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

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Summary

We used key words and letter sequences to identify airway-associated patient safety incidents submitted to the UK National Patient Safety Agency from critical care units in England and Wales. We identified 1085 such airway incidents submitted in the two years from October 2005 to September 2007. Three hundred and twelve incidents (28.8%) involved neonates or babies. Of the total 1085 incidents, 200 (18.4%) were associated with tracheal intubation, 53 (4.9%) with tracheostomy and 893 (82.3%) were post-procedure problems. One hundred and ten incidents (10.1%) were associated with more than temporary harm. Eighty-eight intubation incidents were associated with equipment problems. Partial displacement of tubes resulted in more than temporary harm to the patient more frequently than complete tube displacement (15.7% vs 3.8%). Capnography was not described in any cases of displacement or blockage of tracheal or tracheostomy tubes. Recommendations concerning minimum standards for capnography, availability and checking of equipment and tracheostomy placement are made.

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Critically ill patients are often dependent on airway devices to provide respiratory support and to protect their airways. Airway devices, particularly tracheal and tracheostomy tubes, are associated with significant risks, both during initial placement, at tracheal intubation or tracheostomy, and during subsequent use. Patient safety incidents are reported to the UK National Patient Safety Agency (NPSA) from NHS (National Health Service) organisations, or 'Trusts' in England and Wales [1]. A 'patient safety incident' is 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' [2]. This study aimed to review the airway device incidents in critical care areas reported to the NPSA. The intention was to identify themes associated with these incidents and to provide evidence to support recommendations to improve the reporting of airway incidents and to suggest changes that could be made to improve the safe management of airway devices in critical care.

Methods

Patient safety incident reports are submitted by NHS staff using local reporting systems; each NHS organisation, or 'Trust' in England and Wales, is then expected to submit these 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, which includes details of the location from where the incident was reported. One of the options for location is 'Intensive Care, High Dependency Area'. Details of the submission process have previously been described [1]. Reports are submitted from Trusts in batches with between one week's and several months' data provided at any one time. The submitted reports are then held in a searchable database. Access to the database was granted by the NPSA and the work was completed under the direction of the UK Intensive Care Society (ICS).

We defined airway incidents as patient safety incidents which were associated with either of the following:

1. Incidents relating to tracheal intubation or tracheostomy which occurred on the critical care unit or at the time of admission to the unit, or where the procedure was performed by staff from the unit. We also included incidents where the performance of a tracheostomy in theatre, or a delay in the procedure, caused a problem with the patient's care on ICU.
2. Incidents associated with the airway after device placement, where these incidents occurred during the critical care stay or during intra hospital transfer during that stay. This second group of incidents included blockages and unplanned removal of devices. We included incidents associated with the connection of an airway device to the breathing circuit, but excluded any other sections of the breathing circuit. We also excluded incidents associated with airway equipment or drugs that had no direct effects on patients (for example non-availability of tracheal dilators when they were not actually required).

We initially reviewed the free text description of 12,240 patient safety incidents submitted in the 6 months from August 2006 to February 2007 and identified 207 airway incidents reported in this sample. This review was conducted primarily to identify and classify incidents associated with medication [3] and with equipment use [4]. It was clear from this review that, unlike medication and equipment incidents, the text descriptions of airway incidents contained repetitive words. These could be grouped by repeated letter sequences and all of the identified airway incidents contained at least one of the sequences shown in Table 1.

We then selected all of the incidents that contained at least one of these letter sequences from the sample of all patient safety incidents submitted to the NPSA that occurred during the two years from 1st October 2005 to 30th September 2007, and when the incident was submitted from the location 'Intensive Care or High Dependency.' The search was conducted 4 months after September 2007 to allow time for submission of reports from Trusts. The selected incidents were then extracted with their data entry fields, these fields included the free text description of the incident and managers' reports together with other classifications.

