

## Sensitivity of routine system for reporting patient safety incidents in an NHS hospital: retrospective patient case note review

Ali Baba-Akbari Sari, Trevor A Sheldon, Alison Cracknell, Alastair Turnbull

### Abstract

**Objective** To evaluate the performance of a routine incident reporting system in identifying patient safety incidents.

**Design** Two stage retrospective review of patients' case notes and analysis of data submitted to the routine incident reporting system on the same patients.

**Setting** A large NHS hospital in England.

**Population** 1006 hospital admissions between January and May 2004: surgery (n = 311), general medicine (n = 251), elderly care (n = 184), orthopaedics (n = 131), urology (n = 61), and three other specialties (n = 68).

**Main outcome measures** Proportion of admissions with at least one patient safety incident; proportion and type of patient safety incidents missed by routine incident reporting and case note review methods.

**Results** 324 patient safety incidents were identified in 230/1006 admissions (22.9%; 95% confidence interval 20.3% to 25.5%). 270 (83%) patient safety incidents were identified by case note review only, 21 (7%) by the routine reporting system only, and 33 (10%) by both methods. 110 admissions (10.9%; 9.0% to 12.8%) had at least one patient safety incident resulting in patient harm, all of which were detected by the case note review and six (5%) by the reporting system.

**Conclusion** The routine incident reporting system may be poor at identifying patient safety incidents, particularly those resulting in harm. Structured case note review may have a useful role in surveillance of routine incident reporting and associated quality improvement programmes.

### Introduction

Patient safety incidents (defined as any unintended event caused by the health care that either did or could have led to patient harm) have been shown to cause harm in between 3% and 17% of hospital inpatients.<sup>1-5</sup>

After the development of the national risk management standards in 1995, most NHS hospitals in England and Wales established reporting systems as part of their risk management programme.<sup>6</sup> People involved in or witnessing a patient safety incident complete a form that is sent to the local reporting system, where the incident is classified and entered into a database.<sup>7</sup> The National Patient Safety Agency developed a national reporting and learning system in 2003 to collate reports of patient safety incidents from local organisations.<sup>8</sup> This system aims to help the NHS to learn from patient safety incidents and to identify trends and patterns relating to patient safety.<sup>8,9</sup> The system should, therefore, be able to identify a representative sample of patient safety incidents and provide adequate data

about the cause, contributory factors, preventability, and impact of these incidents.<sup>9,10</sup> In this paper we evaluate the relative performance of a local routine incident reporting system that feeds into the national reporting and learning system, by comparing it with a well validated method of systematically reviewing case notes.<sup>1-3</sup>

### Methods

We did the study in a large NHS hospital trust in England in 2005. We selected a stratified random sample of 1006 admissions (>24 hours' stay) between January and May 2004 from eight specialties: surgery; urology; orthopaedics; general medicine; medicine for the elderly; oncology; ear, nose, and throat; and ophthalmology. All data extracted were anonymised and kept confidential. The study consisted of using structured data extraction tools to do a two stage retrospective case note review of the sample admissions and reviewing the patient safety incidents reported by the routine hospital reporting system for the same admissions.

#### Review of medical records

We used previously described methods to do the case note review.<sup>1-3</sup> Five trained nurses screened patients' records by using 18 explicit criteria (box). We used one (or more) positive criterion as an indicator of a patient safety incident and scrutinised these medical records in stage two. One of the other nurses independently reviewed a 10% sample to assess inter-rater reliability. In addition, medical staff fully reviewed 10% of admissions for which no positive criteria were identified to identify false negatives (fig 1).

In stage two, three hospital doctors reviewed the records that had one positive criterion in stage one. The doctors were trained to use a structured review form to judge if a patient safety incident had occurred and to assess its type and consequences. One of the other doctors independently reviewed 90 medical records to assess the inter-rater reliability (fig 1).

