

NRLS RESEARCH AND DEVELOPMENT

**NIHR Patient Safety Translational Research Centre at Imperial
College London and Imperial College Healthcare NHS Trust**



**NIHR IMPERIAL PATIENT SAFETY TRANSLATIONAL
RESEARCH CENTRE**

The NIHR Imperial Patient Safety Translational Research Centre (PSTRC) is part of the National Institute for Health Research and is a collaboration between Imperial College London and Imperial College Healthcare NHS Trust.

The NIHR Imperial PSTRC undertakes research to drive forward improvements in patient safety within the NHS. We use our funding to deliver sustainable long-term, high impact programmes of translational research in patient safety. Our research has the potential to translate into real benefits for patients, such as reducing prescription errors, improving diagnosis and reducing accidents during surgery.

Our strategy is to develop patient safety in the NHS and internationally through engagement with patients, carers, the public, clinical partners, healthcare organisations, social care, industry and government. We do this by carrying out research in our unique areas of academic strength in safety information, design and technology, patient engagement, teamwork, economics and policy.

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**NATIONAL REPORTING
AND LEARNING
SYSTEM
RESEARCH
AND DEVELOPMENT**

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FOREWORD

Measuring what happens to patients during their care is the first step towards improving health services. It is especially important in patient safety, as it provides insight about when patients are most vulnerable, and where new safeguards are most needed. The NHS has multiple conduits through which patient safety information can reach providers, policy makers and the public. The most established and extensively used is the National Reporting and Learning System (NRLS).

The NRLS was instituted in 2003, just two years after *To Err is Human* instigated a global movement towards patient safety. It collects incident reports from frontline staff and aims to enhance accountability, patient safety culture and shared learning. The NRLS has helped raise the profile of patient safety and promoted the fundamentals of measurement as a mechanism for improvement. Fifteen years on, however, it is time to evaluate its impact and explore options for its future direction.

With expert leadership and support from Mike Durkin and his team at NHS England, we at the Institute of Global Health Innovation, Imperial College London have devoted three years to that endeavour. We would like to thank Liam Donaldson for spending the three years with us on this programme.

Our research has evaluated the NRLS's conceptual premise, the user experience with reporting and mechanisms to enhance the culture of reporting and the all important feedback to improve shared learning. The aim of this work was not simply to evaluate, but to stimulate innovation around the NRLS. Researchers analysed NRLS data in novel ways and devised creative strategies for breaking down the most entrenched challenges facing incident reporting systems.

The result of this work is a blueprint for NRLS progress with two central pillars:

- Integrating design principles and the use of behavioural insights to renovate the reporting platform such that it facilitates uptake and data utilisation
- Differentiating between the goals of reporting and learning, and the various tools they require at the local and national level

The future of the NRLS is rich in possibilities, and this report details the evidence base and technologies behind them. It details how we build a reporting platform to support shared learning, and an overarching system to enhance it. We must maintain a firm commitment to the principles of patient safety measurement, supporting a culture of transparency and openness when things go wrong and minimising avoidable harm in order to protect the patients we care for.



Ara Darzi
Professor the Lord Darzi of Denham

EXECUTIVE SUMMARY

This report presents the findings of the NRLS Research and Development Programme conducted by the Patient Safety Translational Research Centre (PSTRC) and the Centre for Health Policy (CHP) at Imperial College London.

It sets out the current state of affairs regarding patient safety incident reporting in the NHS, and specifies where the most pressing areas of concerns are, including thorough descriptions of the various incident reporting systems used in the NHS today. Furthermore it identifies areas for improvement in the overall landscape of incident reporting, and suggests how systems like the NRLS can capitalise on developments in technology.

The main body of the report is then devoted to explaining the findings from the research programme. The research was divided into four domains, and the report details the new findings discovered about each of them:

1. Purpose of incident reporting in healthcare
2. User experience with reporting systems
3. Data quality and analysis
4. Effective feedback for learning

Building on these findings, the report moves on to describe how they can be applied to the next generation of incident reporting. Specifically, it focuses on a prototype for a new incident reporting system that incorporates the improvement ideas generated by the research.

Finally, the report concludes with a description of an evidence-based framework for evaluating incident reporting systems and an 'Achievement Toolkit' of ten recommendations for improvements to incident reporting systems.



DOMAIN 1

Purpose of incident reporting

- Explore reporting aims, practices and functions
- Explore and define user requirements for the NRLS
- Specification of attributes and elements of a reporting system for the future



DOMAIN 2

User experience with reporting systems

- Review and usability testing of the current NRLS online reporting platform
- Development of an information architecture that supports the aims and objectives of the NRLS
- Design and development of an enhanced NRLS online platform
- Usability testing and evaluation of enhanced NRLS online platform



DOMAIN 3

Data quality and analysis

- Assess the validity of the current NRLS system to classify patient safety incidents
- Investigate the potential to automate and enhance the free text analysis of reported patient safety incidents including the development of an improved classification of patient safety incidents
- Systematic review of incidents that impact on patient quality of life
- Measure incidents that are important to patients from multiple routine and non-routine national databases
- Comparison of incident reporting to measurable incidents at organisational level



DOMAIN 4

Effective feedback for learning

- Scoping review to establish evidence base for effective feedback from incident reporting
- Retrospective evaluation of the impact of feedback upon reporting rates
- Investigation of social media in health as a technology for feedback and learning
- Develop a research-based model for effective feedback from national reporting

IMPORTANCE OF THIS WORK TO THE NHS

The health service's commitment to patient safety is the strongest it has ever been. In the last five years, several important milestones have elevated this agenda to the highest urgency and priority.