The complete extract was then imported to an Access database (Office Professional 2003 Microsoft Inc, Seattle USA) for subsequent classification and the incidents were then individually reviewed. Incidents that were either repeated entries (identified by multiple similarities in the reports), or unconnected with the critical care stay (often an incident that necessitated ICU referral) or were unconnected with the airway were then noted, but not classified. Incidents associated with airway equipment that did not directly involve patients were also noted but not classified.

Table 1 Words and letter sequences (occurring as part of words) used to identify airway incidents and the taxonomy used to classify identified airway incidents.

1. Words and letter sequences (occurring in words) used to identify airway incidents:

ETT, ET tube, tubat, trach, traco, tiach, speaking v, nasal t, laryng, fenestrated, airway, cuff (excluding 'BP' and 'pressure cuff'), NTT, inner tube. For initials, all letter spaces and full stop combinations were included.

2. Taxonomy for classification of airway incidents (incidents can fall in multiple classifications):

a. Airway incidents associated with tracheal intubation:
- Problem:
  - Failure to intubate, Delay in intubation, Neurological injury, Dental injury, Endobroncheal intubation, Oesophageal intubation, Aspiration of gastric contents, Other.
- Contributing factors:
  - Patient problems, Operator skill, experience or availability, Lack of trained assistants, Lack of capnography, Lack of other functioning equipment, Other.

b. Airway incidents associated with tracheostomy
- Type of procedure used:
  - Percutaneous device (single or serial dilator), Open tracheostomy, Other device.
- Problem:
  - Equipment failure or non availability, Loss of airway, Unsuccessful, Bleeding, Damage to larynx, Damage to trachea, Damage to oesophagus, Damage to large vessel, Damage to lung or pleura, Hypoxia, Surgical emphysema, Delay, Other problem.
- Contributing factors:
  - Patient problems, Operator skill, experience or availability, Lack of trained assistants, Lack of capnography, Lack of other functioning equipment, Other

c. Airway incidents occurring after device placement:
- Airway device:
  - Tracheal tube – oral, nasal or undefined, Tracheostomy tube – Inner sleeve yes/no, Cuffed yes/no or Tracheostomy tube undefined. Other airway device.
- Problem:
  - Displaced from trachea and patient, Displaced from trachea in to soft tissues, Displaced from trachea into pharynx, Displaced from trachea into oesophagus, Displaced from trachea into bronchus, Displaced within trachea, Blocked, air leak/cuff failure.

d. For all incidents:
- Complications:
  - Hypoxia, transient or not significant (less than 5 min or saturation remaining above 85%), Hypoxia, significant (more than 5 min or saturation below 85% unless normally hypoxic), Bradycardia, Cardiac arrest or cardiopulmonary resuscitation, Haemorrhage requiring transfusion, Haemorrhage causing hypoxia, Pneumothorax, Dental injury, Oesophageal injury, Tracheal injury, Laryngeal injury, Large vessel injury, Neurological damage, Other complication.
- Grade of incident:
  - Lower risk, Moderate risk, Major risk, Life threatening
- Level of patient harm
  - None or minor physiological change, Temporary harm, Temporary harm – increased length of critical care or hospital stay, Permanent harm, Intervention needed to sustain life, Reaction may have caused or contributed to death
- Patient age group:
  - Neonate/baby under 18 months old, Adult/older child/age could not be determined.

The remaining airway incidents were then classified using a taxonomy for airway incidents which had been developed from the review of previous incidents and

was refined during the classification process as shown in Table 1. The classification was carried out by the two authors separately reviewing the free text descriptions of incidents and with discussion and resolution of difficult incident reports. Other themes, particularly the circumstances around displacement of tubes were then explored in more detail by re-reviewing the text of incidents allocated to particular groupings.

