

The UK experience: the National Patient Safety Agency's Patient Safety Observatory

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Abstract

The National Patient Safety Agency (NPSA) was set up in 2001 in order to make changes at a national level, and lead work on improving patient safety in England and Wales. A core function of the NPSA is to identify trends and patterns in patient safety problems, using its own National Reporting and Learning System (NRLS) and data from other sources. Almost all reports to the NRLS come directly from local risk management systems; staff can also report directly to the NPSA via an electronic form. By the end of August 2005, nearly 230,000 incidents had been reported to the NRLS; 76% of these were reported from acute/general hospitals. The analysis of data in the NRLS is a function of the NPSA's Patient Safety Observatory (PSO), which has been established to quantify, characterise and prioritise patient safety issues in order to support the NHS in making healthcare safer. The PSO works with key national organisations which hold data relevant to patient safety, such as healthcare regulators, patient's organisations, clinical negligence bodies and national information and statistics functions. Triangulating information from different data sources enables a fuller picture of the nature and severity of patient safety incidents to be obtained. The key challenges for the PSO are to strengthen the quality of NRLS data, extend the ways in which feedback from the NRLS is provided, and continue to develop methods and tools for the systematic analysis of the huge volumes of incidents reported to the NRLS.

Key words : patient safety, incident reporting, epidemiology, surveillance, data sources

Introduction

The National Health Service (NHS) in England and Wales treats over a million patients a day [1], in a range of settings, from consultations with general practitioners, to treatment in hospitals and specialist clinics. In common with other healthcare systems, a number of programmes have been established to tackle and prevent unintended harm to patients. The impetus for these developments was the publication of the Chief Medical Officer's report "An organisation with a memory" in 2000 [2], and its follow-up action plan, *Building a safer NHS for patients* [3]. These reports were instrumental in establishing that the NHS had to improve its capacity to learn from patient safety incidents and specified that a unified reporting system would be a crucial step in achieving this.

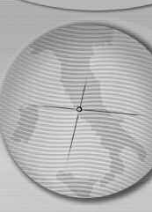
The National Patient Safety Agency (NPSA) was set up in 2001 in order to make changes at a national level, and lead work on improving patient safety. The NPSA aims to:

- identify trends and patterns in patient safety problems by 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 to be able to act on them, for example the *Root Cause Analysis Toolkit*, *Incident Decision Tree*, and *Being Open* policy and guidance, for ensuring that patient's are informed when harm has occurred;
- develop solutions at a national level. For example, the NPSA has led a national campaign to improve hand hygiene in hospitals (*Cleanyourhands*). The NPSA is currently working on over 50 projects to develop solutions to safety problems [4].

From 2005, the NPSA has also taken on new roles in relation to poorly performing doctors and dentists, the ethical review process for research, national confidential enquiries, as well as food, cleaning and design.

A necessary contribution to improving safety is 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



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problems to be identified and supports efforts to prevent harm to patients [2,5,6].

However, incident reporting on its own can never tell us all we need to know; to support its role the NPSA needs to understand the potential 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 do this the NPSA has set up a Patient Safety Observatory in collaboration with a number of partners from both the NHS and elsewhere [7,8]. These include a number of key national organisations, for example the Healthcare Commission [9], the independent regulator of health services in England; the Office for National Statistics [10]; the Medicines and Healthcare products Regulatory Agency [11] which regulates medicines and medical devices in the UK; patient organisations such as Action against Medical Accidents [12]; the NHS Litigation Authority [13], and medical defence organisations.

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, as a basis for identifying and monitoring patient safety incident trends, highlighting areas for action and setting priorities.

