

SPECIAL ARTICLES



Major complications of airway management in the UK: results of the Fourth National Audit Project of the Royal College of Anaesthetists and the Difficult Airway Society. Part 1: Anaesthesia†

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Background. This project was devised to estimate the incidence of major complications of airway management during anaesthesia in the UK and to study these events.

Methods. Reports of major airway management complications during anaesthesia (death, brain damage, emergency surgical airway, unanticipated intensive care unit admission) were collected from all National Health Service hospitals for 1 yr. An expert panel assessed inclusion criteria, outcome, and airway management. A matched concurrent census estimated a denominator of 2.9 million general anaesthetics annually.

Results. Of 184 reports meeting inclusion criteria, 133 related to general anaesthesia: 46 events per million general anaesthetics [95% confidence interval (CI) 38–54] or one per 22 000 (95% CI 1 per 26–18 000). Anaesthesia events led to 16 deaths and three episodes of persistent brain damage: a mortality rate of 5.6 per million general anaesthetics (95% CI 2.8–8.3): one per 180 000 (95% CI 1 per 352–120 000). These estimates assume that all such cases were captured. Rates of death and brain damage for different airway devices (facemask, supraglottic airway, tracheal tube) varied little. Airway management was considered good in 19% of assessable anaesthesia cases. Elements of care were judged poor in three-quarters: in only three deaths was airway management considered exclusively good.

Conclusions. Although these data suggest the incidence of death and brain damage from airway management during general anaesthesia is low, statistical analysis of the distribution of reports suggests as few as 25% of relevant incidents may have been reported. It therefore provides an indication of the lower limit for incidence of such complications. The review of airway management indicates that in a majority of cases, there is ‘room for improvement’.

Keywords: airway; audit; brain damage; complications; cricothyroidotomy; death; emergency department; intensive care, tracheostomy

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Airway management is fundamental to safe anaesthetic practice and in most circumstances is uncomplicated, but it has been recognized for many years that complications of airway management occur with serious consequences.^{1–2} Good-quality information on the frequency and nature of major adverse events related to anaesthetic airway management is incomplete. Litigation-based analyses add some insight into the severity of such events and have driven changes in practice.^{3–6} These indicate that airway and respiratory complications leading to litigation are a small proportion of all claims against anaesthetists but are associated with notably high rates of death and brain damage, high rates of ‘less than appropriate care’, and high costs.

Owing to the complexity of the relationship between complications and litigation, and the lack of denominators, they do not add information about prevalence or incidence of complications.^{7–8} Analyses of critical incident reports in the UK have also added useful information, but these reports largely focus on minor incidents and are likely to miss a considerable proportion of major events.⁹

Knowledge of the incidence of such complications should be an important component of clinical decision-making, risk management, and the consent processes. Information on serious and common complications should guide the specialty into appropriate areas for research by demonstrating areas in which our current practice or performance can improve.

† This article is accompanied by the Editorial.

The Fourth National Audit Project of the Royal College of Anaesthetists (RCoA) and the Difficult Airway Society (DAS) (NAP4) was established to estimate the incidence of major complications of airway management in NHS hospitals in the UK and to perform a quantitative and qualitative analysis. Three areas of clinical practice were identified and considered separately:

- airway management during anaesthesia;
- airway management in the intensive care unit (ICU);
- airway management in the emergency department.

This paper, which reports complications of airway management during anaesthesia, and the accompanying paper, which reports on complications during airway management in ICU and the emergency department, present the major results of the project.¹⁰ For reasons of space, this paper is limited to an overview of events that were reported to the project and their quantitative analysis. It should be read in conjunction with the full report of the project available on <http://www.rcoa.ac.uk/index.asp?PageID=1089>.

Methods

A two-part project was devised using methods based on the Third National Audit Project of the RCoA.¹¹ First, a census of airway management techniques used in the UK National Health Service (NHS) provided information on anaesthetic activity and airway management techniques in current use (for denominator information); secondly, a registry of the major complications of airway management over a 12 month period recorded details of serious adverse events (for numerator information). Discussions with the National Research Ethics Service indicated that ethical approval was not required. The project was examined by the Patient Information Advisory Group of the Department of Health and the project design was assessed to ensure current standards of patient confidentiality were met. There was wide consultation with other specialist societies and organizations with an interest in this area of clinical care.

Using surface mail, e-mail, and telephone, the anaesthetic department in every NHS hospital in the UK was contacted and invited to participate in the project and to nominate a local reporter who would act as the point of contact for the audit, co-ordinate the census of current activity, and assist with the second phase during which reports of individual serious complications were to be submitted. Data were not sought from private hospitals or Independent Sector Treatment Centres. However, data were collected from treatment centres attached to NHS hospitals.

A detailed written explanation of the NAP4 project and the purpose of the census were placed on both the DAS and RCoA websites. Data collection forms and information sheets were also made available for downloading. The project was very widely advertised in UK journals of anaesthesia, by specialist societies (see Supplementary Appendix) and by a poster campaign to promote awareness and encourage participation. Reminders were sent to hospital local

reporters approximately every 6–8 weeks throughout the data collection period.

Part 1: census of clinical activity (denominator data)

A detailed description of the census phase has been published,¹² but a brief summary is appropriate here. Each local reporter was asked to return data for a 2-week period in September 2008 on the number of anaesthetics performed in the hospital other than in the ICU and emergency department. For each general anaesthetic, detailed information on the primary airway management technique, defined as that 'used for maintenance of anaesthesia' (facemask, supraglottic airway device, or tracheal tube), was requested. Tracheal intubation included all forms of intubation of the trachea, that is, single- and double-lumen tubes, tracheostomy, surgical bronchoscopy, transglottic, and trans-tracheal techniques. The decision on how to collect these data was left at the discretion of the local reporter. Local data were summed to give cumulative totals and submitted to the project team. After collating all returns, the project team used the submitted data to estimate national annual activity and primary airway techniques used.

Part 2: event reporting (numerator data)

Inclusion criteria

Triggers for inclusion and notification to the project were *complications of airway management* that led to: death, brain damage, the need for an emergency surgical airway, unanticipated ICU admission, or prolongation of ICU stay.

Reports of events occurring in the ICU, in the emergency department, or during transfer were also requested, but these were not used for the calculation of incidence of complications associated with anaesthesia and are the subject of a separate publication.¹⁰ The project did not collect data on events occurring out of hospital or on hospital wards.

Definitions

Brain damage was available as an inclusion criterion. Although this was not defined in detail, the manifestations of central nervous system injury and deficit at 1 month were requested.

Emergency surgical airway was taken to include all forms of emergency access to the upper trachea as part of airway management (i.e. surgical tracheostomy, surgical cricothyroidotomy, needle or cannula cricothyroidotomy, or tracheotomy). Emergency surgical airway was an inclusion criterion only when it did not form part of the primary airway management plan. Thus, if a patient presented with critical airway obstruction and required a surgical airway which was planned and performed successfully either after tracheal intubation or without attempting intubation, the case did not meet inclusion criteria. Where the primary airway management plan failed and a needle/cannula or a surgical airway was performed, this was deemed to meet inclusion criteria.

