## Complications and failure of airway management

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## **Editor's key points**

- Most airway complications are unanticipated and can lead to harm and death, particularly in the intensive care unit and emergency department.
- Complications include pulmonary aspiration, oesophageal intubation, and failed airway management.
- Factors to reduce complications include preparedness, assessment, planning, communication, teamwork, skill with multiple techniques, and situation awareness.

Summary. Airway management complications causing temporary patient harm are common, but serious injury is rare. Because most airways are easy, most complications occur in easy airways: these complications can and do lead to harm and death. Because these events are rare, most of our learning comes from large litigation and critical incident databases that help identify patterns and areas where care can be improved: but both have limitations. The recent 4th National Audit Project of the Royal College of Anaesthetists and Difficult Airway Society provides important detailed information and our best estimates of the incidence of major airway complications. A significant proportion of airway complications occur in Intensive Care Units and Emergency Departments, and these more frequently cause patient harm/ death and are associated with suboptimal care. Hypoxia is the commonest cause of airway-related deaths. Obesity markedly increases risk of airway complications. Pulmonary aspiration remains the leading cause of airway-related anaesthetic deaths, most cases having identifiable risk factors. Unrecognized oesophageal intubation is not of only historical interest and is entirely avoidable. All airway management techniques fail and prediction scores are rather poor, so many failures are unanticipated. Avoidance of airway complications requires institutional and individual preparedness, careful assessment, good planning and judgement, good communication and teamwork, knowledge and use of a range of techniques and devices, and a willingness to stop performing techniques when they are failing. Analysis of major airway complications identifies areas where practice is suboptimal; research to improve understanding, prevention, and management of such complications remains an anaesthetic priority.

Keywords: airway; complications, legal

There is one skill above all else that an anaesthetist is expected to exhibit and that is to maintain the airway impeccably. M. Rosen and I. P. Latto 1984

The most compelling educational effort for the anaesthesia community should be to reduce the frequency and severity of complications related to managing the airway.

Benumof 1995

Expertise in management of the airway is to some extent the prime clinical skill that defines anaesthetists. Anaesthesia is increasingly safe, and colleague and patient expectations are therefore high. Major complications of airway management are rare but can be amongst the most life-threatening in medicine.<sup>1</sup> <sup>2</sup> As an example the 'can't intubate can't ventilate' (CICV) situation occurs in fewer than 1 in 5000 routine general anaesthetics and requires an emergency surgical airway (ESA) in ≈1 in 50 000 but accounts for up to 25% of anaesthesia-related deaths.<sup>3</sup> <sup>4</sup> Conversely minor complications, including difficulty with components of

airway management such as lung ventilation via facemask or laryngeal mask, or direct laryngoscopy, are common (each around 0.5–1%) but only rarely of great clinical consequence.<sup>5–7</sup> Airway complications are more frequent in patients with difficult airways, but the infrequency of such cases means many complications occur far more often in patients with an easy airway. For example 80% of laryngeal injuries follow easy intubation, primarily in healthy low-risk patients.<sup>8</sup>

The context of airway management is important. The rate of complications is affected by definitions used<sup>9</sup> and by the clinical setting. The incidence of failed intubation is  $\approx 1$  in 1-2000 in the elective setting,<sup>9</sup> <sup>10</sup>  $\approx 1$  in 300 during rapid sequence induction (RSI) in the obstetric setting,<sup>11</sup> and  $\approx 1$  in 50-100 in the emergency department<sup>12</sup> (ED), intensive care unit (ICU),<sup>13</sup> and pre-hospital setting.<sup>14</sup> The rate of CICV requiring ESA may rise to 1 in 200 in the ED.<sup>15</sup> <sup>16</sup>

This review cannot cover all aspects of the topic, about which several books have been written, and therefore focuses on the more serious end of the spectrum of airway complications and the more recent literature. The review does not cover in any detail airway complications in specific patient groups such as the obstetric or paediatric populations, nor minor complications such as dental damage.

## **Evidence and sources of information**

#### Limitations of the literature

Difficult airways and clinically important complications of airway management are rare and poorly predictable, so structured study of these areas is problematic. Randomized, controlled trials are unsuited for studying many aspects and in many areas where such studies might be possible, they have not been done.<sup>17</sup> Consequently much of the evidence-base for current airway management is low in the hierarchy of evidence-based medicine,<sup>18</sup> comprising case reports (level 4) and expert opinion (level 5), with even case control and cohort studies (level 3) being rare. Practices vary according to local expertise and facilities and in the absence of good evidence this may well be appropriate.<sup>19</sup> As a consequence expert opinion is variable: recently, a complex airway management case was reviewed by nine recognized international airway experts who were asked independently how they would manage the airway.<sup>20</sup> Remarkably, eight different primary airway plans were suggested with some experts spontaneously stating that techniques that others had independently offered were unsafe or even dangerous.

Several important observational sources exist that provide important insights into the epidemiology of airway complications. These can generally be divided into critical incident, litigation datasets, or both. These publications arise from several countries and some report outcomes generated over a considerable period of time (sometimes several decades). Closed claims datasets solely collect data on events that lead to litigation. Clinical incident datasets generally try to include both incidents leading to patient harm and similar events that do not ('near miss' or incipient incidents) in an attempt to identify themes and system errors. Occasionally, sentinel cases provide important learning. However, issues of confidentiality may compromise clinical detail and generalizable learning may be limited.

Of note, legal claim and critical incident datasets differ markedly. The Harvard Medical Practice studies reported adverse events affecting 3.7% of 30 121 in-patients with 14% of events leading to death.<sup>21</sup> Similar rates of incidents continue.<sup>22-24</sup> However, the Harvard group reported that only 1.5% of patients experiencing an adverse negligent event filed a malpractice claim.<sup>25</sup> Confusingly, although notes review identified seven times more negligent incidents than malpractice claims, most claims did not arise from patients with identifiable negligent events. Studdert and colleagues<sup>26</sup> in a study of 14 700 patients reported that only 3% of those experiencing negligent adverse events sued, yet of 18 malpractice claims there was evidence of negligent practice in only four, and in >50% no adverse event was identified. There is a mismatch between clinical error, negligent error, and litigation and, although both critical incident and closed claim analyses are valuable, they are unlikely to study similar case distributions: closed claims analyses may therefore not accurately reflect the relative prevalence of relevant clinical incidents.

### **Lessons from litigation**

#### The USA perspective: American Society of Anesthesiologists' Closed Claims Project

The American Society of Anesthesiologists' Closed Claims Project (ASACCP) is an important benchmark against which many studies of anaesthesia-related complications are judged. While this is rightly so, the limitations inherent in the ASACCP methodology are important to understand.

The closed claims analysis was set up in 1985: the included insurers represent around 50% of anaesthesiologists. Cases are summarized by volunteer clinical reviewers, who have access to full patient notes, and reviewed by the ASA's Committee on Professional Liability. For each case, the standard of care delivered is judged on 'reasonable and prudent' practice at the time of event and rated 'acceptable' or 'substandard' and whether it might have been prevented by the use of additional monitoring.

Due to rarity of claims and legal time-course cases are reviewed  $\approx$ 7-10 years after the event the ASACCP likely reviews as few as 5% of critical incidents. The reviews are retrospective, based on limited amounts of data and have no denominator. All retrospective expert data reviews have limitations,<sup>27</sup> including 'outcome bias' (where 'knowledge of the severity of outcome influences reviewers' judgement of the appropriateness of care'),<sup>28</sup> 'hindsight bias' (an exaggerated belief that a poor outcome could have been prevented),<sup>29</sup> and simple variation in 'expert interpretation'.<sup>30</sup> Interpretation must also take into account changes in practice, training, equipment, and patient expectations that have occurred since the closed cases took place. The preceding comments in no way reduce the key importance of the ASACCP, but aim to put their findings in context.

