you about plans for training in root cause analysis in your area. The NPSA has also developed a web-based learning package about root cause analysis techniques:

www.npsa.nhs.uk/health/resources/root_cause_analysis

The latest solutions and advice from the NPSA:

www.npsa.nhs.uk/advice

Other useful websites:

Healthcare Commission, England:

www.healthcarecommission.org.uk

Department of Health, Safety Alert Broadcast System, England:

www.info.doh.gov.uk/sar/cmopatie.nsf

NHS Modernisation Agency, England: **www.modern.nhs.uk**

Healthcare Inspectorate Wales: **www.hiw.wales.gov.uk**

Institute of Quality Assurance, US: **www.iqa.org**

Institute of Medicine, US: **www.iom.edu**

Joint Commission on Accreditation of Healthcare Organisations, US:

www.jcaho.org

National Patient Safety Foundation, US: **www.npsf.org**

National Center for Patient Safety, US: **www.patientsafety.gov**

The Leap Frog Group for Patient Safety, US:

www.leapfroggroup.org

International Society for Quality in Healthcare, Australia:

www.isqua.org.au

Step 1

Build a safety culture

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Step 1

Build a safety culture

Improving patient safety^a in the UK requires change in many different areas; not least of these is a cultural change within the healthcare system. A true safety culture is one in which every person in the organisation recognises their responsibilities to patient safety and works to improve the care that they deliver; this is the essence of clinical governance. There is also a recognition that mistakes and incidents will happen, and that healthcare is not without its risks. Evidence shows that if the culture of an organisation is safety-conscious and people are encouraged to speak up about mistakes and incidents, then patient safety and patient care is improved.^{1,2,3}

Organisations have unique cultures; a merging of values, beliefs and behaviours that define the way they work. In primary care there is a huge agenda to face – a real change in the complexity of workloads which will impact on each organisation's safety culture. Factors such as changes in working arrangements, advances in technology, the shifting workload from secondary to primary care, changes in the workforce such as nurses being able to prescribe and triage, patients' growing health and social care needs (including more complex drug regimens and challenging national clinical standards), and greater external scrutiny. The last 15 years have also seen changes in the management of patients with chronic diseases, driven by better drug therapies and knowledge. These patients are now routinely cared for in primary care settings rather than in hospital. For example, people with diabetes used to be under the care of a hospital physician. A national survey of GPs in 1997 showed that 75 per cent of patients with diabetes are now managed largely outside hospitals.⁴

In this first Step we focus on the patient safety issues in primary care and on changing the culture to improve safety for patients. We explain what the NPSA means by a 'safety culture', which includes being open and fair, and we describe the systems approach to safety. We identify how primary care organisations^b 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 levels.

^a **Patient safety:** the identification, assessment, analysis and management of patient-related risks and incidents in order to make patient care safer and minimise harm to patients.

^b **Primary care organisation:** primary care trusts (England); local health boards (Wales).

The key principles

A safety culture is where organisations, practices, teams and individuals have a constant and active awareness of the potential for things to go wrong. Both the individuals 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 with patients and their families, balanced by fair treatment for staff when an incident happens. This is vital for both the safety of patients and the wellbeing 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 are working. Looking at what was wrong in the system helps organisations to learn lessons that can minimise the chances of the incident recurring.

What are the patient safety issues in primary care?

With more than one million people receiving treatment in a primary care setting every day, the NPSA recognises that all staff who work in primary care, including contractor professions, have a vital role to play in taking the patient safety agenda forward.

Risk management has until now been focused on technological interventions in acute care, and is less well developed in primary care, but the enthusiasm for learning from patient safety incidents is clear. We know that primary care professionals consider patient safety a priority, want more time to deal with their clinical governance agenda, and want help, training and practical advice on how to improve risk management and patient safety, as well as the opportunity to share lessons. At the NPSA, we are committed to finding ways to help staff, teams and organisations make patient safety a priority and an achievable goal.

The issues facing primary care are complex and there is a growing shift of services from the hospital to the community. Over 70 per cent of patients' contact with the NHS is now at home or in primary care facilities and this will increase significantly with changes expected in the way healthcare is delivered, as set out in the government's NHS Improvement Plan⁵: primary care trusts and local health boards now also oversee a range of practitioners who are not directly employed by them. Further increases in activity within the primary care sector include:

- The number of prescriptions per year rose from 550 million in 2000/01, to 615 million in 2002/03.
- The introduction of new services such as NHS direct and NHS walk-in centres.
- Growing numbers of primary and community clinics are able to offer more services to patients, and helping people avoid a hospital visit. For example, from 2002 to 2003, the growth in referrals by GPs to hospitals was only 0.1 per cent.

There is huge variation in practice across the primary care sector, and GPs are dealing with an increasingly wide range of symptoms, many of which cannot easily be categorised or clearly diagnosed.⁶ Changes in healthcare, such as early discharge from hospital, the prescribing and monitoring of potentially high-risk drugs (such as methotrexate for rheumatoid arthritis, and infertility drugs), and an increasingly diverse range of services and areas that fall under the remit of primary care, all increase the risk of unintentional patient harm.⁷

Our patient safety knowledge in this area, however, is limited.⁸ Although there have been some academic studies relating to patient safety in primary care, most of the research into patient safety, in the UK and abroad, has been conducted in the acute sector. A useful review of studies was published by researchers from Manchester, which showed wide variations in error rates – between five and 80 per 100,000 consultations.⁹ In this review, errors related to diagnosis were consistently the most common category. The low error rate, however, is more likely to reflect the lack of evidence in this area than to be a true indication of the level of errors in primary care. A study published in 2004,¹⁰ on the epidemiology of error using an analysis of databases of clinical negligence litigation, found that:

- By far the most common error in primary care (50 per cent of cases) was a failure or delay in diagnosis. Other common errors included medication prescription errors, failure or delay in referral, and failure to warn of, or recognise, side-effects of medication (each around five per cent). Not all of these errors result in serious harm.
- The most commonly recorded outcome of these errors in primary care was the death of the patient (in 21 per cent of cases). Other commonly cited outcomes included deterioration in clinical condition (six per cent) and unnecessary pain (four per cent).

This research also calculated standardised incidence ratios of errors in relation to total consultations in primary care. The results show that the standardised incidence ratio of error was highest for patients in groups with neoplasms, congenital problems, and complications of pregnancy. More detailed analysis revealed a number of conditions, such as septicaemia, meningococcal infection, appendicitis and various neoplasms, were associated with high standardised incidence ratio of error/claim.

In another UK study of ten general medical practices in 2003, 940 errors were recorded over a two week period. The overall error rate was 7.5 per cent (75.6 per 1,000 appointments). The errors were classified as 42 per cent related to prescriptions, 30 per cent related to communication errors (with missing case notes being the most common source) and three per cent of the errors cited as clinical (with inaccurate note-keeping the main source¹¹). In an international study comparing patient safety in general practice, patient harm was reported in around 30 per cent of incidents: between three and nine per cent of these were 'very serious or extremely serious'; with consequences of error involving a hospital admission in four per cent of cases; and death in one per cent of cases.¹²

A key research study in the US demonstrated that most errors in general practice can be attributed to two main categories: a) aspects of care delivery systems, for example, administrative errors, failure to investigate, miscommunication; and b) lack of clinical skills and/or knowledge, for example, a receptionist failing to make an urgent appointment for an acutely ill child.¹³ The crucial areas for improving patient safety in general practice appear to be diagnosis, medication prescribing, dispensing and administration; and communication within practices, between different professions, and between primary and secondary care.¹⁴

While the research has given some insight into the breadth of patient safety incidents in primary care, it is widely acknowledged that there is a need for a more accurate assessment of the number and severity of these incidents in order to develop safe and effective solutions to improve patient safety.¹⁵ A number of institutions are devoting time and expertise to increase our knowledge of patient safety incidents. These include the patient safety research networks led by the University of Manchester, the University of Plymouth, the design-led approach to patient safety network at the University of Surrey, and patient safety research programme at the University of Birmingham. Examples of research projects currently being undertaken through the patient safety research programme include: medication errors in primary care; medication errors in nursing and residential care homes for older people; and diagnostic errors in primary care.

What is certain is that a better understanding of the nature and number of patient safety incidents in primary care will help the NPSA develop solutions and advice for local implementation to prevent patient harm. If the NPSA is to build a clearer picture of the problems affecting patient safety in primary care and develop ways to help organisations protect patients, it is vital that anyone working in primary care reports things that go wrong.

Case study: community midwifery

In GP surgery X, a community midwife runs a fortnightly antenatal clinic. A woman was seen at 32 weeks pregnant and found to have slightly elevated blood pressure (120/90). The midwife suggested that the woman should return to have her blood pressure re-checked by the GP the following week.

When the woman told the receptionist that she needed to return for a blood pressure check the following week, she was given an appointment at the hypertension clinic with the practice nurse. The woman duly attended the clinic and her blood pressure was taken. It was even more elevated than the week before (140/95). However, the practice nurse failed to recognise the significance of this in a pregnant woman. No other investigations were carried out and the woman was advised to return to the midwife's clinic the next week.

Later that same day the woman developed severe oedema and epigastric pain and was admitted to hospital with severe pregnancy-induced hypertension. She had an emergency Caesarean section, developed Disseminated Intravascular Coagulation disease and spent five days in the intensive therapy unit.

What is a safety culture?

The culture of a team or an organisation is shaped by the pattern of beliefs, values, attitudes, norms, unspoken assumptions and entrenched processes that influence how people behave and work together. It is a very powerful 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,¹⁶ but it is essentially a culture where individuals and teams 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 teams and organisations with a safety culture, people are able to learn about what is going wrong and then put things right.¹⁷ In these teams and organisations patient safety is at the forefront of everyone's mind; not only when delivering healthcare but also when setting objectives, developing processes and procedures, purchasing new products and equipment, and redesigning clinics and departments. It influences the overall vision, mission and goals of a team or organisation, as well as day-to-day activity.

Why is a safety culture important?

There is evidence to show 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 a team or an organisation.¹⁸ Therefore, a safety culture will help primary care organisations and practices achieve improvements within their clinical governance^c agenda. A key part of achieving good clinical governance is recognising that it is not always possible to achieve the perfect clinical outcome and that lessons learned are an important and integral part of a continuous programme for quality improvement.¹⁹

A safe team or organisation is also an informed team or organisation.³ The key benefit of this for healthcare is that each team, practice or organisation is aware of what can go wrong and what has gone wrong. As more errors and incidents are reported on a regular basis, each team or 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, resources can then be targeted at the areas that require further investigation. This can then be used to share learning across practices, with patient safety organisations and with secondary care.

Other important benefits of a safety culture in healthcare are:

- A potential reduction in the recurrence and the severity of patient safety incidents through increased reporting and organisational learning.
- A reduction in the physical and psychological harm patients can suffer due to people being more aware of patient safety concepts, working to prevent errors and 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.
- A reduction in costs incurred for treatment and extra therapy.^{20,21,22}
- Improved resource management with effective risk assessment and changing practices as a result of incidents, e.g. a reduction in the number of different types of equipment. This standardisation across the health service will eventually reduce training costs for all.

^c **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.

^d **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. This is described in more detail in **Step 4**.

- A decrease in the wider financial and social costs incurred through patient safety incidents, including lost work time and disability benefits.

The balanced approach to safety

Having a safety culture encourages a working environment where many factors are taken into consideration and recognised as contributing to an incident, or to the events leading up to it. Research around patient safety has highlighted that the majority of staff try to create a safe environment and prevent things from going wrong. Despite some high profile cases, such as the inquiry into children's heart surgery at the Bristol Royal Infirmary, 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

Patient safety incidents should be reviewed to consider events far beyond the actions of the individual healthcare staff directly involved. While human error may immediately precede an incident, in a technically and socially complex system such as healthcare, there are usually entrenched systemic factors at work.⁵ The move away from focusing blame solely on individuals, and looking at what was wrong with the system in which the individuals were working, is called the systems approach.¹

Identifying the system factors which affect patient safety will help organisations learn about the reliability of the processes within their organisation. The aim is to improve this reliability by:²³

- **prevention:** designing the system to prevent failure;
- **identification:** making failures obvious before they occur by undertaking proactive risk assessments;
- **mitigation:** designing the procedures and building capabilities for mitigating harm caused by the failures when they are not detected or intercepted.

However, the systems approach does not mean that individual actions are put to one side and not considered when reviewing an incident.²⁴ There is a fine balance between individual actions and system failures that result in an incident either occurring or having the potential to occur. This balance is different for every case; in some incidents individual actions or human error contribute to a much larger extent than systems factors; whereas in other incidents this could be the opposite.

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

An important factor in any approach to safety is awareness by individuals, teams and organisations of their own levels of safety. With regard to organisations, this is often identified during the annual risk assessment process, and the risk register is the evidence of how safe an organisation is and what measures that organisation is taking to reduce its levels of risk. This is described in more detail in **Step 3**.

Staff delivering the care, however, can feel that they have little opportunity to influence the organisational levels of risk or change the system within which they work. A simple tool for individuals and teams to understand their own safety levels has been devised by Professor James Reason.²⁵ This model is called the three buckets model. This self-review tool asks each individual (it could also apply to teams) to give themselves a score in relation to three factors: self, context and task. They score themselves either one for low-risk, two for medium or three for high-risk. The three factors are taken into account in the following ways:

- **self:** how they are feeling that day; are they preoccupied; are they inexperienced or do they lack knowledge; are there physical factors such as fatigue; are emotional factors and life events affecting their day;
- **context:** what is the environment, both physical and cultural, in which they will be working; what are the expected distractions, skill mix, team factors, number of interruptions, number of changes or handovers, levels of authority, hierarchy and team interactions;
- **task:** the procedures and activities they will be undertaking during the day; what are their levels of experience, resources, equipment, knowledge and complacency; are there any specific issues in relation to individual patients, such as complexity, vulnerability, or even infectious status.

Scores for each factor are then added together. A score of three does not necessarily mean that the individual or team is at its safest, and a score of nine does not necessarily mean that they are at their riskiest. The self-review simply helps individuals to become more aware of how safe they potentially are that day and can adjust their actions accordingly. This can be described as error wisdom or self vigilance.

Why is the balanced approach to safety important?

A difficult but essential aspect of a safety culture is the need to accept that people, processes and equipment will fail. By accepting this, organisations can focus on change and can 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 incident happening again.²⁶

Being open and fair

A fundamental part of any organisation with a culture of safety is to ensure that it is open and fair. For primary care organisations, staff, teams and practices this means that people are:

- open about incidents they have been involved in;
- able to talk to their colleagues and superiors about any incident;
- accountable for their actions;
- open with patients and/or their carers when things have gone wrong, and able to explain what lessons will be learned;
- 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 censure²⁷ and subsequent media attention. Additionally, the National Audit Office report on suspensions of clinical staff following patient safety incidents highlighted that staff were sometimes suspended despite evidence of systemic failures as oppose to individual shortcomings.²⁸

To create an open and fair environment we need to dispel two key myths:²⁹

- **perfection:** if people try hard enough, they will not make any errors;
- **punishment:** 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 patient safety issues, there is increasing public interest in the performance of the health service and therefore 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. Primary care organisations, practices and teams need to demonstrate the right balance between accountability and openness.

Why is it important to be open and fair?

One of the fundamental barriers to incident reporting is the fear of blame and punishment; staff are less likely to report incidents if they believe that they are going to place themselves or their colleagues at risk of being disciplined or reprimanded. An open and fair environment will help to ensure the reporting of incidents, from which lessons can be learned and patient safety improved.

The leadership of any primary care organisation and team is central to setting the values and beliefs of a group's culture. Leaders have a vital role to play in building a safety culture that is open and fair. They need to establish an environment where whole organisations, practices and teams learn from safety incidents, and where their staff are encouraged to proactively assess risks^e and report incidents. To demonstrate that an organisation or practice is serious about being open and fair, the local disciplinary policy should clearly describe how staff will be managed when they are involved in incidents, complaints and claims.^{6,30} Incidents should be reviewed

^e **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.

and investigated fairly and free from bias over the outcome of the incident or from hindsight. In England and Wales there are a number of organisations which can be consulted by all primary care organisations in relation to their disciplinary procedures. These include: local medical committees (LMC), statutory bodies representing all NHS GPs in a particular area, local pharmaceutical committees (LPC), local dental committees (LDC), the British Medical and Dental Associations (BMA, BDA), and royal colleges.