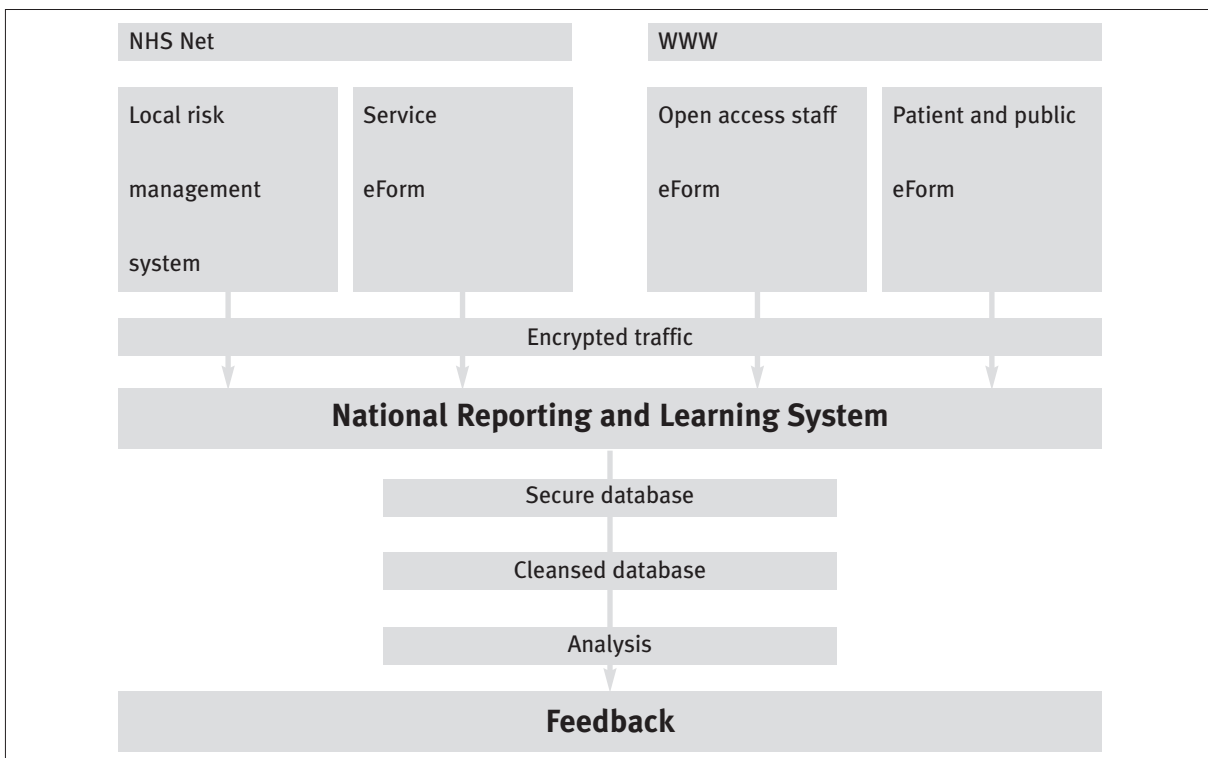
In the remainder of this paper we provide examples of data and analysis from the NRLS and PSO, and outline challenges and opportunities for the future.

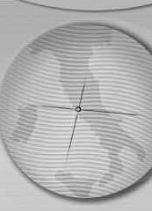
Incident reporting in the UK: the National Reporting and Learning System

The NRLS is the primary mechanism for the NPSA to collect information on patient safety incidents, including near misses, from across England and Wales. The data set is designed to collect a report of a single patient safety incident soon after it occurs. It covers: free text description of 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. The data set also includes contributory factors and factors that might have prevented harm, but does not collect detailed root cause analysis information.

Patient safety incidents are reported electronically to the NPSA [14] (Figure 1). In most cases, information is taken directly from local risk management systems (LRMS). 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

Figure 1. The National Reporting and Learning System





have a LRMS [15], and for staff who wish to report without going via their trust.

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

- by incident types and trends, within the coded categorical 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 [16];
- reviewing particular types of incidents by NPSA specialist staff and clinical advisors on a regular and ad hoc basis.