ICU admission that was required as a result of an airway problem was an indication for inclusion. For patients on the ICU, an airway event which would have led to admission to

ICU or which led to prolongation of ICU treatment was an inclusion criterion.

Obesity. Reporters were asked to indicate the patient's weight and height and body habitus. Obesity was defined as a body mass index (BMI) of $>30 \text{ kg m}^{-2}$ or obese body habitus.

Notification of events

The RCoA-lead (T.M.C.) was notified of events meeting inclusion criteria by e-mail. Local reporters or clinicians involved in the event usually informed the RCoA-lead of an event, but notifications were accepted from any source. The notifier was required to provide their name, the date of the event, the hospital name, and the location of the event. No other identifying data were accepted, including patient or clinician details. The RCoA-lead then e-mailed the local reporter for that hospital, specifying the project inclusion criteria, and requesting confirmation that the case met the criteria and was not a duplicate notification.

Moderator

A moderator was available who was able to discuss the case and offer a confidential opinion on inclusion/exclusion. The moderator was not part of the case review process and could be contacted directly rather than via the RCoA-lead. Cases deemed not to meet the inclusion criteria were withdrawn from the project before being submitted for panel review.

Secure website

For cases meeting criteria, the local reporter was issued with a *unique identifying number* and *website access password* using a remote process enabling a secure connection to the project website for on-line data submission. The RCoA-lead had no access to the password but was aware of the unique identification number, which was used to 'track' the case.

Data submission

Data were submitted by the local reporter or the clinician involved in the case according to the local preference. After logging on for the first time, a mandatory change of access password was required before proceeding to the reporting forms. The website directed the person submitting data to specific submission forms for reporting of events during anaesthesia, in ICU, or the emergency department. The clinician submitting data could make multiple visits to the website to enter additional data as more information became available. When a report was complete, it was closed and submitted electronically, after which no further changes could be made. The RCoA-lead was unable to view the submitted data but could follow the progress of cases on-line by using the unique identifier to note whether the case was recorded as 'password unchanged', 'password changed', or 'form closed'. Regular review of the website enabled the RCoA-lead to identify where there were delays

in data submission and to encourage submission by direct contact with the local reporter. When a file was completed and submitted, this was notified automatically to the DAS-lead (N.W.). Files were downloaded by the DAS-lead and saved in Word and Excel format for review. If more information was needed, files could be re-opened and a message sent to the local reporter through the project website by a remote process. The DAS-lead was able to access all submitted files but had no knowledge of their origin. In contrast, the RCoA-lead knew event locations but had no access to any files. It was a pre-condition of the project imposed by the Patient Information Advisory Committee of the Department of Health that these two pieces of data could not be linked. Identifying numbers were not present on any information reviewed by the review panel.

Events were included in NAP4 from September 1, 2008, to August 31, 2009: notifications were accepted until June 2010, after which the identification numbers issued to local reporters were destroyed by the RCoA-lead.

Case review panel

Each clinical report was reviewed by a panel of representatives from all the parties involved in the project: the RCoA, DAS, the Association of Anaesthetists of Great Britain and Ireland, the Association of Paediatric Anaesthetists, the Association for Peri-operative Practice, British Association of Otorhinolaryngologists (ENT-UK), the College of Emergency Medicine, the College of Operating Department Practitioners, the Intensive Care Society, the National Patient Safety Agency, the Obstetric Anaesthetists Association, and the Patient Liaison Group of the RCoA.

Case review process

Each clinical case was reviewed at least twice. At each review meeting, the reviewers were in two equal groups (at least five members with differing clinical backgrounds). Each group reviewed half of the cases and when these had been reviewed, the two groups re-joined. Each case was then presented and re-reviewed by the whole panel. If a report was unclear, more information was sought using the process outlined previously. The case was first reviewed to determine whether it met inclusion criteria and to identify duplicate reports. Cases meeting inclusion criteria were included and reviewed, those which did not were removed. The review panel indicated if the event showed underlying contributory, causal, or positive factors (Table 1). Causal factors were those that were considered directly linked to the event whereas contributory factors were those with evidence of impact on the event without being causal. Positive factors indicated areas judged to be of notably good management. The degree of harm attributable to the event was graded using the National Patient Safety Agency (NPSA) severity of outcome scale for patient safety incidents (Table 2).¹³ Cases with an outcome of death and persisting brain damage were also extracted. Cases were analysed for learning points and some were selected to act as illustrations of

Table 1 Categories of incident contributory factors. Each case was examined for causal, contributory or positive factors in these categories. Categories are taken from the National Patient Safety Agency document *Seven Steps to Patient Safety: A Guide for NHS Staff*¹³

| Factors |
|---|
| Communication (includes verbal, written, and non-verbal: between individuals, teams, and/or organizations) |
| Education and training (e.g. availability of training) |
| Equipment/resource factors (e.g. clear machine displays, poor working order, size, placement, ease of use) |
| Medication (where one or more drugs directly contributed to the incident) |
| Organization and strategic (e.g. organizational structure, contractor/agency use, culture) |
| Patient (e.g. clinical condition, social/physical/psychological factors, relationships) |
| Task (includes work guidelines/procedures/policies, availability of decision-making aids) |
| Team and social (includes role definitions, leadership, support, and cultural factors) |
| Work and environment (e.g. poor/excess administration, physical environment, work load and hours of work, time pressures) |
| Other |

Table 2 Severity of outcome scale. Categories are taken from the National Patient Safety Agency document *Seven Steps to Patient Safety: A Guide for NHS Staff*.¹³ *First aid, additional therapy, or additional medication. Excludes extra stay in hospital, return to surgery or readmission. **Return to surgery, unplanned re-admission, prolonged episode of care as in- or out-patient or transfer to another area such as intensive care. ***Permanent lessening of bodily functions, sensory, motor, physiological, or intellectual

| Grade of severity | Description |
|-------------------|--|
| None | No harm (whether lack of harm was due to prevention or not) |
| Low | Minimal harm but necessitating extra observation or minor treatment* |
| Moderate | Significant, but not permanent harm, or moderate increase in treatment** |
| Severe | Permanent harm due to the incident*** |
| Death | Death due to the incident |

clinical care for inclusion in a detailed report of the project. Airway management was classified as good, poor, mixed (elements of both good and poor management), or unclassifiable, reviewers were reminded of likely outcome¹⁴ and hindsight bias.¹⁵ Reviewers were instructed on the strict confidentiality of the process and if a reviewer was aware of a case (e.g. the case came from their hospital), external knowledge was not admissible in the review process. Clear errors in submitted data (e.g. a fatal outcome not being recorded) were corrected at this time.

Incidence calculations

Cases were included in the numerator where an airway complication of anaesthesia met inclusion criteria and had been performed within the data collection period in an NHS hospital. Data were collected on events in the ICU and emergency departments but were not used in calculation of the incidence of complications during anaesthesia.

