The Royal College of Anaesthetists

The Difficult Airway Society

NAP4

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

Major complications of airway management in the United Kingdom

Report and findings
March 2011

Editors
Dr Tim Cook, Dr Nick Woodall and Dr Chris Frerk

The National Patient Safety Agency Patient Safety Division

The Intensive Care Society

The College of Emergency Medicine

Review Panel

The review panel was composed of experts interested in airway management, often with a sub-specialty interest. Nomination was by the supporting organisation, not NAP4. Some panel members were invited for specific expertise but did not represent organisations.

Dr Ann Black (Association of Paediatric Anaesthetists)

Professor Jonathan Benger (College of Emergency Medicine)

Dr David Bogod (Medico-legal expert)

Ms Tracey Coates (National Patient Safety Agency and Association for Peri-operative Practitioners)

Dr Tim Cook (Royal College of Anaesthetists, NAP4 co-lead)

Dr Chris Frerk (Difficult Airway Society)

Dr Les Gemmell (Association of Anaesthetists of Great Britain and Ireland)

Dr Jane Harper (Intensive Care Society)

Mr David Huggins (College of Operating Department Practitioners)

Professor Ravi Mahajan (Royal College of Anaesthetists Council Member)

Mr Sat Parma (Maxillofacial surgeon)

Dr Anil Patel (Airway expert, also UK representative of European Airway Management Society)

Dr Adrian Pearce (Airway expert)

Dr Mansuhk Popat (Association of Anaesthetists of Great Britain and Ireland)

Mr Paul Pracey (ENT–UK)

Dr Audrey Quinn (Obstetric Anaesthetists Association)

Dr Jairaj Rangasami (Difficult Airway Society)

Ms Joan Russell (National Patient Safety Agency)

Dr Jan Shaw (Human Factors Advisor)

Dr Nick Woodall (Difficult Airway Society, NAP4 co-lead)

Mr Richard Youngs (Patient Liaison Group, Royal College of Anaesthetists)

The panel was chaired by

Dr Tim Cook (Project Lead, Royal College of Anaesthetists)

Dr Nick Woodall (Project Lead, Difficult Airway Society)

Acknowledgements

The authors would like to express their thanks to the network of LRs who were responsible for collecting and supplying data. Their role was difficult and demanding, this report would not have been possible without their hard work, persistence and diligence.

In addition to the Royal College of Anaesthetists and the Difficult Airway Society a number of organisations contributed to the development of the project in various ways, including being represented on its Working Group. These include the Association for Peri-operative Practitioners, Association of Anaesthetists of Great Britain and Ireland, Association of Paediatric Anaesthetists of Great Britain and Ireland, College of Emergency Medicine, College of Operating Department Practitioners, Intensive Care Society, National Patient Safety Agency, Intensive Care National Audit and Research Centre, Obstetric Anaesthetists Association and Patient Liaison Group of the Royal College of Anaesthetists.

The project was also endorsed/supported by the Chief Medical Officers of England (Sir Liam Donaldson), Northern Ireland (Dr Michael McBride), Scotland (Dr Harry Burns) and Wales (Dr Tony Jewell), the Medical Protection Society and Medical Defence Union.

We are also indebted to the President, Council and the Head of Professional Standards (Mr Charlie McLaughlan) at the Royal College of Anaesthetists. We would also like to acknowledge the advice of Mrs Karen Thomson, Patient Information Advisory Group at the Department of Health.

Dr Ian Calder performed an essential role by acting as a moderator outside of the running of the project. He used his extensive background knowledge and understanding of airway management and of the project to aid the LRs in discussions about inclusion criteria.

We thank the following statisticians for advice Rosemary Greenwood and Hazel Taylor (Research Design Service – South West, Bristol), Gordon Taylor (University of Bath).

We thank the following for the use of photographs in the report Tim Cook, Mansukh Popat, Jairaj Rangasami, Audrey Quinn, Nick Woodall, Adrian Pearce, S Chapman, Alma Medical (ramping Chapters 20 and 22, copyrighted) and Jan Shaw.

Dr Fiona Kelly, Dr Clare Hommers, Dr Rob Jackson and Dr Tim Cook are thanked for permission to use the various documents and algorithms that form Appendices 1–4.

The production of the report was principally by Mrs Mandie Kelly, Mrs Edwina Jones and Mr Philip Fey.

Finally, we are particularly indebted to Miss Shirani Nadarajah at the Royal College of Anaesthetists for her major contribution to the prompt collection and accurate collation of census data and for project administration.

We are grateful to the editor and publisher of the *British Journal of Anaesthesia* for allowing us to reproduce material published in that journal.

The Royal College of Anaesthetists | The Difficult Airway Society | The National Patient Safety Agency Patient Safety Division | The Intensive Care Society | The College of Emergency Medicine

NAP4

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

Major complications of airway management in the United Kingdom

Report and findings
March 2011

THE ROYAL COLLEGE OF ANAESTHETISTS
Churchill House 35 Red Lion Square London WC1R 4SG
020 7092 1500 info@rcoa.ac.uk www.rcoa.ac.uk
Registered Charity No: 1013887 VAT Registration No: GB 927 2364 18 Registered Charity in Scotland No: SC037737

Design and layout by The Royal College of Anaesthetists.

ISBN 978-1-900936-03-3

CONTENTS

FOREWORD

You will now be familiar, and probably tired of the constant comparisons between pilots and anaesthetists. Yet since the death of my late wife in 2005 I've met so many of you who in private conversations have confirmed a number of things which lead me to believe we're closer than you think. Like flying, anaesthetics are a usually routine process, you develop processes that work for you, you know what you are doing and you achieve success, sometimes despite the system and colleagues around you. You anaesthetise well because... 'You're a good professional anaesthetist'. When a patient presents some difficulties it presents a challenge, but one you can overcome, maybe sometimes not at first attempt, but you're good at what you do.

And then one day something happens which reminds you you're not perfect. You make an honest mistake, perhaps, probably in the heat of the moment. It shakes you to your core, your assumptions about yourself are maybe wrong; colleagues are judging you behind your back.

Life is a hard teacher, first comes the exam, then the lesson.

The use of simulation is a valuable tool because it allows us an insight into ourselves when the odds are stacked against us. Every pilot has screwed up in the simulator, and those events allow us to develop more resilient and reliable ways of thinking and working so when things really do turn bad we have a much greater chance of success. But this is an insight that many of you won't have experienced. Sitting around a coffee table anaesthetists will tell me how they wouldn't have behaved in the way the anaesthetists did on my late wife's case. It's incomprehensible. But place those same anaesthetists and colleagues into the simulator a week later; you'd be surprised how many do follow the same path when presented with the same stressors and human factors.

In aviation we learned that what we took to be the 'right stuff' was actually out of date, and in fact in a very complex and fast moving environment was often 'the wrong stuff'. The days of the brave lone pilot battling the odds to win through are over, it's a team effort that wins the day, and there are plenty of examples of that. Modern medicine is becoming too complex and too fast paced to ignore the human factors that can turn a disaster into an heroic save, or vice versa. You can't ignore the impact of your own thinking, tuned to normal, routine success, and the impact of those around you when things turn nasty.

But I have been privileged to meet a new type of anaesthetist; who recognises that safety and productivity isn't just about one person. These anaesthetists recognise it's also about developing systems and cognitive strategies; that using techniques such as briefings and checklists along with 'standardised processes' brings greater reliability and resilience; and that when the chips are down the team around can really help, if you've made it clear through your words and deeds that it is the way you do business. And this generation is going beyond the frontline, to look at the tools of the trade. For example, what is the point of a connector that can be connected to something that it shouldn't be, or a drug label very similar to another yet very different in purpose? Give us the tools that make it easy to get it right, give us the processes that give safety a better chance, and give us the training so that we can use these and behave in a way to make a quantum leap in safe practice.

NAP4 gives us good data on the scale and nature of the problem, narrative evidence such as Elaine's and Gordon's makes it real, making this new type of anaesthetist the rule not the exception is up to you.

Mr Martin Bromiley
Founder Clinical Human Factors Group

QUOTATION

An excerpt from a fatal accident enquiry in 2010.

The cause of death was barotrauma as a result of perforation of the right lung as a complication of anaesthetic administration. The relevant underlying condition was a fracture of the distal phalanx of the right little finger... The termination of the anaesthetic procedure thereby allowing Mr X to waken up was a reasonable precaution which might have prevented his death. There were several opportunities when that decision could and should have been taken... There was a failure to observe and follow clear operating instructions for the safe use of the airway exchange catheter... There was a breakdown of communication among the anaesthetic team as to the experience of those present in the use of the airway exchange device... The most striking feature of this Inquiry was that none of the three experienced anaesthetists in attendance gave any consideration to the fundamental option of waking the patient, particularly having regard to the minor nature of the surgery involved. Anaesthetists need to be *actively* aware of that option, particularly, in anaesthesia for elective procedures for minor or non-essential surgery.

By permission
Sheriff Linda M Ruxton
in Fatal Accident Inquiry 15
into the death of Mr X
7 April 2010

THE ROLE OF THIS REPORT

The NAP4 project has performed for the first time a prospective study of all major airway events occurring throughout the four countries of the United Kingdom during anaesthesia, in the intensive care unit and the emergency department. Its primary role (a challenging one) was to was to determine, as accurately as possible, the incidence of complications of airway management in anaesthesia and we believe we have gone a long way to achieving this.

However we believe that the greatest value of this project has been the opportunity to learn from review of a large series of such sentinel events and analysis of emerging themes.

Section 1 of the report contains the quantitative aspects of this report. The rationale and methodology are described in Chapters 1–3 and the results in Chapters 4–6.

Section 2 is a clinical review of the cases reported to the project.

By location
Chapters 7–8 examine the events during different phases of anaesthesia and Chapters 9–10 report on events occurring in the intensive care unit and the emergency department.

By technique
Chapters 11–16 report on the complications reported organised by clinical technique.

Specialty areas, training and organisation
Chapters 17–24 examine areas of clinical specialty and important overview topics of assessment, human factors, organisation and training.

Each chapter is presented to offer maximum information on the topic and the cases reported to the project while maintaining patient and clinician anonymity. Clinical vignettes are used to describe cases which are either typical or illustrative. In these, clinical detail is necessarily presented, but identifying information is removed as much as possible.

Each clinical chapter is set out as follows

- ***Headline:*** a summary of the key contents of the chapter.
- ***What we already know:*** describing, in a brief literature review, the relevant current knowledge and areas of particular interest.
- ***Case review:*** presenting an overview of the cases reported, organised into themes wherever possible. All reported cases of interest are included here.
- ***Numerical analysis:*** enumerating the demographics and other quantitative aspects of the cases in the chapter.
- ***Discussion:*** indicating how the review of cases further informs what is known already about the chapter topic.
- ***Learning points and recommendations:*** garnered from the case reviewed but informed also by the literature review.
- ***References***.

Each chapter stands alone, but there are many issues which are relevant to several others and these are cross referenced as necessary.

The learning points sections aim to indicate where the project has identified new information or reinforced existing knowledge. The chapter authors and editors have taken as broad a view as possible in producing these learning points in an attempt to maximise the value of the report. As such they represent a combination of literature interpretation, case review and expert opinion.

The report is neither a primer nor textbook of airway management. It is not positioned either to support or condemn one particular aspect of airway management. The report does make recommendations and these recommendations that follow the learning points are intended to change practice.

Dr Tim Cook, Dr Nick Woodall

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.

EXECUTIVE SUMMARY

- 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.

- 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.

Dr Tim Cook, Dr Nick Woodall, Dr Chris Frerk

Section 1

Project description and quantitative analysis

CHAPTER 1
Introduction

Dr Tim Cook

'There is one skill above all else that an anaesthetist is expected to exhibit and that is to maintain the airway impeccably'

M Rosen, IP Latto 1984

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

Jonathan Benumof 1995

The two quotations above remind us that anaesthetists are almost defined by their ability to manage the airway. Most of the time this is a routine and highly successful procedure but it can never be assumed to be so.