#### Review of patient safety incidents reported by routine reporting system

We inspected data on the routine adverse incident reporting system for the 1006 admissions in our sample to see if patient safety incidents had been reported. We calculated the number, percentage, and type of patient safety incidents identified by the case note review and routine reporting system and classified them into three groups according to the routine reporting system policy (table 1). We calculated the proportion of admissions with patient safety incidents identified by each method and the proportion of these incidents that were judged to have caused

patient harm for each method, along with 95% confidence intervals. We used Cohen’s  $\kappa$  to assess the inter-rater reliability.<sup>11</sup>

Results

*Patient safety incidents*—According to a combination of case note review and the reporting system, a total of 324 patient safety incidents were reported in 230 of the 1006 admissions (22.9%; 95% confidence interval 20.3% to 25.5%). Case note review identified 303 (94%) of the 324 incidents. The reporting system identified

54 (17%) of the total number of patient safety incidents, all of them of group I type (table 1).

*Patient safety incidents causing harm to patients (adverse events)*—Of the 1006 admissions, 110 (10.9%; 9.0% to 12.8%) had at least one patient safety incident resulting in harm to the patient (a total of 136 adverse events). In other words, 42% of patient safety incidents resulted in adverse events, of which all were detected by the case note review and 6 (5%) by the reporting system. All 21 patient safety incidents missed by case note review were minor (fig 2), whereas 130 (44.7%) incidents missed by the reporting system led to patient harm.

**Screening criteria used in the first stage of case note review<sup>1</sup>**

- Unplanned admission related to previous healthcare management
- Injury to patient incurred in hospital (for example, fall, burn, pressure ulcer)
- Other complications (for example, DVT, MI, CVA, PE, ARF)
- Hospital acquired infection/sepsis
- Cardiac/respiratory arrest; low Apgar score
- Adverse drug reaction
- Unplanned transfer from general care to intensive care
- Unplanned transfer to another acute care hospital
- Unplanned return to the operating theatre
- Unplanned removal of, injury to, or repair of an organ during surgery
- Development of neurological deficit not present on admission
- Inappropriate discharge to home
- Unexpected death
- Injury related to abortion or delivery
- Dissatisfaction with care documented in medical record
- Documentation or correspondence indicating litigation
- Any other undesirable outcomes not covered above
- Unplanned readmission after discharge from index admission

ARF = acute renal failure; CVA = cerebral vascular accident; DVT = deep vein thrombosis; MI = myocardial infarction; PE = pulmonary embolism.

Discussion

We found that 23% of hospital admissions in eight specialties were associated with patient safety incidents and 11% with adverse events. This is similar to rates found in studies using similar methods in the United Kingdom (10.8%)<sup>1</sup> and internationally (7.5% to 16.6%).<sup>2–5</sup>

The routine reporting system as implemented in this large hospital missed most patient safety incidents that were identified by case note review and detected only 5% of those incidents that resulted in patient harm. This suggests that the routine reporting system considerably under-reports the scale and severity of patient safety incidents.

Strengths and weaknesses

Structured case note review, when carried out by trained professionals, has been shown to reliably detect adverse events.<sup>1–3 6 12</sup> The reviewers in this study were specifically trained, and inter-rater reliability was good at both stages<sup>11</sup>: 84% between nurses in the first stage ( $\kappa=0.67$ ) and 90% between doctors ( $\kappa=0.76$ ) in the second stage (table 2).

