

Building a memory: preventing harm,  
reducing risks and improving patient safety

The first report of the National Reporting and  
Learning System and the Patient Safety Observatory

July 2005



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“ Kevin died. Kevin should not have died. We mourn for Kevin. That is right and proper. The tragic outcome in relation to Kevin cannot be changed. But can that outcome be a catalyst for change in the reformed health service? By examining Kevin’s patient journey there can be real learning and real improvement at all points of patient contact. Perhaps Kevin’s destiny was to highlight for us the deficiencies and the challenge for us is to learn from his experience and to ensure that healthcare is safer for future patients.”

A patient’s mother

## Acknowledgments

The NPSA would like to thank all the organisations and individuals who have made this report possible, and who have contributed to the learning needed to improve patient safety. This includes:

- staff who have reported incidents, both to their local risk management systems and to the NPSA directly;
- patients and patient groups who have shared their experiences and helped with the development of solutions;
- NHS risk managers and others who have worked hard to enable the NPSA to link local risk management systems with the National Reporting and Learning System, and to promote patient safety within their organisations;
- leaders of individual NHS organisations and professional bodies who have championed work to improve patient safety in their own organisations and across the NHS;
- organisations who have contributed to the development of the Patient Safety Observatory (see Appendix 2);
- the vendors of commercial risk management systems who have collaborated with the NPSA.



# Foreword

Every day in the NHS in England and Wales, over a million patients are treated by committed and dedicated staff. As one of the largest organisations in the world, using a range of technologies, equipment, drugs, skills and expertise, sometimes things do go wrong. In common with other healthcare systems in the developed world, and through the World Health Alliance for Patient Safety, a movement is growing to tackle and prevent unintended harm to patients. As part of the drive to improve the quality of care in the NHS, the National Patient Safety Agency (NPSA) has spent the last four years working with other national organisations, NHS staff and patients to pilot and develop an approach to understanding the types of things that go wrong, and to test and implement methods to reduce risks in the healthcare system.

This is our first national report of patient safety incidents. It describes the Patient Safety Observatory and provides information from the National Reporting and Learning System (NRLS) and shows how this is being used. Almost all of the patient safety incidents reported to the NPSA come from local incident reporting systems and the responsibility for investigating incidents lies with individual NHS providers, and not with the NPSA. This report shows that there is a variation in incident reporting rates between NHS organisations. It is important to note that high incident reporting rates do not equate to unsafe care: organisations with a strong reporting culture and effective local mechanisms for investigating incidents would be expected to report more.

Rolling out the successful connection of all 607 NHS organisations in England and Wales to the NRLS has not been easy. From Treasury approval to connection has taken two years. In particular, we have relied on the support of risk managers across the NHS and the seven vendors of commercial risk systems who have integrated national requirements into their systems so that staff on the ground do not have to enter information twice.

Patient safety is a key part of the overall clinical governance framework. It needs to take its place as the first concern of everyone who works with, and manages services for, NHS patients. I hope that this report will support that aim.

**Gilbert Smith Ph.D.**  
**Chair, NPSA**

## Executive summary

### Why do we need to know more about patient safety?

Every day the NHS helps more than a million people<sup>1</sup> with health problems to get better. However, occasionally things go wrong and sometimes patients are harmed. Many of these incidents are preventable by identifying systems' failures and then changing them. However, hitherto, not enough has been known about what kinds of incidents happen and what their underlying causes are.

The National Patient Safety Agency (NPSA) was set up in 2001 in order to make changes at a national level. The NPSA aims to:

- identify trends and patterns in patient safety problems using its own national reporting and learning system, and data from other sources;
- provide tools for staff locally to understand the underlying causes of incidents and then be able to act on them;
- develop solutions at a national level. For example, the NPSA has led a national campaign to improve hand hygiene in hospitals. The NPSA is currently working on 39 projects to develop solutions to safety problems.

From 1 April 2005, the NPSA's work also includes safety aspects of hospital design, cleanliness and food. This responsibility has been transferred from NHS Estates. The NPSA is also ensuring research is carried out safely, through its responsibility for the Central Office for Research Ethics Committees (COREC), and is supporting local organisations in addressing their concerns about the performance of individual doctors and dentists, through its responsibility for the National Clinical Assessment Service (NCAS). It also manages the contracts with the three confidential enquiries. This responsibility has been transferred from the National Institute for Clinical Excellence (NICE).

### Establishing the National Reporting and Learning System and the Patient Safety Observatory

The establishment of the National Reporting and Learning System (NRLS) is a core function of the NPSA. The NRLS is the first comprehensive national reporting system for patient safety incidents. We know from international evidence that incidents have generally been under-reported. In the past, doctors, nurses and other healthcare professionals have been reluctant to report things that go wrong, but there is now greater awareness of the need to report and learn from these incidents. In order to encourage reporting, the NPSA's reporting system is confidential.

Local NHS organisations are responsible for investigating incidents and the NPSA has provided a range of tools and guidance to support this<sup>2</sup>.

Incident reports on their own cannot tell us all that we need to know about patient safety. This is why the NPSA has set up the Patient Safety Observatory to compare and combine data from the NRLS with other sources of information such as litigation bodies, industry and patients. Together, these provide a more complete picture of patient safety.

This is the first in a series of reports from the NPSA's Patient Safety Observatory. It provides an analysis of reported patient safety incidents and emerging trends, and uses case studies to illustrate the way in which we combine sources of data to improve understanding. The report also compares

information from the UK with that from reporting systems from other countries: patient safety is an international concern and similar levels of patient safety incidents have been reported across healthcare systems in developed countries.

Good information is the first step to understanding what needs to be done to improve patient safety. But without action, information is meaningless. Early data are being used to identify trends and highlight priority areas for the NPSA to develop solutions. The NPSA will continue to work with NHS staff to identify areas where action is needed, at both a local and national level, to make the NHS as safe as possible for patients.

### **What does this report tell us about patient safety in 2005?**

This report provides the first public analysis of national patient safety data in England and Wales.

It has been over six months since all NHS organisations in England and Wales were connected to the NRLS. Encouragingly, the number of organisations reporting regularly is increasing, therefore future reports should provide more complete data which will strengthen our understanding of possible threats to patient safety.

The first NHS organisations were connected to the NRLS in November 2003 and all NHS organisations have had the capacity to report incidents to the NRLS since December 2004. The information in this report is based on information from the 230 organisations that have reported up to 31 March 2005. Reporting rates vary from organisation to organisation, but places with low (or no) reported incidents are not necessarily safer. In fact, organisations with higher rates of reporting may have more open cultures where action is more likely to be taken to prevent further incidents.

Three-quarters of the incidents reported to the NPSA so far have come from acute hospitals: local reporting systems have been developed earlier in acute hospitals, and therefore their staff are more used to reporting incidents. As a result, the incidents reported to the NPSA do not represent the whole of the NHS, and care is needed when interpreting these early data. Overall, the number of reporting organisations has increased month by month, with encouraging increases in particular sectors such as mental health. Over time, the reported data will become more representative of all healthcare settings. With the present data, our analysis has largely focused on hospital settings since they are the main providers of reports.

Up until the end of March 2005, 85,342 patient safety incidents were reported. Most of these incidents (68 per cent of the total) resulted in no harm to patients. Of the reported incidents, about one in 100 led to severe harm or death. The NPSA has established a system to review all deaths reported to the NRLS.

In acute hospital settings, about three in every 1,000 reported incidents resulted in death. This is a very similar rate to that from other comprehensive reporting systems (for example Pennsylvania in the USA). The information shows a rate of five incidents reported per 100 admissions for acute hospitals. This compares with a rate of around eight per 100 admissions in the published international literature, which relied on a review of patients' notes rather than reports of incidents.

Based on incidents and deaths reported over a three month period by 18 trusts, the NPSA has estimated that each year there would be approximately 840 deaths and 572,000 incidents reported in acute trusts in England. The estimated number of incidents is of the same order of magnitude as previously quoted estimates of 850,000, but the estimated number of deaths is considerably lower than the widely quoted figure of 40,000<sup>3</sup>. Further work is needed to arrive at a more precise figure.

The most common types of incidents reported are patient accidents (in particular, falls) and incidents associated with treatment, procedure and medication. This varies for different types of patients receiving care. For example, accidents contribute to a greater proportion of incidents in medical than in other specialties. Insufficient communication, education or teamwork are associated with many of the reported patient safety incidents across all settings and types of incidents.

## **How is this information being used to improve patient safety?**

Incidents reported by healthcare staff to the NRLS have provided the first national picture of patient safety in England and Wales. They have helped us to identify new patient safety concerns and to recognise those that are causing the greatest harm to patients. But they do not represent the complete picture; not all organisations have reported incidents and there are gaps in the kind of incidents reported. We address these gaps by bringing together other relevant sources of information through the Patient Safety Observatory.

Patient safety incidents reported to the NPSA have prompted work to improve the safety of healthcare. The following are examples of issues that have been identified:

### **Anticoagulant medication**

The NPSA reporting system included 311 incidents linked to anticoagulant medicine, including two deaths, up to 31 March 2005. The NPSA obtained information from other sources, including 600 cases reported to medical defence and negligence bodies from 1990 to 2002, with one in five reports resulting in the death of a patient. This issue was identified as a priority by the NPSA for further work, and solutions are being developed in collaboration with the British Society for Haematology (see page 26).

### **Patient identification, including problems with wristbands**

The NPSA reporting system included 493 reports from 45 reporting trusts where there have been mismatches between patients and their care. One in eight of these incidents involved wristbands, for example, missing wristbands or discrepancies between information on the wristband and other documentation. The analysis has shown that there is a lack of a systematic and standardised process to support the identification of patients. The NPSA is preparing advice for the NHS to reduce the risk of mismatching for autumn 2005, and is undertaking further work to assess the potential of using electronic technologies to reduce the risk to patients (see page 19).

### **Crash call trolleys**

A review of reported deaths has revealed a number of incidents where equipment needed to care for patients who had suffered a cardiac arrest was missing or could not be found quickly on the crash call trolley. The NPSA is alerting the NHS to this issue and is collaborating with the Helen Hamlyn Trust to fund the design of a crash call trolley which eliminates the risk of missing equipment going unheeded by staff (see page 39).

## **The impact of NPSA work**

Alongside the development of solutions, the NPSA ensures that the impact of solutions on healthcare is evaluated. For example, we issued an alert to prompt hospitals to put safety controls in place to ensure the safe storage of potassium chloride concentrate. The aim was to help protect clinical staff from mistakenly administering the concentrate with potentially fatal consequences. Before the alert, only 32 per cent of trusts restricted the number of clinical areas holding stocks of potassium chloride. Evaluation shows that this figure has now risen to 98 per cent.

## **Who is this report for?**

This report is aimed at all those working in, and using, the NHS and who have an interest in improving patient safety and the quality of care. This includes clinical staff, managers, medical and nursing directors, non-executive directors, risk managers, and patients, their relatives and health representatives.

For more information about how the NPSA can help you and your local NHS organisation to improve patient safety, visit our website<sup>2</sup> where you will be able to access a range of tools to help you investigate incidents locally and act on the findings, along with details of our national alerts and safety solutions.

# Key messages from the NRLS

- The flow of data to the NRLS increased rapidly over the six months prior to March 2005.
- NRLS data are already identifying new issues that require urgent action, as well as providing evidence to support action to resolve problems that were considered to be intractable.
- The majority of the incident reports received to date are from acute hospitals.
- Reported incidents are representative of the in-hospital population in terms of both patient age and treatment specialties.
- Most incidents result in no harm or are 'near misses'.
- The recent increase in the number of reports received from mental health trusts is encouraging.
- Patient accidents, incidents associated with treatment or procedure, and medication incidents are the most common types of incidents reported to the NRLS.
- Reporting rates vary across NHS organisations: a higher incident reporting rate may be an indicator of openness to reporting incidents at a local level.
- Communication factors and lack of teamwork are associated with many types of incidents.
- Most reports did not have information on contributing factors: the NPSA and local NHS trusts need to emphasise the importance of recording contributing factors. Such recording will be supported by greater use of methods, such as root cause analysis, at a local level.

# Part one

## Incident reporting and the Patient Safety Observatory

### Introduction

Patient safety is an important challenge for all modern health services. Healthcare is a risky business; it brings together sick and vulnerable patients with medical services and often complex technology and requires the effective coordination of many people. Complex systems in any industry are prone to human error.<sup>4,5</sup> No matter how committed, skilled and hard working the staff, the complexity of modern NHS care and the nature of human behaviour means that unwelcome incidents do happen and errors are made. Very few errors are due to a lack of care or commitment from healthcare professionals or from a desire to deliberately harm patients.<sup>4</sup> Patient safety incidents also have emotional, psychological, social and economic consequences for the families involved, and for healthcare staff; so it is vital that we strive to reduce their frequency and severity. Major reports and studies from developed countries around the world consistently demonstrate that there are real opportunities to make healthcare safer through improvements in the systems for delivering that care.<sup>6,7</sup>

The National Patient Safety Agency (NPSA) is leading national work in England and Wales to improve the safety of patient care.<sup>8</sup> The agency was set up in 2001 in order to make changes at a national level and aims to:

- identify trends and patterns in patient safety problems, using its own national reporting and learning system and data from other sources;
- provide tools for staff locally to understand underlying causes of incidents and then be able to act on them;
- develop solutions at a national level. For example, the NPSA has led a national campaign to improve hand hygiene in hospitals. The NPSA is currently working on 39 projects to develop solutions to safety problems.

From 1 April 2005, the NPSA's work also includes safety aspects of hospital design, cleanliness and food. This responsibility has been transferred from NHS Estates. The NPSA is also ensuring research is carried out safely, through its responsibility for the Central Office for Research Ethics Committees (COREC); and is supporting local organisations in addressing their concerns about the performance of individual doctors and dentists through its responsibility for the National Clinical Assessment Service (NCAS). It also manages the contracts with the three confidential enquiries. This responsibility has been transferred from the National Institute for Clinical Excellence (NICE).

A necessary contribution to improving safety, as evidenced by other industries, is to encourage the reporting of safety incidents. One of the NPSA's core functions has been the development of the National Reporting and Learning System (NRLS) to collect reports of patient safety incidents and their root causes, and to learn from them, including developing solutions to enhance safety. Incident reporting enables the types and causes of safety problems to be identified and supports efforts to prevent harm to patients.<sup>6,7,9</sup>

However, incident reporting on its own can never tell us all we need to know. This was recognised in the government report, *Building a safer NHS for patients*<sup>10</sup>, which envisaged the NPSA developing an understanding of a range of data sources. This will enable us to develop a much more comprehensive understanding of patient safety so that we can effectively reduce risk across all

healthcare sectors. In order to develop this understanding the NPSA has set up a Patient Safety Observatory in collaboration with a number of partners from both the NHS and elsewhere. These include the Healthcare Commission, the Office for National Statistics, the Medicines and Healthcare products Regulatory Agency, Action against Medical Accidents, the NHS Litigation Authority, and medical defence organisations. Through a stakeholder group we are working together to identify and summarise the key data sets which will help us better understand and improve patient safety (see Appendix 2).

**The primary function of the Patient Safety Observatory is to quantify, characterise and prioritise patient safety issues in order to support the NHS in making healthcare safer.**

The Observatory enables us to draw upon a wide range of data and intelligence to paint a clearer picture of the issues for patients and for the NHS. In doing this, the Observatory will drive the work programme of the NPSA through identifying and monitoring patient safety incident trends, highlighting areas for action and setting priorities.

This report is the first of a planned series of Observatory reports. This first section describes the Observatory approach, demonstrating how the Observatory can embed the NRLS within a wider context, to enhance and supplement the value of NRLS data and better support the NPSA and the NHS in meeting the goal of improved patient safety.