The 4th National Audit Project of the Royal College of Anaesthetists (NAP4) examines a large cohort of major airway complications (leading to death, brain damage, emergency surgical airway or unexpected ICU admission) in the specialties of anaesthesia, intensive care medicine and emergency medicine. This introduction offers some context as to why this is necessary.

Anaesthetists (and other experts managing the airway) are used to high levels of success. Routine airway management does not usually fail. However, all modes of airway management employed by anaesthetists may fail and it is when they do that anaesthetists metaphorically 'earn their corn'. Broadly speaking there are only four modes of managing the airway: face mask, supraglottic airway (SAD), tracheal tube and direct access to the trachea.

Face mask ventilation fails in about 1 in 1,500 cases.[1,2] Tracheal intubation fails in around 1 in 1–2,000 routine cases,[3,4] laryngeal mask placement in around 1 in 50 cases[5] and the situation of both intubation and ventilation failure ('Can't Intubate Can't Ventilate' – CICV) is unexpectedly impossible in about 1 in 5,000 to 10,000 cases.[2,6] However the consequences of these infrequent problems are potentially catastrophic. CICV accounts for over 25% of all anaesthesia-related deaths.[6]

In emergencies all these failure rates increase several-fold. Importantly other complications of airway management also undoubtedly increase in cases of predicted difficulty and during emergency care. Failed tracheal intubation in emergencies is reported between 1 in 300 and 1 in 800.[3,7,8] CICV in the emergency department may occur as often as 1 in 200.[9]

When failure occurs other complications become more likely. These include:

- hypoxia (and its consequences – brain damage, cardiac events, death)
- hypoventilation
- oesophageal intubation
- aspiration
- airway trauma (both major life-threatening and minor)
- awareness.

It is also important not to dismiss complications arising from 'easy' and elective cases as the evidence suggests that many of these complications may occur even when airway management is apparently successful and uneventful.

When things do go wrong with airway management the consequences are significant. Most importantly there is a significant risk of patient harm and as the patient is likely to have 'presented for surgery' rather than 'for anaesthesia' these complications are of particular concern as they occur during a process that facilitates treatment rather than being the treatment itself. Such complications are also likely to figure prominently in adverse publicity and in litigation.

Detailed evidence on the epidemiology of complications is limited. Critical incident registries are poorly complied with by doctors and tend to attract reports of mostly low severity incidents. At present the best evidence has historically come from litigation-based studies. These analyses are valuable but have several limitations: as they are incomplete (often not including all insurers), delayed (often up to a decade), lack denominators, focus only on those cases that lead to litigation (and which lawyers are interested in pursuing) as opposed to all major complications and are prone to expert analyst bias. Most importantly the relationship between complications and litigation is complex[10] and it cannot be assumed that the patterns seen in litigation analyses reflect complications. Despite this they currently offer us the best information available.

In the American Society of Anesthesiologists Closed Claims Project (ASACCP) analysis, respiratory cases (which include airway events) represent about 20% of the total.[11,12] These claims are more likely than non-respiratory claims to lead to death/brain damage (78% vs 29%), be assessed as 'preventable' (50% vs 9%) and involve 'substandard care' (64% vs 28%) and a higher proportion were settled by payment (69% vs 48%). Costs associated with these claims were also substantially higher.

Inadequate ventilation, oesophageal intubation and difficult intubation are the 'big three' accounting for around up to 60% of all respiratory claims, with approximately 5% being related to pulmonary aspiration. In 2005 a review of 179 'Difficult airway claims' found more than 50% of claims described death or brain damage and care was judged as 'less than appropriate' in 50%. Claims were not restricted to the elderly and infirm, with claimants having a median age of 40, 43% ASA 1–2 and 75% related to anaesthesia for elective surgery. Almost 50% of claims were in patients in whom airway difficulty was predicted: many of whom still had a 'standard anaesthetic'. Two-thirds of anaesthesia claims occurred at induction while cases occurring after induction had a poorer outcome.

Oesophageal intubation and major airway trauma are of interest. Oesophageal intubation was often only recognised by late cardiovascular changes.[12] Lung auscultation was often unreliable. Outcome was mostly poor, with the percentage of cases paid out and the costs both being high. In recent years capnography reduced the incidence, but has not eliminated it. The vast majority of lower airway and oesophageal injuries were associated with difficult intubation: these may present late and have mortality rates of up to 20%.[13] In contrast laryngeal injuries which comprised 33% of all airway trauma claims occurred after routine intubation in 80% of cases.[14]

When major complications occurred many cases progressed from intubation difficulty to CICV, emphasising the importance of emergency surgical airway as a rescue technique. However, there was evidence of delay in performing surgical airway often until the patient was beyond rescue or in fact dead.

Another important study examining complications of airway management by Mort[14] examined over 10,000 emergency tracheal intubations in one institution over a period of 10 years. He found multiple attempts at laryngoscopy to be highly associated with marked increases in rates of complications. Compared to intubation which was achieved on first or second laryngoscopy those requiring >2 laryngoscopies led to a seven-fold increase in hypoxia (14-fold severe hypoxia), six-fold increase in oesophageal intubation, seven-fold increase in regurgitation, four-fold increase in aspiration and seven-fold increase in cardiac arrest. The absolute rates of complications are notably high: after >2 attempts at intubation the rates of complications were 70% hypoxia (28% severe hypoxia), 52% oesophageal intubation, 22% regurgitation, 13% aspiration, 11% cardiac arrest. The closed claims reports contain similar indicators of increased problems with repeated attempts at tracheal intubation and also reported that those cases occurring outside theatre fared less well with 100% suffering brain damage or death.[13] While it is clear that it is the most difficult cases that require most attempts to achieve intubation we can infer that if intubation attempts are failing something else should be tried. Put simply: if it's not working, stop trying it and do something different! The widely promulgated Difficult Airway Society guidelines strongly emphasise exactly this message.[15]

Intensive care

Airway management is similarly important in ICU with the vast majority of critically ill patients requiring tracheal intubation. Limited physiological reserve and aspects of the logistics of ICU make this potentially hazardous. This has become an area of increasing interest in the last few years. Issues of staffing, tracheostomy management and use of capnography have all come under the microscope. The limited data available documenting complications of tracheal intubation in critically ill patients, is depressing. In 1995 Schwartz reported 297 emergency intubations with an 11% initial failure rate, 8% oesophageal intubation rate, 4% aspirations and 3% deaths.[16] In 2006 Jaber and colleagues reported the results of a multi-centre study of 253 ICU intubations.[17,18] There was a 28% incidence of serious life-threatening complications, including severe hypotension (26%), severe hypoxaemia (25%), cardiac arrest (1.6%), and death (0.8%). Complications were independently increased when acute respiratory failure or shock were indications for intubation. The presence of two operators reduced complications. Both Schwartz and Jaber reported multiple attempts at intubation in more than 10% of patients. Whether such results are replicated in different countries with differing healthcare systems is unknown.

Emergency department

Due to the nature of patients attending UK emergency departments (severe trauma, critical airways etc) airway management is routinely necessary. There is increasing involvement of emergency physicians in delivery of this care and this is an evolving process. Regardless of which specialty undertakes airway management it is acknowledged that failure and complications are more frequent than under the controlled conditions in the operating theatre. Rates of difficult intubation as high as 9% and of emergency surgical airway of up to 0.5% are reported.[19–21]

The need for NAP4

There is no closed-claims system in the UK and while a recent publication explored the very limited data available on airway-related litigation (finding results that closely mirror those of the ASACCP) the analysis suffered from at least the same limitation as the ASACCP. There remains more that is unknown than known.[10] Based on its methodology NAP4 should overcome many of the limitations of clinical incident and litigation-based analyses: it focuses on major complications, is prospective and has studied a large and inclusive population over a prolonged period of time. It is hoped the report will be of interest to anaesthetists, intensivists, emergency physicians and many others.

References

1 Langeron O et al. Prediction of difficult mask ventilation. *Anesthesiology* 2000;**92**:1229–1236.

2 Kheterpal S et al. Prediction and Outcomes of Impossible Mask Ventilation. *Anesthesiology* 2009;**110**:891–897.

3 Rose DK, Cohen MM. The incidence of airway problems depends on the definition used. *Can J Anaes* 1996;**43**:30–34.

4 Samsoon GLT, Young JRB. Difficult tracheal intubation: a retrospective study. *Anaesthesia* 1987;**42**:487–490.

5 Cook TM, Lee G, Nolan JP. The ProSeal laryngeal mask airway: a review of the literature. *Can J Anaesth* 2005;**52**:739–760.

6 Nagaro T et al. Survey of patients whose lungs could not be ventilated and whose trachea could not be intubated in university hospitals in Japan. *J Anesthesia* 2003;**17**:232–240.

7 Hawthorne L, Wilson R, Lyons G, Dresner M. Failed intubation revisited: 17 year experience in a teaching maternity unit. *Br J Anaesth* 1996;**76**:680–684.

8 Rocke DA et al. Relative risk analysis of factors associated with difficult intubation in obstetric anesthesia. *Anesthesiology* 1992;**77**:67–73.

9 Sakles JC et al. Airway management in the emergency department: A one-year study of 610 tracheal intubations. *Ann Emerg Med* 1998;**31**:325–332.

10 Cook TM, Scott S, Mihai R. Litigation following airway and respiratory-related anaesthetic morbidity and mortality: an analysis of claims against the NHS in England 1995–2007. *Anaesthesia* 2010;**65**:556–63.

11 Caplan RA et al. Adverse respiratory events in anesthesia: a closed claims analysis. *Anesthesiology* 1990;**72**:828–833.

12 Peterson GN et al. Management of the Difficult Airway. *Anesthesiology* 2005;**103**:33–39.

13 Domino KB. Closed Malpractice Claims for Airway Trauma During Anesthesia. ASA Newsletter 1998;**62**:10–11.

14 Mort TC. Emergency tracheal intubation: complications associated with repeated laryngoscopic attempts. Anesth Analg 2004;**99**:607–613.

15 Henderson J et al. Difficult airway Society Guidelines. *Anaesthesia* 2004;**9**:675–694.

16 Schwartz DE, Matthay MA, Cohen NH. Death and other complications of emergency airway management in critically ill patients: a prospective investigation of 297 tracheal intubations. *Anaesthesiology* 1995;**82**:367–376.

17 Jaber S, Amraoui J, Lefrant JY. Clinical practice and risk factors for immediate complications of endotracheal intubation in intensive care unit: A prospective multiple-center study. *Crit Care Med* 2006;**34**:2355–2361.

18 Leibowitz AB. Tracheal intubation in the intensive care: extremely hazardous even in the best of hands. *Crit Care Med* 2006;**34**:2497–2498.

19 Sakles JC et al. Airway management in the emergency department: a one-year study of 610 tracheal intubations. *Ann Emerg Med* 1998;**31**:325–332.

20 Bair AE et al. The failed intubation attempt in the emergency department: analysis of prevalence, rescue techniques, and personnel. *J Emerg Med* 2002;**23**:131–140.

21 Graham CA et al. Rapid sequence intubation in Scottish urban emergency departments. *Emerg Med J* 2003;**20**:3–5.

CHAPTER 2
Evidence-based medicine and airway management: are they incompatible?

Dr Tim Cook

Dr David Bogod

The chapters that follow describe the methods, results and implications of NAP4. The project is based on review of the reports of a series of 184 major airway-related events occurring in the UK over a period of a year. From this the project team has identified themes and, combining this with previous knowledge, extracted lessons that might be learnt before outlining a series of recommendations that may guide improvement in care. It is certain that not all cases were reported, and even in the area of anaesthesia, where the project had the best coverage of hospitals in terms of LRs, we anticipate that up to three-quarters of cases may not have been reported.

Viewed in a pessimistic light, NAP4 is a collection of case reports, albeit a large one. It is far removed from the higher levels of evidence-based medicine.[1,2] The cohorts which the project team have examined are from disparate areas both geographically and clinically. In terms of evidence level (which ranges from 1++ to 4) the evidence acquired from the NAP4 database and its review would be assessed as level 3, which is actually seventh in a ranking of eight levels (Table 1). Our recommendations which are based on extensive, structured review of all cases are consensus-based expert opinion: the lowest quality (grade D) recommendations (Table 2).