This study is based on data from one large hospital, where the performance of the incident reporting system may differ from that in other hospitals. However, this trust is a high reporter to the national reporting and learning system and the distribution of the types of patient safety incidents detected in this study was similar to that found in a recent analysis of patient safety incidents from 230 NHS organisations.<sup>8</sup> Some hospitals report hospital acquired infections to systems other than the

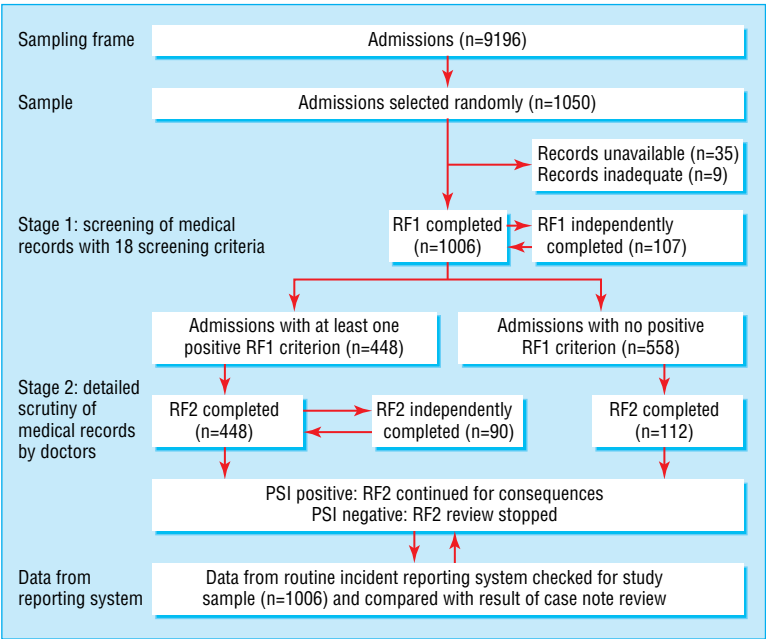


Fig 1 Summary of case note review process. RF1=review form 1; RF2=review form 2

**Table 1** Type of patient safety incidents recorded by case note review (CNR) and routine adverse incident reporting system (AIRS). Values are numbers (percentages)

Type of patient safety incident	Detected by combination of methods	Detected by CNR*	Detected by AIRS*	Missed by AIRS	Detected by both methods*
Group I incidents†:	139	118 (85)	54 (39)	85 (61)	33 (24)
Pressure ulcer	13	13 (100)	3 (23)	10 (77)	3 (23)
Fall	52	48 (92)	29 (56)	23 (44)	25 (48)
Drug problems	24	19 (79)	7 (29)	17 (71)	2 (8)
Operation cancelled	4	4 (100)	0	4 (100)	0
Intraoperative/postoperative complications (except infection)	5	5 (100)	0	5 (100)	0
Patient dissatisfaction	17	17 (100)	0	17 (100)	0
Other group I incidents	24	12 (50)	15 (63)	9 (38)	3 (13)
Group II incidents‡:	127	127 (100)	0	127 (100)	0
Unplanned transfer to ICU	13	13 (100)	0	13 (100)	0
Unplanned return to operation	4	4 (100)	0	4 (100)	0
Inappropriate/self discharge	25	25 (100)	0	25 (100)	0
Unplanned readmission	85	85 (100)	0	85 (100)	0
Group III incidents (infection)	44	44 (100)	0	44 (100)	0
Admission with at least one group I, II, or III incident	230	209 (91)	54 (23)	155 (67)	33 (14)
Total incidents	324	303 (94)	54 (17)	270 (83)	33 (10)

ICU=intensive care unit.

\*Percentages are of total number of patient safety incidents (PSIs) reported by both methods. Because some admissions had more than one PSI recorded, total number of PSIs is greater than total number of records with at least one PSI.

†Incidents always expected to be reported by AIRS.

‡Incidents not necessarily reported by all organisations.

adverse incident reporting system<sup>13</sup>; however, even excluding infections, the reporting system detected only 24% of all patient safety incidents and only 5% of those resulting in patient harm. This suggests that our results may be generalisable.

