EXECUTIVE SUMMARY

While it is generally accepted that airway management may sometimes be problematic and that complications occur, it was not known how frequently these occur or the nature of the events. NAP4 sets out to address this.

The 4th National Audit Project of the Royal College of Anaesthetists and the Difficult Airway Society (NAP4) was designed to answer the questions;

- What types of airway device are used during anaesthesia and how often?
- How often do major complications, leading to serious harm, occur in association with airway management in anaesthesia, in the intensive care units and in the emergency departments of the UK?
- What is the nature of these events and what can we learn from them, in order to reduce their frequency and consequences?

Phase one of the project established that approximately three million patients are anaesthetised in the UK each year in the NHS and delineated the airway devices used to manage these.

Phase two sought to identify all cases of major complications of airway management in the same population as in phase one, but also in ICUs and emergency departments. Each reported case was reviewed by an expert panel to ensure the correct cases were included and to maximise the amount that could be learnt. In total 186 cases met inclusion criteria and were reviewed in detail.

We acknowledge that it is very likely that not all relevant cases were reported to the project and this is discussed in detail in Chapter 5. We estimate that the project might have detected as few as one in four relevant cases.

Major findings

This report is an in-depth analysis of the reviewed cases. Each chapter includes a final section enumerating learning points and recommendations. The recommendations are extensive in number and breadth, reflecting the unique opportunity this project offers to examine airway management in the UK.

This summary does not reproduce or cover all findings in the report but highlights the major themes running through the report. Those with a responsibility for organising airway management policy and for carrying out airway management are encouraged to read the relevant parts of the report in full, including detailed recommendations. The recommendations are reproduced in a single document in Appendix 5.

- Approximately 2.9 million general anaesthetics are administered in the United Kingdom National Health Service each year. In approximately 56% of these cases the airway management is with a supraglottic airway device (SAD), 38% with a tracheal tube and 5% with a face mask.

Clinical themes

- **Poor airway assessment** contributed to poor airway outcomes. This was due to omission, incomplete assessment or a failure to alter the airway management technique in response to findings at assessment. Assessment to predict both potential airway difficulty and aspiration risk were equally important.
- Poor planning contributed to poor airway outcomes. **When potential difficulty with airway management is identified a strategy is required**. An airway plan suggests a single approach to management of the airway. A strategy is a co-ordinated, logical sequence of plans, which aim to achieve good gas exchange and prevention of aspiration. Anaesthetists should approach airway management with strategies rather than plans.
- **Failure to plan for failure**. In some circumstances when airway management was unexpectedly difficult the response was unstructured. In these cases outcome was generally poor. All anaesthetic departments should have an explicit policy for management of difficult or failed intubation and for impossible mask ventilation (e.g. formal adoption of the Difficult Airway Society guidelines as departmental policy) and for other airway emergencies. Individual anaesthetists should use such strategies in their daily practice.
- The project identified numerous cases where **awake fibreoptic intubation (AFOI) was indicated but was not used**. The project methods did not enable us to determine why AFOI was not used but there were cases suggesting, lack of skills, lack of confidence, poor judgement and in some cases lack of suitable equipment being immediately available. This latter problem was prevalent on ICU. Awake intubation should be used whenever it is indicated. This requires that anaesthetic departments and individual anaesthetists ensure such a service is readily available.
- Problems arose when **difficult intubation was managed by multiple repeat attempts** at intubation. The airway problem regularly deteriorated to a 'can't intubate can't ventilate' situation (CICV). It is well recognised a change of approach is required rather than repeated use of a technique that has already failed.

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- Events were reported where **supraglottic airway devices were used inappropriately**. Patients who were markedly obese, often managed by junior trainees, were prominent in the group of patients who sustained non-aspiration events. Numerous cases of aspiration occurred during use of a first generation SAD in patients who had multiple risk factors for aspiration and in several in whom the aspiration risk was so high that rapid sequence induction, should have been used.
- **SADs were used to avoid tracheal intubation in some patients with a recognised difficult intubation**. There was often no evidence of a back-up plan. Under these circumstances if the airway is lost (e.g. due to oedema or mechanical displacement) this becomes an anaesthetic emergency. Awake fibreoptic intubation or fibreoptic intubation through a SAD before surgery may offer a lower risk alternative to SAD use in cases of known difficulty with tracheal intubation.
- Anaesthesia for **head and neck surgery** featured frequently in cases reported to NAP4. These cases require careful assessment and co-ordinated planning by skilled anaesthetists and surgeons. Excellent teamwork is required as when any part of this process fails the risk of adverse outcomes is high.
- Management of the **obstructed airway** requires particular skill and co-operation between anaesthetist and surgeon. This is best performed in a fully equipped environment with full surgical, anaesthetic and nursing support. An operating theatre is the ideal location. Tracheostomy under local anaesthesia may offer a safer alternative to tracheal intubation after induction of anaesthesia, and it should be actively considered. When surgical airway performed by a surgeon is the back-up plan, preparation should be made so this is instantly available.
- The proportion of **obese patients** in case reports submitted to NAP4 was twice that in the general population, this finding was even more evident in the morbidly obese. Too often obesity was not identified as a risk factor for airway difficulty and the anaesthetic technique was not modified. Particular complications in obese patient included an increased frequency of aspiration and other complications during the use of SADs, difficulty at tracheal intubation and airway obstruction during emergence or recovery. When rescue techniques were necessary in obese patient they failed more often than in the non-obese. Obesity needs to be recognised as a risk factor for airway difficulty and plans modified accordingly.
- There was a **high failure rate of emergency cannula cricothyroidotomy**, approximately 60%. There were numerous mechanisms of failure and the root cause was not determined; equipment, training, insertion technique and ventilation technique all led to failure. In contrast a surgical technique for emergency surgical airway was almost universally successful. The technique of cannula cricothyroidotomy needs to be taught and performed to the highest standards to maximise the chances of success, but the possibility that it is intrinsically inferior to a surgical technique should also be considered. Anaesthetists should be trained to perform a surgical airway.
- **Aspiration was the single commonest cause of death in anaesthesia events**. Poor judgement was the likely root cause in many cases which included elements of poor assessment of risk (patient and operation) and failure to use airway devices or techniques that would offer increased protection against aspiration. Several major events occurred when there were clear indications for a rapid sequence induction but this was not performed.
- **Failure to correctly interpret a capnograph trace led to several oesophageal intubations going unrecognised in anaesthesia**. A flat capnograph trace indicates lack of ventilation of the lungs: the tube is either not in the trachea or the airway is completely obstructed. Active efforts should be taken to positively exclude these diagnoses. This applies equally in cardiac arrest as CPR leads to an attenuated but visible expired carbon dioxide trace.
- **One third of events occurred during emergence or recovery** and obstruction was the common cause in these events. Post-obstructive pulmonary oedema was described in one in ten reports. This phase of anaesthesia, particularly when the airway was difficult at intubation or there is blood in the airway, needs to be recognised as a period of increased risk and planned for.
- The commonest cause of the events reported to NAP4, as identified by both reporters and reviewers, appeared to be **poor judgement**. While this assessment is made with hindsight it was a consistent finding. The next most common contributory factor was education and training. Choosing the safest technique for airway management may not necessarily be the anaesthetist's most familiar. It may be necessary to seek the assistance of colleagues with specific skills, for example in regional anaesthesia or airway management.

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- In more than a third of events from all sources; during anaesthesia, in ICU and the emergency department, airway management was judged to be poor. More often there were elements of both good and poor management. In approximately one fifth of cases airway management was judged to be exclusively good.

ICU and the emergency department

- **At least one in four major airway events reported to NAP4 was from ICU or the emergency department**. The outcome of these events was more likely to lead to permanent harm or death than events in anaesthesia. 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 due to lack of or failure of interpretation of capnography. The project findings suggest avoidable deaths due to airway complications occur in ICU and the emergency department.
- **Failure to use capnography in ventilated patients likely contributed to more than 70% of ICU related deaths**. Increasing use of capnography on ICU is the single change with the greatest potential to prevent deaths such as those reported to NAP4.
- **Displaced tracheostomy**, and to a lesser extent displaced tracheal tubes, were the greatest cause of major morbidity and mortality in ICU. Obese patients were at particular risk of such events and adverse outcome from them. All patients on ICU should have an emergency re-intubation plan.
- **Most events in the emergency department were complications of rapid sequence induction**. This was also an area of concern in ICU. RSI outside the operating theatre requires the same level of equipment and support as is needed during anaesthesia. This includes capnography and access for equipment needed to manage routine and difficult airway problems.