Of course this is true of many reports and much of medical practice is based on equally low levels of evidence. As a relevant example the Difficult Airway Society guidelines,[3] much quoted, much referred to and widely reflected on in this report are based on a similar level of evidence. The original paper states: 'Controlled studies cannot be performed in unanticipated difficult intubation. The evidence basis of these guidelines best fits the description of expert committee reports, opinions and experience, and is defined as category IV evidence. All DAS recommendations are supported by at least two case reports or series, the strongest evidence available for infrequent emergency situations.'

There are many current debates in airway management.

- Is it important that a predicted difficult airway should be managed awake?

Table 1 Levels of evidence

1 ++	High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low-risk of bias
1+	Well-conducted meta-analyses, systematic reviews, or RCTs with a low-risk of bias
1-	Meta-analyses, systematic reviews, or RCTs with a high-risk of bias
2++	High quality systematic reviews of case control or cohort or studies High quality case control or cohort studies with a very low-risk of confounding or bias and a high probability that the relationship is causal
2+	Well-conducted case control or cohort studies with a low-risk of confounding or bias and a moderate probability that the relationship is causal
3	Case control or cohort studies with a high-risk of confounding or bias and a significant risk that the relationship is not causal
4	Non-analytic studies, e.g. case reports, case series
5	Expert opinion

Table 2 Grades of recommendations

A	At least one meta-analysis, systematic review, or RCT rated as 1++, and directly applicable to the target population; *or* A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results
B	A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; *or* Extrapolated evidence from studies rated as 1++ or 1+
C	A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; *or* Extrapolated evidence from studies rated as 2++
D	Evidence level 3 or 4; *or* Extrapolated evidence from studies rated as 2+

- Is it right to administer neuromuscular blocking agents before confirmation of the ability to ventilate the patient's lungs?
- Does rapid sequence induction increase or decrease safety overall?
- What is the best way to manage the obstructed airway?
- Is small bore cannula, large bore cannula or surgical airway the best route for accessing the trachea in an emergency?
- and many more…

It is possible to find considerable literature on all these topics[4–11] but in essence it is opinion-based, often supported by some (partially) related data, but also with arguments frequently extrapolated from evidence that is only partially relevant.

New equipment is one obvious area where airway management is bedevilled by lack of evidence. There are certain aspects of the medical equipment industry, and its regulation, that mean evaluation is based on shifting sands.[12,13] The rate of new equipment development (and modification) also makes it difficult for research to keep pace, but the reality is that the majority of airway equipment in current use has been incompletely evaluated by the profession that uses it. Evaluation can assess two important aspects: efficacy and safety. Relatively small studies can examine efficacy during routine use (e.g. two supraglottic airway devices, SAD A vs SAD B for ASA 1 arthroscopy). However, the more difficult and perhaps more important questions relating to safety and crisis management remain unanswered.

- Which is the SAD to use during advanced indications such as laparoscopy, obesity, lithotomy and ventilation?
- Is there a safe weight limit for use of a SAD?
- Can some SADs be safely used to manage low-risk emergencies?
- Which SAD is most likely to protect the patient if regurgitation occurs?
- Which SAD is most likely to rescue the airway successfully and safely during CICV?
- Which bougie is safest and most effective in an emergency?
- Which are the best new videolaryngoscopes and how often can they rescue a difficult intubation??
- Which supraglottic airway is best for use as a conduit for fibreoptic guided rescue intubation?
- Does an airway exchange catheter provide safety for difficult extubation?
- Which cricothyroidotomy catheter should we choose?

Some of these questions have been touched on in small studies and discussed in editorials, but to the best of the authors' knowledge they remain unaddressed at any reasonable level of scientific evidence.[12-20]

In routine airway management (e.g. SAD use in low-risk cases, routine intubation with a number of different laryngoscopes, low-risk rescue intubation techniques performed in healthy patients) it is arguable that the failure to answer many questions is a failing of the anaesthetic community. With three million general anaesthetics performed in the UK each year, study of even a small fraction of these cases could answer some very weighty questions. The problem, however, is not all the profession's fault, the increasingly Byzantine processes for conducting research and the ever increasing barriers to publishing simple, low-risk research will put off most clinicians. The poor support which anaesthesia receives from funding organisations, perhaps because it is considered low-risk, means that we are victims of our own success. There are solutions to these barriers and perhaps in the next few years developments, such as the National Institute of Academic Anaesthesia, will lead to a sensible reconfiguration of the research ratchet.[21]

Studies examining safety, rather than efficacy, in airway management are much more difficult to design and this is particularly so if the aim is to study serious adverse outcomes.

- Anaesthesia is safe; major adverse events occur infrequently so massive studies are needed to detect differences between devices or techniques.
- Different major complications occur in differing settings and may not all be examined in the same study.
- Most efficacy studies specifically recruit low-risk patients to avoid the risk of patient complications and other adverse events (and are encouraged so to do by ethics committees); this does not suit a safety based study.
- It may be considered by some, including ethics committees, unethical to seek out patients at high-risk of complications, even when clinical equipoise exists.
- Even if such studies are approved they need to run for extended periods of time and in multiple sites to identify and recruit sufficient patient numbers.
- Funding for such studies is difficult to acquire.

CHAPTER 2

Evidence-based medicine and airway management: are they incompatible?

Randomised controlled trials, RCTs, (the benchmark of high quality research) are often not a suitable methodology for such studies. This is particularly so when the researchers wish to study emergency airway management (e.g. what is the best anaesthetic induction technique to use for management of a high-risk obstructed airway or which equipment is most efficient for safely rescuing a high-risk lost airway). Specifically, impediments to performing high quality studies in emergency airway management include:

- major events are infrequent
- these events are unpredictable
- Where events are predictable, considerable effort is usually made to use alternative techniques so that the event does not occur
- when events do occur they do so most frequently in patients who are already anaesthetised and therefore unable to consent to take part in research
- if events occur or are predicted in those who are not anaesthetised, the clinical setting means the patient is often not in a position to give informed consent
- clinicians who attend these emergencies need to act swiftly and decisively to minimise harm and likely have little or no time to consider the possibility of performing research
- success of any technique is very much based on user experience and preference.[22]

Perhaps the most important issue is that each event that leads to a major complication is a unique situation framed by a combination of patient history, location, personnel, available equipment, available skills, pathophysiology, urgency and surgical and anaesthetic requirements. Research drawn from a small number of similar cases may therefore not be widely generalisable.

However, the research questions that remain unanswered are nevertheless important. Anaesthetic and surgical interventions are relatively unusual in that they involve the physician performing an act that is predictably dangerous for the patient (in anaesthesia this involves intentionally causing unconsciousness, respiratory arrest and inevitable airway obstruction) and then using interventions to prevent complications of these actions. Complications are therefore 'active complications' (i.e. complications of commission) rather than 'passive' ones (complications of omission). When complications arise in these circumstances they are often considered to represent failure perhaps by peers but certainly by the press and even during litigation. Compare a death from hypoxia due to failure to manage the airway after induction of anaesthesia, with a death from myocardial infarction due to failure to appropriately manage hypercholesterolaemia in general practice. It is likely there are more of the latter, but individual cases of the latter gain little adverse publicity or litigation, and the former group gain only a small slice of the research funding pie.

Study methodologies other than the RCT (prospective cohort studies, with or without prospective or historical cohort controls, critical incident database analysis and prospective complication registries – as in NAP4) may be the only methods of studying a large enough number of events to identify sufficient cases for conclusions to be drawn. However, most databases do not contain enough clinical data to extract useful learning.

Studies that involve expert review and recommendations are rightly subject to criticism. Experts may differ in their opinion,[23,24] be affected by hindsight bias,[25] change their opinion according to patient outcome,[26] have a tendency to agree with peers when placed in a group[27] and of course they may simply be wrong.

NAP4 has managed to gain approval and involvement from every NHS hospital in the four countries of the UK. Considerable efforts have been made to collect the highest quality data and to focus on those complications that are likely to be important to patients, clinicians and institutions. NAP4 review processes tried to take account of all the pitfalls described above: see Chapter 3.

So NAP4 draws on information about relevant complications, derived from a cohort of 2.9 million anaesthetics and a large number of airway interventions in the intensive care units and emergency departments of the UK. Considered in a positive light NAP4 is the synthesis of learning extracted from a large series of major airway events collected in a systematic manner, prospectively, from a large area (the whole of the UK) over a relatively long period (one year) and with 100% participation.

Industries with good safety records recognise the value of collecting, analysing and learning from incident reports relating to adverse outcomes and near misses. NAP4 has used this process in an attempt to improve the safety of airway management. We are grateful to all the clinicians who reported events and to the panel of clinicians who gave their time to review them and develop the recommendations.

It is our hope that systems for learning will become embedded in our professional culture.

References

1 Harbour R, Miller J. The Scottish Intercollegiate Guidelines Network Grading Review Group. A new system for grading recommendations in evidence-based guidelines *British Medical Journal* Br 2001;**323**:334–336.

2 Scottish Intercollegiate Guidelines Network SIGN 50: A guideline developer's handbook. Annex B: Key to evidence statements and grades of recommendations (www.sign.ac.uk/guidelines/fulltext/50/annexb.html).

3 Henderson JJ et al. Difficult Airway Society guidelines for management of the unanticipated difficult intubation. *Anaesthesia* 2004;**59**:594–675.

4 Calder I, Yentis SM. Could 'safe practice' be compromising safe practice? Should anaesthetists have to demonstrate that face mask ventilation is possible before giving a neuromuscular blocker? *Anaesthesia* 2008;**63**:113–115.

5 Broomhead RH, Marks RJ, Ayton P. Confirmation of the ability to ventilate by face mask before administration of neuromuscular blocker: a non-instrumental piece of information? *Br J Anaesth* 2010;**104**:313–317.

6 Kheterpal S et al. Incidence and predictors of difficult and impossible mask ventilation. *Anesthesiology* 2006;**105**:885–891.

7 Neilipovitz DT, Crosby ET. No evidence for decreased incidence of aspiration after rapid sequence induction. *Can J Anaesth* 2007;**54**:748–764.

8 Levy D. Traditional rapid sequence induction is an outmoded technique for Caesarean Section and should be modified. *Int J Obs Anaes* 2006;**15**:227–232.

9 Vanner RG, Asai T. Safe use of cricoid pressure. *Anaesthesia* 1999;**54**:1–3.

10 Mason RA, Fielder CP. The obstructed airway in head and neck surgery. *Anaesthesia* 1999;**54**:625–628.

11 Nouraei SA et al. Physiological comparison of spontaneous and positive-pressure ventilation in laryngotracheal stenosis. *Br J Anaesth* 2008;**101**:419–423.

12 Cook TM. The classic laryngeal mask airway: a tried and tested airway. What now? *Br J Anaesth* 2006;**96**:149–152.

13 Wilkes AR, Hodzovic I, Latto IP. Introducing new anaesthetic equipment into clinical practice. *Anaesthesia* 2008;**63**:571–575.

14 Cook TM. Spoilt for choice? New supraglottic airways. *Anaesthesia* 2003;**58**:107–110.

15 Fabregat-López J , Rojo BG, Cook TM. A case series of the use of the ProSeal laryngeal mask airway in emergency lower abdominal surgery. *Anaesthesia* 2008;**63**:967–971.

16 Annamaneni R et al. A comparison of simulated difficult intubation with multiple-use and single-use bougies in a manikin. *Anaesthesia* 2003;**58**:45–49.

17 Mihai R et al. A quantitative review and meta-analysis of performance of non standard laryngoscopes and rigid fibreoptic intubation aids. *Anaesthesia* 2008;**63**:745–760.

18 Frerk CM, Lee G. Laryngoscopy: time to change our view. *Anaesthesia* 2009;**64**:351–354.

19 Pandit JJ et al. Comparison of times to achieve tracheal intubation with three techniques using the laryngeal or intubating laryngeal mask airway. *Anaesthesia* 2002;**57**:128–132.