The second section of this report demonstrates the value of this approach and presents the first analysis of data from the NRLS.

## **What is a patient safety incident?**

The NPSA defines a patient safety incident as “any unintended or unexpected incident that *could have* or did lead to harm for one or more patients receiving NHS-funded healthcare”.<sup>11</sup>

This definition includes errors in treatment and care which did not harm patients. Some of these will be ‘near misses’; where the problem was identified and rectified such that any effect on the patient was avoided. In other cases the incident may not have been noticed until some time after treatment and, although the patient was at risk, no harm occurred. In some cases, particularly where patients are receiving emergency and life-saving treatment, patients may be harmed or die as a result of their care. The NPSA definition of a patient safety incident excludes cases where a patient was harmed but the effect was an expected or recognised outcome of treatment. There are likely to be many more near misses than events that actually harm patients.

## **An international perspective on the rate of patient safety incidents**

Patient safety is an international concern and broadly similar levels of patient safety incidents have been found across healthcare systems in developed countries. A range of sources and methods have been used over the past 40 years to quantify and describe patient safety. Different methods used to measure patient safety incidents and different definitions will produce differing results. For example, results will differ depending on whether events which did not lead to harm are included or not, and the thresholds that are used for deciding whether harm to patients was unexpected or unintended. At present there is no internationally-accepted taxonomy for patient safety incidents.<sup>12</sup> Examples of the different methods that have been used are summarised in Table 1. This illustrates the range of methods and how they may lead to different estimates of the size of the problem. Other sources of information about the nature and causes of patient safety incidents (such as negligence claims and complaints from patients) can also contribute to our wider understanding.

**Table 1: Examples of potential sources of information about the frequency of patient safety incidents**

Information source	Examples of factors that will affect findings	Examples of findings
Incident reporting systems	More likely to record near misses and errors which did not lead to harm. May be less likely to report known side-effects and complications of treatment.	4.9 incidents reported for every 100 hospital admissions, and 1.2 incidents reported for every 100 bed days (England, see page 52). 1.1 to 3.8 incidents for every 100 bed days (Regions, Pennsylvania, USA). <sup>13</sup>
Medical record review	The threshold that is used for including minor errors or deviations from standards of care. The threshold that is used for determining that harm to a patient was preventable.	Four to 17 adverse events in every 100 hospital admissions (studies in North America and Europe, see page 53).
Routine data collection	Recording of adverse events likely to be incomplete. Recording likely to improve with greater awareness of issues.	About two adverse events in every 100 hospital admissions in England. <sup>3</sup> 16 deaths from MRSA in every million men, and 8.5 deaths for every million women. <sup>14</sup>
Surveys of patients and staff	Level of awareness of staff and patients. Patient's condition: for example, people with long-term conditions are more likely to be aware of errors than those receiving life-saving treatment.	35 in every 100 NHS staff reported seeing at least one error or near miss that could have harmed patients during the month before the survey. <sup>15</sup> 18 to 28 in every 100 patients with health problems from five countries believe a medical mistake or medication error affecting them had occurred in the two years before the survey. <sup>16</sup>

## The National Reporting and Learning System

### What are incident reporting systems?

Incident reporting systems are an important tool to help identify patient safety problems and provide data for services to learn from errors. Much of the design of reporting systems in healthcare has drawn upon successful experiences in other high-risk industries, particularly aviation. However, experience of reporting in healthcare (with a few notable exceptions, such as the confidential enquiries<sup>17</sup>) is relatively recent.

The primary purpose of an incident reporting and learning system is to help make healthcare safer for patients. Incident reporting typically involves healthcare staff actively recording information on events that led to unintended harm or potential harm to patients. Most incidents involve a complex interplay of individual, team, technical and organisational factors. Although each incident is unique, there are likely to be similarities and patterns which may otherwise go unnoticed if incidents are not reported and analysed.

Reporting systems typically seek to capture information including the type of incident, where it happened, who was involved, the outcome for patients, and factors that may have contributed to, or helped prevent, the impact of the incident. As well as capturing such information in a way that can be counted and aggregated, it is common for systems to collect descriptive information too, i.e., the story of what happened. This narrative content can provide additional qualitative insights.

### Example of a reported incident and local action

A patient attended for routine replacement of their tracheostomy tube (a tube inserted in the throat to assist with breathing). The wrong size tube was used and this was later highlighted by a family member.

Immediate action was taken to arrange for the tube to be replaced. All stocks of tubes were checked in order to prevent recurrence of the incident.

Insights provided from reports and their analysis can help to prevent future incidents, identify risks and hazards within existing systems, identify new or rare events, and generally help to better understand the safety issues facing an organisation or health system. Individual healthcare organisations have the primary responsibility for investigating incidents and ensuring that action is taken to prevent their recurrence.

The NPSA has developed a range of tools for NHS organisations to use to investigate patient safety incidents locally. These include the *Seven steps to patient safety guide*<sup>11</sup>; an incident decision tree; and training and guidance for undertaking root cause analysis. In parallel to the implementation of the NRLS, the NPSA has supported extensive training across the NHS in the methods of analysing the root causes of incidents (training more than 6,000 staff) to enable each organisation to investigate better and respond to incidents at a local level.

### Why have a national reporting system?

A national reporting system can add value to local approaches. There are two main reasons for this. Firstly, rare and newly emerging issues will not appear significant at a local level. In an Australian incident reporting system, it has been estimated that only ten per cent of the incident types that occur will be encountered more than once every two months in an average 250 bed hospital. The remaining 90 per cent of incidents would occur less frequently and are represented by 500 different types of event.<sup>18</sup> Secondly, some types of incident may not be reported locally because of concern by staff that they will be blamed for the incident. Although the vast majority of incidents will be reported locally, the existence of an independent and confidential reporting system provides a safety net for staff to report incidents to, which they would perhaps not report locally. For example, the Veterans Administration, which manages a large number of hospitals in the USA, has established a separate independent reporting system to meet this need and to supplement local reporting.<sup>19</sup>

In addition, a national system has the capacity to embed reporting into a national programme that develops and disseminates interventions and solutions across the healthcare system. In some cases, national action is also needed to address safety issues. For these reasons, the NPSA has developed the NRLS so that healthcare organisations can learn from others' experiences of adverse events and accidents.

### **Example of a reported incident and national action**

The NPSA received a number of reports about two common childhood vaccines, Repevax<sup>®</sup> and Revaxis<sup>®</sup>, which are for use with different age groups. In January 2005, 93 schoolchildren were vaccinated with Repevax instead of Revaxis and so received a dose of the whooping cough vaccine that is usually recommended for pre-school children.

As a direct result of these reports, the NPSA, working in collaboration with the Medicines and Healthcare products Regulatory Agency (MHRA), issued a safer practice notice to describe actions which NHS clinicians and procurement managers should take to prevent further occurrences.

The NPSA is continuing to monitor events through the NRLS and other sources, and is working with the MHRA to influence the pharmaceutical industry to make changes to labelling and packaging that will help distinguish between medicines, and different strengths of the same medicine, to prevent selection errors.

Incident reporting systems can come in many forms. There are systems which focus on specific types of events (for example, blood transfusion events<sup>20</sup> or sentinel events<sup>21</sup> which lead to serious patient harm or death), areas of practice (for example, intensive care units<sup>22</sup>) or across whole healthcare organisations. To date, most incident reporting systems have been established in hospitals. Typically, data collected by such local reporting systems are used to identify incidents that might require further investigation and to monitor organisational trends.

## The NPSA's National Reporting and Learning System

### NRLS at a glance

- The NRLS receives reports about patient safety incidents from NHS organisations throughout England and Wales. The majority of these reports come directly from local information systems.
- Local NHS organisations continue to have primary responsibility for investigating and acting on local patient safety incidents.
- Over time, the NRLS database will contain hundreds of thousands of patient safety incident reports.
- Clinical teams review all reported deaths.
- Computerised data analysis tools help identify potential clusters, patterns and trends across these reports.
- The reports help the NPSA learn from incidents and develop interventions to reduce risk for patients.
- The NPSA will regularly publish information and learning from national analysis of patient safety incidents.
- The NRLS is piloting feedback of analysis and benchmarking to the NHS to allow organisations to make better use of the data.

The NRLS is the primary mechanism for the NPSA to collect information on patient safety incidents, including near misses, from across England and Wales. It is the first national system of its kind in the world.

The NPSA was formed following the publication of two reports on patient safety in the NHS, *An organisation with a memory*<sup>7</sup>, and its follow-up, *Building a safer NHS for patients*<sup>10</sup>. These reports were instrumental in establishing that the NHS had to improve its capacity to learn from patient safety incidents and that a unified reporting system would be a crucial step in achieving this. In particular, *Building a safer NHS for patients* laid down the blueprint for the NRLS.

The NRLS collects data from nine service areas:

- Acute hospitals
- Ambulance service
- Community and general dentistry
- Community nursing, medical and therapy service (including community hospitals)
- Community optometrists/opticians
- Community pharmacy
- General practice
- Learning disabilities
- Mental health

The data set is designed to collect a notification report of a single patient safety incident soon after it occurs. It focuses on what happened, when and where it happened, characteristics of the patient(s) involved (such as age, sex, ethnicity), the outcome for the patient, and the staff involved in the incident and/or making the report. Additional data are collected on incidents that involve

medicines and medical devices, and we also encourage the collection of data on contributory factors and factors that might have prevented harm. The majority of reports also contain free text that explains what happened in varying degrees of detail.

Although the NRLS collects some information on causal and contributory factors, it does not collect detailed root cause analysis data and the NPSA does not currently routinely follow up individual reports with those who provide them. The main reasons for this are:

- the reports come from local services that have the primary responsibility for investigation of incidents (the NPSA has no powers to investigate);
- the sheer volume of reports makes this impractical;
- the main purpose of a national system such as this is to identify trends and patterns, generate hypotheses and spot opportunities for learning.

### **Why is the NRLS a confidential reporting system?**

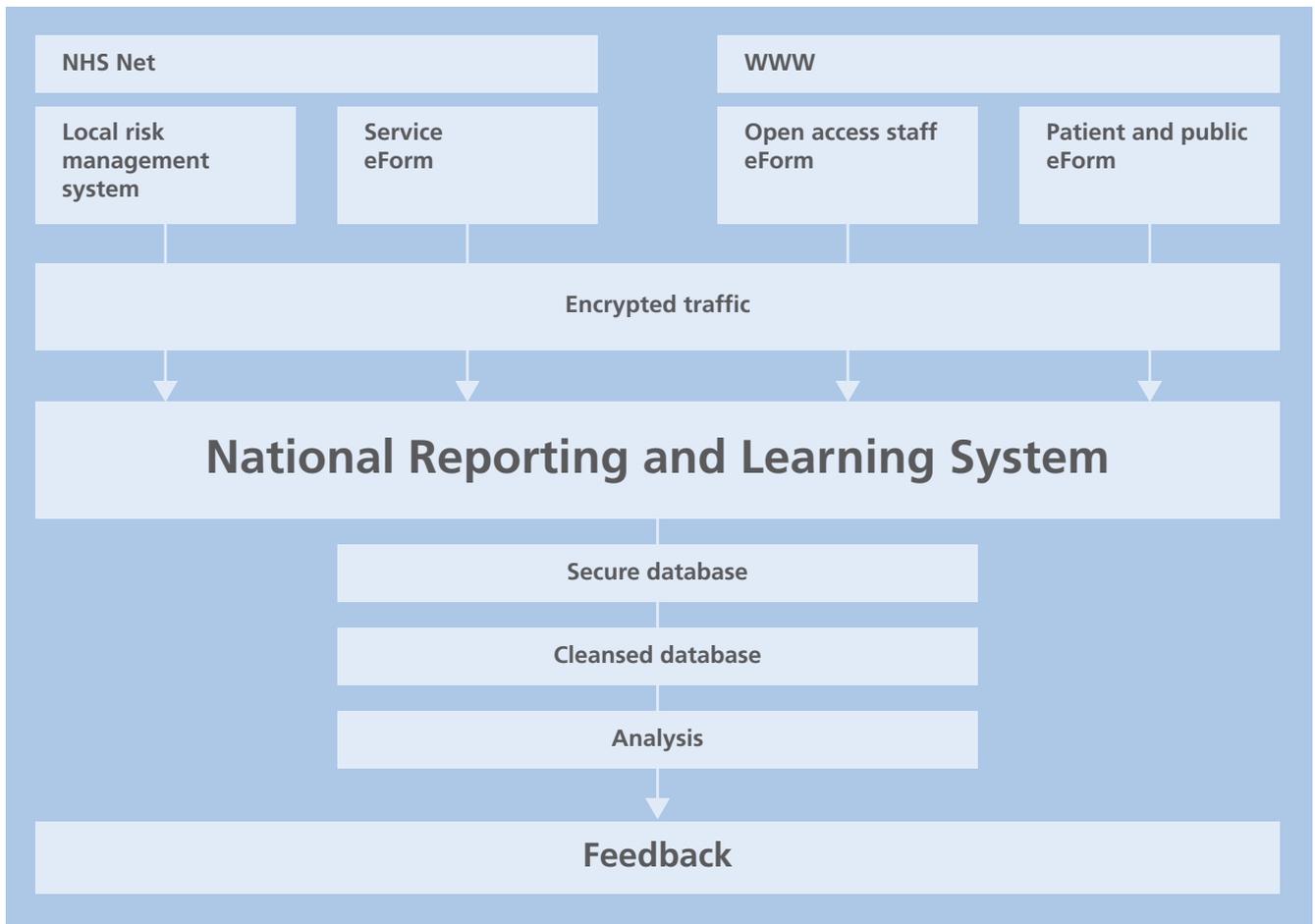
The NRLS is a confidential reporting system because experience across the world, in both health and other industries, shows that providing a means for reporting incidents confidentially promotes reporting and facilitates the necessary learning. The NPSA holds incident data in a confidential database. Patient safety incidents are usually the result of failing systems rather than failing people. For this reason, it is important that a reporting system should be non-punitive.

“When medical errors do surface, often with heart rending accounts of the suffering of the primary victims – the patient harmed – the reaction in medical settings is most commonly an attempt to fix blame and to punish someone. This will not work. If we can take any lessons from the stunning progress in safety in aviation and other high risk industries, it is that fear, reprisal, and punishment produce not safety, but rather defensiveness, secrecy and enormous human anguish. Scientific studies in human factors engineering, organisational psychology, operations research, and many other disciplines make it clear that, in complex systems, safety depends not on exhortation, but rather on the proper design of equipment, jobs, support systems and organisations. If we truly want safer care we will have to design safer care systems.”

Berwick D, Leape L. *Reducing errors in medicine. It's time to take this more seriously*<sup>23</sup>

### **How is NRLS data collected?**

Patient safety incidents are reported electronically to the NPSA. A key feature of the NRLS is that, in most cases, information is taken directly from local risk management systems (LRMS) that are already in use in hospitals and other organisations. This reduces the need for staff to report incidents both locally and to the NRLS. An electronic reporting form is also available for use by those trusts which do not have a LRMS. From September 2004, this reporting form has also been available on the internet so that staff can report directly to the NPSA, without going via their trust. However, the NPSA encourages staff to share information with their local NHS organisation wherever possible, as this facilitates learning at a local level. The NPSA is also piloting an electronic form for use by patients and their carers. In addition, information is shared electronically with the MHRA database for medical device incidents, and the NPSA is working with the MHRA to share more information on adverse drug reactions. The NRLS is outlined diagrammatically in Figure 1.

**Figure 1: The National Reporting and Learning System****What does the NPSA do with NRLS data?**

The NRLS provides a springboard to develop national solutions to patient safety problems and to identify priorities for the NPSA (and others). This is further described in the section on the Patient Safety Observatory. The NRLS can also act as a mirror to reflect data back to the service and help provide evidence to back up local action to improve safety. Furthermore, through working closely with the NHS across England and Wales, the NPSA can bring together groups of incidents for more detailed root cause analysis that will help us protect patients.