The first ASACCP **'respiratory events'** publications in the 1990s included >500 events, accounting for 34% of all claims in the database with 85% of claims relating to death or brain damage.<sup>8</sup> <sup>31</sup> The main categories of injury were inadequate ventilation (i.e. evidence of inadequate gas exchange despite no clear cause identified, 38% of claims), oesophageal intubation (18%), and difficult tracheal intubation (DTI) (17%). Most events affected healthy patients undergoing non-emergency surgery. Compared with non-respiratory claims, respiratory claims were more likely to be judged substandard (76 vs 30%, P<0.05) or preventable (72 vs 11%, P<0.05) and payments per case (median \$200 000) were markedly and statistically significantly higher. A short time later, the ASA practice guidelines on difficult airway management were published.<sup>32</sup>

ASACCP reports followed on airway trauma in 1999<sup>33</sup> (discussed below), difficult airway management in 2005,<sup>34</sup> and

pulmonary aspiration in 2000 and 2010<sup>35 36</sup> (discussed below). Using the original publication<sup>8</sup> and the 2005 review of 179 'difficult airway claims from 1983 to 99' which compares a 1885-92 and 1993-9 group, it is possible to broadly compare three groups of such claims from the 1970s, 1980s, and 1990s. In the latter two decades, the 'big three' (inadequate ventilation, oesophageal intubation, and DTI) still accounted for >50% of claims leading to death or permanent brain damage. The number of respiratory claims peaked in the 1980s and the proportion of claims for respiratory complications decreased from 34% in the 1970s to 15% in the 1990s, though whether this was due to decreasing incidence of respiratory claims or increasing non-respiratory claims is uncertain. In the 1990s, claims relating to oesophageal intubation fell to 6%, while those describing aspiration and premature extubation increased, difficult airway cases were less likely to describe death or brain damage (67%), although substandard care remained >50%, and preventability fell to 20% (all notably higher than non-respiratory cases: 26, 24, 5%, respectively).

Half of the claims described patients with predicted airway difficulty: many of whom still had a 'standard anaesthetic'. Two-thirds of the claims occurred at induction and 20% at extubation/recovery. Cases occurring after induction were associated with poorer outcomes. A reduction in the number of claims and severity of outcomes at induction of anaesthesia hinted at benefit from the ASA difficult airway management guidelines. Claims occurring outside the operating theatres described 100% mortality. Subsequent work has studied the extent of this problem in more detail.<sup>33</sup>

#### Canada

A publication describing airway-related claims against Canadian anaesthesiologists between 1993 and 2003 identified 33 cases.<sup>37</sup> Sixteen poor outcome cases involved young patients (mean 41.5 yr), undergoing elective surgery: 13 suffered moderate/severe brain damage or death. Half of the cases involved management of a difficult airway. The issues identified in these cases include lack of airway assessment, failure to alter technique when difficulty was predicted, lack of strategy, multiple attempts to solve a problem with the same (failing) technique, progression from DTI to CICV, oesophageal intubation, and problems at emergence or recovery. This distribution has startling similarities to those of the NAP4 project (see below).

#### The UK

There is no closed claims system in the UK, but all hospitals in England contribute to a risk pooling scheme, the NHS Litigation Authority (NHSLA) that manages negligence claims for these hospitals. Data on anaesthesia claims 1995–2007 were recently acquired with a Freedom of Information application and analysed.<sup>1</sup> Data quality is limited (non-verified clinical details, no denominators) and this limits detailed analysis. Costs in this dataset include legal costs. Anaesthesia claims (1067 claims in 12 years) represent 2.5% of all **Table 1** Comparison between claims of airway trauma reported in the American Society of Anaesthesiologist Closed Claims Project (ASACCP) in 1991,<sup>31</sup> in 1999<sup>33</sup> and those notified to the National Health Service Litigation authority (NHSLA).<sup>1</sup> Adapted from Rosenstock *et al.*<sup>39</sup> with permission. \*Denominator adjusted to exclude dental damage (as per ASACCP). <sup>†</sup>Pharyngeal and oesophageal injuries were 28% combined, but were not subdivided: a 50:50 split is assumed. <sup>‡</sup>Ninety per cent were perforations. <sup>¶</sup>All were perforations. <sup>§</sup>Likely an underestimate of true incidence as a result of methodology

	ASACCP 1991 (%)	ASACCP 1999 (%)	NHSLA 1995–2007 (%)
Percentage of all anaesthesia claims	5	6	3*
Deaths	12	8	14
Payments to claimant	60	54	61
Laryngeal injury	33	33	36
Pharyngeal injury	$14^{\dagger}$	19	32
Oesophageal injury	$14^{\dagger}$	18 <sup>‡</sup>	14 <sup>¶</sup>
Difficult airway	42	39	9 <sup>§</sup>

claims. Airway and respiratory claims account for 12% of these but 53% of deaths, 27% of cost, and 10 of the 50 most expensive claims in the dataset.<sup>38</sup> The financial cost of claims is reported elsewhere. Relative to other anaesthesia categories, airway claims rank 5th by number, 3rd by overall cost, 2nd by cost per case, and first in the proportion of cases with poor clinical outcomes (72% severe harm or death; 60% brain damage or death). Airway claims typically described events at induction of anaesthesia and complications causing severe hypoxia. The girway device when identified was a tracheal tube (TT) in 77% and a tracheostomy in 21% (no claims relating to facemask ventilation, supraglottic airway device, fibreoptic intubation, or ESA). Oesophageal intubation was described in four claims (6%) and aspiration in 16% of airway claims, often citing inappropriate angesthetic techniques, particularly failure to use RSI when indicated. Airway trauma accounted for one in three claims, half describing severe harm or death. Only 20% of claims described airway difficulty.

Respiratory claims all described profound hypoxia and usually failed ventilation (akin to the ASACCP 'inadequate ventilation' group): the group had high rates of harm (71% severe harm or death, 63% brain damage or death). Almost one-third of these claims occurred in recovery or after operation, while one in six described equipment issues. Miscellaneous claims of note included: death during paediatric adenotonsillectomy; from laryngospasm; during gaseous induction to avoid cannulation in a needle phobic youth; and severe harm from throat pack retention. The NHSLA and ASACCP datasets show similar distribution of cases despite differences in methodology, medical and legal practices (Table 1).

Data from Denmark are remarkably similar. In the late 1990s, 21% of anaesthesia claims described respiratory

complications, with a mortality rate of 50% and substandard care identified in one-third of the cases.<sup>39</sup> Anaesthesia claims accounted for 4.5% of all claims relating to death and one in four of these related to airway or respiratory management.<sup>40</sup>

#### Critical incident datasets

Litigation databases include relatively small numbers of cases with notably poor outcomes often with frequent substandard care: learning from individual cases may be useful but perhaps not generalizable. Conversely critical incident databases include large numbers of cases with none or minimal patient harm. In a study of >12 000 anaesthesia-related clinical incidents notified to the UK National Reporting and Learning System (NRLS), >75% of incidents caused no harm with severe harm or death in 2%.<sup>41</sup> Learning from large critical incident databases requires focused interrogation and filtering of results. The Safer Anaesthesia Liaison Group (SALG; http://www.rcoa.ac.uk/salg) examination of the NRLS database is a good model for this.

Too few critical incident databases provide feedback to those reporting cases, and consequently enthusiasm for reporting events and reporting rates are low.<sup>42</sup> Local reporting systems identify ~14% of events that are documented in the notes and 5% of those causing patient harm;<sup>43</sup> national reporting systems may fare less well. Focused critical incident reporting may be more valuable in identifying patterns of critical incident.

#### Australian Incident Monitoring Study

The Australian Incident Monitoring Study (AIMS) in the late 1990s aimed to 'capture information from a wide variety of sources . . . from near misses to sentinel events . . . (so that) detailed analysis is possible'.<sup>44</sup> Anaesthetists 'were invited to report . . . any unintended incident which reduced, or could have reduced, the safety margin for a patient'. An extensive structured paper record of the event was completed (including the details of process, mitigating or exacerbating factors and human or system factors). The first 2000 incidents reported to AIMS were analysed: these had morbidity (6%) and mortality (1%) rates considerably higher than a normal incident reporting system, suggesting reporters filtered out minor incidents.<sup>45</sup> Airway and respiratory reports accounted for one-quarter of reports with 317 (15.9%) problems with ventilation (half of these due to circuit disconnection) and 189 (9.5%) problems with TTs (bronchial intubations, leaks, and obstructions).<sup>46-48</sup> Eighty-five reports described DTI (4.3% of all reports), 35 oesophageal intubations (1.75%). One-third of DTI reports were emergencies, one-third were managed by trainees alone, and one-fifth occurred out of hours.

#### 4th National Audit Project of the Royal College of Anaesthetists and Difficult Airway Society

The 4th National Audit Project of the Royal College of Anaesthetists and Difficult Airway Society (NAP4) included a prospective registry for voluntary reporting of major complications of airway management during 12 months through 2008–9 in all 309 NHS hospitals of the four countries of the UK.<sup>2 49 50</sup> Inclusion criteria were airway complications leading to death, brain damage, admission to (or prolongation of stay on) ICU and ESA. The universal involvement of UK NHS hospitals and prospective nature of the project perhaps make it the largest study of major complications of airway management ever performed and it is therefore considered in some depth.