All of the identified airway incidents were classified by the age of the patient into one of two groups; 'neonate or baby less than 18 months' or 'adult, older child or age not determined.' For clarity these are referred to in the text as 'baby' or 'adult/older child.' This was initially done at the extraction of data from the NPSA by using referring specialty of 'neonatal medicine' and additional key words to select neonates using a search strategy that was designed to be specific rather than sensitive. Cases were then added to the 'baby' group on the review of the free text description of incidents. This was done if, for example, the text described the patient as 'baby' or included reference to tracheal tubes with an internal diameter suitable in the clinical circumstance for a baby, or reference was made to equipment such as incubators used in neonatal practice.

The classified data were then exported into an SPSS table (SPSS Inc., Chicago IL, version 13.0) for subsequent analysis of frequencies of incidents and cross tabulation of variables. The significance of these cross tabulations were then explored with Chi-squared tests with p values of < 0.05 being described as significant.

Results

During the two-year study period 150 Trusts in England and Wales submitted 44 675 incidents with a described location of 'intensive care/high dependency'. Of these, 2327 incidents contained one or more of the letter sequences shown in table one. These all contained a free text description of the incident and 276 contained a manager's report with additional information. Amongst these incidents, 1242 (53%) were either repeat entries (15), were non-critical care incidents (37) or were not airway incidents (1176) or a combination of these (15). The non airway incidents mostly used airway terms to describe a patient in another incident class ('a patient with a tracheostomy was given the wrong drug') or to describe levels of dependency during staff shortages ('one nurse looked after three intubated patients').

The remaining 1085 incidents involved the patient's airway or airway devices as previously defined. Of these 1085 incidents, 312 (29%) occurred in neonates or babies. 218 of these were identified by the original NPSA classifications and 94 additional cases were identified on review of the text description of the incident. The remaining 773 (71%) incidents occurred in adults, older children or the patient's age could not be determined. Of the 1085 airway incidents, 423 (39%) involved no identifiable harm, 547 (50%) temporary harm, 15 (1%) temporary harm with increased length of stay, three (< 1%) permanent harm, 68 required intervention to sustain life (6%) and 25 (2%) may have contributed to the patient's death, four (< 1%) incidents could not be classified. With respect to the grade of incident, 168 (15%) were classed as life threatening, 111 (10%) as major, 647 as moderate (59%) and 159 (15%) as lower risk or unclassified. Incidents were distributed between 15 of the NPSA main incident groups, the most common being treatment or procedure (542 incidents) and medical device or equipment (210 incidents).

The broad incident classifications of intubation, tracheostomy and post-placement incidents are summarised in Fig. 1. There were 53 incidents that were classed as

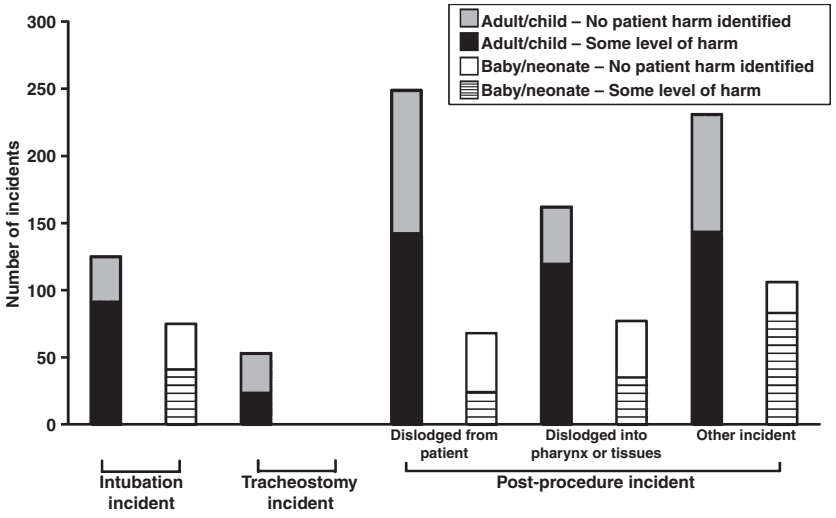

Figure 1 Frequency of distribution of incidents by main airway groups divided by the two age groups, Adult/older child or baby. Darker shading represents frequency of incidents associated with some patient harm, lighter shading were no harm was described in the report.