- In the **NHS Constitution**, patients are given the 'right' to expect a standard of safe care and "to expect NHS bodies to monitor, and make efforts to improve continuously, the quality of healthcare they commission or provide," including safety.¹
- In the latest major strategic document from NHS England, the **Five Year Forward View**, the first set of ambitions stated are to improve healthcare quality and reduce variation in the safety of care. It says, "as national bodies we can do more by measuring what matters, requiring comprehensive transparency of performance data."²
- The recent high-profile expert **reviews from Bruce Keogh,³ Robert Francis,⁴ and Don Berwick⁵** have lent profile and weight to an agenda which historically lacked visibility and priority.
- Organisationally, **NHS Improvement** now consolidates the responsibilities for improving the safety of care across NHS England's patient safety directorate, the Trust Development Authority, and Monitor.
- The introduction of a statutory **duty of candour** into the professional responsibilities of frontline staff signals a turn away from secretive and self-protective attitudes that have characterised responses to patient safety incidents in the past.

At the same time, however, the NHS's tools for assuring the quality of care and measuring progress against the aspirations outlined above are inadequate to the importance of the challenge. Of particular concern are the information systems which are meant to gather actionable accounts of instances of unsafe care.

Too often, the data are missing, or the data that is gathered does not consistently inform and inspire change. Duplication of effort and confusion about the purpose of reporting into these systems is commonplace. We cannot say with confidence how many patients are harmed in NHS care, although some estimates suggest that around 3.6% of all deaths in hospitals are avoidable.⁶ Because patient safety issues are dangerously under-reported, it is likely that these figures are underestimates, meaning our energies would be best placed to make care safer.

If the NHS is to cement its commitment to patient safety in the information age, it must begin with an honest account of its challenges, and put in place a reliable mechanism for monitoring progress against the goals that have been outlined above and echoed across the health service.

CHAPTER ONE

NRLS STATE OF PLAY

Patient safety information systems in the NHS today

National Reporting and Learning System (NRLS)

The idea that better information could lead to safer care is not new. In 2001, policymakers created the National Patient Safety Agency (NPSA), which subsequently set up the NRLS in 2003, the first of its kind to be modelled after the example set in other, safety-critical industries like aviation and nuclear power.

Box 1: Key features of the NRLS

- A voluntary system for NHS staff to report safety incidents and near-misses
- Collects data mainly through local risk management systems in hospitals
- Reporters are usually identifiable at the local level, and always anonymised at the national level
- Reports composed of a combination of structured data fields and free text narrative
- Risk managers at hospitals report into a central database hosted by Imperial College Healthcare NHS Trust on behalf of NHS England
- Reports form the basis of Patient Safety Alerts and advice from NHS England (formerly from the NPSA)

The NRLS has collected over 10 million incident reports since its inception, making it in all likelihood the largest patient safety-focused database in the world. On average, a new NRLS report is created once every 35 seconds.

What has happened as a result of these reports? The majority of incidents are reported locally via risk management systems, providing the opportunity for local use before submission to the NRLS. From the NRLS, a number of Patient Safety Alerts⁷ have been generated providing a national view to inform local practice and a resource to local hospitals to better understand the safety of care they deliver, in some places more than others.

The premise of the NRLS was correct by casting the net shallow and wide to encourage and support reporting. As a result of its own success, however, we capture a large volume of high frequency, low intensity incidents relative to the low frequency, high intensity incidents.

This has led to external criticism such as:

“It is a significant criticism of the NRLS that its approach to data collection is ‘wide and shallow’, whereas it should be ‘narrow and deep’. The latter approach would entail focusing on gathering in-depth analysis of reported incidents that are less common in type and more serious in the degree of actual or potential harm associated with them.” (Commons Select Committee on Health, 2009)

Also, the Francis Inquiry Report in response to the Mid Staffordshire NHS Foundation Trust scandal noted that:

“The NRLS is not yet producing high quality, actionable information on the patterns, trends, and underlying causes of harm to patients.”

The NRLS is an information system which has collected a vast quantity of reports about patient safety incidents in the NHS, by virtue of the efforts of frontline staff. The quality and utility of that information, however, has not achieved its intended potential; the goal of collective learning has not been fully realised.

A series of other incident reporting systems exist across the NHS. On one hand these augment the information about patient safety that is available nationally, but on the other hand, they compound the complexity of the data landscape and increase the effort staff must devote to incident reporting. These include:

Strategic Executive Information System (StEIS)

Unlike the NRLS, which is open to NHS frontline staff, access to StEIS is restricted to operational managers and executives in the health service, who use the system to record serious incidents, especially but not exclusively ‘never events’.⁸ There are 25 ‘never events’, of which three account for the vast majority of reported incidents: retained foreign object post procedure, wrong site surgery, and wrong implant/prosthesis. StEIS reporting procedures vary by locality, having previously been administered through individual Strategic Health Authorities in the previous NHS management structure, but generally consist of a manual process which alerts relevant stakeholders that an event has occurred, triggering an investigation.

Medicines and Healthcare products Regulatory Agency (MHRA) Yellow Card and medical device reporting

Drugs and medical devices can present a unique challenge for patient safety because they often change – new technologies are introduced which are unfamiliar to staff, may interact adversely with other technologies, or may be defective. The regulatory agency responsible for these technologies, the MHRA, has established reporting systems which enable pharmacists and other frontline staff to report patient safety incidents of this type directly to a central database.

Care Quality Commission (CQC) notification database

All registered health services must also notify the CQC when adverse incidents occur. This can be done through the NRLS, however certain things like deaths, unauthorised absences of people who are detained under the Mental Health Act 1983, abuse and other extreme incidents that may impair the service from operating safely need to be reported separately.

Public Health England notifications

NHS services are also obliged to report all confirmed or suspected cases of infectious diseases to their local authority or local health protection team. This is then submitted to Public Health England, which analyses and publishes the reported trends. These can be reported by phone, letter, email or fax but must be securely transferred to the dedicated team.

NHS Safety Thermometer

Whilst the NHS Safety Thermometer is typically thought of as a use of safety reports for quality improvement, it is also an important example of yet another reporting outlet for staff to navigate. The NHS Safety Thermometer is a 'Point of Care' survey in which staff can track the amount of harm patients on their ward or within their service face in near real time. Staff report into it by answering a variety of survey questions about the occurrence of harm during a particular shift, and that data contributes to a temperature check on safety. The thermometer data can be used in conjunction with a variety of other data to monitor the state of safety.