The data were entered into a Microsoft Excel 2007 spreadsheet (Microsoft Corporation, USA) and incidences were calculated (by dividing the numerator for a given group by the relevant denominator). Confidence intervals (CIs) were derived using binomial probability tests with the stat-conf programme (*Handbook of Biological Statistics* 2008, <http://udel.edu/~mcdonald/statconf.html>).

Missing reports

Although the individual case reports were anonymous, the RCoA-lead retained the date and source of individual reports. Data on the number and source hospital of events were examined for evidence of clustering by time and place in an attempt to assess the completeness of data collection. Reports from local reporters (i.e. in which the local reporter was also the anaesthetist) were identified. It was assumed that all local reporters would return all cases meeting inclusion criteria and therefore that this small highly motivated group could be used to create an upper estimate for the number of cases that might have been reported if all anaesthetists acted as local reporters did.

Results

Agreement to participate and appointment of a local reporter was established in all 309 NHS hospitals by September 2008. In total, 286 local reporters were appointed with some representing more than one hospital.

Numerator data (complications reported)

A total of 286 cases were reported to the RCoA-lead or discussed with the moderator. Seventy-nine reports were withdrawn after discussion with the moderator or the reporter reviewed the inclusion criteria sent by the RCoA-lead: 207 cases were reviewed by the review panel. During the review process, additional information, using the methods described above, was requested from the reporters of 12 of the cases. After final review, 184 reports met the inclusion criteria. Of the 184 reports, 133 complicated the management of anaesthesia, 36 occurred in patients on ICU, and 15 in the emergency department.

Capture of cases

Hospital clustering

Reports were received from 42% of hospitals and a minority of hospitals accounted for disproportionately high percentages of reported cases (Table 3). Four per cent of hospitals reported 23% of cases, 6% reported 34%, and 15%

reported 59% of the cases. An analysis of the distribution of reports suggested that they did fit a Poisson distribution, consistent with complete data capture, but not confirming it.

Person clustering

Local reporters reported 19 anaesthesia-related events (i.e. the local reporter was also the anaesthetist) out of 130 where this information was provided. There were 286 local reporters and the 2007 RCoA census identified 6233 consultant anaesthetists¹⁶ (i.e. 4.6% of all consultant anaesthetists). If all consultant anaesthetists behaved as local reporters, we might anticipate $19 \times 6233 / 286 = 414$ reports from consultants. As 36% of cases occurred in the absence of a consultant, this figure for all anaesthetists might increase to $414 \times 100 / (100 - 36) = 414 \times 1.56 = 646$. As this figure is based on only 130 of the 133 anaesthesia cases, our upper limit of cases is $646 \times 133 / 130 = 661$. This figure suggests that, at worst, we captured approximately one in five of relevant cases. It is likely that this figure should be adjusted further: part-time consultants account for 10% of the consultant workforce and up to one-third of departmental 'consultant anaesthetist' activity is delivered in ICU, pain clinics, management, and academia. Further adjustments might be made that are almost limitless and increasingly speculative, but we conclude that we may only have captured one in three or one in four cases that occurred.

Patient characteristics

There were a total of 113 males and 71 females, including 82 male and 51 female anaesthesia cases (Table 4). The majority of anaesthesia cases were ASA I or II (56%), males (62%), and age <60 yr (61%). A BMI of >30 kg m⁻² or obesity was recorded in 40% and a BMI of <20 kg m⁻² or cachexia in 11%. The majority (54%) of the procedures were elective or scheduled. The event occurred during normal working hours (08:01–18:00) in 69%, out of hours before midnight (18:01–24:00) in 17% and out of hours after midnight (00:01–08:00) in 14%. The anaesthesia events occurred in the operating theatre (47%), anaesthetic room (37%), and recovery unit (14%). The phase of anaesthesia was induction (52%), maintenance (20%), emergence (16%), and in the recovery phase (12%). In 63% of anaesthesia cases, the most senior anaesthetist present at the start of the event was a consultant. A locum anaesthetist was the main anaesthetist in 5% of cases. A request for help around the time of an anaesthetic airway event was recorded in 95 (70%) cases and assistance arrived without request in a further four. The time to arrival of assistance was recorded in 99 cases: 32 in <1 min, 43 in 1–4 min, 21 in 5–30 min, and three after >30 min. Of 97 identified responders, 69 were consultants in anaesthesia/intensive care medicine, 13 consultant surgeons, 11 senior anaesthesia trainees, two anaesthetic non-consultant career grades, and two surgical trainees. Of 70 requests for help made

Table 3 Clustering of cases by hospital. Analysis of 207 reviewed cases

| Number of cases reported | Number of hospitals | Per cent of hospitals | Per cent of all cases |
|--------------------------|---------------------|-----------------------|-----------------------|
| 7 | 1 | 0.3 | 3.3 |
| 6 | 0 | 0.0 | 0.0 |
| 5 | 1 | 0.3 | 2.4 |
| 4 | 9 | 2.9 | 17.2 |
| 3 | 8 | 2.6 | 11.5 |
| 2 | 26 | 8.5 | 24.9 |
| 1 | 85 | 27.7 | 40.7 |
| 0 | 177 | 57.7 | 0.0 |
| Sum | 307 | 100 | 100 |

Table 4 Incident reports classified: by ASA grade and type of event; by age and type of event; and by inclusion criteria provided by the reporter. More than one inclusion criterion could be chosen. Note that some deaths were considered by the review panel not to be causally related to the event, in other cases patients reported with an inclusion criterion of brain damage either made a full recovery at the time of reporting or died. Therefore, figures in this table do not exactly match final outcomes in Table 5. *Prolongation of stay in the case of patients already in ICU

| | All cases (n=184) | Anaesthesia (n=133) |
|--------------------------------------|-------------------|---------------------|
| ASA | | |
| I | 26 | 23 |
| II | 62 | 51 |
| III | 59 | 40 |
| IV | 29 | 13 |
| V | 3 | 2 |
| Not recorded | 5 | 4 |
| Age | | |
| <10 | 10 | 8 |
| 11–20 | 8 | 6 |
| 21–40 | 39 | 26 |
| 41–60 | 56 | 41 |
| 61–80 | 60 | 44 |
| >80 | 10 | 7 |
| Not recorded | 1 | 1 |
| Reporter provided inclusion criteria | | |
| Death | 33 | 14 |
| Brain damage | 13 | 6 |
| ESA | 75 | 54 |
| ICU admission* | 122 | 100 |
| Sum | 243 | 174 |

during the airway event, in 21 the response time was <1 min, in 36 was 1–4 min, in 11 was 5–30 min, and in two was >30 min: five of the 13 events with a response time >5 min occurred out of hours.

Inclusion criteria and event outcomes

Death

Death resulting from an airway problem was the inclusion criterion for 33 reports (Table 5), of which 14 occurred during anaesthesia, 16 in ICU, and three in the emergency department (Table 4). In 10 further cases, the reporter indicated a lower severity inclusion criterion but also that the patient died before the report was submitted. Of these 10 'late deaths', the airway event was judged causal in three, contributory in two, and unrelated in five. In total, there were therefore 38 deaths attributable to an airway event: 16 during anaesthesia, 18 on ICU, and four in the emergency department. Hypoxia was the common theme in deaths caused by an airway problem, though in several late deaths, sepsis and single or multi-organ failure was recorded. Death rate for all cases was 38/184 (20.7%) and for events during anaesthesia 16/133 (12.0%).