both intubation and post-intubation incidents, for example where an incorrectly secured tube became displaced or where there were problems in replacing tubes that had blocked or become displaced. Nine incidents were associated with problems with the tracheostomy procedure that subsequently caused a post-procedure incident. Tracheostomy would not normally be carried out in a critical care area on a small child and this is reflected in the incident profiles. With respect to the other incidents, there were no significant differences between neonates and adults in the level of harm. The distribution of intubation and post-procedure incidents however was different in adults/older children (intubation 12%, post-procedure 88%) and babies (intubation 20%, post-procedure 80%) ($p = 0.01$).

There were 200 incidents associated with tracheal intubation (18% of all 1085 airway incidents). A more detailed summary of their classifications is shown in Table 2. There were no significant differences between adults/older children and babies with respect to either the main groups of intubation incident reported or their contributing factors. Adults/older children had significantly higher levels of harm than babies; the types of harm suffered were also different with, for example, bradycardia being more common in babies. Forty-three (22%) of the 200 described incidents were associated with more than temporary harm and where these were associated with problems with equipment, assistance or operator availability or experience, they could have been potentially avoidable.

There were 53 incidents reported as associated with tracheostomy procedures (5% of the total 1085 reported incidents). Fourteen of these incidents were classed as major or life threatening, they involved either percutaneous tracheostomy (12 incidents) or mini-tracheostomy (two incidents), and eight of these serious incidents required interventions to maintain life or may have contributed to death. Problems often included loss of the airway during or immediately after the procedure, haemorrhage and/or severe surgical emphysema, which was associated with the placement of fenestrated tubes in two incidents. Two life threatening incidents were only reported as part of other incidents, once due to blood in the eye of a member of staff and once in association with severe staff shortages.

The commonest group of incidents were post-placement problems, occurring in 893 (82%) incidents. Those associated with the displacement or blockage of tracheostomy and tracheal tubes, leakage from around the tube and associated sores and infections are summarised with their level of harm in Table 3. Partial dislodgement of a tube into the pharynx or soft tissues was more than twice as likely to cause more than temporary harm than complete removal. The level of harm was greater in adults than children for both completely ($p = 0.005$) and partially removed tubes ($p = 0.001$). The high risk of partial displacement may have been caused by delay in recognising the problem. Tracheostomy tubes were more likely to become blocked than tracheal tubes, and this may represent problems with humidification in open circuits. Some incidents of blocked tubes may also have represented displacement into soft tissues with 10 incidents classified as both blocked and displaced tubes.

There were also 14 incidents associated with other airway devices, including six involving suction devices [5]

Table 2 Intubation incidents ($n = 200$) divided into two groups: Delay/failure to intubate ($n = 142$; 92 adult/children incidents, 50 babies less than 18 months old) or other problems ($n = 61$; 36 adult/children, 25 babies, 3 incidents also involving delay). Incidents classified by level of harm and contributing factor, divided into age categories. Percentages refer to the total number of incidents in the age category in each of the groups.

	Levels of harm*						Contributing factors†							
	No harm		Temporary harm		More than temporary harm		Patient problem		Operator factors		Assistance factors		Equipment factors	
Patient age group	Adult/child	Baby	Adult/child	Baby	Adult/child	Baby	Adult/child	Baby	Adult/child	Baby	Adult/child	Baby	Adult/child	Baby
Delay/failure to intubate	24 (26%)	29 (58%)	42 (46%)	18 (36%)	26 (28%)	3 (6%)	24 (26%)	6 (12%)	39 (42%)	24 (48%)	9 (10%)	7 (14%)	48 (62%)	28 (56%)
Other problems	10 (27%)	5 (20%)	15 (41%)	15 (60%)	11 (31%)	5 (20%)	7 (19%)	3 (12%)	11 (31%)	16 (64%)	3 (8%)	3 (12%)	10 (21%)	2 (8%)

*Adults having higher levels of harm, $p = 0.009$.
†May be more than one or none per incident.