20 Frerk C, Frampton C. Cricothyroidotomy; time for change. *Anaesthesia* 2006;**61**:921–923.

21 Pothier DD. Introducing the concept of the research governance 'ratchet'. *Research Ethics Review* 2006;**2**:272–273.

22 Hung O, Murphy M. Context-sensitive Airway Management. *Anesth Analg* 2010;**110**:982–983.

23 Cook TM, Morgan PJ, Hersch PE. Equal and opposite expert opinion. Airway obstruction of a retrosternal thyroid mass: management and prospective international expert opinion. *Anaesthesia* (In press), January 2011.

24 Posner KL, Caplan RA, Cheney FW. Variation in expert opinion in medical malpractice review. *Anesthesiology* 1996;**85**:1049–1054.

25 Henriksen K, Kaplan H. Hindsight bias: outcome knowledge and adaptive learning. *Quality and Safety in Health Care* 2003;**122(supp 2)**:ii46–50.

26 Caplan RA, Posner KL, Cheney FW. Effect of outcome on physician judgments of appropriateness of care. *JAMA* 1991;**265**:1957–1960.

27 Crosby E. Medical malpractice and anesthesiology: literature review and role of the expert witness. *Can J Anaesth* 2007;**54**:227–241.

CHAPTER 3
Methods of NAP4


Dr Tim Cook


Dr Nick Woodall


Dr Chris Frerk

This chapter is based on the original paper reporting the results of the NAP4 project.

It appears here by kind permission of the Editor-in-Chief and board of the *British Journal of Anaesthesia* where it was first published.

Cook TM, Woodall N, Frerk C. Major complications of airway management in the UK: results of the 4th National Audit Project of the Royal College of Anaesthetists and the Difficult Airway Society. Part 1 Anaesthesia. *Br J Anaesth* 2011.

The 4th National Audit Project of the Royal College of Anaesthetists and the Difficult Airway Society (NAP4) was established to estimate the incidence of major complications of airway management in NHS hospitals in the United Kingdom (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.

The following chapters describe the results of this project for both events during anaesthesia and occurring in ICU and the emergency department.

Methods

A two-part project was devised using methods based on the 3rd National Audit project of the Royal College of Anaesthetists.[1] First, a census of airway management techniques employed in the UK National Health Service (NHS) provided information on anaesthetic activity and airway management techniques in current use (for denominator information: see Chapter 4); second, 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 organisations with an interest in this area of clinical care.

Using surface mail, email 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 LR 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 Difficult Airway Society (DAS) and Royal College of Anaesthetists (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 and by a poster campaign to promote awareness and encourage participation. Reminders were sent to hospital LRs approximately every six to eight weeks throughout the data collection period.

Part 1 Census of clinical activity (denominator data)

A detailed description of the census phase has been published,[2] and this methodology is described in greater detail in Chapter 4. Briefly, each LR was asked to return data for a two-week period in September 2008 that indicated the number of anaesthetics performed in the hospital with the exception of those performed 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' (face mask, supraglottic airway device or tracheal tube) was requested. Tracheal intubation included all forms of intubation of the trachea: i.e. 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 LR. 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
- 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 to or from these departments were also requested but these were not to be used for the calculation of incidence of complications associated with anaesthesia. 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 one 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 to 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 $kg.m^{-1}$ or obese body habitus.

Notification of events

The RCoA-lead (TMC) was notified of events meeting inclusion criteria by email. LRs 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 emailed the LR for that hospital, specifying the project inclusion criteria, and requesting confirmation that the case did or did not meet criteria and that it 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 LR was issued with a unique identifying number and website access password enabling a secure connection to the project website for online data submission. Passwords were issued by the RCoA-lead through the project website using a remote process. The RCoA-lead had no access to the password itself but was aware of the unique identification number, which was used to 'track' the case.

Data submission

Data were submitted by the LR 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 online by using the unique identifier to note whether the case was recorded as 'password unchanged', 'password changed' or 'form closed'.

Table 1 Categories of incident contributory factors. Categories are taken from the National Patient Safety Agency document Seven steps to patient safety: a guide for NHS staff[12]

Factors	Positive	Contributory	Causal
Communication (includes verbal, written and non-verbal: between individuals, teams and/or organisations)			
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)			
Organisation and strategic (e.g. organisational 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			

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 LR. When a file was closed (i.e. completed and submitted) this event was notified automatically to the DAS-lead (NW). 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 LR through the project website by a remote process (i.e. so the DAS-lead was unaware who the recipient was). 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 precondition 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.

The period during which events were included in NAP4 ran from 1 September 2008 to 31 August 2009: notifications were accepted until June 2010, after which the identification numbers issued to LRs 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 Royal College of Anaesthetists, the Difficult Airway Society, 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 divided into 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 review 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, causative or positive factors under the categories described in Table 1. Causal factors were those that were so prominent that they were considered directly linked to the event while contributory factors were those that had 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).[3] Cases with an outcome of death and persisting brain damage (i.e. brain damage that had not shown evidence of improvement or recovery at the time the case was reported) were also extracted. Cases were analysed for learning points and some were selected to act as illustrations of clinical care for inclusion in the current report. Airway management was classified as good, poor, mixed (elements of both good and poor management), or unclassifiable, reviewers were reminded of likely outcome[4] and hindsight bias.[5] 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.

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[3]

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

* 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, physiologic or intellectual.

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 were derived using binomial probability tests with the stat-conf programme Handbook of Biological Statistics, 2008 (http://udel.edu/~mcdonald/statconf.html).

For patients in ICU and Emergency Departments 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 Emergency Department activity was completed by one of the authors of this paper.[6]

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 was examined for evidence of clustering by time and place in an attempt to assess the completeness of data collection. Reports from LRs (i.e. in which the LR was also the anaesthetist) were identified. It was assumed that all LRs 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 (consultant) anaesthetists acted as LRs did.

References

1 Cook TM, Counsell D, Wildsmith JAW. On behalf of the Royal College of Anaesthetists Third National Audit Project. Major complications of central neuraxial block: report on the 3rd National Audit Project of the Royal College of Anaesthetists. *Br J Anaesth* 2009:**102**:179–190.

2 Woodall NM, Cook TM. A national census of airway management techniques employed during anaesthesia in the UK: results of the first phase of the 4th National Audit Project at the Royal College of Anaesthetists. *Br J Anaesth* 2010; e-published December 2010 doi: 10.1093/bja/aeq339.

3 Seven steps to patient safety: a guide for NHS staff. National Patient Safety Agency, 2004 (www.nrls.npsa.nhs.uk/resources/?entryid45=59787, accessed 26 December 2010).

4 Caplan RA, Posner KL, Cheney FW. Effect of outcome on physician judgements of appropriateness of care. *JAMA* 1991;**265**:1957–1960.

5 Henriksen K, Kaplan H. Hindsight bias: outcome knowledge and adaptive learning. *Qual Saf Health Care* 2003;**122(supp 2)**:46–50.

6 Benger J, Hopkinson S. Rapid sequence induction of anaesthesia in UK Emergency Departments: a national census. *Emerg Med J* 2010 doi: 10.1136/emj.2009.085423.

CHAPTER 4

Results of the first phase of NAP4: census

Dr Nick Woodall

Dr Tim Cook

Dr Chris Frerk

This chapter appears by kind permission of the Editor-in-Chief and board of the *British Journal of Anaesthesia* where it was first published.

Woodall NM, Cook TM. National census of airway management techniques used for anaesthesia in the UK: first phase of the 4th National Audit Project at the Royal College of Anaesthetists. *Br J Anaesth* 2011;**106**:266–271.

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 commonest 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 Anaesthesiologists (ASA) has a long-standing interest in closed malpractice claims arising in the United States of America (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 United Kingdom (UK), although the National Patient Safety Agency (NPSA) collects reports of, and responds to, critical incidents.[7] The 4th National Audit Project of the Royal College of Anaesthetists is an attempt to investigate these areas. This chapter describes a census, taken over a two-week period, of current UK airway management practice employed 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, email and telephone the anaesthetic department in every National Health Service (NHS) hospital in the UK was contacted and invited to participate in the 4th National Audit Project of the Royal College of Anaesthetists (NAP4) and to nominate a LR (LR) who for phase 1 of the project would co-ordinate a census of current activity. 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 by electronic or surface mail for the two-week period from 15–28 September 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: 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 two-week period an anaesthetic face mask, supraglottic airway device (SAD) or tracheal tube was employed 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: e.g. single and double lumen tubes, tracheostomy, surgical bronchoscopy, transglottic and transtracheal 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, were distributed to LRs for use, if they elected to use a paper based method, though 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, email 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 15 September 2008 or if local circumstances had prevented data collection during the planned census period LRs were invited to submit data for an alternative two-week period. Where no data had been received before the end of August 2009 data for the two-week period from the 14–27 September in 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 identified 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 two 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 31 August 2008 to 1 September 2009 was divided by the total general anaesthetic 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.

Validation. 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 2008–2009 period were analysed. This database records the primary procedure performed on NHS patients over each financial year. The HES data provides numbers for procedures performed on all NHS patients in England including those treated within the private sector or in independent sector treatment centres. The database provides no information on the type of anaesthesia. A group of senior clinicians including anaesthetists with experience in all clinical specialties (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 United Kingdom.

Results

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

In the two-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 SAD 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, Maidenhead, UK), 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 1,000 general anaesthetics and fewer than 1 in 500 tracheal intubations. Anaesthesia by face mask 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 a SAD, 1.1 million with a tracheal tube and 0.15 million with an anaesthetic face mask. Subtypes of airway device are summarised in Table 2.

CHAPTER 4

Results of the first phase of NAP4: census

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%
Face mask	6,167	154,200	5.3%	82%

In 2,554 (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%) with intravenous induction of anaesthesia, with a minority being managed by inhalational induction (9%) or awake fibreoptic intubation (10%). In children with predicted difficult airways inhalational induction (63%) was much more common than intravenous 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 employed 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.

A study period of two weeks is relatively short and consideration was given to asking reporters to collect information over a longer 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'

Table 2 Detailed breakdown of airway techniques used (* = to the nearest 100)

(Accurate or close estimate)	Two-week total	Annual estimate *	% of all airways	% of subgroup
Face mask (80)				100
Anaesthetic face mask	4,784	119,600	4.2	77.6
Hudson type of mask	1,383	34,600	1.2	22.4
Supraglottic airway (80)				100
Laryngeal mask	56,388	1,409,700	49.2	87.3
i-Gel	4,574	114,400	4.0	7.1
ProSeal LMA	1,920	48,000	1.7	3.0
Other	1,741	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	3,300	0.12	0.3
TTJV	83	2,100	0.07	0.19
Bronchial blocker	60	1,500	0.05	0.14
Other	53	1,300	0.05	0.12

for the primary airway management device) supports the decision to pursue a 'snapshot' approach, meaning that robust denominator data are available for use with the data from the 12-month review of complications. The 100% compliance rate probably reflects the recognised importance of the overall aim of the project and the persistence with which data were sought. The support of all the key organisations (see Acknowledgements) was vital in demonstrating that importance: their support, as well as that of the LRs, is greatly appreciated.

To provide an estimate of annual activity the results of the two-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 work, and two to three weeks of emergency only work, this having a differential effect on the several anaesthetic sub-specialties. 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 specialty, and an overall multiplier of 24.9. When the number of general anaesthetics for the year 2008 was divided by the number of general anaesthetics performed at the Norfolk and Norwich hospital during the survey period in September 2008 the multiple was 24.5. Therefore on the basis of these data 25 was accepted and applied to all data.

Though not a prime aim of the census our data suggests 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 this figure excludes regional analgesia for labour which would add an additional 110,000 cases.[10] Depending on whether these cases were captured 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) are drawn from the same population as the census. Cases reported from ISTC and private sector hospitals may have been submitted during the second phase of NAP4 but these were not to be used for the calculations of incidence.

