Anaesthesia 2012, 67, 706–713 doi:10.1111/j.1365-2044.2012.07141.x

Original Article

Review of patient safety incidents reported from critical care units in North-West England in 2009 and 2010

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Summary

We categorised and established the rates of patient safety incidents reported during 2009 and 2010 from critical care units in 12 hospital trusts in North-West England. We identified a total of 4219 incidents reported during 127 467 calendar days of critical care with a median (IQR [range]) of 31 (26–45 [20–57]) incidents per 1000 days per trust. A median (IQR [range]) of 10 (7–13 [3.5–27]) incidents per 1000 days were associated with harm. Pressure sores were the most common cause of harm, with a median (IQR [range]) of 3.9 (1.0–6.6 [0–20.4]) incidents per 1000 days. Only 89 (2.1%) incidents described more than temporary harm, of which 12 were airway related incidents. Five incidents described the use of inappropriate arterial flush solutions. It is possible to compare rates of incident reporting in different trusts over time to determine if different methods of care are associated with different reporting rates. The wide range of reported pressure sore rates suggests that their incidence could be reduced.

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Accepted: 28 February 2012

Patient safety incidents have been reported by critical care units for many years [1]. In 2001, 'patient safety incidents' were defined by the UK National Patient Safety Agency (NPSA) as 'incidents that could have or did affect the safety of one or more patients receiving NHS care' [2]. Since then, hospital trusts have been obliged to collect these incidents and report them to the NPSA [3, 4]. These reports have allowed researchers to look at national trends in these incidents reported from critical care units [5], and to suggest changes in care to improve patient safety [6, 7].

Previous reviews have not had access to details of the clinical activity, ways of working and reporting processes used by the units submitting the incidents. The process of obtaining the details of incidents from the NPSA was also complex, which made it difficult to look at the changes in incident reports over time to judge the effectiveness of interventions on improving patient care.

In this study, we obtained details of patient safety incidents directly from critical care units, together with descriptions of the clinical activity, methods of working and reporting systems used within these units. During 2011, we retrospectively collected the incidents that had been reported during the years of 2009 and 2010 from the critical care units in 12 hospital trusts in the North-West of England.

Methods

The study was an audit, as defined by the National Research Ethics Service [8], and so ethical approval was

not sought. We originally planned to review incidents from 12 critical care units in the North-West of England; units were recruited at local network and regional meetings and by direct approach to colleagues with an interest in the subject. The units represented a convenience sample, but included all but one unit in one of the three North-West critical care networks. Recruitment stopped after incidents were submitted from 12 hospital trusts. Units were invited to identify incidents they had submitted to their trust risk management departments during 2009 and 2010. The risk management departments were already required to store details of the incidents in electronic format to allow submission of these incidents to the NPSA. We asked the departments for the date the incident was reported, the description of the incident given by staff, and any manager's report describing a review of the incident. Any patient or staff identifiers accidentally left in the reports by risk management departments were removed. The collected reports made no use of any classifications already used in preparation for submission to the NPSA and the process of submitting incidents to the NPSA was not affected by the study. Units were also asked to collect basic information about clinical activity (including number of calendar days, admissions, deaths and length of stay) and to provide details of methods of care, including equipment commonly used.

Incident details were imported separately for each trust into an Access database (Microsoft Office® 1997–2003; Microsoft Inc. Redmond, WA, USA) to allow classification of the reported incidents. This process placed each incident into one or more main incident group, based on the NPSA classification system, with added classifications for incidents that were associated with the airway, led to actual or potential injury to staff, were repeats of a previous incident submission, or that occurred before the critical care admission process (not critical care). We also separated incidents relating to pressure sores into their own incident group, not as a subset of the implementation of care. The grades of pressure sore were transcribed from the incident report or calculated from the free text description using the National Pressure Ulcer Advisory Panel and European Pressure Sore grading system [9]. If insufficient information was available in this field, then sores were recorded as 'ungraded'. Other iatrogenic wounds excluding surgical wounds were graded as 'other'.

All incidents in each main group were then further classified into one or more subgroups. The level of harm reported in each group was also categorised, as was the actual or potential seriousness of the incident. The classification system is summarised in Table 1 and described in detail on the UK Intensive Care Society (ICS) website [10], which also describes in detail how the classification was carried out using the database.