The incident reports are held in a database. Reports are reviewed and analysed in a number of ways, including:

- by incident types and trends, within the coded data fields, using analytical software;
- identifying themes and patterns from free text information: the NPSA is developing the use of specialised software to do this;
- reviewing particular types of incidents by NPSA specialist staff and royal college clinical advisors on a regular and ad hoc basis.

The NPSA is developing a range of reports from the NRLS and is currently testing out ways to feed back data to local NHS organisations and to different groups of NHS staff. Feedback to NHS organisations will include some comparisons with similar organisations to look at common themes and patterns of safety incidents.

Feedback will help encourage reporting and support trusts in continually improving the quality and completeness of incident data.

Below is an example of how themes and patterns have been identified following the analysis of NRLS data.

### ***From learning to safer healthcare: patient identification and wristbands***

Misidentification of patients is a theme that occurs in any analysis of patient safety. The NPSA has already released an alert on correct site surgery to address one specific area of this source of harm to patients. The NPSA is also working on other areas which are related to misidentification such as ensuring compliance with wristband wearing in acute services and reducing incidents of incompatible blood transfusions.

The NPSA believes that there is considerable scope in the NHS for improving patient safety, both through the development of fail-safe methods of manual identification and checking and through applying technologies such as barcodes, radio frequency identification and biometrics.

A search and analysis of the NRLS data to identify incidents of mismatching showed that:

- 493 reports of mismatching were found from 45 reporting trusts;
- two-thirds of these reports were from medical, surgical and diagnostic specialties in acute hospitals;
- one in every eight incidents specifically related to issues with identification of patients with wristbands, and half of these were due to a missing wristband;
- of 32 incidents where the wristband was missing, three led to patients having unnecessary x-rays;
- two patients with missing wristbands received treatment intended for another patient (one a blood transfusion, one an antibiotic);

***From learning to safer healthcare: patient identification and wristbands continued***

- four out of ten reports included discrepancies with information on the wristbands or where the information on the wristband differed from other relevant documents;
- of these 26 incidents, there were 22 occasions when the information on patients' wristbands was incorrect and the staff involved would therefore not proceed with the treatment until they could confirm the patients' identity;
- in eight of these cases, a patient had been transferred to theatre before the error was discovered.

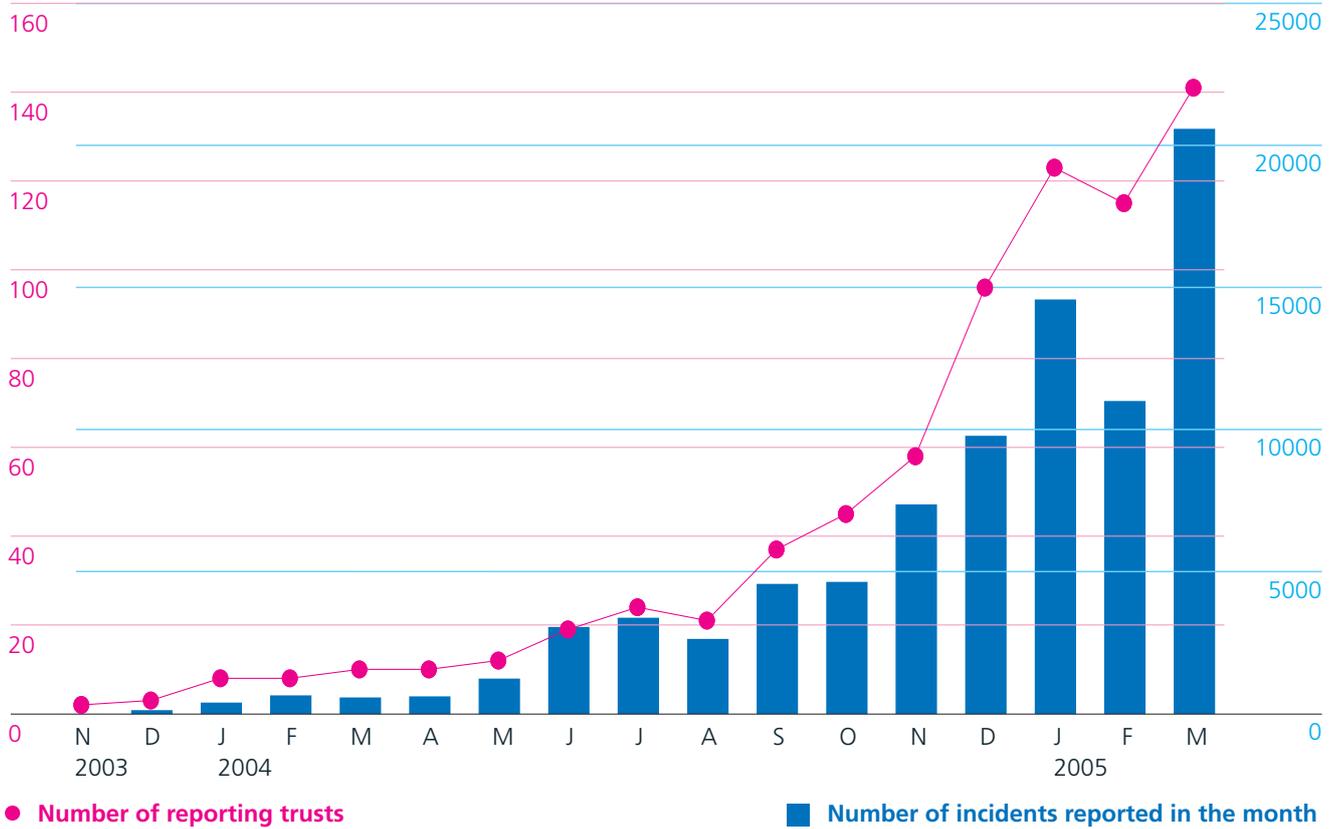
The data have confirmed that there is a lack of a systematic and standardised process to support the identification of patients in a way that allows healthcare staff to match them to their care, treatment and records. This work will inform further advice for the NHS scheduled for autumn 2005, and additional work to produce a standard for patient identification.

**Reporting to the NRLS**

The NRLS was developed with considerable involvement from groups of people across the NHS and all NHS organisations in England and Wales have had the capability to report since December 2004. However, reporting is much easier for trusts that have a history of reporting and have well-established local risk management systems. At present, most reports are received from local risk management systems, with over 99 per cent of incidents to date coming through this route. These largely exist in hospitals (predominantly acute general hospitals, but also in other settings such as mental health). As more and more trusts were connected to the NRLS, there has been a rapid increase in the number of reports received (see Diagram 1). At 31 March 2005, there had been 85,342 incidents reported to the system, affecting 86,142 patients. Reporting should increase as the number of organisations that report increases; as individual staff members within these organisations have the ability to send reports directly to the NRLS; and as the culture within organisations develops so that staff feel more able to report incidents.

The data in this report come largely from incidents reported by NHS organisations. There are early indications that the information received from staff directly via the reporting form on the NPSA's website will also be a rich source of information for learning about patient safety incidents. Encouragingly, 94 per cent of the 108 reports that have come in via this route from September 2004 up to the end of March 2005 have agreed that their report can be shared with the trust involved. In addition, although it is very early days, 13 per cent of the reports coming in via this route are from medical staff who may be less likely to report incidents locally. The NPSA began a campaign to raise awareness of this route in March 2005, and the number of people using it has increased since that date.

Diagram 1: Roll out of the NRLS: reported incidents and number of reporting trusts, by month



## Developing the NRLS

Although it already has thousands of reports, the NRLS is still in its infancy. More than half of the reports analysed here were received from January to March 2005. The NPSA has a number of streams of work to extend the functionality of the NRLS and to extend the ways in which data are used and analysed.

The NPSA is extending the functionality of the NRLS by:

- developing a version of the eForm for patients and the public to use. This is currently being tested with users and will be launched in February 2006;
- working with community pharmacy providers to link their local risk management systems to the NRLS. All community pharmacies will be reporting incidents involving serious harm to patients to the NRLS by October 2005;
- developing a web-based system for NHS trusts to receive feedback from the NRLS. This is currently being piloted;
- improving data quality by working with trusts to promote good practice and to improve the quality of reports from local risk management systems.

As the data set develops, the NPSA is also extending the range of ways that incident reports are analysed. The NPSA is:

- extending the review of incidents by clinical experts and NPSA staff, so that themes and issues relevant to different clinical areas can be identified;
- developing the use of data mining methods, working in collaboration with international partners, such as NASA (in the USA) and Uppsala (in Sweden); data mining techniques aim to find unsuspected relationships and summarise information from large data sets;<sup>24</sup>
- extending the use of software to identify clusters within NRLS data;
- undertaking more detailed analysis of specific topics and groups of records. For example, reports obtained directly from staff via the electronic reporting form on the NPSA's website.

In addition, the NPSA will evaluate both the data set and how the NRLS has been implemented. This will inform future work with 'Connecting for Health'. It is envisaged that over time the NRLS requirements will form part of a national specification for risk management systems.

### **Patient and public reporting**

Patients, relatives and carers have a different perspective on patient safety incidents from healthcare staff, and it is essential that the NHS hears their voices in order to learn from incidents and improve the quality of care.

The NPSA receives reports from patients through a number of routes – in person, by phone and in writing – and it also involves patients in scoping problems and developing solutions. For example, patients have been involved in our work on anticoagulants, learning disabilities, maternity services, mental health and oral methotrexate.

The Patient and Public Reporting project involves a web-based form specifically designed to enable patients to report incidents directly into the NRLS. This is being piloted during summer 2005 and will be launched in February 2006. Alongside the eForm, the NPSA is working with patient organisations and other bodies which patients may contact about their concerns, to ensure that patients direct their concerns to the organisation that can meet their needs. Information from patients and patient organisations also feeds into the Observatory – in the form of patient surveys, complaints information and feedback from patient organisations.

## **The Patient Safety Observatory**

### **Why do we need a Patient Safety Observatory?**

Although incident reporting is fundamental to understanding patient safety, on its own it does not give the whole picture of what does or could lead to patient harm. Focusing on incident reporting as a single source of information is like trying to complete a jigsaw puzzle when half of the pieces are missing; the end result is an incomplete picture.

Incident reporting needs to be part of a broader approach to surveillance and monitoring. The findings from incident reporting must be considered alongside a range of data and intelligence, including the published literature, clinical experts, medical record reviews, hospital episode statistics, death certification data, complaints, prospective risk assessments, patient safety indicator studies, observational research, confidential enquiries, and audits and reviews of healthcare organisations. It is only by triangulating information from these different data sources that the true nature and severity of patient safety incidents can be understood. This is the rationale behind the NPSA's Patient Safety Observatory.

Other healthcare systems around the world have also realised the importance of triangulating different sources of data. For example, the Agency for Healthcare Research and Quality (AHRQ) in the USA recently published the preliminary findings from 16 studies, commissioned to understand the contribution incident reporting can make to reducing harm. On the basis of the findings from these studies, AHRQ has stated that incident reporting findings need to be triangulated with other data sources in order to maximise the safety lessons learnt.<sup>25</sup>

There are many agencies involved in collecting and using information about patient safety, both formally and informally. The particular importance of the Patient Safety Observatory is that we know that no one source of information can tell us everything we need to know about patient safety in our healthcare system. There are a number of factors that explain this:

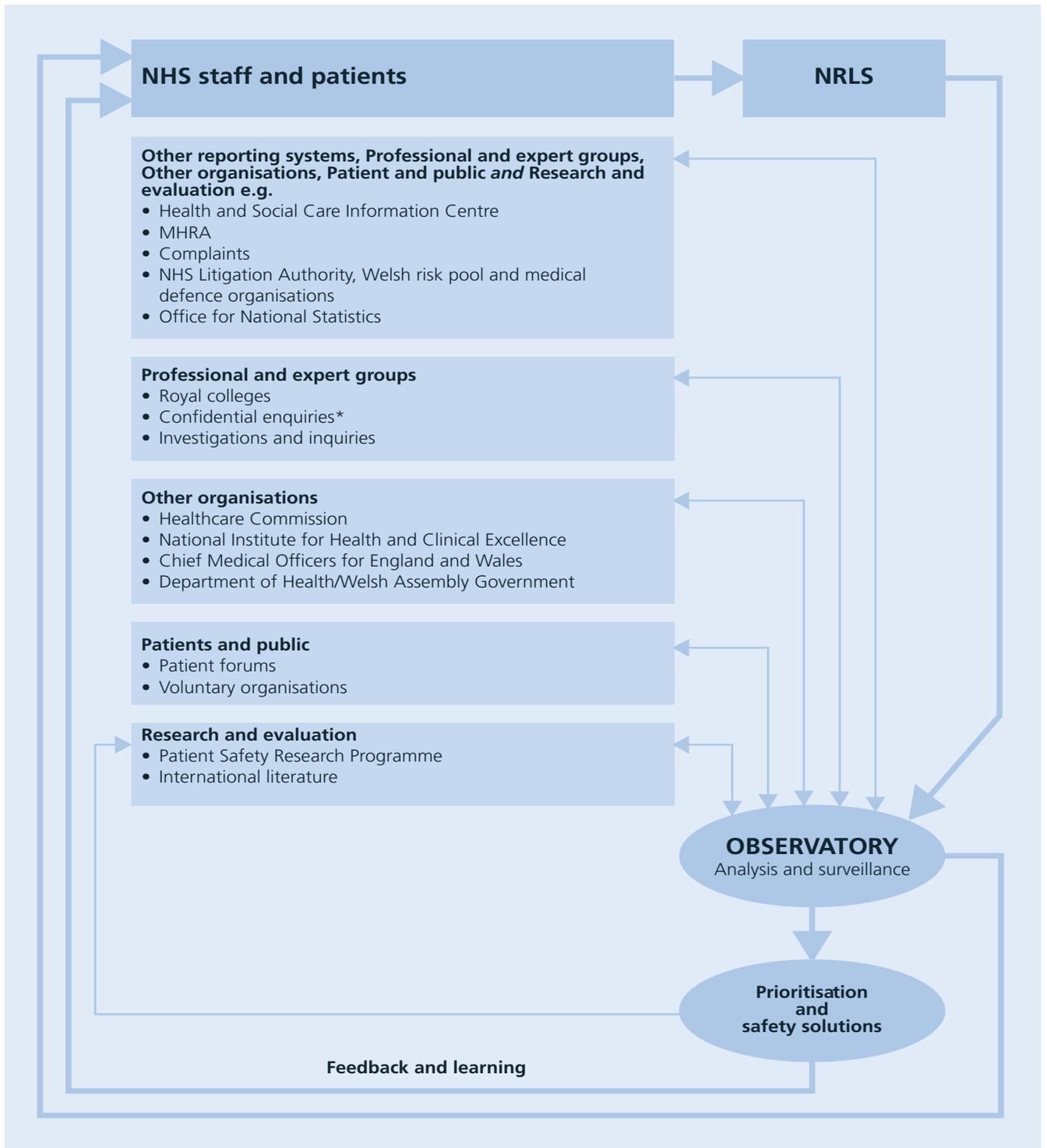
- incident reporting systems are not comprehensive – there is a gap between what occurs and what is reported;
- incident reporting provides a particular perspective on safety. For example, incident reporting is more likely to identify low harm or near miss incidents than a review of medical records, but less likely to tell us about known side-effects and complications;<sup>26</sup>
- reports on certain types of incidents may be reported through other systems, such as incidents involving medical devices reported in the UK to the MHRA;
- some staff are more likely than others to use incident reporting systems;
- different reporting systems themselves provide a different profile of reports. For example, a system set up by doctors in a local intensive care unit may capture incidents not reported to the hospital risk management system;
- incident reporting cannot provide some of the detail that can be provided by, for example, more detailed root cause analysis;
- serious events are rare and information on them distributed across the healthcare system;
- the healthcare system as a whole could make better use of data sets already in existence to explore safety, even if such existing data collections were designed for different purposes.