We believe the results of this census are the first robust attempt to determine the number of general anaesthetics delivered in the UK: this is something of a surprise. The RCoA census of anaesthetic activity in 2007 estimated 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 one-third of anaesthetics are delivered by two anaesthetists (consistent with figures from the authors' hospitals) our figures would equate to the average figure of general anaesthetics delivered by UK anaesthetists in NHS hospitals of approximately 340 per annum. If 10% of all anaesthetists (as in the RCoA census) work half-time the mean full-time equivalent figure rises to 360 general anaesthetics per annum. Of course this figure does not include cases managed under local or regional anaesthesia alone: perhaps accounting for an additional 25% based on data collected in this audit. 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, pre-operative 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 324–333 general anaesthesia cases per annum for consultants with local or regional anaesthesia accounting for 20–30% of anaesthetics administered.

The vast majority of tracheal intubations were performed with a single lumen tube (over one million). Our estimate of the frequency of use of other tracheal intubation techniques are based on small numbers and are therefore the least reliable of those we quote. 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 1,000 general anaesthetics and fewer than 1 in 500 tracheal intubations. Accepting any reservations about the absolute 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: 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. Indeed they are relevant for instance to the finding in this report of a low success rate for rescue cannula cricothyroidotomy when performed by anaesthetists, as discussed elsewhere in this report (see Chapters 5 and 13).

The study has intrinsic weaknesses. First, whatever method was used to collect data it is likely any final figure will be an under-estimate of actual activity as cases are far more likely to be missed or omitted than fabricated. Second, 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 be affected by lapse of memory of the individual anaesthetists, leading to omissions. Third, the increasing subdivisions 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. As a result we have more confidence in the broader figures (e.g. mask vs SAD vs tracheal tube) than subdivisions. Fourth, 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 in our final figure 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 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 three million derived from HES data which also includes NHS patients treated in private hospitals and ISTCs. Independent sector treatment centres were estimated to account for 1.8% of elective NHS activity in 2007–2008[13] and private practice accounts for approximately 10% of surgical activity in the UK.[14] Using these broad estimates it is likely the overall number of general anaesthetics in the UK is between 3.1–3.3 million: though the assumptions used make this figure rather less accurate than the figure reported here for activity in NHS hospitals.

In conclusion, a national survey of the four countries making up the UK was undertaken to provide an estimate of the number of general anaesthetics performed in one year in UK NHS hospitals and to identify the pattern of airway management techniques used for these cases. We estimate 2.9 million general anaesthetics were performed in this population in 2008–2009: 56% utilising a supraglottic airway, 38% via tracheal tube and 5% using an anaesthetic face mask. These data are used as the dominator for calculating an estimated incidence of major complications of airway management techniques in the UK: see subsequent chapters.

References

1 Utting JE. Pitfalls in anaesthetic practice. *Anaesthesia* 1987;**59**:877–890.

2 Gannon K. Mortality associated with anaesthesia. A case review study. *Anaesthesia* 1991;**46**:962–966.

3 Cook TM, Scott S, Mihai R. Litigation related to airway and respiratory complications of anaesthesia: an analysis of claims against the NHS in England 1995–2007. *Anaesthesia* 2010;**65**: 556–563.

4 Caplan RA et al. Adverse respiratory events in anesthesia: A closed claims analysis. *Anesthesiology* 1990;**72**:828–833.

5 Gene N et al. Management of the Difficult Airway. A Closed Claims Analysis. *Anesthesiology* 2005;**103**:33–39.

6 Special Article. Practice Guidelines for Management of the Difficult Airway. An Updated Report by the American Society of Anesthesiologists Task Force on the Management of the Difficult Airway. *Anesthesiology* 2003;**98**:1269–1277.

7 Smith AF, Mahajan RP. National critical incident reporting: improving patient safety. *Br J Anaesth* 2009;**103**:623–625.

8 HES online. *Hospital Episode Statistics* (www.hesonline.nhs.uk/Ease/servlet/ContentServer?siteID=1937&categoryID=459, accessed 6 April 2010).

9 Population estimate for UK in 2008. *Office of National Statistics* (www.statistics.gov.uk/cci/nugget.asp?id=1352, accessed 6 April 2010).

10 NOAD report Data. *OAA*, London 2007 (www.oaa-anaes.ac.uk/assets/_managed/editor/File/NOAD/NOAD_2007_data_report.pdf, accessed 6 May 2010).

11 McLaughlan C. *RCoA Bulletin* 2008;**50**:2577–2578.

12 Cook TM, Alexander R. Major complications during anaesthesia for elective laryngeal surgery in the United Kingdom: a national survey of the use of high pressure-source ventilation. *Br J Anaesth* 2008;**101**:266–272.

13 Naylor C, Gregory S. Independent sector treatment centres. *Kings Fund Briefing*, October 2009 (www.kingsfund.org.uk/document.rm?id=8457, accessed 7 May 2010).

14 Laing's Healthcare Market Review and Directory of Financial Information. *Laing and Buisson*, 2009–2010. 22nd edition (ISBN: 978-1-85440-140-3).

CHAPTER 5

Results of the second phase of NAP4: overall results and anaesthesia

Dr Tim Cook

Dr Nick Woodall

Dr Chris Frerk

This chapter is based on the original paper reporting the results of the NAP4 project.

It appears here by kind permission of the Editor-in-Chief and board of the *British Journal of Anaesthesia* where it was first published.

Cook TM, Woodall N, Frerk C. Major complications of airway management in the UK: results of the 4th National Audit Project of the Royal College of Anaesthetists and the Difficult Airway Society. Part 1 Anaesthesia. *Brit J Anaesth* 2011.

Introduction

Airway management is fundamental to safe anaesthetic practice and in most circumstances is uncomplicated but it has been recognised 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 litigation 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. Due 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.

The 4th National Audit Project of the Royal College of Anaesthetists and the Difficult Airway Society (NAP4) was established to estimate the incidence of major complications of airway management in NHS hospitals in the United Kingdom (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.

The following chapter describes the results of this project in ICU and the emergency department.[10]

Methods are described in Chapter 3.

Results

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

Table 1 Clustering of cases by hospital. Analysis of reviewed cases

Number of cases reported	Number of hospitals	% of hospitals	% 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%

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 after 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 Chapter 3, 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 1 shows numbers of cases reported by hospitals for the 207 reviewed. Four percent of hospitals reported 23% of cases, 6% reported 34% and 15% reported 59% of these cases. An analysis of the distribution of reports suggested they did fit a Poisson distribution, consistent with complete data capture, but not confirming it.

Person clustering: LRs reported 19 anaesthesia-related events (i.e. the LR was also the anaesthetist in 19 cases) out of 130 where this information was provided. There were 286 LRs and the 2007 Royal College of Anaesthetists census identified 6,233 consultant anaesthetists[11] (i.e. LRs are 4.6% of all consultant anaesthetists). If all consultant anaesthetists behaved as LRs we might anticipate 19 x 6,233/286 = 414 reports from consultants. As 36% of cases occurred in the absence of a consultant this figure for all anaesthetists might increase to 414 x 100/(100–36) = 414 x 1.56 = 646. As this figure is based on only 130 of the 133 anaesthesia cases our upper limit of cases is 646 x 133/130= 661. This figure suggests that, at worst, we captured approximately 1 in 5 of relevant cases. It is likely this figure should be adjusted further: part-time consultants account for 10% of the consultant workforce and up to a 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 1 in 3 or 1 in 4 cases that occurred.

Table 2 Incident reports classified (1) by ASA grade and type of event, (2) by age and type of event, and (3) 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 3.

	All cases (n=184)	Anaesthesia (n=133)
ASA		
1	26	23
2	62	51
3	59	40
4	29	13
5	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)

*prolongation of stay in the case of patients already in ICU

Demographic data

The distribution of patients by ASA grade is shown in Table 2. In all cases there were 113 males and 71 females and in anaesthesia cases 82 males and 51 females. The majority of patients involved in anaesthesia cases were ASA grade 1 or 2 (56%), males (62%) and age <60 years (61%). A BMI of >30 $kg.m^{-2}$ or obese body habitus was recorded in 40% of reported anaesthesia cases and a BMI of <20 $kg.m^{-2}$ or cachexia in 11%. The majority (54%) of the procedures for which anaesthesia was being induced were elective or scheduled. Sixty-nine percent of all events occurred during normal working hours (08.01–18.00), 17% out of hours before midnight (18.01–24.00), 14% out of hours after midnight (00.01–08.00): for events during anaesthesia a greater proportion took place during the day (76%, 08.01–18.00), and a lesser proportion overnight (6%, 00.01–08.00). The anaesthesia events occurred most commonly in the operating theatre 47%, then anaesthetic room 37% and recovery unit 14%. The phase of anaesthesia was at induction 52%, during maintenance 20%, during 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 speed of response to a request for help was recorded in 99 cases: 32 in less than one minute, 43 in one to four minutes, 21 in five to 30 minutes and three after more than 30 minutes. 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 less than one minute, in 36 was one to four minutes, in 11 was five to 30 minutes and in two was more than 30 minutes: five of the 13 events with a response time exceeding five minutes occurred out of hours.

Inclusion criteria and event outcomes

The inclusion criteria indicated by reporters are presented in Table 3. The final outcome of events is presented in Table 4, first focusing on outcomes of death and brain damage and also by NPSA classification of severity of harm.

Deaths

Death resulting from an airway problem was the inclusion criterion for 33 reports (Table 3), of which 14 occurred during anaesthesia, 16 in ICU and three in the emergency department. In ten further cases the reporter indicated a lesser severity inclusion criterion but also that the patient died before the report was submitted. Of these ten '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%.

Table 3 Final outcome 1) Narrative outcome, 2) NPSA classification (see Chapter 3)

	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

Brain damage

In 13 patients brain damage was provided as an inclusion criterion (Table 3), 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 one month although it would require one year to elapse before this diagnosis could be made). Combined rate of death and brain damage for all cases was 46/184, 25.0% and for events during anaesthesia 19/133, 14.3%.

Emergency surgical airway

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

In 29 anaesthesia cases the first choice for emergency surgical airway was tracheostomy: 18 in semi-controlled circumstances where intubation had failed or not been attempted but the airway could be maintained on a face mask or laryngeal mask and in 11 cases as a true emergency rescue technique for a patient in extremis. All emergency tracheostomies were successful (i.e. tracheal tube placement in the trachea was achieved, though not always without difficulty or delay). Two patients in this group died, one because the tracheostomy was not able to bypass a lowlying 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 (≥2mm) 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 anesthetist 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, myocardial ischaemia or cardiac arrest in four. Other reports cited problems with oxygenation and ongoing airway obstruction. Of the 100 admitted to ICU following 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 in 23 aspiration during anaesthesia was the primary airway event, while in six it complicated another primary event: eight of these patients died and two suffered brain damage.