Feedback on action taken following reporting of incidents is also vital. The reporter should be informed of what changes have been made 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.

Finally, being open and fair is also the basis of the relationship between patients and their clinicians. Patients should be more involved and also be encouraged to take greater responsibility for the safety of their care. This is described further in **Step 5**.

What can healthcare providers do?

Changing values, beliefs and attitudes is not easy.³¹ Developing a safety culture in an organisation needs strong leadership and careful planning and monitoring. It also requires changes at all levels. It is vital that not only clinical staff, but all those who work in healthcare, as well as patients and carers, ask themselves how *they* can help to improve the safety of patients.

To help NHS organisations adopt the balanced systems approach after a patient safety incident, the NPSA is developing a safety culture assessment framework, and has created the Incident Decision Tree (IDT). The IDT can help organisations assess incidents, and the actions of the individuals involved, to help them understand their actions, i.e. the circumstances and systems failures that lead to the incident happening and how those circumstances and failures affected individual staff performance. 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 to the patient.³² The IDT is described in more detail in the section 'How can the NPSA help?' later in this Step.

Safety culture review

The first stage in developing a safety culture is to establish where you are now. A number of tools are already available to help you do this. Most are in the form of checklists or questionnaires for staff to complete (good examples can be found at www.ihl.org). 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 (e.g. fatigue, distractions, equipment design or usability).

Baseline reviews of the safety culture are suitable for any primary care setting, so they are as equally applicable for a primary care trust and local health board as they are for a general medical or general dental practice, and so on. When choosing a tool to review your 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 review regularly to check your progress.

How can the NPSA help?

During 2006 the NPSA aims to put 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 now available or are in development. The NPSA has reviewed the safety culture surveys currently available and will be developing a review tool that is tailor-made for use across the NHS.⁴ This will enable primary care organisations to undertake a baseline review of their safety culture; against which they can measure progress over time.

Manchester Patient Safety Framework

Resulting from collaboration between the National Primary Care Research and Development Centre, and Manchester University's psychology department, and based on Westrum's³³ theory of organisational safety, the Manchester Patient Safety Framework (MaPSaF)³⁴ aims to help primary care staff measure the safety culture in their organisation. This tool is now available for primary care.

The MaPSaF classifies primary care organisations against nine dimensions of risk management:

- overall commitment to quality;
- priority given to patient safety;
- perceptions of the causes of patient safety incidents and their identification;
- investigating patient safety incidents;
- organisational learning following a patient safety incident;
- communication about safety issues;
- personnel management and safety issues;
- staff education and training about risk management;
- team working around risk management.

The framework is presented in the form of a matrix (with organisational type on the x-axis and the risk management criteria on the y-axis). You can find further detail on matrices in **Step 3**. In each of the matrix boxes there is a description of organisational behaviour. The framework instructs organisations to put together a focus group comprising healthcare managers and/or healthcare teams and ask them to pick out which description best fits their organisation or department. Where there are different perceptions among group members, a discussion should take place about why staff have different viewpoints, and a consensus should be achieved. After focus group participants have gone through all nine dimensions, actions should be developed which aim to help an organisation to mature their patient safety culture.

The framework is designed to identify any differences in perception about patient safety culture between members of staff and to stimulate discussion about the strengths and weaknesses of the patient safety culture within the organisation. In addition, 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).

Manchester Patient Safety Framework for community pharmacy

As part of a collaborative project between the School of Pharmacy and Pharmaceutical Sciences, and the Department of Psychology at the University of Manchester, a version of the MaPSaF has been developed to help staff working in community pharmacies measure the prevailing safety culture in their organisations.³⁵

Copies of the community pharmacy version of MaPSaF can be ordered by contacting Mrs Irene Sung, Professional and External Affairs Administrator, Academy for the Study and Development of the Pharmacy Workforce, School of Pharmacy and Pharmaceutical Sciences, University of Manchester (irene.sung@manchester.ac.uk Tel: 0161 275 2324).

The framework consists of a matrix in which five levels of organisational safety culture (pathological, reactive, calculative, proactive and generative) have been mapped against qualitative statements characterising the following eight dimensions of patient safety:

- commitment to patient safety;
- perceptions of the causes of incidents and their reporting;
- investigating incidents;
- learning following an incident;
- communication;
- staff management and safety issues;
- staff education and training about risk management;
- team working.

Changes in attitudes and behaviour can take time to develop and they require an understanding and willingness to adjust. Primary care organisations and community pharmacies therefore need to raise the level of understanding around patient safety and the systems approach to error and incidents. The benefits of speaking up and talking about things that have gone wrong need to be made explicit, especially when reporting (in particular for independent contractors) is not currently mandatory.

Team Climate Assessment Measure

The NPSA is currently collaborating with Aston University to develop and pilot a Team Climate Assessment Measure (TCAM). A TCAM is a questionnaire, completed by team members, which assesses the dimensions of their team climate that are associated with effective team functioning in general, and the specific area of patient safety. The climate dimensions included in the TCAM are those most often associated with effective team functioning and patient safety incident management. These are:

- task reflexivity;^{f,36}
- participation, trust and safety;
- team learning behaviour;
- individual development;
- credibility;
- inter-professional learning;
- team member contact;
- mutual trust;
- team efficacy;
- team stability and longevity;
- shared leadership and leadership clarity.

The TCAM questionnaire is completed by team members before they use the TCAM training guide. The training guide comprises a collection of tools that help teams to develop and improve their team climate (as measured by their TCAM). It includes documentation, exercises and materials which support the development of team working skills, practices and procedures that have positive effects on team performance in general and on improving patient safety via patient safety incident management and error reporting in particular. The TCAM is currently being piloted in primary care and acute trusts and will be launched by the NPSA later in 2006.

^f **Task reflexivity:** the degree to which team members review their objectives, their ways of achieving them, and their methods of working.

Creating the virtuous circle: patient safety, accountability and an open and fair culture³²

In February 2003, the NPSA and the NHS Confederation co-launched a report exploring how to support a culture in which the NHS will encourage open reporting of incidents and determine system-wide accountability. The report is available at www.nhsconfed.org/publications. The report is accompanied by a CD-ROM and the package is designed for NHS executives and non-executives, clinical governance, risk management⁹, health and safety leads, human resources leads, clinical managers, and patient group representatives.

Incident Decision Tree

In November 2003, the National Audit Office (NAO) released a report on the management of suspensions of clinical staff, which found that between April 2001 and July 2002 over 1,000 full-time clinical staff were suspended at an estimated cost of £29 million to the NHS. The NAO identified occasions where clinicians were excluded despite evidence of systematic failures rather than individual shortcomings, and highlighted the need to improve the management of suspensions.

In order to help healthcare managers determine a fair and consistent course of action towards staff involved in a patient safety incident, the NPSA has developed the Incident Decision Tree (IDT).

The IDT supports the aim of creating an open and fair culture, where employees feel able to report patient safety incidents without undue fear of the consequences. The IDT is an electronic, interactive tool designed for healthcare managers dealing with staff involved in an incident. Based on a model developed by a world leading academic in the field of understanding error, Professor James Reason, it prompts the user with a series of questions to help them take a systematic, transparent and fair approach to decision making. The IDT helps managers to decide whether it is necessary to suspend staff from duty following a patient safety incident and to explore alternatives, such as temporary relocation or modification of duties. It comprises a flowchart with accompanying guidelines. It does not provide firm answers or decisions, but rather flags up a range of possible solutions and/or additional factors to be explored.

⁹ **Risk management:** identifying, assessing, analysing, understanding and acting on risk issues in order to reach an optimal balance of risk, benefit and cost.

As the 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 healthcare organisations and across different professional groups;
- act as a quick decision-support tool for chief executives, human resources, healthcare managers and local medical committees;
- prompt decision-makers to think about systemic and organisational issues in patient safety;
- encourage a fair response to incidents prior to a full investigation and indicate when an immediate review may be needed;
- be adaptable to local circumstances.

The IDT is now available for secondary care organisations and is currently being adapted for the primary care sector. It will be available later in 2006, with detailed guidance notes and example scenarios for staff to work through.

Visit www.npsa.nhs.uk/npsa/newsletter to subscribe to our newsletter for updates on all of the above work

Good practice in building a safety culture

Do you have a good practice story and would you like to share that story with your healthcare colleagues? If so, please send it to pcsevensteps@npsa.nhs.uk

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Step 2

Lead and support your staff

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Step 2

Lead and support your staff

Patient safety^a affects everyone in healthcare. We stated in **Step 1** that evidence indicates that the level of patient safety of an organisation can be improved if there is a safety culture that is open and fair. A fundamental part of this 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.^{1,2,3,4}

However, this is not always as clear cut in primary care. Leadership can be provided at different levels for different staff groups. For example, a GP practice may have a senior partner but practice staff may consider the practice manager to be the leader of their group. In the same way, the community nursing team may be led by the PCT or the mental health team by the mental health trust. Therefore, it is even more important to build on a partnership of team working by strong leadership and good communication channels.

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

For key terminology and definitions of what we mean by teams, staff and leaders, refer to the introduction to all the Steps. All these people have a vital role to play in building a safety culture that is open and fair.

The key principles

Delivering the patient safety agenda requires motivation and commitment from the top of each primary care organisation and from clinical and managerial leaders throughout the service, including general medical and general dental practices.

To show that safety is a priority and that the management of the organisation is committed to improvement, leaders must be visible and active in leading patient safety improvements. Staff and teams should feel able to say if they do not feel that the care they provide is safe; irrespective of their position.

^a **Patient safety:** the identification, assessment, analysis and management of patient-related risks and incidents in order to make patient care safer and minimise harm to patients.

Why is good leadership and support important?

The NPSA recognises that patient safety may be perceived by some as yet another initiative to add to an already busy workload. The agenda in primary care is huge; with local delivery plans, agenda for change, complex commissioning, payment by results, assessments by the Healthcare Commission and Health Inspectorate Wales, and so on. But it is not about doing more – it is about doing things differently. Primary care organisations, practices and teams can improve patient safety when leaders are visibly committed to change. Leaders need to facilitate a change in culture by listening to, and supporting, their staff, including independent contractors, when they report patient safety incidents^b. They should demonstrate the importance of safety in principle and through example.⁵

Good communication and feedback is also vital. It is important that all staff know how well healthcare is being provided, understand their contribution to safety and identify opportunities for improvements. A vibrant, motivated and skilled workforce is critically important to continuous improvement and is a key ingredient to the delivery of high quality, safe care.⁶

What can primary care leaders do?

Organisations that have a great reputation for safety from around the world all have one thing in common: improvements have been led directly from the top. To help staff achieve success in patient safety, those with clinical and managerial leadership responsibility within primary care need to work towards a number of objectives, as outlined in the respective Steps.

In response to requests from chief executives, we have developed a checklist to help them assess the position of their organisation. We have tested this list with chief executives, and appreciate that each area will need to determine how this fits with their own priorities and previous achievements. We do hope it provides you with some practical actions you can take to address this issue successfully.

^b **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' or 'clinical errors', and 'near misses' respectively.

Leadership checklist for NHS chief executives

1 Build a safety culture

To help your organisation learn about patient safety, you should create a culture where staff share information freely as this is known to improve levels of safety.

This can be fostered by:

- undertaking a baseline cultural assessment of your organisation and assessing whether it is open and fair;
- having policies and procedures that support a culture in which:
 - staff can talk to colleagues and managers about incidents they have been involved in;
 - reviews of incidents focus on why it occurred, not simply who was involved;
 - staff are treated fairly and are supported when an incident happens;
 - tools such as the NPSA's Incident Decision Tree are used to determine the reasons behind an individual's actions.¹

2 Lead and support your staff

A safety culture requires strong leadership and a willingness to listen. The following three actions are known to make the biggest impact:

- Patient safety briefings by yourself or regular executive visits throughout an organisation; meeting staff and patients to specifically discuss safety issues.
- Mechanisms that encourage staff to suggest ideas on how to improve. They should encourage discussions around patient safety incidents which have happened, were prevented or nearly happened (near misses).
- Developing communication and feedback mechanisms are vital so that staff understand their contribution to safety and are encouraged to participate.

Additional clearly identified roles and responsibilities may also be helpful:

- appoint patient safety champions for every part of an organisation and ensure they feed into the risk and clinical governance management agenda;

- nominate a board executive to oversee risk management and safety;
- appoint someone sufficiently senior, with access to you, who is responsible for risk management, and ideally is part of a central team taking an integrated approach (see section 3).

3 Integrate your risk management activity

Safety is known to improve when organisations' leaders ask themselves the following:

- Is patient safety reflected in the organisational strategy, structures, functions and systems? Patient safety should be integrated with clinical risk, non-clinical risk, health and safety, internal controls, complaints and clinical negligence.
- Do patient safety objectives feature in your clinical governance strategy and plan?
- Are all clinical risk assessments for each specialty fed into the organisational risk register? Is this up-to-date, have actions been implemented, followed up and monitored?
- Are board agendas structured to ensure that risk management and patient safety are on an equal footing with finance and performance targets?

4 Promote reporting

Reporting things that go wrong is fundamental for building a safer NHS for patients. The three important actions are:

- To encourage all staff to report patient safety problems, particularly those groups that have low reporting levels. High reporting levels usually equate to a safer organisation.
- To link your local reporting system to the National Reporting and Learning System.
- To aim to reduce the severity of incidents: your risk manager (or equivalent) should see all reports of unexpected or unintended deaths before sending them to the NPSA. You should receive reports and action plans for all deaths directly related to a patient safety incident.

5 Involve patients and the public

Open organisations are safer organisations. Patients and their carers need to know when harm has occurred and be involved in incident investigations. This can be done by:

- producing a policy in line with our *Being open* guidance;
- obtaining board level support for the policy and then providing training for staff;
- involving patients and, where appropriate, their families and carers in root cause analysis (RCA) investigations of incidents which led to severe harm or death;
- involving patients, their families and carers in the recommendations made and the solutions developed following a patient safety incident.

6 Learn and share safety lessons

Healthcare will only become safer if we create a memory of things that go wrong both nationally and locally. This can be achieved by:

- Using RCA techniques or significant event audits¹ to investigate incidents effectively.
- Ensuring up to eight key staff, including your risk manager or equivalent, have received NPSA training in RCA. They should become your local investigation team and train others.
- You or your lead executive taking part in at least one RCA review a year.
- Analysing the frequency, type and levels of severity of incidents, and the lessons learned over time, to demonstrate continuous improvement. Routinely report this work to the board.

7 Implement solutions to prevent harm

Real progress will not be made in delivering safer healthcare unless necessary changes are implemented. The first steps should be to:

- review practice in relation to NPSA alerts, recommendations and solutions, and the findings of local, regional and national enquiries;¹
- use your clinical governance committee to steer action plans following local and national incident investigations; ensure recommendations are implemented and evaluated; assess what remains to be done; and feed back your organisation's actions to national bodies;

- establish a network which includes your and other organisations' patient safety champions to learn from those who have successfully implemented solutions.

Key objectives

As discussed, 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 primary care service depends on the work of multidisciplinary teams across organisational boundaries. An effective and safe team is one where people can share the same set of values, 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 'if you're not sure it's safe, then it's not safe' and to tell your colleagues by whatever means are available.⁷

People and tools to help with this are:

- patient safety champions;
- patient safety briefings;
- team briefings and de-briefings.

Patient safety champions

To ensure that safety is not one person's job and to engage clinicians in safety, primary care organisations, teams or practices should think about nominating one of their clinical team to 'champion' patient safety. This demonstrates a strong commitment to safety.

Patient safety champions 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;
- have an understanding of risk management, 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 within their working environment;
- understand the risks within their area, how to do risk assessments and develop a risk register;

- support and guide their colleagues, and create a culture where people feel respected and able to be open and honest about an incident they are involved in;
- promote the *Being open* policy with patients and their carers (described in **Step 5**);
- provide training and support to staff on patient safety, where relevant;
- establish processes for learning lessons and implementing changes to improve patient safety using significant event audit or root cause analysis, and implement appropriate monitoring and review mechanisms to measure improvements.

Support should be provided for local patient safety champions who, where possible, should meet and share patient safety information and issues across the teams and practices.