Airway management is a fundamental anaesthetic responsibility and skill; anaesthetic departments should provide leadership in developing strategies to deal with difficult airways throughout the entire organisation.

Interpretation of results

Many of the events and deaths reported to NAP4 were likely to have been avoidable. Despite this finding, the incidence of serious complications associated with anaesthesia is low. This is also true for airway management in ICU and the emergency department, though it is likely that a disproportionate number of airway events occur in these locations. The aim of this report is that detailed attention to its contents and compliance with the recommendations will make airway management safer.

Many of the findings of NAP4 are neither surprising nor new, but the breadth of the project, covering the whole of the UK for a full year, will hopefully provide impetus to changes that can further improve the safety of airway management in the UK in anaesthesia, intensive care and the emergency department. Our goal should be to reduce serious complications of airway management to zero.

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RESPIRATION AND THE AIRWAY

National census of airway management techniques used for anaesthesia in the UK: first phase of the Fourth National Audit Project at the Royal College of Anaesthetists

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Editor's key points

- The preliminary stage of Fourth National Audit Project of the Royal College of Anaesthetists (NAP4) reports on all anaesthetics given in a 2 week period.
- Three hundred and nine hospitals reported on airway management of nearly 115 000 cases.
- Supraglottic devices were used in 56% and tracheal intubation in 38%.
- This demonstrates current trends in airway management techniques and provides the denominator for the NAP4 objective to determine the incidence of major airway complications.

Background. The first stage of the Royal College of Anaesthetists Fourth National Audit Project (NAP4) (to determine the incidence of major complications of airway management in the UK) required a national census of airway management techniques currently in use.

Methods. A network of local reporters (LRs) was established, with a link to each of the 309 National Health Service hospitals believed to undertake surgery. LRs were requested to report the primary airway management technique used for all general anaesthetics performed in their hospital during a specified 2 week period. Individual unit's data for the survey period were extrapolated using a multiplier of 25 to provide an estimated annual usage.

Results. Data were received from all 309 hospitals. The number of general anaesthetics reported in the 2 weeks was 114 904 giving an estimate of 2.9 million annually. Eighty-nine per cent of returns were reported by the LR to be 'accurate' or 'a close estimate' (an error of $<10\%$). The primary airway management device for general anaesthesia was a supraglottic airway in 64 623 (56.2%), a tracheal tube in 44 114 (38.4%), and a facemask in 6167 (5.3%).

Conclusions. The second stage of NAP4 is designed to register and collect details of each major airway complication from the same hospitals over a 12 month period. The individual case reports will produce the numerator to calculate the incidence of airway complications associated with general anaesthesia in the UK. The results of the census presented here will provide the denominator.

Keywords: airway; airway, complications; anaesthetic technique, supraglottic airway; anaesthetic technique, tracheal intubation; laryngeal mask

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Airway management is fundamental to safe anaesthetic practice and anaesthetists need to be skilled in airway management techniques. However, complications of airway management have been reported to be both common and serious.[1 2] A recent analysis of the National Health Service Litigation Authority data for the period 1995–2007 showed claims related to airway management to be the fifth most common reason for anaesthesia-related litigation, but this group of claims was ranked equal highest in terms of the proportion of claims related to damage or fatalities and these claims accounted for 20% of the 50 most costly claims.[3]

The American Society of Anesthesiologists (ASA) has a long-standing interest in closed malpractice claims arising in the USA.[4] Claims relating to airway management are reviewed on a regular basis;[5] these reviews guide clinical practice and allow the role and effectiveness of recommendations and guidelines to be evaluated.[6] No similar systematic detailed appraisal exists in the UK, although the National Patient Safety Agency (NPSA) collects reports of, and responds to, critical incidents.[7] The Fourth National Audit Project of the Royal College of Anaesthetists (NAP4) is an attempt to investigate these areas. It will determine current trends in airway management practice and provide an indication of the incidence of major airway complications. This paper describes a census, taken over a 2 week period, of current UK airway management practice used for general anaesthesia. The census provides an estimate of the annual number of general anaesthetics performed and the airway management techniques in use.

Methods

Using surface mail, e-mail, and telephone, the anaesthetic department in every National Health Service (NHS) hospital in the UK was contacted and invited to participate in NAP4 and to nominate a local reporter (LR) who would act as the point of contact for the project, co-ordinate a census of current activity and assist with the second phase where reports of individual serious complications were to be submitted. Data were not sought from private hospitals or Independent Sector Treatment Centres (ISTCs); however, data were collected from treatment centres attached to NHS hospitals.

Each LR was asked to return a Hospital Data Submission Form (Supplementary Appendix 1) by electronic or surface mail for the 2 week period from September 15 to 28, 2008. Information was requested under two categories, essential and desirable.

Essential data

Essential data were requested on the number of anaesthetics performed anywhere in the hospital with the exception of those performed in the intensive care unit (ICU) and emergency department (ED): anaesthetics performed in these areas were explicitly excluded. Required data were broken down into two categories: the number of local or regional anaesthetics performed by an anaesthetist without general anaesthesia and the number of general anaesthetics performed. For procedures undertaken under general anaesthesia, detailed information on the primary airway management technique used was requested. Specifically, the total number of times during the 2 week period an anaesthetic facemask, supraglottic airway device (SAD), or tracheal tube was used as the primary airway management technique was requested. The primary airway was defined as that 'used for maintenance of anaesthesia'. Tracheal intubation included all forms of intubation of the trachea: for example, single- and double-lumen tubes, tracheostomy, surgical bronchoscopy, trans-glottic, and trans-tracheal techniques.

Desirable data

Supplementary detailed information was requested on the specific type of airway device used. Additional questions were also included on the anaesthetic induction methods for patients in whom airway problems were anticipated.

The decision on how to collect these data was left at the discretion of the LR. The data collection exercise could be performed using a paper-based method or, if facilities existed locally, information could be collected electronically. To assist, electronic copies of the NAP4 Anaesthetist's Data Collection Form (Supplementary Appendix 2) were distributed to LRs for use, if they elected to use a paper-based method, although they were free to create their own if they deemed this appropriate. A detailed written explanation of the NAP4 project and the purpose of the census were placed on both the Difficult Airway Society (DAS) and Royal College of Anaesthetists (RCoA) websites and the Anaesthetist's Data Collection Form was also available for downloading from both websites. An Anaesthetist's Data Collection Advice Sheet explaining the data to be collected was provided for distribution by the LRs to individual anaesthetists. The project was very widely advertised to promote awareness and encourage participation. LRs collected data on the activities of individual anaesthetists and submitted a return based on the activities of the whole hospital.

For each figure submitted, LRs were asked to indicate its accuracy as: accurate (0–2% error), close estimate (2–10% error), estimate (>10% error), or guess (no data to support the figure).

LRs were contacted at regular intervals by surface mail, e-mail, or telephone and encouraged to return data. If they found they were unable to fulfil their role, alternative volunteers were identified in their hospitals. When this occurred after September 15, 2008, or if local circumstances had prevented data collection during the planned census period, LRs were invited to submit data for an alternative 2 week period. Where no data had been received before the end of August 2009, data for the 2 week period from September 14 to 27, 2009, were requested instead.

Submitted electronic data were checked to identify rogue data such as data entry errors, mathematical errors, or illogical data, and these were corrected where possible after consultation with the LR responsible. If submitted data were conflicting and correction by the LR was not possible, those data deemed by the LR on the submission form to be the most accurate were used. If an assessment was not possible, data were accepted as presented.

Data for each category from all hospitals were added to provide a cumulative national total for the 2 week period. These totals were then multiplied by 25 to provide an estimate of annual activity. The multiplier of 25 was based on calculation made in the authors' base hospitals. The surgical activity during year August 31, 2008, to September 1, 2009, was divided by the surgical activity recorded during the study period. These were found to be 24.5 at the Norfolk and Norwich University Hospital and 24.9 at the Royal United Hospital Bath. These were rounded to 25 to create the multiplier for calculating annual activity.

In an attempt to validate the data returned by LRs for the total number of general anaesthetics, Hospital Episode Statistics (HES) data[8] collected from hospitals in England for the 2008–9 period were analysed. This database records the primary procedure performed on NHS patients over each financial year. The HES data provide numbers for procedures performed on all NHS patients in England including those treated within the private sector or in ISTCs. The database provides no information on the type of anaesthesia. A group of clinicians including anaesthetists with experience in all clinical specialities (including general, orthopaedic, obstetric, gynaecological, urological, paediatric, vascular, thoracic, cardiac, head and neck, plastic, otorhinolaryngological, oro-maxillary-facial, and neuro-surgery) reviewed the list of primary procedures and estimated the percentage of

cases performed under general anaesthesia as 100%, 95%, 75%, 50%, 25%, 5%, or 0%. These multipliers were used to estimate the total performed under general anaesthesia, for each procedure listed in the HES database. This figure for England was then multiplied by 1.2 (based on population census figures for England, Wales, Scotland, and Northern Ireland)[9] to provide an estimate for the population of the UK.