Table 3 Post-airway device placement incidents after categorisation (n = 893). The incidents are further divided by age (642 adult/children incidents and 251 involving babies less than 18 months old), the level of harm, and the type of airway device.

	Dislodged from patient		Dislodged into pharynx/soft tissues		Blocked		Air leak		Skin pressure sores or infections	
	Babies	Adult/child	Babies	Adult/child	Babies	Adult/child	Babies	Adult/child	Babies	Adult/child
Number of incidents	68 (27%)	249 (39%)	77 (31%)	162 (25%)	28 (11%)	51 (8%)	6 (2%)	44 (7%)	31 (12%)	42 (7%)
Tracheostomy tube	2 (3%)	87 (35%)	2 (3%)	76 (47%)	1 (4%)	42 (82%)	0 (0%)	21 (41%)	3 (10%)	17 (40%)
Tracheal tube	66 (97%)	162 (65%)	75 (97%)	86 (53%)	26 (98%)	7 (14%)	6 (100%)	23 (52%)	28 (90%)	25 (60%)
Level of harm										
No harm	44 (65%)	104 (42%)	42 (55%)	46 (28%)	10 (35%)	7 (14%)	4 (67%)	16 (36%)	0 (0%)	2 (5%)
Temporary harm	20 (29%)	137 (56%)	25 (32%)	95 (59%)	15 (54%)	31 (61%)	2 (33%)	24 (55%)	31 (100%)	38 (90%)
More than temporary harm	4 (6%)	8 (3%)	10 (13%)	24 (15%)	3 (11%)	13 (25%)	0 (0%)	4 (9%)	0 (0%)	2 (5%)

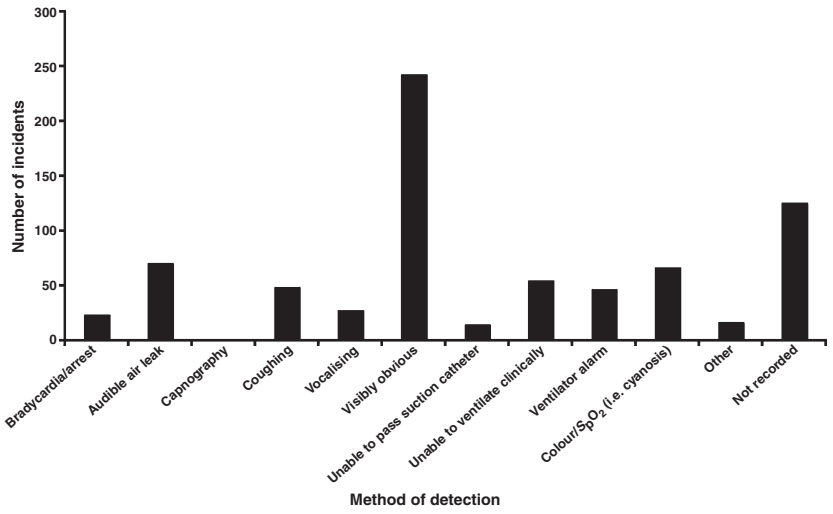

Figure 2 Methods described as being used to identify the displacement of tracheal and tracheostomy tubes.

and three mouth swabs [6] as previously described. Bite blocks, dental work and other swabs found in the airway were associated with four other incidents.