Brain damage

In 13 patients, brain damage was provided as an inclusion criterion (Table 5), and three other cases were identified during case review. Six of these patients died and two made a full recovery (e.g. post-event fitting or depressed level of consciousness that fully resolved). Eight cases of persistent non-fatal brain damage were identified: three events occurred during anaesthesia, four in ICU, and one in the emergency department. Reported outcomes included permanent low conscious level, neuro-behavioural deficit, or 'persistent vegetative state' (recorded after 1 month, although it would require a year to elapse before this diagnosis could be made). The combined rate of death and brain damage for all cases was 46/184 (25.0%) and for events during anaesthesia 19/133 (14.3%).

Table 5 Final outcome: narrative outcome and NPSA classification (Table 2)

| | All cases (n=184) | Anaesthesia (n=133) |
|----------------------------------|----------------------|------------------------|
| 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 |

Emergency surgical airway

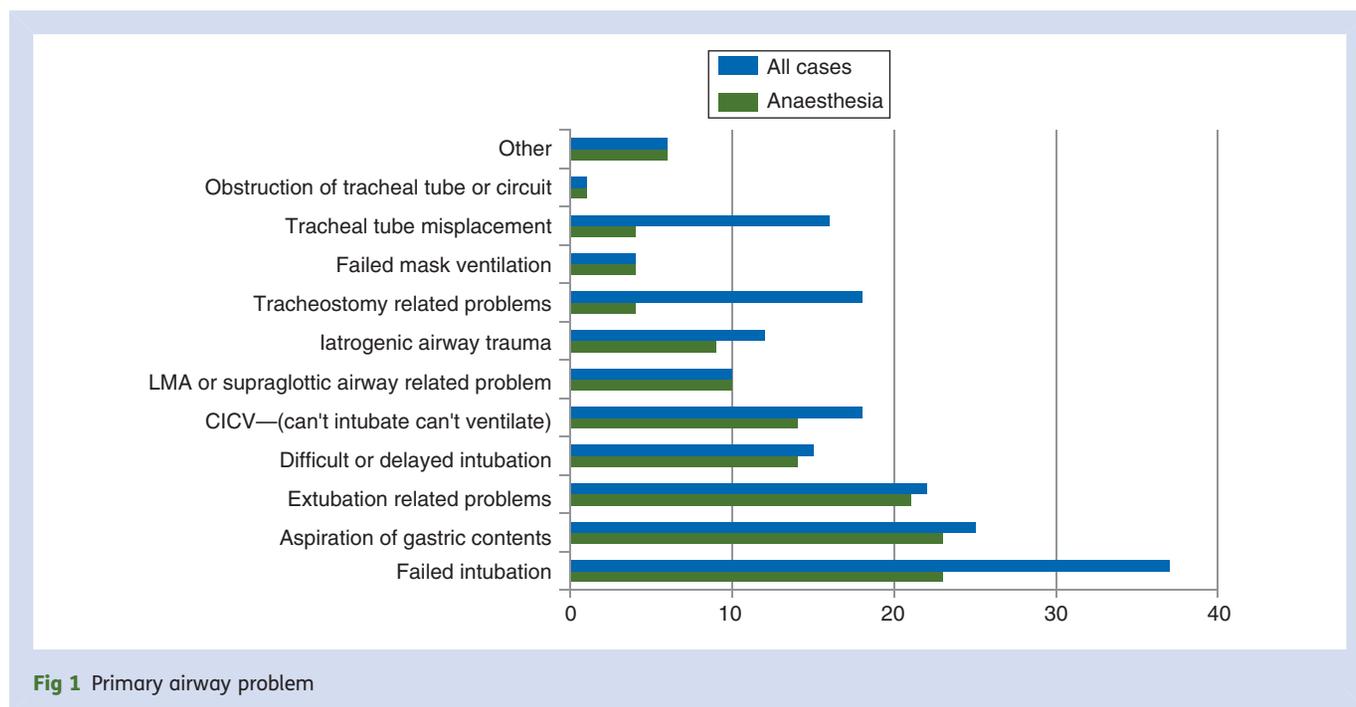
An attempt at emergency surgical airway was reported in 80 of 184 reported cases (43%) with only 75 being recorded as indications for inclusion. An emergency surgical airway was attempted in 58 (43%) of the 133 anaesthesia-related reports.

In 29 anaesthesia cases, the first choice for emergency surgical airway was tracheostomy: 18 in semi-controlled circumstances where intubation had failed or not been attempted, but the airway could be maintained on a face-mask or laryngeal mask and in 11 cases as a true emergency rescue technique for a patient in extremis. All emergency tracheostomies were successful, although not always without difficulty or delay. Two patients in this group died, one because the tracheostomy was not able to bypass a low-lying obstructing tracheal tumour and one died later due to severe hypoxia occurring before the tracheostomy was performed. Cricothyroidotomy was the first approach in 29 cases: 19 with a narrow-bore (≤ 2 mm) cannula, seven with a wide-bore cannula, and three with a surgical approach. Twelve of 19 narrow-bore cannula cricothyroidotomy failed with rescue achieved by surgical tracheostomy in seven, surgical cricothyroidotomy in two, wide-bore cannula in one, and successful oral intubation in two. Three out of seven wide-bore cannulae failed and were rescued with tracheostomy, surgical cricothyroidotomy, or tracheal intubation. The three first-choice surgical cricothyroidotomies were all successful. Of 58 attempts at emergency surgical airway, nine (16%) failed to rescue the airway: 51 (88%) patients made a full recovery from the incident, three (5%) a partial recovery, and four (7%) died: two after successful surgical airway and two after failure.

Of the 58 cases requiring emergency surgical airway, this was performed by a surgeon in 33 cases (mostly head and neck surgeons during relevant cases) and by an anaesthetist in 25. Only nine of these 25 anaesthetic attempts were successful in rescuing the airway; 11 failures were rescued by a surgeon-performed tracheostomy, one by percutaneous tracheostomy placed by a colleague, three by tracheal intubation, and one patient died.

ICU admission

ICU admission (or prolongation of stay) was reported as an inclusion criterion in 122 cases, including 100 patients following an airway event during anaesthesia. Reported indications for admission to ICU following anaesthesia-related events were to manage airway swelling or trauma in 38 patients, aspiration of gastric contents or blood in 32, hypoxia due to post-obstructive pulmonary oedema in 13, failure to awaken after surgery in 13, or myocardial ischaemia or cardiac arrest in four. Of the 100 admitted to ICU after an anaesthesia-related airway event, 12 died, seven made a partial recovery, and 81 were reported to have made a full recovery. Of the 29 patients admitted to ICU with aspiration of gastric contents, aspiration during anaesthesia was the primary airway event in 23, while in six it



complicated another primary event: eight of these patients died and two suffered brain damage.