Results

By September 2008, all 309 NHS hospitals had agreed to participate and had appointed an LR. All 309 hospitals (100%) returned data: 'essential data' were returned by 100% and 'desirable data' by 98%.

In the 2 week study period a total of 114 904 general anaesthetics were recorded as having been performed (Table 1). The primary airway management device for general anaesthesia was a supraglottic airway in 64 623 (56.2%). The majority of these were reported to be standard laryngeal masks. Approximately 10% of anaesthetics were delivered via one of the newer SADs, the i-gel (Intersurgical, Wokingham, UK) and ProSeal LMA (Intavent Direct), with the former being used more than twice as often as the latter. A tracheal tube was the primary airway in 44 114 (38.4%) general anaesthetics. The majority of tracheal intubations were performed with a single lumen tube. Anaesthesia via a double lumen tracheal tube or tracheostomy represent, between them, fewer than 1 in 100 general anaesthetics and general anaesthesia using a surgical laryngo-bronchoscope, trans-tracheal techniques and bronchial blockers are very infrequent each being used in less than 1 in 1000 general anaesthetics and fewer than 1 in 500 tracheal intubations. Anaesthesia by facemask alone was used for 6 167 procedures (5.3%). The percentage of data returns reported as 'accurate' or close estimate' were: number of general anaesthetics 89% and by airway device 82–84%.

Extrapolating to annual activity suggests that in the UK, 2.9 million general anaesthetics were performed during the year of the NAP4 study in the units surveyed. This represents an annual activity of 1.6 million general anaesthetics in which the airway was maintained with an SAD, 1.1 million with a tracheal tube, and 0.15 million with an anaesthetic facemask.

In 2554 (2.2%) patients, airway management was expected to be difficult as judged by the anaesthetist. Of these reported predicted difficult airways, 91% were in adults and 9% in children. Management of patients with predicted difficult airways in adults was predominantly (81%)

Table 1 Main results and airway management techniques. *To the nearest 100

	Uses during Census	Number per annum*	Percentage of general anaesthetics	Indicated as 'accurate' or 'close estimate'
General anaesthetics	114 904	2 872 600	100	89%
Supraglottic airway device	64 623	1 616 100	56.2	83%
Tracheal tube	44 114	1 102 900	38.4	84%
Facemask	6167	154 200	5.3	82%

Table 2 Detailed breakdown of airway devices used. *To the nearest 100

Device (accurate or close estimate)	2 week total	Annual estimate*	% of all airways	% of subgroup
Facemask (80)				100
Anaesthetic facemask	4784	119 600	4.2	77.6
Hudson type of mask	1383	34 600	1.2	22.4
Supraglottic airway (80)				100
Laryngeal mask	56 388	1 409 700	49.2	87.3
i-Gel	4574	114 400	4.0	7.1
ProSeal LMA	1920	48 000	1.7	3.0
Other	1741	43 500	1.5	2.7
Tracheal tube (81)				100
Single lumen	42 752	1 068 800	37.3	96.9
Double lumen	634	15 900	0.55	1.4
Tracheostomy	399	10 000	0.35	0.9
Surgical laryngo-bronchoscope	133	3300	0.12	0.3
TTJV	83	2100	0.07	0.19
Bronchial blocker	60	1500	0.05	0.14
Other	53	1300	0.05	0.12

with i.v. induction of anaesthesia, with a minority being managed by inhalation induction (9%) or awake fibreoptic intubation (10%). In children with predicted difficult airways, inhalation induction (63%) was much more common than i.v. induction (37%) and awake fibreoptic intubation was not reported at all.

From the HES data (which includes ISTCs and NHS patients treated in private hospitals) using the method described, we estimated that 3.0 million general anaesthetics per annum were performed in all UK hospitals in 2008.

Although not a prime aim of the census, our returns indicated 27 096 cases performed under local or regional anaesthesia during the census: an annual estimate of activity of 0.68 million cases. Using our estimate of general anaesthetic activity, this gives a split of 81:19% for general to regional/local anaesthetic activity, for cases in which an anaesthetist is involved.

Discussion

This census of general anaesthesia and airway management activity was primarily designed to provide a realistic estimate of the total number of general anaesthetics performed annually in the UK within NHS hospitals. Additional information on the airway management techniques used during general anaesthesia was collected. These data will form the denominators in the calculations of the incidence of major complications associated with such techniques. Ideally, such information would be available from a continuous nationwide analysis of practice. Currently, these data are collected and available in some UK hospitals, but no national co-ordinated analysis is available to provide this information for the NHS or the country as a whole.

Consideration was given to asking reporters to collect information over a longer (12 month) period; however, it was thought that a prolonged period of measurement might represent an unreasonable burden, ultimately leading to a lower response rate. The response rate (100%) is excellent and, although self-rated, the reported accuracy of the data (89% described as 'accurate' or a 'close estimate' for the type of anaesthetic and >82% as 'accurate' or a 'close estimate' for the primary airway management device) supports the decision to pursue a 'snapshot' approach, meaning that robust denominator data are available once a 12 month review of complications has been completed. The 100% compliance rate probably reflects the recognized importance of the overall aim of the project and the persistence with which data were sought.

To provide an estimate of annual activity, the results of the 2 week census were multiplied by 25 on an empiric basis supported by data from the authors' hospitals. It is postulated that elective surgical activity is reduced during holiday periods, by bank holidays, and perhaps when new trainees are introduced, though urgent/emergency surgery continues. Our multiplier of 25 equates to approximately 49–50 weeks of both elective and emergency works, and 2–3 weeks of emergency only work, this having a differential effect on the several anaesthetic subspecialities. In the Royal United Hospital, Bath, a large district general hospital, the total number of procedures performed annually is available and leads to multiplication factors between 23.5 and 26 for each speciality, and an overall multiplier of 24.9. At the Norfolk and Norwich hospital during the survey period, the multiple was 24.5. Therefore, on the basis of these data, 25 was accepted and applied to all data.

Although not a prime aim of the census, our data suggest approximately 19% of anaesthetists' NHS surgical activity (about 0.7 million cases per annum) involved cases performed under regional or local anaesthesia alone. The framing of this question in the census means it is possible that this figure excludes regional analgesia for labour which would add an additional 110 000 cases.[10] Regional anaesthesia, without general anaesthesia, is likely to account for 20–22% of anaesthetic activity.

The Royal College of Anaesthetists has direct links to all NHS hospitals and these links were considered to form a reliable collection network (for both this and the second stage of the project). In order to ensure that incidence calculations are as accurate as possible, numerator data (numbers of complications) will be drawn from the same population as the census. Cases reported from ISTC and private sector hospitals may be submitted during the second phase of NAP4, but these will not be used for the calculations of incidence.

We believe that this census is the first robust attempt to determine the number of general anaesthetics delivered in the UK, which is something of a surprise. The RCoA census of anaesthetic activity in 2007 estimated that there were 12 600 anaesthetists in the UK.[11] Our data could therefore mean each anaesthetist delivers an average of 230 general anaesthetics per year in the NHS. On initial examination, this figure may appear to be low and this justifies further examination. We have collected data on the number of general anaesthetics, not the number of anaesthetists delivering them. If we assume that one-third of anaesthetics are delivered by two anaesthetists (consistent with figures from the authors' hospitals), our figures would equate to an average of approximately 340 per annum. If 10% of all anaesthetists (RCoA census) work half-time, the mean full-time equivalent figure increases to 360 general anaesthetics per annum. This figure does not include cases managed under local or regional anaesthesia alone, perhaps an additional 25%. The mean figure is also lowered by the inclusion of anaesthetists on long-term sickness, or maternity leave. Finally, anaesthetists are heavily engaged in other activities including provision of intensive care, obstetric analgesia, acute and chronic pain management, preoperative assessment clinics, research, teaching, and hospital management: each of these activities will reduce the number of general anaesthetics delivered by those involved and the mean figure overall. Pooled data from each of the authors' hospitals gave a mean figure which ranged from 324 to 333 general anaesthesia cases per annum for consultants with local or regional anaesthesia accounting for 20–30% of overall workload.