The classification process was carried out by experienced intensive care unit (ICU) consultants locally in six trusts. In the remaining trusts, the classification was carried out by the lead investigator, in order to speed up the process; long delays experienced in obtaining the details of the incidents from the risk management departments within these trusts would otherwise have significantly delayed the study.

The completed classifications were then exported into SPSS tables (SPSS® version 16; SPSS Inc., Chicago IL, USA) for subsequent analysis to determine the number of incidents in each group and subgroup and the level of harm and risk associated with these incidents. The number of characters used by staff in the free text used to report the incidents was also measured (18 reports had been truncated at a maximum of 2048 characters). Summary data were then imported into Excel tables (Microsoft Office 1997–2003; Microsoft Inc.) and linked to the details of the clinical activity reported in individual units to allow the reporting of incident rates per 1000 calendar days. The reporting structure allowed comparison between trusts as well as between ICUs and high dependency units (HDUs). Individual trusts were then provided with a report setting out their incident profile with comparative pooled information from other trusts. A fictitious example of such a report is shown on the ICS website [10].

Missing data describing the date of incidents or the length of incident reports were excluded from the analysis. Differences in the number of incidents in different groups were compared using the chi-squared test, whilst comparison of the number of letter-characters used within different reports was made using the Kruskal–Wallis test. Comparison of the rates of pressure sores recorded in teaching hospitals and district hospi-

Table 1 Main categories used to classify incidents. Incidents could be placed in more than one main group. Incidents were also classified by the level of actual or potential seriousness of the incident and level of patient harm. Detailed information about definitions and the sub-classification of main groups is available on the UK Intensive Care Society website [10].

Main incident groups based on the NPSA classification system	1. Access, admission, transfer, discharge (including missing patient) 2. Clinical assessments (including scans, tests, assessments) 3. Consent, communication, confidentiality 4. Organic confusion or disruptive, aggressive behaviour 5. Documentation (including records, identification) 6. Implementation of care and ongoing monitoring/review 7. Infection control 8. Infrastructure (including staffing, facilities, environment) 9. Medical device/equipment 10. Medication 11. Patient abuse (by staff/third party) 12. Patient accident 13. Self-harming behaviour 14. Treatment, procedure 15. Others
Additional main groups added by the investigators	1. Airway/airway procedure 2. Injury to staff (actual or potential) 3. Pressure sore or other iatrogenic non-surgical wound 4. Non-critical care (often before critical care referral) 5. Repeat entry of the same incident
Level of actual or potential seriousness of the incident and level of patient harm	*Level of actual or potential seriousness of the incident:* Minor risk; moderate risk; major risk; life-threatening *Level of patient harm:* None; temporary harm; temporary harm with increased length of stay; permanent harm to patient; Intervention needed to sustain life; reaction may have caused or contributed to death

NPSA, National Patient Safety Agency

tals was performed using the Mann-Whitney U test. A probability of 0.05 or less was considered to be of statistical significance.

Results

Twelve hospital trusts took part in the review; four were teaching hospital trusts and the remainder were district hospitals. Two trusts provided information only from ICUs, two separated incidents from ICUs and HDUs and the remaining trusts provided information from combined units. There were a total of five ICUs, three HDUs and nine combined units across all of the trusts, with a total of 127 467 patient-calendar days reported. One trust was only able to provide reports from April 2009 and two trusts were unable to link the incident reports reliably to their reporting date. Three trusts provided descriptions of the incidents that were probably summaries of the original staff descriptions of the incidents.

There were 4640 incident reports; 204 were repeats of an incident previously submitted and 217 were incidents not directly related to the critical care episode. The remaining 4219 incidents occurred during the critical care stay or at the time of admission or transfer and were not repeats. The nine trusts that reported dates of incidents for the whole 24-month period reported 3005 of the 4219 critical care incidents, with a mean (SD) of 125 (13) incidents reported per month. There was no trend for incidents to be increasingly reported over the 24 months of the study, with 1489 incidents reported in 2009 and 1516 reported in 2010. There was also no increase in reported incidents during the episodes of pandemic influenza that occurred in the winters of 2009 and 2010; for the eight winter months in December to March 2009 and 2010, 121 (8) incidents occurred per month, with no increase when compared with the 128 (14) incidents per month for the other 16 months of 2009–2010.