The NPSA wants to strengthen the availability, use and usefulness of information about patient safety at a national level in order to help make patient care safer. This requires us to have in place a set of information and measurement capabilities to be able to routinely identify shortcomings in the safety of patient care, understand why these are occurring and know enough to be able to ensure that the right preventative strategies are developed.

Figure 2 outlines the inputs and outputs of the Patient Safety Observatory with examples of the possible sources of information that will feed in to it.

It is critical for the Observatory to work in collaboration with other organisations in order to put this approach into practice. The NPSA has established a stakeholder group of representatives from organisations who hold information of relevance to patient safety to support the Observatory (see Appendix 2). The Observatory is working with stakeholders to develop a compendium of information sources about patient safety, as an important first step in developing a better understanding of available information.

Figure 2: The Patient Safety Observatory



\* The National Confidential Enquiry into Patient Outcome and Death (NCEPOD); The Confidential Enquiry into Maternal and Child Health (CEMACH); The National Confidential Enquiry into Suicide and Homicide by people with mental illness (NCISH).

## What does the Patient Safety Observatory do?

The five main functions of the Patient Safety Observatory support the broad work programme of the NPSA:

- 1 It helps to identify and understand patient safety issues and problems through data mining and analysis. This includes the NRLS as well as existing data collections both nationally and internationally.
- 2 It helps the NPSA to set priorities for national action. As the NPSA has limited resources, careful choices need to be made about where it can add the most value with its work. The Observatory helps the NPSA to quantify patient safety issues and to gather the best available evidence to inform decision-making. This information then feeds into the NPSA's prioritisation process, which is a formal mechanism that allows key issues to be identified and the future work programme to be planned.<sup>2</sup>
- 3 The Observatory supports the NPSA in the development of national solutions to safety problems. This is achieved by ensuring that the factors that contribute to patient safety problems are understood, and the risks that need to be minimised if care is to be made safer, are identified.
- 4 Research data on patient safety is identified and assimilated as part of the Observatory's functions. This ensures that solutions to safety problems are grounded in the best available evidence base. This also allows us to identify gaps in knowledge and priorities for research into safety which the NPSA can pursue in collaboration with the NHS Patient Safety Research Programme (part of NHS Research and Development).
- 5 Once the NPSA has developed solutions, the Observatory helps to monitor and evaluate their impact. For example, through ongoing analysis of patterns and trends across different data sources to see if the problem has been addressed or whether new risks are emerging which also need attention.

### Observatory case study 1: anticoagulants

This example illustrates how several different sources of data can be assimilated and compared to scope a patient safety problem.

A proposal to develop solutions to improve the safety for patients on anticoagulants has been agreed by the NPSA's prioritisation process, and the NPSA now has a programme of work to develop safety solutions in this area.

#### What are anticoagulants?

Anticoagulants thin the blood to reduce the risk of blood clots. They are used to treat patients who have a blood clot, or to prevent blood clots developing in patients at risk. Patients who need long-term anticoagulation take tablets such as warfarin.

#### What are the patient safety issues?

These medicines need to be given in exactly the right amount; not only to ensure that they are effective, but also to minimise side-effects. Too low a dose could result in a life-threatening blood clot. Too high a dose could result in bleeding which could be fatal. Patients on tablets must have regular blood tests to assess the effect of the anticoagulation.

## Observatory case study 1: anticoagulants *continued*

### Scoping the patient safety problem

The NPSA used a wide range of sources and methods to scope this problem:

#### *The NRLS*

- The NRLS database included 311 incidents involving anticoagulants, including two deaths, up to 31 March 2005. The most frequent types of error were overdose, poor record keeping, contraindications for use and problems with monitoring.

#### *Other reporting and information systems*

- Around 500,000 patients in the UK take warfarin or similar anticoagulant tablets.<sup>27</sup>

#### *Other organisations*

- There were 600 negligence claims reported to healthcare negligence and defence organisations, as a result of harm or near harm associated with the use of anticoagulants, in the UK between 1990 and 2002. Of these cases, 20 in every 100 (120 cases) had resulted in the death of the patient.
- An analysis of 223 cases reported to the Medical Defence Union (MDU) identified 80 deaths, 60 reported from general practice and 20 from other care settings. The main causes for the fatal incidents were inadequate laboratory monitoring and clinically significant drug interactions usually involving pain killers.
- The MDU data also show that the number of negligence claims each year involving anticoagulants has increased since 1990.

#### *Research and evaluation*

- Risk of significant bleeding whilst on long-term anticoagulation varies between one per cent and 15 per cent per year.<sup>28</sup> The risk is higher in the first three months of treatment, but reduces after this period.<sup>29</sup>
- In the USA,<sup>30</sup> and Australia,<sup>31</sup> anticoagulants have been identified in the top five medicines associated with patient safety incidents. In primary care in the UK, anticoagulants are one of the three types of drugs most commonly associated with fatal medication incidents.<sup>32</sup>

#### *Professional and clinical groups*

- An extensive risk assessment was conducted, involving clinical staff and patients, to identify high risk areas associated with anticoagulant treatment.

#### *Prioritisation*

- A brief for further work on anticoagulants was presented to the NPSA's prioritisation programme, and this work is now taking place, in collaboration with the British Society for Haematology.

## Observatory case study 2: nasogastric feeding tubes

This example demonstrates the importance of using local intelligence and expertise from across the NHS and partner organisations to understand patient safety problems.

The NPSA was contacted by a Coroner following an inquest in April 2004 into the death of a child in December 2002. The decision of the Coroner was that death arose as a consequence of feeding through a misplaced nasogastric feeding tube. The feeding tube was inadvertently inserted into the child's lungs, rather than stomach.

### What are nasogastric tubes?

Nasogastric feeding tubes are used for patients who have swallowing or feeding difficulties. This could be because they are unconscious, critically ill, need extra nutrition, or have difficulty in swallowing safely because of a stroke or other illness.

### What are the patient safety issues?

Nasogastric feeding tubes are passed through the nose into the stomach. As the tube cannot be seen it may inadvertently enter the lungs, particularly if the patient cannot assist by swallowing as the tube reaches their throat. A tube inadvertently placed in the lungs will usually cause no damage if the incorrect placement is recognised and the tube is removed before feeding commences. However, if nutrients are fed through a misplaced tube it may result in a life-threatening situation and even death.

### Scoping the patient safety problem

#### *The NRLS*

- The NRLS included 39 patient safety incidents involving nasogastric feeding tubes up to December 2004 including one case of severe harm caused by a misplaced tube.

#### *Aggregate root cause analysis*

- The root causes were investigated by working with a range of staff from four NHS trusts who had similar incidents in different settings. The participants were willing to share their learning and experiences with each other and the NPSA, to try and understand the root causes of these incidents and to develop solutions to prevent their recurrence.

#### *Other organisations*

- Working with representatives from the four NHS trusts, the National Nurses Nutrition Group, the British Association of Parenteral and Enteral Nutrition, the Department of Health and the MHRA, the NPSA developed a patient safety alert to raise awareness of the risks of misplaced nasogastric feeding tubes and offer guidance on best practice based on current evidence.

#### *Research and evaluation*

- A search of the published literature on nasogastric feeding tube insertion and testing methods was undertaken to identify evidence-based practice, policies and procedures. Studies in the USA suggest that less than one in every 100 nasogastric feeding tube placements may result in some form of complication, whether minor or serious.<sup>33,34</sup>

### **Observatory case study 2: nasogastric feeding tubes** *continued*

- The NPSA also recognised a need for further research to investigate reliable methods of testing whether the tube is in the right place. As a result of collaboration with the NHS Patient Safety Research Programme, further research is being commissioned. Once the findings from this research are known, the guidance from the NPSA on the most reliable testing method will be updated.

#### *Professional and clinical groups*

- Information and advice was sought from experts from organisations such as medical and non-medical advisory groups, royal colleges and their clinical networks.
- Informal surveys of current practice were undertaken through the NPSA's network of patient safety managers, who are based across England and Wales. This included gaining opinions on the different tests used to assess the position of nasogastric feeding tubes.

#### *Prioritisation*

- The development of an alert about nasogastric feeding tubes was fast-tracked, given the high level of risk to patients of misplaced feeding tubes.

#### *Feedback and learning*

- The NPSA has issued an alert to raise awareness of the issue and guide current practice and, working with the NHS Patient Safety Research Programme, has commissioned further research to support better evidence for safe practice.<sup>2</sup>

## **Developing the Patient Safety Observatory**

This section has described the Observatory approach and explained not only how the NPSA's NRLS is the essential core to the model, but also how the Observatory will use NRLS data alongside other data and intelligence to maximise its value. By taking this approach we can be confident of building an accurate understanding of key patient safety issues which will lead to robust, sustainable solutions.

Over the next twelve months, the Observatory will deliver timely outputs that demonstrate the value of the approach. Key features of the work programme of the Observatory include:

- putting the Patient Safety Observatory model into practice by working with other organisations to identify and analyse information on patient safety issues;
- developing methods for using data which are routinely available in the NHS to inform patient safety issues;
- disseminating information from the NRLS and the Observatory; building on this first report.

# Part two

## From learning to safer healthcare

The NRLS collects reports of patient safety incidents. As part of the work of the Patient Safety Observatory, incident reports are analysed to help us understand:

- what sort of things go wrong or are likely to go wrong;
- what factors contribute to patient safety incidents;
- whether any new hazards are emerging.

This part of our report presents an overview of findings from the NRLS, including incidents reported from the beginning of the roll-out in November 2003 up to and including 31 March 2005.

Throughout this section there are examples of how the NRLS data are being used to improve patient safety. Where appropriate, we have compared findings from the NRLS with other reporting systems.

### How to interpret the data

There are a number of notes of caution in interpreting these data:

- The data from the NRLS do not allow us to present data on incidents across all of England and Wales. Two hundred and thirty NHS organisations in England and Wales have reported data included in this analysis, and these organisations do not have the same mix of care settings as the whole of the NHS.
- International research suggests that there is significant under-reporting of incidents, so the reports we have analysed may underestimate the number of events.<sup>35-39</sup>
- Similarly, reports made to local risk management systems may not capture all types of incidents that occur. For example, device-related incidents may be reported to the MHRA rather than to the NRLS.
- The profile of reporting organisations is not representative of the whole of the NHS; to date, reports are more likely to come from acute hospitals than other settings.
- The data are confidential. We do not hold information on the identities of staff or patients, and this means that the data are not routinely checked with the reporter. However, we do take steps to maximise the quality of the data we hold, for example, checking for duplicate reports, and feeding back to individual trusts if there are problems.
- There are no reports from the public or patients included in this analysis. Work is underway to develop ways in which the public and patients can report incidents.
- A higher number of reported incidents from a trust, specialty or location does not necessarily mean that the trust, specialty or location has a higher number of incidents; it may reflect greater levels of reporting. Organisations reporting higher numbers of patient safety incidents may have a better developed safety culture, resulting in greater reporting and learning from reports.
- Incidents recorded in local risk management systems include some that are not due to patient safety incidents. For example, all suicides and still births may be included regardless of whether they arise from a patient safety incident; similarly, some organisations collect information on all unexpected deaths.

As a result, reports on the NRLS are not only of patient safety incidents.

- Deciding whether a patient safety incident has happened and whether it has led to harm to a patient is not always straightforward. The data set is therefore likely to include incidents where the impact on the patient is not clear. For example, if a patient dies as a result of severe illness, and they were affected by a patient safety incident, it may be difficult to know if their health outcome was affected by the incident or as a result of the underlying illness.
- The level of detail collected locally varies. For example, some organisations and local data collection systems do not currently collect contributing factors or ethnicity.

The following section includes aggregate analysis of NRLS data as well as a number of case studies that demonstrate learning from use of NRLS data linked to the NPSA work programme.

### ***From learning to safer healthcare: oral methotrexate***

Oral methotrexate is a well-established, effective treatment originally used in oncology but now widely used in rheumatology, dermatology and gastroenterology. However, occasionally it can lead to harm if it is not prescribed and monitored appropriately.

In July 2004, the NPSA issued a patient safety alert which included actions to improve safer use of the treatment.<sup>2</sup> This required the NHS to:

- 1 agree local action required;
- 2 provide patient information before and during treatment;
- 3 update prescribing and dispensing software programmes;
- 4 review purchasing.

Subsequently, reports to the NRLS have been monitored for incidents associated with the use of oral methotrexate. This has identified additional factors to do with the use of the drug which may previously have existed but were not evident within the original data used. Up to 31 March 2005, 25 reports have been received by the NRLS that are directly associated with the use of oral methotrexate. Common incidents from these reports are:

- inaccurate transcribing on to drug administration charts in hospital;
- transcription errors between hospital consultants and GPs such as problems in communicating correct dose or frequency of dose within documentation;
- delayed or no action to toxic effects of abdominal discomfort, nausea and vomiting of hospitalised patients.

The NPSA has agreed to review the core patient information that it issued with the original alert, in collaboration with rheumatology, dermatology and gastroenterology representative bodies. This may result in a re-issue of the information to the NHS and, if so, will provide a timely opportunity to raise awareness of these incidents.

The NPSA will:

- continue to monitor reports to NRLS to identify previously unreported causal or contributory factors;
- add new safety messages or solutions based upon these reports and evidence collected;
- evaluate the impact of the alert for a 12 to 24 month period to determine the uptake and application across the NHS.

## The source of incidents reported to the NRLS

The NRLS records the care setting in which an incident occurs, and also the organisation reporting the incident. In most cases the incident setting and the reporting organisation are the same but they may differ, for example, an incident occurring in a hospital may be reported by someone in primary care, or vice versa. Table 2 shows the settings in which incidents reported to the NRLS have occurred.

**Table 2: Settings of incidents reported to the NRLS**

Care setting	Number	Per cent of total
Acute / general hospital	67,344	78.9
Mental health service	10,667	12.5
Community nursing, medical and therapy service (including community hospital)	5,618	6.6
Learning disabilities service	813	1.0
General practice	438	0.5
Ambulance service	396	0.5
Community pharmacy	54	0.1
Community and general dental service	11	<0.1
Community optometry / optician service	1	<0.1
<b>Total</b>	<b>85,342</b>	<b>100</b>

Source: Reports in the NRLS database up to 31 March 2005

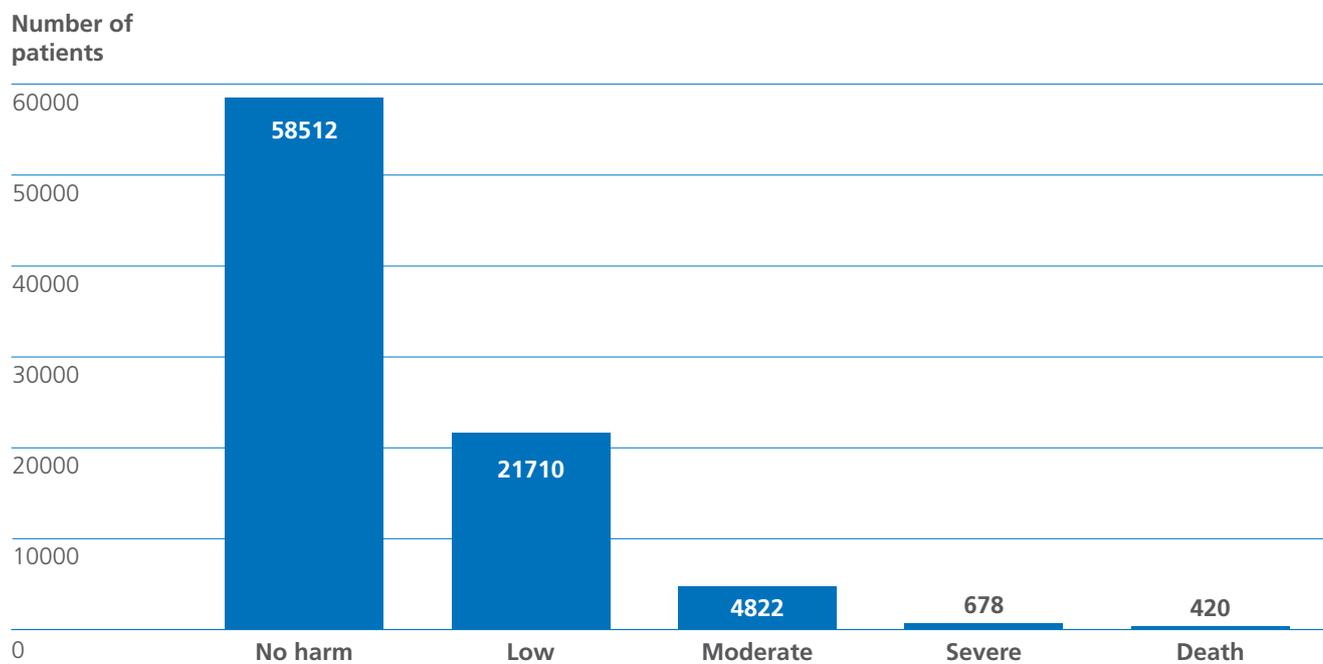
Incidents occurring in general/acute hospitals currently make up over three-quarters of the NRLS database. This is partly due to the widespread availability and use of local risk management systems in acute hospitals. In recent months there has been a marked increase in reports received from mental health trusts. To date, there are fewer reports from other service areas where less is also known from the research literature, but over time we expect to see an increasing number of reports from general practice, ambulance services and learning disabilities services.