Of >280 reported cases, 184 met inclusion criteria and were reviewed by two expert panels.<sup>27</sup> The authors estimated that as few as one in four relevant cases might have been detected. The first stage of NAP4 identified a <u>denominator</u> of 2.9 m <u>general anaesthetics</u> and the types of airway management used.<sup>51</sup> Of the 184 reports, there were 34 deaths (18%) and 46 cases of death or brain damage (25%): there were 133 anaesthesia reports, 36 from ICU, and 15 from the ED.

Figure 1 shows the primary airway problems: problems with tracheal intubation were the most frequent (failure, difficulty, delay, and CICV accounting for 39% of cases) followed by aspiration then extubation. The intended airway was TT of any sort (68%), supraglottic airway device (26%), and facemask (5%).

Sixty-two per cent of patients were male, 56% ASA I–II, 61% aged <60 years, and 54% of procedures were elective. Obesity was recorded for 40% of patients and cachexia 11%. Events occurred at induction in 52%, during maintenance 20%, during emergence 16%, and in recovery 12%. A consultant attended 63% of anaesthesia cases.

The inclusion criteria and final outcome of events are presented in Table 2. Of 133 anaesthesia cases, there were 16 deaths (12%) and 3 cases of brain damage (death and brain damage 14%). The commonest cause was hypoxia with sepsis and single or multi-organ failure recorded in several late deaths. An attempt at ESA was reported in 80 of 184 reported cases (43%) and in 58 (43%) of 133 anaesthesia-related reports. This group is discussed below.

ICU admission was an inclusion criterion in 100 anaesthesia cases most commonly for management of aspiration, hypoxia due to post-obstructive pulmonary oedema, failure to awaken after surgery, myocardial ischaemia, or cardiac arrest. Of these patients 12 died, 7 made a partial recovery and 81 a full recovery.

As the project produced both numerator and denominator, incidences of events were calculated and are presented in Table 3. The point estimate of event rates was approximately <u>1 per 22 000 general anaesthetics</u> and of <u>death</u> <u>1 per 180 000</u>. Point estimates for events and mortality with TT general anaesthesia was ~2- to 4-fold higher than SAD general anaesthesia which might be expected as the TT is the preferred airway device for almost all complex cases.

Aspiration of gastric contents was the primary event in 17% of cases and occurred in 23% in all (e.g. during difficult or failed intubation). It was the <u>commonest cause of death</u> (50% of such events) and <u>brain damage (53%).</u> It is discussed further below. Head and neck cases accounted for 39% of

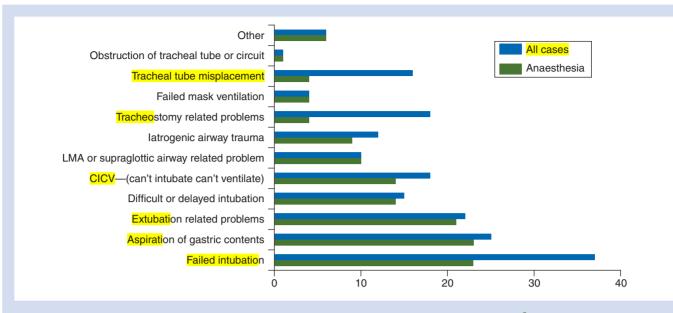


Fig 1 Primary airway problem for all events and for anaesthesia events reported to NAP4. From Cook et al.,<sup>2</sup> with permission.

**Table 2** Inclusion criteria (multiple criteria possible) and final outcomes (classified by inclusion criteria and by severity of harm using National Patient Safety Agency classification) of cases reported to NAP4.<sup>158</sup> From Cook *et al.*,<sup>2</sup> with permission. \*Prolongation of stay in the case of patients already in ICU

	All cases (n=184)	Anaesthesia (n=133)				
Reporter provided inclusion criteria						
Death	33	14				
Brain damage	13	6				
Emergency surgical airway	75	54				
ICU admission* (sum)	122 (243)	100 (174)				
Final outcome (narrative)						
Death	38	16				
Brain damage	8	3				
Other partial recovery	10	6				
Full recovery	124	106				
Unrelated death	4	2				
Final outcome (NPSA definitions)						
Death	38	16				
Severe	10	5				
Moderate	126	103				
Low	7	6				
None	3	3				

anaesthesia reports (70% involving airway obstruction), with higher rates of death, brain damage, ESA, and poor care than in other anaesthesia cases. Reports of anaesthesia events in obese patients were predominantly of aspiration, problems at extubation, and airway trauma. Obstetric and paediatric cases were infrequent. One child died from aspiration of blood after tonsillectomy, total airway obstruction, and delayed airway clearance. Events at emergence and in <u>recovery occounted for 29%</u> of cases: all involved airway obstruction, often when blood was in the airway and frequently leading to hypoxia from post-obstructive pulmonary oedema. Organizational and diagnostic delay meant that appropriate treatment was sometimes not prompt. Four cases progressed to cardiac arrest and two patients died.

The use of monitoring was universal in anaesthesia cases, but not outside theatre. Nevertheless, in four anaesthesia cases (including two deaths) suboptimal interpretation of capnography contributed to harm when the absence of a capnography trace during cardiopulmonary resuscitation (CPR) was not correctly interpreted as indicating failure to ventilate the lungs (either because of oesophageal intubation or because of absolute airway obstruction—clot or aspirated material): during CPR, an attenuated capnography trace is seen (Fig. 2). In total, there were three cases of unrecognized oesophageal intubation during anaesthesia causing one death and one brain injury.

Review panel analysis included structured assessments of causal, contributory, and positive aspects of care (Table 4) and the quality of care. There are limitations to both analyses as the NAP4 process did not include case-notes review or clinician interview and may have been influenced by review bias.<sup>27-30</sup> The most frequent causal and contributory factors in anaesthesia cases were the patient (79% of cases), judgement (62%), and education/training (47%). Equipment/resource and communication factors were causal or contributory in more than a quarter of cases. Positive factors were identified in half of the cases. The quality of airway management in the anaesthesia cases was assessed as good in 18% of the cases, mixed in 41%, and poor in 34%.

**Table 3** Incidence estimates of major airway complications by airway type for events and death/brain damage: expressed as events per million cases and fractions (one in *n* cases). The denominator for each calculation is from the Fourth National Audit project Census.<sup>15</sup> For each, point estimate and lower and upper confidence limits (CL) are presented. From Cook *et al.*,<sup>2</sup> with permission

Type of event	Numerator	Denominator	Events per million cases			Events as fractions one in <i>n</i> cases		
			Point estimate	Lower CL	Upper CL	Point estimate	Lower CL	Upper CL
Events	133	2 872 600	46.3	38.4	54.2	21 598	26 02 1	18 461
Deaths	16	2 872 600	5.6	2.8	8.3	179 538	352 033	120 495
Death/brain damage	19	2 872 600	6.6	3.6	9.6	151 189	274 717	104 294
Tracheal tube death/brain	91	1 102 900	82.5	65.6	99.5	12 120	15 254	10 054
damage	10	1 102 900	9.1	3.4	14.7	110 290	290 087	68 089
SAD events	35	1 616 100	21.7	14.5	28.8	46 174	69 051	34 684
SAD death/brain damage	8	1 616 100	5.0	1.5	8.4	202 013	657 942	119 325
FM event	7	154 200	45.4	11.8	79.0	22 029	84 985	12 654
FM death/brain damage	1	154 200	6.5	0.0	19.2	154 200	0	52 095



**Fig 2** Capnography during CPR in a patient in cardiac arrest. The attenuated capnography trace is seen when pulmonary ventilation is occurring. A flat capnograph trace should be assumed to be because of oesophageal intubation (or rarely airway blockage) until this has been actively excluded (with permission of Dr S. Chapman and Prof. J. Benger).

Qualitative aspects of the project included:

- poor assessment of airway and aspiration risk (omission, incomplete assessment, or failure to alter the airway management technique in response to findings at assessment).
- Poor planning and 'failure to plan for failure'.
- Lack of 'institutional preparedness' (e.g. policies, staffing, equipment, standard operating procedures—SOPs) and 'individual preparedness' (e.g. training, knowledge of local policies, knowledge of the limits of own capabilities).
- Use of plans where strategies were required. A plan suggests a single approach to management while a strategy is a coordinated, logical sequence of plans, which aim to achieve good gas exchange and prevention of aspiration.