Patient safety briefings and de-briefings

At the beginning of a shift, start of the day, or start of a clinic, staff could spend ten minutes together to talk through the particular issues expected to happen that day; with an emphasis on the safety of care.⁸ These meetings can be held at both the beginning and end of the day and are about supporting and learning and not about performance management. They should focus on safety and clinical governance issues, for example, the expected complexities of the day, and the types of significant events or patient safety incidents that have occurred and any action taken to reduce the chances they will happen again. Staff should be able to raise safety issues and share their concerns. An important part of the brief and de-brief is follow-up and feedback from previous meetings.

Team briefings are ideal for departments where particular groups of staff form a team for the day, shift or session (e.g. child health clinic, flu clinic, staff meetings, out-of-hours shifts, family planning clinics). 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 10 to 15 minutes at the beginning of a day, or a practice lunch or clinical audit session;

- be 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 the objectives and success criteria are;
- be balanced by de-briefings at the end of the day.

Because training works well when it involves multidisciplinary teams that work together on a regular basis, team briefings provide opportunities for training on patient safety and on how to report incidents. This can help facilitate behaviour change, encourage reporting and boost morale.^{9,10,11}

Over time, team briefings will improve both patient care and patient safety. Your team briefings could follow the outline below:

- meet at the beginning of the day, or in a lunch meeting, training or clinical audit session;
- identify potential patient safety issues, such as complex cases, any patient safety incidents that occurred, how and why they happened, if any potential incidents were identified, and how they were prevented from causing harm;
- identify any opportunities for improvement;
- 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 previous meetings;
- mention the de-briefing meeting at the end of the day, or clinic, i.e. when and where.

Patient safety walkabouts or drive-about

To show that safety is a priority, and that the management of an organisation or practice is committed to improvement, managerial and clinical leaders must be visible and active in leading patient safety improvements. They can demonstrate their commitment to patient safety by conducting patient safety briefings or walkabouts/drive-about.

As yet, we do not have a tradition of patient safety walkabouts/drive-about in primary care (although primary care trusts are already conducting clinical governance visits to practices and this can be seen as an extension to this activity). These are not about inspection or monitoring, but support, guidance and two-way feedback. They can take place at all levels of primary care, including within individual surgeries with lead GPs or safety leads talking to their practice staff, identifying problems and issues, and working towards a more open culture.

We are able to draw upon the experience of the recent past with respect to medical audit advisory groups (MAAGs). These were set up by family health service authorities (FHSAs) in the early nineties and were successful in raising the numbers and standards of clinical audit in general practice.¹² MAAGs were professionally led and had a difficult task, at least in the early days, of demonstrating to clinicians that they were there to help practices improve patient care and not as part of performance management structures. Most MAAGs used senior clinicians as 'audit ambassadors', in the same way we are suggesting the use of patient safety champions. They visited practices and teams by appointment; advised on audit methodologies; and facilitated inter-practice audit at a time (before the onset of primary care organisations) when practices had little tradition of working together. This model worked well in the primary care context and patient safety walkabouts/drive-about could build on this success to take forward the patient safety agenda in primary care.

Why conduct safety briefings and walkabouts or drive-about?

We recognise that making a time commitment to patient safety briefings, walkabouts/drive-about can be extremely difficult to juggle with other pressures. It is worth stating however, that research in the US has identified that regular walkabouts are a key critical factor in developing a safer culture and improving patient safety.

The benefits of patient safety briefings and walkabouts/drive-about 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 and clinical leaders;
- the fostering of an open and fair culture by encouraging staff to discuss incidents openly;
- the opportunity to gather information and ideas from staff to make patient care safer;
- the opportunity to share information gathered across different parts of the service with clinical leaders.

Team checklist

A significant amount of evidence suggests that teams that work well together create a safer environment.¹³⁻¹⁷ The following NPSA checklist picks out the key criteria that improve multidisciplinary teamwork:

Criteria	✓	✗
Are the team members clear about their roles and responsibilities?	<input type="checkbox"/>	<input type="checkbox"/>
Are there identified leaders?	<input type="checkbox"/>	<input type="checkbox"/>
Are those leaders happy with the type of leadership and direction?	<input type="checkbox"/>	<input type="checkbox"/>
Are the team members happy with the type of leadership and direction?	<input type="checkbox"/>	<input type="checkbox"/>
Is each team member valued and respected for their expertise and views?	<input type="checkbox"/>	<input type="checkbox"/>
Can any member of the team challenge any other member of the team without fear?	<input type="checkbox"/>	<input type="checkbox"/>
Are experts used appropriately?	<input type="checkbox"/>	<input type="checkbox"/>
Is there a formal process of getting together and planning objectives and goals?	<input type="checkbox"/>	<input type="checkbox"/>
Are there effective communications systems within and between teams?	<input type="checkbox"/>	<input type="checkbox"/>
Is there a shared understanding of what is required and is this actively checked?	<input type="checkbox"/>	<input type="checkbox"/>
Is the right information passed to the right people at the right time?	<input type="checkbox"/>	<input type="checkbox"/>
Does the team anticipate, discuss and prepare for potential problems, challenges and risks that may occur through a system of briefing and debriefing?	<input type="checkbox"/>	<input type="checkbox"/>
Is feedback given to team members on their performance?	<input type="checkbox"/>	<input type="checkbox"/>
Are there mechanisms for identifying and managing working conditions, such as stress or fatigue within the team?	<input type="checkbox"/>	<input type="checkbox"/>
Is patient safety promoted?	<input type="checkbox"/>	<input type="checkbox"/>

Good practice in building a safety culture

Do you have a good practice story and would you like to share that story with your healthcare colleagues? If so, please send it to pcsevensteps@npsa.nhs.uk

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Step 3

Integrate your risk management activity

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Step 3

Integrate your risk management activity

It is a requirement of clinical and integrated governance that all organisations within the NHS, including those in primary care, address quality issues and deliver appropriate standards of care. Risk management is a crucial part of this process.

In this Step we define how primary care organisations, including practices, can build on the integrated governance approach and develop and integrate risk management systems, how this can improve patient safety, and how the NPSA can support them in achieving this.

Risk is inherent in all aspects of primary care, including:

- treatment and care commissioned and provided to patients and their families;
- the determination of service priorities;
- projects and service developments;
- the medicines and healthcare products purchased;
- the instructions, understanding and follow up of patients.

Integrated risk management is the process of identification, assessment, analysis and management of all potential risks^a and patient safety incidents^b. It applies to all services throughout primary care at every level. If risks are properly assessed, the process will help primary care trusts, local health boards, community teams and practices to set their priorities and improve decision-making to reach an optimal balance of risk, benefit and cost.

In practice, integrated risk management means:

- Ensuring that primary care organisations, including practices, use the same systems for managing all their risk management functions, such as patient safety, health and safety, complaints, clinical litigation, employment litigation, and financial and environmental risk.
- When improvement, modernisation and clinical governance are considered, risk management is a key component of any project design.

^a **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.

^b **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.

- Bringing together 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.
- Using a consistent approach to the training, management, analysis and investigation of all potential risks and actual incidents.
- Using a consistent approach and uniting all risk assessments of all types of risks for an organisation at every level. Incorporating all risks into an organisation or practice's risk assessment programme and risk register^c. This will mean organisations can plan more effectively and develop controls to reduce the effects of the risks identified.
- Using the information gained through incidents and risk assessments to develop future business and strategic plans.

The key principles

Integrated risk management means lessons learned in one area of risk can be quickly spread to another area of risk.

Integration and management of all risk will assist primary care organisations, including practices, in complying with their clinical governance targets, risk accreditations (Clinical Negligence Scheme for Trusts, Risk Pooling Scheme for Trusts, Welsh Risk Pool), and Health and Safety Executive requirements.

Why is integrated risk management important?

It is now well recognised that healthcare involves a wide range of risks and that any development, change or innovation brings new risks as well as rewards.¹⁻⁵

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

Primary care trusts, local health boards and practices are continuously changing, which can cause their risk profile to change. If these

^c **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.

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.

On an international scale, healthcare organisations are benefiting from a more comprehensive approach to manage all their risks more effectively.⁷ By integrating risk management as described in this Step, they are more likely to achieve their objectives and desired outcomes.

Integrated risk management 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. It is also an essential component of good management and provides a focus for building improved organisational resilience^d and flexibility in the face of uncertainty.⁸ 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 weaknesses and vulnerability of procedures, practices or policy changes are not identified. This can result in care that is delivered without well-considered contingency plans.

Benefits of integrated risk management for primary care organisations

- Improves information around 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, significant event audit, complaints management, health and safety assessments, and litigation and claims handling, can quickly be spread to other areas of risk.
- Provides a consistent approach to the identification, analysis and investigation of all risks, i.e. root cause analysis and/or significant event audit can be used for complaints and claims as well as incidents.
- Assists organisations in complying with all relevant standards, as well as clinical governance, CNST, RPST, WRP and HSE requirements.
- Helps organisations plan for uncertainty, cope with the impact of unexpected events, and increases patient and public confidence.

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

What can healthcare providers do?

All primary care organisations and practices need to establish an integrated risk management function. 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 health service. In part, this is because different organisations are at different stages of developing their risk management activity. This means setting up an infrastructure to enhance understanding and communication of risk issues, and involves:

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

To be most effective, integrated risk management must be woven into the normal working processes and existing decision making structures and processes.¹ Action plans can assist in describing how you will develop your approach to risk management and patient safety, and what it will take to incorporate these into objectives, direction, operational systems and day-to-day practice.⁷

Each primary care organisation, including practices, should:

- Describe how things that go wrong should be reported to ensure lessons are learned.
- Ensure that risk is actively managed and appropriately communicated throughout the organisation or practice.
- Set up multidisciplinary groups to discuss risk management in the organisation or practice. These do not have to be separate meetings but can be integrated into the usual organisational, practice or team meetings, or incorporated into clinical audit, or clinical governance meetings. These meetings should evaluate reporting mechanisms for all risk management; feed up to, and receive feedback from, the relevant managerial and clinical leadership; and have the responsibility for ensuring the development and approval of appropriate policies and procedures required for the effective management of risk.

To achieve an integrated risk management approach, primary care organisations should:

- provide appropriate training to ensure that all staff have an awareness of risk management and patient safety;
- promote and support an open and fair culture to facilitate the ongoing identification and reduction of risk to the organisation or practice, and those who we serve;
- achieve compliance with external accreditation;
- establish an effective risk register;
- ensure teams and practices are using a system for reporting incidents, including significant events; either a paper-based system fed through to an electronic risk management system, or the use of the NPSA eForm;
- review aggregated risk management data and risk assessments and other tools (such as failure modes and effects analyses described later in this Step) to help forecast possible problems and contingency planning;
- review root cause analysis (RCA) and significant event audit (SEA) investigations;
- establish a system for reviewing, updating and disseminating clinical policies and procedures to promote and support best practice;
- ensure appropriate systems are in place for sound governance arrangements in services commissioned.

The primary care trust or local health board should be responsible for:

- approval of the risk management strategy and associated policies, and endorsement of corporate objectives relating to risk management for the area;
- where possible, creating a single point of coordination for the overall policy and strategy, and for guidance and support for teams within their community;
- reviewing the effectiveness of the organisation's internal controls for minimising risk;
- being able to demonstrate that they have been properly informed about the totality of the risks and patient safety incidents;

- being able to show evidence that they have systematically identified the organisation's objectives and managed the principal risks to achieving them;
- delegating executive accountability for risk management to the chief executive.

Risk assessment

The Department of Health's report, *Building a safer NHS for patients*⁹, 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.^{6,10,11} When decisions are made within an organisation or practice, they must take into account any potential risks that could directly or indirectly affect patient care. These risks can be clinical, environmental, financial, economic, political, or those which affect public perceptions and the organisation's reputation. Risk assessment is the process that helps primary care 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 impact.

All primary care organisations must have a formal annual organisation-wide local probabilistic risk assessment programme (set out in relevant external standards). This should be used to identify and assess all risks at three levels of the organisation: strategic, policy and clinical/operational.¹² The information collected through this annual risk assessment programme should be incorporated into the 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.

Workshops on risk management are provided by a number of healthcare organisations, including the Centres for Pharmacy Postgraduate Education (CPPE) and the Welsh Centre for Postgraduate Pharmaceutical Education (WCPPE). CPPE and WCPPE are organisations that provide continuing education and professional development opportunities for all community, hospital and primary care pharmacists in England and Wales. For example, they have workshops which will help pharmacists examine their processes for managing medicines and patient issues in the pharmacy, by reviewing, identifying and eliminating possible risks. They also explore medication errors and how it feels for pharmacists and patients, and helps to identify and manage the problem. This helps pharmacists to meet the government's requirements for clinical governance and the requirements for standard operating procedures (SOPs), and in turn improve the quality of their service.

The Medical Defence Union (MDU) has a free online risk assessment tool which enables general medical practitioners to manage risks in their practice. By answering a series of questions, it will help them identify potential areas of risk and create actions to deal with them. Complete with GMC guidance and MDU advice, the tool is designed to help reduce the possibility of a complaint or claim. An example of the online assessment looks at the risks associated with prescribing, and covers areas such as:

- repeat prescribing;
- drug issues;
- practice nurse issues;
- common pitfalls;
- prioritised actions.

Once an assessment is complete the site helps create personalised actions to address any areas of risk. There is also a benchmarking facility which allows comparison against the UK and Ireland average and against previously saved assessments, allowing practices to chart their progress over time.

Integrated risk assessment

An integrated risk assessment helps primary care 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, can also be involved in the decision process where possible. Each service should take ownership of their own risks and feed these into a risk register for the organisation or practice. The risk assessment process is then used to develop local plans and as evidence for service development.

Risk assessment tools

There is a growing awareness that interventions, knowledge and expertise used to improve safety in other industries can help the healthcare sector understand how we can deal with similar incidents and risks. 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

Probabilistic risk assessment (PRA) examines incidents and their contributory factors and determines the likelihood of the event occurring.¹³ It involves a mixture of quantifying risks and judgement, and applies tools such as event tree analysis^e, and fault tree analysis^f.

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. For example, the PRA process could be used to try to understand the potential ways the wrong drug could be dispensed. There could be a number of different ways this could happen:

- the drug was prescribed wrongly in the general practice and was not picked up by the pharmacy;
- the drug was prescribed correctly but the pharmacy selected the wrong drug to be given to the patient;
- the drug prescription was unclear, and the pharmacy selected the drug thought to be written, but this was the wrong one.

The PRA approach works out the likelihood of each outcome and what could be done to reduce that likelihood. It also attempts to quantify the potential risks by scoring the likelihood of a particular risk or incident actually happening, including a consideration of the frequency with which it may arise.

To help with this quantification, incident data can be assessed along with expert estimation of how often a process could fail, or by undertaking a clinical audit of the process to demonstrate actual failure rates.

^e **Event tree analysis:** this is an approach which, like the branches of a tree, maps out the different paths and factors that can lead to an event occurring.

^f **Fault tree analysis:** this is an extension of the event tree which shows the cumulative effects of the faults within a system.

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

Example of a risk probability framework ¹⁴	
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, a 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 primary care organisations to target their limited resources more efficiently.

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 consequences 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’.

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 primary care organisation should take the following factors into account:

- **Training implications:** each area 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.
- **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 of 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/SEA, the organisation must ensure there are enough staff with the expertise and resources to do this.

Failure modes and effects analysis (FMEA)

FMEA is widely used in industry and has been adapted as a tool for risk assessment in healthcare in the US.^{15,16} It is a proactive tool for evaluating a process or a new product or design of service, to identify potential points of failures and the effect 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 care is expected to be delivered?
- **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 professions, processes and services: initial diagnosis (GP practice), prescribing (GP practice), preparation (pharmacy), dispensing (pharmacy), administering (pharmacy or home care) and follow-up (nurses, general practice or home care). Each step in these processes could potentially result in failure.

FMEA may appear to show a specific failure could cause a specific harm, but whether it would actually do so requires an analysis of the controls and defences in place and an expert view of probability.

Seven stages of 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 primary care organisations, including practices, to 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/SEA 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. Additionally, undertaking an FMEA can provide you with a very clear defence if things do go wrong, in that you did everything you could think of to avoid a preventable injury to a patient.

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

The benefits of FMEA

- 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.