The NPSA is encouraging reporting from all care settings, for example, by:

- supporting a programme of significant event auditing in primary care;
- developing links between community pharmacy risk management systems and the NRLS;
- working with local trusts through our network of patient safety managers;
- launching a publicity campaign aimed at doctors in training – one of the groups of staff least likely to report patient safety incidents.

### What is the impact on patients of incidents reported to the NRLS?

Diagram 2 shows the degree of harm that was suffered by the patient, or patients, that were affected by the incidents reported to the NRLS to the end of March 2005. Most incidents reported to the NRLS affect only one patient but they may affect more, or no patients may be affected, so the number of patients differs from the total number of incidents.

**Diagram 2: Degree of harm to patients**

Source: Reports in the NRLS database up to 31 March 2005

The majority of incidents (68 in every 100) that have been reported caused no harm to the patients. Incidents leading to severe harm or death account for about one in every 100 incidents. Amongst the 86,142 patients affected by incidents, there were 420 deaths and 678 patients who suffered from severe harm. However, these figures are likely to be an overestimation of the proportion of reported incidents causing a death for a number of reasons which are discussed below.

The proportion of incidents which are associated with death reported to the NRLS from acute hospitals is three per 1,000. This is very similar to that found by the Pennsylvania State reporting system; a system which is similar to the NRLS in terms of coverage and volume of incident reports.<sup>13</sup>

**Recording degree of harm**

The NRLS data set seeks to capture information on the impact of a patient safety incident on the patient. However, there are a number of reasons why interpreting information on degree of harm is complex.

Many patients, particularly those in acute care settings, are critically ill, and so grading the degree of harm caused by an incident is not straightforward. For example, some deaths following incidents may have occurred as a result of the underlying illness rather than as a result of the incident (see examples in box overleaf).

**The following examples illustrate the difficulties encountered in deciding whether harm was caused by healthcare treatment or the underlying illness.**

**An older patient** has cancer and a chest infection. Probably because of the antibiotics used to treat the chest infection, he develops a Candida (fungal) infection which makes his mouth sore and tender. He eats very little over the following week, and his discharge is delayed by concerns about his weight loss and weakness. It is difficult to judge whether the Candida infection, and consequent eating problems, could have been avoided.

**A small child** is rushed to an emergency department with very severe head injuries after a road traffic accident. She is already receiving cardiopulmonary resuscitation as her heart and breathing stopped during the ambulance journey. During attempts to resuscitate her, she is mistakenly given an adult dose of a drug. Attempts to restart her heart fail. It is difficult to judge whether the medication error contributed to the death of this child.

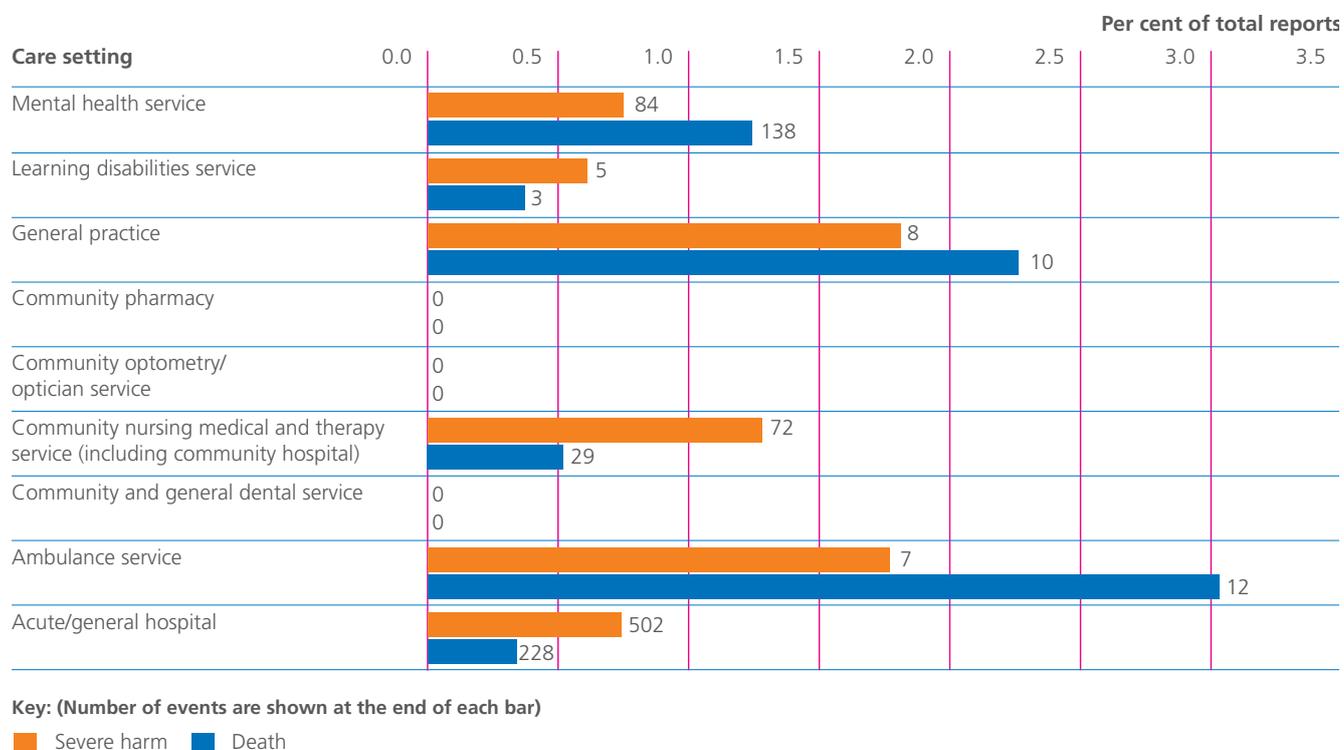
Some serious incidents and deaths recorded in local risk management systems may not be patient safety incidents, but are recorded for other risk management purposes. These include sudden deaths in primary care settings, deaths of mental health patients outside hospital, still births, deaths during or after operations, and otherwise explained deaths. This information is valuable for local investigation, or for reporting to other systems such as the National Confidential Enquiry into Maternal and Child Health.

Some trusts record the potential, rather than actual, impact on patients in their risk management systems. Thus, the patient in the incident may not have had a severe outcome or died, but there may have been a risk of this occurring. In addition, if the incident is reported early, the final outcome for the patient may not yet be known.

### **Degree of harm by care setting**

The proportion of incidents in each care setting which are reported as severe or associated with death is shown in Diagram 3. The proportion of reported incidents that are severe or associated with death appears to be lower in acute hospitals, and higher in the ambulance service and general practice. This is likely to reflect differences in arrangements for reporting of incidents, with fewer less serious incidents being reported in the ambulance service and general practice settings, resulting in the proportion of reports that are serious being higher than in the acute sector. The number of incidents reported by the ambulance service and general practice is less than by acute hospitals. For example, the reports from ambulance settings relate to seven severe incidents and 12 deaths from a total of 396.

For ambulance services, the higher proportion of deaths may reflect the emergency care they provide to severely ill patients, and also ease of reporting: fewer ambulance trusts have risk management systems that are fully connected to the NRLS, and over ten per cent of reports from ambulances are via eForms. Similarly, in primary care, where reporting systems have been less well developed, GPs may be more likely to report incidents that are associated with a greater degree of harm, but it is unlikely that this reflects a profile of more severe incidents in primary care. Up to 31 March 2005, no deaths have been reported from community pharmacy or community optometry services.

**Diagram 3: Incidents by care setting reported as severe or associated with death**

Source: Reports in the NRLS database up to 31 March 2005

### Degree of harm and safety culture

Experience from other industries suggests that the proportion of incidents leading to severe harm or death may decrease over time, both because a higher proportion of all incidents are reported and because safety lessons are learnt. Furthermore, a high proportion of no harm events may indicate that staff understand the importance of learning about errors before they lead to patient harm.

#### ***From learning to safer healthcare: developing a safety culture in the NHS***

The NPSA has a programme of work which aims to improve the safety culture in the NHS. To date it has developed an Incident Decision Tree to support managers when faced with an incident; e-learning and induction programmes; and is piloting an undergraduate programme in medical schools.

Two important elements of this work for 2005–06 are the Manchester Patient Safety Framework (MaPSaF) and *Being open*. MaPSaF is a tool, originally developed for primary care by Dianne Parker and colleagues at the University of Manchester, which helps NHS staff self-reflect on their progress in developing a positive patient safety culture. The NPSA has been collaborating with the University of Manchester to tailor this framework to acute, mental health and ambulance settings. It will be available to NHS staff from August 2005.

### ***From learning to safer healthcare: developing a safety culture in the NHS continued***

*Being open* involves communicating effectively with patients and carers who have been involved in a patient safety incident. It comprises a *Being open* policy, safer practice notice, an e-learning toolkit, and a one-day video and role play-based training programme for clinicians who have to explain what happened to patients and/or their carers following an incident that led to moderate harm, severe harm or death. The NPSA plans to launch the policy and safer practice notice in 2005, and the training tools will be available from autumn 2005.

## **Can we believe the estimates of the number of incidents and deaths?**

Several estimates have been made of the number of patient safety incidents that occur each year, and the number of people who die as a result. For example, estimates that have been widely quoted are of 850,000 incidents per year<sup>7</sup> and 40,000 deaths in England<sup>3</sup>, although other sources have suggested 25,000 deaths in the UK each year<sup>40</sup>. The accuracy of these estimates, and of similar estimates from other countries, has been widely debated<sup>41</sup>. Such estimates are likely to depend on a number of factors including the source of the original data and the definitions used in the original studies from which the estimates were derived.

One of the reasons for setting up the Patient Safety Observatory is because no individual data source can provide the full picture. Nonetheless, it is worth looking at the data in the NRLS to date to see how extrapolations from this might compare with these other estimates. Information from the NRLS has been used to produce an estimate of the number of reported incidents and of reported deaths caused by patient safety incidents in acute trusts in England.

The estimate has been made using the following method (for further information, refer to the NPSA website<sup>2</sup>):

- trusts that had reported data consistently over a three month period from October to December 2004 were identified;
- the numbers of incidents and deaths reported to the NRLS in each of these 18 trusts during this time period were identified;
- an adjustment was made for reports of deaths not related to patient safety incidents or reports of risk of death;
- the reported incident and death rate in each trust was calculated using Hospital Episode Statistics data for admissions to these trusts;
- the rates of reported incidents and deaths at the 18 trusts, together with the variation between them, was then used to estimate the number of incidents and the deaths caused by patient safety incidents that would be reported in acute trusts in England.

Based on this approach, we estimate that each year in NHS acute hospitals in England there are approximately:

- 572,000 reported patient safety incidents;
- 840 reported deaths resulting from patient safety incidents.

A number of important caveats need to be borne in mind when interpreting these data. These estimates are:

- based on *reported* incidents and deaths; as previously discussed this will not be a complete picture and will not take into account likely under-reporting of incidents. For example, we know that very few hospital acquired infections are reported to the NRLS, but that during 2003 there were 493 deaths in England and Wales where *Staphylococcus Aureus* was included as an underlying cause<sup>14</sup>;
- calculated only from incidents and deaths in acute trusts in England;
- based on a small number of trusts who may not be representative of the whole of the NHS;
- based on a small number of deaths (46) over a three month period;
- based on incidents where the impact on the patient is very difficult to assess, particularly since many patients affected are critically ill;
- not directly comparable to extrapolations from medical record review studies, because these have used different definitions of events to the NRLS (see page 53).

The total number of incidents estimated from these 18 trusts is of the same order of magnitude as previous estimates. However, the same caveats and difficulties of comparisons apply, given that the NRLS includes near misses that were not included in the study from which the original estimates of 850,000 events was derived.

The estimate of deaths is much lower than the widely quoted figure of 40,000. Does this mean that previously quoted extrapolations have over-estimated the numbers of deaths caused by patient safety incidents, even allowing for the different definitions and sources of data? This may be the case, but we cannot reach a definitive conclusion based on incidents reported to the NRLS, although our data add to the debate. The NPSA will explore the potential to fund a study to ascertain the number of deaths as a result of patient safety incidents.

Whilst there is a clear argument for ongoing debate and research to provide a more precise estimate, each death occurring from an incident is a tragedy. Hence, the most important role of the NPSA is to minimise risk and reduce the harm to patients through development and dissemination of solutions. The NPSA recognises the learning which can be gained from severe and death incidents, particularly from national data, where themes may emerge which would appear as isolated incidents within local reporting systems. As a result, the NPSA is reviewing these incidents on a regular basis. The regular review of deaths has already identified issues which the NPSA is highlighting to NHS organisations for local action (see box overleaf).

### ***From learning to safer healthcare: crash call trolleys***

Patients in acute hospitals often have serious and life-threatening illnesses and they are at risk of cardiac arrest. The NPSA has already called for a standardisation of the crash call telephone number across the NHS to 2222 to ensure consistent arrangements for staff moving between sites.

Recent analysis of reports to the NRLS that relate to cardiac arrest and use of resuscitation reveal a number of incidents where the equipment on the crash call trolley was incomplete. For example, incident reports state that:

- “Apparatus missing from crash trolley.”
- “Crash trolley found not to have been replenished with essential drugs.”
- “Equipment on crash trolley was incomplete rendering it unusable and delaying the ability to obtain a clear airway.”
- “Incomplete equipment on crash trolley meant unable to provide appropriate care.”

This is clearly a systems problem that can be solved through improved processes for ensuring that trolleys are appropriately maintained and equipment replaced speedily when it is used. In addition, there are potential safety gains through improving the design of the crash call trolleys to support emergency teams in delivering the highest standard of care.

The NPSA will:

- review other information sources to supplement information from the NRLS;
- highlight the problem to the NHS and advise on how the NHS can address this issue;
- work with the Helen Hamlyn Trust to fund the design of a crash call trolley which eliminates the risk of missing equipment going unheeded by staff.