Serious Adverse Blood Reactions & Events (SABRE)

In addition to the general incident reporting systems, there are also reporting systems that capture information about a certain category of incidents. For instance, SABRE, operated by the MHRA, is a mechanism for reporting adverse incidents specifically related to blood events. It provides an online platform for users to submit blood incidents and reactions to them.

Serious Hazards of Transfusion Scheme (SHOT)

This is a voluntary scheme also related to adverse blood events. However, use of this reporting scheme is highly encouraged by the Chief Medical Officer and researchers who require continuity of data year on year to make evidence-based recommendations. Reporting to this system can also be completed through SABRE to reduce duplication of effort, but data is received by SHOT independently of the MHRA.

Local complaints departments and patient stories

In addition to the many reporting systems in place across NHS organisations, there are also collections of patient perspectives on safety through local complaints departments, free text comments on patient surveys and other online outlets like Patient Opinion. Aside from local complaints, it is unclear how services should reply to or act upon incidents that first emerge from these sources. Often these reports remain in the general repository of patient safety information with little guidance on how they should be handled.

The future of patient safety information systems in the NHS

The current patchwork of information systems does not adequately meet the needs of the NHS. The amount of disparate reporting systems, and the overlap between them, causes confusion about how and what to report. Senior leaders in the NHS are committed to making significant improvements to the current systems and reducing duplication of reporting where appropriate. However, at the moment the systems and the data contained within them are highly inaccessible, making it difficult to identify how to improve the systems or how to use their data more effectively. Subsequently,

the systems themselves remain isolated, and they are inhibited in their ability to drive safer care.

A variety of new technologies, and an influx of emerging behavioural insights, are now available to modernise existing systems and design novel approaches to incident reporting. Firstly, technology has moved on considerably since the original design of the NRLS and there are many new reporting capabilities, which simply would not have been possible in 2003. For instance, communication between reporting systems and other healthcare record keeping is now much more attainable. This is referred to as the interoperability of systems. Interoperability has been substantially enhanced by the availability of things like cloud computing, which can store and process vast amounts of information from different sources and locations online. Given these capabilities, it has become increasingly possible to centralise reporting for all types of problems, meaning blood events could be reported using the same process and platform as other incidents. Data could be collected centrally, but directed to the relevant agency or regulator depending on the nature of the incident.

Beyond technology, the NHS is now in the position to adopt suggestions from the field of behavioural insights, such as human-centred design of reporting platforms. Behavioural insights help us understand the gap between staff's intended behaviours around incident reporting and their actual ones. Human-centred design helps create interventions to bridge this gap. Inviting staff to the reporting process requires not only a simplification of the systems, but a shift in how they are designed – meeting the needs of staff and encouraging uptake is a crucial means to ensuring systems work. (Options for how to achieve this are discussed in Chapter 4: Demonstrating Feasibility Through Prototyping.)

Aside from leveraging the new technology and behavioural insights, improving the effectiveness of reporting systems heavily revolves around how they are structured and how their purpose is conceptualised. There is the opportunity to depart from the current structure of the NRLS and direct incident data about frequently occurring incidents towards local improvement bodies, and send more critical, in depth data to national databases for further investigation. Staff would only have to report once, but the mandatory data about serious and rare adverse incidents would be funneled to the national

dataset. The more basic incidents, some of which may not be mandatory, but still very relevant to individual providers, can be funneled to local risk managers. This structure has the ability to engage staff, as they will know their report is going to a relevant risk manager, and engage risk managers, especially national ones who will not be overwhelmed by surface level data.

The discussion of incident reporting improvement is not unique to the UK and there is ample opportunity to learn from other countries' experience

These technologies and ideas represent exciting prospects for the NHS to match the pace of development in information systems generally. There are also hard choices to be made: strategic choices and trade-offs among potential options. As the new body NHS Improvement considers its options and builds support in the NHS and government for this next phase of development, we believe the academic evidence base we have been building for the last three years suggests a clear course of action.

Finally, the discussion of incident reporting improvement is not unique to the UK and there is ample opportunity to learn from other countries' experience. In a study conducted by the Leading Health Systems Network at Imperial College London, health systems from seven different countries, including the UK, reported the details of their protocols for incident reporting as well as their use and effectiveness. While there were standard features across all systems, like the ability for staff to report incidents experienced on the ward, other countries used other unique techniques to enhance the richness of data procured by their systems. For instance Counties Manukau Health (CMH) in New Zealand used a patient survey asking patients whether they felt safe during their care. Embedding the patient voice in understanding patient safety is increasingly important, but has not been achieved to the same degree by the NRLS. Furthermore, the incident reporting system used in one hospital chain in India included specific metrics for staff-reported perceptions of patient safety culture. Considering the dynamic link between culture and the effectiveness of reporting systems, this is an ideal opportunity to understand how we integrate these useful sources of safety information from across the NHS into a unified, revised NRLS.⁹

CHAPTER TWO

RESEARCH PROGRAMME FINDINGS

Findings from research and development programme

The Centre for Health Policy at Imperial College London undertook a detailed study of the NRLS from 2013–2015, commissioned by NHS England to assess the NRLS and identify priority areas for improvement. The work focused on filling existing gaps in the evidence base surrounding the NRLS and its impact. This included research in four domains: (1) the purpose of incident reporting; (2) user experience with reporting systems; (3) data quality and analysis; and (4) effective feedback for learning. Given the scope of the inquiry, we necessarily came to conclusions relevant not only to the NRLS, but patient safety information systems more generally.