The model followed by the NRLS contrasts with incident reporting systems which collect data after investigation, rather than at notification (such as the JCAHO sentinel event system [17]) or which target particular types of incident (such as the Danish system). A strength of the NRLS model is that reporters do not need to send reports twice, once to a local system and once to a national system. However, there are also drawbacks, in terms of data quality (see below), and the level of information available about causes of incidents and contributory factors. This is due to the incident being reported to the NPSA before an investigation has taken place.

The flow of data into the NRLS has increased rapidly over the past year, as NHS organisations become fully connected: Figure 2 shows the

number of trusts who reported, and number of incidents reported, for each month. By the end of August 2005 almost 230,000 incidents had been reported to the NRLS.

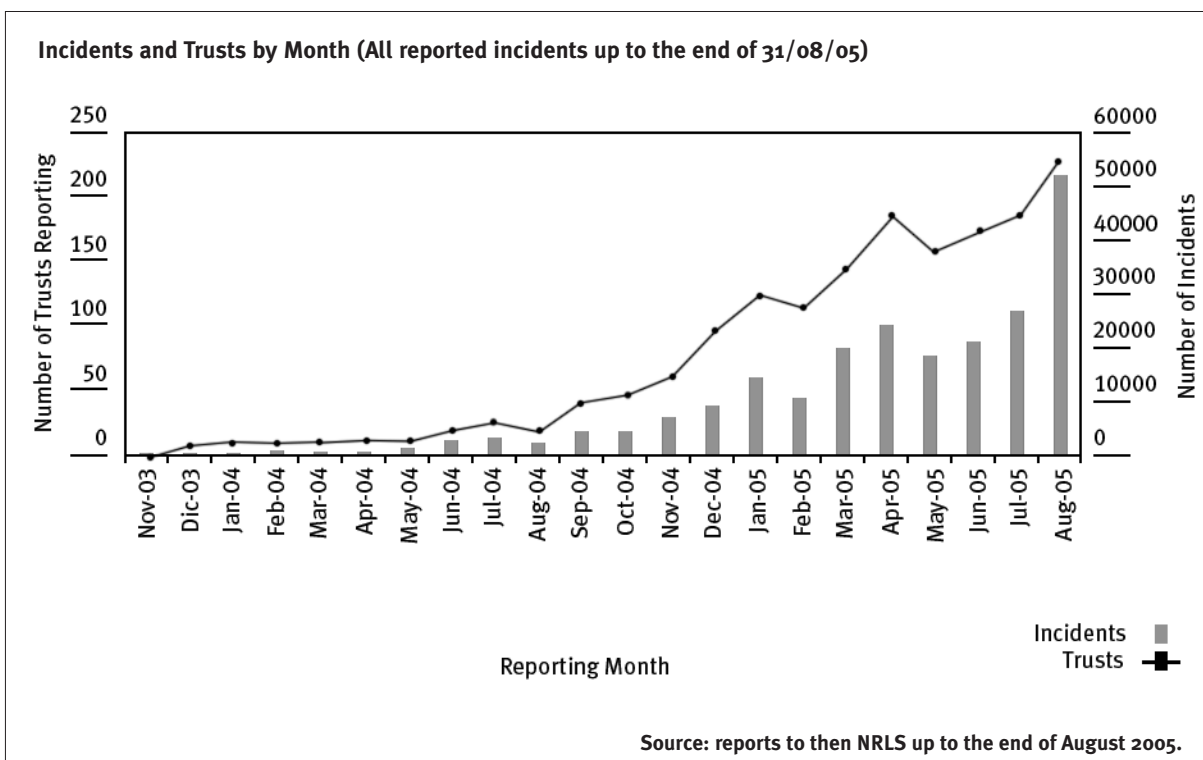
The majority of reports received into the NRLS to date have been from acute hospital trusts, followed by reports from mental health services. Table 1 shows the breakdown of reports by setting.