The vast majority of tracheal intubations were performed with a single-lumen tube. Our estimate of the frequency of the use of other tracheal intubation techniques is based on small numbers and is therefore the least reliable. Anaesthesia with a double-lumen tracheal tube or tracheostomy represent, between them, fewer than one in 100 general anaesthetics and general anaesthesia using a surgical laryngo-bronchoscope, trans-tracheal techniques, and bronchial blockers are very infrequent each being used in less than one in 1000 general anaesthetics and fewer than one in 500 tracheal intubations. Accepting any reservations about the accuracy of these figures, it is likely that these techniques are performed in a relatively small number of centres and by a relatively small number of anaesthetists, and there is corroborative evidence for this for the usage of surgical laryngo-bronchoscope and trans-tracheal techniques.[12] These findings have potential implications for the use of such techniques in emergencies and by non-experts, which will perhaps be better considered once the second phase of NAP4 is complete.

The study has intrinsic weaknesses. First, whatever method was used to collect data, it is likely any final figure will be an underestimate of actual activity as cases are far more likely to be missed or omitted than fabricated. Secondly, repeated approaches to some units were required to obtain data. The delayed recording of data is likely to lead to a further underestimation of the denominator since forms completed retrospectively may lead to omissions. Thirdly, the increasing subdivision of data make the smaller numbers more prone to variance both because sampling infrequently used devices over a short time period is prone to error and because these figures were reported by the LRs as being less accurate. Fourthly, the range of accuracies of reported data makes it difficult to present confidence intervals for the data we report and we simply offer point estimates. Finally, the data we used for validation is itself not externally validated and the method we used to estimate the number of general anaesthetics from that database has considerable weaknesses, although we are not aware of any better methods of validation. We acknowledge all these limitations but complete compliance with the census and the self-assessed accuracy of the data both support the view that these data are of as high a quality as it is feasible to collect. For the number of general anaesthetics, the LRs reported 89% of submissions to be accurate to within 10%. If we accept this figure and assume 50% error, of the remaining 11% we estimate an error of no more than 15%. For reasons outlined previously, most figures returned will be underestimates but some will be in excess of the number of cases actually performed and these will tend to reduce the degree of inaccuracy. We would welcome information from others that might enable us to refine our estimates.

The overall estimate of 2.9 million general anaesthetics performed in the UK within the 309 units surveyed is very similar to the estimate of 3.0 million derived from HES data which also include NHS patients treated in private hospitals and ISTCs. Independent sector treatment centres were estimated to account for 1.8% of elective NHS activity in 2007–8[13] and private practice accounts for ~10% of surgical activity in the UK.[14] Using these broad estimates, it is likely that the overall number of general anaesthetics in the UK is between 3.1 and 3.3 million: although the assumptions used make this figure rather less accurate than the figure reported here for activity in NHS hospitals.

In conclusion, a national survey in the UK was undertaken to provide an estimate of the number of general anaesthetics performed in 1 yr in NHS hospitals and to identify the pattern of airway management techniques used for these cases. We estimate that 2.9 million general anaesthetics were performed in this population in 2008–9: 56% utilizing a supraglottic airway, 38% a tracheal tube, and 5% using an anaesthetic facemask. On completion of the second phase of NAP4, these figures will enable calculation of an estimated incidence of the major complications of airway management techniques.

Supplementary material

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

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Conflict of interest

None declared.

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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 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 outcome[14] 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 anaesthetists[16] (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 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.

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

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 facemask 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 ($\leq$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

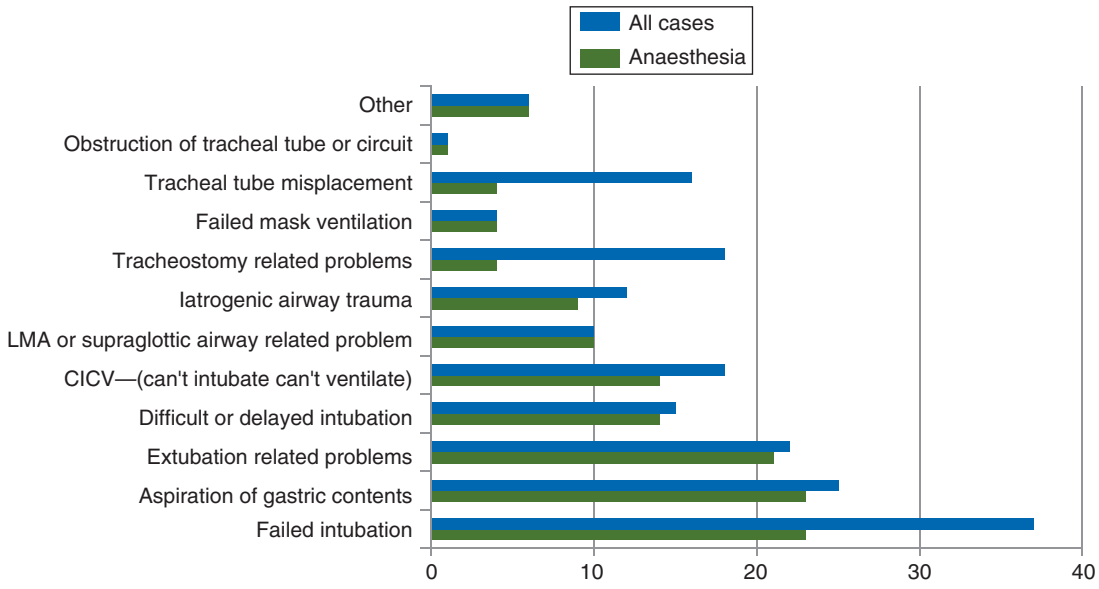

Fig 1 Primary airway problem

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.

Table 6 Primary airway used or intended for maintenance of anaesthesia

Airway	
Tracheal intubation (including fibreoptic 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

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 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 *n* 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 CO_2'. 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).

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				
	Good	Mixed	Poor	Not classified	Sum
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

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 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 1999[17] analysed death certificates to identify cases, a questionnaire was then sent to the certifiers. In the USA, Li and colleagues[18] 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 America[20] and the UK[3] 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 study[17] 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 study[18] 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 $\sim$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 45 000[26] to 1 in 240 000[27] 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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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 2: intensive care and emergency departments†

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Background. The Fourth National Audit Project of the Royal College of Anaesthetists and Difficult Airway Society (NAP4) was designed to identify and study serious airway complications occurring during anaesthesia, in intensive care unit (ICU) and the emergency department (ED).

Methods. Reports of major complications of airway management (death, brain damage, emergency surgical airway, unanticipated ICU admission, prolonged ICU stay) were collected from all National Health Service hospitals over a period of 1 yr. An expert panel reviewed inclusion criteria, outcome, and airway management.

Results. A total of 184 events met inclusion criteria: 36 in ICU and 15 in the ED. In ICU, 61% of events led to death or persistent neurological injury, and 31% in the ED. Airway events in ICU and the ED were more likely than those during anaesthesia to occur out-of-hours, be managed by doctors with less anaesthetic experience and lead to permanent harm. Failure to use capnography contributed to 74% of cases of death or persistent neurological injury.

Conclusions. At least one in four major airway events in a hospital are likely to occur in ICU or the ED. The outcome of these events is particularly adverse. Analysis of the cases has identified repeated gaps in care that include: 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 due to lack of or failure of interpretation of capnography. The project findings suggest avoidable deaths due to airway complications occur in ICU and the ED.

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

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Active airway management takes place most frequently in anaesthetic practice, but is often required outside the operating theatre. Several studies of airway management outside the operating theatre have identified higher rates of complications, including failed intubation, oesophageal intubation, hypoxia, and cricothyroidotomy. These include studies in intensive care units (ICU)[1–4] and emergency departments (EDs).[4–8] Differences in factors such as case mix, availability of skilled and trained staff, levels of assistance, and working environment all likely contribute. Recent data from analysis of the National Reporting and Learning System (NRLS) of the National Patient Safety Agency (NPSA) indicated that ICU may be an area where airway complications are relatively frequent,[9] but the data were limited by the nature of NRLS reporting, which numerically focuses on low impact events.[9 10]

The Fourth National Audit Project of the Royal College of Anaesthetists and Difficult Airway Society (NAP4) had the primary aim of identifying the incidence of major complications of airway management during anaesthesia. At an early stage in planning NAP4, it was decided that it would be important to study similar complications in the environments of ICUs and EDs for the reasons stated above. This paper describes the major findings of this section of the NAP4 project.

For reasons of space, this paper cannot explore many facets of events that were reported. This paper should be read in conjunction with the accompanying paper[11] and the full report of the project is available on http://www.rcoa.ac.uk/index.asp?PageID=1089.

