



## Patient safety incidents associated with equipment in critical care: a review of reports to the UK National Patient Safety Agency

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### Summary

We reviewed all patient safety incidents reported to the UK National Patient Safety Agency between August 2006 and February 2007 from intensive care or high dependency units. Incidents involving equipment were then categorised. A total of 12 084 incidents were submitted from 151 organisations (median (range) 40 (1–634) per organisation). Of these, 1021 incidents were associated with use of equipment, most commonly involving syringe pumps/infusion devices (185 incidents), ventilators (164 incidents), haemofilters (107 incidents) and monitoring equipment (70 incidents). Twenty-nine incidents were associated with more than temporary harm to patients. Failure or faulty equipment was described in 537 incidents (26% with some harm) and incorrect setting or use was described in 358 incidents; these were more likely to be associated with harm (39%;  $p = 0.001$ ). We suggest changes to improve the reporting of incidents and to improve equipment safety.

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The care of critically ill patients is dependent on the use of complex medical equipment. Unfortunately this equipment has the potential to develop faults, to be used incorrectly or to fail. Previous reviews of critical incidents from intensive care have identified problems with equipment as being an important cause of actual or potential harm to patients [1, 2]. We have reviewed patient safety incidents submitted to the UK National Patient Safety Agency (NPSA) from intensive care units (ICUs) and high dependency units (HDUs) to identify and classify incidents associated with use of equipment. We describe the distribution of these equipment related incidents and suggest ways to improve the reporting of incidents and to improve the safety of medical equipment used in critical care.

### Methods

Patient safety incidents are defined as 'any unintended or unexpected incident which could have harmed or did lead to harm for one or more patients being cared for by the NHS' [3]. Such incidents are submitted by staff using local reporting systems; each NHS organisation or 'Trust' in England or Wales is then expected to submit their

reports to the NPSA using an electronic submission process. In this process the free text description of the incident is provided together with a classification of the incident, which includes details of the location from which the incident was reported. One of the options for location is 'Intensive Care, High Dependency Area'. Details of the submission system have previously been described [4]. Reports are submitted from Trusts in batches with between one week's and several months' data provided at any one time, and the submitted reports are then held in a searchable database. Access to the database was granted as part of a collaboration between the UK Intensive Care Society (ICS) and the NPSA. We selected all incidents from 'Intensive Care or High Dependency' submitted from acute general NHS hospitals in England and Wales between 1 August 2006 and 28 February 2007.

The incidents were incorporated into an ACCESS database (Microsoft Inc, Seattle, WA, USA) for review and classification. The first stage was to identify incidents associated with use of equipment. We defined equipment as a mechanical or electrical device used in patient care on a critical care unit or for the transfer of critically ill patients where the transport equipment was the responsibility of the critical care unit. We also included disposables

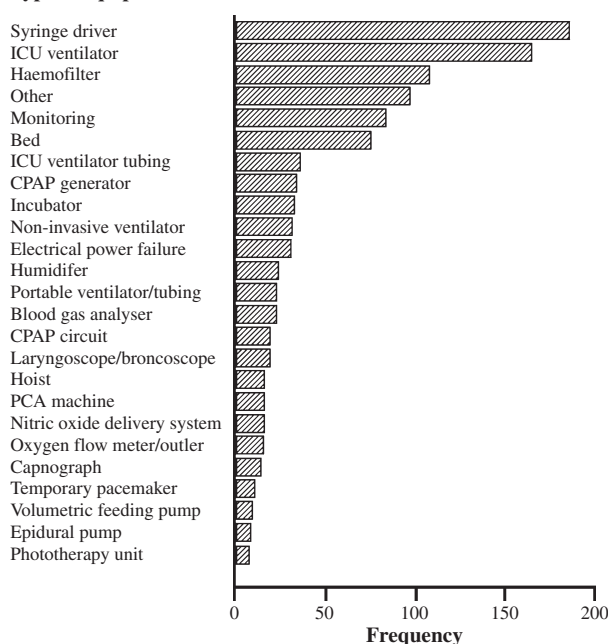
attached to the equipment, but not normally inserted into the patient (we also excluded syringes and lines as problems with these have previously been analysed separately [5]). We therefore included ventilators, ventilator tubing and humidifiers but excluded tracheal tubes and other indwelling devices, operating theatre equipment, fixed radiology equipment and ambulances.