Primary airway problem during anaesthesia

The recorded primary airway problem for all events and for anaesthesia events is shown in Figure 1. Problems with tracheal intubation were the most frequently recorded. Difficult or delayed intubation, failed intubation and 'can't intubate can't ventilate' (CICV) were prominent problems accounting for 39% of all events and events during

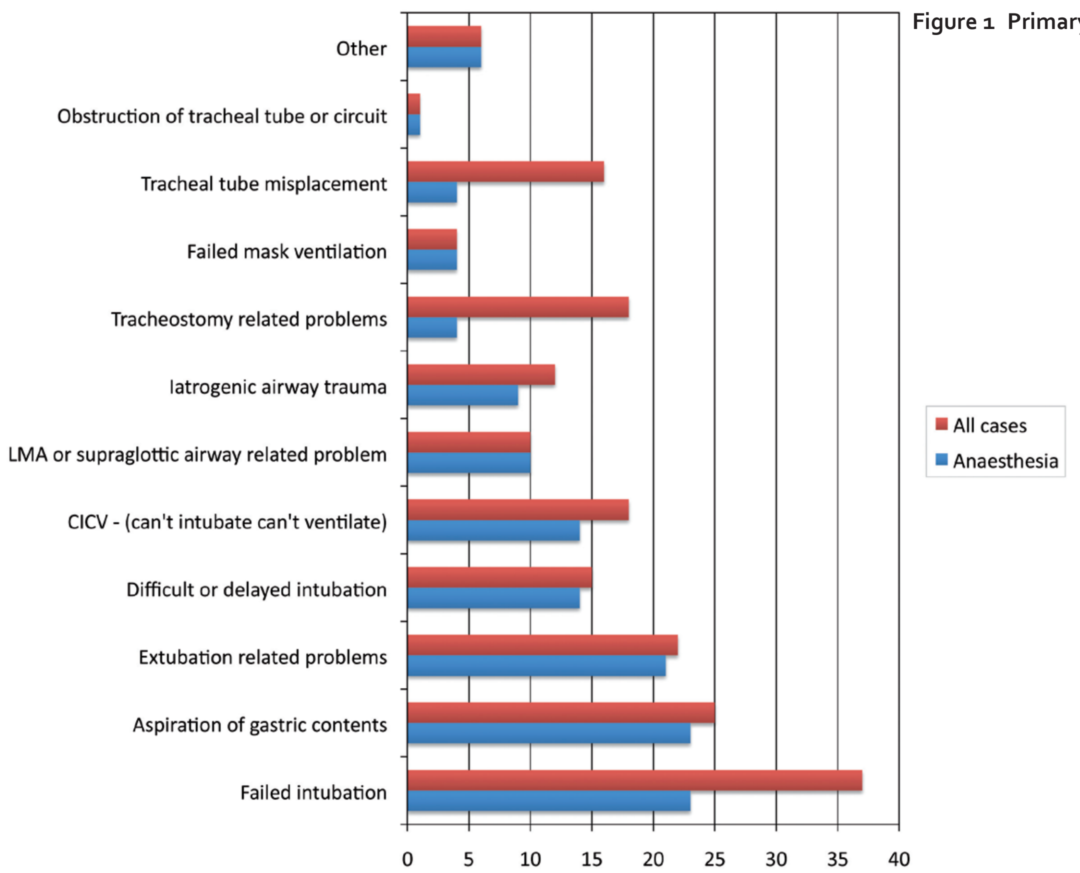

Figure 1 Primary airway problem

Table 5 Incidence estimates of major airway complications by airway type for events and death/brain damage: expressed as events per million cases and fractions (1 in n cases). The denominator for each calculation is from the 4th National Audit project Census.[12] For each, point estimate and lower and upper confidence limits (CL) are presented

			Events per million cases			Events as fractions 1 in n cases		
Type of event	Numerator	Denominator	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

anaesthesia. Aspiration then extubation problems followed tracheal intubation in frequency of reported complications. Amongst 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.

Table 4 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 face mask +/- oropharyngeal airway	3
Tracheostomy	3
New tracheostomy or cricothyroidotomy	2
TOTAL	133

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), face mask (seven). More detail is given in Table 4.

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 confidence interval of 38 per million (though 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 confidence intervals for incidence of death (or death and brain damage) from an airway event during general anaesthesia (Table 5), The census data also provided estimates of frequency of use of airway devices (tracheal tube, supraglottic airway device and face mask) and estimates of the risk of events and poor outcomes with these devices can be derived (Table 5).

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 commonest 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 one, tracheal tube eight, none one. 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 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 ten patients complications arose during induction of anaesthesia primarily to secure a critical airway. Three complications were reported in patients following elective head and neck surgery, who returned to theatre from wards for urgent re-operation. The reviewers assessed airway management as poor in nearly one-third of reported cases. Issues of assessment, planning and communication within teams were prominent in these cases.

Obstetrics

There were four reported events in pregnant women: all involved emergency Caesarean section and problems at the time of intubation. All took place out of hours and involved complex patients (two of whom had a BMI >35kg/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 cricoithyroidotomy attempt and one a successful surgical airway. All were admitted to ICU and made a full recovery.

Paediatrics

There were ten events in children under the age of ten years: eight during anaesthesia, and one each in ICU and in the emergency department. Five cases involved infants and nine children aged <4. Outcomes included three deaths. Of the eight anaesthetic complications, there were four cases of difficult intubation (two of which were 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 anaesthetised in the presence of a consultant. The review panel considered 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 primary airway problem related to tracheal intubation in similar proportions of 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 room, 16 in the recovery room and two occurred in transit between these locations. 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

Table 6 Factors assessed by review panel to contribute or cause events and factors indicating good practice. For definitions of factors listed (see Chapter 3)

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
Organisation 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

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

The use of monitoring was universal in 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 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 four 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 2 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 unrecognised 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 unrecognised oesophageal intubation during anaesthesia leading to one death and one case of brain damage.

Review panel analysis

Degree of harm

The outcomes ascribed to all 184 cases by the review panel are presented in Table 4.

Causal, contributory and positive aspects of care

All reports were assessed to identify causal and contributory factors (Table 6). 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 a 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 organisation/strategic (19%).

In the anaesthesia-related cases similar patterns were observed (Table 6). 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%). Organisation/strategic factors were also causal or contributory in more than a quarter of cases. Positive factors were identified in 65 cases (49%): the most frequent positive factors were organisation/strategic (21% of cases) and team/social and communication (each 15%).

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% (Table 7). 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 7).

Discussion

This project has for the first time performed a prospective study of all major airway events occurring throughout the four countries of the United Kingdom during anaesthesia, in ICU and the emergency department. It has identified a cohort of such patients, a minimum prevalence and enabled calculation of a minimum incidence of such events. This chapter 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, face mask) 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.

Table 7 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

A detailed analysis of events which occurred in ICU and in emergency departments is presented in Chapter 6.

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 United Kingdom over a period of one year. A similar study of deaths related to airway complications performed in France during 1999[13] analysed death certificates to identify cases, a questionnaire was then sent to the certifiers. In the United States Li collected reports by using the International Classification of Diseases (ICD-10) codes to identify anaesthesia-related complications.[14] Deficiencies with death certification in the UK have been highlighted previously in the earliest confidential enquiry into Peri-operative deaths and problems remain.[15] 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 LRs to identify cases. This enabled us to identify those cases that we believe most would identify 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 has 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 one year 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) 1 in 180,000 anaesthetics, ICU admission (at least) 1 in 29,000 and emergency surgical airway (at least) 1 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 5).

An important finding in this project is the relative frequency of major airway events occurring with different airway devices. Importantly comparisons between these groups are likely to be robust as reporting rates are likely to be equal. Categorising 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, face mask 6.6 per million, supraglottic airway five 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 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.

In this project aspiration (primary airway event in 16.5% of anaesthesia-related events, secondary event in another 5%, primary event in 50% of deaths) was the single commonest primary cause of fatality in anaesthesia events. Aspiration is the cause of litigation in about 10–15% of anaesthesia airway-related claims in America[16] and the UK[3] and of about one third of cases where litigation is related to death. In Auroy's study aspiration was the cause of death in 83 of 131 deaths (63%). While the absolute incidence of such events is rare, these data emphasise 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 rapid sequence induction 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 indicating intubation difficulty (failed intubation, delayed or difficult intubation, CICV). 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 Auroy's study 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. Auroy's point estimate for deaths related to difficult intubation is 21 per million with a very wide confidence interval of (3–77). Li's study identified failed, difficult intubation or wrongly placed tracheal tubes to account for 2.3% of all anaesthesia-related deaths. When the fact that the majority of airway events occurred in elective surgery, in ASA 1–2 patients aged under 60 this project acts as a reminder that major airway complications 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 approximately 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 percent of all patients notified to NAP4 were obese. Obesity was identified in 40% of anaesthesia cases and cachexia in 11%. The incidence of adult obesity in the UK in 2008 was reported to be 24.5%[17] 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,[18] perhaps tracheal intubation[19] 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.[20] 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.

In terms of timing of events 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 might have led to a change in clinical management and outcome. Each of the cases serves to remind that absence of expired carbon dioxide (i.e. a flat capnograph) 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
- those whose airways are being maintained with supraglottic or other similar airway devices.'[21]

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 commonest extrinsic (care-related) 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 approximately 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, amongst other factors would likely have mitigated the events or even prevented some. Amongst 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 less than four minutes 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 organisation/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 1,000 anaesthetists may be involved with such events each year (approximately one event for a consultant every six years). 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.

Limitations

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 confidence interval surrounding it. Our estimate is of 46 events per million (95% Confidence Interval 38–54) and with 12% of these leading to death a fatality rate of 5.6 per million (CI 2.8–8.3). Auroy's study identified 'airway deaths' of 20 per million (CI 7–36): while these confidence limits overlap those of Auroy are wide and suggest a higher rate of complications than the current study.[13]

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 maximise reporting but acknowledge that many factors may have contributed to under-reporting. There may be a personal or organisational reluctance to release information if there is an ongoing investigation or if litigation is anticipated. Furthermore after facing challenging events some anaesthetists will have suffered personal trauma. 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% confidence interval 1 in 212,000–1.1 million). Other large studies have reported rates of fatal aspiration associated with anaesthesia from 1 in 45,000[22] to 1 in 240,000[23] with one study identifying no cases in 198,000 paediatric anaesthetics.[24] These data suggest, but cannot confirm under-reporting to the NAP4 project and cannot 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 LRs in 100% of NHS hospitals in the UK and all LRs 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 our review process was robust. It can be summarised as a structured implicit review performed in teams. Pitfalls of retrospective case review include variation in reviewer opinion, outcome bias,[25] hindsight bias,[26] and a bias we will call 'consensus bias'. The latter bias occurs because teams reviewing cases often reach internal agreement but disagree with other teams.[27] 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 categorising 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 organisations 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.

Conclusions

Airway management during anaesthesia is associated with serious complications and 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 rise to one death per 45,000 general anaesthetics.

Important findings related to anaesthesia cases in this project.

1. More than half of patients were male, ASA 1–2, aged under 60 and most events occurred during elective surgery under the care of anaesthetic consultants.
2. Aspiration was the most frequent cause of anaesthesia-airway-related mortality.
3. Obese patients were disproportionately represented.
4. Obstructing airway lesions generated a large number of complications, many reports showed evidence of poor planning of primary and rescue techniques.
5. Cricothyroidotomy by anaesthetists was associated with a high rate of failure.
6. One in four events occurred at the end of anaesthesia or in the early recovery room.
7. Omission or incorrect interpretation of capnography led to undiagnosed oesophageal intubation.
8. 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.

References

1 Utting JE. Pitfalls in anaesthetic practice. *Anaesthesia* 1987;**59**:877–890.

2 Gannon K. Mortality associated with anaesthesia. A case review study. *Anaesthesia* 1991;**46**:962–966.

3 Cook TM, Scott S, Mihai R. Litigation related to airway and respiratory complications of anaesthesia: an analysis of claims against the NHS in England 1995–2007. *Anaesthesia* 2010;**65**:556–563.

4 Caplan RA et al. Adverse respiratory events in anesthesia: A closed claims analysis. *Anesthesiology* 1990;**72**:828–833.

5 Gene N et al. Management of the Difficult Airway. A Closed Claims Analysis. *Anesthesiology* 2005;**103**:33–39.

6 Special Article. Practice Guidelines for Management of the Difficult Airway. An Updated Report by the American Society of Anesthesiologists Task Force on the Management of the Difficult Airway. *Anesthesiology* 2003;**98**:1269–1277.

7 Brennan TA et al. Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I. *New Eng J Med* 1991;**324**:370–376.

8 Studdert DM et al. Negligent care and malpractice claiming behavior in Utah and Colorado. *Medical Care* 2000;**38**:250–260.

9 Smith AF, Mahajan R.P. National critical incident reporting: improving patient safety. *Br J Anaesth* 2009;**103**:623–625.

10 Cook TM et al. Major complications of airway management in the UK: results of the 4th National Audit Project of the Royal College of Anaesthetists and the Difficult Airway Society. Part 2 Intensive care and Emergency Department. *Br J Anaesth* (January 2011) in press.

11 McLaughlan C. The Royal College of Anaesthetists census report 2007. *RCoA Bulletin* 2008;**50**:2577–2578 (www.rcoa.ac.uk/docs/Censusreport-final.pdf).