Methods

The full methodology of the NAP4 project is described in the accompanying paper.[11] In brief, a multi-speciality group was established to plan delivery of NAP4 (see Supplementary

† This article is accompanied by the Editorial.

Appendix). The project leads established a network of local reporters in all anaesthetic departments in UK National Health Service (NHS) hospitals believed to be performing surgery. Efforts were made to also recruit a local reporter in every ICU and ED. The local reporters were tasked with supporting the project at the local level and assisting in ensuring all cases meeting inclusion criteria were identified and fully reported to the project.

For patients in ICU and EDs, the main aim of the project was to study the nature of major airway events in the two identified non-anaesthetic environments. No formal census was planned to identify a denominator for such events. However, during the project, such a census for ED activity was completed by one of the authors of this paper.[12]

A registry of the major complications of airway management was established to collect detailed reports on such cases over a 12 month period. Discussions with the National Research Ethics Service indicated that ethics committee approval was not required. The project was examined by the Patient Information Advisory Group of the Department of Health and a methodology was agreed that ensured patient confidentiality. Data were not sought from private hospitals or Independent Sector Treatment Centres (ISTCs), but were collected from treatment centres attached to NHS hospitals. The project was widely advertised.

Inclusion criteria for complications in ICU and the ED were the same as for complications during anaesthesia. 'A complication of airway management that led to death, brain damage, the need for an emergency surgical airway (including a needle, cannula, open cricothyroidotomy or tracheostomy), unanticipated ICU admission or prolongation of ICU admission'.

Events occurring during transfer to or from the ICU or ED were included.

The process of notification, confirmation of inclusion criteria, submission, and case review was identical to that for anaesthesia cases: see accompanying paper.[11] As with anaesthesia cases, the NAP4 moderator was available to discuss cases where a clinician was uncertain about inclusion criteria. The same high levels of data protection and confidentiality that applied to all of the NAP4 project were applied to cases submitted from ICU and the ED.

An event was included if it occurred in the period from September 1, 2008, to August 31, 2009. Notification of events was accepted until June 2010.

Case review panel

An expert review panel examined each submitted clinical report. The panel incorporated representatives from all specialities involved in the project including the College of Emergency Medicine and the Intensive Care Society. Case review was a structured process; the review panel specifically considered cases under the categories described (Supplementary Table S1). Contributory or causative factors were identified as were factors considered to have had a positive effect. The degree of harm caused was graded using the National Patient Safety Agency (NPSA) severity of outcome scale for patient safety incidents (Supplementary Table S2).[13] Aspects of the care were analysed for learning points and pertinent cases were selected to act as illustrations of clinical care for inclusion in a detailed report of the project. Airway management was classified as good, poor, mixed (i.e. elements of both good and poor management), or unclassifiable.

Incidence calculations

No attempt was made to calculate the incidence of events in the ICU and EDs due to both lack of denominators and the fact that not all hospitals had specific local reporters for the ICU and ED.

Missing reports

No formal attempt was made to identify the extent of missing cases, as it was never the expectation of this part of the project that all cases meeting inclusion criteria would be reported.

Results

Agreement to participate and appointment of a local reporter was confirmed in all 309 hospitals by September 2008. In total, 286 anaesthesia local reporters were appointed with some representing more than one hospital. In addition, 118 ICU local reporters (for 253 UK ICUs: 47%) and 115 ED local reporters (for 239 major UK EDs: 48%) were recruited. Anaesthesia local reporters were encouraged to report cases from ICU and the ED when there were no additional local reporters.

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 in the accompanying paper,[11] 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 ED. The results of the anaesthesia cases are presented in the accompanying article.[11]

Patient characteristics

Of the ICU cases, the male:female ratio was 21:15 (58% males), 22% were ASA grade I–II, and 61% aged <60 (Table 1). In ICU, 19 patients were receiving invasive ventilation, eight non-invasive ventilation, eight were not receiving mechanical ventilation before the airway event: in one case, this information was not provided. Supplemental oxygen was being given in 94% before the event and in 35% the $F_{I_{O_2}}$ was ≥ 0.6. Thirteen had organ failure other than respiratory and nine were receiving vasoactive drugs or continuous renal replacement therapy. A BMI of >30 kg m^{-2} was recorded in 47% of ICU cases and a BMI of <20 kg m^{-2}

Table 1 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 2. *Prolongation of stay in the case of patients already in ICU

	ICU ($n=36$)	Emergency department ($n=15$)
ASA		
I	1	2
II	7	4
III	14	5
IV	13	3
V	1	0
Not recorded	0	1
Age		
<10	1	1
11–20	2	0
21–40	6	7
41–60	11	4
61–80	14	2
>80	2	1
Not recorded	0	0
Reporter provided inclusion criteria		
Death	16	3
Brain damage	6	1
ESA	10	11
ICU admission*	12	10
Sum	44	25

Table 2 Final outcome: Narrative outcome and NPSA classification (see Supplementary Table S2)

	ICU ($n=36$)	Emergency department ($n=15$)
Final outcome (narrative)		
Death	18	4
Brain damage	4	1
Other partial recovery	3	1
Full recovery	9	9
Unrelated death	2	0
Final outcome (NPSA definitions)		
Death	18	4
Severe	5	0
Moderate	12	11
Low	1	0
None	0	15

in 6%. In the ICU, 46% of events for which a time was recorded took place out-of-hours (18:01–08:00). Although consultants were present for 58% of all events, there was a notable difference between events in hours (80%) and out-of-hours (36%). Several events were managed by doctors who would not be expected to have airway expertise because of lack of seniority [e.g. specialist trainee (ST) year 2] or primary speciality (e.g. ST2 in medicine).

Of the ED cases, the male:female ratio was 10:5 (67% males), 40% were ASA grade I–II, and 80% aged <60 (Table 1). A BMI of >30 kg m^{-2} was recorded in 46% and <20 kg m^{-2} in 7%. Fifty-three per cent of events took place 'out of hours'. All but three cases involved attempts at tracheal intubation, the exceptions being facemask anaesthesia for cardioversion and two surgical airways for airway obstruction. In 11 cases (73%), airway management was performed by an anaesthetist and in eight (53%) a consultant. Anaesthetist involvement decreased from 6/7 during the day (08:01–18:00) to 5/8 out-of-hours and consultant involvement was 4/7 in-hours and 4/8 out-of-hours. Several events were managed by doctors who would not be expected to have airway expertise, including two ICU trainees with minimal anaesthetic experience and one Acute Care Common Stem trainee with 5 months anaesthetic experience. In a further three cases, the anaesthetist present at the start of the airway event was a year 3 specialist trainee, and in eight events, no consultant was present at the start of the airway event.

Inclusion criteria and event outcomes

The inclusion criteria indicated by reporters are presented in Table 1. The final outcome of events is presented, both focusing on outcomes of death and brain damage and by NPSA classification of severity of harm (Table 2).

Death resulting from an airway problem was the inclusion criterion for 33 reports: 16 occurred in ICU and three in the ED (Table 1). Three further cases resulted in late deaths, two in ICU, and one in the ED. In total, there were 38 deaths attributable to an airway event, 18 on ICU, and four in the ED. Hypoxia was the common theme in deaths caused by an airway problem in both ICU and the ED. Death rate for cases in ICU was 18/36 (50%) and in the ED 4/15 (27%).

Brain damage

In 13 patients, brain damage was recorded as an inclusion criterion, six in reports of events on ICU, and one in the ED (Table 1). After excluding those who died or recovered, there were four cases of persistent non-fatal brain damage in ICU and one in the ED. The combined rate of death and brain damage for ICU cases was 22/36 (61%) and in the ED 5/15 (33%).

Emergency surgical airway

An attempt at emergency surgical airway, either tracheostomy or cricothyroidotomy, was reported as an inclusion criterion in 75 cases (Table 1). Twelve attempts took place on ICU (33% of all ICU cases), with three failing to rescue the airway, a failure rate of 25%. Five needle cricothyroidotomies were attempted on ICU, three of which failed. One patient

with successful surgical airway died and one suffered persistent brain damage; two patients with failed placement of an emergency surgical airway died.

Ten emergency surgical airways were placed in the ED (67% of ED cases) with no total failures. However, in all three cases where a needle cricothyroidotomy was attempted, this failed and had to be replaced by a surgical or percutaneous technique. Of the 10 patients requiring a surgical airway in the ED, two died and one suffered persistent brain damage.