Domain 1: The purpose of incident reporting in healthcare

We sought to understand, by consulting international experts and interrogating the body of published literature on this topic, what incident reporting can be reasonably expected to deliver in the service of patient safety. Through a process of consensus building known as a Delphi study, we asked an expert group to consider various hypotheses about how incident reporting systems should work. Experts agreed that incident reporting had a strong function to play in local monitoring and evaluation, but that they should not be used as epidemiological tools to appraise the rate of harm nationally. Rather, at the national level they are best suited to capturing more serious incidents requiring national-level policy decisions. These include incidents like medication error, device failures, hospital-acquired infections and never events.¹⁰

These findings from the Delphi study generated lines of inquiry to explore in our literature review; for instance, we looked into information about the proper role incident reporting systems ought to play in a healthcare system.

Through this work, we learned that there are two basic roles that incident reporting systems can play: either a learning role, or a reporting role. At a fundamental level, these two ends require different means. Systems need to be explicit about their goals towards either learning or reporting and exactly how they will facilitate those goals. Box 2 demonstrates some of the typical roles of reporting versus learning systems as a map for developing either.

Box 2: Characteristics of learning and reporting systems

Reporting systems:

- Require mandatory reporting of a standard set of events
- Enable quantifiable, epidemiological analysis
- Provide a means of accountability and a basis for investigation

Learning systems:

- Invite voluntary reporting of any event the reporter believes is of interest
 - Enable the discovery of new types of events and qualitative analysis
 - Provide a means to generate and disseminate interesting insights
-

At present, the NRLS is seen (as in its name) as both a reporting and learning system. There is therefore considerable confusion among frontline staff over, for example, what ought to be reported and what action ought to result – confusion which stems from these two conflated roles. The voluntary nature of reporting and anonymity guaranteed at the national level preclude the NRLS from serving as a meaningful reporting system.¹¹ Yet the learning role also goes unfulfilled because of the overwhelming volume of reports which do not lead to meaningful feedback to reporters. We believe scale is at the core of this issue, and recommend a new approach which provides for a learning system at a local level and a reporting system at the national level.

Domain 2: User experience with reporting systems

We sought to understand what it is like to report into the NRLS as a frontline staff member in the NHS. While it is worth noting that there is for the most part no single ‘NRLS’ interface common to all frontline staff, we were able to draw out common themes from their experience and also draw on published literature about barriers and facilitators for using incident reporting systems.

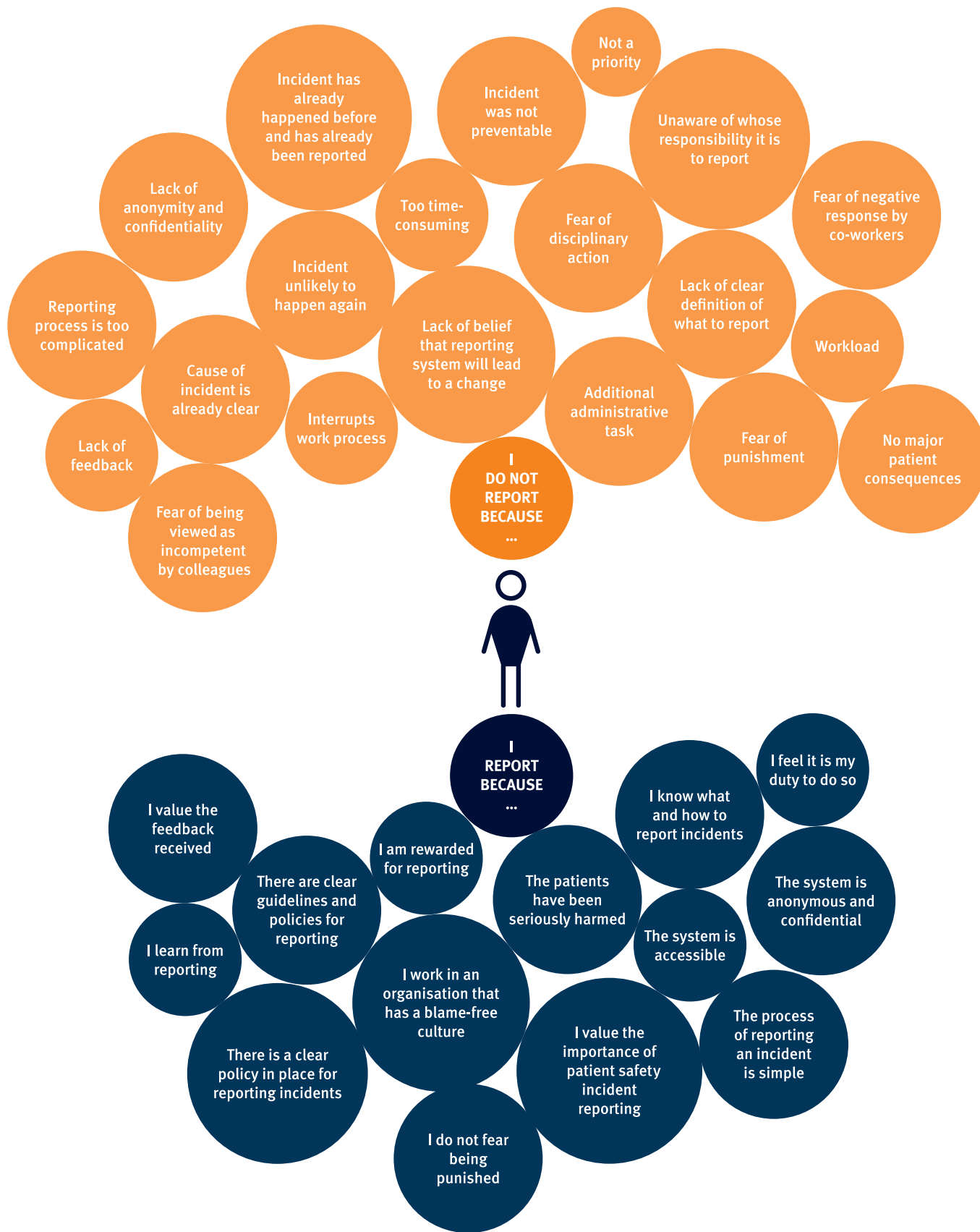


EXHIBIT 1: Barriers and facilitators to incident reporting¹¹

User experience survey

We worked with user experience experts to survey staff on the context in which they make reports, the relative ease or difficulty in doing so, and their overall attitude toward incident reporting. In general, there are three users who support incident reporting as being ‘useful’ for every one that does not. However, there are significant difficulties experienced by both groups and 47% of respondents agreed that there is significant repetition of incidents which happen frequently, such as problems with discharge letters, falls, or medication errors. Furthermore, approximately half of respondents replied that they had trouble categorising the type or severity of the incident. This indicated that attention should be given to the taxonomy of incidents offered by the NRLS reporting platform in order to alleviate staff confusion. Taken in sum, these challenges reflect a workforce that is ‘putting up with’ incident reporting, rather than valuing it as a resource.