Primary airway problem during anaesthesia

Problems with tracheal intubation were the most frequently recorded primary airway problem (Fig. 1). Difficult or delayed intubation, failed intubation, and 'can't intubate can't ventilate' (CICV) accounted for 39% of all events and events during anaesthesia. Aspiration then extubation problems followed tracheal intubation in frequency of reported complications. For anaesthesia events, aspiration, CICV, and problems during use of a supraglottic airway, iatrogenic airway trauma, and failed mask ventilation were the next most prominent complications.

Primary airway device during anaesthesia

For anaesthesia events, the airway in use or intended for maintenance was: tracheal tube of any sort (91), supraglottic airway device (35), and facemask (7) (Table 6).

Incidence of incidents

The total number of events reported in relation to anaesthesia was 133. The number of anaesthetics administered in the same period derived from the census phase of NAP4 was 2.9 million (2 872 600),¹² giving a minimum incidence (point estimate) of 133/2 872 600: i.e. 46 per million or approximately one per 22 000 general anaesthetics. Using binomial statistics, we can estimate an upper 95% confidence limit of 54 per million and a lower CI of 38 per million (although as the actual event rate in our

population cannot be lower than that we observed, some might omit this value).

Using the same methodology, we can calculate the point estimate and CIs for incidence of death (or death and brain damage) from an airway event during general anaesthesia (Table 7). The census data also provided estimates of frequency of use of airway devices (tracheal tube, supraglottic airway device, and facemask) and estimates of the risk of events and poor outcomes with these devices can be derived (Table 7).

Case-mix

Aspiration of gastric contents

Aspiration of gastric contents was the primary event in 23 anaesthesia cases, two emergency department cases, and no ICU cases. It was the most common cause of death in the anaesthesia group accounting for eight deaths and two cases of brain damage. Aspiration occurred most frequently in patients with risk factors (>90%), at induction of anaesthesia or during airway instrumentation (61%). Planned airway management was as follows: laryngeal mask 13, i-gel 1, tracheal tube 8, and none 1. Aspiration occurred before airway instrumentation in five cases and during airway placement in two. Two cases had clear indications for rapid sequence induction (RSI) and in several others, its use could be argued, one case occurred during RSI laryngoscopy. Management of the cases was judged good in four, mixed in seven, and poor in eight, with management judged poor in four deaths. Aspiration also complicated

other primary events (secondary aspiration), most frequently difficult or failed intubation. There were six such events in anaesthesia cases. Aspiration of blood was the primary event in five anaesthesia cases, one of which led to death.

Head and neck cases

Seventy-two reported cases (39%) involved an airway problem in association with an acute or chronic disease process in the head, neck, or trachea. Approximately 70% of these reports were associated with obstructive lesions within the airway. The qualifying airway event was death or brain damage in 13 cases, emergency surgical airway in 50, and unexpected ICU admission in 27. The outcome at the time of form completion (if recorded) was death in 17, partial recovery in two, and full recovery in 51 cases. These cases included 55 anaesthesia cases. Forty-two involved anaesthesia for diagnostic or resection surgery, with problems occurring at induction in 21 cases, during maintenance in eight and during extubation or recovery in 13. In 10 patients, complications arose during induction of

anaesthesia primarily to secure a critical airway. Three complications were reported in patients after elective head and neck surgery, who returned to theatre from wards for urgent reoperation. The reviewers assessed airway management as poor in nearly one-third of reported cases. Issues of assessment, planning, and communication within teams were prominent in these cases.

Obstetrics

There were four reported events in pregnant women: all involved emergency Caesarean section and problems at the time of intubation. All took place out of hours and involved complex patients (two of whom had a BMI >35 kg m⁻²) and were managed by senior anaesthetists: in two, a consultant was present throughout; in one, a staff grade; and in one, a year 6 specialist trainee. Consultants attended in all cases. Two cases occurred during an operation where anaesthesia was induced for failed regional anaesthesia. One patient had a secondary aspiration (i.e. aspiration complicated another primary airway event), one had a failed cricothyroidotomy attempt, and one a successful surgical airway. All were admitted to ICU and made a full recovery.

Paediatrics

There were 10 events in children under the age of 10 yr: eight during anaesthesia, and one each in ICU and in the emergency department. Five cases were infants and nine were children aged <4. Outcomes included three deaths. Of the eight anaesthetic complications, there were four cases of difficult intubation (two due to subglottic narrowing), two aspirations (one of blood after tonsillectomy), one due to tracheal tube blockage by secretions, and one patient required an emergency tracheostomy during the removal of a foreign body. One child died, one had persistent stridor, and six recovered fully. All patients were anaesthetized in the presence of a consultant. The review panel considered

Table 6 Primary airway used or intended for maintenance of anaesthesia

| Airway | |
|---|-----|
| Tracheal intubation (including fiberoptic intubation) | 82 |
| Laryngeal mask airway | 32 |
| Hudson mask/nasal cannulae | 4 |
| Rigid bronchoscopy | 4 |
| Another supraglottic device | 3 |
| Anaesthetic facemask ± oropharyngeal airway | 3 |
| Tracheostomy | 3 |
| New tracheostomy or cricothyroidotomy | 2 |
| Total | 133 |

Table 7 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.¹⁵ For each, point estimate and lower and upper confidence limits (CL) are presented

| 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 | 26 021 | 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 events | 91 | 1 102 900 | 82.5 | 65.6 | 99.5 | 12 120 | 15 254 | 10 054 |
| Tracheal tube death/brain 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 |

airway management to be good in two cases, mixed in four cases, poor in one, and had inadequate information to comment in one case.

Obesity

Seventy-seven of 184 patients (42%) were obese; of whom, 19 (25%) suffered death or brain damage, the same rate as the non-obese population. Of 53 events during anaesthesia in obese patients, four resulted in death and one persistent neurological deficit: a rate of 9%, lower than the rate in non-obese anaesthesia cases, 18%.

In anaesthesia cases, some form of airway assessment was recorded in 36 and difficulty was anticipated in 25. The proportion of primary airway problems related to tracheal intubation was similar in obese and non-obese patients (23 of 53 vs 33 of 80). Eight reports described aspiration, seven extubation problems, and four airway trauma. Airway management was assessed as good in 12 cases, mixed in 23, poor in 15, and unassessable in three. The most frequently cited causal or contributory factors were patient in 42 cases, judgement in 29, and education/training in 20. Several patients experienced complications of airway management during general anaesthesia when regional anaesthesia would have been a suitable alternative for surgery, but of note five obese patients also developed airway complications after requiring general anaesthesia when a regional anaesthetic technique or sedation failed: a situation observed in only one non-obese patient.