We went on to review the circumstances of the 615 tube displacements. With respect to the underlying associated causes, nursing and medical procedures were described in 61 incidents, with turning the patient described 95 times. Physiotherapy was described seven times and moving the patient for X-rays 15 times. Nurse distraction or break was described 80 times, staff shortages 22 times with the use of side rooms described 13 times. Patient agitation was described 91 times, in the context of reductions in sedation 55 times. Methods reported to diagnose extubation that was not visually obvious are shown in Fig. 2. Measurement of arterial oxygen saturation with recorded values were described in 83 out of the 681 incidents of dislodged and/or blocked airway devices, and in a further 151 incidents references were made to 'desaturation' without a description of absolute values of oxygen saturation. Capnography was not described as a method to diagnose any tube displacement or blockage, and was only described three times in the whole dataset of 1085 airway incidents. With respect to delayed consequences of extubation, only 305 incidents had sequelae described. Immediate reintubation was described in 100 reports, delayed intubation in 29 reports and reintubation was identified as not being required in 176 reports.

Discussion

The ability to search a national database has allowed us to review a large sample of airway incidents. These incidents will only have represented a convenience sample of all of the incidents that occurred in England and Wales in the two-year study period. Staff will have decided whether or not to report incidents for many reasons, including the reporting system provided [7], fear of the consequences

of reporting incidents [8] and perceptions as to how incidents would be used to improve patient care. Previous studies suggest incidents are more likely to be reported by nursing staff than medical staff [7] and our results are consistent with this. Our reviews of patient safety incidents also suggest that airway incidents are less common than medication incidents [3] or equipment incidents [4], but that they are associated with more patient harm, observations that are consistent with other studies [9, 10]. The identified relative frequencies of different types of airway incident were also consistent with other studies [11].

As well as having limitations with respect to the incomplete number of incidents reported, the classification of incidents was also not normally informed by subsequent local investigations. We also had no comparative information about different techniques used on different units to manage airway devices so we do not know how these will have affected the distribution of different incidents. We also had no opportunity to feedback incident classifications to individual units. These and other issues could be addressed by setting up a proposed new reporting system for patient safety incidents in critical care as previously described [3].

With respect to the main divisions of airway incidents, incidents occurring during tracheal intubation were less common than post-placement problems, but were still associated with significant patient harm. There were associated factors of lack of suitably trained staff or equipment in the development of more than half of all intubation incidents. Staffing issues often involved medical staff being needed in more than one place at the same time and these issues may be difficult to resolve. Other staffing issues could, however, be resolved with improved training or better use of other staff. The lack of functioning equipment, which occurred in half of the intubation incidents, would have been potentially avoidable if each ICU had a fully stocked difficult intubation trolley which was regularly checked by staff who have an good understanding of the equipment, and by the provision of regularly checked and functioning laryngoscopes, and by ensuring that nursing staff were familiar with intubation equipment that was likely to be needed. This is consistent with ICS guidance on the management of tracheostomy tubes [12]. The finding that intubation incidents were more likely to cause harm in adults was surprising and may reflect either an under reporting of more minor incidents in adults or difficulties in ventilating adults with severe lung injury after failed intubation.

With respect to tracheostomy procedures, the incidents reported probably represent only a small sample of the total incidents that occurred. A single centre study reviewed more incidents over a four-year period than we identified as having been reported nationally in two years [13]. This may be because medical staff should have discussed serious incidents locally and may then have seen no advantage to reporting an incident when they did not perceive there to be any national review of these incidents. The small number of incidents that were reported suggested that ICS guidance on tracheostomy placement [12] should be followed, particularly in the avoidance of fenestrated tubes at initial placement and in the meticulous conformation of correct placement at each stage of the procedure. The incidents also suggest that rapidly developing, life threatening airway problems can develop unexpectedly at, or immediately after, percutaneous tracheostomy. We would therefore recommend that someone competent to deal with these problems should be available on the ICU during and immediately after all 'routine' percutaneous tracheostomies.