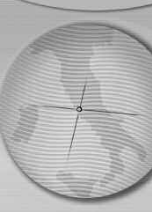
The NPSA published the first analysis of data from the NRLS in July 2005, and this report provides a breakdown of reports by incident type and setting, degree of harm, and contributory factors [7].

The Patient Safety Observatory (PSO)

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. There are a number of factors that explain this. Incident reporting systems are not comprehensive, because of under-reporting, biases in what types of incident are reported, and the existence of several reporting systems. For example, in the UK, in addition to the NRLS there are separate reporting systems for medical device incidents [18], adverse drug reactions [19], healthcare associated infections [20] and maternal and infant deaths [21]. Further serious events are rare, and therefore information on them is distributed across the healthcare system. In addition, the healthcare system as a whole could

Figure 2. reporting to the NRLS – number of trusts and incidents reported by month





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Table 1. number and percentage of reports by care setting, up to 31st August 2005

Care setting	Total	Percentage
Acute / general hospital	173,819	76
Mental health service	32,038	14
Community nursing, medical and therapy service (incl. community hospital)	17,462	8
Learning disabilities service	4,504	2
General practice	948	<1
Ambulance service	798	<1
Community pharmacy	154	<1
Other	36	<1
Total	229,759	100

Source: reports to then NRLS up to the end of August 2005.

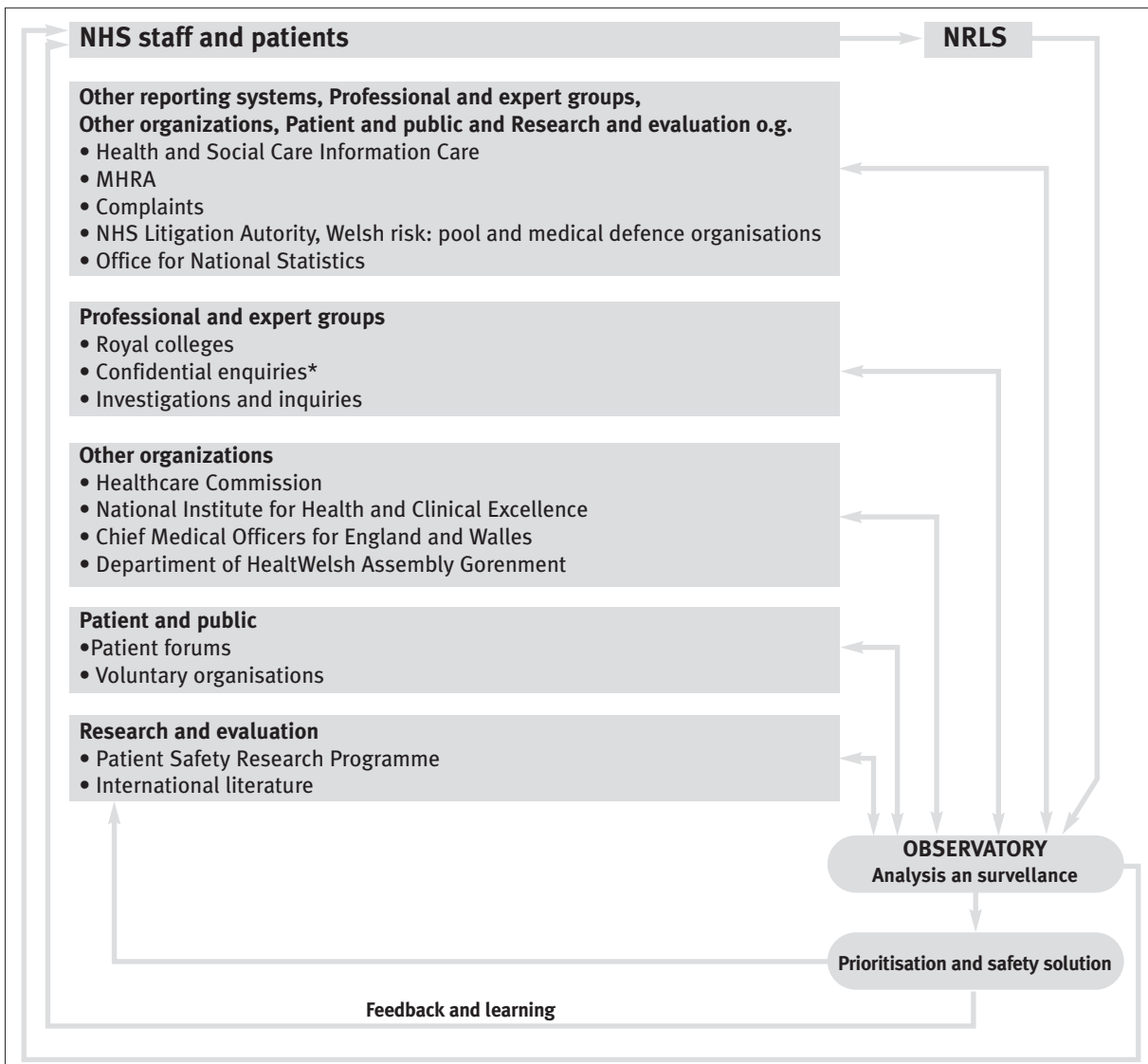
make better use of data sets already in existence to explore safety, even if such existing data collections were designed for different purposes.