ICU admission

Of 122 cases included in NAP4 because of ICU admission or prolongation of ICU stay, 12 arose in patients already on ICU and 10 in ED cases. The most common reasons for prolongation of stay on ICU after an airway event were failure to awaken in five, aspiration of gastric contents or blood in four, and airway swelling in two. The most common reasons for ED cases to be admitted to ICU were management of airway swelling/trauma in four, failure to awaken in three, and aspiration in two.

Primary airway problem

In the ICU, tracheostomy-related events were the most frequently occurring problem (n=18, 50%) (Table 3). Next most frequent was failed intubation or tracheal tube misplacement (including unrecognized oesophageal intubation and inadvertent extubation). Displacement of an existing tracheostomy or standard tracheal tube combined accounted for 18 events and half of all cases of death or brain damage. These events occurred most frequently in obese patients and during patient movement, sedation holds (e.g. sudden awakening and coughing or manually removing a tube) or airway interventions (e.g. tracheal suction or nasogastric tube placement). Of all tubes that became dislodged, 13 were recorded as taped (ties, Velcro straps), two sutured, and three both taped and sutured. There were three unrecognized oesophageal intubations and two led to death (there was also one fatal oesophageal intubation as a secondary event). Displacement or obstruction of a tracheostomy and difficult intubation required a fibrescope on several occasions and delays in accessing one was a recurrent problem.

Events in the ED were predominantly related to tracheal intubation and included delayed or failed intubation, unrecognized oesophageal intubation, the cannot intubate, cannot ventilate (CICV) scenario, aspiration, and perforation of the trachea with a bougie. The two unrecognized oesophageal intubations led to death. Airway management in both of these cases was undertaken by a non-anaesthetist intensive care doctor, one junior and one senior, the latter with limited anaesthetic experience. The case of significant airway trauma occurred during an uneventful intubation by an emergency physician.

Table 3 Primary reported airway event

ICU (n=36)	
Tracheostomy-related problems	14
Tracheal tube misplacement/displacement	7
Failed intubation	7
Oesophageal intubation	3
CICV—the cannot intubate, cannot ventilate scenario	2
Latrogenic airway trauma	2
Problems at the time of extubation	1
Emergency department (n=15)	
Failed intubation	7
Aspiration of gastric contents	2
Oesophageal intubation	2
CICV—the cannot intubate, cannot ventilate scenario	2
Iatrogenic airway trauma	1
Difficult or delayed intubation	1

Paediatrics and obstetrics

There were no cases reported from ICU or the ED that involved pregnant women.

One event occurred in ICU in a child under 10 yr: a dysmorphic neonate required multiple attempts to intubate and the tracheal tube was then repeatedly displaced. Intubation became impossible and attempts were made to transfer the patient to theatre for a surgical tracheostomy, but the airway was again lost during transfer and the patient died. There was one paediatric event reported from the ED: a case of inadvertent oesophageal intubation in an infant. During cardiac arrest, a flat capnography trace was not recognized as indicating 'non-intubation'. The patient died.

Review panel analysis

Degree of harm

The outcomes ascribed to all ICU and ED cases by the review panel are presented in Table 2.

Causal, contributory and positive aspects of care

Causal and contributory factors were identified in all 36 ICU cases (Table 4). The most frequent causal and contributory factors were patient-related (69% of cases), followed by education/training (58%), judgement (50%), equipment/resource (36%), and communication (31%). Positive factors were identified in 19 cases (54%): the most frequent positive factors were communication (36% of cases) and organization/strategic (19%).

Causal and contributory factors were identified in all 15 ED cases (Table 4). The most frequent causal and contributory factors were patient-related (73% of cases), followed by judgement (57%), education/training (40%), and task (33%). Positive factors were identified in eight cases (53%), the most frequent positive factor being communication (33% of cases).

Quality of airway management conduct

Reviewers assessed airway management in ICU cases as good in 11% of cases (n=4), mixed in 52% (n=19), and poor in 36% (n=13) (Table 5). In the ED, airway management

Table 4 Factors assessed by review panel to contribute or cause events and factors indicating good practice. For definitions of factors listed, see Supplementary Table S2

Factors	ICU ($n=36$)			ED ($n=15$)		
	Causal	Contributory	Positive	Causal	Contributory	Positive
Communication	2	9	13	0	3	5
Education and training	2	19	2	0	6	2
Equipment and resources	0	13	4	0	4	1
Medicines	0	7	0	0	4	0
Organization and strategic	0	7	7	0	0	0
Patient	6	19	0	3	8	0
Task	0	6	2	2	3	1
Team and social	0	7	1	0	3	1
Work and environment	0	4	0	0	1	0
Judgement	3	15	4	0	8	1
Other	0	3	0	0	2	0

Table 5 Airway management and degree of harm number of cases: *n* (includes all reported cases—anaesthesia, ICU, and ED)

Clinical area	Airway management				
	Good	Good and poor	Poor	Not classified	Sum
All	30	79	65	10	184
All deaths	3	14	20	1	38
All death and brain damage	3	16	27	2	48
ICU	4	19	13	0	36
ICU death	0	10	8	0	18
ICU death and brain damage	0	11	11	0	22
Emergency department	2	5	7	1	15
Emergency department death	0	0	4	0	4
Emergency department death and brain damage	0	1	4	0	5

was assessed as good in 13% ($n=2$) cases, mixed in 33% ($n=5$), and poor in 46% ($n=7$) (Table 5). Airway management was assessed as poor in almost half of ICU deaths and all ED deaths.

Discussion

This project has performed a prospective study of major airway events occurring throughout the UK during anaesthesia, in ICU and the ED for the first time. In-depth structured review of these cases has identified specific issues and recurrent themes. While such a study will be ranked low in a hierarchy of research quality, it is likely to have considerable clinical relevance and importance.

There is much that could be discussed, but this discussion is structured in three sections.

- What have we observed?
- What do we learn from these observations?
- What can be done to improve airway management in the environments of ICU and the ED?

Space limits the extent of these discussions and the reader is referred to a full report of the project available at http://www.rcoa.ac.uk/index.asp?PageID=1089.

What have we observed?

We have observed that although ICU was the setting for fewer than 20% of notified events almost half of deaths occurred there. More than 60% of events reported from ICU led to death or brain damage (compared with 14% in anaesthesia). While it is not surprising that ICU patients frequently had a high ASA grading, multi-organ failure, and were receiving high inspired oxygen fractions, the high rate of obesity (approaching 50%) of patients experiencing major airway complications is a new and notable finding. Events in the ICU in obese patients led to death or permanent brain damage more often than events in non-obese patients (12 of 17 obese and 10 of 19 non-obese). This is in contrast to anaesthesia, where events in obese patients were not associated with poorer outcomes than in non-obese patients. Primary events leading to complications were more likely than anaesthesia events to involve failed intubation or problems with tracheostomies. These events were more likely than anaesthesia events to occur out-of-hours and to be managed by inexperienced staff. NAP4 identified several cases where management of intubation was by staff who were not adequately experienced and when problems arose, they were not managed in a logical or recognized manner. Issues with equipment arose frequently and included non-availability, lack of training in the use of equipment, and failure to consider using the right equipment. When rescue techniques were used (facemask ventilation,

laryngeal mask ventilation, and cricothyroidotomy), these all had relatively high rates of failure. Issues of preparedness were also identified and included failures to identify patients at risk of complications, failures to formulate a plan for critical events in these patients and failure to ensure that such a plan could be carried out. The assessors judged airway management in the ICU to be good less frequently than in either anaesthesia or the ED.

Observations in the ED were similar, with a high proportion of events occurring out-of-hours and without consultants present; the primary airway problem was predominantly failed or problematic intubation and outcomes were similar to those in ICU, although less severe. Several reports suggested failure of preparation, failure to follow standard practices for airway protection, or airway rescue in cases of difficulty. Emergency surgical airway was required in two-thirds of cases, higher than during anaesthesia or in ICU, and in all cases was ultimately successful, also higher than other settings.

An observation in both ICU and the ED was of unrecognized oesophageal intubation. In total, there were six leading to five deaths (23% of deaths in these areas). All were performed by clinicians with very limited airway experience. Capnography was not used in five cases and in one case, it was used, but a flat capnograph trace was misinterpreted as being 'due to cardiac arrest'.

In both groups, there was a high failure rate of needle cricothyroidotomy. Of eight attempted in ICU and the ED, six failed (75%) and the airway was rescued either with a surgical approach (open or percutaneous tracheostomy) or with other non-invasive techniques. Direct surgical approaches to the trachea had high success rates.

What do we learn from these observations?