Of the 4219 incident reports occurring in critical care, 1414 were associated with some patient harm, giving a rate of 33 incidents per 1000 calendar days for all incidents and 11 per 1000 days for those associated with harm. The median (IQR [range]) for individual trusts for all incidents was 35 (26–45 [20–57]) incidents per 1000 days, with the rate of incidents associated with harm being 10 (7–13 [3.5–27]) per 1000 days. There were a total of only 89 incidents (2.1%) that caused more than temporary harm, and 80 of these were also classified as major or life-threatening.

In the nine trusts that reliably provided the free text of the incident description, the median (IQR [range]) number of characters used to describe the incidents not associated with harm was 219 (114–413 [8–2048]); rising to 334 (128–434 [15–2048]) for incidents associated with harm, and with a further increase to 466 (148–967 [155–2048]) characters for incidents that may have contributed to the patient's death ($p < 0.001$). There were significant differences between trusts in the number of characters used in the reports ($p < 0.001$), with median (IQR [range]) values from 140 (78–248 [8–891]) to 342 (189–558 [8–2048]) characters; the reasons for these differences were not clear.

Managers' reports were available to help with classification of incidents in 2106 incidents. They were not available in any of the reports from four trusts, available in some from five trusts and in all of three trusts' reports. They contained only 75 (26–629 [5–2048]) characters, with no increase in the number of characters used with increasing levels of harm.

With respect to the distribution of incidents as a function of incident type, 2878 were placed into a single group (the three medication groups of drugs, fluids and enteral feed being classed as a single group), 1127 were placed into two groups and 214 incidents were placed into three or more groups. There were similar distributions across these groupings for incidents with and without harm.

Figure 1 shows the number of incidents per 1000 days for each main incident group for all incidents and those associated with harm. Figure 2 shows the total number of incidents in each group associated with more than temporary patient harm; this figure also shows how many of these very serious incidents are categorised only within the single main group and not placed in additional groups.

Pressure sores were the most common cause of patient harm described in the incident reports, being described in 814 incidents, of which 659 incidents described sores developing during the critical care episode and 155 described sores present on admission (i.e. not during critical care). The median (IQR [range]) reported rates of sores developing during critical care was 3.9 (1.0–6.6 [0–20.4]) incidents per 1000 calendar days. In 62 incidents (1.5%), the sore was identified as

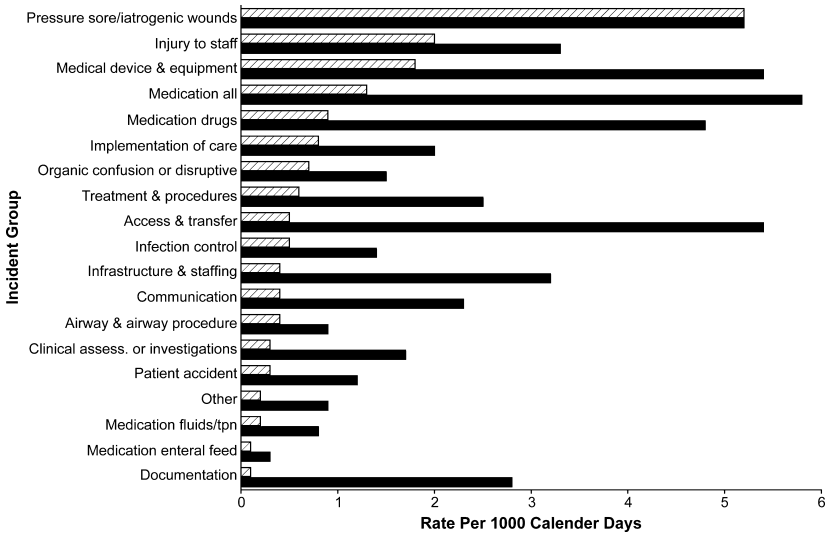

Figure 1 Rate of all incidents ■ and incidents associated with described harm ▨ per 1000 calendar days for each of the main incident groups for all trusts.