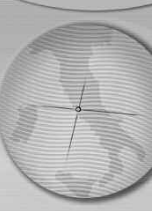
Figure 3 outlines the inputs and outputs of the Patient Safety Observatory with examples of the possible sources of information that will feed in to

it. 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.

Incident reporting needs to be part of a broader approach to surveillance and monitoring, such as

Figure 3: the Patient Safety Observatory





that taken for the surveillance of communicable and other diseases. 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. Triangulating information from different data sources enables a fuller picture of the nature and severity of patient safety incidents to be obtained. 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. Examples of the work of the PSO to use data from a range of sources, and make use of routine data, are shown in Box 1.

The future – challenges and opportunities

Although having compiled thousands of reports, the NRLS is still in its infancy, with more than half of the reports up to the end of August 2005 being received after April 2005. The volume of incident reports being received, and the range of reporting routes, presents a huge opportunity to identify, feedback and learn from incidents, in order to improve patient safety across the NHS. However, there are also a number of key challenges which we are working to address.

Box 1. The PSO in action

Patient safety incidents relating to a specific issue: the example of tracheostomy

A patient safety related issue was raised by a clinician about the inappropriate care of patients who have a tracheostomy when they are transferred from ICU to general wards. Information was obtained from a range of sources to assess this issue:

- 36 incidents of this kind have been reported to the NRLS from November 2003 to March 2005, including one death;
- the NHS Litigation Authority indicated that there have been 45 litigation claims involving tracheostomy or tracheostomy tubes from February 1996 to April 2005, of which 13 related to the management of tracheostomy tubes, including 7 deaths;
- the Medicine and Healthcare Device Regulatory Authority has had 10 similar incidents reported since 1998;
- an analysis of hospital episode statistics shows an increase in the number of tracheostomies being performed in the last 5 years, and a higher proportion of patients who have had a tracheostomy being cared for outside of surgical and anaesthetic specialties.

Information about this issue was fed back to the NHS via the NPSA's Patient Safety Bulletin [22].

A similar approach has been taken to investigating other topics, for example anticoagulants, naso-gastric tubes and MRI scanners.

