

# Characterising the nature of primary care patient safety incident reports in the England and Wales National Reporting and Learning System: a mixed-methods agenda-setting study for general practice

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**Declared competing interests of authors:** Sir Liam Donaldson was the chairperson of the National Patient Safety Agency (NPSA) (2010–12) and is currently involved in the programme of research associated with the National Reporting and Learning System (NRLS). He is also the World Health Organization's patient safety envoy. Sukhmeet Panesar is a former clinical adviser at the National Patient Safety Agency (2008–10), a former special adviser to Sir Liam Donaldson (2010–12) and a former academic clinical fellow at Imperial College London working for the NRLS research programme. Peter Hibbert has undertaken paid consultancy with Power Health Solutions (PHS), St Vincent's Health Australia and for the Australian Commission on Safety and Quality in Health Care, all regarding incident reporting. Amy Butlin obtained a Cardiff University Research Opportunities (CUROP) scholarship to undertake this work. Gareth Parry received funding to attend the Advisory Group Meetings.

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## Scientific summary

### Characterising patient safety incident reports

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# Scientific summary

## Introduction

Internationally, there is growing recognition that health-care provision can inadvertently result in harm to patients. Policy directives have encouraged quality improvement programmes to reduce avoidable morbidity and mortality, but these have predominantly focused on hospital settings. Despite the fact that 90% of health-care interactions with health-care professionals (HCPs) occur in primary care settings in most developed nations, most patient safety research has been based in secondary care where it has been shown possible to identify patterns in errors, determine those most frequently leading to major harm and identify those most amenable to prevention. Formal experimental studies are now under way, investigating approaches to reducing a number of such errors in hospital settings. Similar advances are now required in primary care settings.

In 2003, a major investment was made in the National Reporting and Learning System (NRLS) to better understand patient safety incidents occurring in England and Wales. This is now the largest repository of patient safety incidents in the world. The NRLS contains over 40,000 reports submitted from general practice over the past decade that have never been systematically analysed to generate learning for primary care improvement. Analysis of safety incident reports is an underexploited area within primary care patient safety research that could help establish the value of safety monitoring and emphasise the benefits of an effective reporting system for those responsible for its delivery and governance.

## Aims and objectives

The aim of this study was to characterise the nature and range of incidents reported from general practice in England and Wales (2005–13) in order to identify the most frequent and most harmful patient safety incidents, and relevant contributory issues, occurring within general practice. We then used these insights to inform the development of recommendations for improving the safety of primary care provision in key strategic areas.

## Methods

We undertook a cross-sectional mixed-methods evaluation of general practice safety incidents in the NRLS database.

Given the inductive and exploratory nature of this study, we analysed all patient safety incidents occurring in general practice that resulted in severe harm or death ( $n = 1199$ ) and a random sample of 12,500 non-fatal reports. A weighting was applied so as to preferentially select more recent reports and reports describing more severe levels of harm outcomes.

Data coding involved five clinicians (four doctors and one nurse) independently reading the structured (i.e. age, location, year) and unstructured (i.e. free-text) data in patient safety incident reports and applying codes to describe the incident type, potential contributory factors, level of harm severity, and incident outcomes. We empirically developed our own classification (coding) system, building on the World Health Organization's International Classification for Patient Safety.

Frequent generation of data summaries using exploratory data analysis methods with subsequent thematic analysis was undertaken to interpret the most commonly occurring codes, such as those describing the

incident, events leading up to it and reported contributory factors, within the contexts in which they were described. The study team discussed quantitative and qualitative analyses and vignette examples to propose recommendations for practice.

## Main findings

Our statements are hypothesis generating and inductive in nature.

### *Observations on National Reporting and Learning System data and their analysis*

Development of a comprehensive classification system to characterise safety incident reports in general practice has permitted the description of events leading up to patient safety incidents, their reported contributory factors (human and system issues) and patient- and system-level outcomes. The four independent classes used to describe the incident, its contributory factors, and type and level of harm should provide sufficient minimal information for practising HCPs to structure their analysis and identify learning for improvements in future practice from their own reports.

Two-thirds of incident reports did not explicitly describe reasons about why the incident occurred, which significantly inhibits learning to improve future practice.