- Failure to use awake fibreoptic intubation when indicated. The methodology did not enable determination of the reasons but lack of skills, confidence, equipment, or poor judgement were all apparent.
- Management of DTI by multiple attempts at intubation, often leading to CICV.
- Inappropriate use of SADs in patients who were markedly obese or at increased risk of aspiration. Firstgeneration SADs were used when a second-generation device was a more logical choice.<sup>52</sup>

Many of the events and deaths reported to NAP4 were likely avoidable. Despite this finding, the incidence of serious complications associated with anaesthesia is very low. Although many of the findings of the anaesthesia section of NAP4 are neither surprising nor new, the breadth of the project, covering the whole of the UK for a full year, means that it can be regarded as revealing the 'state of the nation' in terms of major complications of airway management and shining a light on patterns, themes, and problems. The NAP4 report included >160 recommendations designed to improve overall airway management safety (http://www .rcoa.ac.uk/nap4).

The question arises as to whether NAP4 is relevant to other countries or represents merely a reflection of practice in one country. Some have suggested that NAP4 shows poor practices that are not prevalent in North America.<sup>53</sup> It is worth clarifying that the quality of care in the vast majority of cases reported to NAP4 was either 'good' or 'good and poor' and in 78% of cases the patient (i.e. difficult airway) was judged to be a causal or contributory factor. NAP4 is an analysis of patient harm consequent on airway management, not a report on substandard care provision but a realworld examination of how patients can be harmed by airway management. Events and practice deviations such as those reported to NAP4 inevitably occur in other countries and the literature supports this.<sup>54 55</sup> Until NAP4 is repeated in other countries, it is difficult to quantify any differences in practices of outcomes.

Factors	All cases (n	=184)		Anaesthesia (n=133)			
	Causal	Contributory	Positive	Causal	Contributory	Positive	
Communication	4	38	40	2	26	20	
Education and training	12	77	17	10	52	13	
Equipment and resources	2	46	21	2	30	16	
Medicines	0	31	5	0	21	5	
Organization and strategic	1	42	35	1	35	28	
Patient	37	103	1	28	76	1	
Task	4	31	7	2	22	4	
Team and social	0	36	22	0	26	20	
Work and environment	1	14	3	1	9	3	
Judgement	19	90	23	16	67	18	
Other	0	8	0	0	3	0	

**Table 4** Factors assessed by review panel to contribute or cause events and factors indicating good practice classified using National Patient Safety Agency classification.<sup>158</sup> From Cook *et al.*,<sup>2</sup> with permission

# Incidence, causes, and consequences of airway difficulty and failure

The first complication of note in airway management is failure, which is important for a number of reasons. First, anaesthetists are used to high levels of success at what they do and routine airway management does not usually fail. Secondly, major complications often start with failure of a chosen airway technique. Finally, failures often combine, with failure of one technique being associated with an increased risk of failure in another.

#### Tracheal intubation (direct laryngoscopy)

The incidence of failed tracheal intubation ranges from 1 in <u>1000–2000 cases in the elective setting<sup>6</sup><sup>10</sup> through <mark>1 in</mark></u> 250 during obstetric RSI,<sup>11</sup> to <u>1 in 100 in the ED.<sup>12</sup> Surprising-</u> ly, these figures are derived from rather small and sometimes methodologically flawed studies. The incidence of DTI depends on definition (there are many). Rose reported a <u>Cormack and Lehane (C&L) grade 3–4 view<sup>56</sup> in 10.1%, >2</u> laryngoscopies in 1.9%, and failed laryngoscopy 0.1%.<sup>9</sup> Shiga and colleagues,<sup>57</sup> in a meta-analysis of laryngeal view in  $>50\,000$  apparently normal patients, reported a C&L grade 3 view in 5.8% (95% confidence interval, CI, 4.5-7.5%), a similar figure to that found in the Danish anaesthesia database of 5.2% (CI 5.0-5.3%).<sup>58</sup> An important problem is that the almost universally used (but often poorly recalled)<sup>59 60</sup> C&L laryngoscopy grading is not particularly effective at discriminating between easy, awkward, and genuinely DTI as changes in grade do not correlate with likely changes in technique.<sup>61</sup> Other classifications divide grade 2 into 2a (some of cords visible) and 2b (posterior glottis structures only)<sup>62</sup> or in addition divide grade 3 into 3a (epiglottis can be lifted) and 3b classes (epiglottis cannot be lifted).<sup>61</sup> The latter classification then recombines 1 and 2a as 'easy', 2b and 3a as 'awkward' (e.g. requiring a bougie), and 3b and 4 as 'difficult' (i.e. needing advanced techniques). The latter Cook classification<sup>61</sup> showed better correlation with time to intubate and use of adjuncts than the C&L classification and was also as sensitive and more specific at predicting DTI. The majority of failed intubations are C&L grade 2–3, in five prominent papers accounting for 72% of all failed intubations.<sup>6</sup> <sup>10</sup> <sup>11</sup> <sup>63</sup> <sup>64</sup>

Standard bedside tests are poorly predictive of DTI: for example a Mallampati class 3 view of the oropharynx<sup>65</sup> has a positive predictive value of difficult laryngoscopy of 3-5%.<sup>57</sup> This topic has been elegantly reviewed by Yentis and Lee.<sup>66</sup> The frequency of C&L grade 3 view laryngoscopy varies dramatically with the population: from  $0.3\%^{67}$  (when all patients with neck pathology were excluded) to  $20\%^{68}$  (when only patients with neck pathology were included). Approximately 50% of all DTIs are likely to be unexpected.<sup>69</sup>

The Danish anaesthesia database of approximately 100 000 consecutive intubations has produced important information regarding risk factors for difficult intubation. In a cohort of >1500 repeated anaesthetics, a previous history of DTI (>2 attempts, >1 anaesthetist required, alternative technique required, or failure) was a strong predictor of DTI and failed intubation.<sup>70</sup> DTI occurred in 24% of those with previous DTI and intubation failed in 30% of those with previous failed intubation. While numerous statistics are derived, the most compelling are: the presence (or absence) of previous DTI is associated with a 6-fold increase (or 3% reduction) in the likelihood of DTI, and the presence (or absence) of previous failed intubation is associated with 22-fold increase (or 5% reduction) in the likelihood of failed intubation. Clearly a previous difficult or failed intubation should lead to the assumption that it is likely to recur; however, the absence of such a history is not reassuring by itself.

Regarding obesity, BMI  $\geq$  35 kg m<sup>-2</sup> increased the risk of DTI (odds ratio 1.34, 95% CI 1.19–1.51), but as a stand-alone predictor of DTI BMI  $\geq$  35 kgm<sup>-2</sup> had a sensitivity of 7.5% and a positive predictive value of 6.4%, making it of <u>little use.<sup>58</sup></u> A further paper reporting data from the Danish anaesthesia database examined intubation with and without neuromuscular blocking agents (NMBAs).<sup>71</sup> The absence of use of NMBA was associated with an increase in the risk of DTI (OR 1.48, CI 1.39–1.58, P=0.0001).

DTI and failed intubation are important, because tracheal intubation is the most important technique for management of high risk or difficult cases and because it is the commonest rescue technique when other forms of airway management go wrong. The consequences of DTI and failed intubation are also important.