In both settings, it must be accepted that patients may present with complex conditions which are intrinsically 'high risk': in ICU because of critical illness and oxygen dependency and in the ED because of underling pathology or injury that has precipitated their admission. An American Society of Anesthesiologists' Closed Claims Project (ASACCP) study identified claims related to difficult airway management outside the operating theatre to be considerably more likely to lead to fatal outcomes than in the operating theatre.[4] A study of more than 10 000 emergency intubations outside the operating theatre found multiple attempts at intubation to be associated with dramatic increases and high rates of hypoxaemia (11.8% *vs* 70%), regurgitation of gastric contents (1.9% *vs* 22%), aspiration (0.8% *vs* 13%), bradycardia (1.6% *vs* 21%), and cardiac arrest (0.7% *vs* 11%).[3] For these reasons, the staffing and equipment in both settings must be such that airway management can be timely, skilled, and where necessary utilize highly advanced techniques. This requires planning and communication. In ICU, planning should recognize that intubation sometimes fails, that tracheal tubes and tracheostomies will inadvertently fall out, and that all these events are more likely to occur in obese patients. Tracheal tube and tracheostomy displacement in ICU was repeatedly reported after patient movement or patient interventions and this has been reported before.[9] Similarly, delayed diagnosis of displacement, in the absence of capnography, has been reported before[9] and was reported repeatedly in this project.

Failed intubation or difficult intubation contributed to many events on ICU and the ED. Failure to identify potential difficulty, to have a strategy for failure (plan B, plan C), to assemble the correct equipment, and intubation by inappropriately inexperienced personnel contributed to numerous events. These observations also applied to patients specifically admitted to a critical care unit for airway monitoring and management. Reviewer assessments frequently identified system, organizational, and human factor deficiencies. In a recent study, implementation of a 10-point ICU intubation management protocol ('care bundle') led to a 30–60% reduction in complications.[14] There are various interpretations of this study, but it is notable that the bundle included preoxygenation with continuous positive airways pressure, presence of two operators, rapid sequence induction (RSI), capnography, and early administration of vasopressors if needed. Such a protocol, supported by a checklist is attractive in the light of this study and other checklist-driven successes in ICU.[15]

In the ED, predictable airway emergencies include trauma intubations, stridor, inhaled foreign bodies, and other causes of airway obstruction. The rate of difficult intubation in the ED may be as high as 8.5%, and the need for an emergency surgical airway as high as 0.5%.[5–8] Knowledge of likely scenarios should drive preparedness of personnel, equipment, communication channels, and policies. A survey[12] identified that ~20 000 RSIs of anaesthesia are performed in UK EDs per year and therefore an average size ED will perform RSI approximately every 4 or 5 days with 80% of these performed by anaesthetists, many of whom are trainees. In this project, we identified avoidable harm, including death, caused by airway trauma or oesophageal intubation that occurred during airway management by clinicians with limited airway management experience. The implications are that emergency physicians undertaking these procedures need specific training to establish and maintain their skills, that anaesthetists and intensive care doctors need to understand the particular requirements and difficulties of airway management in the ED, and that channels of communication between the ED and anaesthesia or ICU departments need to be well established to ensure prompt attendance by an appropriately skilled senior clinician.

Diagnosis of oesophageal intubation was hampered by lack of capnography. The current situation in ICU and the ED can be compared with the 1980s when capnography was not universally used for intubation in anaesthesia. The ASACCP identified numerous cases of litigation after oesophageal intubation:[16] delays in diagnosis of more than 5 min were almost universal, auscultation routinely gave false positives, cyanosis was often absent, and it was cardiovascular disturbance or collapse that alerted clinicians to the

problem in more than 80% of cases. The authors commented on 'preconceived notions of likelihood', 'reflex clinical behaviours', 'conflicting environmental data', 'the inherent limitations of diagnostic tests', and 'the potential for a rapid and poorly reversible clinical cascade'. These comments act as a potent reminder of the problem and the potential for human factors to impede correct clinical diagnosis. A more recent study of emergency intubation outside the operating theatre noted that reliance on indirect clinical tests for diagnosing oesophageal intubation during emergency tracheal intubation led to more hypoxaemia, severe hypoxaemia, regurgitation, aspiration, cardiac dysrhythmia, and cardiac arrest.[17]

An important recurrent finding was misinterpretation of capnography when oesophageal intubation occurred during cardiac arrest or cardiac arrest occurred as a consequence of it. This was also noted in anaesthesia cases. Clinicians, mostly anaesthetists, failed to recognize that a flat capnograph trace indicated absence of ventilation and a misplaced tracheal tube. Nevertheless, it has been recognized for many years that during cardiopulmonary resuscitation (CPR) capnography is not flat but indicates a low concentration of expired gas (Fig. 1).[18] The 2010 International Consensus guidelines on Cardiopulmonary Resuscitation specifically addressed the use of capnography to confirm advanced airway placement during CPR.[19] The report describes two studies which included 21 oesophageal intubations in 297 patients at cardiac arrest and in which waveform capnography was 100% sensitive and 100% specific in identifying correct tracheal tube placement.[20 21] In contrast, studies of colorimetric expired carbon dioxide detectors, non-waveform expired capnometers, and oesophageal detector devices (both syringe aspiration and self-inflating bulb types) had similar accuracy to clinical assessment for confirming the tracheal tube position during cardiac arrest.[22–30] The report concludes that 'waveform capnography is recommended to confirm and continuously monitor the position of a tracheal tube in victims of cardiac arrest . . . it should be used in addition to clinical assessment . . . if not available, a non-waveform carbon dioxide detector or oesophageal detector device in addition to clinical assessment is an alternative'.[19]

Capnography, or rather the failure to use it, likely contributed to 17 outcomes of death or brain damage on ICU, including four oesophageal intubations and 14 inadvertent tube displacements: these account for 82% of events leading to death or brain damage in ICU.

In the ED, capnography use was higher, being definitely used 50% of intubation attempts, although this question was poorly completed. Despite this, its use was not universal and failure to use, or misinterpretation of, capnography led to two fatal unrecognized oesophageal intubations in the ED. Correct use and interpretation of capnography would have prevented half of the deaths in the ED.

The contrast between rates of use of capnography in anaesthesia and in ICU and the ED is stark and is reinforced by this project's findings. The use of capnography in ICU has been recommended by various authors and organizations.[9 14 31–35] The breadth of these recommendations has ranged from that it should be available for intubation to recommending its routine use 'from intubation to extubation'. Surveys repeatedly show current use fails even to meet the narrowest recommendation. This project has shown that full implementation would save lives.

In both areas, needle cricothyroidotomy had an unexpectedly high failure rate. It has been widely discussed as to whether needle or Seldinger or surgical approaches to direct tracheal access are best and it may be argued that this project provides evidence that needle cricothyroidotomy has a high failure rate and therefore should be abandoned, particularly as surgical approaches were generally successful (even when following failed needle cricothyroidotomy). There are several reasons to be cautious about such a conclusion. The NAP4 project specifically studied events with poor outcomes and although we did seek reports of all airway complications requiring emergency surgical airway, it is possible that a disproportionate

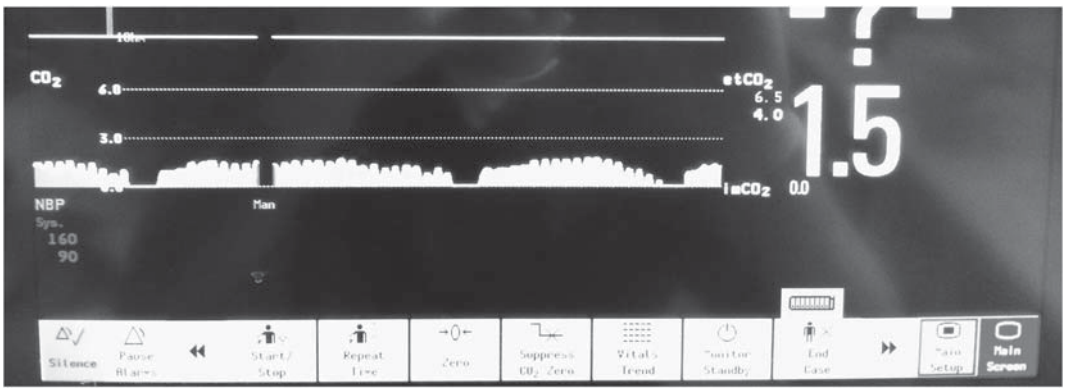

Fig 1 Capnograph trace during cardiac arrest with on-going CPR. The positive trace is an indicator of correct (i.e. tracheal) placement of the tracheal tube.

number of successful rescue needle cricothyroidotomies were not reported. Even if this explanation is not correct, it is not reasonable to abandon the needle cricothyroidotomy technique without a much more robust explanation of failures, which may have been due to failures of training, use of inappropriate equipment, design problems with appropriate equipment, or technical failures during use. Examples of each of these observed in NAP4 include cephalad placement of the device, use of an i.v. cannula for cricothyroidotomy, mechanical failures of a Ravussin cannula, and successful passage of a fine bore needle followed by unsuccessful (and inappropriate) attempts to ventilate with a low-pressure gas source.