One in three reports ( $n = 4668$ , 34% of total reports) were excluded; this was most commonly because reports contained insufficient detail ( $n = 810$ , 26%) or did not describe a patient safety incident ( $n = 784$ , 25%), or the incident was not relevant to health care ( $n = 762$ , 24%). This raises issues about the current knowledge and understanding of the purpose of incident-reporting systems.

### *Safety issues within reports describing serious harm or death*

Diagnosis and assessment-related incidents accounted for the highest proportion of harm to patients; over three-quarters of reports (79%) described a harmful outcome, and half of all reports described serious harm or death ( $n = 366$ , 50%).

In total, 996 reports described serious harm or death to patients. Four main contributory themes underpinned serious harm- and death-related incidents: (1) communication errors in the referral and discharge of patients; (2) physician decision-making hampered by failures of communication arising from human and administrative and/or information technology (IT) interface failures; (3) delays in cancer diagnosis associated with unfamiliar symptom presentation and/or inadequate administration; and (4) delayed management or mismanagement following failures to recognise signs of clinical (medical, surgical and mental health) deterioration.

### *Most frequently reported safety issues*

Five incident-type categories account for the majority of safety incidents. These are, in descending order of frequency: (1) communication with, and about, patients; (2) medication and vaccine provision; (3) errors in investigative processes; (4) treatment and equipment provision; and (5) timely diagnosis and assessment.

Of incidents describing communication-related incidents ( $n = 2805$ , 21% of total reports), barriers accessing clinical services ( $n = 636$ , 23%) and delays in referral ( $n = 669$ , 24%) were associated with the most frequent and most harmful outcomes. Errors in information transfer between care providers ( $n = 756$ , 27%), accessibility to up-to-date patient records ( $n = 427$ , 15%) and miscommunication between patients and professionals ( $n = 240$ , 9%) were described.

Medication- and vaccine-related incidents ( $n = 2484$ , 18.1% of total reports) were mostly underpinned by the need for safer medication provision ( $n = 1429$ , 58% of medication and vaccine-related reports). Immunisation-related errors described in children, the elderly and the immunocompromised were often

caused by administration-related failures, such as inability to access records and inherent discrepancies ( $n = 464$ , 19%). The need to mitigate avoidable adverse drug reactions ( $n = 130$ , 5%), to support clinician decision-making about treatments ( $n = 121$ , 5%) and to provide more reliable therapeutic drug-level monitoring processes ( $n = 120$ , 5%) was identified.

Investigative process-related incidents ( $n = 1339$ , 10% of total reports) were most frequently associated with practical and administrative barriers to the collection and transfer of specimens ( $n = 866$ , 65%), as well as administrative failures to receive and action results ( $n = 240$ , 18%).

Over one-fifth of treatment- and equipment-related incidents ( $n = 754$ , 6% of total reports) resulted in serious harm to patients. The decisions about methods of administering treatment ( $n = 125$ , 17%) and the functioning and availability of care equipment ( $n = 338$ , 45%) were described by HCP reporters as preventable causes. Complications of treatment procedures were also described ( $n = 291$ , 39%).

Diagnosis- and assessment-related incidents ( $n = 728$ , 5% of total reports) were largely underpinned by delayed triage and assessment of unwell patients ( $n = 242$ , 33%) or unsafe discharge assessment processes ( $n = 141$ , 19%). A missed or delayed cancer diagnosis was described in 128 reports (18%). The majority of these reports described human factor issues, particularly issues concerning knowledge and skill competencies.

## Recommendations and future research priorities

Based on our findings, we outline four areas of recommendation for research and development:

1. Maximise opportunities to learn from patient safety incidents via mandatory data capture and a national, co-ordinated effort to support organisations to build the capacity and capability of their workforce to understand the rationale for reporting and contribute report data for learning.
2. Build IT infrastructure to enable details of all health-care encounters to be recorded in one system, aid communication between professionals and services and support safer administrative practices (e.g. prescribing, referral, discharge communication).
3. Develop and test methods to identify, and manage, vulnerable patients at risk of deterioration, unscheduled hospital admission or readmission following discharge from hospital.
4. Identify ways patients, parents and carers can help prevent safety incidents.

We propose three levels of recommendation to support the proposed advances needed: system level, health-care organisation level and general practice level. We end by specifying specific next steps for research.