Failed, difficult, or delayed intubation was the primary event in more than one-third of events reported to NAP4.<sup>2</sup> Failed and DTI are associated with oxygen desaturation (<90%), hypertension (>200 mm Hg), dental damage, admission to ICU, and complications at extubation.<sup>6</sup> It is also associated with arrhythmias, bronchospasm, airway trauma, awareness, CICV, and the sequelae of hypoxia (cardiac arrest, brain damage, and death). Difficult and failed intubation is often managed poorly. An ASACCP analysis of difficult airway management cases<sup>34</sup> indicated that when DTI was anticipated almost 70% of anaesthetists planned to continue with routine general anaesthesia and paralysis. Of those cases managed in this manner, >60% progressed to CICV and poor outcomes were significantly more common than in cases managed differently. Surveys in several countries over more than 20 years have found very similar results.<sup>34 55 72-75</sup> When intubation does prove difficult, there is a tendency for the anaesthetist to repeat the attempt at intubation several times, perhaps followed by another anaesthetist doing the same. NAP4 has shown <mark>this to increase the risk of progression to CICV<sup>2</sup> and the</mark> ASACCP analysis suggested an increase in death and brain damage in such cases.<sup>34</sup> Mort reported a dramatic increase in airway complications when >2 direct laryngoscopies were performed.<sup>76</sup> All national unanticipated DTI guidelines emphasize that the attempts at direct laryngoscopy should be limited and that alternative techniques should be attempted.<sup>77-79</sup> When direct laryngoscopy is unsuccessful, further attempts with the same technique have a close to 80% failure rate with alternative techniques (SAD, indirect laryngoscopy) being more <u>successful.<sup>80</sup></u>In a UK study of failed obstetric intubation, 50% of failures were followed by management that deviated from known recommendations. There were numerous similar examples in NAP4.<sup>2</sup>

#### **Facemask ventilation**

Facemask ventilation is difficult in between 0.9 and 5% of cases, depending on definition.<sup>5 6 81-83</sup> Langeron defined difficult mask ventilation (DMV) as inability to maintain oxygen saturations of >92% with 100% oxygen, requirement to use oxygen flush, major uncontrolled leak, or the need for 2 persons, and reported a <u>5% DMV incidence in 1502 patients</u> and impossible mask ventilation (IMV) in 1 patient (0.07%).<sup>81</sup> Only <u>17% DMV</u> cases were predicted by the anaesthetist.

## Independent risk factors for DMV were a BMI >25 kg m<sup>-2</sup>, age >55 yr, beard, lack of teeth, and history of snoring.

Kheterpal and colleagues<sup>83</sup> who reviewed >50 000 anaesthetics, defining DMV as difficult, unstable requiring two providers with or without neuromuscular blocking agents and IMV as the inability to exchange gas during bag-mask ventilation, despite multiple providers, airway adjuvants, or neuromuscular block, reported DMV in 2.2% and IMV in 0.15%. Independent predictors of IMV were neck radiation changes, male sex, sleep apnoea, Mallampati III or IV, and presence of beard. Of the cases of IMV, 58 were intubated without difficulty, 17 with varying degrees of difficulty, 3 were woken (one of whom then had a tracheostomy), and 1 had an emergency cricothyroidotomy.

In both series, the presence of more than one risk factor dramatically increased the likelihood of difficulty/failure.

#### Laryngeal masks and other supraglottic airway devices

The literature on failure rates of SAD use is remarkably sparse. Several large observational studies of the LMA indicate a low failure rate in the clinical use. Verahese reported a 99.8% success rate in conventional and non-conventional uses over 11 910 uses.<sup>84</sup> Recently a study of 15 795 uses of the LMA-Unique (uLMA®) reported a failure rate of 1.1%.7 In this retrospective database study failure was defined as the requirement to remove the uLMA and replace it with a TT. It is likely rates of 'difficulty' were considerably higher than rates of failure. Four independent risk factors were identified for uLMA failure: obesity, male gender, poor dentition and rotation of the operating table. The two commonest causes of uLMA failure were airway leak (43% of failures) and airway obstruction (30%), leading to oxygen desaturation: harmful events were rare. The consequences of failure included an increase in unintended hospital admission and ICU admission though these sequelae were rare: 1 in 877 unplanned hospital admission, 1 in 7898 ICU admission.

Robust data on other devices are incomplete but first time and overall success rates for insertion include LMA classic 93 and  $\approx 100\%$ ,<sup>85</sup> ProSeal LMA 87% and 98%,<sup>85</sup> i-gel 93 and 96%.<sup>86</sup> Blind intubation via the Intubating LMA in routine cases has a success rate after 2 attempts of <u>88%</u> and in the difficult airway setting <u>success</u> including <u>fibreoptic tech-</u> niques is <u>98%.<sup>87</sup></u>

#### **Videolaryngoscopy**

The recent, somewhat uncontrolled, introduction of rigid videolaryngoscopes (VLs) and other novel intubating aids offers a wide variety of alternatives to intubation with direct laryngoscopy. There is substantial evidence that many devices improve laryngeal view, but it is uncertain whether this increases intubation success rates, especially when direct laryngoscopy is difficult or fails.<sup>88</sup> A 2008 metaanalysis identified first time failure rates for intubation (mostly in patients without difficult airways) as follows: Bullard 13%

(from studies totalling 1349 patients), C-Trach 7% (n=638), Bonfils 3% (n=247), Glidescope 4% (n=1076), Shikani 14% (n=175).<sup>89</sup> In patients known or predicted to be difficult to intubate the data are less robust or impressive: Bullard 31% (n=371), C-Trach 9% (n=32), Bonfils 7% (n=69), Glidescope 8% (n=2013), Shikani 71% (n=7).<sup>88</sup> More recent publications have shown benefit with high rates of success after difficult or failed direct laryngoscopy with the Glidescope,<sup>90</sup> Airtrag,<sup>89</sup> McGrath Series 5<sup>91</sup> and Pentax Airway scope.<sup>92</sup> Prediction of failure with a VL or novel intubating aid remains largely unexplored except for the Glidescope<sup>90 93 94</sup> and Airtraq.<sup>89</sup> factors include airway masses, poor laryngeal view during direct laryngoscopy and cumulative predictors of difficult conventional intubation (e.g. <6 on the El Ganzouri risk index test).<sup>95</sup> Evidence as to which of the novel intubation aids performs best remains lacking: it is highly unlikely that all offer equal benefit and some may offer none.<sup>96</sup>

#### **Fibreoptic intubation**

Awake fibreoptic intubation (AFOI) is rightly regarded by many as the gold standard technique for difficult airway management. It is easy to forget that the technique may fail, but this was seen repeatedly in NAP4.<sup>2</sup> A study of 200 anaesthetists undergoing AFOI in the training setting reported an 11% failure rate.<sup>97</sup> Immediate complications included nosebleed (10%), nodal rhythms (3%) and hypoxia (1.5%). Late complications included sore throat/nose (37%), voice change (5%), and fever with rigors (1%). A retrospective study of 1612 sedated fibreoptic intubations reported a failure rate of 1.5%.<sup>98</sup> Severe nasal bleeding requiring suction was reported in 1.3%. Several case reports highlight the link between local angesthetic administration for AFOI and subsequent airway obstruction.<sup>99-101</sup> Topical local an-<mark>aesthesia<u>reduces dynamic air flow</u>with <u>loss of muscle</u></mark> tone and normal reflex responses, potentially precipitating airway collapse in the compromised airway.<sup>102</sup> 103 Conversely, inadequate airway anaesthesia can also cause laryngospasm or airway obstruction in reaction to fibrescope introduction.<sup>104</sup>

#### **Emergency surgical airway**

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ESA is a rescue technique: CICV occurs in about 1 in 5-10 000 general angesthetics with ESA performed in approximately 1 in 50 000 general anaesthetics but such cases may account for >25% of all anaesthesia related deaths.<sup>3 4</sup> ESA may be required in as many as 1 in 600 intubations in the ED.<sup>14</sup> In the ASACCP study of difficult airways the occurrence of CICV increased the risk of a poor outcome 15-fold.<sup>34</sup> The rarity, invasiveness and emergency nature of ESA makes its study difficult and much of the evidence is derived from models and simulations whose fidelity is uncertain. Failure of ESA puts the patient at significant risk of death. NAP4 included a cohort of 80 cases of ESA (43% of all reports), perhaps the largest in-hospital series. Thirteen of these patients died (16%) and seven suffered permanent harm

(25% permanent harm or death). Despite high rates of failure of ESA in this series most patients made a full recovery. Failed initial ESA was rescued variously by intubation, SAD placement, the patient awakening or an alternative ESA technique. Several cases of CICV and attempted ESA occurred in which anaesthetists intentionally avoided use of NMBA even during CICV and also cases where ESA was attempted without ever attempting airway rescue with a SAD. The NAP4 report recommended both should be used before CICV progresses to ESA. The ASACCP reported high rates of failed ventilation and of barotrauma when narrow bore cricothyroidotomy was used to manage CICV.<sup>34</sup> In NAP4 needle cricothyroidotomy performed by anaesthetists had a high failure rate (63%) and surgical tracheostomy/cri-<mark>cothyroidotomy a <u>100% success</u>rate. Despite this the</mark> context in which the procedures were performed means that it is not possible to conclude that the latter technique is intrinsically safer than the former. Needle techniques were predominantly performed by an anaesthetist on patients who were in extremis and open techniques largely by surgeons, often while the anaesthetists maintained oxygenation making the procedure less time-critical. Evidence from a large series of various ESA techniques in sheep in a 'wet-lab' suggests well trained anaesthetists have a high success rate with needle cricothyroidotomy in life-like situations.<sup>105</sup> The topic has recently been extensively reviewed.<sup>106</sup>

Delay in performance of ESA is as important as equipment choice. In the ASACCP analysis of difficult airway management, 79 (42%) of cases progressed from intubation difficulty to CICV,<sup>34</sup> and in two-thirds a surgical airway was performed but too late to prevent an adverse outcome. ESA was often performed when the patient was either moribund or in fact dead. Similarly in NAP4 there was clear evidence of delay in performing ESA and even cases where ESA was not performed at all despite clear need.<sup>4</sup> There is a natural reluctance to perform such techniques but the evidence is clear:<sup>107</sup> when ESA is required it is not the procedure that kills patients, but delaying or not doing it that causes harm. Training programmes could usefully emphasize behavioural aspects of cricothyroidotomy as equally important as technical training.