12 Woodall NM, Cook TM. A national census of airway management techniques employed during anaesthesia in the UK: results of the first phase of the 4th National Audit Project at the Royal College of Anaesthetists. *Br J Anaesth* 2010; e-published December 2010 – doi: 10.1093/bja/aeq339.

13 Auroy A et al. Mortality related to anaesthesia in France: analysis of deaths related to airway complications. *Anaesthesia* 2009;**64**:366–370.

14 Li G et al. Epidemiology of anesthesia-related mortality in the United States 1999–2005. *Anesthesiology* 2009;**110**:759–765.

15 Tuffin R et al. A review of the accuracy of death certification on the intensive care unit and the proposed reforms to the Coroner's system. *J Inten Care Society* 2009;**10**:134–137.

16 Domino KB et al. Airway injury during anaesthesia. *Anesthesiology* 1999;**91**:1703–1711.

17 Statistics on obesity physical activity and diet: England, 2010. *The Health and Social Care Information Centre*, 2010 (ISBN:978-1-84636-382-5) (www.ic.nhs.uk/webfiles/publications/opad10/Statistics_on_Obesity_Physical_Activity_and_Diet_England_2010.pdf, accessed 2 January 2011).

18 Kheterpal S et al. Incidence and predictors of difficult and impossible mask ventilation. *Anesthesiology* 2006;**105**:885–891.

19 Kristensen MS. Airway management and morbid obesity. *Eur J Anaesthesiol* 2010;**27**:923–927.

20 Farmery AD, Roe PG. A model to describe the rate of oxyhaemoglobin desaturation during apnoea. *Br J Anaesth* 1996;**76**:284–291.

21 Safety Statement Capnography outside the Operating Theatre. *AAGBI* (www.aagbi.org/aboutaagbi/pressoffice/statements/aagbi_safety_statement_capnography_jan09.htm, accessed 2 January 2011).

22 Olsson GL, Hallen B, Hambraeus-Jonzon K. Aspiration during anaesthesia: a computer-aided study of 185,358 anaesthetics. *Acta Anaesthesiol Scand* 1986;**30**:84–92.

23 Harrison GG. Death attributable to anaesthesia. A ten year survey (1967–1976). *Br J Anaesth* 1978;**50**:1041–1046.

24 Tiret L et al. Complications related to anaesthesia in infants and children. A prospective survey of 40,240 anaesthetics. *Br J Anaesth* 1988:**61**:263–269.

25 Caplan RA, Posner KL, Cheney FW. Effect of outcome on physician judgements of appropriateness of care. *JAMA* 1991;**265**:1957–1960.

26 Henriksen K, Kaplan H. Hindsight bias: outcome knowledge and adaptive learning. *Qual Saf Health Care* 2003;**122(supp 2)**:46–50.

27 Crosby E. Medical malpractice and anesthesiology: literature review and role of the expert witness. *Can J Anaesth* 2007;**54**:227–241.

CHAPTER 6

Results of second phase of NAP4: ICU and the emergency department


Dr Tim Cook


Dr Nick Woodall


Dr Jane Harper


Professor Jonathan Benger

This chapter is based on the original paper reporting the results of the NAP4 project.

It appears here by kind permission of the Editor-in-Chief and board of the British Journal of Anaesthesia where it was first published.

Cook TM et al. Major complications of airway management in the UK: results of the 4th National Audit Project of the Royal College of Anaesthetists and the Difficult Airway Society. Part 2 Intensive care and the emergency department. *Br J Anaesth* 2011.

Introduction

Active airway management takes place most frequently in anaesthetic practice. However, the same skills and techniques are often required outside the operating theatre. Several studies of airway management outside the operative theatre have identified higher rates of complications including failed intubation, oesophageal intubation, hypoxia and cricothyroidotomy. These include studies in Intensive Care[1–4] and emergency departments.[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 Intensive Care 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 4th 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 Intensive Care Units (ICU) and emergency departments for the reasons stated above. This chapter describes the major findings of this section of the NAP4 project.

This chapter should be read in conjunction with Chapters 3 and 5.[11]

Methods

The full methodology of the NAP4 project is described in Chapter 3.

Results

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

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 Chapter 3, 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.

Demographic data

Of the ICU cases the male: female ratio was 21:15 (58% male), 22% were ASA grade 1–2 and 61% aged under 60 (see Table 1). In ICU 19 patients were receiving invasive ventilation, eight non-invasive ventilation, eight were not receiving mechanical ventilation prior to the airway event: in one case this information was not provided. Ninety-four percent were receiving supplemental oxygen before the event and in 35% this was a FiO_2 of 0.6 or more. Thirteen had organ failures other than respiratory and nine were receiving vasoactive drugs or continuous renal replacement therapy. A BMI of >30 $kg.m^{-2}$ or obese body habitus was recorded in 47% of ICU cases and a BMI of <20 $kg.m^{-2}$ or cachexia in 6%. While 24% of anaesthesia events took place out of hours (18.01–08.00) the figure for ICU was 46% of events for which a time was recorded. 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 specialty (e.g. ST2 in medicine).

Of the emergency department cases the male: female ratio was 10:5 (67% male), 40% were ASA grade 1–2 and 80% aged under 60 (see Table 1). A BMI of >30 kg.m^{-1} or obese body habitus was recorded in 46% of emergency department cases and a BMI of <20 kg.m^{-1} or cachexia in 7%. Fifty-three percent of events took place 'out of hours'. All cases except three involved attempts at tracheal intubation, the exceptions being face mask 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 fell from 6/7 during the day (0801–1800) 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 five 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, in Table 2.

Death

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

Table 1 Incident reports classified 1) by ASA grade and type of event, 2) by age and type of event, 3) 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

	All cases (n=184)	ICU (n=36)	Emergency department (n=15)
ASA			
1	26	1	2
2	62	7	4
3	59	14	5
4	29	13	3
5	3	1	0
Not recorded	5	0	1
Age			
<10	10	1	1
11–20	8	2	0
21–40	39	6	7
41–60	56	11	4
61–80	60	14	2
>80	10	2	1
Not recorded	1	0	0
Reporter provided inclusion criteria			
Death	33	16	3
Brain Damage	13	6	1
ESA	75	10	11
ICU admission*	122	12	10
(sum)	(243)	(44)	(25)

*prolongation of stay in the case of patients already in ICU

Table 2 Final outcome (1) Narrative outcome, (2) NPSA classification (see Chapter 3)

	All cases (n=184)	ICU (n=36)	Emergency department (n=15)
Final outcome (narrative)			
Death	38	18	4
Brain damage	8	4	1
Other partial recovery	10	3	1
Full recovery	124	9	9
Unrelated death	4	2	0
Final outcome (NPSA definitions)			
Death	38	18	4
Severe	10	5	0
Moderate	126	12	11
Low	7	1	0
None	3	0	15

Brain damage

In 13 patients brain damage was recorded as an inclusion criterion, six in reports of events on ICU and one in the emergency department (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 emergency department. Combined rate of death and brain damage for ICU cases was 22/36 (61%) and in the emergency department 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): case review identified 80 attempts in 184 reported cases (43%).

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 in 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 emergency department (67% of emergency department 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 ten patients requiring a surgical airway in the emergency department 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 ten in emergency department cases. The commonest 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 commonest reasons for emergency department 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 unrecognised 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 unrecognised oesophageal intubations and two led to death (a further fatal unrecognised oesophageal intuation was a secondary event). Displacement or obstruction of tracheostomies and difficult intubation required a fibrescope on several occasions and delays in accessing one was a recurrent problem, in some cases associated with harm.

Events in the emergency department were predominantly related to tracheal intubation and included delayed or failed intubation, unrecognised oesophageal intubation, the CICV scenario, aspiration and perforation of the trachea with a bougie (Table 3). The two unrecognised oesophageal intubations led to death. Airway management in both 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.

Paediatrics and obstetrics

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

One event occurred in ICU in a child under ten years: 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 emergency department: a case of inadvertent oesophageal intubation in an infant. During cardiac arrest a flat capnography trace was not recognised as indicating 'non-intubation'. The patient died.

Table 3 Primary reported airway event

ICU n=36	
Tracheostomy related problems	14
Tracheal tube misplacement/displacement	7
Failed intubation	6
Oesophageal intubation	4
CICV – the can't intubate can't ventilate scenario	2
Iatrogenic airway trauma	2
Problems at time of extubation	1
Emergency department n=15	
Failed intubation	7
Difficult or delayed intubation	1
Oesophageal intubation	2
CICV – the can't intubate can't ventilate scenario	2
Iatrogenic airway trauma	1
Aspiration of gastric contents	2

Review panel analysis

Degree of harm

The outcomes ascribed to all ICU and emergency department 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 organisation/strategic (19%).

Causal and contributory factors were identified in all 15 emergency department 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 8 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 emergency department airway management 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 emergency department deaths.

Discussion

This project has performed a prospective study of major airway events occurring throughout the United Kingdom during anaesthesia, in Intensive Care and the emergency department 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 emergency department?

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 to 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 vs ten of 19 non-obese): this contrasts 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 inadequately experienced and when problems arose they were not managed in a logical or recognised 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 (face mask ventilation, laryngeal mask ventilation, and cricothyroidotomy) these all had relatively high rates of failure. Issues of preparedness were also identified

Table 4 Factors assessed by review panel to contribute or cause events and factors indicating good practice. For definitions of factors listed see Chapter 3

Factors	ALL cases (n=184)			ICU (n=36)			ED (n=15)		
	Causal	Contributory	Positive	Causal	Contributory	Positive	Causal	Contributory	Positive
Communication	4	38	40	2	9	13	0	3	5
Education and Training	12	77	17	2	19	2	0	6	2
Equipment and resources	2	46	21	0	13	4	0	4	1
Medicines	0	31	5	0	7	0	0	4	0
Organisation and strategic	1	42	35	0	7	7	0	0	0
Patient	37	103	1	6	19	0	3	8	0
Task	4	31	7	0	6	2	2	3	1
Team and Social	0	36	22	0	7	1	0	3	1
Work and Environment	1	14	3	0	4	0	0	1	0
Judgement	19	90	23	3	15	4	0	8	1
Other	0	8	0	0	3	0	0	2	0

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 (i.e. right equipment and right expertise immediately available). The assessors judged airway management in the ICU to be good less frequently than in either anaesthesia or the emergency department.

Observations in the emergency department 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, though 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 the ICU, and in all cases was ultimately successful, also higher than other settings.

An observation in both ICU and the emergency department was of unrecognised 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 emergency department, 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 emergency department because of underlying 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.[13] Mort's 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% versus 70%), regurgitation of gastric contents (1.9% versus 22%), aspiration (0.8% versus 13%), bradycardia (1.6% versus 21%) and cardiac arrest (0.7% versus 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 utilise highly advanced techniques. This requires planning and communication. In ICU planning should recognise 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 before9 and was reported repeatedly in this project.

Failed intubation or difficult intubation contributed to many events on ICU and the emergency department. 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 an ICU for airway monitoring and management. Reviewer assessments frequently identified system, organisational and human factor deficiencies. In a recent study by Jaber and colleagues, implementation of a ten-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 pre-oxygenation with continuous positive airways pressure, presence of two operators, rapid sequence induction, 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 emergency department predictable airway emergencies include trauma intubations, stridor, inhaled foreign bodies and other causes of airway obstruction. The rate of difficult intubation in the emergency department 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. Benger and Hopkinson's survey[12] identified that approximately 20,000 rapid sequence inductions of anaesthesia (RSIs) are performed in UK emergency departments per year and therefore an average size emergency department will perform RSI approximately every four or five 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 and that anaesthetists and ICU doctors need to understand the particular requirements and difficulties of airway management in the emergency department. Channels of communication between the emergency department 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 emergency department can be compared to 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 five minutes 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 over 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. In a more recent study of emergency intubation outside the operating theatre Mort 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]

Table 5 Airway management and degree of harm. Number of cases: n

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		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

CHAPTER 6

Results of second phase of NAP4: ICU and the emergency department

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, repeatedly failed to recognise that a flat capnograph trace indicated absence of ventilation and a misplaced tracheal tube. Nevertheless it has been recognised for many years that during cardiopulmonary resuscitation capnography is not flat but indicates a low concentration of expired gas (Figure 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 amongst 297 patients in 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 section concludes '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 emergency department capnography use was higher, being definitely used 50% of intubation attempts though this question was poorly completed. Despite this, its use was certainly not universal and failure to use or misinterpretation of capnography led to two fatal unrecognised oesophageal intubations in the emergency department. Correct use and interpretation of capnography would have prevented half of the deaths in the emergency department.