Events at the end of anaesthesia and in recovery

There were 38 events at the end of anaesthesia or during the recovery period; 20 in the operating theatre, 16 in the recovery room, and two occurred in transit. Airway obstruction was the most common problem: causes included laryngospasm, complete occlusion of an airway device by patient biting, blood in the airway or airway swelling (in three patients, this followed surgery in the Trendelenburg position). Diagnosis of airway obstruction was not always prompt, particularly in recovery. Two patients died following events occurring in the recovery room. In one case, an inhaled blood clot after tonsillectomy produced total tracheal obstruction which was initially attributed to asthma and led to fatal cardiac arrest. In the other, airway obstruction resulted in pulmonary oedema and severe hypoxia requiring cardiopulmonary resuscitation (CPR). The patient subsequently died in ICU. In total, five patients developed severe hypoxia requiring CPR. Negative pressure pulmonary oedema was seen frequently after these obstructive events and required admission to ICU in 13 cases, 12 of whom made a full recovery. Several cases of laryngeal mask occlusion were deemed preventable by the use of a bite block. Sixteen of the 38 events followed surgery within the airway and in this group, the reviewers noted evidence of poor anticipation and planning for management after extubation in the face of known problems.

Capnography and monitoring

Monitoring was used in all anaesthesia cases. In contrast to cases reported from the ICU and emergency departments, capnography appeared to be used universally for intubation and in the operating theatre. Reviewers judged that the use of capnography in the recovery area (and its appropriate interpretation) would have led to earlier identification of airway obstruction in several cases. There were three anaesthesia-related cases, including two deaths in which optimal interpretation of capnography might have altered the clinical course. In one case, described above, prolonged airway obstruction in recovery due to an aspirated blood clot was diagnosed as asthma for an extended period. It was not stated whether capnography was used. In the second case, laryngeal mask misplacement in an ASA II patient led to severe hypoxia; intubation was performed while the patient was peri-arrest. Intubation was difficult, as was ventilation and the capnograph showed 'minimal CO₂'. Capnography was 'flat' during prolonged cardiac arrest and this appeared to be a case of unrecognized oesophageal intubation. In the third case, a healthy patient was intubated and transferred into theatre but became hypoxic with a flat capnography trace. Anaphylaxis was suspected but senior anaesthetic help promptly diagnosed the tracheal tube in the oesophagus: the patient was transferred to ICU and made a full recovery. In total there were three cases of unrecognized oesophageal intubation during anaesthesia leading to one death and one case of brain damage.

Review panel analysis

Degree of harm

The review panel ascribed outcomes to all 184 cases (Table 5).

Causal, contributory and positive aspects of care

All reports were assessed to identify causal and contributory factors (Table 8). Of all 184 cases, the most frequent causal and contributory factors were the patient (77% of cases), followed by judgement (59%) and education/training (49%). Equipment/resource and communication factors were causal or contributory in more than one-quarter of cases. Medication and work/environment were the least frequently cited factors. Positive factors were identified in 91 cases (49%): the most frequent positive factors being communication (22% of cases) and organization/strategic (19%).

In the anaesthesia-related cases, similar patterns were observed (Table 8). The patient was considered causal in one-fifth of cases and causal or contributory factors included patient (79% of cases), followed by judgement (62%) and education/training (47%). Organization/strategic factors were also causal or contributory in more than one-quarter of cases. Positive factors were identified in 65 cases (49%): the most frequent positive factors were organization/strategic (21% of cases) and team/social and communication (each 15%).

Table 8 Factors assessed by review panel to contribute or cause events and factors indicating good practice. For definitions of factors listed, see Table 2

| 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 |

Quality of airway management conduct

Of 184 airway events, the review panel assessed the airway management as good in 16% cases, mixed in 43%, and poor in 35% (9). In only three of 46 events leading to death or brain damage, did the reviewers assess airway management as good and in 25 (54%), it was assessed as poor.

Of 133 airway events during anaesthesia, airway management was assessed as good in 18% cases, mixed in 41%, and poor in 34% (Table 9).

Discussion

This is the first prospective study of all major airway events occurring throughout the UK during anaesthesia, in ICU and the emergency department. It has identified a cohort of patients, a minimum prevalence, and enabled calculation of a minimum incidence of such events. This paper focuses on quantitative data relating to events during anaesthesia collected during the project. Combined with data from the matched anaesthesia census,¹² we are able to estimate an incidence of such complications occurring during anaesthesia. The incidence calculations have limitations and these are discussed below. Of equal importance, the project enables comparisons between rates of major complications when different airways (tracheal tube, supraglottic airway device, facemask) are used for anaesthesia. Finally, and perhaps most importantly, the project offers the opportunity to learn from review of a large series of such sentinel events and analysis of emerging themes. A complete report of this project with expanded clinical details and analysis to identify clinical learning points and recommendations has been compiled and this will be made available on the RCoA website (<http://www.rcoa.ac.uk/index.asp?PageID=1089>). A detailed analysis of events which occurred in ICUs and in emergency departments is presented in an accompanying paper.¹⁰

While the ideal solution for identifying the incidence of rare complications is a continuous process of notification of critical incidents and their analysis, this is currently

Table 9 Reviewers' assessment of quality of airway management and degree of harm. Mixed refers to an assessment of both good and poor elements

| Clinical area | Airway management | | | | Sum |
|---|-------------------|-------|------|----------------|-----|
| | Good | Mixed | Poor | Not classified | |
| Anaesthesia (n=133) | 24 | 55 | 45 | 9 | 133 |
| Anaesthesia death (n=16) | 3 | 4 | 8 | 1 | 16 |
| Anaesthesia death and brain damage (n=19) | 3 | 4 | 10 | 2 | 19 |
| All (n=184) | 30 | 79 | 65 | 10 | 184 |
| All deaths (n=33) | 3 | 14 | 20 | 1 | 38 |
| All death and brain damage (n=46) | 3 | 16 | 25 | 2 | 46 |

impracticable. Alternatives require study of a very large population or a prolonged period of assessment. The current project has observed complications in the whole of the UK over a period of 1 yr. A similar study of deaths related to airway complications performed in France during 1999¹⁷ analysed death certificates to identify cases, a questionnaire was then sent to the certifiers. In the USA, Li and colleagues¹⁸ collected reports by using the International Classification of Diseases (ICD-10) codes to identify anaesthesia-related complications. Deficiencies with death certification in the UK have been highlighted previously in the earliest confidential enquiry into perioperative deaths and problems remain.¹⁹ The use of death certification is retrospective, identifies mortality but not morbidity, relies on accurate certification data, and analysis of individual cases is problematic. In this project, we chose a prospective methodology with a system of local reporters to identify cases. This enabled us to identify those cases that we believe most would classify as major complications, even when the degree of harm was temporary. In addition to the NPSA

classification of severity, we also assessed frequency of death and death/brain damage as this is clinically relevant and is the outcome used by several litigation-based-analyses.^{3 4}

This study identified 33 deaths and 46 cases of death or brain damage as a result of airway complications during anaesthesia, in ICU and the emergency department over a 1 yr period. We calculate the incidence of serious airway complications during general anaesthesia to be (at least) 133 per 2.9 million or one per 22 000 general anaesthetics, death and brain damage (at least) one in 180 000 anaesthetics, ICU admission (at least) one in 29 000, and emergency surgical airway (at least) one in 50 000 general anaesthetics. Since the reports represent a timed sample, it is possible that the true incidence could be higher or lower than this figure; therefore, 95% confidence limits are provided (Table 7).