Emergency surgical airway is the 'final common pathway' for all difficult airway algorithms. While much emphasis is placed on the choice of device and technique, there is relatively little written about the decision-making process and timing of emergency surgical airway. An anaesthetic litigation review found that 42% of 179 difficult airway cases terminated in CICV.[4] Errors of technique were frequent causes of failure, particularly failure to ventilate with a high-pressure source when a narrow cricothyroid cannula was inserted.[36] Of equal importance, persistent attempts at intubation occurred before rescue techniques and the authors noted that 'our data suggest the rescue ability of (supraglottic airways) may have been reduced by the effects of multiple preceding attempts at conventional intubation' and that 'in 2/3 of the claims where CICV occurred a surgical airway was obtained but was too late to avoid poor outcomes'. In NAP4, there were also cases, in anaesthesia and also in the ICU and ED, where persistent attempts at intubation perhaps precipitated CICV, likely led to failure of rescue techniques and definitely delayed emergency surgical airway.

What can be done to improve airway management in the environments of ICU and the ED?

Intensive care unit

Capnography

- Capnography should be used for intubation of all critically ill patients irrespective of location.
- Continuous capnography should be used in all ICU patients with tracheal tubes (including tracheostomy) who are intubated and ventilator-dependent. Cost and technical difficulties may be practical impediments to the rapid introduction of routine capnography. However, these need not prevent its implementation.
- Where capnography is not used, the clinical reason for not using it should be documented and reviewed regularly.
- Training of all clinical staff who work in ICU should include interpretation of capnography. Teaching should focus on identification of airway obstruction or displacement. In addition, recognition of the abnormal (but not flat) capnograph trace during CPR should be emphasized.

Intubation

- An intubation checklist should be developed and used for all intubations of critically ill patients. A checklist might usefully identify preparation of patent, equipment, drugs, and team. A checklist should include identification of back-up plans.

Recognition of difficulty and back-up planning

- Every ICU should have algorithms for management of intubation, extubation, and re-intubation. National efforts should be made to develop evidence-based algorithms for ICU.
- Patients at risk of airway events (i.e. those patients at increased risk of problems or for whom the standard algorithms are not appropriate) should be identified and clearly identifiable to those caring for them.
- A plan for such patients should be made and documented. The planning should identify primary and back-up plans. The plan should also identify any additional equipment and skills necessary to carry out the plan. The plan should be communicated to on-coming staff at each staff handover, including confirmation that the plans can still be carried out.

Tube displacement

- Staff education should recognize and emphasize the risks of airway displacement. Airway displacement may occur at any time but is more frequent in obese patients, in patients with tracheostomy, during or after patient movement, and during sedation holds.

Obesity

- Obese patients on ICU should be recognized as at increased risk of airway complications and at increased risk of harm from such events. Plans to manage the airway should be particularly meticulous.
- Responsible bodies (e.g. Royal College of Anaesthetists, Intensive Care Society) should work with other stakeholders and manufacturers to explore two aspects of tracheostomies for obese patients. (i) Can design be improved to reduce risk of displacement? (ii) Can the optimal mode of fixation be determined?

Airway equipment

- Every ICU should have immediate access to a difficult airway trolley. This should have the same content and layout as the one used in that hospital's operating department.
- The airway trolley needs regular checking, maintenance, and replacement of equipment after use which should be appropriately documented.
- A fibrescope should be immediately available for use on ICU.

Cricothyroidotomy

- Training of staff who might be engaged in advanced airway management of these potentially difficult patients should include regular, manikin-based practice in the performance of cricothyroidotomies. Correct identification of the landmarks, especially on obese patients, should be encouraged.
- Research is required to identify the equipment and techniques most likely to be successful for direct tracheal access in critically ill patients. This research should specifically address whether the same solutions are effective in obese patients.

Transfers

- Recognizing that transfers, whether inter- or intra-hospital, are high-risk episodes, an airway assessment that includes patient, equipment, back-up, and staff skills should be made before transfers.

Staffing

- Trainee medical staff who are immediately responsible for management of patients on ICU need to be proficient in simple emergency airway management. They need to have access to senior medical staff with advanced airway skills at all hours.
- Where senior intensivists do not have an anaesthetic background with advanced airway management skills, it is recommended that specific protocols are in place to ensure experienced anaesthetic cover can be called on to assist in management of difficult cases. Trust management should support the financial implications.

Education/training

- Junior medical staff who are to be immediately responsible for management of patients on ICU need airway training. This should include basic airway management, familiarization with algorithms for management of predictable airway complications, and use/interpretation of capnography. Training should identify the point at which trainees reach the limit of their expertise and mechanisms for summoning more experienced clinicians. Such training is likely to include simulation and team training.
- Regular audit should take place of airway management problems or critical events in the ICU.

Emergency department

Many of the above recommendations apply equally to the ED. To these are added:

- Capnography should be used for all intubations in the ED.
- Capnography should be used for all anaesthetized patients in the ED.
- Capnography should be used for intubated patients during transfers from the ED to other departments.
- An intubation checklist should be developed and used for all intubations of ED patients. A useful checklist may identify preparation of patient, equipment, drugs and team, and also back-up plans.
- EDs should perform a risk assessment to identify the type of patients and their airway problems that they can anticipate receiving. Equipment, training, and strategies should be planned around, although not restricted to, the anticipated patient groups.
- Every ED should have the airway equipment necessary to manage the anticipated clinical scenarios. This needs regular checking, maintenance, and replacement of equipment after use.
- Every ED should also have a difficult airway trolley. This should have the same content and layout as the one used in that hospital's operating department and also needs regular checking, maintenance, and replacement of equipment after use.
- In cases of airway compromise, it is generally preferable to secure the airway before moving the patient out of the ED, but local considerations apply. Any decision to move a patient with a threatened airway should be made by a senior clinician.
- Robust processes should be established to ensure the prompt availability of appropriately skilled and senior staff at any time to manage the airway within a reasonable timeframe.
- Joint training of emergency physician and anaesthesia/ICU staff is recommended—as described above.
- Staff training should focus on the anticipated clinical presentations. Training should also include management of failed intubation and emergency surgical airway techniques using the airway equipment available in the ED.
- Strong links and good communication between senior clinicians in the ED, anaesthesia, ICU, ear, nose, and throat surgery, and other relevant specialities are essential in planning for, and managing, the emergency airway problems that present to the ED. Consideration should be given to designating consultant leads from each involved speciality to agree and oversee the management of emergency airway problems presenting to the ED.
- Regular audit should take place of airway management problems or events in the ED.

Research

- NAP4 has identified numerous areas of concern and potential improvement in airway management in ICU and EDs. Airway management on ICU and in the ED is as suitable an area for future research as many other interventional areas. It is currently under-explored. Grant awarding bodies should recognize this. Several areas of potential research are indicated above.

The main limitations of the NAP4 project are described in the accompanying paper.[11] In contrast to the anaesthesia

events where every UK NHS hospital had a local reporter, our network of local reporters for ICU and EDs likely covered only 50% of hospitals. Although many cases in these areas will have been reported by anaesthesia local reporters, it is likely that a higher proportion of events arising in ICU and EDs were not notified. We cannot quantify these, but it is certainly possible that the cohort of patients we studied represent only the 'tip of the iceberg' of such cases in ICU and EDs.

Before surgery, airway management is generally a necessary part of the process of anaesthesia to facilitate an operation, while in both ICU and the ED, the primary aim may be securing the patient's airway, with anaesthesia a necessity for that. Owing to preceding patho-physiological disturbance, it may be difficult in these patients to determine to what extent an adverse airway event was the cause of a poor outcome and this was relevant to several cases in NAP4. At the reviewing stage, we aimed only to include those cases where the outcome was judged likely to be related to the airway event.

In conclusion, at least one-quarter of major complications of airway management in hospitals are likely to occur in the ICU and ED. These complications are more likely to lead to permanent harm or death than events in anaesthesia. Case review has identified avoidable deaths and areas of care that need improvement. We have outlined recommendations on which to base such improvements.

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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