Risk assessment checklist

The Department of Health (England) has published a concise guidance document, *Building the Assurance Framework: A Practical Guide for NHS Boards*.¹⁷ This gives advice on how boards and senior managers can bring together the existing fragmented risk management activity.

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 organisation¹³);
- 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 leaders⁹, new organisational chairs and non-executive directors.

⁹ **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.

The NPSA will help ensure they are supported in doing their work by providing expertise and access to training tools and programmes.

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.

Partnership for patient safety

Improving patient safety is part of the work of all national organisations and groups working in the NHS. Collaboration 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 regularly meets the Department of Health, Welsh Assembly Government, Strategic Health Authorities (StHA), and Regional Offices, Wales. We also liaise closely with review bodies such as the Healthcare Commission, 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

To support NHS organisations in making NHS care safer, the NPSA has set up a network of patient safety managers. There are currently 31 positions, 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 boundaries. Essentially their aim is to provide two-way communication between the NPSA and all local NHS organisations in England and Wales, including primary care organisations.

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, particularly towards 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 building a safety culture

Do you have a good practice story and would you like to share that story with your healthcare colleagues? If so, please send it to **pcsevensteps@npsa.nhs.uk**

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Step 4

Promote reporting in primary care

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Step 4

Promote reporting in primary care

Healthcare incidents typically happen one at a time. The only way in which the total number of incidents can be identified is to set up a reporting system. This is a fundamental requirement to improve patient safety. Without this information, local organisations cannot focus and allocate their resources appropriately to ensure change.

However, reporting in primary care is highly complex. There is huge variation across the care setting in terms of capacity to report and willingness to do so. Factors affecting reporting rates include a lack of integrated computer systems and diverse reporting responsibilities amongst staff who are not in direct line management. Independent contractor professions, such as general medical and dental practitioners and community pharmacists, have reporting requirements which are different to those of primary care organisational staff who work in a variety of settings (including community nurses and allied health professionals). Each primary care organisation needs to consider the best route to obtain patient safety incident information from these disparate, and often fragmented, groups.

There are also pharmacy or optometry companies and other independent contractors that function as a commercial organisation across numerous sites. These companies also have their own specific corporate governance requirements which may include reporting so that they can learn about any incident which occurs. A single reporting format is ideal if the burden of reporting is to be minimised. This will help any professional locum who works across numerous boundaries as they will only receive one format of report form; irrespective of their location. Therefore consideration needs to be given to a reporting format which can meet the needs of the company, and the primary care trust or local health board, while ensuring the burden of reporting is kept to a minimum.

In this Step we explain the importance of creating a local reporting culture in your primary care organisation, practice or team. We will describe the benefits of, and barriers to, reporting, how these will feed into the National Reporting and Learning System (NRLS) at the NPSA, and what this means for local organisations. We also highlight what primary care organisations can do to encourage reporting by, for example, using a common safety language, and what the NPSA can provide in order to 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 reporting incidents important?

As we have already stated in previous Steps, most people receive the majority of their healthcare in primary care settings but our patient safety knowledge in this area is limited.¹ The previous Steps have described how most of the research into patient safety in the UK and abroad has been conducted in the acute sector although there have been some academic studies relating to patient safety in primary care.

If we are going to make a difference we need to understand how the increasing complexity of primary care and the problems encountered by community staff such as general practitioners are affecting patient safety.^{2,3} The changes in healthcare, such as early discharge from hospital, the prescribing and monitoring of potentially high-risk drugs (such as methotrexate for rheumatoid arthritis) and the increasingly diverse nature of primary care, are all increasing the risk of unintentional patient harm.⁴

An organisation with a memory identified an NHS culture which is swift to blame or seek retribution. It also highlighted that as more incidents are reported and the more information is available about what is going wrong, 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 ability to report all patient safety incidents, both locally and nationally. To encourage reporting, therefore, it is necessary to promote an open and fair culture (described in **Step 1**) where reporting is congratulated and individuals are not blamed or penalised if they speak out.

For reporting to work properly, the management, review and understanding of incidents requires clinical expertise, as well as a good understanding of the healthcare environment and the many factors which may contribute to a poor outcome. The NPSA has established the NRLS so that we can start to find out about patient safety problems across the health service. This will allow the NHS to learn lessons and develop solutions to minimise the risk of the same incident happening again.

It should be noted that the NRLS is not a whistleblowing mechanism. The Department of Health issued guidance on whistleblowing in July 2003, including a policy pack which aims to provide support to organisations in developing and/or reviewing whistleblowing policies and procedure. The pack has been produced in partnership with Public Concern at Work. This updates the existing guidance on whistleblowing in the NHS contained in HSC 1999/198 (issued in September 1999 following the coming into force of the Public Interest Disclosure Act (PIDA) 1998).

To be effective, local risk management systems and the NRLS will require the reporting of all incidents which could have or did lead to harm, whatever the level of severity. Analysis at a national level will enable service-wide action where patterns, clusters or trends reveal the scope to reduce risk or prevent reoccurrence for future patients.

The National Reporting and Learning System

The NRLS will provide a core of reliable information on which to base analysis and recommendations. 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. This is a new system, designed by the NPSA and based on international experience and best practice.⁵⁻⁸ The NRLS is an anonymous system for individuals. The NPSA will not retain any names of individual staff or patients. However, the NPSA will know the identity of the organisation for incidents reported through local risk management systems. This will enable all individuals who provide care for NHS-funded patients to have the confidence to report patient safety incidents.

It is important to note that national reporting should be seen as complementary to robust local reporting systems rather than as a replacement for them. Although the NRLS has been designed to extract information from existing local risk management systems, the NPSA recognises that staff in different care settings require flexibility in reporting patient safety problems.

When patient safety incidents are reported to the NPSA, they will be entered into a specially designed, confidential and anonymous national database. They will be aggregated and analysed, with expert clinical input and computerised analytical tools, to help understand the frequency of types of patient safety incidents, patterns and trends, and underlying contributory factors^a. By doing this, the NPSA will inform national and international learning about risks to patient care, establish priorities for action and work with the health service to develop practical solutions to improve patient safety.

The NRLS was developed with the help of 39 English and Welsh NHS organisations and reflects a range of healthcare settings, including primary care and community care 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 system will:

- Collect reports about patients only. It will not collect reports about incidents where staff or third parties, such as visitors, are harmed.
- Enable incidents which involve groups of patients to be captured easily.
- Request only factual information, in answers to free-text questions, rather than opinion.

^a **Contributory factors:** those factors which contributed to the incident either nearly happening or happening – these are explained in detail in **Step 6**.

- Not store the patient's date of birth. This mitigates any Caldicott^b 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 reassure them that no patient-identifiable information will be held.⁹
- Consist of high-level generic categories applicable for the whole service. These categories will provide the NPSA with sufficient information to detect patterns in reported incidents; other information from the form, especially the free-text, will provide the narrative from which we can learn.

How to report incidents to the NPSA

Healthcare professionals are able to report incidents in a variety of ways. They can send reports directly to the NRLS, although we will always encourage staff to share reports with their local primary care organisations. This will enable valuable learning and action to take place at a local level.

Reports will either be received via a technical link to local risk management systems, already in use in primary care organisations, or direct reporting to the NPSA via an electronic reporting form (eForm).

In addition, to help primary care organisations with reporting, the NPSA has developed an individual paper form for use in the practices and teams within their remit. The form is intended to be used as a template that can be adapted to their own reporting needs. The contents meet the requirements of the NRLS as well as the HSE, Clinical Negligence Scheme for Trusts (CNST) and Welsh Risk Pool (WRP). Local patient safety managers can provide organisations and teams with the paper form template.

^b 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:

- 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 in the NRLS.

Reporting via the local risk management systems

Once integrated, incidents that are reported to local risk management systems locally are then fed through to the NRLS. The NRLS can receive incident reports in this way from all primary care organisations, practices, teams and individuals including independent contractors. Patients and their carers can also share their safety concerns with the NPSA via an online Patient and Public Reporting eForm, which can be accessed at:

www.npsa.nhs.uk/pleaseask

The eForm

The eForm can be found on the NPSA website at **www.npsa.nhs.uk/staffreports**. Staff can follow this link and go directly to the form.

Primary care staff or contractors who report incidents into the NRLS will have a choice of reporting through the eForm. The eForm is a user-friendly electronic reporting form that normally takes less than ten minutes to complete. There are eForms for PCOs, general practice, community pharmacy, dentistry and optometry. When reporting directly to the NPSA via the 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, and will not have to identify either themselves or their organisation, if this is the only way they feel able to report an incident.

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 in this way and feedback to local organisations with regard to generic lessons that can be learnt and acted upon.

The NPSA will monitor reporting by all the different routes and will share lessons learned by feeding back information. The NRLS will be able to identify how many incidents are associated with particular specialties or settings and examine themes and common factors.

Benefits of reporting

Reporting will:

- Help build a comprehensive national picture of patient safety in the health service. Over time, the analysis will be available so organisations can benchmark themselves against other similar organisations – for training and raising awareness.
- Give greater weight to local reporting and ensure incidents will be taken more seriously at management and board level.²
- Help individuals and organisations learn lessons about why incidents happen through identifying incidents which require root cause analysis or significant event audit investigations. Local investigations will help develop national solutions in order to reduce the chances of reoccurrence and severity of incidents locally.
- Help the NPSA to prioritise its work programme.
- Increase patient safety knowledge and, in turn, increase patient and public confidence that action is being taken to improve patient safety.

Benefits of reporting are:

- Reported incidents provide evidence to target resources more effectively. They identify areas for change and improvement in both patient care and patient safety.
- 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.
- In primary care, patient safety incidents which originate in secondary care can be picked up when the patient is discharged – identifying these can improve the interaction between secondary and primary care.
- 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, therefore saving time and resources.
- Financial benefits arise from reduced severity of incidents, e.g. reduced costs of treatment and/or reduced length of stay.¹⁰

- 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 regularly inform the health service of the lessons being learned and the recommended changes to prevent errors or systems failures reoccurring. It is extremely important that staff receive feedback and understand how important incident reporting is to enable these changes to happen.

Terminology and definitions

The NPSA has developed a common language around patient safety, following a review of global safety terminology and definitions, together with a number of workshops with local health service organisations, risk managers, patients and the public. Table 1 sets out the NPSA's preferred terms, their meaning, and the terms they are designed to replace. It should be noted that these terms are not in general use internationally and may have to be adopted as work on an international taxonomy progresses.

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 as well as creating a consistent approach in risk management systems throughout the health service. The dataset is available in full from the NPSA website.

Local risk management system software vendors are integrating this dataset into their products. Consequently, if individuals choose to report incidents to their local risk management system, and the system is linked to the NPSA, they will automatically be reporting to the NRLS without any additional burden on the reporter or their organisation.

Table 1
The 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. '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
- 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.

In fact, a 'near miss' should be described as a patient safety incident that either had the potential to cause harm or was prevented from causing harm to one or more patients. The very fact that two aeroplanes experience a near miss, means that an incident has happened, i.e. two aeroplanes flew too close. A prevented patient safety incident could be an incident that was prevented by action, by a colleague noticing a mistake was about to happen before the mistake was made, e.g. a dentist about to remove the wrong tooth or a GP prescribing daily methotrexate rather than weekly, which is picked up by the pharmacist. Both of these incidents caused no harm, but could have.

It is vital that prevented or potential incidents are reported and analysed in the same way as other incidents. These are really good ways of learning about the barriers or controls that worked, or the actions taken to prevent an incident from having an impact.

Grade incidents according to harm

Care delivered to patients may also lead to various levels of harm, whether as a consequence of treatment, ineffective care, human error, or harm as a result of the processes within the care providing system. 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 may require an inpatient stay. 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, primary care organisations can ensure consistency and comparability of data. This consistent approach locally will enable the NPSA to compare and analyse data nationally.

While the national system does not require it, local organisations may also want to grade incidents for potential harm, likelihood of reoccurrence, impact such as adverse publicity or loss of public confidence (noting that this is difficult to quantify), or cost of potential litigation damages.

Table 2
The NPSA's terms and definitions for grading patient safety incidents

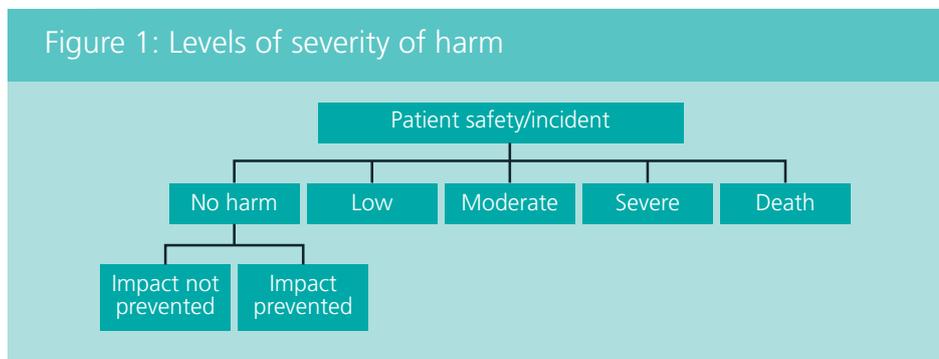
Old terms	New terms
None/ insignificant	No harm: <ul style="list-style-type: none"> • Impact prevented – Any patient safety incident that had the potential to cause harm but was prevented, resulting in no harm to people receiving NHS-funded care. • Impact not prevented – Any patient safety incident that 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 ^d 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 ^e 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 ^f to one or more persons receiving NHS-funded care.
Death/ catastrophic	Death: Any patient safety incident that directly resulted in the death ^g of one or more persons receiving NHS funded care.

Mitigating circumstances

When reporting to the NRLS, primary care 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 ten because of actions taken at the time).

-
- ^d **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 out-patient, or continued treatment over and above the treatment already planned. Nor does it include a return to surgery or re-admission.
- ^e **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 out-patient, cancelling of treatment, or transfer to another area such as intensive care as a result of the incident.
- ^f **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.
- ^g The **death** must relate to the incident rather than to the natural course of the patient's illness or underlying condition.

Figure 1: Levels of severity of harm



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

What should be reported?

Incidents which should be reported include:

- Those that harmed patients.
- Those that did not lead to harm because they were prevented from reaching the patient. Reporting these means that we can learn about what actions prevent incidents from occurring and how these can be shared in different circumstances.

Components of a patient safety incident

The analysis of incidents using a robust methodology is described in detail in **Step 6**. However, there are a series of components which need to be considered when reviewing the incidents in order to improve patient safety.

Causal factors play a significant part in any patient safety incident. Removing them can prevent or reduce the chance of a similar incident happening again. There is usually more than one causal factor in any incident. 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 such as stress, inadequate training and assessment, poor supervision or high workload.

Examples of active failures

- Drug-related errors, such as those resulting from prescribing the wrong medication or dose, misinterpreting the correct prescription or prescribing instructions, or using incorrect routes of administration. For example, the drug fridge in a general dental practice is regularly re-stocked with new supplies. The old stock is normally brought forward and the new stock placed behind it. However, this system gets forgotten and a patient is given a drug which is beyond the 'use-by' date.
- Diagnostic error, such as misdiagnosis leading to an incorrect choice of therapy, failure to use an indicated diagnostic test, misinterpretation of test results and failure to act on abnormal results.
- Equipment failure, such as defibrillators with dead batteries.
- Communication failure, for example, a patient phones in for a visit by a general practitioner. The receptionist taking the call is very busy and, rather than stopping to locate the visit book, writes the visit details on a piece of paper to add to the visit book later. This gets forgotten and the visit gets missed.

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. Latent conditions combined with local conditions (active failures and contributory factors) create the potential for incidents to happen.

Examples of latent system factors

Planning: staffing levels and rotas take into account sickness and annual leave, but fail to make allowances for extreme circumstances with large numbers of staff sick and services for patients being suspended.

Designing: designing a new clinic, or practice, without considering vulnerable groups, such as children or mental health patients, and leaving dangerous equipment within easy reach.

Policy-making: latent factors in primary care can also be affected by policy making in secondary care, for example, there may be a secondary care policy regarding take home policy for drugs, which doesn't take into account difficult times to get to a pharmacy (for example, holidays such as Christmas) or rare drugs that may not be local stock items; causing knock-on effects for local practices and patients.