With respect to post-procedure problems, the relative frequencies of these incidents were consistent with other studies [11] as was the finding that they are sometimes associated with serious harm [14, 15]. We are unable to comment on the delayed consequences of tube displacement, particularly the potential to develop pneumonia, however, these issues have previously been reviewed [16, 17]. With respect to tube displacement, previous studies suggest that a continuous improvement approach can reduce the frequency of these incidents by encouraging early extubation and physical restraint [18, 19], however early extubation will only be suitable in some patients and unnecessary physical restraint has both ethical and practical problems [20]. The recognition that over sedation is potentially harmful [21, 22] and the increased use of side rooms [23] make it necessary to develop robust methods to reduce the incidence of accidental tube displacement. These methods may include design improvements to tube fixation, an issue that has received some limited review [24], and the increased use of variable flange tubes in patients with deep tracheas, as previously recommended [12, 25]. Harm can also be reduced by correct early recognition and treatment of tube displacement. Our results clearly show that displacement into soft tissues or pharynx is several times more dangerous than complete removal of the tube and this may be because the problem is often difficult to diagnose prior to severe hypoxia without the use of capnography. Although many methods were used by staff to diagnose tube displacement, capnography was not described in any of the incidents of tube displacement or obstruction and was only described three times in the whole series of 1085 airway incidents. This contrasts with the use of pulse oximetry which was clearly implied in many incident reports. It would seem intuitive that at least the same standards for capnography should be used in the ICU as

are routinely used during anaesthesia [26]. Managing a hypoxic, critically ill patient with an unclear diagnosis of partial tube displacement will be extremely challenging, particularly to inexperienced staff working at night. As well as the routine use of capnography we would also recommend the use of simple clear airway drills [12] that are practiced and reviewed by staff; with the provision of bag valve mask systems by each bed area, as ways of reducing permanent harm associated with tube displacement.

Methods to reduce harm by rapid diagnosis with capnography and correct treatment would also help in the management of blocked tubes. Blocked tubes have also previously been shown to be life threatening but less common than displaced tubes [15]. The use of inner sleeved tracheostomies is recommended to reduce blockage rates [12], however, our study does not allow us to determine if these tubes should have been used more often. Improvements in ventilator technology may also help in the diagnosis of blocked tubes [27]. Air leaks around tracheal tubes were often caused by accidental damage to the pilot tube, a situation which occasionally went on to harm patients. As suggested in one report, a 23G needle will cannulate a cut pilot tube to allow the cuff to be safely re-inflated so that a tube could be changed later under optimal conditions, this, and other techniques for dealing with this problem, have been well described [28].

Skin damage due to the securing of tubes and at stoma sites was more commonly reported in babies. This may reflect more complex methods used to secure tubes and it was note worthy that a number of incidents of damage to skin on the nose were only noted after nasal tubes were removed. Babies' skin is also more delicate and damage is likely to be more upsetting to relatives and staff and these factors might increase reporting rates. Skin problems in all age groups could be more extensively investigated with comparative studies of different methods for the fixation and care of stoma sites. The development of agreed standards for describing skin damage by site, degree and cause would help in such studies.

In summary our study has highlighted the potential for improvement in the reporting of patient safety incidents from critical care in England and Wales. We have also made a number of achievable recommendations to improve the safety of airway devices in critical care, summarised in Table 4.

Table 4 Recommendations to improve patient safety during airway management in critical care.

1. Capnography should be used in critical care at least to the minimum standards already required during anaesthesia.
2. Intubation equipment should be checked regularly by someone competent to do so, and each unit should have a difficult intubation trolley that staff is familiar with.
3. Simple drills to manage displaced and blocked tubes should be practiced and followed. Bag valve mask systems should be ready to use at each bed area.
4. Guidelines from the ICS concerning placement of tracheostomy tubes should be followed and someone capable of dealing with major airway problems should be available on the unit at the time of procedure and immediately afterwards.
5. Variable flange tubes should be used in patients with abnormally placed tracheas and the position of the tube tip should be checked.
6. Tubes with inner sleeves should be used where appropriate.
7. Investment should be made in design solutions to improve the fixation of tubes.
8. Cut pilot tubes can be cannulated with 23 Gauge needles to allow cuff re-inflation to stabilise the patient before elective tube change.
9. Standard descriptive terms for associated skin damage and ulceration should be developed to allow audit of these problems.

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