## **Incident types in each care setting**

This section summarises the most frequent types of incident that have been reported to the NRLS from primary care, mental health, learning disabilities, and ambulance settings. To date, the majority of incidents have been reported from acute and general hospitals, which is addressed in the next section.

### **Patient safety incidents in primary care**

Table 3 shows reported incidents from primary care. Relative to the number of patient contacts in primary care settings, only a small number of incidents have been reported, and these reports may not be typical of all incidents occurring in primary care.

**Table 3: Reported incident types in general practice**

Incident type	Number	Per cent of total
Patient accident	27	6.2
Medication	91	20.8
Documentation (including records, identification)	104	23.7
Consent, communication, confidentiality	70	16.0
Access, admission, transfer, discharge	44	10.0
Clinical assessment (including diagnosis, scans, tests)	40	9.1
Infrastructure (including staffing, facilities, environment)	12	2.7
Medical device / equipment	7	1.6
Treatment, procedure	12	2.7
Implementation of care and ongoing monitoring / review	5	1.1
Disruptive, aggressive behaviour	2	0.5
Infection control	1	0.2
Patient abuse (by staff/third party)	2	0.5
Other	21	4.8
<b>Total</b>	<b>438</b>	<b>100.0</b>

Source: Reports in the NRLS database up to 31 March 2005

Within general practice, documentation is the most common incident type that has been reported so far, followed by medication and confidentiality, and consent and communication. These findings are broadly consistent with other sources of data from general practice.

### Patient safety incidents in general practice

Fewer studies of patient safety incidents have been conducted<sup>42,43,44</sup> in primary care than in hospital care. There are considerable challenges to undertaking studies in primary care, both in defining an incident, and in defining a denominator (the base for expressing the frequency or percentage of patient safety incidents).

*“Primary care differs from secondary care in several key respects. It aims to provide longitudinal personalised care that is customised to individual beliefs, needs, values, and preferences across a broad spectrum of concerns relating to health and illness... Given the different population of patients, the different priorities for their care, and the ambiguities of that care in relation to diagnosis and patient choice, delineating ‘right or wrong’ practice is more complex in primary care than in secondary care.”*

*Wilson and Sheikh*<sup>43</sup>

Patients may use services in both primary and secondary care over the course of an illness. Lack of coordination of care between the hospital and primary care team may pose significant safety risks. A national survey of patients in England found that ten in every 100 patients admitted for a stroke and six in every 100 patients admitted for coronary heart disease reported that the GP did not have all the necessary information about the treatment or advice received in hospital.<sup>45,46</sup>

### **Patient safety incidents in general practice** *continued*

A study in the USA contacted a sample of 400 patients and found that about 19 out of 100 had adverse events that affected them after discharge from hospital, including side-effects of newly-prescribed medication, inadequate pain relief, and re-admission to hospital.<sup>47</sup>

Incident reporting systems have only recently been introduced into primary care settings and there is currently insufficient coverage to assess incident report rates reliably. However, although the frequency of primary care incidents is difficult to determine, a number of sources of information can tell us about the impact and nature of incidents in primary care. These include information from negligence claims<sup>48</sup> and complaints<sup>49</sup>, as well as research studies.

Taking the various sources of information together, the main findings are:

- estimates of the frequency of patient safety incidents in primary care range from five to 80 in every 100,000 consultations; from under one to 11 in every 100 prescriptions; and six in every 100 patients are aware of having had a medication error in the last two years<sup>50</sup>;
- outcomes for patients following a patient safety incident in primary care vary widely, depending on the source of information: 20 in every 100 cases of negligence against primary care teams related to a patient death<sup>51</sup>; from patient survey data, 20 in every 100 patients reporting a medication error state that the error caused them a serious health problem<sup>50</sup>; and incident reporting studies in primary care suggest that diagnostic errors are the most likely cause of harm to patients<sup>52</sup>;
- common types of error in primary care include delayed or incorrect diagnosis (particularly prominent in negligence claims), medication errors (for example, prescribing contraindicated drugs, prescribing despite known allergies, prescribing or dispensing the wrong drug) and communication problems (for example, informal communications lost or forgotten, transcription errors, communication problems during transition from hospital to community, access to patient information, overload of information and misunderstandings in doctor/patient communication).

Within the area of primary care the NPSA:

- will publish *Seven steps to patient safety for primary care*<sup>11</sup>;
- has collaborated with the Royal College of General Practitioners to disseminate information to raise awareness of patient safety issues with GPs<sup>53</sup>;
- is working with GP IT prescribing system suppliers to redesign their programmes to reduce the risk of 'picking from a list' errors, and overload of severe alerts in the software, based on research about the most important safety features<sup>54</sup>;
- will be encouraging further reporting and the use of incident reports in primary care through a project on significant event auditing (see box overleaf);
- will be collaborating with an appropriate supplier to develop a safer 'doctors bag' for use by GPs. Design features will be used to reduce the risk of the wrong dose of drug being selected and to improve temperature control of drugs;
- is working with the *NHS: Connecting for Health* programme to ensure that new technology solutions in primary care enhance patient safety.

**From learning to safer healthcare: sharing learning in general practice**

In the year 2005–06, the NPSA will be taking forward a programme of work on ‘sharing the learning’ from significant event auditing (SEA). SEA is a professionally-led multi-disciplinary activity that is widespread in British general practice. However, the lessons learnt from SEA have generally remained within the individual practices. The ‘sharing the learning’ initiative will support SEA and encourage practices to develop the technique further. In particular, it will encourage a structured method of sharing the learning across the primary care organisation and nationally. The project will also encourage incident reporting as practices will be encouraged to take an integrated approach to reporting and SEA.

**Patient safety incidents in mental health settings****Table 4: Reported incident types in mental health trusts**

Incident type	Number	Per cent of total
Patient accident	3,652	34.2
Medication	366	3.4
Documentation (including records, identification)	20	0.2
Consent, communication, confidentiality	117	1.1
Access, admission, transfer, discharge	1,082	10.1
Clinical assessment (including diagnosis, scans, tests)	13	0.1
Infrastructure (including staffing, facilities, environment)	320	3.0
Medical device / equipment	9	0.1
Treatment, procedure	37	0.3
Implementation of care and ongoing monitoring / review	51	0.5
Disruptive, aggressive behaviour	2,635	24.7
Infection control	7	0.1
Patient abuse (by staff/third party)	134	1.3
Self-harming behaviour	1,895	17.8
Other	329	3.1
<b>Total</b>	<b>10,667</b>	<b>100.0</b>

Source: Reports in the NRLS database up to 31 March 2005

In mental health trusts, patient accidents are the most frequent type of incident, but make up a smaller proportion of the total than in acute hospitals. Incidents from disruptive and aggressive behaviour, together with self-harming behaviour, are also common. Four out of five reported incidents in mental health units are either patient accidents, result from disruptive/aggressive behaviour or are problems of access, admission, discharge or transfer. The incident type ‘access, admission, transfer and discharge’ occurs frequently in the mental health setting: over 80 per cent of these 1,082 incidents involved missing or absconded patients.

## Patient safety incidents in mental health settings

Studies of patient safety incidents in mental health settings have highlighted incidents which disproportionately affect mental health patients, such as absconding, self-harm, suicide, and violence and aggression. It should also be remembered that many of the types of events which occur in other settings are also likely to be important in mental health, such as adverse events involving medication; slips, trips and falls; diagnosis, treatment and management of illness; and effective emergency and resuscitation procedures. However, the initial analysis of NRLS data indicates that incidents involving aggression, self-harm and absconding account for over half of the incidents reported by mental health trusts.

A recent review of patient safety issues in acute mental health inpatient settings mirrors the NRLS report (see Table 5). Death by suicide and other unnatural deaths are rare, whilst deaths during restraint and homicides committed by an inpatient are extremely rare.

**Table 5: Relative frequency of selected patient safety incidents on acute psychiatric wards<sup>55</sup>**

	Number of incidents/ year in England and Wales	Number of admissions/ incident <sup>A</sup>	Interval between incidents for an average ward <sup>B</sup>
Aggression/minor assaults	300,000	0.5	1 day
Absconding	50,000	3	6 days
Sexual harassment/assault	45,000	4	1 week
Self-harm	25,000	6	12 days
Absconding – does not return	4,500	35	10 weeks
Death by suicide	200	800	4 years
Unnatural death of detained patient	85	1,800	9 years
Homicide by inpatient	1.3	115,000	600 years

<sup>A</sup> Assumes that there are 150,000 admissions per year to acute psychiatric wards (based on HES data for 2003)

<sup>B</sup> Assumes there are 800 acute psychiatric wards in England and Wales

A profile of patient safety incidents for mental health patients outside of hospital settings is more difficult to piece together. Approximately one quarter of suicides in England, Wales, Scotland and Northern Ireland had been in contact with mental health services in the year before death; this represents around 1,200 cases per year. Mental health teams across all care settings in England and Wales regarded 22 in every 100 suicides as preventable (with lower figures in Scotland and Northern Ireland), but around three-quarters identified factors that could have reduced risk; mainly improved patient compliance and closer supervision<sup>56</sup>.

### ***From learning to safer healthcare: psychotropic medication***

Psychotropic drugs commonly prescribed to people with mental health problems include antidepressants, antipsychotic drugs for schizophrenia, hypnotics and mood stabilisers. These are strong drugs with potential side-effects. In England in 2003, more than 50 million prescriptions were dispensed by community pharmacists for antidepressant, antipsychotic and hypnotic drugs.

The NRLS is receiving increasing numbers of medication incident reports from specialist mental health trusts (366 up to 31 March 2005) as more organisations begin reporting to the NRLS. Errors are likely to include:

- unfamiliarity with medicines;
- communication issues including unclear prescriptions;
- medication issues such as transcription errors and failure to monitor side-effects;
- off-label prescribing. For example, use of psychotropics above recommended levels and the use of anti-epileptic drugs as mood stabilisers.

There are risks to patients from use of these highly effective but potentially toxic drugs. There is potential both to save lives and to reduce ill health; the former by preventing potentially fatal adverse effects and drug interaction and by reducing access to the most toxic antidepressants by those at risk of suicide; and the latter by minimising the long-term adverse effects of psychotropic drugs on physical health and lifespan.

There is potential, through changes in prescribing, to:

- realise the full benefits of medication;
- improve quality of life;
- improve life expectancy;
- reduce risks of serious harm and death due to severe adverse effects and interactions;
- reduce risks of suicide and overdoses.

The NPSA has prioritised work in this area for 2005–06 and will promote safer medicines practice in specialist mental health services by:

- the targeted dissemination of patient safety alerts and notices about safe prescribing in mental health;
- the identification of priorities for further primary and secondary research into safer prescribing in mental health;
- ensuring that data collection and interventions mediated through the Prescribing Observatory for Mental Health UK take full account of patient safety issues;
- promoting safer medicines practice in specialist mental health services.

In the area of mental health, the NPSA will in addition:

- develop the safer medicines practice in specialist mental health services work programme;
- improve the safety of patients in acute psychiatric units, through the 'Safer Wards for Acute Psychiatry' initiative. This aims to understand better the factors that underpin safety on acute psychiatric inpatient units. This knowledge will be used to develop and test solutions that will address the problems that compromise patient safety;
- undertake an aggregate root cause analysis for inpatient suicide.

### Patient safety incidents in learning disabilities services

Up until 31 March 2005, 813 incidents had been reported to the NRLS from learning disabilities services. The pattern of patient safety incidents reported so far indicates that there are three main issues reported: patient accidents, disruptive/aggressive behaviour, and self-harming behaviour. As the number of reports from this sector grows, the pattern of reporting may change.

**Table 6: Reported incident types in learning disabilities services**

Incident type	Number	Per cent of total
Patient accident	341	41.9
Medication	46	5.7
Documentation (including records, identification)	0	0.0
Consent, communication, confidentiality	1	0.1
Access, admission, transfer, discharge	23	2.8
Clinical assessment (including diagnosis, scans, tests)	1	0.1
Infrastructure (including staffing, facilities, environment)	14	1.7
Medical device / equipment	2	0.2
Treatment, procedure	1	0.1
Implementation of care and ongoing monitoring / review	4	0.5
Disruptive, aggressive behaviour	222	27.3
Infection control	1	0.1
Patient abuse (by staff/third party)	6	0.7
Self-harming behaviour	116	14.3
Other	35	4.3
<b>Total</b>	<b>813</b>	<b>100.0</b>

Source: Reports in the NRLS database up to 31 March 2005

The NPSA is developing solutions and safer ways of working to improve the safety of people with learning disabilities. This is in response to the priorities highlighted in the 2004 report, *Understanding the Patient Safety Priorities for People with Learning Disabilities*. A report detailing solutions aimed at reducing the risk of aspiration pneumonia will be launched in September 2005. The NPSA is also taking forward the first stage of a confidential enquiry into premature deaths among people with learning disabilities. The scoping study will include a systematic review of the avoidable and unavoidable causes of mortality among people with learning disabilities and will report in spring 2006. In addition, the NPSA has received details of several local solutions aimed at improving the safety of people with learning disabilities in acute hospitals. The next stage of this work is to look at which local solutions may be taken forward to national development.

## Patient safety incidents in ambulance services

Up to 31 March, 396 incidents have been reported by ambulance services. Thirteen ambulance trusts have reported to date, including five via local risk management systems. Most frequent incident types are those involving medical devices/equipment, patient accidents, access, admission, transfer and discharge, and medication. The profile of incidents from ambulance settings may change, as the number of reports and the organisations reporting increases.

**Table 7: Reported incident types in ambulance services**

Incident type	Number	Per cent of total
Patient accident	80	20.2
Medication	35	8.8
Documentation (including records, identification)	0	0.0
Consent, communication, confidentiality	20	5.1
Access, admission, transfer, discharge	66	16.7
Clinical assessment (including diagnosis, scans, tests)	4	1.0
Infrastructure (including staffing, facilities, environment)	36	9.1
Medical device / equipment	125	31.6
Treatment, procedure	18	4.5
Implementation of care and ongoing monitoring / review	1	0.3
Disruptive, aggressive behaviour	2	0.5
Infection control	1	0.3
Patient abuse (by staff/third party)	4	1.0
Other	4	1.0
<b>Total</b>	<b>396</b>	<b>100.0</b>

Source: Reports in the NRLS database up to 31 March 2005

Key themes emerging from the NRLS database, along with issues identified from a risk assessment of pre-hospital care, are being used to design an exemplar ambulance for patient safety. The design will address issues relating to patient accidents, ambulance equipment and infection control. The NPSA is also extending the clean**your**hands campaign to the ambulance service.

## Patient safety incidents in acute care settings

The majority of incidents reported to the NRLS have been from acute hospitals, and more detailed analysis of these incidents is presented in the following section.

**Table 8: Reported incident types in acute hospitals**

Incident type	Number	Per cent of total
Patient accident	30,063	44.6
Medication	5,797	8.6
Documentation (including records, identification)	3,746	5.6
Consent, communication, confidentiality	2,894	4.3
Access, admission, transfer, discharge	3,863	5.7
Clinical assessment (including diagnosis, scans, tests)	3,065	4.6
Infrastructure (including staffing, facilities, environment)	4,526	6.7
Medical device / equipment	2,709	4.0
Treatment, procedure	6,632	9.8
Implementation of care and ongoing monitoring / review	1,352	2.0
Disruptive, aggressive behaviour	440	0.7
Infection control	624	0.9
Patient abuse (by staff/third party)	129	0.2
Other	1,504	2.2
<b>Total</b>	<b>67,344</b>	<b>100.0</b>

Source: Reports in the NRLS database up to 31 March 2005

Patient accidents, for example slips, trips and falls, comprise a little under half of the incidents that have been reported to the NRLS by acute hospitals. This is consistent with previous studies. As part of the 'Building a Safer Hospital' initiative, the NPSA is developing interventions to reduce the frequency and severity of slips, trips and falls.