Communicating: there may not be structures and processes in place for staff in primary care to share and learn from patient safety incidents, which means vital lessons are not learned across the organisation, practice or team.

Violations

These are when individuals or teams fail to, or choose not to, follow a known procedure, policy or guideline for a number of reasons, including:

- **awareness:** they may not be aware of the procedure, policy or guidelines;
- **pressure:** external pressures including workload, targets, or staffing, require a deviation;
- **situational:** the clinical situation dictates a deviation as it is 'in the best interests of the patient';
- **habitual:** it has become habit ('this is how we always do it in this organisation') or people have 'got away with it' for some time;
- **applicability:** the procedure, policy or guideline has been found not to work; or the procedure, policy or guideline has been surpassed by a new one but it has yet to be rewritten.

Violating a procedure, policy or guideline is not necessarily the wrong thing to do; in fact it can be a fairly common event in healthcare. Healthcare is often a combination of rules, procedures and expert clinical judgement. It may well be, as stated above, that the current guidance is outdated or not applicable but this has not yet been expressed in writing. It may also be that staff and teams are required to use their judgement in the best interests of the particular patient. A purely rule-based organisation that never violates policies or procedures could even be considered riskier than one that allows violations in certain circumstances.¹³ Again this requires a balanced approach.

Contributory factors

The complete NPSA classification of contributory factors is available on the NPSA website: www.npsa.nhs.uk These are factors that can contribute to an incident in relation to the following:

Other considerations when analysing an incident:

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

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

Mitigating factors: some factors, whether action 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.

Incident reporting in primary care

The chief aim of any risk management system developed in primary care is that it fits in with unique local circumstances and requirements. Some primary care organisations have purchased a local risk management system and have placed terminals in each general practice for teams to use. Some have decided to use the NPSA eForm as their sole reporting mechanism.

Clearly, one of the key areas for change is the reporting requirements of independent contractors. They not only need to have internal mechanisms for knowing what is going wrong in their practice, but need systems for informing their local primary care trust or local health board in accordance with the General Medical Services (GMS) contract and organisation's policies.

A successful reporting programme is dependent on an open and fair culture, where staff are supported when things have gone wrong, as described in **Step 1**. In England and Wales there are a number of organisations which can be consulted by all primary care organisations in relation to their disciplinary procedures. These include: local medical committees (LMC), statutory bodies representing all NHS GPs in a particular area; local pharmaceutical committees, (LPC), local dental committees (LDC), the British Medical and Dental Associations (BMA, BDA), and the royal colleges.

A key aspect of the primary care setting will be the interface between the primary and secondary care settings. Primary care locations will undoubtedly identify issues that have happened in acute care or ambulance care, or vice versa, i.e. wrong medication, difficult discharge, test follow-ups, inappropriate admission information, and so on. These incidents should be reported locally, with the primary care organisation and shared with the originators of the incident to enable learning across all the care settings.

Increasing reporting

It is important that all staff know what patient safety incidents to report, how to report them and what the benefits are. Incident reporting systems need to be well defined and easy to use. The key success factors of both local and national systems are to understand the barriers to reporting and to develop a reporting culture which is open and fair. Tips to increase reporting are:

- Make it simple to report, and communicate this widely.
- Ensure timely and valuable feedback – one of the biggest challenges in the patient safety agenda but vital to ensuring continued reporting.
- Provide ongoing training sessions to explain the process and the benefits and demonstrate the importance of reporting. Use stories of change to show how changes can be made.
- Inform all new staff on orientation, including all grades of staff and professions.
- Disseminate safety information through newsletters, local intranet sites, presentations, safety focus meetings, safety briefings, executive walkabouts/drive-about etc.
- Disseminate success stories, good practice and improvement tips.
- Ensure clinical and managerial leadership support.
- Provide a 'reporting pack' of background information, key contacts, roles and responsibilities, example feedback reports, patient safety definitions, etc.
- Undertake surveys and audits of reporting levels, evaluate the percentage of staff who report (typically between 70 and 80 per cent of reporting is from nursing staff, with between two and three per cent of reporting by doctors) and focus presentations and training to those that under-report. Find out what would make it easier for them to report and demonstrate what particular benefits they can gain.

Barriers to reporting

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 health service must overcome:²

- **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. Independent contractors may have concerns that reporting incidents may be perceived as evidence of poor performance and jeopardise future work with healthcare organisations. An open and fair culture is addressed in **Step 1**.
- **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 solely the responsibility of the clinical professions.
- **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.

Confidentiality and anonymity

The NPSA needs to maximise the trust of all 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 into 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 to 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 primary care organisations directly where there is a pattern of concern emerging from our data analysis.

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 and complexity);
- the ability to feedback to primary care organisations reporting via the local risk management system;
- the ability to request focused root cause analysis for key incidents;
- the opportunity for 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 their local primary care organisation, the data will be shared with that organisation.

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

- 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 identifying information is included within the incident report received via a local risk management system or eForm, it will be removed via cleansing software, prior to storage in the NRLS database. Any identifiable data which passes through this stage 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.

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 is establishing 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 of further work to determine the scale and general severity of any issue(s) highlighted.

What do primary care healthcare providers need to do?

Currently, healthcare staff who move around the service have to become familiar with a variety of different systems wherever they go and there is often a lack of clarity about what issues to report, how to report them and to whom. In this section we outline some of the things that need to happen to help people report at a local level. 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.

2 Link local reporting systems with the National Reporting and Learning System

Implementation of the NRLS took place in 2004. Rolling out the NRLS may require primary care organisations, practices and teams to change the way that they record and report patient safety incidents internally. Although there will be variation in how people report to the NRLS, the following are the three core foundation stones for successful reporting:

Awareness and understanding: people 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.

Readiness and planning: people 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.

Installation and connectivity: those responsible for local information systems will need to access technical support from the NPSA (and the local risk management system 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:

- all primary care trusts and local health boards 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 and the local NPSA patient safety manager (who have already established contacts with their local patient safety manager) will need to work together to agree an implementation plan;
- the local lead contact must decide their preferred reporting route to the NPSA.

How can the NPSA help with connectivity?

To help primary care trusts and local health boards develop their local implementation plans, and support the roll-out of the NRLS, the NPSA will:

- **Support** them 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 back-up 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 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.

Support functions

Help desk: it is planned that, wherever possible, the queries of primary care organisations will be dealt with in the first instance by the relevant patient safety manager. Additional information can be gained from the NRLS implementation help desk: telephone 020 7927 9500.

Detailed guidance on how to get connected and 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 primary care 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 primary care 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 primary care 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.

eForm templates: these are for use by primary care 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.

Examples of primary care incidents according to severity

No harm (impact not prevented):

- Two patients with the same name have their records amalgamated; this is picked up when the patient is seen again (e.g. in a GP clinic) before any incorrect diagnosis or treatment.
- A patient is on medication that requires blood pressure monitoring. The hospital discharge letter does not 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 observations are then found to be normal.

No harm (impact prevented):

- Wrong bottles used for blood tests taken at GP practices, causing false readings and irregular results with the potential for wrong diagnosis. The irregular results cause concern so that the blood is re-tested before any treatment is prescribed.
- A patient is receiving warfarin as an out-patient and the GP surgery forgets 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 the normal limits.
- A patient rings their GP practice for a follow-up appointment to monitor cholesterol levels after commencing statin drug therapy. The patient is provided with an appointment, but would have been forgotten if the patient had not rung.
- A GP prescribes an inappropriate dose of a drug, which the local community pharmacist picks up when dispensing the prescription.

Low:

- A patient trips and falls in the practice, resulting in a wound which requires stitches and a dressing.
- 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.

Moderate:

- Continuing treatment with warfarin without monitoring clotting levels for a length of time which results in an overdose and bleeding problems, which require close monitoring and follow-up.
- 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.

Severe:

- Continuing treatment with warfarin without monitoring clotting levels for a length of time 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.
- A patient, who is a heavy smoker, visits the GP with a cough. The patient's name is Mr JJ Jones. He has a chest x-ray and the report suggests a suspicious lesion with the advice to refer for further investigations. The GP writes on the report that an urgent appointment is needed and the receptionist files the report in Mr J Jones's file. Mr JJ Jones rings the surgery for his results and the receptionist looks in his file and says that no report has been received yet and that the practice will ring him if there is any news in the next week. Mr JJ Jones doesn't hear so assumes everything is OK. Two months later Mr J Jones visits the GP on a routine appointment and Mr JJ Jones's urgent request is found. Mr JJ Jones is referred and it is found that he has lung cancer.

Death:

- Continuing treatment with warfarin without monitoring clotting levels which results in a brain haemorrhage and death.
- A practice receives a telephone call from a mother with a small child who seems unwell. The details are taken and a non-urgent note is left for the GP to give the mother a call at the end of surgery. When the GP rings, the child is now quite ill with suggested meningitis symptoms. The GP immediately visits the child and gives antibiotics and arranges an emergency admission. However, the child collapses on route and is pronounced dead on arrival to hospital.
- A patient suffering from chest pains is asked to wait for a free slot in the GP surgery, as he feels difficulty in getting his breath; he goes for a walk, collapses and dies in the GP surgery's car park.

Good practice example

Paul Manson, a prescribing adviser with Plymouth teaching Primary Care Trust (tPCT) was undertaking a review of medication for care home patients in a surgery, when he came across an instance where concentrated peppermint water was inadvertently prescribed when the normal diluted formulation was intended for an adult patient. Peppermint water concentrate is 40 times stronger than peppermint water. Fortunately the community pharmacist realised the prescribing error and only peppermint water was supplied.

Plymouth GPs and pharmacists were sent an alert by the PCT advising caution when 'peppermint water concentrated' is prescribed. The peppermint water was ordered on a computer-generated prescription by the practice which uses the InPractice (Vision) GP system. The drug database (which is provided by FirstDataBank) used to list only the concentrated peppermint preparation.

Paul Manson contacted both InPractice Systems and FirstDataBank alerting them to the problem with peppermint concentrate. Both have now taken action and dilute peppermint has been added to the Drug Dictionary – and comes up first on the list under 'peppermint'. As an interim measure practices were instructed to make peppermint water the default dosage for both 'peppermint con' and 'peppermint water conc'. An instruction has been added on the concentrate: 'Warning: Must not be given undiluted'.

Promoting reporting

Do you have a good practice story and would you like to share that story with your healthcare colleagues? If so, please send it to pcsevensteps@npsa.nhs.uk

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Step 5

Involve and communicate with patients and the public

Step 5: involve and communicate
with patients and the public

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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.¹ The risk of health problems decreases when patients take responsibility for their own lifestyle, safety and health. Experience shows that patients' definitions of harm and error sometimes differ from the definitions used by clinicians. 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 health service must be open and receptive to engaging with patients.

In this Step we outline NHS guidelines for patient and public involvement to date, describe some of the initiatives the NPSA is undertaking and look at how primary care organisations, practices and teams can encourage openness and engage with patients to help make the service safer. The Step discusses three areas of involvement:

- involving patients and the public in developing safer services;
- involving patients in their own care and treatment;
- encouraging an open, two-way dialogue between health professionals and patients when things go wrong, known as 'being open'.

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.

What can primary care organisations do?

1 Involve 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 health service as experts in their own condition and this expertise can be harnessed to help identify risks and devise solutions to patient safety problems.²

All primary care trusts and local health boards 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 patients 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.

Patients should also be represented on committees that make decisions about how risks are managed and safety issues dealt with. Patient advisory liaison services (PALS) and community health councils (CHCs) can help by acting as an early warning system for primary care organisations by monitoring trends, highlighting gaps in services and making reports for action to management.

2 Involve patients in their own care and treatment risks

There is plenty of evidence to show that patients want to be involved as partners in their care.^{3,4,5} This kind of partnership, already well developed in primary care, 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

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.^{7,8} 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. Primary care organisations need to encourage good risk communication between health professionals and patients. Individuals and teams may need to have training to achieve this.

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There are a number of tools to encourage patients to play a part in preventing errors and systems' failures. For example, the approach known as 'speak up',⁹ 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 for the UK:

SPEAK UP

- 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 and treatment.
- 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.

Speak 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;
- 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 healthcare staff if something doesn't seem right.

Pay 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;

- make sure healthcare staff confirm your identity when they give you medicines or administer treatment;
- notice if healthcare staff wash their hands before and after your treatment or when you are being examined – it is OK to remind a doctor or nurse to do this.

Educate yourself about your diagnosis and treatment:

- 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.

Ask 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 ask;
- make sure your advocate understands your preference for care.

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Know 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;
- tell healthcare staff about any 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 may not be able to either.

Understand more about your local NHS organisation:

- you have a choice of the treatment prescribed for you – find out all the options;
- 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.
- has your primary care organisation been assessed by the Healthcare Commission and Health Inspectorate Wales? What did they report?

Participate in all decisions around your treatment:

- agree with healthcare staff exactly what will be done during each step of your care;
- participate in decisions around your treatment such as medications or investigations;
- participate in decisions taken to refer you to secondary care.

3 **Being open: encourage an open, two-way dialogue between health professionals and patients when things go wrong**

Openness and honesty 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 patient who is harmed, and/or their relatives or carers want to be given information about what has happened. Often they want someone to say sorry. 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.¹⁰ Openness and honesty can also help prevent such incidents from becoming formal complaints and litigation claims.¹¹

A MORI survey commissioned for the Department of Health's consultation document, *Making amends*,⁹ interviewed 8,000 people in the UK. Just under five per cent of them considered they had suffered injury or other adverse effects as a direct result of their medical care with the NHS. Of these:

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

Therefore, there are three important elements of being open:

- an apology and explanation;
- a thorough investigation following the incident;
- support in coping with the physical and psychological consequences of what happened.

When things go wrong, local primary care organisations and practices can help ensure a two-way dialogue exists between the health service and patients by:

- developing a local policy on *Being open*;
- engaging with patients during investigations;
- designating key staff to have responsibility for *Being open*;

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- providing training and support to staff in communication skills;
- providing support for patients.

The NPSA has developed a *Being open* policy and a safer practice notice which are now on the NPSA website (www.npsa.nhs.uk). To support the implementation of local *Being open* policies, a package of tools and resources, including one day video and forum theatre-based training sessions and an e-learning tool are now available. For more information visit the *Being open* academy www.msnpsa.nhs.uk/boa

***Being open* policy**

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 or admit liability. Developing a local policy that sets out the process of communication with patients will provide practices, teams and individuals 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 and their relatives or carers;
- details of external reporting requirements;
- details of the support and follow-up required for both the patient and staff.

Framework for a *Being open* policy

Policies and procedures for being open with patients should be developed in line with our national guidance document, *Being open* which is now available 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

Staff should strive to acknowledge all patient safety incidents 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 is 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, or medical jargon which they may not understand.

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, and be given as early as possible.

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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 and 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, CHCs in Wales and other relevant support groups should be given to the patient as soon as possible.

5 Principle of professional support

Primary care 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 *Being open* policy 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. 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^a

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 the privacy and confidentiality for the patient, their relatives and/or carers, and staff. 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.

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:

^a **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.

Step 5: involve and communicate
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- 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, which may be someone from outside the team or organisation. Referral to another care provider may occasionally be required.

Designating key staff to have responsibility for *Being open*

The person who should inform the patient and their relatives or carers about the incident should be senior, credible and have a knowledge of the patient's care. 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 and their 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 and their relatives or carers.

In addition, primary care organisations should identify clinical, nursing and managerial opinion leaders who will promote the *Being open* process across the practice, service or organisation. Most healthcare provision involves multidisciplinary teams, so *Being open* needs multidisciplinary representation.

Providing training and support to staff in communication skills

The NPSA is developing tools 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.

4 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 is 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;
- 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 <i>Being open</i> policy should be implemented.

Step 5: involve and communicate with patients and the public

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 or significant event audit 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 primary care organisation will do to prevent the incident from happening again.

5 Providing support for patients

Providing support for patients and their relatives or carers is crucial. Primary care 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 bereavement or counselling services, religious support, and PALS/CHCs;
- information on external support services such as the Citizens Advice Bureau, Action against Medical Accidents (AvMA), and other patient support groups.

How can the NPSA help?

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

- developing best practices for communication with patients, which incorporates the principles of *Being open*;
- ensuring patient safety is a priority throughout healthcare by setting clear objectives in our guidance for primary care organisations and leaders;
- providing advice and guidance through primary care 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.