From hospital to hospital, one will find a significant degree of variation in the barriers and motivators present

Barriers and facilitators

We learned through interviews and surveys with frontline staff that there are a variety of barriers and facilitators that ought to be considered in any new approach. While the catalogue of potential motivating or discouraging factors (see Exhibit 1) helps to illustrate the psychological influences playing on reporters, there is a larger context to this work which we would also highlight. From hospital to hospital, one will find a significant degree of variation in the barriers and motivators present, which are largely a function of the safety culture which pervades the institution.

Heuristic evaluation of reporting platforms

We have learned that when frontline staff have decided to make a report, there are significant frustrations involved in the mechanics of submitting a report. We undertook a heuristic evaluation of the most widely used interface for reporting (through a commonly implemented local risk management system) as well as the NRLS ‘eForm’ which allows staff to submit directly to

a central database via the internet. In both cases, there were critical flaws identified which, in the view of user experience experts, detract from the usefulness of the tool and could prevent its proper functioning. These are sometimes issues of poor design, but are also a result of the long lifespan of the original NRLS system, which has had to be updated to reflect changing priorities for data collection, and also the desire to allow local organisations to collect data using whatever system they prefer.

Domain 3: Data quality and analysis

Understanding and interrogating the current dataset

We used advanced computational techniques to examine the contents of the NRLS database and the reports contained within. At the first level of analysis, we wanted to understand the structure and completeness of the data. For example, we found that in practice the non-mandatory structured data fields are rarely completed, while the mandatory free text box provides the majority of the usable information in the database. These free text entries, ranging from single-word submissions (e.g., ‘fall’) to, at most, over 800-word narratives of the incident, are often written in medical shorthand and vary considerably across reporters. Furthermore, they often included spelling inconsistencies that compromised the ability to derive findings about frequently occurring words and what they are associated with.

Although free text comments can be difficult to analyse, their potential to improve the value of existing reports and help generate a better system for categorising incidents in the future is significant. Many free text descriptions in the existing NRLS dataset include details about the incident, providing important insight into how it could be classified. We proceeded to apply natural language processing techniques to the free text fields and were able to build a classifier algorithm that could pick out instances of harm from the terms contained within the free text. In practice, this could be helpful in removing some of the subjectivity involved in classifying events, and accurately flagging the most concerning cases for the attention of risk managers. Our computer programme was able to pick out cases of harm with 85% accuracy having been ‘trained’ by clinicians to distinguish between cases of true harm or otherwise.

Testing the NRLS data against other sources

We have learned that the current dataset is not necessarily reflective of other measures of hospital quality and safety.¹³ By correlating quantitative metrics taken from the dataset (such as reporting rates, or number of reports per hospital bed capacity) with other metrics (such as standardised hospital mortality rates, NHS Litigation Authority claims, or CQC rating) we can test the validity of the database. In other words, we asked the question, “What does the NRLS tell us about hospitals which we think are more or less safe based on other datasets?”

We found that, bar one exception, there was no statistically significant correlation between reporting rates and any other measures of hospital quality and safety. The one exception was reporting culture, as described in the NHS Staff Survey. It should be no surprise that hospitals where a positive reporting culture (respondents agreeing with the statement “I am encouraged to report patient safety incidents”) prevails would have more reporting. This does not, however, necessarily mean that these hospitals are any safer.

Capitalising on opportunity in primary care

We have learned that less than 1% of NRLS reports originate in primary care. This impacts patient safety across care settings, as secondary care staff have little information about incidents in prior interactions with the health service, meaning the sector-wide visibility of where and to what extent patients experience incidents remains blurry. A focus group and small-scale survey of GPs showed significant interest in better understanding patient safety issues in primary care. Of particular interest are the transfers of care to and from the acute setting, where lack of coordination and information can contribute to unsafe care. Incident reporting could prove useful in monitoring these interfaces.

Need to obtain better intelligence about incidents

We also sought to understand the potential impact of an improved database of patient safety incidents in improving the standard of patient care. To do this, we focused on specific clinical situations where patient safety incidents would be documented in the course of clinical care through electronic medical record systems. A research database, the Clinical Practice Research Datalink (CPRD) aggregates these clinical records. We

can see clearly in this database that harm continues despite advancements in the standard of clinical care, and also that a better quantified understanding of this harm can provide valuable intelligence to clinicians and health system leaders to make needed improvements.^{14,15}

In order to obtain better intelligence from these events it will also be important to develop learning platforms that are separate from incident reporting. These could be dashboards constructed through advanced analytics demonstrating the rate and causes of certain incidents. Ideally these dashboards could also enable communities of stakeholders, experts and interested parties to discuss the results; people could engage with forums about certain types of incidents, possible preventative measures and even personal stories about handling difficult incidents. To complete the circle of learning for quality improvement, it will also be important to explore options for linking incident data to other sources of quality information like Hospital Episode Statistics (HES) or the National Patient Survey Programme.

Domain 4: Effective feedback for learning

We have learned that another crucial step to learn from incident reporting is about ‘closing the loop’ between reporting and feedback for learning. We know from existing studies that outputs from incident reporting systems can serve as encouragement, or a wake-up call, helping to change both specific clinical practices and the overall safety culture of a hospital. However, a survey we commissioned showed that clinicians do not access one of the principal forms of feedback available from the NRLS today: making institutional data available through the data feedback system. Although risk managers are able to view the data, it is not clear that clinical staff, who are doing the majority of the reporting, benefit from even this limited form of feedback.