An important finding is the relative frequency of major airway events occurring with different airway devices. Comparisons between these groups are likely to be robust as reporting rates are likely to be equal. Categorizing devices as broadly as possible, it is notable that while airway events are more frequent during anaesthesia with a tracheal tube (point estimate 83 per million) than with, for instance, a supraglottic airway device (22 per million), the range of incidences is not extreme and this is even more evident if only deaths and brain damage are included: tracheal tube 9.1 per million, facemask 6.6 per million, supraglottic airway 5 per million. It is not surprising that events are more frequent for tracheal tubes as these cases include the vast majority of higher risk cases and also the group includes intrinsically more complicated techniques (e.g. tracheostomies, trans-tracheal ventilation, etc.). While some might argue that the rates of complications of the simpler techniques should be considerably lower, the fact that we have not demonstrated markedly higher rates of the most severe outcomes in one particular group is reassuring in terms of the airway techniques chosen 'en masse' in UK anaesthetic practice.

Aspiration was the single most common primary cause of fatality (primary event in 50% of deaths) in anaesthesia events. Aspiration is the cause of litigation in about 10–15% of anaesthesia airway-related claims in America²⁰ and the UK³ and of about one-third of cases where litigation is related to death. In the French study, aspiration was the cause of death in 83 of 131 deaths (63%).¹⁷ While the absolute incidence of such events is rare, these data emphasize the importance of aspiration as a major contributor to airway-related morbidity and mortality in anaesthetic practice. Case review identified several cases where airway management was with a laryngeal mask, despite clear evidence of risk factors for aspiration and also cases where RSI was not performed in patients with bowel obstruction. Various strategies are available to reduce the risk of aspiration in low- and high-risk patients: in NAP4 some deaths occurred without these precautions being used.

Approximately 42% of anaesthesia events reported had a primary airway event indication intubation difficulty. Many of

these cases involved patients with head and neck cancer and airway obstruction, with emergency surgical airway being necessary in 43% of anaesthesia cases. Poor planning of airway strategies and failure to change routine plans despite evidence of likely difficulty or when that plan failed were identified problems. In both the French study¹⁷ and this project, 13% of airway deaths were associated with difficult tracheal intubation. Put another way, 87% of deaths were not associated with difficult intubation. The French study's point estimate for deaths related to difficult intubation is 21 per million with a very wide CI of 3–77. In the US study¹⁸ failed, difficult intubation or wrongly placed tracheal tubes accounted for 2.3% of all anaesthesia-related deaths. As the majority of airway events occurred in elective surgery, in ASA I–II patients aged <60, this project acts as a reminder that a major airway complication can occur during complex and also apparently 'straightforward' routine anaesthesia.

When emergency surgical airway was required, this was performed most frequently by head and neck surgeons performing a rescue tracheostomy, all of which were successful. Cricothyroidotomy was the rescue technique of choice for anaesthetists but ~65% of these attempts failed to secure the airway. As two-thirds of emergency tracheostomies were performed in semi-controlled conditions, the cricothyroidotomies likely did represent a greater proportion of 'in extremis' cases. As NAP4 studied events with poor outcomes, it is possible that a disproportionate number of successful rescue cannula cricothyroidotomies were not reported. Even accepting these caveats, the high failure rate of this technique is a cause for concern. Whether this is due to failures of training, use of inappropriate equipment, equipment design problems, or technical failures during use requires further exploration and research. Anaesthetists might usefully study this area and ensure their competence with both cannula and surgical techniques.

Forty-two per cent of all patients notified to NAP4 were obese and 11% cachectic. The incidence of adult obesity in the UK in 2008 was reported to be 24.5%,²¹ and although we do not know the incidence of obesity or cachexia in the surgical population both groups are likely over-represented. An excess of cachectic patients is accounted for by a significant number of events occurring in patients with recurrent (sometimes pre-terminal) head and neck cancers. In contrast, the excess of obese patients underscores the fact that obese patients are at increased risk of an adverse airway event. Reasons for this include mechanical difficulty in securing the airway (mask ventilation,²² tracheal intubation,²³ and emergency surgical airway), increased risk of aspiration, increased risk of airway obstruction during difficulty, and accelerated speed and extent of oxygen desaturation during airway obstruction.²⁴ Of the 53 anaesthesia-related cases reported, mechanisms of injury and outcomes were notably similar to the non-obese reports. The fact that airway events occurred in obese patients who might have had their surgery performed under regional anaesthesia, but also after attempted

regional anaesthesia or sedation failed, illustrates that these patients are a major challenge for all anaesthetic techniques and anaesthetists. In view of the trends in population obesity in developed countries, the number of patients at risk of such events due to obesity is almost certain to increase.

It was notable that events occurred at all phases of the anaesthetic process. While induction was the phase when most (52%) events occurred, a significant minority occurred during emergence (16%) and in (or during transfer to) the recovery area (14%). The latter phase being particularly dangerous as the anaesthetist may be neither present nor immediately available to respond to an emergency.

In the cases of tracheal obstruction or tube misplacement, capnography and correct interpretation may have led to a change in clinical management and outcome. Each of the cases serves to remind us that the absence of expired carbon dioxide indicates lack of ventilation. When this occurs in an intubated patient, even during cardiac arrest, the possibility of tracheal tube occlusion, tracheal obstruction, or oesophageal intubation must be excluded before treating other causes. The capnograph trace is not flat in a correctly intubated patient during CPR and this is discussed in depth in the companion paper.¹⁰

Cases of high airway pressure and ineffective ventilation with inadequate capnograph trace were erroneously attributed to asthma or anaphylaxis. Endoscopic examination of the tracheal tube would have assisted earlier diagnosis of intraluminal obstruction or oesophageal intubation.

The AAGBI recently published a statement recommending that 'Continuous capnography should be used in the following patients, regardless of location within the hospital: Those whose tracheas are intubated and those whose airways are being maintained with supraglottic or other similar airway devices'.²⁵

The statement specifically includes recovery rooms. Capnography in recovery would likely have mitigated several events reported to NAP4. Other potential methods of improving diagnosis of airway obstruction in recovery include nursing education, observation of 't-bag' movement to monitor respiration, and the presence of an anaesthetist in the recovery area.

Analysis of reviewer's opinions indicates that intrinsic patient features contributed to the airway event in more than three-quarters of anaesthesia events. The most common extrinsic contributory factors were judgement and training. After excluding the patient as a contributory/causal factor, the ratio of contributory/causal factors to positive factors was ~2.5 for all cases and for anaesthesia cases. This reinforces the finding that reviewers assessed airway management to have elements that were poor in three-quarters of anaesthesia events and in more than 80% of deaths. A caveat is that the NAP4 process was good at identifying procedural and narrative events but was not, because of its design, suited for in-depth analysis of human factors. Despite this, and limitations described below, the assessment was that in many cases better planning, better knowledge, better judgement, or better communication, among

other factors, would likely have mitigated the events or even prevented some. Among the human factors most frequently identified were elements of poor communication, poor teamwork, poor leadership, and task fixation.