Examples from the NPSA

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

- Involving the public, patients and the voluntary sector in workshops to discuss how we should prioritise patient safety issues to work on.
- Including patient and public representation on the NPSA Expert Advisory Panel for the prioritisation process.¹²
- Involving patient representatives and members of the public in developing the system for patient and public reporting. This will complement the National Reporting and Learning System (NRLS) for NHS staff and organisations.
- Recruiting patient representatives as active members of the working groups set up to develop solutions to patient safety problems.
- Working with patients and patient groups to design products and materials and test their effectiveness.

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.

Step 5: involve and communicate
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'Ask About Your Medicines' leaflets

A MORI poll in 2003 showed that up to 50 per cent 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. These are placed across the health service wherever medications are prescribed and dispensed. The card features five key questions and five top tips to help patients learn more about the medicines they are prescribed.

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.

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.

Good practice in involving and communicating with patients

Case study: Sheffield South West PCT Podiatry

Department

This department set up a patients' panel in 2000, which enables patients to be consulted on service planning and delivery. There are five patient places on the panel, which meets at varied intervals from one to four months depending on the need. They were recruited through the clinics run by the department via posters in waiting areas, the patient newsletter and direct approaches to patients showing an interest. The panel is representative in terms of gender, ethnicity, age and disability. The patients on the panel are collected by taxi, provided with lunch and given a small gift in recognition of their contribution, but are not paid for their time in attending.

The panel is chaired by the head of the podiatry service or the deputy head of the service. The department collates issues to be raised with the panel from their service perspective. Panel members can also ask for particular items to be placed on the agenda either by telephone or in writing.

The panel influences all aspects of service quality including clinical/care pathways. The issues explored are varied and informed by new service developments and have included empowerment and podiatric surgery, information sheets and correspondence to be made available for patients, non-attendance for clinical appointments, general policy, complaints, and resource issues and allocation. The group discuss patient safety incidents and potential solutions to these identified issues.

Action tasks are created from the minutes and fed into relevant groups through appropriately identified people within the department, or members of the panel; particularly if members are undertaking specific tasks. Issues may also be fed out of the department into other PCOs groups for consideration, or even into the national arena as happened with the Workforce Planning report that came out of this group.

The panel has influenced patient safety through clinical audit visits, where they pick up on environmental issues and elicit viewpoints from other patients on all matters, which could include safety issues, through suggestions which have improved failed attendance and therefore contributed to appointment availability and reduced waiting times.

Step 5: involve and communicate
with patients and the public

Promoting reporting

Do you have a good practice story and would you like to share that story with your healthcare colleagues? If so, please send it to **pcsevensteps@npsa.nhs.uk**

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Step 6

Learn and share safety lessons

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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^a. It is equally important that primary care organisations look at the underlying causes of patient safety incidents and learn how to prevent them from happening again. When things go wrong, human error is routinely blamed as the cause. However, quick assumptions and routine assignment of individual blame do not get to the heart of the problem. Closer analysis reveals that there are many underlying causes which contribute to patient safety problems and, in the majority of cases, these causes extend beyond the individual staff member or team involved.

Incidents may occur because of any one of multiple reasons. It may be that staff have not had access to the necessary training, or because the policy or procedure that they are working with is outdated and does not reflect current practice or apply to existing equipment.

In this Step we explain how to use chronological investigation techniques – significant event audit (SEA) and root cause analysis (RCA) – to find out what went wrong in a patient safety incident, how and why. We suggest how primary care organisations, practices, including pharmacies, and teams can learn safety lessons through SEA/RCA and what the NPSA can do to help.

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 **Patient safety:** the identification, assessment, analysis and management of patient-related risks and incidents in order to make patient care safer and minimise harm to patients.

Why is it important to learn and share safety lessons?

When the safety of a patient has been compromised it is tempting to explain it as the product of negligence, incompetence or carelessness on the part of staff, or as a rare misfortune that is neither predictable nor preventable. But 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.²⁻⁵ 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 crucial 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 balanced systems approach to error is 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^b of future harm^c. 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}

For staff and primary care contractors to feel comfortable reporting significant events or incidents, they must have confidence in the culture: that it is open and fair, and that staff can feel able to speak up when they have concerns, and where they know they will be treated fairly if they do so. Creating, nurturing and sustaining that culture is a responsibility of each and every one of us; as is the responsibility to report significant events and patient safety incidents.

An open and fair culture does not detract from the individual's professional responsibility and accountability as set out in their codes of conduct on practice. These quite clearly define that the individual practitioner is responsible for maintaining competency to practice.

^b **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.

^c **Harm:** injury, suffering, disability or death – physical, psychological, social.

A summary of the benefits of a consistent approach to incident investigation

Significant event audit (SEA) can be applied to all aspects of healthcare, and should be undertaken by all primary care practices including medical, dental, pharmacy and optometry. It fosters a practice team spirit as it requires a multidisciplinary approach and can be incorporated into day-to-day practice life. It does not usually involve major data collection and can bring about real change to patient care. Staff, patients and carers are reassured that lessons are being learnt, necessary actions taken and improvements made to healthcare delivery.

In addition, SEA forms an integral part of practice framework for delivering clinical governance and meets the requirements of the new General Medical Services (GMS) contract; additional points and funding can be awarded if a general practice undertakes SEA.

SEA has benefits for staff too. They feel listened to and empowered to bring about change, their training and development needs are identified and they are provided with a formal process through which to celebrate their successes and champion best practice.

Root cause analysis (RCA) is another form of incident investigation that can help primary care organisations, staff and teams address patient safety problems. It is a technique for undertaking a systematic investigation that looks beyond individual staff involved in an incident and seeks to understand the underlying causes and environmental context in which the incident happened. Although it has not been widely used in primary care to date, it is an effective and useful method of uncovering the real causes of incidents so that learning and action can take place.

The RCA approach:

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

When to do an SEA or RCA

The level of analysis of an incident depends on the severity and complexity of the problem; time and resources available; and capacity and capability. The length of time an investigation takes will vary depending on the complexity; it could take one hour, one day, one month or even one year.

In primary care, most incidents or events which result in either no harm to the patient or low to moderate harm should be reviewed using SEA. Incidents which result in severe harm or death should be reviewed using RCA. If the data identifies themes and patterns, the organisation may want to undertake a focused or aggregate RCA/SEA, bringing together a number of incidents.

Table 1
Levels of severity of harm

Grade	Levels of severity
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	Any patient safety incident that required extra observation or minor treatment ^d and caused minimal harm, to one or more persons receiving NHS-funded care.
Moderate	Any patient safety incident that resulted in a moderate increase in treatment ^e and which caused significant but not permanent harm, to one or more persons receiving NHS-funded care.
Severe	Any patient safety incident that appears to have resulted in permanent harm ^f to one or more persons receiving NHS-funded care.
Death	Any patient safety incident that directly resulted in the death ^g of one or more persons receiving NHS-funded care.

- ^d **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 out-patient, or continued treatment over and above the treatment already planned. Nor does it include a return to surgery or re-admission.
- ^e **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 out-patient, cancelling of treatment, or transfer to another area such as intensive care as a result of the incident.
- ^f **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.
- ^g The **death** must relate to the incident rather than to the natural course of the patient's illness or underlying condition.

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.

Table 2
Level of investigation for different grades of patient safety incidents

Grade	Level of investigation
No harm: <ul style="list-style-type: none"> • impact prevented • impact not prevented 	Local organisations and practices, including pharmacies, 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 such as SEA is required.
Moderate:	Organisations should assess their capacity to investigate and undertake a level of investigation accordingly.
Severe:	A full RCA should be undertaken. The patient and carers should be informed and involved in any investigation.
Death:	A full RCA should be undertaken. The patient's carers should be informed and involved in any investigation.

Significant event audit

Significant event audit (SEA) is used predominantly in primary care and in particular in general practice.⁹⁻¹⁶ In essence, a significant event may be something that has gone wrong or something that nearly went wrong – any event thought by anyone in the team to be significant to the care of patients or the conduct of the practice.¹⁷

Equally as important, a significant event may be something that has gone extremely well, where patient care or the working lives of healthcare teams has been enhanced as a result.

SEA is an important part of clinical governance and a key component of the new GMS contract.¹⁸ It helps us to understand what happened in a situation that was generally felt to be outside the norm, to learn from it, and to make changes that will, consequently, lead to improvements in the services we provide. It usually involves investigating a single case or a review of a number of incidents with consistent themes so that

lessons are learned, both positive and negative.¹⁹

Any member of the primary care team should be encouraged to raise events, which are significant to them, for discussion by the whole team. Also, patients' experiences can be highlighted and discussed. All of these viewpoints can be looked at in a systematic and supportive way by using significant event auditing. A structured method, such as this, allows trust to be built so that your team can focus on 'what is wrong' not 'who is wrong'.

The process should be safe and supportive and used to generate solutions. The emphasis is on changing systems not apportioning blame. The techniques can:

- help develop a culture in which safety becomes a daily focus;
- show that reporting makes a difference to patient care and patient safety;
- help increase reporting rates;
- help develop a team culture.

Significant event auditing should be used for events or incidents which resulted in no harm to the patient, and those that resulted in low to moderate harm. For severe harm and patient deaths, there will be the need for a more in-depth root cause analysis. Root cause analysis is described later in this Step.

Significant events include aspects which affect patients, staff, environment, administration and decision-making. All instances provide opportunities for learning, sharing and improving. They can be identified as:

- **Best practice:** an audit can be carried out in relation to a new way of doing things, the identification and implementation of evidence-based practice or the development of local protocols.
- **Feedback from patients:** the process for SEA can be used for verbal or written compliments and complaints, information from patient surveys and suggestion boxes.
- **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. These represent a deviation from the intended care delivery identified through either risk assessments or incident reporting.

Significant event audit stages²⁰

Stage 1: immediate action

Take immediate action and log events/incidents. The significant event/clinical governance lead for the team will have responsibility for ensuring the timely reporting of significant events and outcomes of any analysis. A database should be developed to capture all events and incidents. This should be analysed on a regular basis to provide:

- feedback;
- trend analysis;
- lessons learned for sharing;
- reports to the relevant committee;
- a reference database for clinical and practice teams to refer to for best practice;
- information for the PCT/LHB risk register.

Stage 2: collation of information

Identify the individuals involved and collect relevant documentation. There will be occasions when a significant event involves parties external to the immediate team. For example, an optician may be asked to assist a general practice team to audit a significant event regarding diabetes and a practice team may be asked to assist a health visiting team about immunisations.

Stage 3: meeting

Set up and facilitate a SEA meeting. Each team should meet regularly (at least every other month) to consider the events that have been reported in the last month and to review the recommendations of previous significant events to ensure their implementation. As many members of the team as possible should be present and the meetings should be expertly facilitated. It is essential that, from beginning to end, the ambience of the process is one that is open and fair.

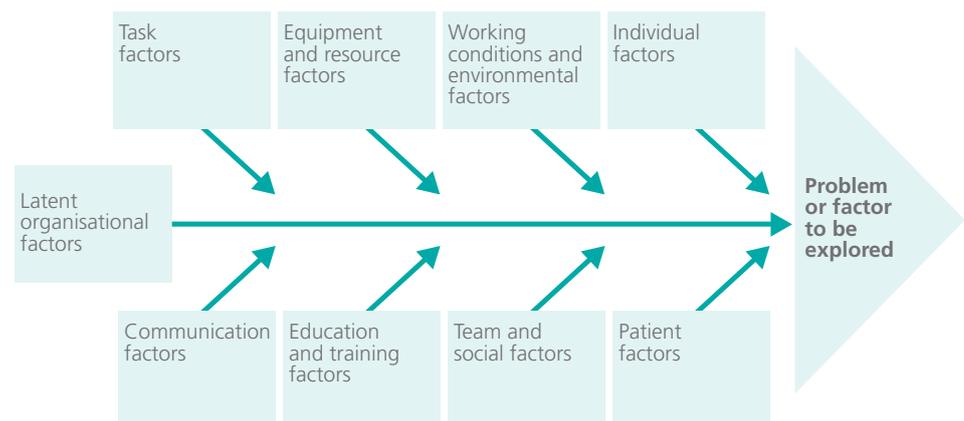
Stage 4: analysis

Use the meeting to identify the chronology, causal factors and contributory factors which led to the outcome and list possible solutions for change. Ensure staff are congratulated for aspects which were handled well. Decide on immediate, short-term actions, long-term actions or no action. Decide on whether there is a need to progress to a full RCA. A simple tool for both SEA and RCA is a process called the 'five whys'. Also known as the 'why-why chart', it focuses on enabling the SEA/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 a team. After the gathering and mapping of information, which identifies problem areas, it asks why each problem occurred until the root cause is found.²¹ 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.

Another tool to use for both SEA and RCA is the fishbone diagram.

Fishbone diagram



The fishbone diagram is a simple pictorial way of representing contributory factor information. 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 overleaf). These represent the main areas in which you may want to explore the active and latent factors that contributed to the identified issue or problem.

The investigators may not find factors for each heading and should not 'force' factors so that there is something in every category.

Active factors or failures are those actions or omissions by staff in the process of care. Latent factors or conditions are those decisions taken some time before the incident or event which lie dormant. It is only when various active and latent factors combine that they are shown to have the potential to cause harm.

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 spoken.
- **Individual factors:** these are unique to the individual staff member(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.

Stage 5: recommendations

It is vital that the team reflects upon previous significant events, particularly the resulting recommendations, to ensure that they have been implemented as agreed. Each team, as part of the SEA process, will define who has responsibility for implementing the recommendations and what the timescale is. This should be recorded on a significant event record form. Following implementation of recommendations the event rating must be reviewed and recorded at the bottom of the significant event record form.

Stage 6: report and share

Nominate a lead to complete a report. Share the learning with others. In some cases the primary care organisation is required to report significant events to external organisations. These include:

- Strategic Health Authority/Regional Office;
- National Patient Safety Agency (NPSA);
- Medicines and Healthcare products Regulatory Agency (MHRA);
- Welsh Health Supplies;
- Health and Safety Executive through RIDDOR (Reporting of Injuries, Diseases and Dangerous Occurrences Regulations).

Examples of significant events in primary care for audit

The following is not meant to be an exhaustive list but provides a guide to the sorts of events which could be referred for a SEA:

- letter received but not acted upon;
- referral letter required and is delayed, not sent or misdirected;
- abnormal results not acted upon;
- breach of confidentiality;
- patient complaints;
- referral letter not sent;
- staff concerns;
- medication error (incorrect patient; incorrect drug; wrong formulation, strength, dose, quantity; wrong advice; illegible or incomplete prescriptions; adverse drug reactions; drug interactions; similar packaging; poor storage and layout);
- incorrect delivery of results, documentation, samples, and so on;
- equipment failure;
- incorrect advice;
- misdiagnosis;
- collapse;
- wrong treatment;
- physical or verbal abuse;
- home visit listed but not done;
- need for urgent appointment missed;
- illegible handwriting;
- phone call received but not passed on;
- lack of written protocols;
- poor inter-professional relations;
- poor internal communications;
- patient taken ill on-site;
- rude/aggressive customers/patients.

A number of examples can be found in **Step 4** and some more are described below:

A patient is prescribed a drug which has the potential to interact with their current medication: this is noticed by the community pharmacist who, following a call to the practice, does not dispense the medication and informs the patient they need to return to the GP who will prescribe another medication.

A GP is out on a visit and receives a telephone call to visit a child in the next street who is unwell and can't come to the surgery. The grandmother is looking after the child and states that the child is not allergic to anything. The GP prescribes penicillin. On return to the surgery the GP enters the information on the computer and notices that the child is allergic to penicillin. The grandmother is contacted and, as the prescription has not been dispensed, an alternative drug is prescribed.

The practice nurse does a smear test on Mrs W and informs her that she will be notified if there are any problems with the results. The result comes back abnormal and the practice tries to contact Mrs W but there is no record of a telephone number and she is ex-directory. A letter is sent but this is returned and it becomes apparent that Mrs W has moved and not notified the surgery. Meanwhile, Mrs W assumes that as she hasn't heard then the result must be normal. Six months later Mrs W comes to the surgery on a routine appointment and is informed of the result and referred.