#### Composite failure of airway management

An important observation from large studies examining airway technique failure is that when one airway technique is difficult or fails, the risk of other techniques being difficult or failing is considerably increased. As some of the predictors of technique difficulty (e.g. Mallampati class 3, obesity, reduced mouth opening) appear in several risk scores this is logical: such patients do not just have a risk of difficult intubation but of an all-round difficult airway.

After failed intubation in the AIMS study, 1 in 7 patients also exhibited DMV<sup>46</sup> and in an obstetric failed intubation setting DMV occurred in 30% and IMV in 10% of cases.<sup>11</sup> In Langeron's study of DMV, when DMV was present the incidence of DTI increased 4-fold (from 8% to 30%) and the incidence of failed intubation increased 12-fold (from  $\approx 0.5\%$  to 7%).<sup>81</sup> Regarding laryngeal masks, failure of uLMA placement was associated with a 3-fold increase in the like-lihood of DMV from 1.9 to 5.6%.<sup>7</sup> In the ASACCP dataset it was suggested that 'LMA rescue ability may be impeded by effects of multiple preceding intubation attempts'.<sup>34</sup> Finally as emphasized previously multiple attempts at direct laryngoscopy are associated with the development of both DMV and CICV.<sup>2</sup>

The ASA practice guideline on difficult airway management exhorts anaesthetists to examine patients to identify predictors of failure of planned airway techniques.<sup>78</sup> When such features are found, particular attention should be paid to assessing the feasibility of rescue techniques, in the knowledge that they are also more likely to fail if the primary technique fails.

# Other complications of specific airway devices

Complications of facemask ventilation, though rare, include airway trauma, nerve injury, gastric insufflation and aspiration.<sup>81 108 109</sup> Similarly SADs can lead to hypoventilation, airway trauma, nerve injury, gastric insufflation and aspiration. SADs comprise a diverse number of cuffed and non-cuffed devices which are placed into several different anatomical positions,<sup>110</sup> with resulting different patterns of injury. Use according to manufacturer's instructions (especially regarding maintaining cuff pressures  $<60 \text{ cmH}_2\text{O}$  is likely to reduce the risk of sore throat and nerve injury.<sup>111</sup> In NAP4 SADs were reported to be used in 58% of all general anaesthetics: rates of complications were lower than for TTs and the majority of complications were contributed to by poor case selection or device use.<sup>2</sup> A meta-analysis found the cLMA® has 13 advantages over the TT including being faster and easier for the inexperienced, faster for anaesthetists, haemodynamically more stable during induction and emergence; requiring less anaesthetic, less coughing and better oxygenation during emergence and fewer sore throats.<sup>112</sup> Disadvantages were lower seal pressures and more frequent gastric inflation. In a recent systematic review use of a SAD rather than a TT significantly reduced laryngospasm, coughing, hoarse voice and sore throat without altering regurgitation, vomiting and nausea rates.<sup>113</sup> Advantages of a cLMA<sup>®</sup> over FMV included being easier for the inexperienced, providing better oxygenation and less hand fatigue, the only disadvantage being increased oesophageal reflux.<sup>112</sup> SADs of all types appear very infrequently in litigation datasets (excluding dental damage).<sup>1 33 34</sup> Overall complications of LMA use is low, between 0.15-7%.84 Tracheal intubation has the potential to lead to airway trauma, oesophageal intubation, bronchial intubation, sore throat and rarely late airway stenosis. Cervical spine injury in trauma patients because of tracheal intubation (or indeed any airway manipulations) is possible but of considerably lower risk than widely assumed.<sup>114</sup>

# Complications and factors of specific interest

### Death

Before NAP4 the best estimate of peri-operative airway related death was Auroy's from surveillance of death certificates which estimated 1 per 7960 general anaesthetics in 1978–82 falling to 1 in 48 200 in 1999.<sup>115</sup> During this period death from circuit disconnections disappeared and death from DTI reduced 4-fold. Practice and systems failures contributed to most deaths. Use of death certification data has considerable limitations.<sup>116</sup> NAP4 provides the best current estimate of the minimum risk of death from airway management and includes incidences stratified by airway type and site of airway management (Table 3).<sup>2</sup> <sup>49</sup> <sup>50</sup> The data are largely reassuring: death 1 in 180 000 general anaesthetics, death and brain damage 1 in 153 000. The lower mortality rate with SAD use makes a large excess of deaths from inappropriate SAD use unlikely.

#### Нурохіа

Hypoxia was the commonest cause of death in NAP4.<sup>2 49 50</sup> Of note, and yet to be fully explored, there were marked variations in response to hypoxia: some patients died after relatively short periods of hypoxia but notably a significant proportion of reports described profound prolonged hypoxia (e.g. saturations  $\approx$ 50% for 30 min) with full recovery. This may have implications in the appropriate duration of attempts to rescue a lost airway, in a similar manner to recent data on cardiac arrest.<sup>117</sup> Notwithstanding this speculative finding, all efforts should be made to maximize the time to desaturation when preparing for anaesthesia. Remembering that the time\_taken to desaturate from an oxygen saturation of 80–40% is approximately 20–40 s.<sup>118</sup> <sup>119</sup> Pre-oxygenation should be used routinely as it dramatically prolongs apnoea time before critical desaturation.<sup>120</sup>

### **Obesity**

In NAP4 obesity was seen twice as often in reports as it is seen in the UK population. In the ASACCP 35% of airway problems at induction of anaesthesia involved obese patients.<sup>34</sup> Although obesity may not dramatically increase the incidence of poor laryngeal view, obesity and obesity-related conditions (e.g. snoring, sleep apnoea, high Mallampati scores) are predictors of DMV, LMA failure and difficult ESA. In NAP4 reports of airway difficulty in obese patients, standard rescue procedures frequently failed. A major risk factor for airway management in obese patients is that time to hypoxia is markedly reduced. Specialized pre-oxygenation including 25° anti-Trendelenburg tilt<sup>121</sup> and continuous positive airway pressure breathing may be indicated.<sup>122</sup>

## **Aspiration**

Aspiration remains an important cause of harm and death during anaesthesia. In the ASACCP it accounts for 3.5% of all claims and <u>9%</u> of respiratory claims (increasing to 15%

in the 1990s),  $^{8}$   $^{31}$   $^{36}\text{in}$  the AIMS study 2.6% of reports described aspiration.  $^{123}$ 

In NAP4 aspiration was the primary event in 17% of reports, occurred in 23% of reports and was the commonest cause of anaesthesia deaths (50%) and death/brain damage (53%).<sup>2</sup><sup>50</sup> In a 2009 French study aspiration accounted for  $\approx$ 20% of deaths fully or partially caused by anaesthesia: a death rate from aspiration of 1 for 221 368 general anaesthesia<sup>124</sup> compared with an incidence in NAP4 of 1 in 359075. In the ASACCP patients in aspiration claims were older, surgery was more frequently abdominal and emergency and more patients died than in non-aspiration claims.<sup>35</sup> All these studies noted significant deviations from recommendations.<sup>2</sup> <sup>35</sup> <sup>124</sup> NAP4 noted particular issues with assessment of aspiration risk and despite increased risk being identified, reports described use of first generation SADs when a second generation SAD (i.e. one designed to reduce risk of aspiration)<sup>52</sup> or TT would have been more suitable and use of a SAD or routine tracheal intubation when RSI was indicated. The planned airway device was a (first generation) SAD in 61% and a TT in 34% of primary aspirations. Aspiration occurred most during induction or airway instrumentation (61%) and 90% had identifiable risk factors; the literature mirrors these findings.<sup>2 35 36 125</sup> Consequences of massive aspiration were notable; hypoxia was rarely extreme. A small proportion of patients died rapidly from airway obstruction; those surviving to ICU admission subsequently dichotomize into either recovery within 24-72 h or deterioration into Adult Respiratory Distress Syndrome, multi-organ failure and death. The ASACCP recently noted care more often judged substandard and plaintiff payments 2.4-fold higher in aspiration claims with identifiable risk factors when cricoid pressure was omitted.<sup>35</sup> ASACCP (52%) and NAP4 (42%) noted high rates of substandard or poor management in aspiration cases, respectively.<sup>35 50</sup>