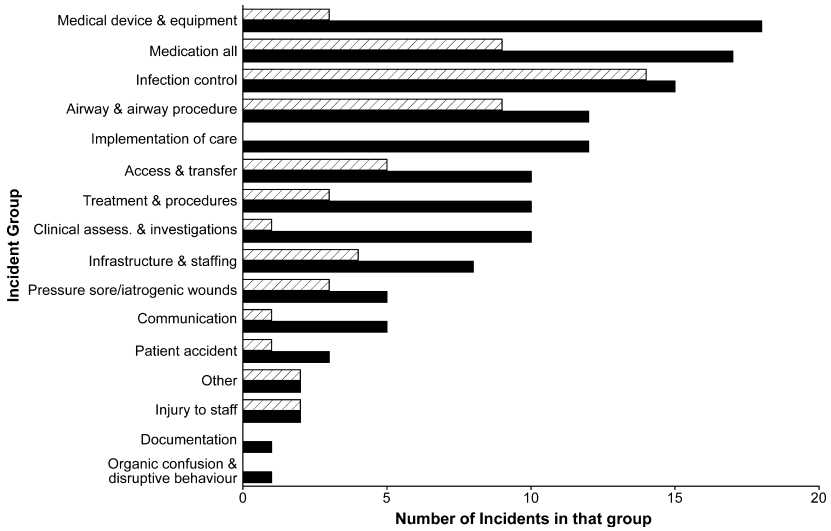

Figure 2 The number of incidents with more than temporary harm in each incident group ■; the graph also shows the numbers of incidents in that group that were placed in no other incident group ▨.

having developed during the critical care stay only at the point of transfer to ward care. The median (IQR [range]) number of reports per 1000 calendar days for sores occurring during the critical care episode was 4.0 (3.0–13.6 [2.2–20.4]) for teaching hospitals and 2.5 (0.2–6.3 [0–7.1]) for non-teaching hospital trusts ($p = 0.1$). Incidents describing sores arising during critical care represented 47% of all incidents associated with some patient harm.

The median (IQR [range]) number of characters in the description of the sores was 186 (133–460 [24–2048]). The quality of the reports was so poor that it was not possible to identify the body site of 21 sores and the grade of 218 sores. Sores more commonly developed on the head and neck during the critical care episode (20% of sores) when compared with the number present on admission (5% of sores) ($p < 0.001$). With respect to the grade of sore developing in critical care, 39 were classed as grade one, 321 as grade two and 118 as more than grade two. For sores present on admission, 35 were grade one, 109 grade two and 62 were more than grade two. Sores were described as being associated with medical devices in 180 incidents; the most commonly described devices were tracheal tubes and tube ties (46 incidents).

Treatment factors were described as contributing to the development of sores in only 113 incidents (17%) of the 659 incidents describing sores that developed during critical care, with more than one factor being present in 21 of these incidents. The most commonly described treatment factors were the use of inotropes or vasopressors (69 incidents), patient instability restricting the ability to position the patient (32 incidents) and use of the prone position (17 incidents). Lack of staff was not described as a treatment factor for the development of pressure sores in any incident. Patient risk factors were described in only 179 incidents, more than one factor being present in 47 incidents, and the most common factors being multiple organ dysfunction (57 incidents) and cachexia (24 incidents).

With respect to other incidents that have been subject to previous NPSA guidance [6, 7], misplaced nasogastric tubes associated with potential harm were described in six incidents, two associated with pulmonary haemorrhage and four with aspiration of feed (in one case, there was no assessment of position, in two, the radiographs were misinterpreted and in one, there may have been a misinterpretation of a pH measurement). None of the incidents indicated tube migration into the lung after confirmed correct placement. With respect to arterial flush solutions, there were five incidents where the wrong arterial flush solution had been used; in three of these, there was the potential for serious harm as the confusion caused inaccuracies in the measurement of blood glucose.

Although airway incidents were unusual, they were the cause of 12 episodes of more than temporary harm.

Similar patterns existed in a previous review into airway incidents in critical care [5]; complete removal of airway devices resulted in significant hypoxia less commonly (8 of 53 episodes) than partial removal (9 of 29 episodes). There were, however, some clear improvements in this current review, with 10 incidents where the use of capnography was described, even if only to illustrate problems with its use. There were also examples of descriptions of the use of described airway algorithms for displaced tubes [11] that clearly prevented patient harm.