Incidents were identified and classified (by one author (AT)) by reviewing the free text description submitted at the time of the incident as well as any supplementary manager's reports or equipment reports added afterwards. Incidents were classified by the equipment involved, the problem with the equipment, the seriousness of the incident and the level of any harm to patients. The equipment problem or problems were defined as: faulty equipment; failure of equipment; incorrect setting or use; lack of training in using the equipment; or incorrect or lack of cleaning. The seriousness of the incidents was defined as: minor; moderate; major; or life threatening. The level of harm was defined as: no identifiable harm; temporary harm; temporary harm with increased length of stay; permanent harm; intervention needed to sustain life; or possible contribution to death. The latter four levels of harm were uncommon so they were combined as 'more than temporary harm' for the purpose of subsequent analysis. Once the incidents had been classified they were exported into an SPSS spreadsheet (SPSS v. 13.0, SPSS inc, Chicago, IL, USA) for subsequent analysis. The incidents were also searched to find key words that allowed exploration of other issues that did not form part of the classification system. We also reviewed the free text descriptions of particular groups of classified incidents, for example reports of incidents that had been categorised as causing more than temporary harm. Where comparisons were made, the statistical significance was tested with chi-squared tests with significance reported as *p* values.

## Results

One hundred and seventy-two out of a total of 185 acute hospital Trusts in England and Wales (93%) submitted patient safety incidents to the NPSA during the study period. Of these, 151 Trusts submitted reports from ICU/HDU and we identified a total of 12 084 incidents from these areas, a median (range) of 40 (1–634) incidents per trust. From these 12 084 incidents, we identified 1021 from ICU/HDU that involved equipment. Of these, 962 were classified by the original free text description of the incident on its own and 59 were classified by the original report with a supplementary manager's report or equipment report; in 438 incidents the supplementary reports had been lost in the computer matching of the NPSA submission process and showed

### Type of equipment



**Figure 1** Number of incidents reported to the NPSA involving different types of equipment used in critical care units or during patient transfer where the equipment is the responsibility of the critical care unit.

only as the phrase 'free text multi-line'. The 1021 incidents involved a total of 65 separate types of equipment; the distribution of the frequency of incidents involving different types of equipment is shown in Fig. 1. The most common types of equipment involved were syringe pumps and intravenous infusion pumps (185 incidents), ICU ventilators (164 incidents), haemofilters (107 incidents) and monitoring equipment (70 incidents).

In the 996 incidents that could be classified by level of harm, 683 (69%) caused no obvious patient harm, 284 (29%) caused temporary harm and 29 (3%) caused more than temporary harm. Of the 1002 incidents that could be classified by the grade of incident; 434 (43%) were classified as minor, 346 (35%) as moderate and 222 (22%) as major or life threatening. The type of equipment problem could be categorised in 989 incidents, multiple problems being present in 207 of these. The relationships between the level of harm and the type of equipment problem is shown in Table 1, which demonstrates that harm was caused by the incorrect use of equipment more often than by faulty or failing equipment. The reports also suggest that some of this harm could be reduced by improved training of staff.

The relationship between types of equipment problems, level of harm and grade of incident for the four most common equipment groups are shown in Table 2. For this analysis different types of monitoring equipment including

**Table 1** Levels of harm to patients caused by different types of equipment problem reported to the NPSA. Values are number (proportion). Incorrect use was associated with more serious harm than that caused by equipment fault or failure ( $p = 0.001$ ).

	Failure of equipment	Faulty equipment	Not available	Incorrect use or setting	Inadequate training	Lack of/incorrect cleaning
More than temporary harm	5 (3%)	10 (3%)	0	18 (5%)	9 (6%)	1 (5%)
Temporary harm	38 (24%)	85 (22%)	47 (29%)	122 (34%)	67 (45%)	1 (5%)
No obvious harm	107 (68%)	275 (73%)	110 (69%)	215 (60%)	72 (48%)	16 (88%)
Unclear	7 (5%)	7 (2%)	3 (2%)	3 (1%)	2 (1%)	0
Total	157 (100%)	377 (100%)	160 (100%)	358 (100%)	150 (100%)	18 (100%)

**Table 2** Equipment problem, grade of incident and levels of harm for the four most commonly described types of equipment reported to the NPSA. Values are number (proportion). Ventilators and syringe pumps/infusion devices were more likely than monitors and haemofilters to cause temporary harm and major and life threatening incidents ( $p < 0.001$ ) and were also more likely to fail or develop faults ( $p = 0.001$ ).