Of the other categories, the most frequently reported are those associated with treatments, procedures and medication. Incidents related to infection account for under one per cent of all incidents, but it is likely that these incidents are predominantly reported through separate systems within trusts.

Comparison with information from other reporting systems is not straightforward because most of the published data from other systems relate to specific types of incidents, for example sentinel events, and are not comprehensive. A lower proportion of incidents from the Pennsylvania system<sup>13</sup>, which internationally is most similar to the NRLS, are reported as falls, and a higher proportion are related to procedures and treatments. The differences may reflect differences in the reporting process and incident categorisation, as well as in the actual pattern of incidents. The NPSA is contributing to work led by the World Health Organisation to develop an international taxonomy of patient safety incidents.

### ***From learning to safer healthcare: patient falls***

A high proportion of reported incidents are patient falls.

The NPSA considered a range of potential actions to address patient falls through the prioritisation process<sup>57</sup>. The prioritisation panel took account of a range of other activities within the NHS to address falls, for example, guidelines for the assessment and prevention of falls in older people<sup>58</sup>.

In this context, the NRLS could be used for national surveillance on falls.

In terms of risk reduction, the NPSA is focusing their work on environmental factors in relation to falls. Within the 'Building a Safer Hospital' initiative the NPSA will be looking at how to reduce both the frequency of slips, trips and falls and their severity through design interventions (for example, floor finishes, colours, light levels, changes of levels and handrails).

### **The specialties in which reported incidents occur in acute hospitals**

The most frequent specialties in which incidents are reported from acute hospitals are shown in Table 9. Approximately half the reported incidents occurred in medical specialties, with a further quarter from surgical specialties. This corresponds closely to the number of days patients spend in hospital in the larger specialties; 55 per cent of hospital bed use is in medical and 28 per cent in surgical specialties. There are differences between Hospital Episode Statistics (HES) data and NRLS data for smaller specialties, which may arise because HES only includes admitted patients. For example, most accident and emergency patients are not admitted, so this specialty accounts for a small proportion of hospital episodes. However, many patients are treated in accident and emergency, hence this specialty accounts for a larger proportion of NRLS incidents. The variation between specialties found from the NRLS is broadly consistent with findings from medical record review studies.

**Table 9: Specialties in which reported incidents occurred in acute hospitals**

Specialty	Number	Per cent of total	Proportion of hospital bed use
Medical specialties	30,238	44.9	55.6
Surgical specialties	16,102	23.9	28.1
Obstetrics and gynaecology	6,625	9.8	7.1
Accident and emergency	3,143	4.7	0.3
Diagnostic services	2,746	4.1	<0.1
Anaesthetics	529	0.8	0.3
Dentistry – general and community	7	0.0	0.3
Other	7,954	11.8	8.0
<b>Total</b>	<b>67,344</b>	<b>100.0</b>	<b>100.0</b>

Source: Reports in the NRLS database up to 31 March 2005; HES 2003-04

### ***From learning to safer healthcare: injectable medication***

Research has shown that there is a high percentage of errors in preparing injectable medicines on the ward, and some of these errors can lead to serious harm and death.

Examples of this reported to the NRLS during a one month period include:

- a diabetic patient received ten times the dose of insulin prescribed (500 units/50ml rather than 50 units) because of an error in the preparation of an insulin infusion. The infusion was prepared by a doctor, and checked by a nurse, who did not notice the mistake. The patient's blood sugar level was checked after 30 minutes and the mistake detected. The patient was given dextrose to correct the insulin overdose;
- a patient was transferred from accident and emergency with an infusion of a respiratory drug being given. The dose stated on the label of the bag was a quarter of the dose on the prescription, and the prescription chart was not signed by the nurse administering the infusion, or at the time the preparation was recorded. The patient was at risk of suffering continued difficulties with breathing, because the drug was not at a high enough dose;
- a patient was prescribed ten times the dose of an anti-viral infusion, Acyclovir. Two doses were given before the pharmacist identified the error;
- a patient was prescribed a 0.25 per cent infusion of an epidural anaesthetic, rather than 0.15 per cent. This was later discovered by the acute pain team. The patient would have experienced much more extensive and prolonged anaesthesia than was intended;
- an infusion of a muscle relaxant was made up in a glucose solution, rather than a saline solution. This was not noticed for 17 hours, even though a glucose solution is only stable for eight hours. The medication would therefore not have been effective.

The following are the common underlying problems identified from research<sup>59-61</sup>:

- practical aspects of drug preparation and administration are not formally taught, and so clinical staff learn how to prepare and administer medication from each other on the wards;
- injectable medications are prepared in the middle of a busy ward where nurses are frequently interrupted and distracted during the process;
- poorly designed medicine products for injection are being supplied to clinical areas with little consideration of the practical difficulties of using them. Medicines with confusing information about preparation and administration, and requiring complex calculation, preparation and administration methods, are supplied with limited help and assistance for ward staff.

The NPSA intends to work with the NHS Medicines Manufacturing and Preparation Modernisation Board and other stakeholders to develop the following safer practice solutions to minimise these risks in all care settings:

- develop a multi-disciplinary standard of practice that will define and clarify safe practice for preparing and administering injected medicines in near-patient areas;

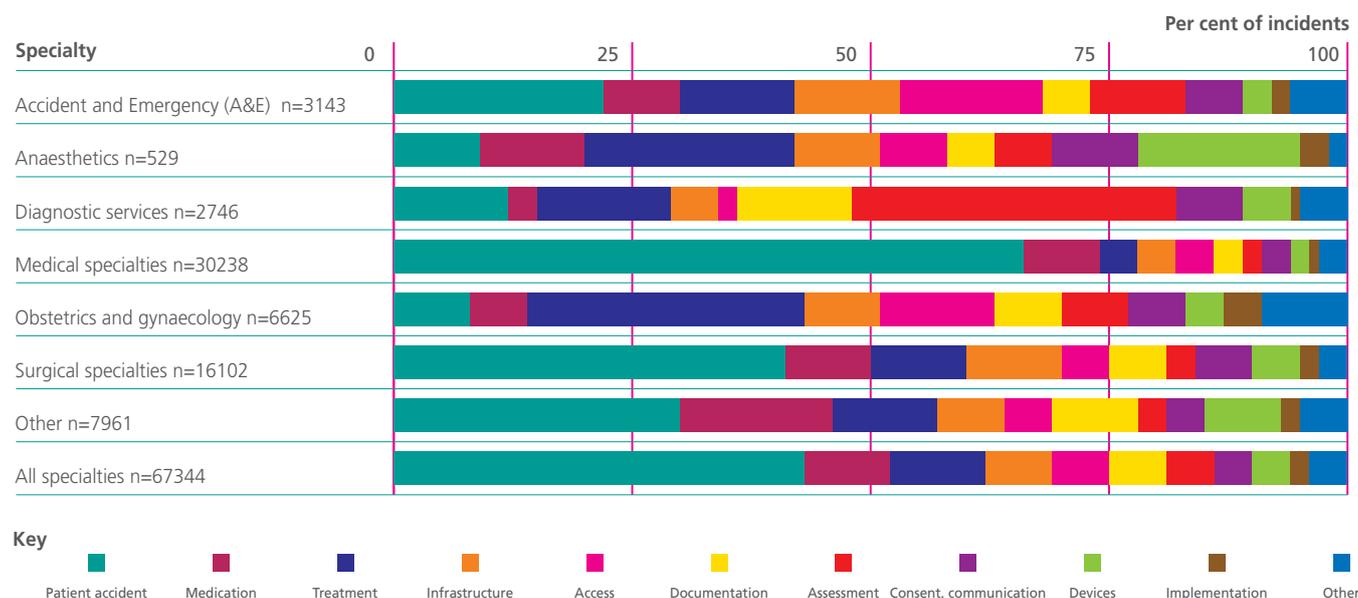
**From learning to safer healthcare: injectable medication** *continued*

- provide access to NHS injectable therapy guide information in all clinical areas to inform and support healthcare practitioners to undertake their role safely and effectively;
- encourage greater involvement from pharmacists to further support, train and audit the preparation and administration of injectable medicines in near-patient areas;
- develop a risk assessment management tool that will help NHS trusts identify high risk products and practices, and provide them with options and advice on how to minimise these risks;
- involve the NHS Medicines Manufacturing and Preparation Board to facilitate the supply of ready-to-use/ready-to-administer injectable products identified as high risk products by the risk assessment tool.

**The types of reported incidents that occur in different specialties in acute hospitals**

An analysis of incident type by specialty is shown in Diagram 4. As already shown, patient accidents are the most common incident type overall. In medical specialties, patient accidents represent 62 in every 100 incidents reported, with medication incidents making up a further nine in every 100. In surgical specialties, patient accidents are again most common and comprise 38 in every 100 incidents, whilst medication incidents again represent nine in every 100. However, a higher proportion of incidents in surgical specialties relate to treatment, infrastructure, devices and documentation. The profile of incidents varies between specialties. For example, treatment incidents are most common in obstetrics and gynaecology, and assessment incidents most frequent in diagnostic services.

**Diagram 4: Incident type, by specialty**



Source: Reports in the NRLS database up to 31 March 2005

An analysis of incident types, by specialty, can allow the NPSA, NHS organisations and professional groups to prioritise work to address patient safety issues, and to target learning and action. The NPSA has a team of clinical advisors from a range of specialties who are involved with reviewing incidents from the NRLS relevant to their clinical area, and engaging with clinical colleagues across the NHS.

### ***From learning to safer healthcare: using clinical networks to engage clinicians and disseminate learning***

The NPSA's clinical specialist advisor for pathology has established an email list (which currently has 93 members) to disseminate and raise awareness of issues identified from the NRLS with clinical colleagues.

Examples of the issues covered so far include:

- problems with histology processing occasionally leading to the destruction of small biopsy samples;
- identification errors;
- diagnostic errors and incident reporting by doctors;
- recovery protocol after diagnostic errors;
- paper labels on slides and impact on mid-identification.

Sharing information and issues from the NRLS in this way is a very direct form of communication and learning, which encourages front-line clinicians to consider safety issues and share local solutions.

### **The age of patients involved in incident in acute hospital**

Table 10 shows the age distribution of patients involved in incidents reported to the NRLS, up to 31 March 2005. Also shown is the age distribution of the inpatient hospital population in England during 2003–04 (Hospital Episode Statistics 2003–04): a total of 57 million bed days arising from 13 million admissions. The proportion of incidents, by age, is similar to the proportion of bed days across most age groups, suggesting that incidents are equally likely among both young and old patients. The exception is in the 0–4 age group, as it includes many newborn babies who spend very little time in hospital.

Previous studies (see page 52) have compared incidents with admission numbers, rather than bed days, and have found that incidents are more likely to occur among older patients. The same pattern is seen in the NRLS data and raises the question of which is the better denominator, bed days or admissions. Access incidents are clearly more likely to take place in the period around admission, as are diagnostic incidents. It has also been shown that patients involved in safety incidents often remain in hospital longer, so 'adjusting' for length of stay with bed days may be incorrect. On the other hand, a patient is at some risk of an incident throughout their hospital stay, and it follows that the longer their stay, the longer the exposure to the risk of an adverse incident. The NPSA will review the most appropriate denominator for calculating incident rates.

**Table 10: Age distribution of patients**

Age group (years)	NRLS incident reports per cent (number)		Hospital bed days* per cent (000s)		Hospital admissions* per cent (000s)	
0 to 4	5.2	(1,693)	0.8	(463)	8.9	(1,170)
5 to 14	1.7	(571)	1.4	(800)	3.8	(505)
15 to 44	19.1	(6,275)	20.5	(11,804)	29.9	(3,933)
45 to 64	15.6	(5,102)	17.7	(10,169)	21.7	(2,852)
65 to 74	14.7	(4,811)	16.0	(9,215)	14.4	(1,894)
75 to 84	27.6	(9,040)	24.2	(13,930)	14.7	(1,936)
85 and over	16.2	(5,317)	19.4	(11,190)	6.5	(854)
<b>Total</b>	<b>100.0</b>	<b>(32,809)</b>	<b>100.0</b>	<b>(57,571)</b>	<b>100.0</b>	<b>(13,144)</b>

Source: Reports in the NRLS database from acute trusts up to 31 March 2005 for which age of patient is available

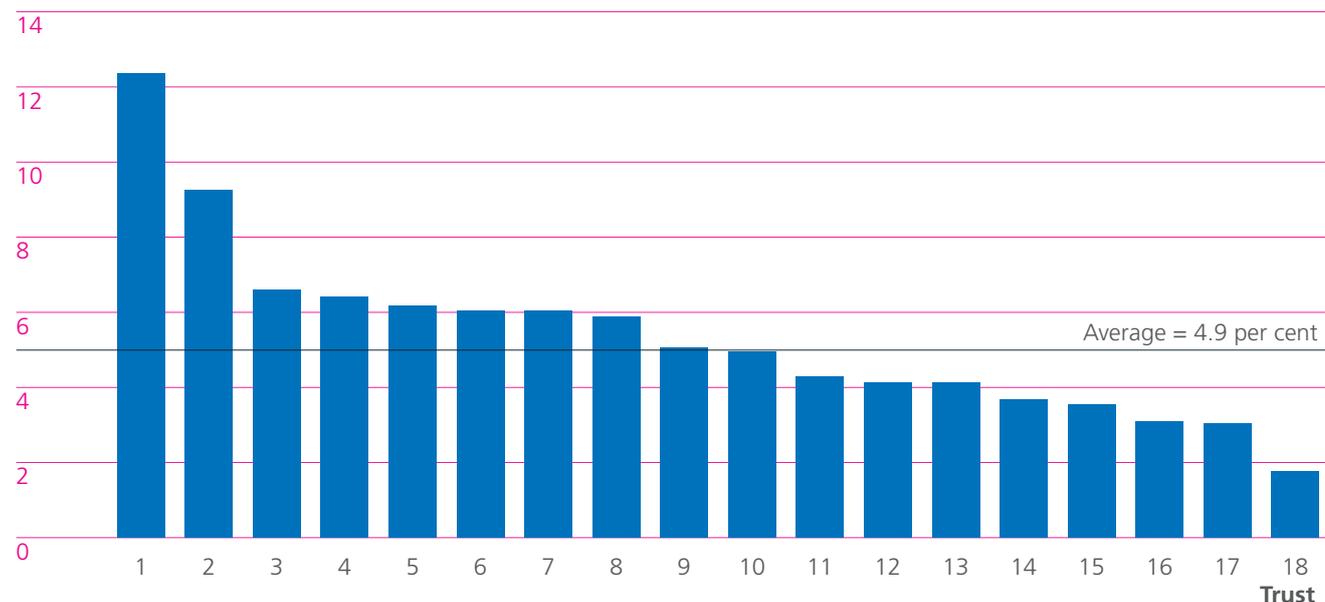
\*HES 2003–04

### Reporting rates – putting NRLS data in context

To better understand the NRLS information, it is often necessary to link it to other data sources. One example is to use the number of patient admissions as a denominator, and to estimate the proportion of patients admitted that experience safety incidents. Diagram 5 shows the reported incident rate for 18 acute trusts that have consistently reported to the NRLS via their LRMS. The incident reporting rate shown is the number of incidents on the NRLS database, occurring within a defined three month period, divided by the predicted number of admissions for the same period. This is comparable to the adverse incident rate for admissions reported in medical record review studies.

### Diagram 5: Reported incident rate for acute trusts

Incident rate (per 100 admissions)



Source: Incidents from the NRLS occurring from October to December 2004; HES 2003-04. This time-frame for incidents is used to allow for the time between an incident occurring and being held within the NRLS. Date of incident, rather than date of reporting, has been used so that the number of incidents relates to the correct time period for admissions data.