### Meaning of the study

A recent report by the House of Commons Committee of Public Accounts<sup>14</sup> was critical of the adequacy of the national reporting and learning system. Our study provides empirical evidence that the data collected by the system may be biased. This is unlikely to be caused by teething problems, as the national reporting system was designed to complement pre-existing local reporting

arrangements.<sup>7</sup> If the NHS is to gather accurate information on serious injuries and deaths resulting from patient safety incidents, as recommended by the Committee of Public Accounts,<sup>14</sup> then relying on voluntary reporting may not be sufficient. Voluntary reporting systems may under-report incidents, owing to lack of feedback; time constraints; fear of shame, blame, litigation, or professional censure; and unsatisfactory processes.<sup>15–19</sup>

The results do not mean that the early themes emerging from the analysis of the national reporting and learning system data are not useful,<sup>8</sup> but estimates of the type and severity of incidents are likely to be biased. More importantly, perhaps, the value of these data locally as a component of safety programmes is questionable.

### Future research

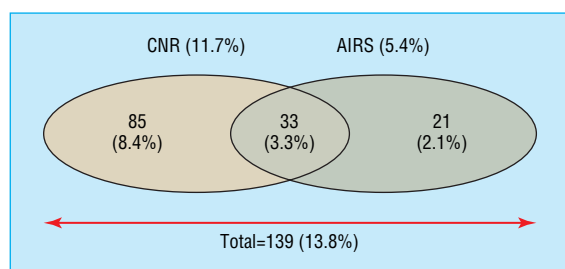
More research is needed to help to develop a reporting system that is capable of providing an accurate picture of the type, nature, and severity of incidents and at reasonable cost. Even if detection is improved, this will not in itself result in improvements in patient safety. We need to develop and evaluate cost effective ways in which good data monitoring can be used as part of quality improvement.

### Conclusion

The routine incident reporting system may not provide an accurate picture of the extent and severity of patient safety incidents, particularly those resulting in harm to patients. Healthcare organisations should consider routinely using structured case note review on samples of medical records as part of quality improvement.

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**Contributors:** AB-AS designed and managed the project, wrote the research proposal, collected and analysed data, and wrote the final paper. TAS supervised the project; commented on the protocol, data collection,

**Fig 2** Group I patient safety incidents reported by case note review (CNR) and adverse incident reporting system (AIRS)**Table 2** Agreement between nurses on presence of screening criteria and between doctors on presence of patient safety incident (PSI)

Reviewer one	Reviewer two		
	Admissions with positive criteria/PSI	Admissions with no positive criterion/PSI	Total
Nurses			
Admissions with positive criteria	36	11	47
Admissions with no positive criterion	6	54	60
Total	42	65	107
Doctors			
Admissions with PSI	23	5	28
Admissions with no PSI	4	58	62
Total	27	63	90

and analysis; was responsible for the quality control; and assisted on the paper. AC and AT piloted the instruments and process, assisted with stage two case note review, provided advice, and commented on the paper. Celia Grant, Eileen Richardson, William Gray, Yvonne Dobson, and Lorraine Wright screened the medical records and collected data in stage one and discussed the findings. AB-AS is the guarantor.

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**Competing interest:** None declared.

**Ethical approval:** Hospital research ethics committee (reference number 04/Q1108/7).

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## What is already known on this topic

Patient safety incidents are common in inpatients, and many of them lead to patient harm or extra cost

Effective strategies are needed to identify, analyse, and learn from these incidents

Case note review is useful but expensive for routine use; routine reporting systems have been introduced in several countries

## What this study adds

Routine incident reporting systems may significantly under-report patient safety incidents, particularly those resulting in harm

Structured case note review may have a role in surveillance and the monitoring of reporting systems

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Department of Health Sciences, University of York, York YO10 5DD

Ali Baba-Akbari Sari *research fellow*

Trevor A Sheldon *professor of health sciences, pro-vice chancellor*

Leeds General Infirmary, Leeds LS1 3EX

Alison Cracknell *specialist registrar*

York Hospital, York YO31 8HE

Alastair Turnbull *consultant physician*

Correspondence to: T A Sheldon tas5@york.ac.uk