### System-level recommendations

Supporting and encouraging primary care professionals to contribute to the NRLS is key to embedding a reporting culture across primary care. Currently, there are numerous channels to report patient safety incidents. These include the NRLS, the National Clinical Assessment Service, the General Medical Council and locally at practice level through significant event analysis. The Care Quality Commission also conducts routine inspections of general practices. These systems do not communicate with each other, resulting in an incomplete national picture on patient safety in primary care. There is a need to create a single mechanism of mandatory data capture.

Currently, in terms of mandatory data capture, the only incidents that must be reported are severe harms or deaths, and those classed as never events. A list of never events has been developed for primary care by de Wet *et al.* (de Wet C, O'Donnell C, Bowie P. Developing a preliminary 'never event' list for general practice using consensus-building methods. *Br J Gen Pract* 2014;**64**:e159–67). Never events for primary care should be considered seriously for further development and implementation.

The future of the England and Wales NRLS must be secured in terms of providing a means for national learning and the expertise and resources needed to undertake regular systematic inquiries into these data.

Large collections of incidents have a unique capacity for allowing the identification and understanding of infrequently occurring patient safety risks that are unlikely to be characterised at a local level. A national, co-ordinated initiative to support organisations to build the capacity and capability of their workforce to report safety incidents in primary care is needed. In addition, timely feedback and generation of learning reports that HCPs find useful and adopt into their own practice is essential.

Organisations must be supported to develop their incident-reporting culture in primary care and contribute to a mandatory data capture system. This would require a combined enterprise between professionals with clinical and governance expertise within the organisation to regularly review the output of analyses, to corroborate with existing insights from research studies and improvement initiatives, and to develop potential action-orientated solutions with strong face validity among their professionals. This co-ordinated collaboration is particularly needed at a national level, where insights from care failures and safety incidents can be more formally corroborated with research, and potential solutions developed for application in practice.

There is a need for a system-wide IT infrastructure within the NHS capable of sharing data between health- and social-care providers. In particular, efforts to link incident-reporting systems with electronic medical records and other public- or social-care registries would enable identifying those at highest risk of experiencing a patient safety incident.

### ***Health-care organisations (including general practice level)***

The incorrect use of the incident-reporting system resulted in a large proportion of reports being excluded from this analysis, indicating that efforts to educate primary care HCPs and staff on the purpose and functions of incident-reporting systems are needed. The assessment of contributory factors can provide insights to inform the design of interventions to mitigate future safety incidents. Training for HCPs to provide more comprehensive accounts of safety incidents could maximise potential to generate learning from reports.

Ensuring the appropriate accessibility of clinical services must be a priority issue for all health-care organisations, and general practices should determine whether or not their existing telephone and call-handling processes meet the needs of their patient population. Practices should explore their current processes for identifying, and managing, vulnerable patients at risk of deterioration, unplanned admission to hospital or readmission following a recent discharge.

Encouraging patient and carer involvement, and creating a culture in which patients and carers feel comfortable challenging HCPs, could prevent safety incidents. Furthermore, providing patients with greater access to their medical records could reduce documentation discrepancies and appointment-related incidents, as well as provide HCPs with a safety net. While waiting for diffusion of new technologies, practices can, at the very least, appoint a patient representative to attend meetings to discuss process changes that will affect how patients receive and interact with primary care services.

To shift perceptions of incident-reporting systems from being a 'blaming system' to a 'learning system', organisations must consider how they can demonstrate that reports are being used to inform improvement. To ensure that this is sustainable, high-quality incident reports need to be written by a workforce capable of leading change in practice. HCPs need human factors training to identify the human and systems issues underpinning safety incidents, and receive training on how to complete an incident report, in order to assure the usefulness of incident reports to inform systems improvement.

### Further research

Further research must now include scoping reviews to identify interventions and improvement initiatives that address the priority recommendations, and then determine their acceptability and feasibility with HCPs in primary care with a view to evaluating their effectiveness when implemented.

Further analysis of general practice reports is also needed; a more in-depth review of all reports related to those included in the frequent and most harmful incident types (e.g. diagnosis and assessment, vaccination errors) as well as specific patient groups (e.g. vulnerable adults, unwell children) is required.

Further work is now needed to develop and test the content and delivery of training to strengthen the ability of organisations to align their quality improvement agenda with learning generated by their incident-reporting system, and prepare their HCPs to provide meaningful and informative incident reports.

Given that 13,699 reports have been manually coded by clinicians, this presents an opportunity to develop algorithms and the technology capable of achieving natural language processing of patient safety incident reports.

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