We also know that effective feedback, across incident reporting systems in multiple industries, tends to have eight essential components:¹⁶

1. Includes visible sponsorship from local leadership
2. Preserves anonymity without compromising learning
3. Rewards reporters and reinforces reporting
4. Supports prioritisation of resources for improvement

5. Involves and engages frontline staff in the safety improvement process
6. Tailored to be specific and relevant to its audience
7. Occurs at multiple points in the alerting and response process
8. Facilitates dialogue between relevant stakeholders.

Feedback cannot just be a passive dissemination of information if it is to become a meaningful portion of the overall improvement project. It is instead better understood as an active process of communication which sustains a continuous cycle of learning, reporting, and learning. Feedback also plays a role in establishing accountability, as staff are more likely to report incidents when they are certain that it will be reviewed and acted upon.

CHAPTER THREE

PATIENT SAFETY INTELLIGENCE IN THE FUTURE

The research findings from each of the four areas under consideration have provided a useful blueprint for designing a new NRLS. The first step is differentiating local learning systems from national reporting systems. At a national level, creating a working incident *reporting* system is an end in itself, but in local systems, it can also be a means to supporting a relevant *learning* system. We therefore see it as important to focus on solidifying the foundation behind the reporting function at both levels. We fully accept that learning starts with reporting, and the use of those reports, but to many frontline staff the notion of ‘reporting’ denotes a regulatory purpose without reflection.

Our research has demonstrated that NRLS’s utility as an effective reporting system at either level is currently compromised by a variety of problems within the structure of the reporting platform as well as the culture that surrounds reporting in general. Renovating the NRLS will require rectifying these internal problems and designing new mechanisms within the systems to mitigate the impact of the external problems. There can be little doubt that this approach will challenge the traditional concept of incident reporting in the NHS, which has been oriented more toward learning in several important ways: anonymity, open-ended reporting for any incident of concern, and reporting infrastructure intermediated by local risk management systems. What we propose largely moves away from these expectations at the national level. The payoff for this new approach, however, is potentially enormous.

Features of a new system will include user-friendly interfaces, effective incident classification systems and leveraging new technologies for better platforms, feedback and analytics. In constructing a picture of the future NRLS, we have been mindful of the need to promote a culture conducive to the system’s success. Engendering cultural change will require a whole-system approach and a sector-wide commitment to safety.¹⁷ From our perspective this requires making sure new ideas for reporting systems are supported by reporters and risk managers, clearly delineating staff roles and responsibilities and ensuring effective feedback loops.

Locally-led, data-driven service improvement

We conclude that local organisations should continue to collect, assess and respond to common patient

safety incidents which are processed through local risk management systems. Not only do these systems serve a valuable management purpose by providing a risk register and record of management actions, but they are ingrained in the workflows and expectations of NHS staff.

It is important to apply the principles of best practice to these systems in order to facilitate reporting

As described before, one of the most consistent findings in our research was that the NRLS casts a wide and shallow net to capture a lot of incidents without extensive detail. This type of monitoring plays a more important role at the local level than the national level. For instance, an exact log of how many patient falls were reported in a single day and where they occurred would support the risk manager in targeting resources towards areas with a high volume of fall reports. This information could be invaluable for designing locally relevant improvement strategy, but is not particularly useful outside that context other than to contribute to an aggregate number of falls. Whereas at the national level, it is more important to have detailed information on rare and serious incidents requiring a concerted response.

There is no need to displace these systems or the day-to-day performance monitoring and improvement which they facilitate. However, it is important to apply the principles of best practice to these systems in order to facilitate reporting. These could include using human-centred design to create user-friendly reporting interfaces and specific feedback mechanisms. It could also include a new functionality to allow patient safety managers to review incident reports more constructively. For instance, the introduction of dashboards that present incident information and allow the user to filter incidents on key characteristics like time, ward, classification and level of harm would facilitate easier, more effective use of the data. Ideally, dashboards would also be enabled to link incidents at the patient level for a more granular understanding of what is occurring along the patient pathway, or link event types at the NHS trust level to investigate what areas present the biggest cause for concern organisationally. Ultimately, while the goals of

local systems do not need to change, the procedures they require from staff should be updated to reflect new findings about what works best to engender a culture of reporting.

Next generation technology and usability

We conclude that while technology has moved on significantly since the inception of the NRLS, the systems remain firmly rooted in the constraints of the past. There is significant scope to adopt cloud-based, multi-platform, flexible and scalable data infrastructure, which places a new emphasis on sharing, speed, and analysis rather than collection and storage.

The first step to utilising these technologies more effectively is establishing a better understanding of how digitally mature the systems already are, and what their prospects are for interoperability with other records systems. In other words, it is important to make sure we know how the current NRLS can communicate with other systems and how adaptable they are to new software and technology. Following a review of digital capabilities of these systems, it will be clearer where work needs to be done to integrate more advanced technological systems into the existing incident reporting infrastructure.

In future incident reporting systems, it will be important to use digital resources which are now very familiar to staff. For instance, smartphone technology could enable staff to report in near real-time via a device they are accustomed to using, and a more advanced back end could allow this information to be stored in a cloud based system.

Furthermore, it will be important to employ behavioural insights from user-centred design so that new systems are built with the aim of limiting staff burden and reducing human error. Considering the pervasive low reporting problem associated with the NRLS, designing a system that invites staff to use it is paramount. Examples of this include making sure reporting interfaces are visually pleasing, that the amount of text and question fields are not daunting and that colours match heuristic interpretations of what certain colours indicate (i.e. using green buttons to move forward and red to stop).

Leveraging these developments will help modernise the NRLS and mobilise a stronger engagement with the reporting process.