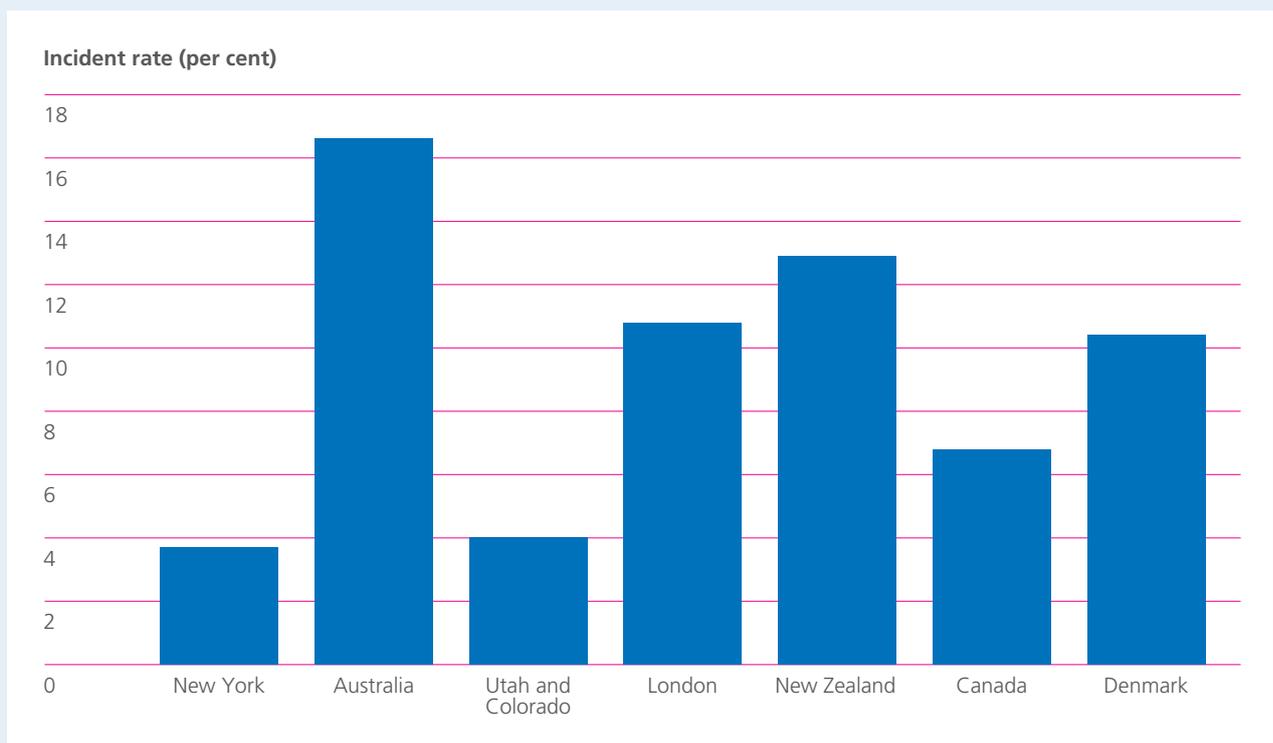
Diagram 5 shows that the reported incident rate varies between just under two to over 12 per 100 admissions, with an overall reporting rate for these trusts of 4.9 incidents per 100 admissions. This equates to 1.2 incidents per 100 bed days, which is similar to the incident rate reported by the Pennsylvania system<sup>13</sup>. It is important to remember that a high incident reporting rate may be a reflection of openness to reporting at a local level and does not mean that a given trust has more incidents than other trusts. As the database matures, these data can be analysed to identify differences in reporting rates between comparable organisations and therefore potential differences in the reporting culture across healthcare organisations.

### Medical record review studies in acute hospital settings

The most detailed information on the frequency of incidents in the developed world comes from a number of studies which used a review of patients' notes in order to identify adverse events.

As well as studies looking at specific groups of patients<sup>62</sup>, there are seven studies<sup>63-72</sup> which have examined the care received by a cross section of acute hospital inpatients. These studies have used broad definitions of adverse events, looking for any harm to patients related to healthcare treatment or to lack of standard healthcare but not including near misses. Incident rates reported by the studies are shown in Diagram 6. Differences between studies may be the result of differences in definitions and methods of collecting information. For example, a secondary analysis of the Utah and Colorado data, using similar criteria to the Australian study, calculated an incident rate of ten per cent.<sup>73</sup>

**Diagram 6: Proportion of patients who experience adverse events from seven studies**



### Medical record review studies in acute hospital settings *continued*

The main findings from these studies are:

- if the results from the studies are combined, about 92 in every 100 patients did not experience an adverse event; five had an adverse event with less than a one in two chance of prevention, and around three had an adverse event where there was a more than a one in two chance of prevention;
- the studies found that, on average, six to nine extra days in hospital were caused by adverse events. Analysis of routine hospital data has found similar increases in hospital stay;<sup>74</sup>
- between two and 14 in every 100 patients admitted to acute hospitals had an adverse event involving minimal or moderate harm. Between 0.4 and 2.4 per cent of all patients admitted to acute hospitals had an adverse event resulting in serious harm or death;
- for around seven in every 100 patients who experienced an adverse event, the event may have contributed to the death of the patient. This is similar to the proportion of medical negligence claims<sup>51</sup>, but higher than in the NRLS data. Routine hospital data have found increased mortality among patients who had an adverse event, ranging from none to over 20 in every 100 patients (for example, for patients with post-operative wound infection);
- a greater proportion of patients experience adverse events in specialties giving complex treatment to patients with complex health problems, such as neurosurgery and vascular surgery, but most incidents occur in medical and surgical specialties;
- errors of omission (for example, failure to order a test, not giving enough medication or not recognising a deterioration in a patient's condition) are usually more common than errors of commission (for example, prescribing the wrong medication);
- adverse events in surgical specialties are likely to be related to the operation and less likely to be preventable, because of inherent risks of operations for some critically ill patients;
- adverse events in medical specialties are more likely to be related to omissions (failure to act) or medication errors and are more likely to be preventable;
- adverse events can occur at any point but are more likely to be in situations where the patient needs urgent or life-saving treatment. In the Australian study, nearly half of adverse events associated with death occurred during life-saving treatment.<sup>75</sup>

### Factors which contribute to patient safety incidents from NRLS data

Contributing factors are those factors which affect the performance of individuals whose actions may have an effect on the delivery of safe and effective care to patients, and therefore effect the likelihood of a patient safety incident occurring. There are often a variety of contributing factors behind each incident.<sup>76-78</sup>

The NRLS has developed a contributing factor framework based on the work of Professor Charles Vincent and colleagues (1998).<sup>79</sup> Each of the factors are explained with examples in Table 11.

**Table 11: Contributing factors and examples**

**Patient factors:** The patient had been advised to avoid alcohol whilst on a particular antibiotic, but ignored this advice and had an adverse reaction.

**Task factors:** The unreliability of the 'whoosh' test for checking the position of a nasogastric feeding tube was not known by clinicians, who therefore continued to use it to detect tube placement.

**Team and social factors:** There were concerns about the quality of surgical practice of an otherwise excellent consultant surgeon in undertaking a particularly difficult operation, but staff felt intimidated and unable to discuss their concerns.

**Work and environmental factors:** Previous medical records were not available to staff to plan the treatment and care for an emergency admission, thereby delaying clinical decisions and treatment.

**Communication factors:** Relatives interpreted a GP's instructions to a patient wrongly due to the doctor's use of complex technical medical jargon.

**Education and training factors:** A patient was given double the dose of medication prescribed, because the nurse had not been trained to prepare an injected medication.

**Equipment and resource factors:** An item of equipment was missing from the crash call trolley, leading to delay in the treatment of a patient who had a cardiac arrest.

**Medication factors:** A GP did not consider the risks of prescribing painkillers for a patient on long-term warfarin therapy; the patient suffered a severe bleed.

**Organisational and strategic factors:** The organisation of a hospital discharge system mean that GPs might not find out about medication prescribed to patients in hospital until some time after discharge.

Contributing factors are not reported for all incidents; to date about 11 in every 100 incidents have such factors recorded. Contributing factors are not held in all local risk management systems and, in addition, these factors may not be known at the time the incident was reported. Further, the concept of underlying contributory factors is still relatively new to healthcare. As root cause analysis techniques become more embedded we would expect to see an increase in the completeness of reporting. From incidents reported up to 31 March 2005, 9,660 contributing factors were identified in relation to reported incidents. For most incidents only one contributing factor was reported. There was more than one factor in about 16 in every 100 incidents with contributing factors reported. Table 12 shows the nine types of contributing factors that can be reported to the NRLS and the number of reported incidents that have been associated with each of these factors.

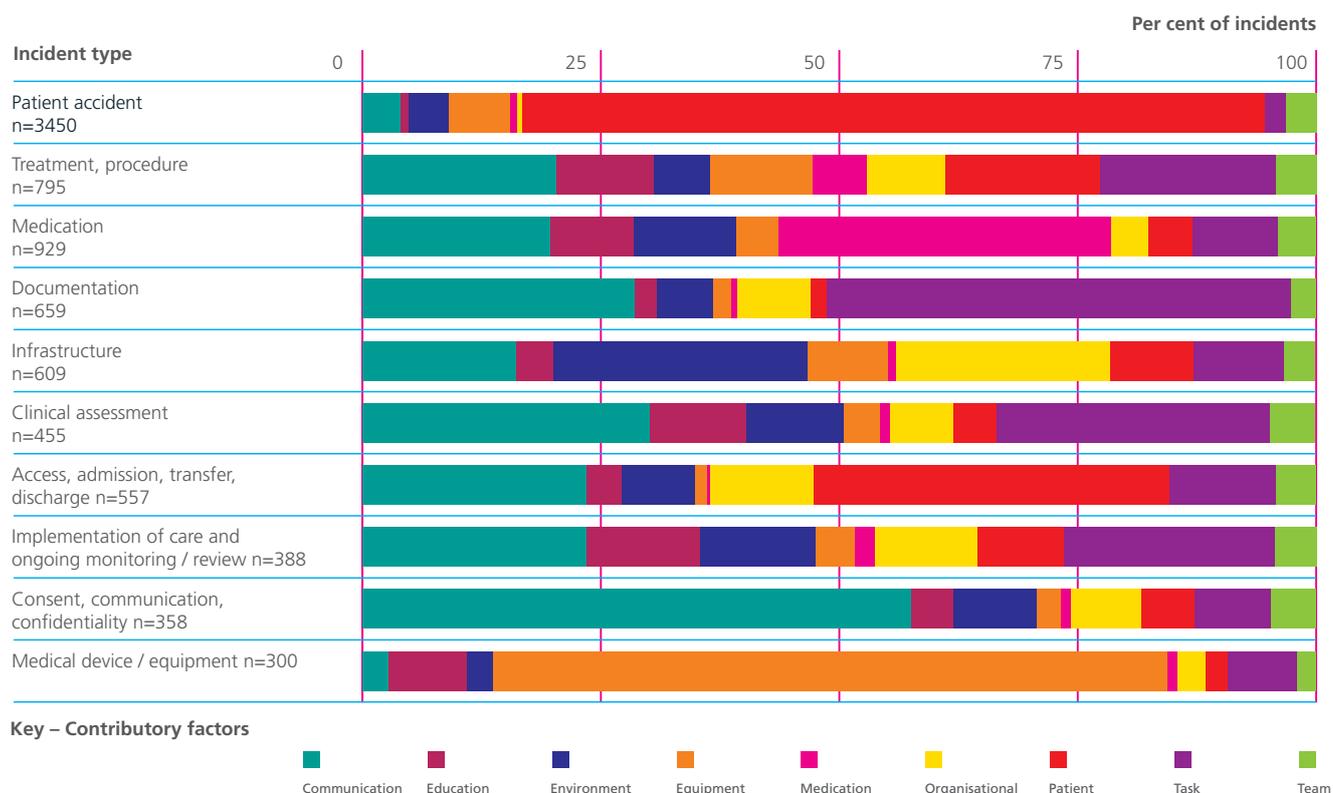
**Table 12: Number of reported incidents associated with contributing factors**

Contributing factors	Number	Per cent of total
Patient factors	3,735	38.7
Communication factors	1,425	14.8
Task factors	1,052	16.9
Work and environmental factors	717	7.4
Equipment and resource factors	712	7.4
Organisational and strategic factors	493	5.1
Medication factors	445	4.6
Education and training factors	424	4.4
Team and social factors	334	3.5
Other	323	3.3
<b>Total</b>	<b>9,660</b>	<b>100.0</b>

Source: Reports in the NRLS database up to 31 March 2005

'Patient factors' is the contributing factor that has been associated with the highest proportion of incidents reported. When looked at in more detail, the vast majority relate to slips, trips and falls, and reflect healthcare professionals' awareness of intrinsic factors in patients who fall (factors such as confusion, poor eyesight or poor mobility). Communication and task factors are the other types of contributory factors that are most often identified in NRLS reports. The NPSA has commissioned Aston University to assist clinical teams with improving how they work effectively together.

**Diagram 7: Incident type by contributory factors**



Source: Reports in the NRLS database up to 31 March 2005

Some factors are implicated in a wide range of incident types, as can be seen in Diagram 7. In particular, communication, education and teamwork appear as factors across all incident types. Other factors are associated predominantly with one type of incident. For example, equipment factors are most often associated with device incidents. The contributory factors are high level categories: the free text descriptions of incidents reveal a richer understanding of what happened and the underlying problems.

Although different reporting systems use different definitions and may collect different types of incidents, some comparison is nonetheless valuable. This preliminary analysis of NRLS data is consistent with studies from the US and Australia that have looked at contributing factors.<sup>76-78</sup>

## Conclusion

This report – the first of a series of reports of patient safety data in England and Wales to be published by the NPSA – has presented a unique overview of patient safety issues in the NHS for all those working in and using the NHS who have an interest in improving patient safety and the quality of care. We hope that you have found it both informative and enlightening.

The report has included:

- a description of the NPSA's Patient Safety Observatory and how this will support improvement in patient safety;
- an analysis of reports to the NRLS up to the end of March 2005, including a breakdown of reports from different healthcare settings;
- an analysis of patient safety incidents and emerging issues from the NRLS;
- an analysis of reported deaths in the NRLS;
- a comparison of reports to the NRLS with other sources of information about patient safety, including international research;
- case studies to illustrate how the NRLS supports the NPSA in improving patient safety.

The report has also outlined the ways in which the NPSA plans to develop use of the data within the NRLS, and, through the Patient Safety Observatory, make full use of incident reports alongside other data sources. Trends and themes emerging from this work will be featured in future reports.

We would welcome any comments and feedback on this report. These should be directed to [pso@npsa.nhs.uk](mailto:pso@npsa.nhs.uk) or in writing to Sarah Scobie, Head of Observatory, National Patient Safety Agency, 4–8 Maple Street, London W1T 5HD

## Appendix 1

### A brief history of the NRLS



## Appendix 2

### Patient Safety Observatory stakeholder group members

Action against Medical Accidents (AvMA)

Confidential Enquiry into Maternal and Child Health (CEMACH)

Department of Health

Dr Foster

Healthcare Commission

Health and Safety Executive

Imperial College London

Medical Defence Union

Medical Protection Society

Medicines and Healthcare products Regulatory Agency (MHRA)

National Clinical Assessment Service (NCAS)

National Confidential Enquiry into Patient Outcome and Death (NCEPOD)

National Confidential Enquiry into Suicide and Homicide (NCISH)

NHS Litigation Authority

Welsh Risk Pool

Health and Social Care Information Centre

National Institute for Health and Clinical Excellence (NICE)

National Joint Registry

North East Public Health Observatory/Association of Public Health Observatories

Northumberland Tyne and Wear Strategic Health Authority

Office for National Statistics

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## **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.

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