Whether use of a SAD is associated with increased risk of aspiration remains contentious: neither the American nor UK medicolegal databases contain claims relating to aspiration during LMA general anaesthesia. An early review reported a risk of 1 aspiration per 5000 cLMA® cases.<sup>126</sup> A systematic review reported similar risk of regurgitation or aspiration compared with a TT<sup>116</sup> and several subsequent large series report low rates of aspiration: Verghese and Brimacombe,<sup>84</sup> 1 case in 11910 cLMA<sup>®</sup> uses; Bernardini and Natalini,<sup>127</sup> 3 cases in 35 620 cLMA® uses; and Ramachandran and colleagues,<sup>7</sup> 3 (possible cases) in 15795  $\mu$ LMA<sup>®</sup> uses. However, deaths have been reported.<sup>128</sup> <sup>129</sup> Risk of SAD-related aspiration increases with gastric inflation which is more likely ( $\sim$ 19%) if a first-generation device is used,<sup>130 131</sup> with high airway pressures,<sup>108</sup> and with poor SAD positioning over the glottis (seen in 40% of cases of gastric inflation).<sup>132</sup> Skilled insertion and SAD use are critical to reducing aspiration risk. Whether SADs with a drainage tube (i.e. second-generation SADs) should be used routinely to improve confirmation of correct positioning and reduce risk of aspiration is an on-going debate.<sup>52</sup> 133-135 The largest study of aspiration before the introduction of the LMA identified an incidence of aspiration of 1 in 4000 in elective cases and 1 in 900 emergencies during 215 000 general anaesthetics: 68.8% of aspirations occurred during laryngoscopy or extubation and the aspiration mortality rate was 1 in 71 829 general anaesthetics.<sup>125</sup> Assessment of aspiration risk and choosing an airway device/technique consistent with the identified risk is fundamental to safe anaesthesia. The risk of dying from aspiration during general anaesthesia appears to be falling.

#### Unrecognized oesophageal intubation

Unrecognized oesophageal intubation is rare, but the litigation literature and NAP4 reconfirm its importance. In the ASACCP, oesophageal intubation accounts for 14% of respiratory claims.<sup>8 31 33 34</sup> In 77%, there was no evidence of difficult intubation: 92 of 94 cases died (81%) or suffered permanent brain damage (17%). Oesophageal intubation claims are predominantly successful (82%) and expensive (median \$217 000). In the 1990s, the proportion of respiratory claims for oesophageal intubation decreased to 6%, but the absolute number decreased only modestly and still more than 90% led to death or brain damage. Claims are notable for errors of diagnosis with most cases preceded by false-positive clinical signs of successful tracheal intubation (auscultation in >60%) and diagnosis most commonly by subsequent cardiovascular collapse. Cyanosis was reported in 34% of cases and cardiovascular collapse in 84%. Misdiagnosis was contributed by 'preconceived notions of likelihood', 'reflex clinical behaviours', 'conflicting environmental data', and 'the potential for a rapid and poorly reversible clinical cascade'. In the Canadian dataset, oesophageal intubation accounted for 9 of 33 claims: 7 were during not difficult intubations; 6 died or suffered brain damage.<sup>37</sup> In the UK dataset, four claims describe oesophageal intubation (6% of airway claims), including three deaths and one of brain injury.<sup>1</sup> None recorded 'airway difficulty'. Capnography was rarely used in any of the reports and where available judgements as to quality of care were highly critical.

In the AIMS study, 35 oesophageal intubations (1 death) accounted for 1.75% all reports and 41% of all TT-related reports.<sup>47</sup> In NAP4, there were 11 oesophageal intubations (4% of reports) causing 6 deaths and 1 brain injury (64% event mortality rate, 16% of all deaths).<sup>2</sup> All were judged avoidable. Although more than half occurred outside theatres and were associated with failure to use capnography, four occurred during routine anaesthesia and failure to correctly interpret capnography, particularly during CPR, contributed. A flat capnography trace should be assumed to be because of oesophageal intubation until that has been actively excluded.<sup>2</sup> It is easy to assume oesophageal intubation is only of historical importance. The literature shows it is not.

#### Major airway trauma

Minor airway trauma is common but mostly transient. For major injury, again litigation summaries are useful for showing patterns of injury and critical incident reports offer some indication of incidence. Airway trauma accounts for 6% of ASACCP respiratory claims: predominantly in young healthy women during non-difficult airway management.<sup>33</sup> <sup>136</sup> The distribution of injuries and the percentage occurring during non-difficult airway management are: laryngeal 33% (80%), pharyngeal 19% (49%), oesophageal 18% (34%), tracheal 15% (34%), and temporomandibular joint 10% (100%), with the vast majority of pharyngeal, oesophageal, and tracheal injuries being perforations. Mortality from tracheal and oesophageal perforation is  $\sim 15-20\%$ .<sup>137</sup> Table 1 illustrates the similarity in distribution of airway claims in the US and UK litigation. Trauma accounted for one-third of UK airway claims including four deaths.

The vast majority of the above injuries occur in cases where TTs are used. <u>Videolaryngoscopy</u> has introduced <u>new</u> <u>risk</u> of <u>upper airway trauma</u> as rigid stylets are passed through the airway to come into vision in the VL field of view: there are numerous reports of injury.<sup>96</sup> Serious airway trauma from FMV and SAD use is vanishingly rare. Injuries to cranial nerves from use of <u>SADs</u> are rare, but can be severe including lingual, hypoglossal, and <u>recurrent laryngeal</u> nerve injury.<sup>138-141</sup> Vocal cord paralysis has also been reported.<sup>142</sup>

Life-threatening airway trauma was rare in NAP4: there was one case of non-fatal tracheal trauma as a result of the use of a bougie.<sup>50</sup> Importantly, however, minor trauma can lead to other complications. Blood in the airway (surgical or trauma) was highly associated with complications at emergence, including deaths. Such a situation was also central to a recent high-profile death in the UK.<sup>143</sup>

## Airway management outside the operating theatre

There is inadequate space to describe this large and important topic in detail. There are several recent reviews.<sup>13 49 50 144</sup> The most up-to-date data come from NAP4: at least 25% of major airway events reported to NAP4 were from ICU or the ED. The outcome of these events was more likely to lead to permanent harm or death than events in anaesthesia (anaesthesia 14%, ED 33%, ICU 61%) and to be avoidable. Overall the incidence of death or brain damage from an airway event was 38-fold higher in the ED and 58-fold higher in the ICU compared with anaesthesia, and  $\sim 1$  in <del>3000 v</del>entilate<del>d patients.<sup>145</sup> E</del>ven <del>accepting th</del>e different case-mixes, these findings are startling. Analysis of the cases identified gaps in care that included poor identification of at-risk patients, poor or incomplete planning, inadequate provision of skilled staff and equipment to manage these events successfully, delayed recognition of events, and failed rescue because of lack of or failure in interpretation of capnography. The frequency with which reports were judged to describe poor care was higher in ICU and ED than in anaesthesia.

<u>Failure to use capnography</u> in ventilated patients likely contributed to more than <u>70% of ICU deaths.</u> Increasing use of capnography on ICU is the single change with the greatest potential to prevent deaths from airway complications on ICU and elsewhere outside operating theatres.

In contrast to anaesthesia events, <u>most events</u> on ICU occurred during the 'maintenance phase' of the ICU stay. <u>Dis-</u> <u>placed tracheostomy</u> and to a lesser extent displaced TTs, were the <u>greatest cause</u> of major morbidity and <u>mortality</u> in ICU. <u>Obese</u> patients were at particular <u>risk</u> of such events and adverse outcome from them.

Most events in the ED were complications of RSI. RSI outside the operating theatre requires the same level of equipment and support as during anaesthesia, including capnography and difficult airway equipment.