Discussion

This study shows that it is possible to collect patient safety incidents from across critical care units and link the reports to clinical activity to establish the rates of these incidents per calendar day or any other more suitable denominator, a finding that is similar to observations made in neonatal intensive care [12]. We have also demonstrated that it is possible to compare rates between different units and that there are wide ranges in the rates with which different types of incident are reported in different units. Where these differences exist, it is possible to establish if they are associated with differences in specific aspects of clinical practice. We have also shown that incidents associated with significant harm are rarely reported so that they have to be collected over a number of trusts for them to be understood or for any estimate of their incidence to be made. The processes that we have used make it possible to establish rates of incident reporting over years. This is important as monitoring incident reporting rates should allow us to determine if interventions used to reduce incidents are working, or if they are contributing to unanticipated damaging consequences. Long-term monitoring of rare incidents across multiple units would be particularly important for airway incidents. Airway incidents are unusual, but may have catastrophic consequences [5, 13]; UK professional bodies have recommended several interventions, including the introduction of capnography in critical care [14–16], to improve airway safety. The reporting system we have described should allow the effect of these interventions to be established without significant additional cost to the health service.

There continue to be important limitations in the reporting processes. The first would be that we cannot establish the reliability with which incidents are reported; this is fundamental to any voluntary incident reporting process [17] and means that, where available, other mechanisms should also be used to collect rates of occurrence of patient safety incidents. This is particularly important for information about infections and information about patient flows into and out of critical care.

For six out of the 12 trusts, the incidents were not classified locally; this means that the classifier could not obtain additional information about the incidents. Local classification would eventually be essential if many units were to use the system, as it would not be practical to classify many thousands of incidents centrally. The lack of local classification resulted from multi-factorial problems with obtaining details of patient safety incidents from risk management departments within a reasonable time, when they had no experience with dealing with such requests. Finally, the classification process relied on the quality of the text within the incident reports; these frequently left out important information. A reporting process that did not require staff submitting incidents to use complex classification processes, but supported staff by prompting them to provide required information would result in more useful information available to improve patient care [18].

With respect to specific incident groups, pressure sores were the most common cause of reported patient harm; this may in part be because of UK guidance [19] that pressure sores of grade two or more should be reported as patient safety incidents. The reported rates are difficult to compare with those previously reported from intensive care [20, 21] due to differences in methods of reporting and patient groups. The significance of these sores is unclear; they may be responsible for considerable costs [22] and patient distress [23, 24] as well as being potential foci of infection [25]. It is clear from previous reviews that pressure sores are often regarded as a nursing problem and not as a medical problem. The very wide range of rates of pressure sores described between different trusts and the lack of focus placed on them by all clinical staff suggest that the incidence of pressure sores across critical care could be significantly reduced. Guidance exists on the prevention and treatment of pressure sores [9, 19, 26], and the implementation of relevant parts of this guidance, as

pressure sore 'bundles', has reduced the incidence of pressure sores [27, 28].

With respect to guidance issued to prevent the measurement of blood glucose from arterial lines flushed with glucose solutions [7], we have shown that glucose solutions continue to be used accidently in arterial lines. This may be because the guidance was not specific in highlighting that units must have systems to ensure correct identification and labelling of flush solutions.

In summary, we have shown that it is possible to establish rates of incident reports across critical care units and to link these with clinical activity. We have highlighted the importance of pressure sores as a potential cause of preventable patient harm and suggested that appropriately robust mechanisms are not in place to protect patients from glucose containing arterial flush solutions.

Acknowledgements

Colleagues from many trusts have helped substantially with this work, particularly those who helped with the classification process. The work would not have been possible without colleagues being ready to share incidents reported in their trusts. We are also grateful to Andrea Berry, lead nurse Greater Manchester Critical Care Network and Dr Richard Ramsaran who helped to collect information. We are also grateful for advice from Dr Paul Dark and colleagues on the ICS standards committee.

Competing interests

The authors have previously published reviews of patient safety incidents. No external funding for this work and no competing interests declared.

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