CHAPTER FOUR

DEMONSTRATING FEASIBILITY THROUGH PROTOTYPING

CareReport – a demonstrator system

We took the combined findings from this research and applied them in a practical way to devise a prototype incident reporting system provisionally called CareReport. We synthesised a single system that accounts for the insights from the four domains of research.

Purpose of the demonstrator

The primary goal of a reporting system is to facilitate the collection of details pertaining to all incidents and harm due to care. As secondary goals, the system aims to render useful, accessible data to promote accountability, learning and improvement; crucially, however, it does not attempt to be directly responsible for these aspects.

These goals provide clarity to what the reporting system should be. The demonstrator system, therefore, is a platform for collecting and storing staff reports about patient safety incidents, including a feedback loop between reporters and risk managers. This enables the counting, tracking and investigation of incidents, and can provide data for separate learning and improvement systems. Finally, given constrained budgets in nearly all health systems, the demonstrator is frugal and adaptable to almost any environment regardless of the existing digital infrastructure.

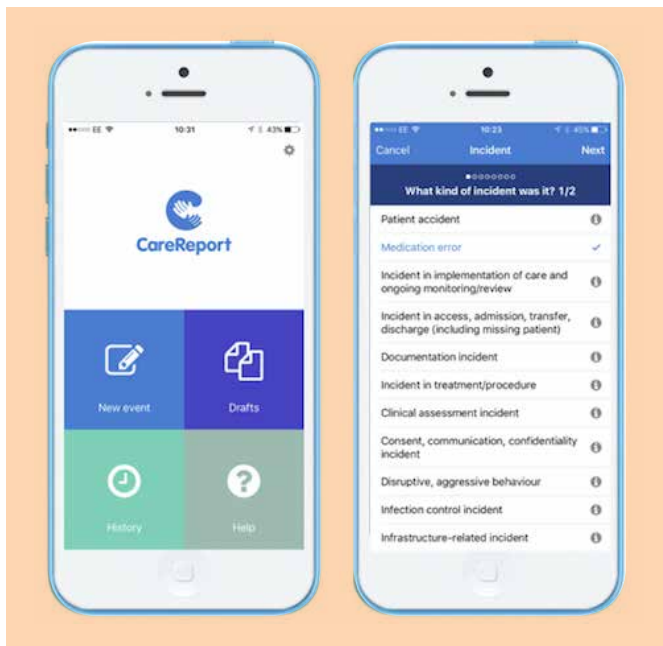


EXHIBIT 3: Care Report demonstrator system app

User experience with the demonstrator

The primary barriers to the success of the current NRLS revolve around staff finding the system difficult to use and time consuming. In the demonstrator system we have sought to rectify this situation by designing a reporting platform that reflects the facilitators to incident reporting.

Our research suggested the importance of reporting systems being quick, easy to use and clear. In order to maximise these areas, our demonstrator system works online but has also been designed to operate as an app for smartphones or tablets capable of offline reporting. The ability to work across devices means the system is adaptable and will not buckle under changing technology or become obsolete. Not only does this allow staff to report using their preferred device, it presents a frugal option for health systems in which services or individual staff members might have compatible mobile phones, but the system does not have the financial capacity for an advanced computing system.

Additionally, the demonstrator requires a significantly reduced number of fields for reporters to complete. The simpler format is designed to change staff perception of incident reporting as a long and cumbersome process, to a simple task that can be accomplished right after the incident.

This change of attitude, however, requires more than a simplified app-based platform. The demonstrator uses behavioural insights as discussed earlier to design an intuitive interface that limits scope for human error and confusion. For instance the questions about what happened during the incident progress from incident category, to what contributed to the incident, to the level of harm and finally into the date and specifics of the incident. Small things like the date being presented in a scroll down menu rather than in free text boxes makes reporting quicker, and maintains a level of consistency around how things are reported. Finally, there is a free text box included so that reporters can elaborate on the details of the event in case the questions did not capture everything they wanted to report.

Ensuring data quality focused on two key considerations: the use of free text comments about incidents and the taxonomy reporters are given to classify incidents

Data quality and analysis from the demonstrator

After being certain that the demonstrator used evidence to improve uptake and engender wider use, we began to tackle the quality of the data it could actually capture. Ensuring data quality focused on two key considerations: the use of free text comments about incidents and the taxonomy reporters are given to classify incidents.

Using natural language processing and machine learning we are able to automatically classify events using key word pairs from small subsets of already classified events. We can use this technique to auto-classify events according to a defined taxonomy with small subsets of manually classified events as a basis. Natural language processing can also be used for auto-generation of headlines and for automatically tagging key words in incident descriptions.

Effective feedback for learning from the demonstrator

Finally, the demonstrator places a significant emphasis on establishing a feedback loop between reporters and the staff who manage and respond to incident reports. For instance on the app platform, when a reporter submits an incident report, it automatically generates a notification to the designated manager. The manager then has options for how to respond to or follow up with the event. The actions the risk manager takes are then relayed to the initial reporter. The reporter can also check up on the status of their report so they are clear what has been done after submission and the process and progress of the submitted information.

The demonstrator also provides a dashboard feature, meaning the data is automatically fed into an analysis system, which can produce easy-to-understand graphs and charts visually depicting the volume and nature of incidents. This helps reporters see how their reports contribute to organisational monitoring and offers a helpful resource to learning systems.