The findings of NAP4 are mirrored in other literature. Concern about displaced tracheostomies has been identified by critical incident reporting.<sup>146</sup> Landmark work by Mort examined >10 000 emergency tracheal intubations in one institution over 10 years.<sup>76</sup> Compared with intubation achieved with 1–2 laryngoscopies, those requiring  $\geq$ 2 laryngoscopies led to a 7-fold increase in hypoxia (incidence 70%), 6-fold increase in oesophageal intubation (52%), 7-fold increase in aspiration (13%), and 7-fold increase in cardiac arrest (11%). Numerous other reports describe repeated laryngoscopy causing progression to CICV.<sup>2</sup> <sup>34</sup> When direct laryngoscopy fails, it should be abandoned sooner rather than later and an alternative strategy to airway management adopted (e.g. wake up, VL, SAD, or cricothyroidotomy).

Several authors have documented high (arguably unacceptable) failure and complication rates of tracheal intubation in ICU.<sup>13</sup> <sup>146</sup> <sup>147</sup> Protocolized care including senior clinicians and use of <u>neuromuscular blocking agents</u> for intubation has been shown to <u>reduce</u> complications.<sup>148</sup> Recent publications indicate a continuing lack of 'preparedness' for emergency and complex airway management<sup>149</sup> <sup>150</sup> and also report that <u>6% of ICU</u> patients may be considered to have '<u>high-risk\_airways'.<sup>150</sup></u>

The NAP4 authors recommended that <u>continuous capno-</u> <u>graphy</u> should be used for <u>all ventilated</u> patients dependent on an artificial airway in <u>ICU</u>. This recommendation is now also made (or expanded) by the Association of Anaesthetists of Great Britain and Ireland,<sup>151</sup> the <u>Intensive Care Society</u>,<sup>152</sup> and the European Board of Anesthesiology.<sup>153</sup> As a consequence of these changes, to not have continuous capnography on ICU (or in the ED) now goes against all mainstream recommendations in the UK and Europe.

## Human factors in major airway complications

Human factors including human error is implicated in up to 80% of anaesthetic critical incidents.<sup>154</sup> In the AIMS study, human failures were found in 83% of reports, including omitting checks, judgement errors, faulty technique, inattention, haste, inexperience, equipment, and communication problems.<sup>155</sup>

Human factors contribute to airway critical incidents in ways as simple as poor communication, poor teamwork,

failure to act (e.g. performing ESA in CICV),<sup>108</sup> and failure to call for help (improved by provision of experienced anaesthetic assistance).<sup>156</sup> Human factors extend to institutional organization and structure, provision or design of equipment, availability, and use of SOPs.<sup>157</sup>

In NAP4, all the above factors were repeatedly seen during case review.<sup>50</sup> Issues of judgement, communication, and training were prominent. Equipment issues and failure of SOPs were more prominent in ICU and reports describing poor outcome. The nature of the 'arms-length' reporting processes for NAP4 makes extracting such factors difficult and this is likely in medicolegal analyses. In NAP4 human factors were noted in 40% of reports and were contributors to poor outcome in one-quarter. A follow-up investigation suggests that human factors can be identified in all such cases (R. Flin, Prof. of psychology, Aberdeen, personal communication, 2012). NAP4 recommended the use of checklists and SOPs in a number of circumstances including intubation outside the operating theatre and recognition and rescue of displaced airways in ICU.<sup>2</sup> <sup>49 50</sup>

Further study of human factors in major airway complications would improve understanding potentially reducing their incidence and improving their management when they occur.

## Conclusions

Complications of airway management that lead to temporary patient harm are common but serious injury is rare. Because most airways are easy, most complications occur in easy airways; these complications can and do lead to harm and death. Avoidance of airway management complications requires careful assessment, good planning and judgement, good communication and teamwork, knowledge and use of a range of techniques and devices, and a willingness to stop performing techniques when they are failing.

All airway management techniques fail and prediction scores are rather poor so that many such cases are unanticipated. Institutions and individuals should be prepared in advance to manage difficulty of failure of airway techniques. Prompt correct management of airway emergencies, through training, should therefore become routine.

<u>Pulmonary aspiration</u> remains a major concern and the <u>leading cause</u> of <u>airway-related anaesthetic deaths</u>. In most cases, risk factors exist and care is not optimal.

A significant proportion of airway complications occur in the ICU and ED. These complications occur more frequently than in operating theatres, are more likely to lead to patient harm/death, and are more often contributed to by suboptimal care and absent capnography.

Research to reduce the risk and impact of airway complications might include the following topics:

- Improving risk prediction.
- Clarifying which second-generation SADs increase protection against aspiration and to what extent.
- Defining which RSI technique is safest.
- Determining whether any novel intubation devices are better than direct laryngoscopy for routine intubation.

- Determining which novel intubation devices are better than direct laryngoscopy for DTI and which ones are best.
- Defining which ESA technique is best for managing CICV.
- Exploring why similar aspiration events apparently lead to distinct clinical responses and whether we can modify the adverse responses.
- Determining why patients differ in their tolerance of profound hypoxia.
- Exploring and learning from human factors in critical airway events.

## Avoidance of airway complications

One aim of the review is to provide learning from a large amount of information on a topic. We suggest 'tips' that we developed in the process of writing this review. These can be seen as aides to reduce the risk of causing airway complications and to minimize harm to patients when they occur.

- Believe the history and act on a history of previous airway <u>difficulty.</u> Using the <u>same technique</u> that was previously difficult is likely to be <u>difficult again</u>, or fail.
- Assess every patient for risk of airway difficulty and of aspiration. Where such risk is identified, ensure the airway strategy (techniques, devices, and back up plans) is consistent with the findings and potential difficulties. When assessment suggests likely difficulty with one technique, pay particular attention to the feasibility of others as they are both more likely to be necessary but are also more prone to failure.
- Never fail to be prepared for failure. It happens: even when not predicted. The skilled, prepared anaesthetist will have numerous options to manage failure and will have decided the appropriate strategy (next step) before starting. Full preparation involves training, institutional preparedness, and personal preparedness.
- **Communicate** strategies to the team before undertaking anaesthesia; and difficulty or failure to the team when they occur. This helps your team (and you) to understand what is going on and seek solutions.
- Do what you can but do not do what you cannot for the patient. Elective airway management should be chosen to suit the patient's needs, not that of the anaesthetist or trainees. Using untried techniques during airway difficulty is not acceptable. Where you do not possess the skills your responsibility is to find someone that does, whether this is in your hospital or another. <u>'Doing your best'</u> is <u>not good</u> <u>enough</u> if your best is not the right thing for the patient. Being skilled in a wide range of skills will reduce the likelihood of this occurrence.

- Do not intubate when it is not indicated. Intubation is associated with more minor and serious complications than alternative techniques. The idea of <u>'intubation</u> as the <u>gold standard'</u> for all airway management is <u>outdated.</u>
- Do intubate when indicated. Intubation provides the most secure and protected airway available and is likely to be needed for all cases at high risk of aspiration, most emergency cases and many high-risk cases.
- Pre-oxygenate fully before every general anaesthetic. Science and logic demand this.
- Know and practice a wide range of anaesthetic airway techniques. The increasing range of available airway techniques means that some anaesthetists are unprepared. All anaesthetists should know alternative methods of intubation (e.g. videolaryngoscopy, intubation via an SAD), how to rescue a failed airway, and when and how they will wake the patient if difficulty occurs.
- Learn techniques you think you will never use. All anaesthetists should be prepared to manage IMV and CICV. These complications occur in most hospitals every year.
- If it is not working stop and do something different. All airway techniques fail on occasions. If a technique fails twice, it is highly unlikely to succeed and alternative techniques have a higher chance of success. Repeating the same failing technique increases both the likelihood of complications and failure of alternative techniques.
- Do not ever forget the possibility of oesophageal intubation and <u>always use capnography</u> to <u>confirm success-</u> <u>ful</u> <u>intubation</u> and ventilation. Unrecognized oesophageal intubation continues to cause deaths. These are 100% avoidable.
- Treat ICU and ED as places of danger. The risk of airway misadventure in these settings is dramatically increased. Demand the same levels of equipment and assistance, and maintain the same standards of airway management, that you would for routine anaesthesia. Capnography is mandatory.

## **Declaration of interest**

T.M.C. has been paid, more than five years ago, by the LMA Company and Intavent Direct (then manufacturers of the laryngeal mask airway). His department has received items of airway equipment for free or at cost for research. Neither author, nor their families, has any financial interest in any such company as far as they are aware. T.M.C. was a lead and first author of the 4th National Audit Project of the Royal College of Anaesthetists and Difficult Airway Society, which is described in some detail.

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