There are numerous positive aspects to the findings in this report and space only allows a brief comment. Perhaps most important is that all UK NHS hospitals took part and individual anaesthetists were willing to report these high impact events. It is also notable that most anaesthesia cases were managed in the presence of a consultant anaesthetist and often by several senior anaesthetists working together. When problems arose a call for assistance was usual (73%), the person responding to the request was a consultant in 85% of cases, and assistance arrived in <4 min in 79% of cases. These findings suggest that appropriately senior anaesthetists manage many difficult cases and that anaesthetic departments in UK NHS hospitals generally have a culture of colleague assistance and structures that enable prompt assistance in the event of a crisis. This is reinforced by the reviewers' analysis of cases which indicated that the factors most commonly identified as 'positive' in anaesthesia cases were organization/strategic followed by communication and team/social. This report has necessarily focused on deaths and brain damage but each of the non-fatal cases reported to NAP4 can be considered a near death. The 133 reports of events during anaesthesia may well be a significant underestimate. As more than one anaesthetist is generally involved in each case, as many as 1000 anaesthetists may be involved with such events each year (approximately one event for a consultant every 6 yr). It is a tribute to the specialty that so few patients came to serious harm and few died, but these were still very serious events and to individual anaesthetists these will probably be events that they will never forget.

One of the aims of this project was to determine the incidence of major complications of airway management in anaesthesia. This has been challenging, both in determining an accurate denominator and in establishing a numerator, because we know there will have been cases that were not reported. We identified 133 major events including 16 deaths and three cases of brain damage related to airway complication of anaesthesia. Accepting the limitations, we are able to calculate a point estimate of this incidence and a CI surrounding it. Our estimate is of 46 events per million (95% CI 38–54) and with 12% of these leading to death, a fatality rate of 5.6 per million (CI 2.8–8.3). The French study identified 'airway deaths' of 20 per million (CI 7–36), and while these confidence limits overlap, they are wide and suggest a higher rate of complications than the current study.¹⁷

Limitations

The project has several limitations. It is likely that not all cases were reported but we cannot know how many, or indeed if any were missed. We tried to maximize reporting but acknowledge that many factors may have contributed to under-reporting. There may be a personal or

organizational reluctance to release information if there is an ongoing investigation or if litigation is anticipated. Cases took up to a year after the event to be fully reported. Our analyses of reporting patterns by institution and by time are compatible with complete reporting but do not guarantee it. Our incidence calculations are based on reported cases; however, statistical advice and analysis indicated the true incidence may be up to four-fold higher. In this project, aspiration of gastric contents was the cause of death in eight patients giving an incidence of 1 in 360 000 anaesthetics (95% CI 1 in 212 000–1.1 million). Other large studies have reported rates of fatal aspiration associated with anaesthesia from 1 in 45 000²⁶ to 1 in 240 000²⁷ with one study identifying no cases in 198 000 paediatric anaesthetics.²⁸ These data suggest under-reporting to the NAP4 project, but cannot confirm or quantify it. Comparisons between NAP4 data and those from studies performed in other countries, several decades ago, with different methodology should be treated with caution.

We are not aware of any better estimates of anaesthesia airway-related morbidity by other researchers. As we recruited local reporters in 100% of NHS hospitals in the UK and all local reporters returned data to the project, we believe our effort approaches the best achievable with current methods. Our explicit description of how many cases we estimate may have been missed enables readers to interpret the data in the knowledge of these limitations.

There were several cases where the decision to include or exclude was not clear-cut. One case of fatal aspiration which occurred while an anaesthetist who had sedated a patient performed a spinal anaesthetic was excluded; the level of sedation was unknown and the primary aim of the project was not to study complications of sedation. In contrast, two cases that initially took place under local anaesthesia or sedation were included. In one, an anaesthetist administered sedation for endoscopy including oesophageal and pyloric dilation before aspiration occurred, the patient died. In the other, tonsillar biopsy under local anaesthesia with 'deep sedation' was complicated by profuse bleeding. The anaesthetist attempted to rescue the airway but intubation failed and an emergency airway was required, this patient made a full recovery. These cases likely fall under the umbrella of 'managed anaesthesia care'. They were considered to be consistent with the sorts of cases the project was designed to study.

A final limitation is inherent when expert panel review is used to 'judge cases'. We relied on submitted questionnaires and did not have access to case-notes nor the facility to speak to the clinicians involved. Despite this, we believe that our review process was robust. It can be summarized as a structured implicit review performed in teams. Pitfalls of retrospective case review include variation in reviewer opinion, outcome bias,¹⁴ hindsight bias,¹⁵ and 'consensus bias'. The latter bias occurs because teams reviewing cases often reach internal agreement but disagree with other teams.²⁹ While it is impossible to overcome all these biases, we made the following efforts to do so. The review

panel was educated in hindsight and outcome bias and at each meeting the reviewers were reminded of these biases, definitions of which appeared on the sheets categorizing outcomes. Each case was reviewed by two teams enabling an exploration of 'between group disagreement' to balance the tendency for 'within group agreement'. Guidelines and recommendations published by other organizations were used in the review process where considered appropriate. When judging case conduct against guidelines, the review panel attempted to ensure they were applicable, based on high-quality evidence, up-to-date and specific to the individual case.

In conclusion, airway management during anaesthesia is associated with serious complications, but these are rare. Optimistically, the incidence of complications resulting in death is 16 in 2.9 million, an incidence of one death per 180 000 general anaesthetics. Pessimistically, based on the assumptions discussed if only 25% of reports have been received, this figure could increase to one death per 45 000 general anaesthetics.

Important findings related to anaesthesia cases in this project include: (i) more than half of the patients were male, ASA I–II, aged <60, and most events occurred during elective surgery under the care of anaesthetic consultants. (ii) Aspiration was the most frequent cause of anaesthesia airway-related mortality. (iii) Obese patients were disproportionately represented. (iv) Obstructing airway lesions generated a large number of complications, many reports showed evidence of poor planning of primary and rescue techniques. (v) Cricothyroidotomy by anaesthetists was associated with a high rate of failure. (vi) One in four events occurred at the end of anaesthesia or in the early recovery room. (vii) Omission or incorrect interpretation of capnography led to undiagnosed oesophageal intubation. (viii) Elements of poor management were observed in the majority of airway complications and most deaths.

Detailed analysis of the reports of individual airway events during anaesthesia will contribute to our understanding of events causing patient harm and should enable improvements in the quality of care delivered.

Supplementary material

Supplementary material is available at *British Journal of Anaesthesia* online.

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Conflict of interest

T.M.C. has been paid by Intavent Orthofix and the LMA Company (manufacturers of laryngeal mask airways) for lecturing. He has never had and has no financial interest in these or any anaesthetic equipment companies.

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