In GP surgery Y, a mother of a four year old boy due to start school had been discussing the MMR (Measles, Mumps and Rubella) vaccination with the GP. She and her husband have delayed giving their son the MMR vaccine as they are very worried about all that they have read in the papers about possible side-effects. They are not convinced that their son should have it as he was a "poorly baby". The doctor documents their decision.

The parents know their son needs his pre-school booster vaccinations and they are happy for those to go ahead. Following notification by the automatic notification system that the vaccinations are due, the mother and son turn up at the immunisation clinic and wait their turn. The practice nurse checks the boy's appointment card, which has generated a requirement for the boy to receive the pre-school booster, minus the whooping cough element, and to receive the MMR. The nurse asks if the mother is happy for the whooping cough element of the booster to be given, to which she agrees. The nurse then proceeds to give both the pre-school booster and the MMR vaccine. It is only after the mother and child have left the clinic and when the nurse checks the boy's notes that she discovers that the parents are refusing to let their son have the MMR vaccine.

Example from a dental practice

A 14 year old patient, John Smith, sees a specialist orthodontist for an assessment following referral by his general dental practitioner (GDP). John's mother is concerned that he seems to have "too many" teeth and they seem rather crooked. The orthodontist explains to John's mother that he has a number of retained baby (deciduous) teeth and insufficient space for all his permanent teeth. Both baby and permanent teeth need to be removed to alleviate the crowding. The treatment plan is then discussed with John and his mother and the orthodontist records, in the patient notes, which teeth are to be extracted. At the end of the clinic a letter explaining the treatment plan is hand written by the orthodontist and given the next day to the secretary for typing. The letter is typed from the orthodontist's hand-written notes. The letter is signed and checked by the orthodontist and posted to John's GDP within a week of the appointment.

John and his parents attend their GDP to begin treatment. John is very nervous and says he wants to go to hospital to have his teeth out. As John has to have teeth out in all four corners (quadrants) the GDP agrees to refer John to the Community Dental Service (CDS) for the possibility of the teeth being extracted under general anaesthetic in an acute hospital. The GDP does this by writing a letter and enclosing a copy of the orthodontist's letter. At no point during this visit is John examined as the treatment plan had been formulated on the advice of the orthodontic specialist.

John attends with his parents for an assessment by the CDS dentist; in this case a locum in a busy clinic. The locum clinician is running behind schedule and because he has the patient letter and the GDP letter, he does not give John an oral examination. The relevant health checks are made and John is booked in for a general anaesthetic for the extractions.

A few weeks later John attends the hospital for the surgery and his father signs the consent form. The consent form states four deciduous teeth and four second teeth to be extracted. John goes into theatre and a sticker is placed on the patient bib detailing the teeth to be taken out. As a charting was not done at the assessment visit, the teeth to be extracted are copied from the orthodontic letter. The dental nurse checks with the patient's arm band that the patient is John Smith. John has his treatment as prescribed by the sticker on the bib and returns to the ward to recover. John's mother is now on the ward to aid his recovery. As John begins to recover his mother becomes increasingly agitated demanding to see the dentist. She states that he still has some of the teeth she thought were coming out. On closer inspection by the CDS dentist, eight permanent teeth had been extracted.

Root cause analysis

A root cause is the cause or causes that, if addressed, will prevent or minimise the chances of an incident recurring. Though the term can imply that there is a single root cause, typically there are often a number of aspects to the incident which, if they were rectified, may have prevented the incident from occurring.

Root cause analysis (RCA) 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. There is usually a chain of events and a wide variety of contributory factors which lead up to an eventual incident.²² 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.

Depending on the level of severity, as referred to earlier, RCA can either build on a significant event audit, or be used as the primary approach to the incident investigation.

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.^{15,23}

Who takes part in root cause analysis?

Any member of staff can take part in an RCA. This may be in the form of providing information, locating records, or providing interviews. While an RCA can be undertaken by one person, usually a core team is set up. At least one person in the team should have had training on the tools and techniques so that they can then train the rest of the RCA team.

For all incidents the investigator(s) needs to be able to demonstrate competence, credibility, objectivity and a degree of independence. For incidents which are severe, or result in the patient's death, the use of a team is strongly suggested. In some instances some independence will be required. There are different levels of independence which can be used, such as using an expert to review the investigation's findings, or using an independent person from another organisation to sit on the team, or asking an independent person to lead the investigation. Any investigation should include relevant staff from the multi-disciplinary team.

External expert advisers, such as the NPSA's patient safety managers, can be consulted to ensure specialist knowledge is used appropriately, depending on the incident specialty.

Patient involvement

The perspective of the patient and carer is invaluable. Patients and their carers should be involved in the incident investigation by, for example, asking for their perception of events and informing them about the investigation, the findings and proposed remedial action. Patients and carers 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 SEA or RCA means;
- advising them on the progress of the investigation;
- asking for their perception of the events leading up to the incident and identifying a chronology of events as they saw them;
- asking them for their views of changes that are required;
- involving them in the relevant meetings;
- informing them of the findings of the process and providing a written report;
- providing information on the proposed changes that the organisation will be putting in place.

Steps to a successful root cause analysis

It is important that all patient safety investigations cover all the stages 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 actions for implementation;
- 7 completing a report and sharing the lessons learned.

The following section shows these stages in more detail.

1 Identifying which incidents should be investigated

As stated earlier in this Step, each organisation, practice or team needs to 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 match the complexity of the incident that has triggered it. Additionally, the organisation needs to prioritise the incidents earmarked for a full RCA according to resources and capacity available.

Each primary care organisation's incident reporting policy or risk management strategy describes a standard approach for each level of patient safety incident. The following guidelines will help primary care organisations determine which incidents should be investigated:

The level of severity of harm to the patient

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.

The potential for learning

RCA could be considered for:

- incidents where the patient needed further treatment, therapy, intervention or transfer to secondary services;
- incidents that were prevented but considered by the investigator to be worth an in-depth review covering not only what, why and how it happened, but also what were the actions that prevented the incident from affecting the patient(s) to enable learning;
- all incidents that trigger external investigations, such as a coroner's inquest, complaints, legal claims or criminal investigations.

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 (note that all patient safety incidents should be recorded in the relevant record relating to the patient including practice, and community 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);
- relevant results and diagnostic aids;
- current policies and protocols;
- relevant integrated care pathways, where available;
- the incident report form (note that the incident report form is not kept in the patient's records, but is kept in the incident report file and the incident, along with treatment implications, are described within the record);
- the list of key staff involved and written reports from staff;
- 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 ambulance switchboard records to check response times, audit reports, minutes of management meetings, service schedules, maintenance reports, safety accreditation information, for example of electrical equipment and risk assessments).

Interviews

Interviews should be held 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. Primary care trusts and local health boards need to consider the mechanisms for ensuring that staff have access to support and/or counselling if required.^{4,24}

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. A technique such as cognitive interviewing can be used to elicit information by trying to get the interviewer to remember exactly what it felt like before and after the incident happened. The interviews will then be compared and used to create the a whole picture of what happened.

The outcomes expected from the interviews are:

- Establishing a chronology of events (i.e. what happened). 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?
- Establishing the factors which led to the incident (i.e. how and why did it happen). This includes 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?

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. Consideration should be given to sending to the MHRA after decontamination. 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 someone 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.

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.^{4,25} This may involve staff from across care settings.

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. Another would be to use techniques such as brainwriting (described later). 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. A timeline can be used to record the information in the team review.

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. Examples of different timelines can be found in the RCA tool kit (www.npsa.nhs.uk/rca).

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, it is vital that the investigator considers 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 paracetamol 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:

- 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:

- a) 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 individuals dominating the activity.
- b) 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 preferable to 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. More detail can be found in the RCA tool kit.

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 or 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'²⁶⁻²⁹ and is designed to identify:

- which barriers should have been in place to prevent the incident;
- why the barriers 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.

a) 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.

b) Natural barriers (barriers of distance, time or placement):

- a system for checking prescriptions in a community pharmacy, i.e. a ten minute break between the first check and the dispensing of the drug.

c) 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.

d) Administrative barriers:

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

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

6 Developing solutions and actions for implementation

Reporting and investigating incidents is worthless if the health service fails to make changes as a result of the lessons learned. Recommendations need to be prioritised to ensure that staff are not overloaded with numerous changes and any solutions need to be realistic and sustainable. Potential actions or solutions that are identified through the investigation may themselves introduce more risks to patients, so a vital part of this process is to risk assess the recommendations and solutions themselves. This process is described in **Step 7**.

7 Completing a report

RCA and SEA 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;
- Primary Care Trust Board/Professional Executive Committee/Local Health Board;
- coroner's office;
- Strategic Health Authority/Regional offices of the Welsh Assembly Government;
- Department of Health;
- 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 SEA/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 SEA/RCA reports and recommendations should be monitored by the practice/organisation on a regular basis (at least quarterly). This can be done by the lead for clinical governance or risk management. The primary care organisation's board and professional executive committee should also be informed and assured that remedial actions are being taken and monitored.

Key actions for primary care organisations

- Develop a consistent approach by using the same tools and techniques used for RCA when conducting an SEA. Practice by using incidents which were prevented and the patients were not harmed.
- Ensure your staff are trained to investigate incidents. You can do this by accessing the training given by the NPSA (up to eight key staff in your primary care trust or local health board are eligible for free RCA training). Ensure that these staff become your local investigation team and trainers for RCA.
- Raise awareness of SEA and RCA through case presentations and multidisciplinary team training.

How can the NPSA help?

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 and to make progress towards improving patient safety faster and more effectively.

One of the key elements of promoting learning has been to develop the technique of RCA for use in the context of healthcare. The NPSA's RCA tool kit is based on a review of the chronological chain of events which has in use for some time.^{30,31} This is based on the work of experts in investigating organisational incidents (see Rasmussen,^{32,33} Reason,³⁴ Taylor-Adams and Vincent,³⁵ and Vincent et al³⁶).

RCA training

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.

The NPSA is providing RCA training for every primary care organisation in England and Wales that begins participating in national reporting. The objective is to ensure that throughout the NHS there are 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 primary care 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.

The NPSA is also offering a one-day RCA foundation course and other bespoke courses at a cost. These will be open to all NHS staff and non-NHS staff. Additionally, master classes and accreditation for more advanced training are being developed.

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 tool kit

Practical support for using RCA can be found in the NPSA's web-based e-learning tool kit (www.npsa.nhs.uk/rca). The tool kit provides NHS staff with guidance on how to collect data and analyse incidents, and includes an interactive tool to help them develop confidence in performing RCA. All the information is useful for both SEA and RCA. This includes advice on how to document and organise evidence, guidelines on patient and staff interviews, details and illustrations of techniques for analysing incident information, barrier analysis tools, and case studies to help staff familiarise themselves with the methodology.

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. The online resource centre contains downloadable documents covering a range of RCA tools, a glossary, key references and links.

Good practice in learning and sharing safety lessons

Case study: Sutton and Merton Primary Care Trust

A resident at a home for people with profound learning disabilities suffered a superficial scald on his buttocks, probably after having been showered. Root cause analysis was used to explore the underlying causes of the incident.

“People jump to conclusions and, for instance, say that the problem was a faulty shower, but that doesn’t uncover all the other issues such as records management and under-reporting,” said Phillip Brown, Sutton and Merton Health and Safety Manager.

“The incident might have seemed like a one-off but it uncovered a huge system problem. It occurred in February, but the investigation highlighted issues going back to November. The root cause analysis training has been invaluable. It can help to establish multiple causes. The different techniques will be used in future to understand incidents and to establish controls to prevent reoccurrences,” added Mr Brown.

The patient, who has no verbal communication, had no immediately obvious injury. It was subsequently unclear when the incident took place as the timing of the shower could only be related to the patient’s bowel management programme and that had not been accurately recorded.

For some time before the incident it had been noted that the temperature of the shower fluctuated, and a person from the maintenance department had identified a possibly faulty temperature control and said it would be replaced. This did not happen.

A series of recommendations resulted from analysing the root causes of the incident. Staff were reminded that they must enter all problems or concerns in the 24-hour book so that everyone is aware of potential risks to residents. An Accident Incident Report Form should be completed as soon as a potential problem is discovered.

Any electrical equipment must be taken out of service immediately after a concern is raised regarding its safe use. Shower temperatures should be checked regularly by members of staff before they bathe each patient.

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," said Ms Brennan.

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.

Good practice example

SEA-change

Significant Event Alerts in Harrow PCT

Jacque Scott, Director of Clinical Governance and Nursing

“SEA-change is a new communication developed by Harrow PCT to alert all relevant local health professionals to issues which may be learnt from recent significant events. The guidelines are developed in conjunction with our local hospital colleagues. The process is about learning rather than being a blaming exercise. The SEA-change alerting system is reserved for important issues and is used infrequently so that the impact of the alerts is maintained. Development of these SEA-change alerts has been well received by the relevant staff. We found it necessary to reiterate advice on one occasion and have developed local referral guidelines as a result. We have also reconfigured our ultrasound service through extended hours of access for patients.

“The process has afforded a good opportunity to link with the relevant NICE guidelines and to draw these to the attention of clinicians in a clinically-relevant setting. Building on this system, we arranged a meeting of our Clinical Reference Group to focus on patient safety. We enjoyed a stimulating discussion of root cause analysis with an advisor from the NPSA, and a local GP described the significant event meetings held regularly by his practice. The challenge now is to maintain this momentum.”

Promoting reporting

Do you have a good practice story and would you like to share that story with your healthcare colleagues? If so, please send it to pcsevensteps@npsa.nhs.uk

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Step 7

Implement solutions to prevent harm

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Step 7

Implement solutions to prevent harm

Primary care trusts, local health boards, practices and teams are already involved in creating safer healthcare environments and are devising their own solutions to patient safety risks. However, despite important breakthroughs in the design and performance of safer systems in healthcare following patient safety incidents, many of these solutions are short-lived and are not shared across the NHS. As described in previous Steps, in particular **Steps 4 and 6**, primary care organisations and practices need to understand the underlying contributory factors of patient safety incidents^a 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 for patients.

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 primary care trusts, local health boards, practices and teams. We describe the NPSA's prioritisation processes and offer guidance on how to incorporate lessons and changes into processes and systems and provide examples of approaches and solutions being developed by the NPSA.

The key principles

- Design systems which make it easy for people to do the right thing.
- Solutions which rely on physical barriers are far stronger than those that rely on human behaviour and action.
- Make sure any changes you make are risk assessed, evaluated and sustainable in the long-term.
- Best practice that is developed locally can be shared at national level via the NPSA, enabling other primary care and community settings 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.

^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' or 'clinical errors' and 'near misses' respectively.

The importance of 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. **Step 3** describes an approach to ensuring lessons are learned, implemented and shared through integrated risk management^c.

One of the problems with spreading change across healthcare services is that unless an individual or team is directly involved in an incident, they may feel it could not happen to them and therefore any change or learning required, does not apply. Another problem is that often learning is a one-off event. If an organisation focuses intensively on a problem for a short time, but forgets about it when new priorities emerge or staff move on, sustained learning cannot take place.

What can primary care organisations, practices and teams do?

Primary care organisations, teams and practices 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^d are recognised when improving patient care and patient safety. This will provide the health service with best practice evidence from primary care that can be shared at a national level and implemented locally.

Stages for developing solutions

Solutions to reduce the risk of patient safety incidents need to be developed in a systematic way, especially if they are to be promoted and adapted and become part of every day practice. Adopting the following procedures can help ensure lessons learned effect a change in culture and practice.

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- ^c **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.
- ^d **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.

Stage 1: understand the problem and identify the changes that need to be made

The first stage is about having a clear understanding of the nature and extent of the problem in terms of the actual or potential outcome for the patient and the root causes. Information can be gathered from various sources including local risk management reporting systems, complaints, claims, significant event audit, patient safety literature, patient and staff surveys, focus groups, and other data such as the confidential enquiries. This can be done proactively also, by applying risk assessment methodologies to identify the potential risks that should be the focus for solution work.

NHS organisations, staff that work in them and patients that experience them first-hand, have a wealth of information about how systems are failing to provide optimum care, although currently our knowledge in primary care is limited. Integrated risk management systems should ensure this data is routinely collected and aggregated to identify areas for change. Analysing a patient journey, for example, can help understand the potential risks and hazards which can occur and identify ways in which those risks can be minimised.