	Level of harm			Equipment problem				Total no. incidents
	Temporary	More than temporary	Major/life threatening incident	Incorrect use	Not available	Faulty equipment	Failure of equipment	
Haemofilter	49 (46%)	1 (1%)	11 (10%)	45 (42%)	15 (14%)	37 (35%)	12 (11%)	107 (100%)
Ventilator/tubing	44 (27%)	6 (4%)	49 (30%)	51 (32%)	11 (7%)	67 (41%)	48 (29%)	164 (100%)
Monitoring	12 (17%)	2 (3%)	7 (10%)	19 (27%)	19 (27%)	20 (29%)	19 (27%)	70 (100%)
Syringe driver	42 (23%)	6 (3%)	52 (28%)	60 (32%)	13 (7%)	90 (48%)	24 (14%)	185 (100%)

CO<sub>2</sub> monitors and portable monitors were grouped together. More than temporary harm and major and life threatening incidents were more common with ventilators and syringe pumps/infusion devices than with monitors and haemofilters. In 10 incidents where haemofilters were incorrectly used this was due to problems with anticoagulation, a particular problem in other reports of serious patient harm during renal replacement therapy [6], and 12 incidents were associated with the incorrect use of bicarbonate in filtration fluid, a problem that could be resolved by improvements in the design of fluid bags [7]. Where monitoring was not available this was often due to a lack of CO<sub>2</sub> monitors (40 incidents) or the nonavailability of correctly sized peripheral equipment for children (20 incidents). Ventilators and syringe pumps were more likely to fail or develop faults than were haemofilters or monitoring equipment.

Power failure was described in 30 incidents: 20 were associated with unanticipated power cuts, five with generator tests and five with power failures with in the unit. Lack of communication about the timing of generator tests was a common problem as was malfunction of equipment following these tests.

Intra-hospital transfer is recognised as an important risk to patients [8]. We identified 55 incidents associated with transfer equipment (18 associated with monitoring, 17 with ventilation, 10 with transport incubators and 10 with other portable equipment). The commonest problem with portable monitors was battery

failure (six incidents). In two of these cases battery failure occurred despite the batteries' having been fully charged before transfer. In the remainder either no cause was identified or batteries were not charged adequately before use. Insufficient cylinder oxygen supplies were responsible for seven incidents involving portable ventilators and transport incubators; these occurred either due to failure to take adequately filled oxygen cylinders (three incidents) on the transfer, or due to leakage of oxygen from the cylinder during transfer (four incidents). Other transfer-related incidents involved lack of availability of CO<sub>2</sub> monitoring (four incidents), accidental disconnections of breathing systems and infusion lines, and damage to equipment during transfer. Although 18 of these incidents were classified as 'major' or 'life threatening', none resulted in more than temporary harm to the patient.

Of the 29 incidents that were associated with more than temporary patient harm, 10 involved ventilators or ventilator tubing, all of which stopped working during use, on one occasion due to the incorrect use of equipment. Eight of these 29 incidents involved continuous positive airway pressure generators or noninvasive ventilators or their circuits; the equipment was inappropriately used in four cases. Problems with syringe pumps were found in six of the 29 incidents; these were similar to other infusion device incidents except that the drugs involved were potentially more dangerous (noradrenaline in four incidents).

## Discussion

Staff decide to report incidents or to not report them for many complex reasons [9] and so it is inevitable that the incidents reported will have represented only a sample of the total number of incidents occurring across all reporting trusts; it was also clear that most of the reports were probably submitted by nursing staff and this will have influenced the type of report submitted. The very wide range in the total number of incidents reported between trusts also suggests wide differences in the reporting structures used in different trusts that may either encourage or discourage staff from reporting incidents [10], as well as differences in the ways that incidents are then reported from the unit to the trust and then on to the NPSA. Our classification of reported incidents was largely based on the original descriptions of the incident without subsequent reports of investigations. This will have produced errors as staff may have assumed that equipment was faulty or had failed when, in actual fact, it was being incorrectly used and this would then only become clear in a subsequent review of the incident. The analysis of the reported incidents was also less extensive than it could have been because we did not have details of the types of equipment involved; for example when syringe pumps or ventilators failed during use, it was not possible to determine if this was a problem with a particular make or model. Information about the units submitting incidents would also have allowed us to calculate failure rates for particular types of equipment and also to determine if some training interventions were more likely to improve equipment safety than others. Many of these issues could have been addressed by the adoption of a national reporting system for patient safety incidents submitted from critical care units as previously described [5] and by being able to link the original incident report with any subsequent investigation and equipment report, including any subsequent report to the Medicines and Healthcare Products Regulatory Agency.