Using routine data sources: the example of hospital data

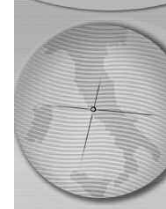
The Agency for Healthcare Research and Quality in the US have developed patient safety episodes which can be derived from routinely collected hospital administrative data [23]. The NPSA is working with the Healthcare Commission to adapt and validate the AHRQ patient safety indicators for use with Hospital Episode Statistics (HES) [24] in the UK. HES data are derived from routine administrative data provided by all NHS hospitals, which describe episodes of inpatient care, including patient characteristics, diagnoses, procedures, specialty and length of stay. HES records are also linked to mortality data, so that mortality within and after hospital episodes can be included in the analysis. It should be noted however that HES data use a different coding scheme for diagnoses and procedures than that defined by AHRQ, and differences in clinical practice between the US and UK mean that the indicators need careful validation.

The quality of data reported to the NRLS needs to improve. The majority of the reports held by the NRLS are obtained directly from local systems. Some data items are not consistently captured across the NHS, and the level of detail within the description of the incident is also variable. This will limit the conclusions which can be drawn from the incident reports and has implications for the methods of analysis used. We are working with NHS organisations to improve data quality of reports from local risk management systems.

Providing feedback to reporters is critical for encouraging reporting, improving data quality and ensuring that learning is disseminated across the NHS. We are developing a range of feedback routes:

- a regular Bulletin aimed at risk managers and clinical staff, highlighting issues that have recently been reported to the NRLS;
- a web-based system for NHS trusts to receive comparative feedback of data from the NRLS; this is currently being piloted;
- feedback via www.saferhealthcare.org, a web portal aimed at NHS clinical staff which was launched in August, in collaboration with the British Medical Journal and the Institute of Health Improvement [25].

We are working to extend the range of reporting routes, and to encourage all staff groups to report. The majority of incidents reported to the NPSA come from staff in the NHS. In February



2006 we will be launching an e-Form for patients and the public to use, and are supporting reporting by community pharmacists. A programme to encourage reporting by doctors includes the launch of "Medical error" [26], a case book aimed at doctors, and a campaign aimed at junior doctors, linked to the launch of www.saferhealthcare.org.

There are a number of challenges in analysis of NRLS data, given the volume of reports and the richness of free text information within reports. The NRLS already holds nearly a quarter of a million incident reports, and the flow of data from the NHS continues to increase over time. A major challenge for the NPSA is to ensure that data within the NRLS is analysed in a systematic way, to identify new types of patient safety incident, to monitor trends and patterns in reporting of known issues, to understand the factors which contribute to incidents, and to identify risk factors - aspects of care or patient characteristics which may lead to incidents. Our analytical strategy incorporates a range of approaches:

- 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); data mining techniques aim to find unsuspected relationships and summarise information from large data sets [27];
- extending the use of software to identify clusters within NRLS data;
- undertaking more detailed analysis of specific topics and groups of records;
- integrating analysis of NRLS data with information from other sources, following the Observatory model.

For the Observatory there are a number of challenges to sharing data and integrating data from a range of sources. Many of the data sources which are relevant to patient safety are collected for other purposes, and there may be limitations to their use for improving patient safety. For example, a study of clinical negligence data encountered issues of confidentiality, data quality and completeness (for the purposes of patient safety), and resources needed to extract relevant information [28]. The NPSA is now planning work with the relevant organisations in England and Wales to develop a more consistent approach to the collection of data about clinical negligence which will support patient safety.

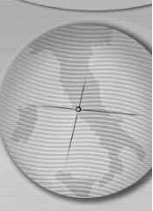
Conclusions

This paper has presented an overview of the approach of the National Patient Safety Agency to establishing a national incident reporting system, the NRLS, linked to the Patient Safety Observatory.

The NRLS is the first national system of its kind in the world, and collects data from across all healthcare settings. It provides a springboard to develop national solutions to patient safety problems and to identify priorities for the NPSA, although there are a number of challenges in order to exploit the data within the NRLS, improve data quality, and provide feedback to reporters. Further, incident data on its own is not sufficient, and 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.

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