Stage 2: identify potential solutions

Having identified the priority risk areas or root causes, potential solutions are identified. This should happen in multidisciplinary teams including frontline staff. The patient perspective also needs to be considered. This could include redesigning systems and processes, increasing or adapting staff training or changing clinical practice. Actual examples include the effective use of computer-based support systems such as computerised records and medication systems, new labelling techniques and redesigning care delivery by reducing delays and improving patient flow and access.

The general approach should be to identify solutions to actively address the root causes of patient safety incidents to reduce the risk of things going wrong, rather than more passive methods which encourage staff to be more vigilant in terms of their working practice. This is different to the approaches taken in the past which would have focused on asking health professionals to take more care, for example when prescribing medication. A number of potential solutions are usually identified. These are prioritised on the basis of judgements about the perceived effectiveness of the solution.

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. Improvement and patient safety is not about introducing more work; it is about working differently. The World Health Organisation (WHO) injection safety programme is an example of this. The programme has achieved profound changes through a focus on education, attitude change and public information combined with relatively simple adjustments to syringe design to render them unusable after a single injection. While some methods with clear-cut benefits can be introduced immediately, others will require piloting and evaluation.

Case study: emergency hormonal contraception

Emergency hormonal contraception (EHC) is available via a doctor's prescription, from family planning clinics or other locations where it may be supplied under Patient Group Directions (PGD), or by purchase from community pharmacies.

Some community pharmacies operate within local primary care trust schemes to supply this medication under PGDs to females in deprived areas or where access to local clinic services is limited.

Given the retail environment of community pharmacies it can be difficult for a female to speak confidentially with the pharmacist to request EHC without being overheard by other people in the pharmacy.

As a solution to this problem, and to encourage young females to seek EHC and other contraceptive advice when needed, one locality introduced a small card which the female presented to a member of staff at the pharmacy counter. This card was an indicator that they wished to speak with a pharmacist in a private and confidential area, and did not require them to initially explain what they wanted to speak to the pharmacist about.

Stage 3: risk assess solutions

All solutions are risk assessed to try and make sure that they are not going to introduce other potential risks. For example, the NPSA's national clean^{your}hands campaign to promote hand hygiene involves the use of alcohol-based products prior to providing care to patients. Using risk assessment, the potential risks of fire, potential risks with children and problems with dermatitis were identified. Working with various experts it was decided that the risks were not high enough to warrant not promoting alcohol-based products and that knowing about these risks enables changes to be made to minimise those risks.

Stage 4: pilot and learn

If the solution is considered to be worth pursuing you need to consider piloting the solution. The purpose of a pilot is to see if the solution is useful, works in practice and to learn lessons for wider implementation. At this time, if appropriate, a cost benefit analysis is undertaken. Model spread sheets can be found on the NPSA website to assist organisations in gathering information to inform decisions about particular solutions if they require financial resources for adoption.

Stage 5: implementation

Depending on the learning from the pilots, solutions are implemented. Some solutions will come from the NPSA which issues patient safety alerts, safer practice notices, and patient safety information.

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.

The impact of these action plans should also be measured over time as part of a core clinical governance activity review programme. This helps primary care organisations develop 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 it is relevant to them and they think it will help them do their job. Primary care organisations need to demonstrate the optimum balance of risks and benefits by comparing current outcomes with potential outcomes. In addition, for innovation and change to diffuse rapidly, they must be compatible with the values of the organisation or service and the individuals who work within it.¹ Therefore, evidence and thorough testing are required before changes can be fully implemented.

Demonstrate effective leadership and spread the message

As stated in **Step 2**, 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 clinical and managerial leaders to spread good practice, prioritise action and ensure appropriate use of scarce resources. Leaders can demonstrate that patient safety is a priority by ensuring recommendations from all risk-related investigations are followed up and monitored.

Any change requires the use of a number of communication channels to spread the message, build awareness of the new ideas and provide support to staff. **Step 2** describes key individuals required in a structure which seeks to improve patient safety. The NPSA suggests patient safety champions are appointed (usually alongside an existing role) to influence a group of staff. Techniques to ensure effective spread, as discussed in **Step 2** are:

- **Safety walkabouts or drive-about and briefings:** these can be used to promote and reiterate the need for reporting, demonstrate organisational or practice commitment to an open and fair culture, explain the reasons behind the recommended changes and feedback on actions taken at board level.
- **Team briefings and de-briefing:** where staff can talk about the events of the day and how prepared they are for the particular tasks and specific patients expected that day with safety as the focus, followed by a review at the end of the day.
- **Demonstrable commitment by the leadership:** where actions taken show the organisation or practice is committed to an open and fair culture and that strategies and policies clearly demonstrate this.

Involve staff and patients

Any design of new solutions should involve the staff and patients affected by drawing on their experiences to ensure the changes work in practice. Communicating remedial action 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. Making patients aware of changes also helps to boost confidence in their health service. Feedback to staff and teams on how solutions are working and any changes to the way they are delivered is also vital if they are to be sustainable.

Safety solutions should be designed around the following principles:

- design tasks and processes to minimise dependency on short-term memory and attention span;
- avoid fatigue: review working hours and workloads;
- re-training is not always the right solution;
- simplify tasks, processes, protocols and equipment;
- standardise processes and equipment where relevant;
- use protocols and checklists wisely;
- resist reliance on policies and protocols as task aids.

Stage 6: evaluation

It is important to evaluate solutions both in terms of process and uptake as well as whether they make a difference in terms of patient safety incidents. The latter is difficult since there is not always a baseline. Evaluation is built into the beginning of the processes so that it is considered early on in the solution development process.

Stage 7: closing the loop

It is important to have some kind of process to check any solution has been implemented and, if not, the necessary follow-up is taken forward. In England, for national solutions there is a safety alert broadcast system which requires hospitals and other health service providers to indicate whether they have taken the necessary action. Further follow-up is undertaken by other organisations such as Strategic Health Authorities and the Healthcare Commission to check on uptake. In Wales, regional offices and the Healthcare Inspectorate Wales perform this function.

How can the NPSA help?

The NPSA recognises that to achieve change wherever 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 NPSA and our network of patient safety managers (described in **Step 3**) will work directly with primary care 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.

The NPSA's approach to developing solutions

As with local solutions, the solutions we develop nationally 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.

To ensure the NPSA's resources are used to their best effect, such as to deliver evidence-based, cost-effective impact at all levels of the NHS, we need to pursue a suite of activities across the organisation. The NPSA has therefore developed a prioritisation process. We aim to prioritise patient safety topics which may require further work to develop solutions, recognising that the term 'solutions' covers a wide range of possible products and activities; from developing a safety culture, helping organisations improve their team working, to practical solutions to reduce particular incident types. There will be an annual cycle and a fast track process for in-year prioritisation.

Within this context, the prioritisation process will:

- inform the NPSA's activity in developing safety solutions ourselves;
- decide on what we will do in partnership with others; or influencing others to take forward; and
- refer suggestions to more appropriate organisations to take a lead as appropriate.

Examples of solutions include:

- specific solutions such as the methotrexate alert and the clean^{your}hands campaign;

- solutions to change culture and practice such as *Being open*, the Incident Decision Tree, safety culture assessments, and *Seven steps to patient safety* guidance;
- solutions to enhance awareness and knowledge such as root cause analysis training and non-executive director leadership training;
- cross-cutting IT solutions such as alerts for drug interactions in primary care prescribing systems.

Valid, reliable and sufficient information is vital for the success of the prioritisation process. The first stage will identify and collect all relevant information on patient safety topics from as wide a range of sources as possible. Patient safety topics may come from a broad range of stakeholders through formal channels or they may arise from informal sources. They may come from external individuals or agencies or may be generated internally by NPSA staff and work programmes.

Additionally, the NPSA aims to ensure the involvement of patients, the public and members of the NHS. Members of the public may be past, current, or future patients, users of services, or carers and people representing any of these groups through community organisations, networks, or campaigning and self-help groups.

Broadly, there are several ways in which information for this prioritisation process will be gained:

- Analysis of the NRLS and other data sources through the work programme of the Patient Safety Observatory, which is being developed to maximise understanding of issues and concerns relating to patient safety. This will help direct and inform the NPSA's safety solutions work. Patient safety topics will arise through a number of components of data analysis from the NRLS, including patient and public reporting. This will then trigger searches using other relevant datasets to validate the data within the NRLS. This data will be published via quarterly reports produced by the Patient Safety Observatory and added to the evidence for the generation of the list of topics for the first advisory panel review.

- An active programme of staff perusal and scanning of selected potential sources including research and audit findings, international patient safety websites, the media, reports from key organisations, and the research literature.
- Targeted consultation with all contacts on the NPSA's mailing list: the NPSA will consult via the NPSA mailing list and through partnership relationships with the public, patients, NHS staff, and NHS and non-NHS organisations, all of whom have a role to play in patient safety. Patients and members of the public on the NPSA mailing list, as well as patient representative organisations, will receive a letter which includes the same proforma as the electronic form to allow the public to send written submissions.
- An electronic suggestion form on the NPSA website for patients, public and NHS staff: the public and NHS staff will be alerted to an electronic suggestion form on the NPSA website. This would be a largely passive approach with occasional reminders about the availability of this route to the service and public.
- An active programme of NPSA staff engagement including the Board, clinical specialty advisors, patient safety managers and their reference groups and communities of interest, as well as integration of results from aggregate root cause analysis data;
- Past topics: patient safety topics that have been previously considered but which either required further work or exceeded the maximum number of topics to be progressed may be reconsidered the following year.

It is expected that this process will flag up:

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

The NPSA will investigate these trends and develop solutions that can be implemented nationally and locally. We will use experts from key specialty areas and a network of clinical specialty advisers who represent most of the royal colleges.

A filtering and reduction process using an external expert panel will then consider all relevant data and submission prior to making recommendations for the NPSA Board who will take the final decision for the way forward. Further details of the prioritisation process and access to submission forms can be found on the NPSA website (www.npsa.nhs.uk).

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 a national level and in the advice given to NHS organisations.

Learning from research

One of the NPSA's key strategic objectives is the promotion of research and development in patient safety and the translation of this into practice. An overview of current international research on patient safety makes it clear that there is a substantial literature and considerable activity, which is likely to expand in the next few years.

The NPSA is committed to working in collaboration with the Department of Health patient safety research programme, led by Professor Richard Lilford at the University of Birmingham², and others in the field, both in the UK and internationally, such as the Medical Research Council (MRC), the Economic and Social Research Council (ESRC) and the Engineering and Physical Sciences Research Council (EPSRC).

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.

There is a clear role for the NPSA in supporting the translation of research into practice. In particular, the NPSA has a role in drawing together the findings of research from different fields and translating this into the context of patient safety in the NHS.

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 disabilities

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 group. We are working in partnership with *Speaking Up!*³ – 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 so far 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.

Safer prescribing

The NPSA has an ongoing programme of work in primary care, including a partnership with the National Programme for Information Technology (NPfIT) in the NHS. The outcome of this work will be that the primary care computer systems are able to support doctors and nurses in delivering safer care, especially in areas such as prescribing. Much of what is learned from the work with primary care systems can be applied to clinical systems across the wider NHS.

‘Right patient, right care’

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

The ‘right patient, right care’ project is developing a mistake-proof system 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.

Team resource management

Team resource management enhances operational effectiveness and patient safety through the introduction of briefing and de-briefing practices. The Royal Cornwall Hospitals Trust carried out a project comprising team resource management training and education, de-briefing, 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: ‘cleanyourhands’

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.⁴ It is estimated that one-third of these infections are preventable with better hand hygiene.

‘cleanyourhands’ 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 learning from the pilot project has directly informed the phased national roll-out of the campaign, which began in September 2004. The NPSA is currently looking at transferring the campaign to the primary care sector.

Reducing the risk of 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. Methotrexate 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 dispensed in packs of 28 tablets, which patients could interpret as a month's supply and assume they should take one a day.

Other key underlying factors that put patients at risk include patients having insufficient information about how the drug should be taken; confusion between different tablet strengths; lack of clear messages on packaging; mistakes in prescribing; and variations in patient monitoring and treatment reviews.

Following widespread consultation with patients, carers, clinicians and representatives from the pharmaceutical industry and IT software suppliers, a three-pronged solution to combat risks associated with the drug was launched in July 2004.

- Prescribing support IT systems and pharmacy dispensing IT systems are being adapted to design-out opportunities for human error in prescribing, using default settings incorporating warnings and prompts about methotrexate. The NPSA has worked with major database and system suppliers to ensure that safety enhancements to software are ready for application. Other system suppliers should apply the development changes to their systems as quickly as possible and by November 2004 at the latest.

- The NPSA has provided core information that should be communicated to patients both prior to commencing treatment with methotrexate tablets, and during treatment. Pre-treatment patient information leaflets and patient held monitoring and dosage records should now be provided to all patients taking the drug. Sample leaflets and guidance about the layout are available.
- In an unprecedented collaboration with the pharmaceutical industry, the three UK manufacturers or license holders of methotrexate, Pfizer, Goldshield (currently Wyeth) and Mayne Pharma, are working with the NPSA to develop safer, patient-friendly packaging. The companies which produce the 10mg tablet have already changed the shape of this tablet to help clinicians and patients distinguish it from the 2.5mg tablet, and have recalled all previously round shaped tablets in order to prevent any further confusion.

Patient safety alert: reducing the harm caused by oral methotrexate

Oral methotrexate is a safe and effective medication if taken at the right dose and with appropriate monitoring. However, the NPSA is aware of 137 patient safety incidents over the last ten years in England alone due to problems with taking the medication. This includes 25 patient deaths and 26 cases of serious harm.

Action for the NHS

NHS acute trusts, primary care organisations and local health boards in England and Wales should take the following steps by March 2005:

1 Agree local action required

Agree appropriate local risk reduction actions through your Drugs/Medicines and Therapeutic Committee.

2 Provide patient information before and during treatment

Recommended core content for a pre-treatment information leaflet provided before treatment starts and a patient-held monitoring and dosage record during treatment is attached to this alert.

3 Update prescribing and dispensing software programmes

All prescribing and dispensing software programmes in primary and secondary care locations must be updated with the latest software which includes methotrexate alerts and prompts.

4 Review purchasing

Purchasers of 2.5mg and 10mg tablets should ensure that the tablets are visually distinguishable by shape, and that packaging contains the cautionary wording required by the Medicines and Healthcare products Regulatory Agency.

29 July 2004

Where there is a strong body of evidence that a particular approach is effective in reducing serious patient safety incidents, the NPSA will issue patient safety alerts and advice with the expectation that NHS organisations will adopt the revised practice.

Good practice example

Examples of good practice have also been highlighted in the Royal College of General Practitioner's newsletter *In Safer Hands* which is sponsored by the NPSA and is available at www.rcgp.org

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 – organisations 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.⁵

Evidence from 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.⁶

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 per cent of NHS trusts. This had risen to 68 per cent six months after the alert and is expected to continue rising. The alert also prompted a 27 per cent 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

Do you have a good practice story and would you like to share that story with your healthcare colleagues? If so, please send it to pcsevensteps@npsa.nhs.uk

References

- 1 Berwick DM (2003). *Escape Fire: Designs for the Future of Health Care*. San Francisco: Jossey-Bass, John Wiley & Sons
- 2 Visit www.bham.ac.uk for more information
- 3 Visit www.speakingup.org for more information
- 4 National Audit Office (2000). *The Management and Control of Hospital Acquired Infection in Acute NHS Trusts in England*. Report by the Controller and Auditor General. London: The Stationery Office (accessed at: www.nao.gov.uk January 2004)
- 5 Joint Commission on Accreditation of Healthcare Organizations (1998). Quote by Lucian Leape MD, Harvard School of Public Health, in the *Sentinel Event Alert*. Issue 1 (accessed at: www.jcaho.org January 2004)
- 6 Joint Commission on Accreditation of Healthcare Organizations (1998). 'Medication Error Prevention – Potassium Chloride'. *Sentinel Event Alert*. Issue 1 (accessed at: www.jcaho.org January 2004)

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 for primary care

We have set out the seven steps that primary care organisations in the NHS 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 and risk management targets.

Further copies

If you would like to order printed copies of *Seven steps to patient safety for primary care*, please call the NHS response line on 08701 555455. Individual sections are available online at:

www.npsa.nhs.uk/sevensteps

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