The contrast between rates of use of capnography in anaesthesia and in ICU and the emergency department is stark and is reinforced by this project's findings. Use of capnography in ICU has been recommended by various authors and organisations.[9,14,32–36] 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 its 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 rare. There have been numerous discussions as to whether needle or Seldinger or surgical approaches to direct tracheal access are best and it might 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 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 intravenous 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

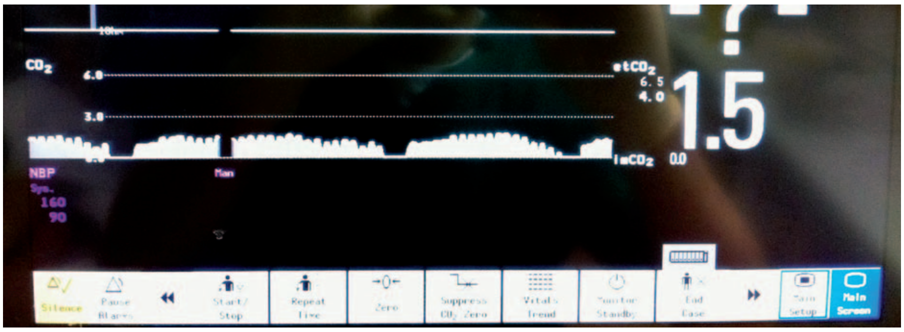

Figure 1 Capnograph trace during cardiac arrest with on-going cardiopulmonary resuscitation.
The positive trace is an indicator of correct (i.e. tracheal) placement of the tracheal tube

and timing of emergency surgical airway. Peterson, in an anaesthetic litigation setting, 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.[31] Of equal importance persistent attempts at intubation occurred prior to rescue techniques and the authors noted '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 as well as in the ICU and emergency department, 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 emergency department?

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 problems 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 emphasised.

Intubation

- An intubation checklist should be developed and used for all intubations of critically ill patients. A checklist might usefully identify preparation of patient, 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 recognise and emphasise 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 recognised 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 in this group.
- Responsible bodies (e.g. Royal College of Anaesthetists, Intensive Care Society) should work with other stake-holders and manufacturers to explore two aspects of tracheostomies for obese patients. 1) Can design be improved to reduce risk of displacement? 2) 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 theatre 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. Trainers should regularly encourage their trainees to identify the correct landmarks especially on obese patients.

- Research is actively needed 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

- Recognising 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 prior to 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, familiarisation 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 emergency department. To these are added.

- Capnography should be used for all intubations in the emergency department.
- Capnography should be used for all anaesthetised patients in the emergency department.
- Capnography should be used for intubated patients during transfers from the emergency department to other departments.
- An intubation checklist should be developed and used for all intubations of emergency department patients. A checklist might usefully identify preparation of patient, equipment, drugs and team. A checklist should include identification of back-up plans.
- Emergency departments 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, though not restricted to, the anticipated patient groups.
- Every emergency department should have the airway equipment necessary to manage all the anticipated clinical scenarios. This needs regular checking, maintenance and replacement of equipment after use.
- Every emergency department should also have a difficult airway trolley. This should have the same content and layout as the one used in that hospital's theatre 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 emergency department, 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 of the day or night to manage the airway within a reasonable timeframe (the concept of the right practitioner, right place, right time).
- Joint training of emergency physician and anaesthesia/ICU staff is recommended. As above this training should also 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.
- Staff training should focus on the anticipated clinical presentations. Training should also include management of failed intubation and emergency surgical airway techniques. Training should include use of the airway equipment available in the emergency department.
- Strong links and good communication between senior clinicians in the emergency department, anaesthesia, ICU, ear nose and throat surgery, and other relevant specialties are essential in planning for, and managing, the emergency airway problems that present to the emergency department. Consideration should be given to designating consultant leads from each involved specialty to agree and oversee the management of emergency airway problems presenting to the emergency department.
- Regular audit should take place of airway management problems or events in the emergency department.

Research

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

The main limitations of the NAP4 project are described in Chapter 5.[11] For anaesthesia events every UK NHS hospital had a LR: in contrast our network of LRs for ICU and emergency departments likely covered only 50% of hospitals. Although many cases in these areas will have been reported via anaesthesia LRs it is likely that a higher proportion of events arising in ICU and emergency departments 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 emergency departments.

Prior to surgery, airway management is generally a necessary part of the process of anaesthesia to facilitate an operation, while in both ICU and the emergency department the primary aim may be securing the patient's airway, with anaesthesia a necessity for that. Due 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.

Conclusions

At least one-quarter of major complications of airway management in hospitals are likely to occur in the ICU and emergency department. Case review has identified avoidable deaths and areas of care that need improvement. We outline recommendations to make such improvements.

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 and these events are more likely to lead to permanent harm or death than events in anaesthesia. 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 emergency department.

References

1 Schwartz DE, Matthay MA, Cohen NH. Death and other complications of emergency airway management in critically ill patients: a prospective investigation of 297 tracheal intubations. *Anaesthesiology* 1995;**82**:367–376.

2 Jaber S, Amraoui J, Lefrant JY. Clinical practice and risk factors for immediate complications of endotracheal intubation in intensive care unit: A prospective multiple-center study. *Crit Care Med* 2006;**34**:2355–2361.

3 Mort TC. Emergency tracheal intubation: complications associated with repeated laryngoscopic attempts. *Anesth Analg* 2004;**99**:607–613.

4 Peterson GN et al. Management of the Difficult Airway: A Closed Claims Analysis. *Anesthesiology* 2005;**103**:33–39.

5 Chang RS, Hamilton RJ, Carter WA. Declining rate of cricothyroidotomy in trauma patients with an emergency medicine residency: implications for skills training. *Acad Emerg Med* 1998;**52**:47–51.

6 Sakles JC et al. Airway management in the emergency department: a one-year study of 610 tracheal intubations. *Ann Emerg Med* 1998;**31**:325–332.

7 Bair AE et al. The failed intubation attempt in the emergency department: analysis of prevalence, rescue techniques, and personnel. *J Emerg Med* 2002;**23**:131–140.

8 Graham CA et al. Rapid sequence intubation in Scottish urban emergency departments. *J Emerg Med* 2003;**20**:3–5.

9 Thomas AN, McGrath BA. Patient safety incidents associated with airway devices in critical care: a review of reports to the UK National Patient Safety Agency. *Anaesthesia* 2009;**64**:358–365.

10 Catchpole K, Bell MD, Johnson S. Safety in anaesthesia: a study of 12,606 reported incidents from the UK National Reporting and Learning System. *Anaesthesia* 2008;**63**:340–346.

11 Cook TM, Woodall N, Frerk C. Major complications of airway management in the UK: results of the 4th National Audit Project of the Royal College of Anaesthetists and the Difficult Airway Society. Part 1 Anaesthesia. *Br J Anaesth*, submitted January 2011.

12 Benger J, Hopkinson S. Rapid sequence induction of anaesthesia in UK emergency departments: a national census. *J Emerg Med* 2010 doi: 10.1136/emj.2009.085423.

13 Peterson GN et al. Management of the Difficult Airway: A Closed Claims Analysis. *Anesthesiology* 2005;**103**:33–39.

14 Jaber S et al. An intervention to decrease complications related to endotracheal intubation in the intensive care unit: a prospective, multiple-center study. *Intensive Care Med* 2010;**36**:248–255.

15 Berenholtz SM et al. Eliminating catheter-related bloodstream infections in the intensive care unit. *Crit Care Med* 2004;**32**:2014–2020.

16 Caplan RA et al. Adverse respiratory events in anesthesia: A closed claims analysis. *Anesthesiology* 1990;**72**:828–833.

17 Mort TC. Esophageal intubation with indirect clinical tests during emergency tracheal intubation: a report on patient morbidity. *J Clin Anesth* 2005;**17**:255–262.

18 Falk JA, Rackow EC, Weil MH. End-Tidal Carbon Dioxide Concentration during Cardiopulmonary Resuscitation. *N Engl J Med* 1988;**318**:607–611.

19 Deakin CD, Morrison LJ, Morley PT. 2010 International Consensus on Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science with Treatment Recommendations Part 8: Advanced life support. *Resuscitation* 2010;**81S**:93–174.

20 Silvestri S et al. The effectiveness of out-of-hospital use of continuous end-tidal carbon dioxide monitoring on the rate of unrecognized misplaced intubation within a regional emergency medical services system. *Ann Emerg Med* 2005;**45**:497–503.

21 Takeda T et al. The assessment of three methods to verify tracheal tube placement in the emergency setting. *Resuscitation* 2003;**56**:153–157.

22 Ornato JP et al. Multicenter study of a portable, handsize, colorimetric end-tidal carbon dioxide detection device. *Ann Emerg Med* 1992;**21**:518–523.

23 Varon AJ, Morrina J, Civetta JM. Clinical utility of a colorimetric end-tidal CO2 detector in cardiopulmonary resuscitation and emergency intubation. *J Clin Monit* 1991;**7**:289–293.

24 Anton WR et al. A disposable end-tidal CO2 detector to verify endotracheal intubation. *Ann Emerg Med* 1991;**20**:271–275.

25 MacLeod BA et al. Verification of endotracheal tube placement with colorimetric end-tidal CO2 detection. *Ann Emerg Med* 1991;**20**:267–270.

26 Schaller RJ, Huff JS, Zahn A. Comparison of a colorimetric end-tidal CO2 detector and an esophageal aspiration device for verifying endotracheal tube placement in the prehospital setting: a six-month experience. *Prehosp Disaster Med* 1997;**12**:57–63.

27 Bhende MS, Thompson AE. Evaluation of an end-tidal CO2 detector during pediatric cardiopulmonary resuscitation. *Pediatrics* 1995;**95**:395–399.

28 Li J. Capnography alone is imperfect for endotracheal tube placement confirmation during emergency intubation. *J Emerg Med* 2001;**20**:223–229.

29 Pelucio M, Halligan L, Dhindsa H. Out-of-hospital experience with the syringe esophageal detector device. *Acad Emerg Med* 1997;**4**:563–568.

30 Bozeman WP et al. Esophageal detector device versus detection of end-tidal carbon dioxide level in emergency intubation. *Ann Emerg Med* 1996;**27**:595–599.

31 Cook TM et al. Needle Cricothyroidotomy. Anaesthesia 2007;**62**:289–290.

32 Cheifetz IM, Myers TR. Respiratory therapies in the critical care setting. Should every mechanically ventilated patient be monitored with capnography from intubation to extubation? *Respiratory Care* 2007;**52**:423–438.

33 Cook T, Haslam M. Complications of airway management in ICU – time for a closer look. *Care of the Critically Ill*;2008;**24**:35–37.

34 Goldhill D, Cook TM, Waldmann C. Airway incidents in critical care, the NPSA, medical training and capnography. 'Every breath you take… I'll be watching you'. *Anaesthesia* 2009;**64**:354–357.

35 Safety Statement Capnography outside the Operating Theatre. *AAGBI*, 2009 (www.aagbi.org/aboutaagbi/pressoffice/statements/aagbi_safety_statement_capnography_jan09.htm, accessed 2 January 2011).

36 Standards for the care of adult patients with a temporary tracheostomy. *ICS*, 2008 (www.ics.ac.uk/intensive_care_professional/standards_and_guidelines/care_of_the_adult_patient_with_a_temporary_tracheostomy_2008, accessed 2 January 2011).