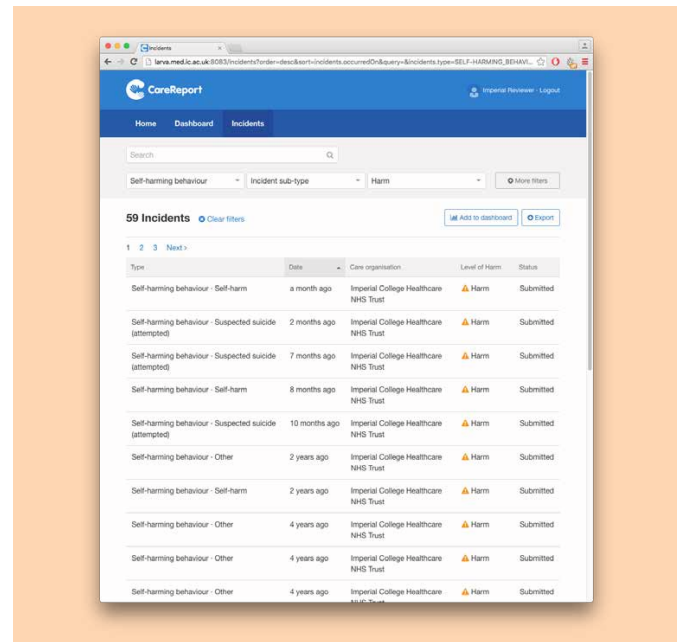


EXHIBIT 4: Care Report demonstrator system dashboard

Conclusion

The pillars of the demonstrator system are evidence based and forward thinking to enable an effective and modern reporting system. It offers an enhanced design for a reporting system with a specific focus on driving national monitoring as well as local learning. It is intended to preserve detailed local reporting and capture incident specifics to inform individual providers' improvement strategies. It offers risk management teams customisable incident dashboards so they can easily visualise the information staff are reporting. It also introduces a new way of feeding this information into a national reporting and learning system. The learning from local safety initiatives, specifically the processes which have demonstrated success in reducing harm, will be directed to a national shared learning platform. This promotes a system of enhanced reporting at the local level and sharing solutions rather than problems at the national level.

CHAPTER FIVE

ASSESSING USAGE AND IMPACT THROUGH EVALUATION

The research from the four domains has culminated in the demonstrator system, but we also recognise the need to establish a standard evaluation procedure to monitor the success of systems like it in the future. An evaluation framework has been created based on the principles of best practice in incident reporting, and it aims to provide a standard method for monitoring and evaluation that ensures future systems can be benchmarked against the evidence we collected during this research.

The evaluation framework includes five strands: readiness and resources, uptake and usage, capturing relevant information, analysis and publication, generating learning and improvement. These five areas are considered levels of maturity because they will apply to certain systems and not others depending on how established or advanced a reporting system is. For instance a system that is in its embryonic stage will have a different set of considerations for success than one that has been around for decades. Monitoring success based on maturity levels helps ensure that the system develops appropriately, rather than in a rush to the highest levels of maturity. A recently implemented system will need to look closely at resource and readiness measures to make sure the functioning of the system is possible given the financial and staff resources available.

Once systems have passed resource and readiness evaluations, uptake and usage measures can be used to evaluate how well a reporting system is able to overcome the barriers discovered in the user experience research. These measures can also help identify which groups of staff are using it most often and where there seems to be lags in uptake. Following from uptake and usage, the system needs to be evaluated on the quality of the information it captures. Especially as new systems will attempt to reduce reporting time, it will be necessary to ensure that changes do not result in compromised data quality. Furthermore, it is necessary for the data to be accessible to those who need to use it for quality improvement. Once assurances have been made for adequate data quality, the final level of evaluation, and highest level of maturity, is its ability to generate impact. This does not necessarily mean assessing the system for whether or not it has produced quantifiable differences in safety, but whether the data it produces is clear and

MATURITY GROUP	INDICATOR
1. RESOURCES & READINESS	<ul style="list-style-type: none"> • Appropriate financial and staff resources • Designed based on user-needs • Objectives clearly articulated • Established culture around safety
2. UPTAKE & USAGE	<ul style="list-style-type: none"> • Training for staff • Clear definitions of what should be reported • Anonymous • Direct feedback loop from manager to reporter • Web-based • Simple reporting platforms
3. INFORMATION CAPTURE	<ul style="list-style-type: none"> • Reports reflect the actual number of incident reports • Reports are made in a timely manner • Collaborative reporting to ensure data supports action
4. ANALYSIS & PUBLICATION	<ul style="list-style-type: none"> • Data is analysable • Data is understood by staff responsible for acting on it • Managers have immediate access to data • All staff are involved in analysis
5. GENERATING LEARNING & IMPROVEMENT	<ul style="list-style-type: none"> • Prioritisation of efforts prior to designing improvements • Established system for monitoring improvements • Innovative approaches to engaging staff in improvement

EXHIBIT 5: Incident reporting system evaluation framework

useful for quality improvement managers. If the reports are inaccessible – in terms of location or content – the system is less likely to deliver impact.

SUMMARY LIST OF RECOMMENDATIONS FOR NHS IMPROVEMENT

Achievement Toolkit

Following our research, we conclude with a series of recommendations for next steps regarding the NRLS. The recommendations can be considered an ‘Achievement Toolkit’, as they are derived from the evidence about what makes the most effective reporting system.

Recommendation 1: Achieve clarity of purpose for distinct local and national systems, specifically a national system that will provide the necessary quantifiable monitoring data on a mandatory basis

Recommendation 2: Specify a limited number of incidents which will be collected nationally and collect structured and free text data about them through a web portal

Recommendation 3: Make the collected national data available to NHS Trusts to compare performance, and set ambitious targets for reducing quantifiable harm

Recommendation 4: Maintain existing local risk management systems, and empower local service improvement efforts by using Patient Safety Collaboratives to share solutions and advancements

Recommendation 5: Conduct routine analysis on future data, and apply novel/cutting-edge data-mining technologies to the existing reservoir of data so it can be used by the Royal Colleges to answer clinical questions

Recommendation 6: Apply the principles of user-focused design to all new tools, incorporating elements of our prototype systems as applicable

Recommendation 7: Undertake an extensive communication and education campaign to re-centre staff on the importance, role, and impact of incident reporting

Recommendation 8: Articulate the potential benefits and track progress against usage and impact targets using the framework we have suggested

Recommendation 9: Begin to nationally track patient safety incidents in certain priority areas like primary care, mental health and community care where there is an unmet need for enhanced patient safety using comparable methodology

Recommendation 10: Look to international best practice and benchmarks to understand how other countries approach patient safety information systems and share the new approach globally

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