There are a number of previous reports of critical incidents associated with equipment use in critical care and anaesthesia. Many of these reports are particularly focused on anaesthetic equipment and so are difficult to compare with our study. It is clear, however, that the pattern of critical incidents associated with the use of equipment has changed over time as the design of equipment has improved; for example both Australian [11] and French [12] studies from the 1990s show very different patterns of incidents to those found in our study. More recent studies focusing on intensive care are also difficult to interpret as they often include incidents involving indwelling medical devices such as tracheal tubes and venous catheters. The Sentinel Events Evaluation study [1], however, also

highlighted the importance of mechanical problems with ventilators and syringe pumps and highlighted the importance of haemofilters and of electrical power failure as causes of critical incidents.

Although the incidents we reviewed are only a convenience sample it is still noteworthy that there were only just over a thousand incidents reported from 154 acute hospital Trusts over six months, and that only 29 were associated with more than temporary harm. There are several factors that will have protected patients from harm. These include improvements in the design of equipment both in its reliability and its interface with staff and physiological monitoring of patients [13], and monitoring of equipment to identify unexpected problems. The structures in place on units are also clearly important in reducing patient harm. Some of these, together with suggestions for maintaining safe use of equipment, are shown in Table 3.

Electrical failure across critical care units was a problem in several incidents in our study and has also previously been noted as a problem [1]. Failure during generator tests would presumably be preventable with better protection of equipment from brief surges in power. Improved battery back-up and the use of uninterrupted power supplies could help to reduce the effects of unplanned power failures; units should also have clear plans in place for how to deal with these power failures, particularly when they occur at night.

The methods used in previous reviews of equipment problems have often focused on technical problems with equipment; the results of our study however suggest that incorrect use of equipment is at least as common as is equipment failure. There are many reasons why equipment may not be used correctly. Previous studies have suggested that nursing staff in ICU have an ambivalent attitude to medical equipment [14, 15]; there are also many types of

**Table 3** Methods used in critical care units to maintain a low level of harm as a result of problems with equipment.

1. Systems are in place for the training of staff and maintaining a workforce that is competent to use the equipment in the critical care area.
2. Equipment is correctly serviced and maintained.
3. Risks of using outdated equipment are clearly understood by trust managers even when the existing equipment is still functional but lacks important safety features that are standard in current models.
4. Back-up systems to deal with unexpected power failures and failures of mechanical ventilators and other equipment, including transfer equipment, are in place and understood by staff.
5. Equipment is checked before use, at shift handovers and before transfer of patients, and medical staff understand how to check the transfer equipment.
6. There are enough capnographs to monitor all patients requiring ventilation, particularly during transfers, and there is a selection of correctly sized equipment for children and neonates if appropriate.
7. There are plans to deal with unusual peaks in demand for renal replacement therapy.

equipment used in critical care and much of it is complex. Indeed, complex equipment like haemofilters and nitric oxide delivery systems were disproportionately represented in the incidents we have reviewed. Problems with the equipment/staff interface are also increasingly recognised as important [16] and this interface may often be of poor quality. It is unfortunate that advances in equipment design that could improve patient care are frequently denied to patients because the existing equipment is still functional, and this may be a particular issue for the replacement of syringe pumps [17]. It was clear from the reports that many incidents associated with incorrect use of equipment could be resolved with better training of staff; this is a particular issue for new or complex equipment. The number of incidents in this category suggests that the NHS Litigation Authority's requirement that 'all staff are trained in the use of diagnostic and therapeutic equipment' [18] is appropriate and should improve the previously low importance placed on this activity [19].

In summary, we have described incidents reported to the NPSA involving use of equipment in critical care. These incidents appear to be uncommon (probably as a result good practice) but are often the result of incorrect use of equipment, a problem that could be improved by improvements in the training of staff.

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